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# THE MULTICENTER AIDS COHORT STUDY: RATIONALE, ORGANIZATION, AND SELECTED CHARACTERISTICS OF THE PARTICIPANTS

RICHARD A. KASLOW,[1] DAVID G. OSTROW,[2] ROGER DETELS,[3] JOHN P. PHAIR,[2] B. FRANK POLK,[4] AND CHARLES R. RINALDO, JR.,[5] FOR THE MULTICENTER AIDS COHORT STUDY[6]

**Kaslow, R. A. (NIAID, NIH, Bethesda, MD 20892), D. G. Ostrow, R. Detels, J. P. Phair, B. F. Polk, and C. R. Rinaldo, Jr., for the Multicenter AIDS Cohort Study. The Multicenter AIDS Cohort Study: rationale, organization, and selected characteristics of the participants. *Am J Epidemiol* 1987;126:310–18.**

**The Multicenter AIDS Cohort Study was designed to 1) elucidate the natural history of the infection causing acquired immunodeficiency syndrome (AIDS), 2) identify risk factors for occurrence and clinical expression of the infection, and 3) establish a repository of biologic specimens for future study. A variety of recruitment techniques, including special assurance of confidentiality, were used to enroll participants. Nearly 5,000 homosexual men volunteered for semiannual interview, physical examination, and laboratory testing in four metropolitan areas. A significant majority of these men in each center (69–83%) reported having 50 or more lifetime sexual partners, and over 80% had engaged in receptive anal intercourse with at least some of their partners in the previous two years. By the time of the participants' initial evaluation (April 1984–April 1985), infection with the human immunodeficiency virus (HIV) had occurred in higher proportions of men in Los Angeles (51%) and Chicago (43%) than in Baltimore/Washington, DC (31%) and Pittsburgh (21%), presumably as a result of the higher number of partners and proportion with whom these men had engaged in high-risk practices (e.g., receptive anal intercourse). Follow-up evaluations are underway in this comprehensive longitudinal investigation of HIV infection.**

**acquired immunodeficiency syndrome; homosexuality; human immunodeficiency viruses**

## BACKGROUND

The acquired immunodeficiency syndrome (AIDS) was first described in 1981 (1) and recognized as an epidemic of major public health importance shortly thereafter. By March 1983, the Centers for Disease Control had received reports of more than

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Abbreviations: AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus.

[1] Epidemiology and Biometry Section, National Institute of Allergy and Infectious Diseases (NIAID), Westwood 739, NIH, Bethesda, MD 20892. (Send reprint requests to Dr. Richard A. Kaslow at this address.)

[2] Howard Brown Memorial Clinic-Northwestern University, Chicago, IL.

[3] UCLA School of Public Health, Los Angeles, Ca.

[4] The Johns Hopkins School of Hygiene and Public Health, Baltimore, MD.

[5] University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA.

[6] Centers of the Multicenter AIDS Cohort Study: *Baltimore*. The Johns Hopkins University School of Hygiene and Public Health: B. Frank Polk, Principal Investigator; Robin Fox; Ronald Brookmeyer; University of Maryland Cancer Center: Richard D. Leavitt. *Chicago*. Howard Brown Memorial Clinic-Northwestern University Medical School: John P. Phair, Principal Investigator; Joan S. Chmiel; David G. Ostrow. *Los Angeles*. University of California, Schools of Public Health and Medicine: Roger Detels, Principal Investigator; Barbara R. Visscher; John L. Fahey; Janis V. Giorgi; Jan Dudley. *Pittsburgh*. University of Pitts-

1,200 cases, about 75 per cent of which had occurred in homosexual men (2). Unexplained generalized lymphadenopathy, oral thrush, thrombocytopenia, wasting, and other clinical and laboratory findings, now considered features of a less well-defined syndrome of AIDS-related conditions, had also been associated epidemiologically with AIDS (3). Epidemiologic evidence for involvement of a transmissible agent was increasingly convincing. However, prior to discovery of the etiologic agent, human immunodeficiency virus (see below), early studies used various immunologic measurements, such as the ratio of T-helper to T-suppressor lymphocytes in peripheral blood, as surrogate markers of the immune derangement peculiar to AIDS.

In mid-1983, neither the early course of the presumed infectious process nor the full spectrum of the syndrome was well understood. Completed and projected epidemiologic investigations of AIDS still consisted largely of studies of AIDS and cases of AIDS-related conditions or limited cross-sectional studies of clinically unaffected individuals in high-risk categories. Data from a large comprehensive longitudinal investigation of the early pathophysiology of AIDS were needed. Moreover, concern had been raised that not all scientists who wanted to study AIDS had access to epidemiologically well-characterized biologic specimens needed for such research. It was in this context that the collaborative research culminating in the Multicenter AIDS Cohort Study was conceived.

## Objectives

Early planning of the study, in the absence of a putative etiologic agent, established the following general goals for a prospective study in a population of homosexual or bisexual men:

1) Describe the early pathophysiologic events in the course leading to AIDS-related conditions, AIDS, and other potentially related outcomes.
2) Define and quantify the factors suspected of initiating or modulating the immunopathologic process leading to AIDS. These included specific psychoactive drugs, sexual practices, and infections.
3) Provide access to a repository of biologic specimens with detailed epidemiologic data for investigators with promising ideas for research.

Once the human immunodeficiency virus (HIV) was shown to be a necessary causal agent (HIV is the name recently proposed by the International Committee of Viral Taxonomy for human T-lymphotropic virus III (HTLV-III) (4), lymphadenopathy associated virus (LAV) (5), and AIDS-associated retrovirus (ARV) (6)), the study converged on the following specific objectives:

1) Identify and study men who were seropositive for HIV at entry into the study.
   a. Identify and quantify the correlates of HIV seropositivity.
   b. Examine seropositive participants at regular intervals for changes in clinical and pathophysiologic characteristics (e.g., T-cell alterations and development of generalized lymphadenopathy, AIDS-related conditions, and AIDS).
2) Identify and study men who develop antibody (seroconvert) to HIV.
   a. Detect and quantify factors associated with seroconversion, as distinct from pre-existing seropositivity.
   b. Examine more frequently the participants who seroconvert and describe manifestations of immunodeficiency that develop, with emphasis on the temporal sequence of the pathophysiologic and clinical events.
   c. Search for the virus in serial biologic specimens to determine such relationships as 1) clinical status to viremia and virus shedding and 2) antigenic drift to host immunity.
3) Study men who remain seronegative for HIV.
   a. Search for the virus in serial biologic specimens from subjects who are at high risk of infection but have not seroconverted.
   b. Explore possible protective factors in true negatives.
   c. Identify the determinants of apparent immunologic unresponsiveness in seronegatives infected with virus.
4) Formulate possible prevention and/or early therapy trials for appropriate segments of the cohort populations.

burgh Graduate School of Public Health: Charles R. Rinaldo, Jr., Principal Investigator; Lawrence A. Kingsley; Monto Ho; David W. Lyter. *NIH*. NIAID: Richard A. Kaslow; Alfred J. Saah; Mark J. Van-Raden; Rachel E. Solomon; National Cancer Institute: Andrew A. Monjan

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## Design issues

At the time these studies were planned, homosexual men represented the optimal population in which rates could be expected to be high enough to permit meaningful longitudinal inquiry in a reasonable period of time. The difficulties in planning were both generic to prospective epidemiologic investigations and specific to homosexual men. Prospective epidemiologic investigations are often difficult to plan, time consuming, and expensive. In the case of AIDS, in mid-1983, pressures to accelerate such research in the absence of information about the rates of disease or exposure in the groups at high risk magnified these problems.

From early clinical observations in several hundred men at risk in San Francisco and New York, it appeared that during the previous year about 1 per cent of those followed had developed AIDS. We estimated that, at a minimum, 2,500 person-years of follow-up would be needed for a worthwhile prospective study in a high-risk area. No one could predict how fast the epidemic might exhaust the "susceptibles" in such an area, how soon it might spread into low-risk areas, or how willingly or rapidly subjects in any location would actually enroll. Difficulties of recruitment and retention beyond those usually encountered in a cohort study were predictable. For example, although intense interest in AIDS research was expected among homosexual men, deep-seated concern would undoubtedly persist about confidentiality of sensitive personal data to be collected as part of a federally supported project.

Another major concern was that no population sampling scheme could achieve representativeness of all men at risk; hence, generalizability of results would be limited. There was also an increasing emphasis within the community at risk on behavior modification (e.g., of specific sex practices and drug use), whose uncertain impact would have to be assessed throughout the study. Finally, hopes were repeatedly raised for some promising biologic intervention that would require still further modifications in study design and execution.

Despite these concerns, the arguments for beginning work as soon as feasible were compelling. In response to a formal request, investigators in both high- and low-risk cities proposed cohort studies for evaluating approximately 1,000 homosexual/bisexual men periodically for at least 2–3 years. However, aside from the questions about scientific and social feasibility, there had been no assurance that such a large cohort approach would receive federal financial support.

In fact, only very late in the review process was the decision made to select several institutions on the basis of 1) scientific merit, 2) the probability of infection in their metropolitan areas, 3) likelihood of success in recruitment and retention, and 4) sensitivity to the local social and political environment. This approach offered the opportunity to capture comparable information from individuals with ostensibly different risks and to capitalize on large numbers of subjects. Eventually, investigators in Baltimore, Chicago, Los Angeles, and Pittsburgh agreed to blend their separately designed studies into a unified collaborative multicenter approach with standardized procedures for research on the set of "core" issues already described.

## The multicenter AIDS cohort study core protocol

The recruitment process in the four centers shared certain features, such as the approach to assurance of confidentiality. The essential parts of the baseline and follow-up evaluations, the "core" elements, were standardized at all centers. These "core" elements included the major portions of the clinical-epidemiologic interview, the physical examination, and the specimen collection and laboratory tests to be performed (table 1).

### *Recruitment and enrollment*

In none of the four geographic areas was an entirely population-based approach to sampling feasible. In all four areas, the

TABLE 1

*Core data collected on Multicenter AIDS Cohort Study participants at entry*

| | |
|---|---|
| Questionnaire | Laboratory tests |
| Identifying information | Complete blood count, platelets, and white cell differential count |
| Demographic data | HIV (human T-lymphotropic virus type IIIB) enzyme immunoassay |
| Age | Lymphocyte phenotyping |
| Race, ethnicity | T-lymphocytes (Leu 4) |
| Education | T-helper lymphocytes (CD4, Leu 3) |
| Occupation | T-suppressor lymphocytes (CD8, Leu 2) |
| Selected past medical history | Hepatitis B surface antigen |
| Immune disorders | Hepatitis B core antibody |
| Sexually transmissible diseases | Cytomegalovirus antibody |
| Current medical history | Rubella antibody |
| AIDS, related symptoms | Immunoglobulin G, A, M levels |
| Psychological symptom screening (CES-D (10)) | Chem-screen—26 serum biochemical tests† |
| Transfusions and other parenteral exposure | Rapid plasma reagin/fluorescent treponemal antibody |
| Medicinal and recreational drug use | Central repository storage |
| Sexual practices | Serum |
| Physical examination | Plasma |
| Skin tests for delayed hypersensitivity* | Urine |
| | Feces |
| | Lymphocytes |
| | Throat washing/saliva |
| | Semen |

* Optional, performed in Baltimore, Chicago.
† Testing at entry, Baltimore, Chicago

collaborating institutions launched aggressive campaigns to enroll volunteers with specific characteristics (i.e., by age and clinical status) in the metropolitan areas they served. Each center recruited men through combinations of media publicity (including the gay press), personal connections of both gay activists and early participants in the study, promotional events or offerings (e.g., raffles, medical screening), and previous clinical contacts with largely gay medical practices or through research on other conditions in gay men.

The principal sources of subjects differed somewhat in each of the four locations. The center in Baltimore depended heavily on respondents to gay and metropolitan newspaper stories, along with personal communication between the investigators and the leaders of the gay communities in both Baltimore and Washington, DC. In Chicago, a clinic founded by and for homosexual men provided a familiar focal point. The investigation could draw upon deep existing roots in the clinic's established patient population and, more specifically, upon participants in an existing cohort study of hepatitis B vaccine efficacy. In Los Angeles, homosexual men drawn from a preexisting AIDS study cohort, from numerous organizations, from referrals by other health professionals, and by announcements in gay media were recruited without extraordinary recruitment efforts. In the Pittsburgh area, a smaller and less visible population of homosexual men required development of several active recruitment techniques. For example, clinical research staff made multiple visits to all known gay bars and baths to enroll men in a local screening study, from which men volunteered for the Multicenter AIDS Cohort Study.

All centers tried to make long-term participation as attractive as possible. Carefully constructed community advisory boards ensured direct involvement of local gay civic leaders. Where possible, the loca-

tion and hours of the clinical evaluation were chosen to accommodate the subjects' patterns of activity; at two centers, more than one location was available. Professional staff were selected for their sensitivity to general health matters, as well as their sensitivity to specific apprehension among subjects about AIDS and other primarily homosexual concerns. Some form of screening and referral for sexually transmissible diseases was offered at each center. On the other hand, there was considerable reluctance to provide individual clinical information, such as the results of immunologic (T-cell subset) studies and, subsequently, of human immunodeficiency virus serologic testing. With the help of careful deliberations by its advisory board, each center struggled with the fine balance between the positive recruitment incentive of disclosing results of these tests to the subject and the potential for misinterpretation, which might lead to fear and despondency. In some centers, specific test results were made available only upon request of the participant and then only through qualified study staff or the individual's personal physician. In others, results were provided more routinely but were likewise accompanied by careful explanation and staff discussion, as necessary.

### *Protection of confidentiality*

A Federally authorized procedure for protecting confidentiality of participants' identifying information in studies of illicit drug use, alcohol abuse, and mental health can provide immunity to subpoena or other legal proceedings (7). Each center offered such protection through a Confidentiality Certificate obtained from the Department of Health and Human Services. In addition, all centers agreed not to release any information without the written permission of the subject.

### *Baseline evaluation*

Table 1 summarizes the core elements of the participant entry visit. A face-to-face interview was designed to be comprehensive but not exhaustive. The final screening procedures were adopted after two cycles of pretesting with revisions of the instruments. Questions on demographic and psychosocial factors were self-administered. The remainder of the questionnaire was administered by trained interviewers. Interview coordinators from each center underwent three days of collective training in common on the purposes and pitfalls of the questionnaire. The majority of interviews were conducted in under 45 minutes, with few exceeding one hour. A physician, physician's assistant, or nurse practitioner performed a standardized physical examination designed to identify features of AIDS, AIDS-related conditions, and certain other sexually transmissible diseases. At the inception of the study, enumeration of helper and suppressor T-lymphocytes appeared to be the most critical immunologic correlate of either exposure to an AIDS agent or outcome. Although, from the outset, logistic difficulties and the urgency of conducting the initial evaluations precluded identical procedures for T-cell phenotype testing at all centers, a commitment was made to use identical flow cytometry equipment and reagents and to exchange specimens for comparison purposes.

### *Repository*

Specimens from each subject were obtained and processed, and aliquots were derived according to a standard protocol. At least half of the aliquots obtained were consigned to a central repository in Bethesda, Maryland, with the remainder to be retained for use by the individual investigators. Specimens in the central repository are available to other investigators for properly conceived collaborative AIDS-related research. Guidelines and procedures for use of the specimens have been established and are available from the National Institute of Allergy and Infectious Diseases (8).

## RESULTS OF ENROLLMENT PHASE

After a brief pilot phase, baseline evaluations began in April 1984 and proceeded at a variable pace from center to center. By

December 1984, nearly 90 per cent of the total projected number of participants had been seen for what usually turned out to be a 2–4-hour initial evaluation, depending on the subject's history and clinical status. All initial evaluations were completed by April 1985.

Table 2 shows selected demographic features of the cohort by study site. The groups of men enrolled at the four centers do not show large center-to-center differences in their tabulated characteristics. The median age and ethnic mix were remarkably similar, and no important differences in other characteristics were noted.

Table 3 shows the distributions of men who engaged in sexual activities which are likely to contribute to transmission of human immunodeficiency virus infection. Although the median ages at first intercourse and when regular intercourse began are nearly identical at the four centers, men in the Baltimore/Washington, DC cohort and particularly men in the Pittsburgh/Tristate area cohort had fewer different sexual partners in their lifetime and during the previous two years. Slightly fewer men in Baltimore and Pittsburgh reported the most intensive exposures. Likewise, the percentage of men with sexually transmissible infections during their lifetime was somewhat higher for Los Angeles, intermediate for Chicago and Baltimore/Washington, DC, and lower for the Pittsburgh/Tristate area. While the differences were rather small, the comparability observed among centers

TABLE 2

*Demographic features of homosexual men, by center of the Multicenter AIDS Cohort Study, at entry, April 1984–April 1985*

| | Baltimore/ Washington, DC | Chicago | Los Angeles | Pittsburgh/ Tristate area |
|---|---|---|---|---|
| Ages (years) | 18–60 | 18–60 | 18–50 | ≥18 |
| Health status | No AIDS | No AIDS or cancer except skin cancer | No AIDS or cancer except skin cancer, no radiation therapy | No AIDS |
| Calendar period of baseline evaluations | 4/84–11/84 | 4/84–3/85 | 4/84–4/85 | 4/84–4/85 |
| Total enrolled | 1,153 | 1,102 | 1,637 | 1,063 |
| Median age (years) | 33 | 32 | 32 | 31 |
| Race/ethnicity (%) | | | | |
| White (includes white-Hispanic) | 94 | 94 | 95 | 95 |
| Black (includes black-Hispanic) | 5 | 5 | 3 | 4 |
| Other | 1 | 1 | 2 | 1 |
| Occupation (%) | | | | |
| Manager/professional | 59 | 54 | 51 | 40 |
| Technical/sales | 26 | 25 | 29 | 22 |
| Service | 8 | 14 | 13 | 18 |
| Craft/repair | 3 | 3 | 4 | 3 |
| Operator/laborer | 3 | 3 | 2 | 7 |
| Other | 1 | 1 | 1 | 10 |
| Highest education attained (%) | | | | |
| Up to high school completion | 12 | 11 | 11 | 20 |
| Some college | 21 | 25 | 34 | 34 |
| College degree | 22 | 25 | 26 | 20 |
| Some graduate work | 16 | 13 | 12 | 9 |
| Graduate degree | 29 | 25 | 17 | 17 |

TABLE 3

*History of homosexual activities, selected sexual practices, and specific infections of homosexual men, by center of the Multicenter AIDS Cohort Study, at entry, April 1984–April 1985*

| | Baltimore/ Washington, DC | Chicago | Los Angeles | Pittsburgh/ Tristate area |
|---|---|---|---|---|
| Duration and intensity of homosexual activities | | | | |
| Median age (years) at first homosexual intercourse | 17 | 17 | 17 | 17 |
| Median age (years) when regular homosexual intercourse began | 21 | 20 | 20 | 20 |
| % of men who began regular homosexual intercourse 10 or more years prior to entry | 59 | 59 | 62 | 51 |
| Homosexual partners | | | | |
| Lifetime, % with | | | | |
| 0–49 | 25 | 19 | 17 | 31 |
| 50–499 | 49 | 51 | 48 | 48 |
| 500+ | 26 | 30 | 35 | 21 |
| Previous two years, % with | | | | |
| 0–9 | 25 | 19 | 19 | 25 |
| 10–49 | 47 | 42 | 43 | 43 |
| 50+ | 28 | 39 | 38 | 32 |
| Nature and frequency of homosexual practices | | | | |
| % of partners with whom engaged in: | | | | |
| Receptive anal intercourse | | | | |
| None | 15 | 12 | 10 | 17 |
| Some | 66 | 67 | 70 | 68 |
| Most/all | 19 | 21 | 20 | 15 |
| Receptive fisting | | | | |
| None | 93 | 90 | 90 | 95 |
| Some | 6 | 9 | 9 | 4 |
| Most/all | 1 | 1 | 1 | 1 |
| Enema/douche before sex | | | | |
| None | 64 | 58 | 49 | 76 |
| Some | 24 | 26 | 32 | 17 |
| Most/all | 12 | 16 | 19 | 7 |
| Experience with specific infections | | | | |
| % with history of: | | | | |
| Gonorrhea | 57 | 65 | 67 | 40 |
| Syphilis | 19 | 22 | 31 | 11 |
| Non-specific urethritis | 40 | 48 | 49 | 40 |
| Selected enteric infections | 17 | 21 | 28 | 7 |
| Genital warts, lice, or scabies | 85 | 86 | 88 | 81 |
| % seropositive. | | | | |
| Rapid plasma reagin | 6 | 6 | 6 | 4 |
| Cytomegalovirus indirect immunofluorescent antibody titer >30 | 92 | 95 | 96 | 89 |
| Hepatitis B virus core antibody or surface antigen (anti-HBc, HBsAg) | 64 | 64 | 72 | 53 |
| % reporting known sexual partner who developed AIDS | 14 | 21 | 26 | 4 |

should not be equated with generalizability to all homosexual males in the United States. There was, from inception, neither the possibility nor the intention of obtaining a totally "representative" sample of homosexual men. Many participants presumably volunteered partly because they considered themselves at relatively high

risk of developing AIDS. As mentioned earlier, some of the men had actually been recruited from established populations who attended clinics that treated sexually transmissible diseases in homosexuals. These data therefore should not be assumed to reflect the social characteristics of all homosexual men in the United States or even in the metropolitan areas under study.

Table 4 gives the prevalence of human immunodeficiency virus antibody using ELISA (DuPont, Wilmington, DE), as described by Saxinger and Gallo (9), in sera obtained at entry, stratified by demographic characteristics. The 25–34-year-old age group, non-whites, men with no more than a high school education, and service workers and craft/repair workers showed a somewhat higher frequency of antibody. It is unlikely that any of these characteristics is causally related to infection by the human immunodeficiency virus. More likely, they represent correlates of high-risk behavior.

## FOLLOW-UP

All subjects have been scheduled for reevaluation at least semiannually. Selected subjects (e.g., seroconverters and stable seronegatives who continue high-risk behavior) will be recalled every three months. In addition, those who leave the cohort after initial enrollment will be followed in order to detect the possible occurrence of AIDS or other designated manifestations of immunodeficiency.

The first and subsequent semiannual follow-up evaluations were planned in the wake of the discovery of the etiologic relationship of the human immunodeficiency virus to AIDS. Most core items of the baseline questionnaire remained pertinent; the abbreviated follow-up interview included questions essentially identical to those of the baseline instrument, but was confined to experiences during the interval since the last visit. The physical examination and battery of laboratory procedures were mod-

TABLE 4

*Prevalence of ELISA* antibody to human immunodeficiency virus and relationship to demographic features among homosexual men, by center of the Multicenter AIDS Cohort Study, at entry, April 1984–April 1985*

| | % seropositive | | | |
|---|---|---|---|---|
| | Baltimore/ Washington, DC | Chicago | Los Angeles | Pittsburgh/ Tristate area |
| Age (years) | | | | |
| 18–24 | 29 | 30 | 42 | 11 |
| 25–34 | 35 | 49 | 53 | 26 |
| 35–44 | 31 | 42 | 52 | 19 |
| 45+ | 18 | 33 | 38 | 11 |
| Race | | | | |
| White | 30 | 42 | 51 | 20 |
| Black | 47 | 60 | 52 | 35 |
| Other | 46 | 50 | 41 | 27 |
| Education level | | | | |
| ≤12th grade | 35 | 60 | 65 | 26 |
| Some college | 34 | 46 | 51 | 21 |
| Some graduate work | 27 | 33 | 46 | 17 |
| Occupation | | | | |
| Management/professional | 29 | 39 | 47 | 21 |
| Technical/sales | 32 | 39 | 51 | 19 |
| Service | 36 | 57 | 62 | 23 |
| Craft/repair | 38 | 71 | 52 | 21 |
| Operator/laborer | 30 | 41 | 50 | 24 |

* ELISA, indirect enzyme-linked immunosorbent assay microtest

ified somewhat to reflect new understanding of the infection. Over 85 per cent of the participants returned to their respective centers for their first and second six-month interval evaluations.

## Summary

In April 1984, after a year of planning and preparation, the Multicenter AIDS Cohort Study began with collaborative prospective studies of the biologic events leading to AIDS in four metropolitan areas of the United States. During the next year, approximately 5,000 male homosexual volunteers enrolled in these studies. After the discovery of human immunodeficiency virus as the etiologic agent, it was possible to use serologic and virologic techniques to characterize cohort members, to define the risk factors for infection, and to monitor the clinical and immunologic expression of infection. At entry, the four cohorts were broadly comparable with respect to their sexual experiences and history of infectious diseases; the slightly lower indices of sexual activity among the Baltimore/Washington, DC and Pittsburgh/Tristate area participants were reflected in lower rates of human immunodeficiency virus seropositivity along with lower rates of other sexually transmissible infections. Non-whites, 25–34-year-olds, less educated men, and those in the service and craft/repair occupational categories had the highest prevalence of seropositivity at the initial evaluation. Participants are now being followed, at least semiannually, until they reach designated clinical milestones; over 85 per cent have returned for the first two follow-up visits. New components, such as neuropsychiatric evaluation, have been added at subsequent visits, as appropriate. The Multicenter AIDS Cohort Study promises to produce a cohesive longitudinal picture of the occurrence and consequences of human immunodeficiency virus infection in homosexual men.

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