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Trends in HIV antibody testing

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TRENDS IN HIV ANTIBODY TESTING

A Thesis

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The Faculty of the Department of Nursing

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In Partial Fulfillment

of the Requirements for the Degree

Master of Science

By

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December, 1990

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ABSTRACT

TRENDS IN HIV ANTIBODY TESTING

by Tamara Hertenstein McKinnon

This retrospective study analyzed trends in HIV antibody testing over a 5 year period. The purpose of this analysis was to identify trends in demographics and risk factors of individuals presenting for HIV antibody testing, as well as trends in those testing HIV positive.

The most striking trend in primary risk factors of individuals presenting for testing is the shift from gay and bisexual males to heterosexuals with multiple sex partners. Analyses of demographics of individuals presenting for testing indicate that the county's Hispanic population is under-represented in the testing population. Further analysis indicates that the testing population is younger now than at the inception of testing. There was a significant decrease in percentage of positive tests for gay and bisexual men and a rise in seropositivity among intravenous drug users. The study should be replicated on a larger scale, analyzing results from various testing programs.

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Chapter 1

INTRODUCTION

Purpose and Need

The purpose of this study was to obtain information about trends in risk factors and demographics of individuals receiving anonymous HIV (Human Immunodeficiency Virus) antibody testing in a particular county from the inception of testing through October of 1989. This information is valuable for health care providers who are planning programs in the areas of HIV antibody testing, HIV disease clinics, and AIDS education and prevention.

Problem Statement

There is a saying among health care workers that "planning an AIDS program using statistics on AIDS cases is like driving your car down the road by looking in the rear view mirror." While it is true that gathering epidemiological information on AIDS cases is important, such statistics are insufficient for adequate planning of health care and educational programs. In order to best prepare for future health care needs of our society, we must have an idea of who will be requiring services, as well as who may be at risk.

In the United States, there is no routine method for collecting data on HIV seroprevalence. Although some states do report HIV infection data, this information is obtained from confidential testing only (Dondero, Pappaioanou, & Curran, 1988). In the few studies which have been performed on HIV seroprevalence, risk factors and other variables have not had consistent definitions, and therefore the results cannot be compared (Goldblum & Marks, 1988).

In late 1987, the Morbidity and Mortality Weekly Report (HIV in the U.S.) acknowledged that little is known about the trends or incidence of HIV infection. Unfortunately, that fact remains true to date. The gravity of the AIDS epidemic has commanded that the majority of public health resources are on the front lines, fighting the disease. The intent of this study was to obtain information which will allow public health officials to be proactive and anticipate the movement of this dread disease.

The benefits of early treatment of individuals with HIV infection have been well documented in recent months (Lewis, 1989). This discovery is significant for health care providers for the following reasons:

1. HIV positive clients must be educated about medical and other therapeutic regimens. Nurses working with these clients must have current information about available options.

2. Although gay men currently comprise the largest group of people with AIDS (Update, 1989), the risk factors of individuals currently seroconverting may be different. Nurses must be aware of these differences in order to provide appropriate nursing care. The unique health care and psychosocial needs of clients, as well as information about behaviors which have placed them at risk, are all important pieces of information which warrant consideration by the nurse.

3. Testing, once discouraged by AIDS activist groups and at times by the medical community, is now being encouraged so that individuals may take advantage of the benefits of early prophylactic treatments.

If statistics on HIV infection were routinely collected, health care providers would have important data for program planning. Nurses would also be alerted to significant facts such as individuals at risk who may not be testing and therefore not taking advantage of the potential benefits of early treatment. Hospitals could more accurately predict the number of beds needed in the future. Currently, data are compiled by funding sources but are not routinely analyzed for trends.

Research Questions

1. What is the relationship between selected demographic characteristics and known risk factors among

individuals presenting for anonymous HIV antibody testing in Santa Cruz County, California?

2. Which of the known risk factors and selected demographic variables correlate with seropositivity?

The objectives of this study were:

1. To explore the usefulness of the information to health care providers.

2. To document the need for standardized assessment tools to be used in HIV data collection.

Definition of Terms

For this study, the following definitions will be used:

1. Acquired Immunodeficiency Syndrome (AIDS): an immunosuppressed health condition defined by the presence of specific opportunistic diseases. With laboratory evidence of HIV infection and diagnosis of indicator disease; or without laboratory evidence of HIV infection, with no other causes of immunodeficiency, with definite diagnosis of indicator disease (Luckmann & Sorenson, 1987).

2. Alternative Test Site (ATS): clinics in which clients receive anonymous testing for antibodies to HIV. State certified counselors provide pretest and posttest counseling.

3. Demographics: information regarding age, sex, ethnicity, and residence of a specific population.

4. Human Immunodeficiency Virus (HIV): the causative agent for AIDS.
5. Intravenous Drug User (IVDU): an individual who has injected non-prescription drugs.
6. Seroprevalence of HIV: the rate or number of persons testing positive for HIV antibodies.

Significance

While public health programs continue to develop increasingly sophisticated data collection techniques for AIDS incidence, little is being done to study the trends in HIV seroprevalence. While information pertaining to AIDS incidence is significant, public health programs must focus their attention on prevention and early intervention.

Gathering and analyzing statistics on HIV infection will allow public health professionals to more effectively plan programs. The number of individuals who will be requiring prophylactic medication, social support services, and/or hospital beds may be projected with HIV seroprevalence data. By identifying trends, health educators will be able to identify populations at risk who may not be presenting for testing and thereby focus educational programs on those with the greatest need. Although the best scenario would have been data collection on HIV seroprevalence from the inception of testing, a

retrospective and continuing analysis will provide public health officials with much needed information.

Research Procedures

This study explored trends in risk factors and demographics of individuals presenting for anonymous HIV antibody testing from 1985 to the present. Analysis was based on information compiled on monthly reporting forms which were available for the time period of March, 1985, to the present. These forms contained hand tallied information about demographics and risk factors for each individual tested during each month.

The process of data collection is routine for each ATS client. Questions are asked by state certified HIV counselors and documented on laboratory slips (Appendix B). At the end of each month, ATS laboratory slips are collected and information is hand tallied onto monthly state reporting forms (Appendix C). These documents, filed chronologically and kept in a central location at the health department, were utilized for data collection.

Scope and Limitations

This study is a descriptive, retrospective study which analyzes trends over a 5 year period. Since it is impossible to match client data with any individual, no informed consent was necessary. Permission to conduct this

study was obtained from the County Health Officer as well as the AIDS Program Coordinator (Appendix A).

Sample size was estimated to be between 5,760 and 9,790. This number was obtained by estimating the average number of clients seen per month (150-170) and multiplying by the 56 months testing has occurred. Since data were easily accessible, and all available test data were analyzed, there was no need for sampling. Information on individuals presenting for testing and then deciding not to test was excluded.

Information pertaining to monthly trends in demographics and risk factors are presented. All information from laboratory slips which is compiled onto monthly reports was analyzed. Demographic variables included age, sex, ethnicity, and residence zip code. Risk factor variables included:

1. Men having sex with other men.
2. Men having sex with men and women (bisexual).
3. Persons having injected non-prescription drugs since 1977.
4. Gay/bisexual people who have injected non-prescription drugs since 1977.
5. Heterosexual persons with multiple sex partners.
6. Hemophiliacs.

7. People having had sex with a person in one of the aforementioned categories or someone infected with HIV.

8. People having received a blood or blood product transfusion during 1977-1985.

Basic descriptive statistics, including frequencies and percentages, were calculated. Histograms and graphs were constructed to display the data. Results were plotted on a series of histograms. The number of individuals testing was plotted on the horizontal axis. On the vertical axis, columns with identifying demarcations represent risk factors and demographic characteristics. One graph is utilized to represent each of these groupings and information is presented by both month and year.

The setting of this research was a public health department located in a seaside county. The population of this county is approximately 220,000. There is a university with a population of 9,700 students. Major sources of income for the population include tourism and agriculture.

Limitations that may influence this study are:

1. Clients may have been reluctant to reveal actual risk factors to counselors.

2. Counselors may have lacked skills with which to elicit accurate information from client.

3. There is a miniscule possibility of a false positive or false negative laboratory test result (less than 1%).

4. Data collection tools may have been used inconsistently by staff.

5. Monthly state reporting forms are hand tallied, thus allowing for human error.

6. Some clients may have been tested more than once. Although this information is present on the laboratory slip, it is not known where that individual was previously tested, and the results were therefore not excluded from this study.

7. Information gathered may be applied to this county only. Generalizing the findings to a larger population is not possible without further study.

Chapter 2

CONCEPTUAL FRAMEWORK AND REVIEW OF RELATED LITERATURE

Related Literature

Although a great deal of information has been collected on the incidence of AIDS, little has been done to address the issue of trends in HIV testing. The trends of HIV testing have been underinvestigated, and this topic warrants research since the implications for nursing and other health care professionals are significant.

Significance of HIV Data Analysis

Planning for health and social service programs requires predicting the number of AIDS cases likely to be diagnosed during the next several years. Unfortunately, such data are generally obtained by extrapolating backwards from the number of AIDS cases to generate an approximation of HIV positive individuals and subsequently using this number to forecast anticipated AIDS cases. Dondero, et al. (1988) have written specifically on the need for data collection and analysis of HIV seroprevalence data. They acknowledge the fact that HIV infection is not routinely ascertained and suggest a comprehensive, multifaceted approach to HIV surveillance.

HIV seroprevalence information is necessary in order to provide data for public health management and policy. Dondero et al. (1988) state that specific uses for monitoring levels and trends include prioritizing, targeting, and evaluating HIV prevention activities; identifying geographic areas and population groups currently affected by HIV; identifying trends in the way the virus is spreading; anticipating future health care needs; setting public and program policies; and evaluating public health testing, education, and outreach programs.

Dondero et al. (1988) suggest a multifaceted approach to data collection, which would be an ideal way to obtain the maximum amount of information. Unfortunately, such data are currently not collected on a local level and, therefore, are not available for review.

Studies of HIV seroprevalence among various population subgroups have enabled providers to predict the number of AIDS cases within these populations in upcoming years, as well as probable health care needs. In a study of female prostitutes, Rosenberg and Weiner (1988) discovered that HIV seroprevalence was not as high as anticipated. This information provides public health officials important data about risk reduction behaviors. By gathering HIV seroprevalence data, a population's risk was redefined, money was saved on unnecessary or inappropriate educational

programs, and useful risk reduction behaviors were identified and communicated.

Today's health care providers are faced with an epidemic unlike any seen before; there are many obstacles to establishing effective public health policies regarding AIDS. According to Brandt (1988), although there is a desire to look at historical models as a means of dealing with the AIDS epidemic, responses to this epidemic must be shaped by contemporary science. Statistical analysis of trends may be an integral component of a comprehensive approach to this dilemma.

Benefits of Early Treatment

Along with examining information about those who are receiving the test, public health programs must attempt to identify populations at high risk who are not presenting for testing. It is imperative that individuals at high risk who are not requesting the test are provided necessary information in order to take advantage of the potential benefits of early treatment. Kizer (1988), Goldblum et al. (1988), and Bowen (1988) contend that HIV antibody testing and counseling are principal methods of preventing the spread of HIV infection. Lewis (1989), Broder and Fauci (1988), and Schoonover (1989) have advocated early, prophylactic treatment of HIV infection. A particularly thorough study of this topic, which was reported by Becker

and Joseph (1988), supports the assertion that education and counseling are of utmost value in the control of HIV infection.

Reporting

Dondero et al. (1988) suggest that HIV seroprevalence data would be a useful complement to existing reporting systems, such as AIDS case reporting, counseling and testing programs, and current surveys and studies. As of 1988, Dondero et al. (1988) had identified 11 states which required reporting of HIV seropositive individuals. The authors acknowledge the value of such information but add that it provides insufficient data with which to evaluate trends, levels, or risk factors of HIV infection in a community. Results of this study will be helpful in a comprehensive analysis of trends in HIV infection.

Statistics

While sources, including the World Health Organization Update (Global, 1988), San Francisco Epidemiologic Bulletin (Continued Seroconversion, 1989), MMWR (Update, 1989), and Centers for Disease Control (HIV/AIDS, 1989), continue to present voluminous statistics on the levels and trends in AIDS cases, very little has been done to demonstrate trends in HIV seroprevalence. Of those sources providing seroprevalence data, most, such as Seavello (1989), merely

present the number of tests performed along with the number of positive tests.

A singular source was identified which presented data on HIV seroprevalence among various exposure categories. The State of California Office of AIDS (1989) provides a monthly compilation of ATS data including the number of individuals tested with specific information on demographic and risk factor information. While this is indeed valuable data, the purpose of the present study was to analyze similar data on a local (county) level to identify trends over the period of time from 1985 to the present in order to project program planning needs.

Changes have recently been observed in the exposure categories of individuals diagnosed with AIDS. The Centers for Disease Control (HIV/AIDS, 1989) have documented the fact that the percentage of cases with the risk factor of male homosexual/bisexual contact is decreasing, while the percentage of heterosexuals with a history of intravenous drug use is increasing. Magura, Grossman, Lipton, Amann, Koger, and Gehan (1989) found that intravenous drug use was the primary risk factor for 18% of the 58,355 adolescents and adults with AIDS reported to the Centers for Disease Control through April of 1988.

What studies of AIDS incidence do not show, however, is if these individuals tested early, took advantage of

available treatments, or benefited from health care programs that were aware of their specific needs and anticipated their entrance into the health care system. Studies of HIV seroprevalence demographics and risk factors would enhance the likelihood that the aforementioned processes could occur.

Some studies have proposed that individuals requesting the test are not those at highest risk of infection. In a blinded study, Hull, Bettinger, Gallaher, Keller, Wilson, and Mertz (1988) found that men who refused HIV antibody testing were 5.3 times more likely to be infected than men who accepted testing. Coates, Stall, Kegeles, Lo, Morin, and McKusick (1988) tested 2,047 gay men for the presence of HIV antibody and found that the group who declined the opportunity to learn their test results were more likely to be men who were "younger, non-White, and less educated" (p. 859). Hull et al. (1988) also found Black men more likely to refuse testing. This information supports the need for increased knowledge regarding demographics of individuals requesting the test; such information must be compared to regional demographics to identify the need for appropriate education and community outreach.

The contention that individuals requesting HIV antibody testing are a distinct group has been made by several authors. Coates et al. (1988), as well as Hull et al.

(1988), found that clients attending alternative test sites are, as a group, highly motivated. Coates et al. (1988) recognized that these individuals:

must identify themselves at risk for exposure to a fatal and stigmatizing illness; undergo an uncomfortable and inconvenient medical testing procedure; publicly admit to a stranger that they are at risk; and return for a second visit to the testing site to learn the results of their HIV test. (p. 863)

One possible outcome of the accumulation and analysis of HIV antibody testing statistics might be the identification and integration into the system of high risk non-testing populations. This is significant since there is some debate about the inherent value of HIV antibody testing. While most health educators concur with Hull et al. (1988) that individualized counseling along with knowledge of HIV status leads to behavior change, McCusker, Stoddard, Mayer, Zapka, Morrison, and Saltzman (1988) found that behavior change was not predicated upon awareness of one's antibody status. This is another aspect of HIV antibody testing which warrants further investigation.

Potential for behavior change is a primary reason for HIV antibody testing. Another potential benefit of antibody status identification is that individuals may take advantage of the potential benefits of early, prophylactic therapies.

Nation's Health (1989) reports that the American Public Health Association (APHA) AIDS working group promotes early HIV antibody testing so that individuals can receive early treatment of opportunistic infections.

The articles reviewed here support the need for an analysis of HIV antibody testing statistics since they present various implications of testing yet are remiss in their description of those requesting the test. Coates et al. (1988) identified the need for studies of the barriers to testing particularly in the non-gay population. When the population presenting for testing has been identified, a comparison may be made to the general population. A comparison may then be made between those presumed to be at risk who request the test and those at risk who do not. Only then will the population under investigation in these studies be truly identified.

Conceptual Framework

The analysis of statistics relating to HIV seroprevalence will assist the nurse in the first step of the nursing process: assessment. Luckmann and Sorenson (1987) identify components of the assessment process as data collection, identification of unmet needs, determination of nursing problems, and assignment of priorities to unmet needs. This process supports the need for this study since

only through adequate assessment of a problem may a nurse progress through the nursing process.

According to Nicoll (1986) and Marriner (1986), nursing theorists such as King and Leininger have identified the significant influence of demographics and environment upon the nurse/client interaction. King states that "adjustments to life and health are influenced by an individual's interaction with his environment" (Marriner, 1986, p. 236). By gathering information about the community, such as trends in ethnicity, age, sex, and predominant risk factors, the nurse is better equipped to interact with clients in the community. Nicoll and Marriner also describe Watson's theory which focuses on the promotion of health and prevention of illness. Watson's theory supports HIV seroprevalence data analysis since the ultimate intent is health promotion and disease prevention.

An epidemiological model was utilized for data analysis. As Coates et al. (1988) pointed out, "testing services must promote each individual's capacity to cope psychologically and behaviorally. Any program lacking these emphases will undoubtedly leave in its wake a flood of psychological and social casualties" (p. 859). This study, therefore, analyzed the demographics and risk factors of individuals receiving anonymous HIV antibody testing in one California county. The information will subsequently be

used for planning education and outreach programs as well as identifying areas of need in testing promotion.

Chapter 3

THE METHOD

This study used an analysis of retrospective data to identify trends in anonymous HIV antibody testing. This chapter deals with the research design, data collection tools, data collection, and data analysis.

Research Design

A retrospective, descriptive method of research was utilized. A total of 6,300 HIV antibody tests were analyzed. The advantages of this approach were: (a) a large number of tests were available for analysis; (b) data were collected anonymously, therefore no consent was necessary; (c) data, compiled onto monthly reporting forms, had been stored in locked file cabinets and were easily accessed. Disadvantages of the retrospective approach to data analysis are: (a) questions asked by the counselors were developed by the State Office of AID (SOA); and possibly did not assess all relevant areas; (b) analysis was limited to that information which was compiled onto monthly reporting forms; (c) data were hand tallied onto forms, thus allowing for the possibility of human error.

Data Collection Tools

The laboratory slip utilized by counselors to collect information from clients was developed by the SOA (Appendix

B). The purpose of the questions was to elicit information pertaining to testing history, ethnicity, risk factors, age, sex, and residence of individuals presenting for testing. Except for risk factors, each category has only one response. In the assessment of risk factors, all appropriate responses are documented. Counselors utilizing these slips had all received counselor training through the SOA. A portion of this course is committed to providing training on proper completion of the laboratory slip.

The monthly reporting form (Appendix C) was also developed by the SOA. The form served as an invoice and was developed for billing purposes. Data obtained from laboratory slips are tallied onto monthly reporting forms. Unlike the laboratory slip, only one risk factor per client is accepted onto the reporting form. That factor considered to be the individual's highest risk factor is indicated on the reporting form.

Data Collection

During pretest counseling sessions, HIV counselors obtained information from clients and entered this data onto laboratory slips. These laboratory slips were processed for billing purposes and then stored in a file cabinet. At the end of each month, information from laboratory slips was hand tallied onto monthly reporting forms. These reports, beginning July of 1985, were stored in a locked file cabinet

until the investigator received permission to analyze the data (Appendix A).

The data collection portion of the laboratory slip and the monthly reporting form have been revised since their inception. In April of 1988, the forms were altered to incorporate data regarding clients' ethnicity, as well as assessment of an additional risk factor, gay or bisexual male IVDU (Intravenous Drug User).

Data Analysis

Forms developed by the investigator (Appendix C) were utilized to facilitate compilation and analysis of data. Data were divided in the following categories: (a) primary risk factor, (b) ethnicity, (c) age, and (d) sex.

Comprehensive testing information regarding total number of tests and percentages of positive results was broken down by year and presented in tabular fashion. Analysis of data was also made from a tabular representation of comprehensive (1985-1989) data depicting total number of tests and percentage of positive results broken down by primary risk factor.

Risk factor data were analyzed on a semi-annual basis using percentage of positive tests and total number of tests performed. Using histograms, data were organized for each risk factor category. Histograms were also utilized to

organize information on percentage of positive tests broken down by ethnicity and age.

Using a semi-annual graphic representation of data, testing was summarized to analyze trends in total number of tests and percentage of positive results. Analysis of county population as compared to testing population and AIDS cases broken down by ethnicity was accomplished by use of a pie graph.

A yearly breakdown, as well as a comprehensive view of the percentage of total tests broken down by primary risk factor, was analyzed utilizing histograms. Finally, a comparison of number testing and percentage testing, organized in tabular fashion, allowed for further analysis of risk factor and ethnicity data. The findings from the data analysis are presented in Chapter 4.

Chapter 4

ANALYSIS AND INTERPRETATION OF DATA

The results of the retrospective analysis are presented in tabular and graphic form. In the following discussion, areas which were investigated will be presented, followed by an analysis of trends for each category.

Figure 1 depicts the trends in testing on a semi-annual basis. The number of individuals testing in a 6 month period ranges from a low of 210, during the second half of 1985, to a high of 1071, in the first half of 1988. The difference between the highest and lowest periods of testing is over 400%. The number of clients presenting for testing from the first half of 1987 through the present has remained relatively stable, with an average of 935 clients presenting for testing each 6 months.

The trend in seropositivity demonstrated in Figure 1 is significant. In the first half of 1986, the seropositivity rate was 16%, while the first half of 1988 and 1989 show a 1% rate of seropositivity. The overall rate of percentage positive for the population being studied is 2.9%. In the first half of 1986, 212 individuals presented for testing, and 16% of those testing were positive. In the first half of 1987, 762 individuals received testing, with 3% testing

TOTAL Semi Annual Trend

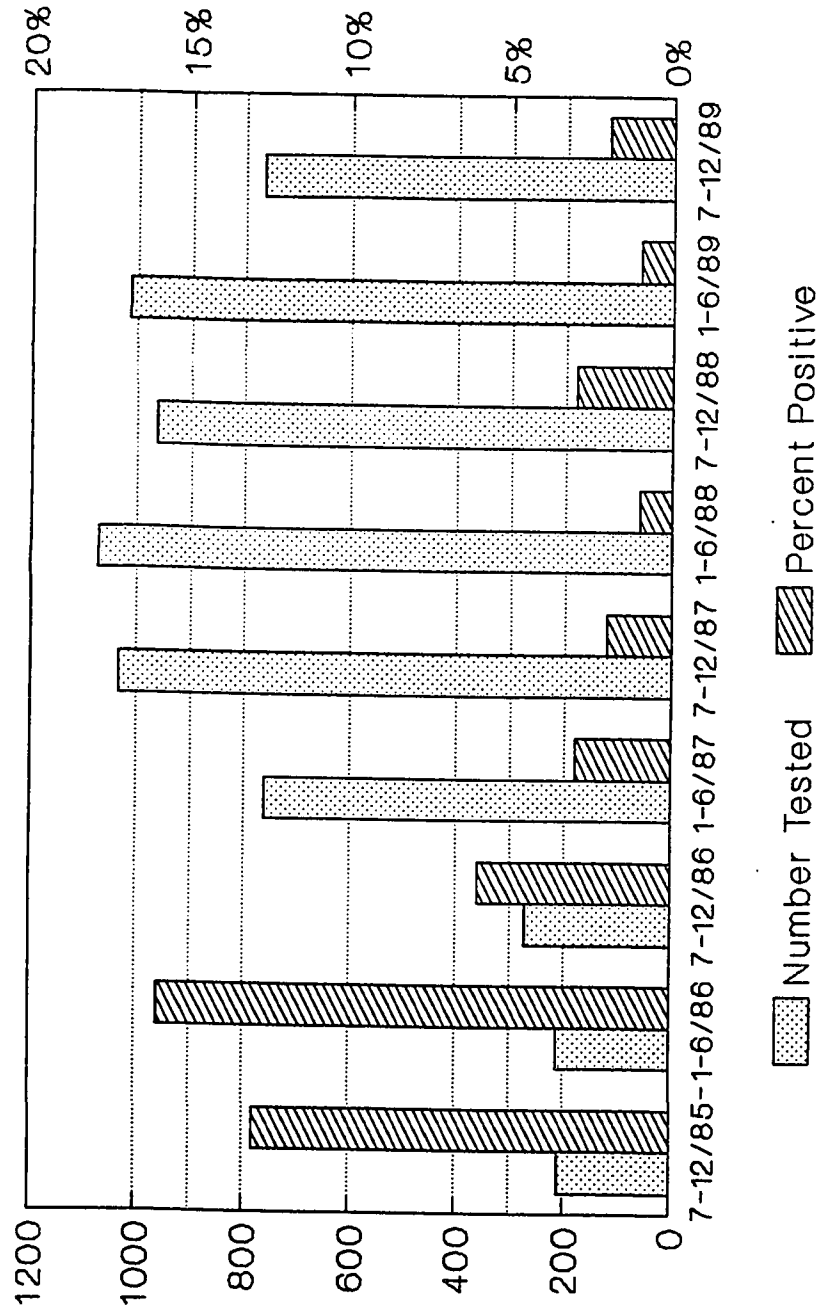


Figure 1

positive. There are two factors which are likely to have caused this phenomenon. First, the decrease in the percentage of individuals testing positive may have been a result of the enormous increase in the number of individuals testing. Another influencing factor is the shift in primary risk factor of those presenting for testing from gay men (1985 and 1986) to heterosexual with multiple sex partners (1987). This trend is observable in Figure 2. The fact that this trend influences seropositivity by virtue of higher numbers of lower risk clients presenting for testing is supported by information presented in Figure 3.

In Figure 2, the percentage of total tests by client's primary risk factor is presented. The most obvious trend is the change in predominant primary risk factor from gay men to heterosexual with multiple partners. From 1985 to 1989, the percentage of total tests by gay men went from 28.6% to 6.1%. This represents a significant decrease. In the same period of time, the percentage of individuals testing whose primary risk factor was being heterosexual with multiple partners increased from 19% to 59%. Trends in other risk factors will be analyzed in further detail utilizing more specific tables.

Significant trends are observable in Figure 3, which depicts seropositivity by primary risk factor. The positivity rate of gay and bisexual men ranges from 33 and

Percent Testing by Primary Risk Factor

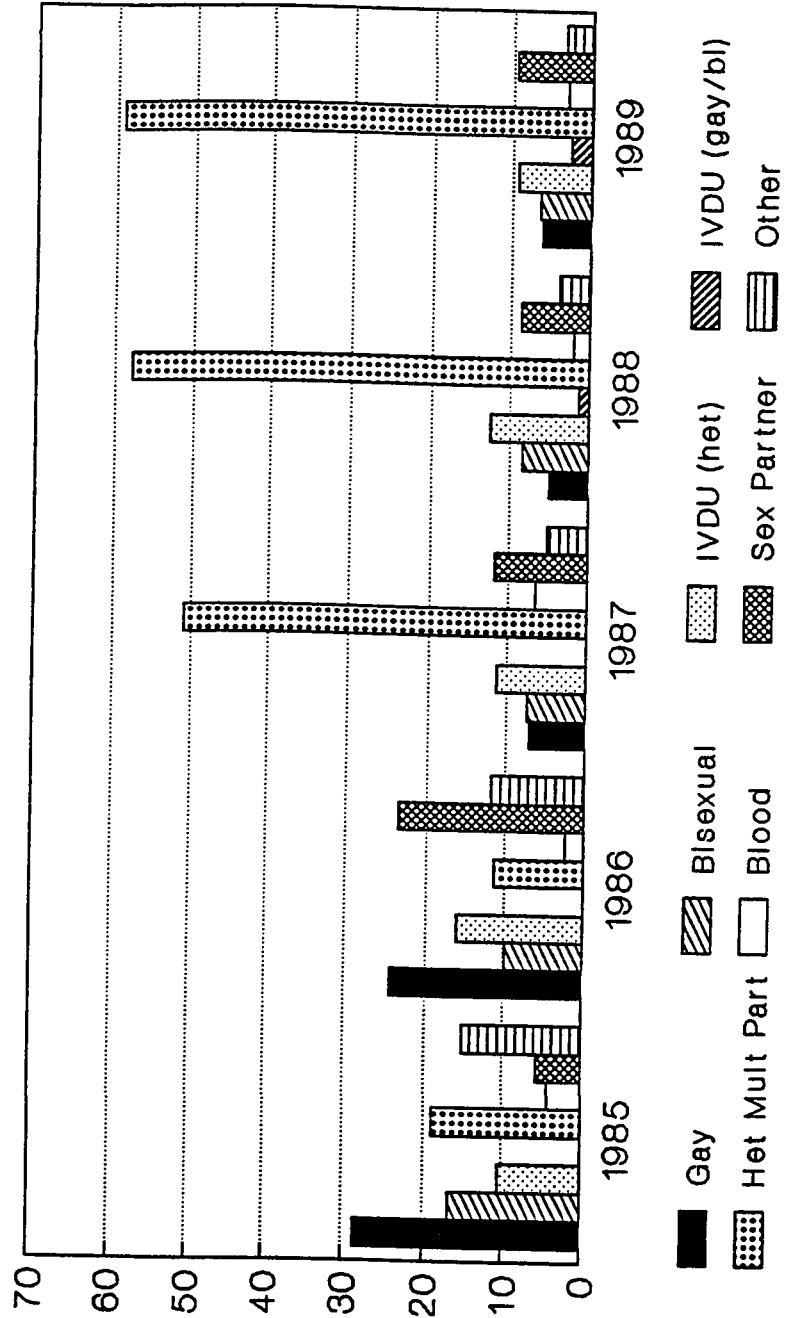


Figure 2

Percent Positive by Primary Risk Factor

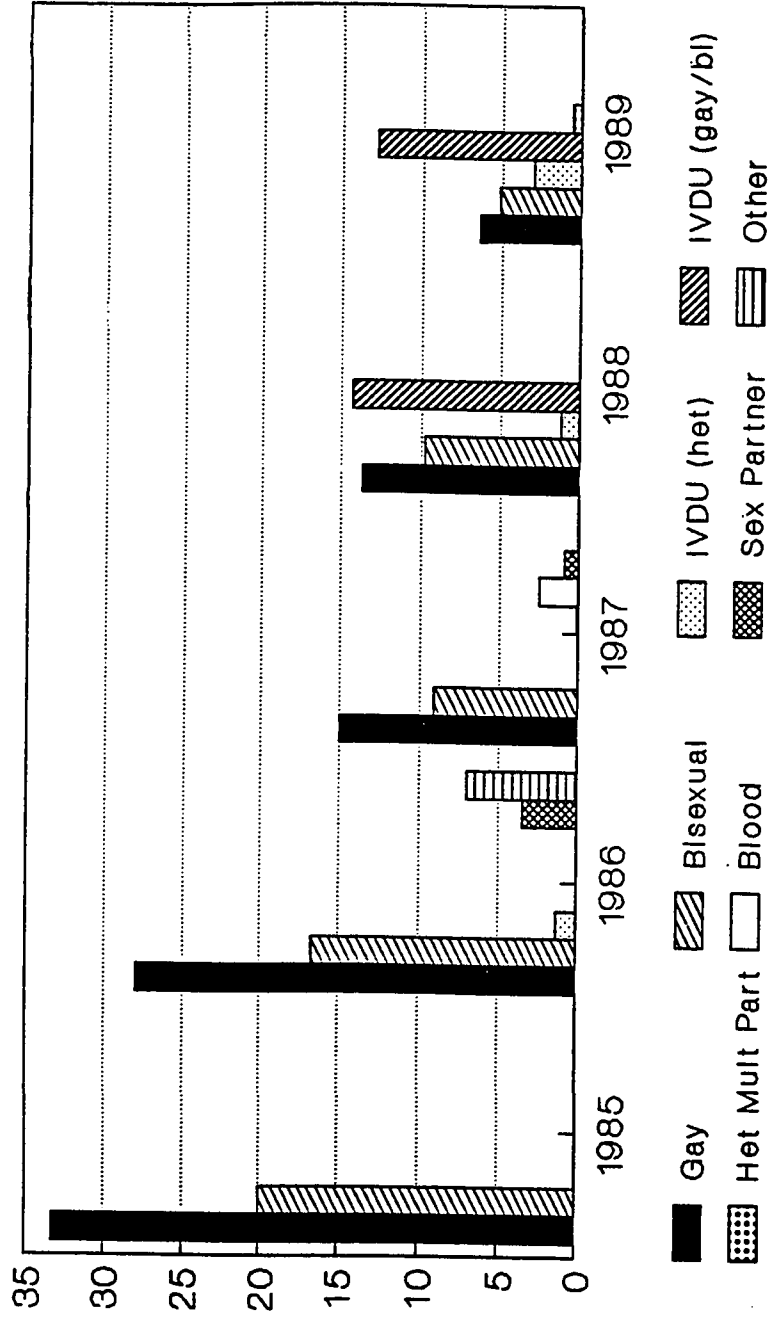


Figure 3

20%, respectively, in 1985, to 6.4 and 5.2%, respectively, in 1989. Gay men remain the risk group with the highest positivity rate from 1985 until 1987. In 1988, the percentage of positive tests for gay men (13.7%) is almost identical to that of IVDU's (14.3%). In 1989, there is a significant shift in primary risk factor positivity. While the seropositivity rate for IVDU's remained relatively stable at 12.8%, the seropositivity rate for gay men testing decreased to 6.4%. This data supports the contention of many authors, such as Brickner et al. (1989) that "intravenous drug users are emerging as the group at greatest risk for both acquiring and spreading HIV infection" (p. 833). It is interesting to note, once again, that while Figure 2 demonstrated the fact that heterosexuals with multiple partners comprise the vast majority of individuals presenting for testing, their seropositivity rate is negligible compared to that of other risk categories. The highest seropositivity rate for this group is 0.5%, which was seen in 1989, while the seropositivity rate for gay men in 1985 was 33.3%.

The Alternative Testing Site (ATS) under investigation has seen shifts in the gender of those presenting for testing (Figure 4). In 1985, 75.7% of individuals testing were male. In 1987, the percentage of tests by males and females was almost identical, being 50.5% and 49.5%

Percent Testing by Sex

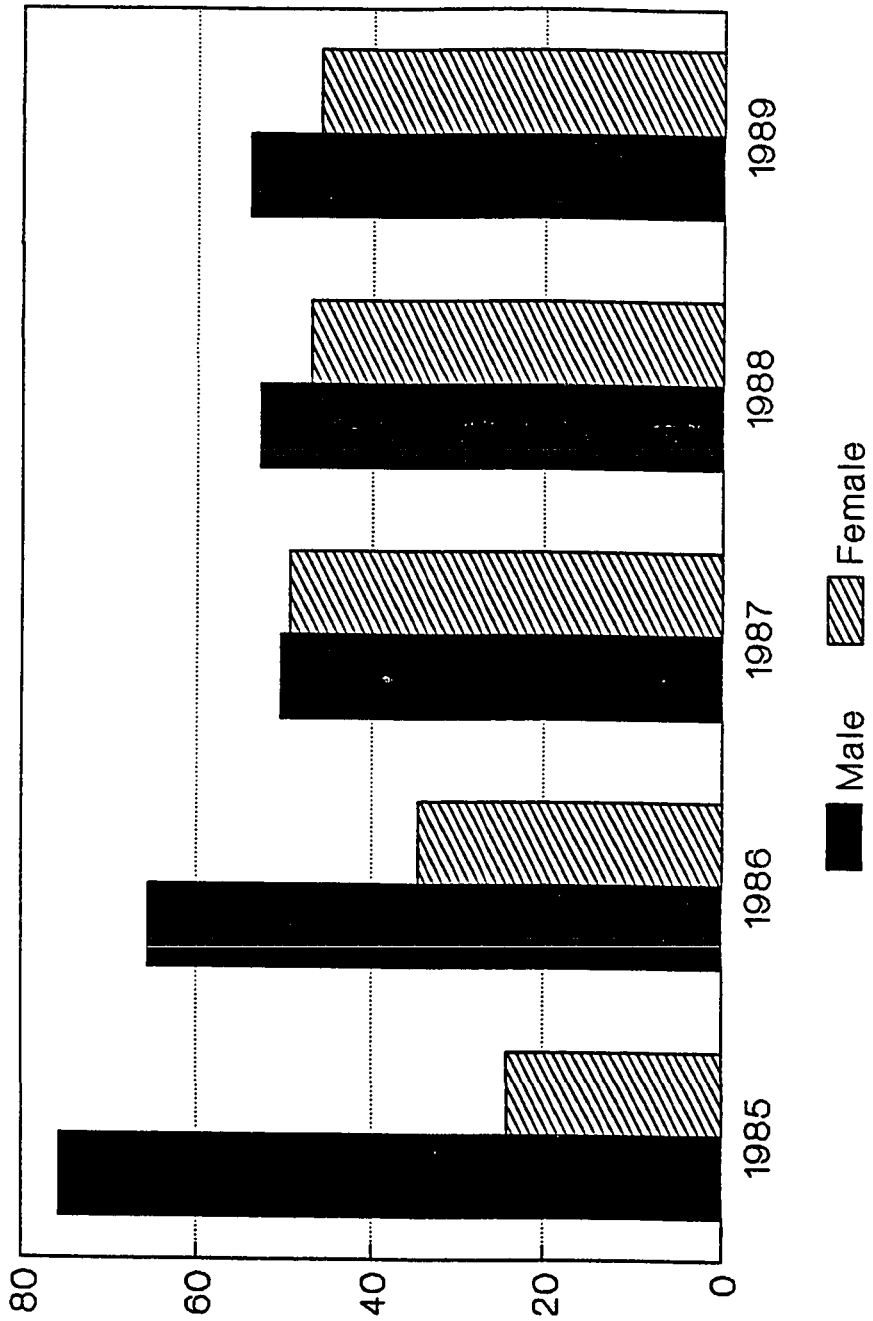


Figure 4

respectively. In the past 2 years, the trend has remained relatively stable, with slightly more testing (12% more in 1988, 17% more in 1989) being requested by males than females.

Figure 5 represents seropositivity by gender. The seropositivity rate for males ranges from a high of 17% in 1985 to a low of 2.8% in 1989. The variation in seropositivity in females is less drastic, with a low of zero in 1985 and 1988, and a high of 2.4% in 1986. While it is obvious that far fewer women than men are testing HIV positive, the trend in seropositivity among women has been sporadic, while the trend for men has seen a continuous decline.

Figure 6 depicts trends in testing by age group. The percentage of tests received by teen-agers in 1989 was nearly three times that of teen-agers requesting the test in 1985. The percentage testing by age group 30-39 decreased by 48% from 1985 to 1989. The age group of 20-29 has demonstrated a gradual increase in their representation of the testing population with a 57% rise over the 5 year period. So, while the number of 30-39 year olds comprising the testing population has gradually decreased, the number of 12-29 year olds has gradually increased.

Figures 7 and 8 depict the contrast between county population, ATS testing population, and AIDS cases in the

Percent Positive by Sex

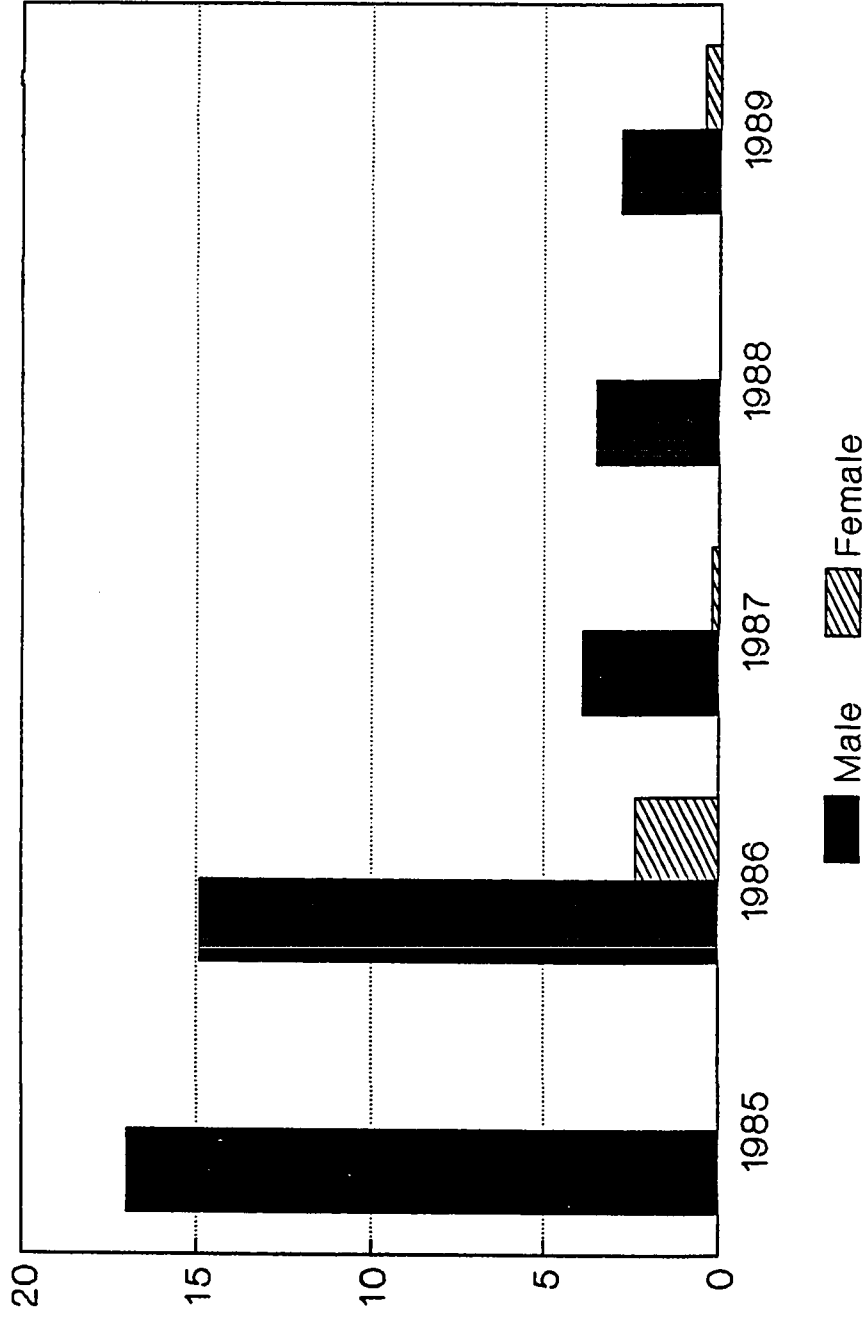


Figure 5

Percent Testing by Age

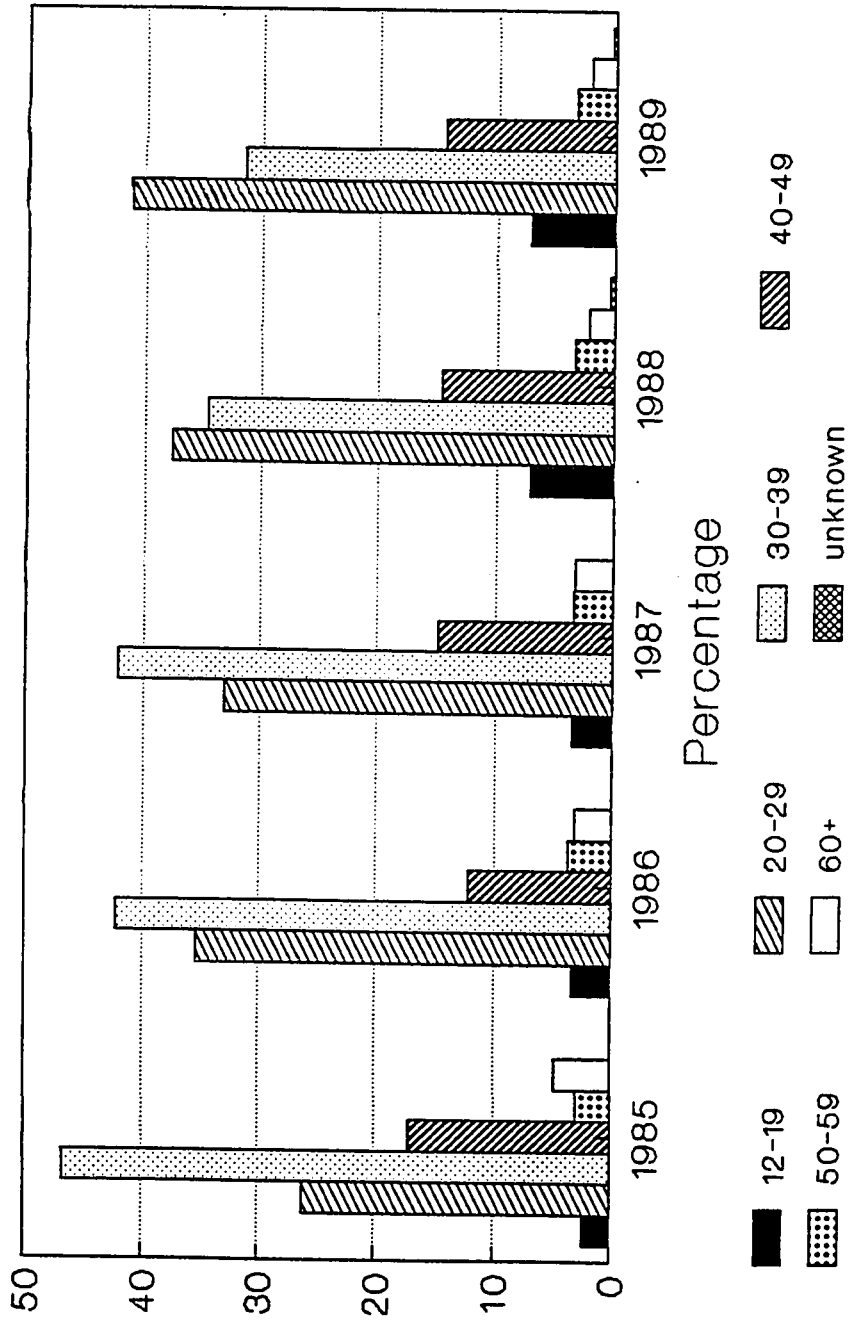


Figure 6

Comparison of County Population and Testing Population

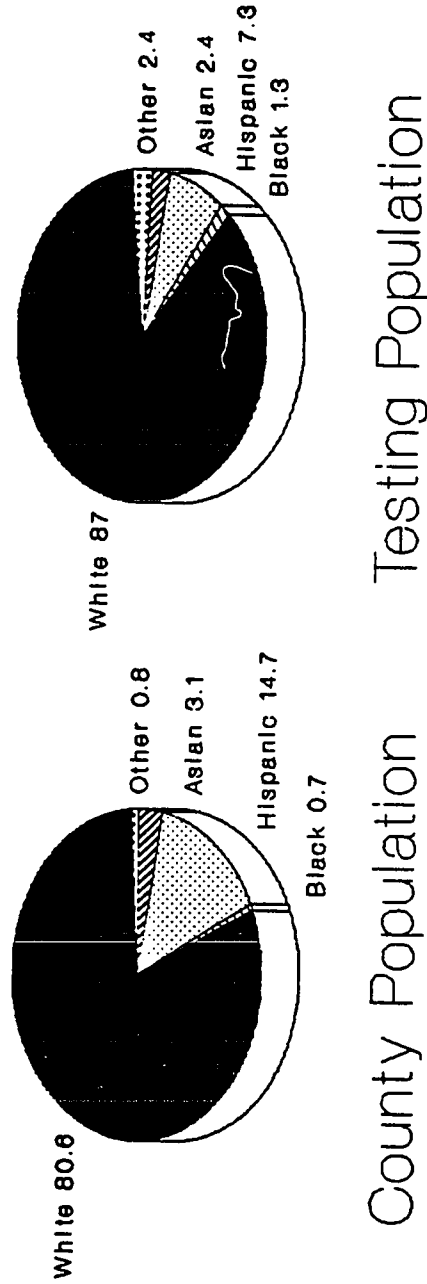


Figure 7

Asian Includes:
Alaskan, Native American, Japanese,
Chinese, Hawaiian

AIDS Cases in Santa Cruz County by Ethnicity

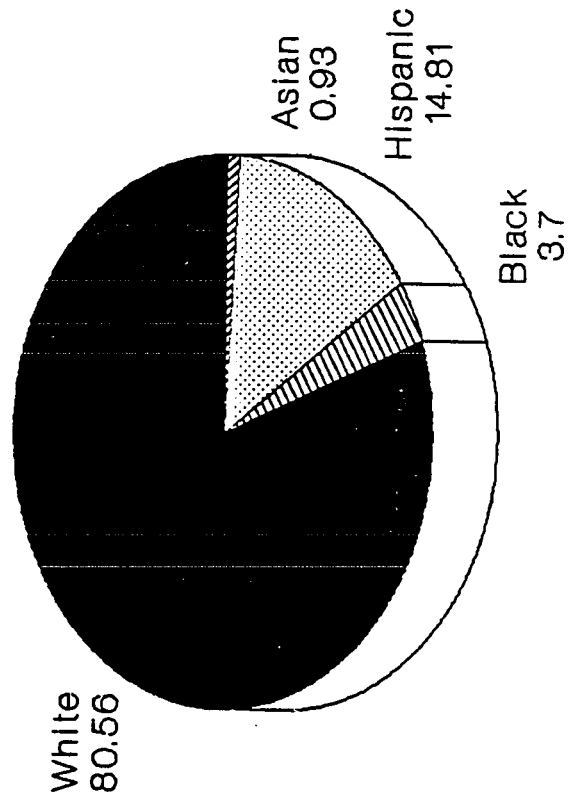


Figure 8

county where the ATS under investigation is located. One observable trend based on these graphs is the fact that while Hispanics' and Whites' representation of county population and AIDS cases in the county are virtually identical, there is a significant discrepancy between these percentages and percentages of the testing population. While Hispanics comprise 14.7% of the county population and 14.81% of the county's AIDS cases, they represent only 7.3% of the testing population. Conversely, Whites represent 80.6% of the county population and 80.56% of AIDS cases, but make up 87% of the testing population.

When analyzing information presented in Figures 7 and 8, it is important to recognize the fact that information regarding ethnic background was not collected in ATS sites until 1988. This, along with the limited number of individuals from other ethnic backgrounds presenting for testing, makes information pertaining to those groups less significant.

The next group of tables present information regarding number of individuals testing and percentage positive, on a semi-annual basis, broken down by primary risk factor. Figure 9 reflects information pertaining to gay men. It is interesting to note that while the seropositivity fluctuates a great deal, the number of individuals testing remains relatively stable. The highest number of gay men testing in

Gay Men Semi Annual Trend by Risk Factor

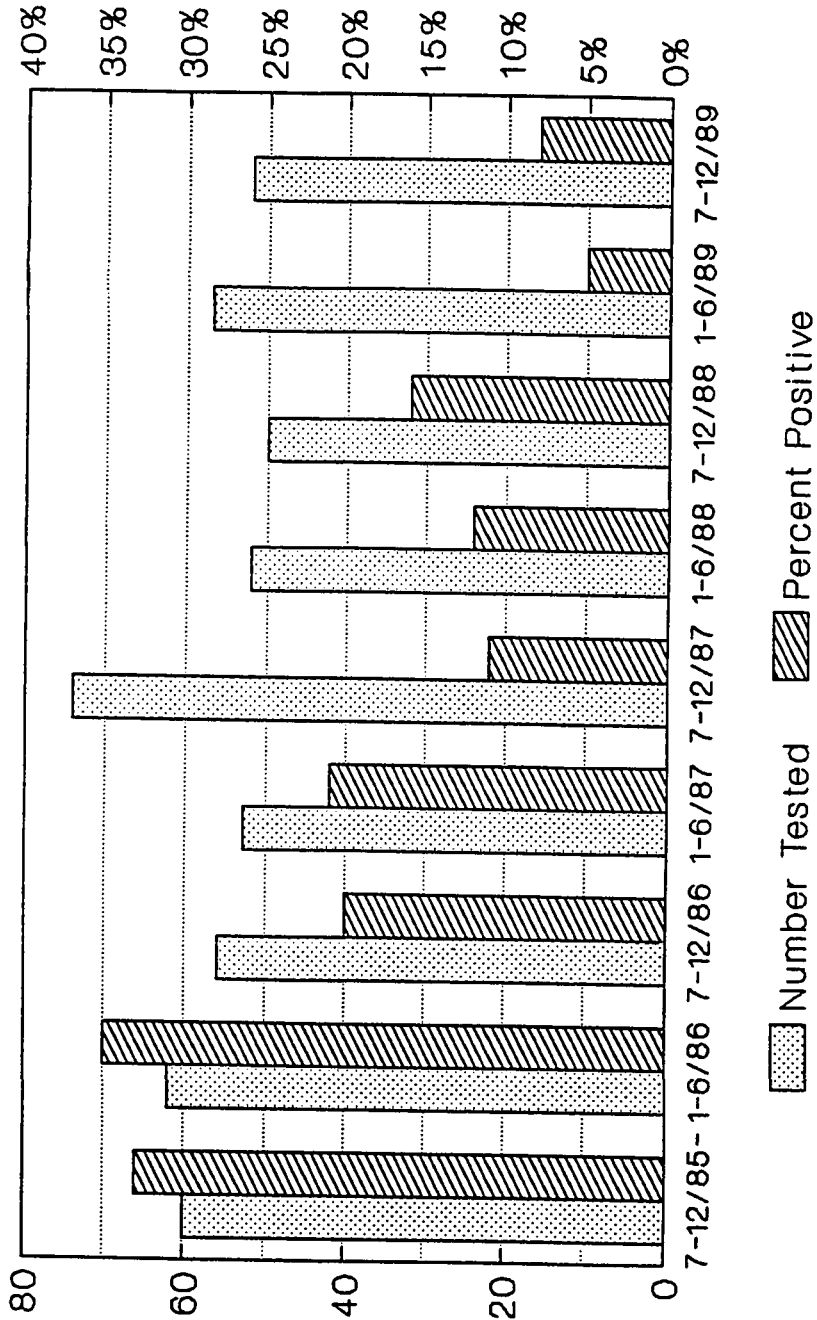


Figure 9

a 6 month period was 74, seen in the second half of 1987. The lowest number of gay men presenting for testing was 50, seen in the second half of 1988. The difference between the first and last periods under investigation is a mere 8 individuals, or 15%. Seropositivity, however, has fluctuated greatly. There is a 600% difference between the highest and lowest percentages of positivity. Observable trends for this category, therefore, are the overall decrease in percentage positive, with little variation in the number of clients presenting for testing.

Figure 10 presents information pertaining to testing of bisexual men. While it would seem that this group, with the common risk factor of having had sex with another man, would demonstrate similar trends in testing to those of gay men, such is not the case. While the number of gay men testing has remained relatively stable, the number of bisexual men testing has fluctuated greatly. In the second half of 1986, only 16 bisexual men received testing, while 87 received testing in the second half of 1987. It is interesting to note that testing by both gay and bisexual men reached a peak in the last 6 months of 1987.

The seropositivity rate among bisexual men has also fluctuated a great deal. In the first half of 1986, the seropositivity rate was 22%, while in the last half of 1989, it was 4%. Table 8 demonstrates the following trend in

Bisexual Men Semi Annual Trend by Risk Factor

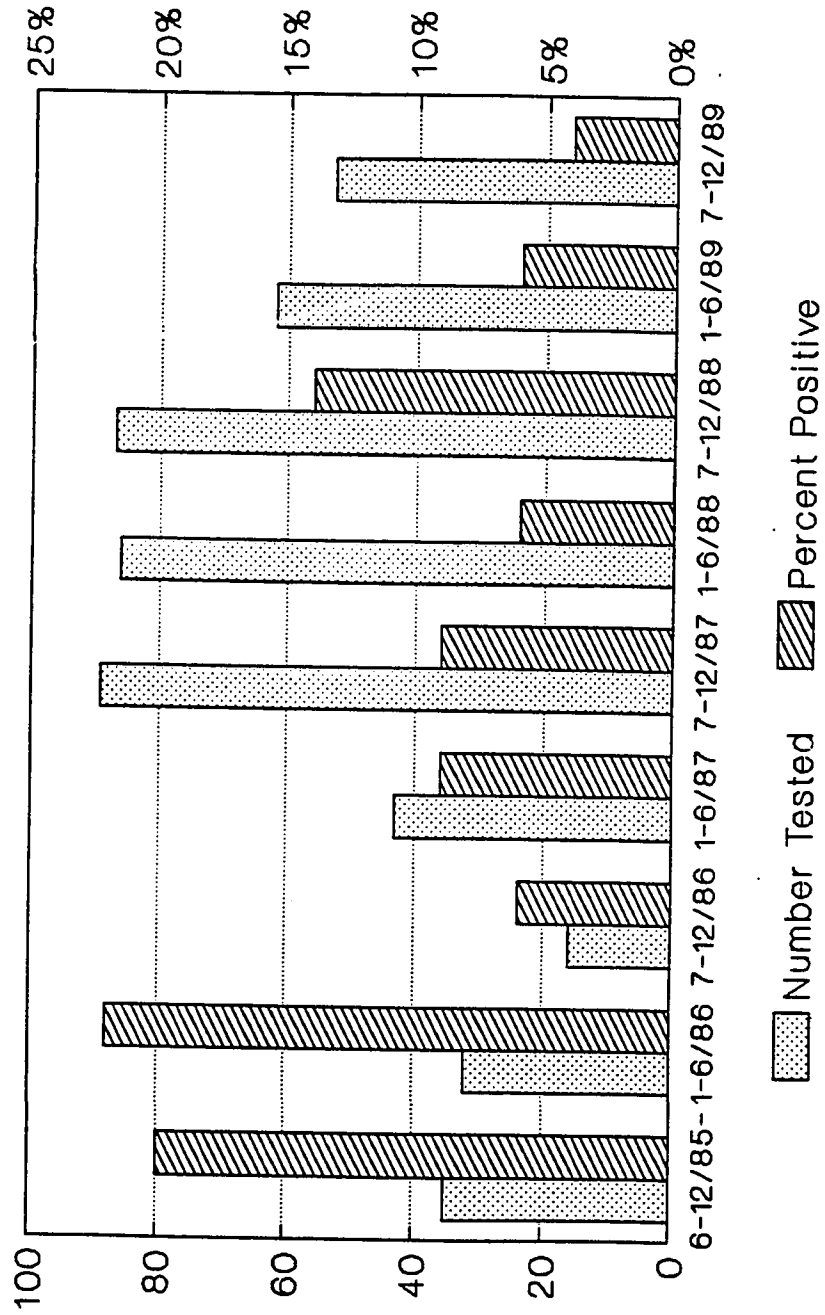


Figure 10

percentage positive: in the first two periods under investigation, the number of clients testing was low, and the percentage positive was high; in the next two periods, the number of individuals testing remained relatively low and the percentage positive decreased significantly (from an average of 21% to an average of 7.5%); in the next three periods, the number testing remained high, averaging 87 clients per period, and the percentage positive also remained high with an average of 9.7%; during 1989, the number of bisexual men testing showed a slight decrease as did the seropositivity rate for this group.

Figures 11 and 12 represent trends in testing for heterosexual male and female IVDU's, respectively. The trend in number of individuals testing is remarkably similar for both groups. For both groups, the number of individuals testing was quite low at the inception of the testing program. The number of male and female heterosexual IVDU's receiving testing continued to rise until the first half of 1988, at which time the number peaked for both groups. Since that time, both groups have experienced a continuous, gradual decrease in the number tested.

The seropositivity rate has been sporadic for both groups, particularly women. This is due to the low number of clients testing in a given 6 month period. It is more valuable, therefore, to analyze the trends in seropositivity

Female IVDU/Heterosexual Semi Annual Trend by Risk Factor

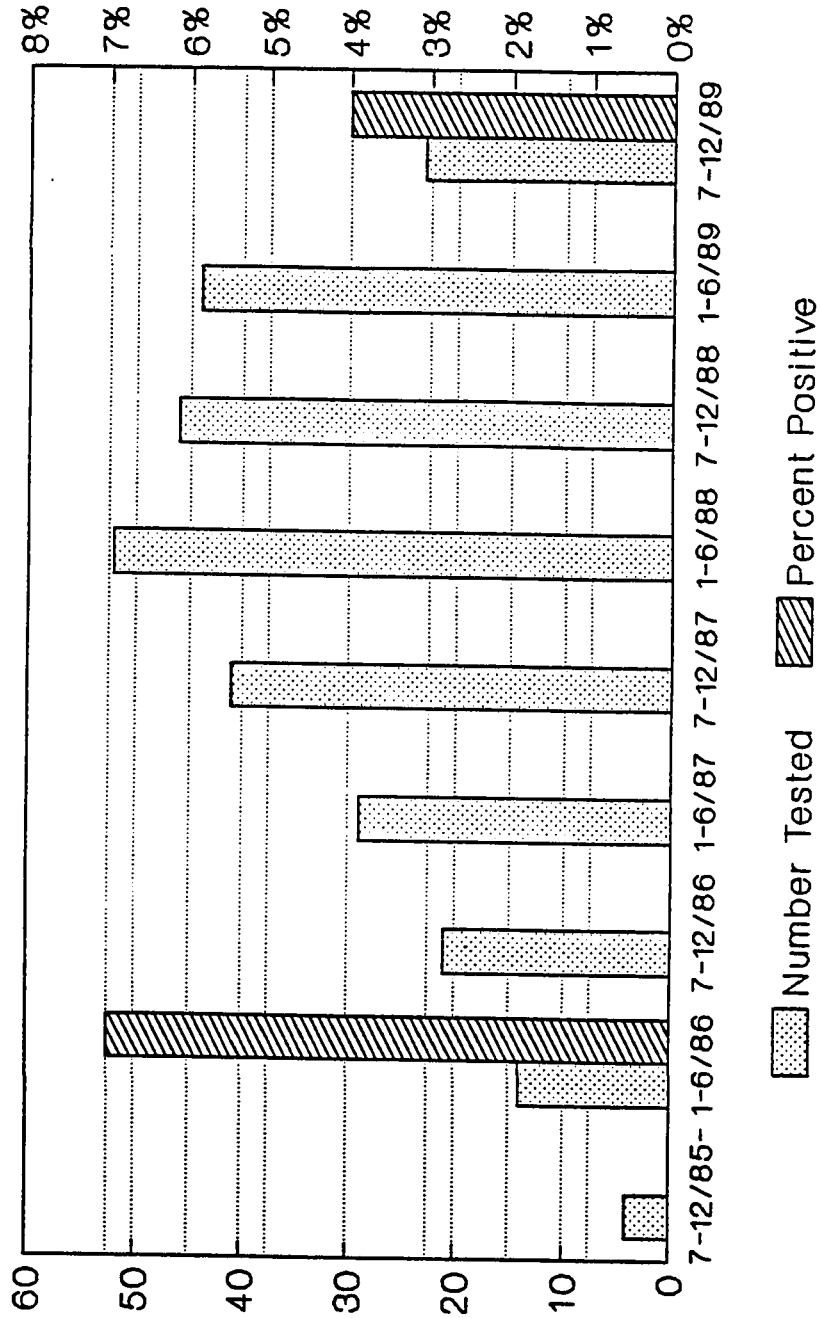


Figure 11

Male IVDU/Heterosexual Semi Annual Trend by Risk Factor

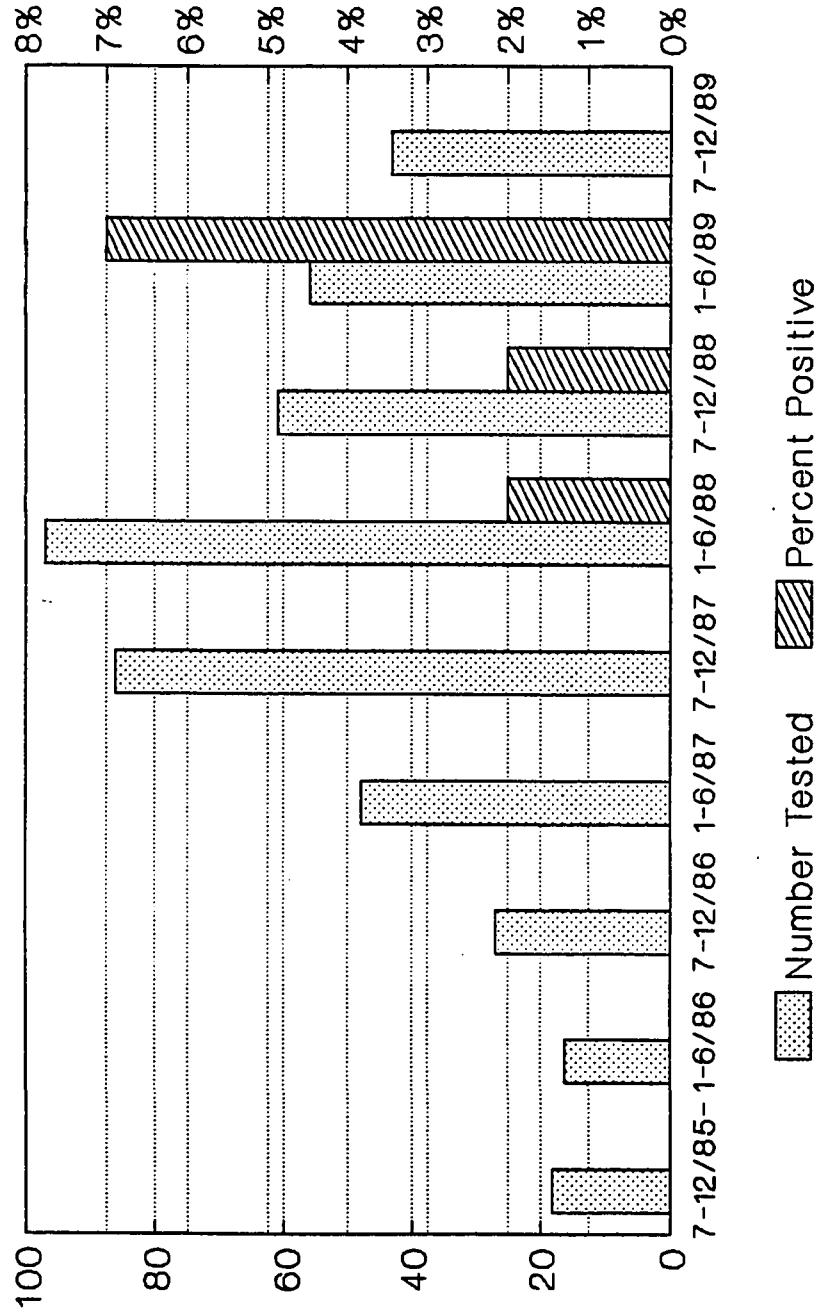


Figure 12

on a larger scale. During the 4 1/2 year period under investigation, two women in this category have tested HIV positive, which constitutes an overall seropositivity rate of 0.73%. The overall seropositivity rate for men in the category is 1.5%. From 1985 to 1987, there were no positive tests for men. In 1988 and 1989, however, 7 men in this category tested HIV positive, which leads to a 2.7% seropositivity rate for that time period.

With Figures 13 and 14, another testing category is broken down by gender. Trends in testing by heterosexuals with multiple sex partners are presented in these two tables. There are distinct trends in testing for both males and females in this category. The number of individuals testing was negligible for both groups in 1985 and 1986. In 1987, however, the number tested rose for both groups, with females increasing from 24 to 212 tested, and males from 15 to 149 tested. Both groups experienced a peak of number tested during the first half of 1988, and both have seen a slight decline in the number testing since that time.

The seropositivity rates for the groups represented in Figures 13 and 14 are much more significant than those of previous groups since the number tested is so much greater. There were no positive tests for either group in 7 of the 9 periods presented in the tables. The seropositivity for the two periods in each group when positive tests did occur was

Female Hetero. with Multiple Partners Semi Annual Trend by Risk Factor

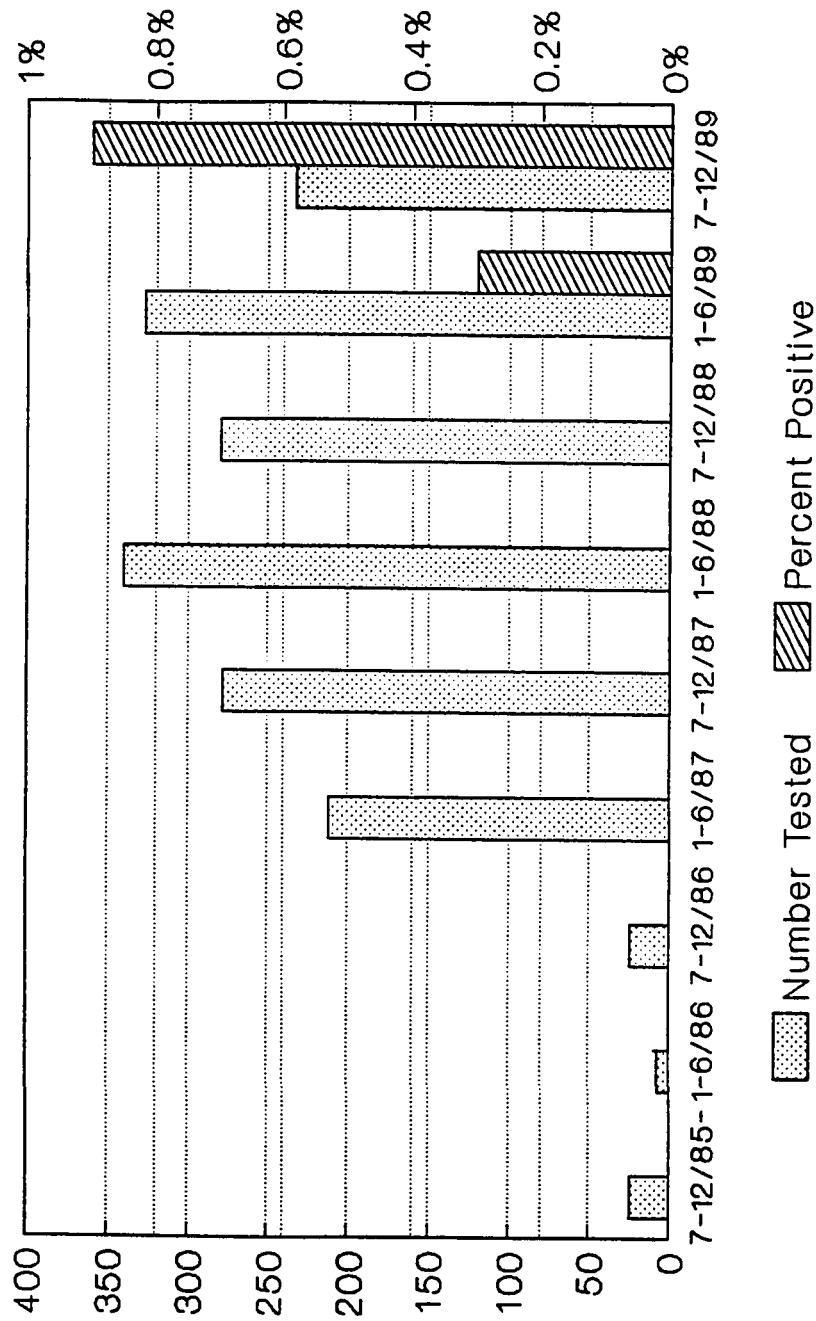


Figure 13

Male Hetero. with Multiple Partners Semi Annual Trend by Risk Factor

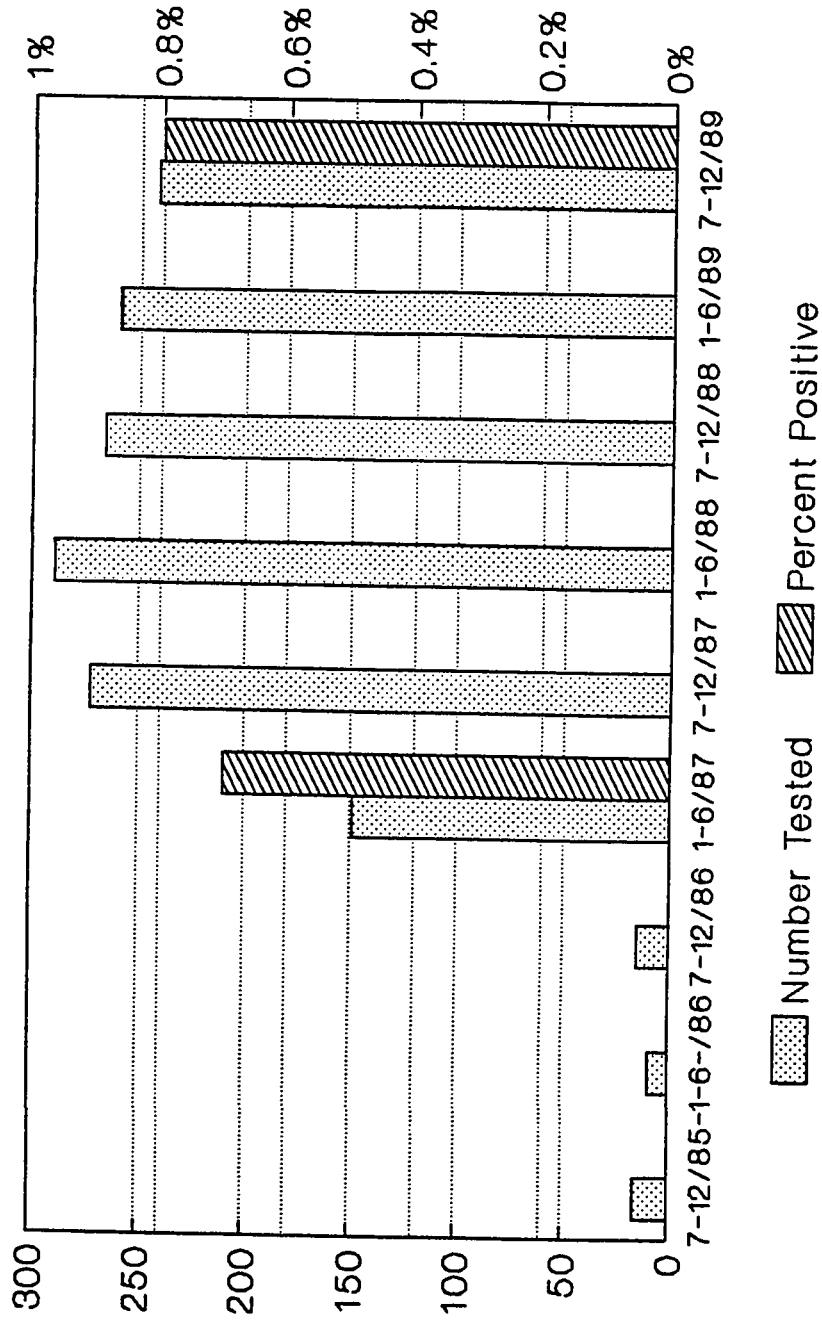


Figure 14

relatively low, the high being 0.9% by females in the second half of 1989, and the low being 0.3% for females testing in the first half of 1989. The seropositivity rates for males were 0.7% and 0.8%, seen in the first period of 1987, and the second half of 1988, respectively.

Figures 15 and 16 provide for another interesting analysis of risk category broken down by gender. With these groups, the individual's primary risk factor is having had a partner who falls into one of the higher risk categories. In Figure 15, one can see that the number of males testing is initially quite low, with only 3 testing in 1985. The number rises significantly, and peaks in the first half of 1987. The number then drops drastically, from 31 to 4 and shows a gradual increase since the second half of 1987. The number of females in this category testing, seen in Figure 16, is also low initially but remains relatively stable from the second half of 1986 through 1989, with the number testing in the 6 month periods ranging from 40 to 90. Perhaps the most interesting data observable in Figures 15 and 16 is the discrepancy in numbers testing between men and women. While the average number of men testing whose primary risk factor is having had a sex partner in a higher risk category is 16 per 6 month period, the average number of women testing who fall into the same category is 60. As with certain previous categories, analyzing data regarding

Male Sex Partner of Above Category Semi Annual Trend by Risk Factor

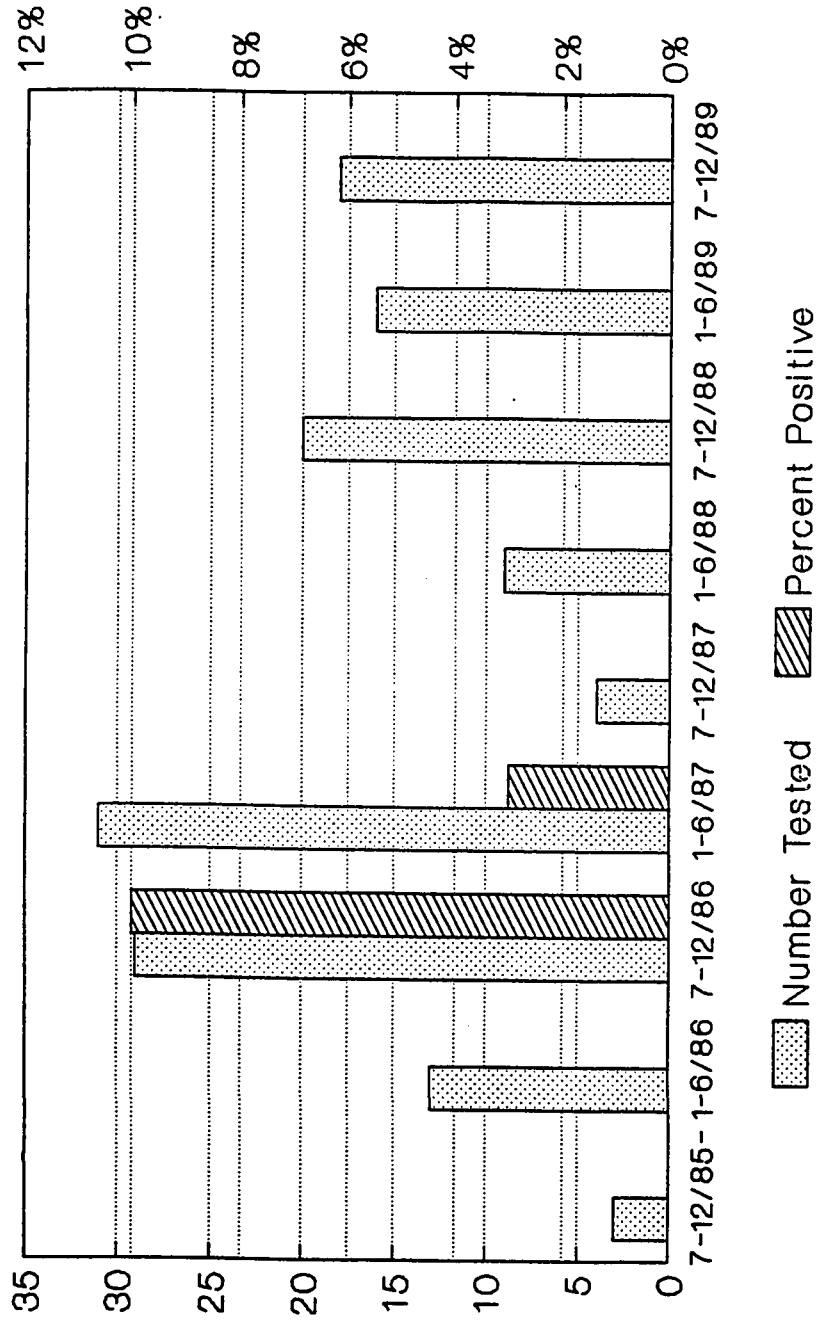


Figure 15

Female Sex Partner of Above Category Semi Annual Trend by Risk Factor

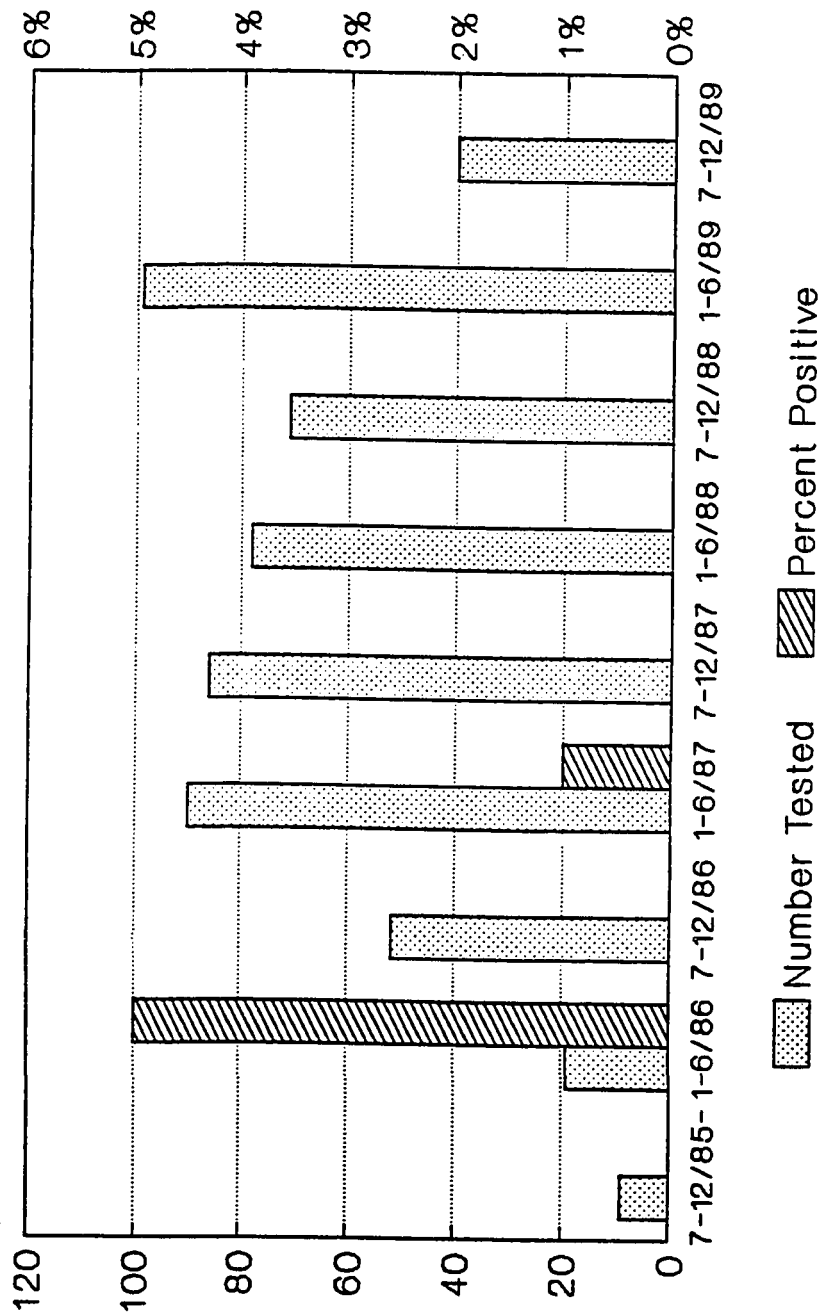


Figure 16

seropositivity is of little significance using low numbers and limited time periods. It is of greater value to assess overall seropositivity for groups such as these. The overall percentage positive for the group described in Figure 15 is 2.8%, while that of the group depicted in Figure 16 is 0.37%.

Data collection techniques used in the ATS system prevented analysis of trends in certain categories. Information regarding percentage positive by age group was not collected until 1988, which makes analysis of trends in this group impossible. Similarly, information regarding total tests and percentage positive by client ethnicity was only collected as of 1988, therefore eliminating the opportunity to observe trends in testing among these groups. Data regarding gay or bisexual male IVDU's, seen in Figure 17, were also collected as of 1988. While the limited data pertaining to this group prohibits analysis of trends, the consistently high seropositivity rate identifies this group as one which warrants special attention.

The risk categories of hemophiliac and blood recipient saw very few individuals presenting for testing. The numbers were so low as to render the results and subsequent analysis of these groups statistically insignificant.

Male IVDU/Gay or Bisexual Semi Annual Trend by Risk Factor

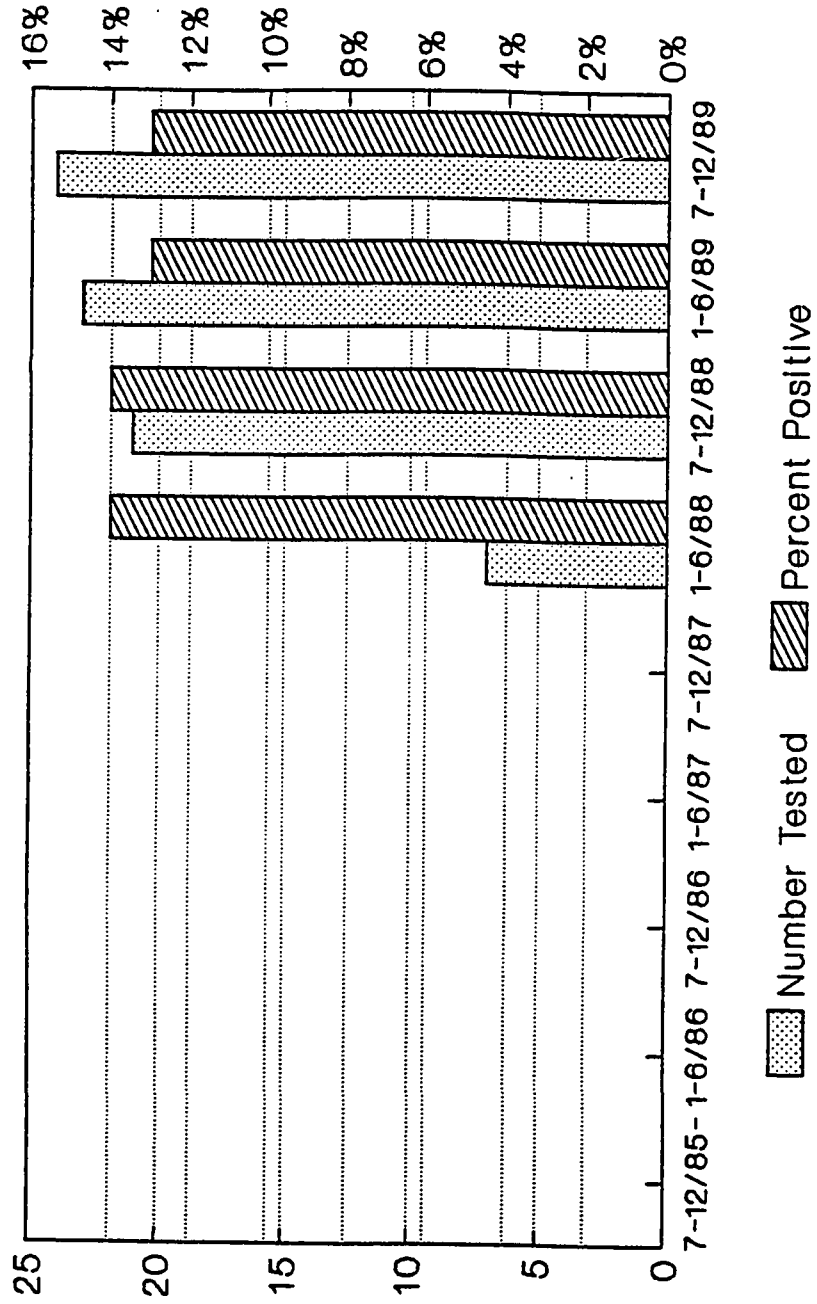


Figure 17

1985 to 1987 there was no data.

Chapter 5

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

The data presented in Figures 1 through 17 revealed interesting and significant information regarding trends in testing and seropositivity by individuals with various risk factors and demographic variables. A marked increase in overall number tested was seen, along with a subsequent decrease in percentage positive. This may be explained by the fact that higher numbers of lower risk individuals are presenting for testing.

The increase in number testing was most dramatic during 1987 and 1988, when number tested reached a peak level. This increase coincides with the rise in testing by IVDU heterosexual clients as well as heterosexuals with multiple partners. While the number testing in these two groups rose dramatically in 1987 and 1988, their seropositivity rate remained low.

The period from 1987 to 1988 demonstrated a rise in number testing within the risk categories of bisexual men, heterosexual IVDU's, and heterosexuals with multiple partners. The dramatic increase in the number of individuals presenting for testing coincides with a time in

which AIDS and HIV infection were receiving a great deal of publicity. Movie stars were dying of AIDS, the media was talking about it, and it was no longer perceived as strictly a "gay disease." It is likely that these factors contributed to the increase in testing among the aforementioned groups.

There have been several notable trends in the population of individuals presenting for testing. One such trend is the increased representation of women. Teen-agers and young adults are two other groups whose numbers are constituting a greater portion of the testing population. Percentage testing by primary risk factor has seen dramatic changes with the influx of heterosexuals with multiple partners presenting for testing.

Due to low numbers of tests and sporadic results, trends in seropositivity have been more difficult to identify and prove less significant for purposes of extrapolation. Several trends, however, were identified in percentage of positive tests. Seropositivity for gay and bisexual men has decreased since 1985, while heterosexuals with multiple partners have experienced an increased number of positive tests. The seropositivity rate for gay or bisexual IVDU's was not assessed prior to 1988, but has remained high since that time period. Overall, the

seropositivity rate in the ATS being studied has decreased significantly since 1985.

Figures 7 and 8 demonstrated the fact that certain ethnic categories are misrepresented in the testing population. Unfortunately, the paucity of data prior to 1988 precludes the analysis of trends within this testing category. It may be concluded, however, based on available data, that the Hispanic population, although at known risk for HIV infection (Figure 8), is not well represented in the ATS system being studied.

Although the number of individuals testing has continued to rise since 1985, there was a decrease during the second half of 1989. After reviewing the monthly ATS reports for that time period, it seems likely that the decrease in number testing during that period was a result of the October 17, 1989, earthquake. A precipitous drop in number tested occurred immediately following the earthquake. Data gathered during 1990 will help to determine if the results indicate initiation of a trend, or a mere observation due to a natural disaster. Because of the large numbers of lower risk clients presenting for testing, the trend in seropositivity from 1985 to 1989 has been decreasing. The overall number of individuals testing HIV positive, however, has continued to increase. This information must be taken into consideration when

extrapolating information for future program planning and will be reviewed in the following discussion of recommendations.

Recommendations

Several recommendations may be made based on the data presented in this study. Although the analysis of trends in testing presented here revealed interesting and significant information, the fact that data were obtained exclusively through ATS, which serves a self-selected population, limits its application. In order to obtain information from which generalizations to the community at large may be made, testing must be analyzed on a larger scale.

In order to obtain a broader base of testing data, future analyses must utilize data from blinded testing, confidential testing from the public and private sector, as well as ATS. By obtaining all available testing data from a specific population or community, extrapolations and generalizations will be more valid. If broader based testing data are collected, it is imperative that data collection tools and methods are consistent among the various sources.

Data collection for this study was performed by review of monthly state reports. Unfortunately, these reports make no allowance for comparison of data among various subgroups. Slight alterations of the monthly reporting form would

enable staff to compare and contrast trends within groups. Significant information regarding ethnicity, age, and sex of individuals with various risk factors may be obtained. An example of such an analysis would be assessment of ethnic breakdown of IVDU's, presenting for testing. Another is assessment of age breakdown of gay men testing. This type of information would be more valuable than risk factor or demographic data alone, as it would identify programmatic concerns within distinct groups.

Another area which was neglected on the monthly reporting form is determination of testing history. Currently, reporting forms do not indicate how many of the reported tests are repeats and, more importantly, how many had previously tested positive. It is imperative that such information be accounted for in future analyses of testing trends. Steps are currently being taken to incorporate the two recommendations discussed here into monthly reporting forms.

If this study is replicated with a similar sized population to the one investigated here, it is recommended that certain trends be analyzed on an annual versus a semi-annual basis. Although the total number of tests being analyzed was high (6,300), the representation of some groups was so low as to make semi-annual evaluation of trends less significant than desired. Figures 11 and 12, for example,

demonstrate the fact that a small number of positive tests can render sporadic results in seropositivity trends. An annual analysis of trends for groups with smaller numbers would reduce the effect of aberrations in testing and produce more significant results.

An unsuccessful attempt was made to perform a more in-depth analysis of testing trends of IVDU's than that presented in Figures 11 and 12. A comparison of the number of IVDU's in the county population and those in the testing population was made, but results were irrelevant due to the paucity of information on the monthly reporting form regarding clients' permanent residence and previous testing history. Valuable data are available regarding the estimated number of IVDU's in the county and should be used in future studies which incorporate more specific information about the testing population. Such information would be extremely valuable for the purposes of program planning and needs assessments for the IVDU population. Analysis must, however, be based on more concrete data than was available at the time of this study.

Another important use for information pertaining to HIV seroprevalence is extrapolation of this data for projection of future AIDS cases. Such information must then be shared with other agencies in the community in order to ensure appropriate short- and long-term program planning.

HIV seroprevalence data may be utilized to identify groups who may be at risk for HIV infection, but who are not accessing existing testing services. The Hispanic population in the community being investigated in this study is an example of such a group. Education, outreach, and intervention to these groups is necessary, and HIV seroprevalence data may facilitate their identification.

Seroprevalence data may also be used for other aspects of program planning, such as anticipation of the need for patient beds in long- and short-term care facilities. Keeping abreast of current estimates of incubation periods from HIV infection to AIDS for various demographic and risk groups is imperative for this type of planning. Information about AIDS cases in the community should be utilized along with HIV seroprevalence data, since information about these two aspects of the epidemic serve to complement one another.

An important factor to consider, when planning for education and outreach to target groups, is the reality of existing services within one's community. If testing is being promoted, there should be adequate services to meet the potential response. Services must be appropriate in terms of times they are available, language services, cultural sensitivity, trained and skilled staff members, and adequate funding.

Another potential effect of outreach efforts is an increased demand for treatment slots for IVDU's. If outreach efforts are successful, and IVDU's respond by testing, a response to the concomitant education may be a desire for risk reduction by discontinuation of drug usage. If this occurs on a large scale, and the community is unable to provide necessary services, well intentioned outreach efforts may actually be a disservice to the target population. It is imperative, therefore, that community agencies who provide and promote testing be aware of services available in their community. If those services are inadequate or inappropriate, community groups must work together to ensure necessary services are available when the need arises.

Another beneficial use for HIV seroprevalence data is community education. The media has promoted the idea that individuals affected by HIV infection fall into certain "risk groups." Statistics about the various individuals who are infected with HIV can help to dispel misconceptions about transmission of the virus. Rather than categorizing AIDS as a "gay disease," or one that only affects certain types of people, the public must be educated about the fact that it is one's behavior which places an individual at risk for HIV infection rather than what risk group he or she is associated with. Education which breaks down inaccurate

stereotypes may help to counteract an individual's sense of complacency and force one to analyze personal behaviors and how they may increase the risk for HIV infection.

Finally, it is recommended that analyses of HIV seroprevalence data be performed on a large scale. If county, state, and national agencies work together to gather and analyze statistics from all available sources, very useful data will be obtained. In order for this data to be truly valuable, consistent data collection methods must be employed. The information gathered may then be utilized on a grand scale for the purposes of needs assessment, problem identification, program planning, and projection of future AIDS cases.

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APPENDIXES

APPENDIX A
Letters of Support

HEALTH SERVICES
AGENCY



COUNTY OF SANTA CRUZ

ADMINISTRATION

P.O. BOX 962 1080 EMELINE AVENUE
SANTA CRUZ, CALIFORNIA 95061
(408) 425-2251

March 6, 1990

Institutional Review Board
San Jose State University
1 Washington Square
San Jose, CA 95112

To Whom It May Concern,

The purpose of this letter is to convey my enthusiastic support of the research proposed by Tamara McKinnon. Ms. McKinnon will be analyzing the trends in HIV antibody testing conducted by the Santa Cruz County Health Services Agency AIDS Program.

Retrospective data from our Alternative (anonymous) Test Site Program will be analyzed. Data collected through this program is not linked to the identities of any of the individuals testing. The Health Services Agency has compiled data from 1985 through the present. Ms. McKinnon will have complete access to this information.

We are confident that the results of this research will prove to be valuable for pragmatic needs assessment and planning.

Thank you for your consideration.

Sincerely,

Christine Sippl, M.P.H.
AIDS Program Coordinator

IL:ls

HEALTH SERVICES
AGENCY



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We are confident that the results of this research will prove to be valuable for pragmatic needs assessment and planning.

Thank you for your consideration.

Sincerely,

Ira Lubell, M.D.

Ira Lubell, M.D., M.P.H.
Health Officer

IL:ls

APPENDIX B
Laboratory Slip

ATTACH LABEL TO BLOOD SPECIMEN

67-8053-7

67-8053-7

67-8053-7

67-8053-7

67-8053-7

FORM DHS 827A (1/89)

SEND REMAINING LABELS WITH COPIES 1 & 2 OF FORM TO THE LABORATORIES

70

LABORATORY COPY

LAD NUMBER	ANONYMOUS HIV ANTIBODY TEST	ASSIGNED CODE NO. 67-8053-7 CALIFORNIA STATE DEPARTMENT OF HEALTH SERVICES	LAB USE ONLY
<p>TO BE COMPLETED BY CLIENT</p> <p>Date: _____</p> <p>ETHNICITY: <input type="checkbox"/> WHITE/NOT HISPANIC <input type="checkbox"/> BLACK/NOT HISPANIC <input type="checkbox"/> HISPANIC/LATINO <input type="checkbox"/> ASIAN OR PACIFIC ISLANDER <input type="checkbox"/> NATIVE AMERICAN/ALASKAN <input type="checkbox"/> OTHER <input type="checkbox"/> UNKNOWN</p> <p>HAVE YOU HAD A PRIOR HIV ANTIBODY TEST? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNKNOWN WHEN? MO. _____ YR. _____</p> <p>RESULT OF PREVIOUS TEST? <input type="checkbox"/> POSITIVE <input type="checkbox"/> NEGATIVE <input type="checkbox"/> UNKNOWN</p> <p>CHECK ANY DESCRIPTION THAT APPLIES TO YOU</p> <input type="checkbox"/> A MAN HAVING SEX WITH OTHER MEN <input type="checkbox"/> A MAN HAVING SEX WITH MULTIPLE SEX PARTNERS <input type="checkbox"/> A MAN HAVING SEX WITH MEN AND WOMEN (BIBESUAL) <input type="checkbox"/> HAVE INJECTED NON-PRESCRIPTION DRUGS SINCE 1977 <input type="checkbox"/> GAY / BISEXUAL PERSON WHO HAS INJECTED NON-PRESCRIPTION DRUGS SINCE 1977 <input type="checkbox"/> HEMOPHILIC <input type="checkbox"/> HAVE HAD SEX WITH A ABOVE CATEGORY OR SOMEONE WHO HAS HAD SEX WITH THE ABOVE CATEGORY <input type="checkbox"/> HAVE RECEIVED A BLOOD OR BLOOD PRODUCT TRANSFUSION SINCE 1977 <input type="checkbox"/> NONE OF THE ABOVE/OTHER: _____ <p>COUNTY OF PRIMARY RESIDENCE _____ RESIDENCE ZIP CODE _____</p>		<p>LAB RESULTS</p> <p>ELISA: <input type="checkbox"/> REACTIVE <input type="checkbox"/> NON-REACTIVE <input type="checkbox"/> INDETERMINATE</p> <p>SUPPLEMENTAL IFA: <input type="checkbox"/> REACTIVE <input type="checkbox"/> NON-REACTIVE <input type="checkbox"/> NON-SPECIFIC/UNSATISFACTORY</p> <p>NOTES:</p> <p>LABORATORY NAME & ADDRESS</p> <p>CLINIC / SITE NAME S.C. 60-H.S.A-LABORATORY SERVICES P.O. BOX 962, SANTA CRUZ, CA 95061</p> <p>Return appointment date _____ Date received by lab _____ Date Reported _____</p>	
<p>PRE-TEST SESSION: <input type="checkbox"/> ELECTED TO TAKE TEST <input type="checkbox"/> DECLINED TEST INTERVIEWER: _____</p> <p>POST TEST SESSION: <input type="checkbox"/> YES <input type="checkbox"/> NO INTERVIEWER: _____</p> <p>DATE: _____</p> <p>SEX: <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE AGE IN YEARS _____</p>			

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APPENDIX C
Monthly Reporting Form

HIV ANTIBODY ALTERNATIVE TEST SITE REPORT
This report must be attached with ATS monthly invoice report

County: _____ Month: _____

TESTS		7 Number Tested by Age Group					9 Number Tested by Race/Ethnicity					11 Declined Test					
		12-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90-99	100+	White	Black	Hisp.	Asian	Other	Unk.
4	Risk Group	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
5	Homosexual (Gay)																
6	I.V. Drug Users																
7	Homosexual (Lesb.)																
8	Drug User																
9	Bleeders																
10	Thrombolytic																
11	Blood Products																
12	Heim.																
13	Sexual Partners of an Above Category																
14	None of the Above or Not Stated																
15	unk.																
TOTAL		GRAND TOTAL					GRAND TOTAL					GRAND TOTAL					

12 Test Results		13 Test Results		14 Test Results	
Pos	Neg	Ind	Unk	Pos	Neg
1	2	3	4	5	6
7	8	9	10	11	12
13	14	15	16	17	18
19	20	21	22	23	24
GRAND TOTAL		GRAND TOTAL		GRAND TOTAL	

NOTE: Total test must match monthly invoice form exactly.

Box A and B must match exactly.

Box C, D, and E must match exactly.

SEE INSTRUCTIONS FOR COMPLETION ON REVERSE SIDE

APPENDIX D
Data Collection Forms

TEST RESULTS BY RESIDENCE

Residence	Tests Administered		Test Results			
	Tests	% of total tests	Pos	Neg	Indet.	% Positive
TOTAL						

TEST RESULTS BY SEX

Sex	Tests Administered		Test Results			
	Tests	% of total tests	Pos	Neg	Indet.	% Positive
FEMALE						
MALE						
TOTAL						

TEST RESULTS BY AGE

AGE	Tests Administered		Test Results			
	Tests	% of total tests	Pos	Neg	Indet.	% Positive
12 - 19						
20 - 29						
30 - 39						
40 - 49						
50 - 59						
60 +						
Unknown						
TOTAL						

TEST RESULTS BY RACE/ETHNICITY

Race/Ethnicity	Tests Administered		Test Results			
	Tests	% of total tests	Pos	Neg	Indet.	% Positive
White						
Black						
Hispanic/Latino						
Asian or Pacific Islander						
Native American or Alaskan						
Other						
Unknown						
TOTAL						

ALTERNATIVE TEST SITE (ATS)
 SANTA CRUZ COUNTY HIV ANTIBODY TESTING REPORT

TIME PERIOD: _____

TEST RESULTS BY RISK GROUP

Risk	Tests Administered			Test Results			
	Sex	Tests	% of total tests	Pos	Neg	Indet.	% Positive
Gay	Male						
Bisexual	Male						
IVDU (het.)	Female						
	Male						
IVDU (gay/bi.)	Male						
Heterosexual with multiple partners	Male						
	Female						
Hemophiliac	Both						
Blood recipient	Both						
Sexual Partner of above category	Male						
	Female						
Other	Both/Unk.						
TOTAL							

* Seropositivity total tests =

APPENDIX E
Institutional Review
Board Letter of Approval

Office of the Academic Vice President • Associate Academic Vice President • Graduate Studies and Research
One Washington Square • San Jose, California 95192-0025 • 408/924-2480

To: Tamara H. McKinnon, Psychology
110 Sears Creek
Soquel, CA, 95073

From: Charles R. Bolz
Office of Graduate Studies and Research

Date: March 29, 1990

As required by University policy, the Human Subjects Institutional Review Board has reviewed your proposed project entitled:

"Analysis of Trends in HIV Antibody Testing"

Because your project is to be limited to the collection of existing data that cannot be identified with human subjects, your project is exempt from further review. Therefore, you may proceed without further review by the Human Subjects Institutional Review Board.

I, however, do caution you that whenever people participate in your research as human subjects, they should be appropriately protected from risk. This includes the protection of the anonymity of the subjects' identity with regard to any and all data that may be collected from the subjects. If at any time a subject becomes injured or complains of injury, you must notify Dr. Serena Stanford immediately. Injury includes but is not limited to bodily harm, psychological trauma and release of potentially damaging personal information.

Please also be advised when people participate in your research as human subjects, each subject needs to be fully informed and aware that their participation in your research project is voluntary, and that he or she may withdraw from the project at any time. Further, a subject's participation, refusal to participate or withdrawal will not affect any services the subject is receiving or will receive at the institution in which the research is being conducted.

If you have any questions, please contact Dr. Stanford or me at (408) 924-2480.

cc: Virgil Parsons, Ph.D.