The AIDS Clinical Trials Information Service (ACTIS): A Decade of Providing Clinical Trials Information

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SYNOPSIS

The AIDS Clinical Trials Information Service (ACTIS) is a central resource for information about federally and privately funded HIV/AIDS clinical trials. Sponsored by four components of the U.S. Department of Health and Human Services, ACTIS has been a key part of U.S. HIV/AIDS information and education services since 1989. ACTIS offers a toll-free telephone service, through which trained information specialists can provide callers with information about AIDS clinical trials in English or Spanish, and a website that provides access to clinical trials databases and a variety of educational resources. Future priorities include the development of new resources to target diverse and underserved populations. In addition, research needs to be conducted on the use of telephone services vs. Web-based information exchange to ensure the broadest possible dissemination of up-to-date information on HIV infection and clinical trials.

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The AIDS Clinical Trials Information Service (ACTIS) is a central resource for information about federally and privately funded HIV/AIDS clinical trials. Sponsored by four components of the U.S. Department of Health and Human Services (DHHS)—the National Institute of Allergy and Infectious Diseases (NIAID) and the National Library of Medicine (NLM) of the National Institutes of Health (NIH); the Food and Drug Administration (FDA); and the Centers for Disease Control and Prevention (CDC)—ACTIS has been a key component of U.S. HIV/AIDS information and education services since 1989. This article reviews the evolution of ACTIS through more than a decade of providing HIV/AIDS clinical trial information to the public.

ACTIS provides current information on clinical trials that test drugs and other therapies for adults and children at all stages of HIV infection. Public access to the service is available through either the toll-free number, 800-TRIALS-A (800-874-2572), or through the website, http://www.actis.org. Callers to the service reach trained information specialists who provide information about HIV/AIDS trials in either English or Spanish. The service also maintains a TTY/TDD line to respond to questions from people who are hearing-impaired. Telephone service is available Monday through Friday from noon to 5 p.m. Eastern Standard Time.

Central to the service is the use of two databases, AIDSTRIALS and AIDSDRUGS, which serve as the basis for the information that ACTIS telephone staff provide. The number of records in these databases has grown dramatically over the years. In 1989, the ACTIS databases listed 70 clinical trials and 33 drugs; by August 2001, those numbers had risen to 1,281 clinical trials and 327 drugs.

The AIDSTRIALS database contains summaries of clinical trial protocols as well as bibliographic references to published results. The database includes nearly all HIV/AIDS trials sponsored by NIH and many trials sponsored by pharmaceutical companies. Companies are required by law to list trials that test the effectiveness of potential therapeutic agents. (For trials that test aspects other than effectiveness, the listings are voluntary.) The data are submitted to ACTIS primarily through two sources. NIAID is responsible for most federally funded HIV/AIDS clinical trials. Protocol information and updates for NIAID-funded studies (585 trials, or 45.6% of the database records as of December 31, 2001) are submitted to ACTIS through established reporting channels. Trials sponsored by pharmaceutical companies (533 trials, or 41.6% of the database records as of December 31, 2001) under an Investigational New Drug (IND) application are submitted by FDA to ACTIS. A small number of other studies (163 trials, or 12.7% of the database records as of December 31, 2001) are submitted directly from industry or from other NIH entities to ACTIS. After review by FDA or NIH, these records are added to AIDSTRIALS.

The second database, AIDSDRUGS, contains descriptions of the investigational agents being tested in the trials. As the protocols are summarized for AIDSTRIALS, the names of any pharmaceuticals are noted by members of the ACTIS staff, who then perform literature searches for each pharmaceutical and create an information record for the AIDSDRUGS database.

In 1996, the ACTIS databases were made available on the World Wide Web. Visitors to the ACTIS website can conduct searches of both ACTIS databases. Trial summaries are presented in three formats: a technical description, a nontechnical summary, and a Spanish-language version of the nontechnical summary. A variety of educational and background resources, including glossaries, answers to frequently asked questions (FAQs), and training materials, are also provided on the site to help consumers and health professionals understand what is involved in participating in a clinical trial. Both the toll-free number and the e-mail address are displayed prominently on the site, and visitors are encouraged to contact an information specialist with additional questions.

BACKGROUND

In 1987, HIV/AIDS was a relatively new area of medical research. Because most antiviral agents were still in the development stage, HIV-positive individuals had access to potential treatments primarily through clinical trials.[1] In 1988, NIAID conducted a needs assessment, which found that a centralized telephone service would be the most effective method of providing current, comprehensive information about HIV/AIDS clinical trials to health professionals and the public.[2]

The following year, Congress passed the Health Omnibus Programs Extension (HOPE) Act.[3] This law required the DHHS Secretary to establish services to disseminate information on HIV research, treatment, and prevention. NIH and FDA, with the cooperation of CDC, established ACTIS for the purpose of providing information on NIH-sponsored and privately funded clinical trials for HIV-related diseases. The HOPE Act required that information about clinical trials of investigational drugs be made publicly available.

The ACTIS phone service and the two databases

Table 1. Annual information requests and website hits received by ACTIS, 1989–1999

Type of contact	*1989*	*1990*	*1991*	*1992*	*1993*	*1994*	*1995*	*1996*	*1997*	*1998*	*1999*
Information requests	15,655	25,161	32,013	26,839	31,767	27,758	23,786	16,607	12,398	8,984	7,186
Website hits	—	—	—	—	—	—	—	27,872	97,316	181,794	284,305

described above were established in May 1989**.** In August 1989, through its MEDLARS system, available worldwide, NLM provided an on-line searchable version of the information in the ACTIS databases. The databases were made available via the Web in 1996.

The implementation of ACTIS has served as a model for interagency cooperation within DHHS. Representatives of NIAID, FDA, NLM, and CDC meet quarterly to plan and provide oversight for ACTIS activities and to ensure that work is being done in coordination with other DHHS HIV/AIDS information services.

ACTIS is just one component of the DHHS-supported network of HIV/AIDS information services. The HIV/AIDS Treatment Information Service (ATIS) provides information to the public on available treatments for HIV/AIDS. ATIS, modeled on ACTIS, has become the central source for dissemination of all federally approved HIV/AIDS treatment guidelines and serves as a companion service to ACTIS.

The CDC-sponsored National AIDS Hotline responds to requests from people with questions about prevention, risk behaviors/transmission, testing, and other general HIV/AIDS-related concerns. The CDC National Prevention Information Network (formerly the National AIDS Clearinghouse) develops, identifies, collects, and disseminates educational materials on HIV/AIDS, STDs, and TB. The National HIV Telephone Consultation Service, sponsored by the Health Resources and Services Administration, offers case consultation services to health care professionals. All of these services are linked through close working connections among the sponsoring organizations within DHHS.

USE OF THE ACTIS INFORMATION SERVICE

Since 1989, when ACTIS began, more than 228,000 information requests have been received. Because ACTIS was conceived initially as a telephone service, the majority of information requests received before 1996 came through the toll-free number, although a small number of additional information requests have always been received by e-mail, fax, and regular mail. From 1992 to 1999, a total of 1,312 requests required the services of Spanish-speaking information specialists. In 1993–1999, a total of 50 calls were received through the TTY/TDD service. (TTY/TDD access for the deaf is federally mandated.)

Table 1 shows annual totals for information requests received by ACTIS in 1989–1999 and Web "hits" in 1996–1999. A "hit" is defined as a viewing of an individual Web page. One person viewing the ACTIS home page, "FAQs about Clinical Trials," and "Currently Recruiting Trials" would count as three hits, as would three different individuals viewing the home page only.

Table 1 shows that the development and growth of the Internet has added immeasurably to the public accessibility of ACTIS. With the launch of the website in 1996, information requests received by telephone decreased as information was increasingly sought via the website. The number of Web "hits" has doubled nearly every year since the website went on-line.

DATA COLLECTION

Since ACTIS's inception in 1989, information specialists have recorded data related to information requests. At the beginning, only usage data were collected, but since 1992 an improved system has allowed a more systematic collection of specific data. These data are collected primarily from callers on the toll-free line, since these information requests involve interaction between the caller and the ACTIS information specialist. The small number of information requests that come through letters, fax, and e-mail are included in the data reported here. The ACTIS website does not track information on individual users.

The phone service uses a passive data collection method to gather information on callers. Information specialists use a call record form to capture information such as gender, language spoken, type of caller, subject of question, and response provided. The only question posed directly to callers is where they heard about ACTIS; all other information is gleaned from unsolicited statements by the requestors themselves. If, for example, a caller mentions a personal T-cell count of less than 200, that caller is logged as HIV-positive, but no caller is ever asked about serostatus or any other personal information. The call record form, which was previously paper-based, is now available to

Table 2. Types of callers to ACTIS, 1992–1999

	Percentage of calls							
Type of caller	*1992*	*1993*	*1994*	*1995*	*1996*	*1997*	*1998*	*1999*
HIV-positive individuals	45.9	48.2	33.8	37.2	27.7	27.4	25.4	27.9
General public	20.6	20.4	33.2	30.2	38.3	38.9	40.5	43.7
Health professionals	17.1	14.2	17.0	15.5	16.7	17.8	19.0	12.7
Family/friends of HIV-positive individuals	10.7	12.5	10.8	11.2	9.8	8.2	6.4	6.5
Institutions/organizations	5.7	4.8	5.1	5.9	7.5	7.7	8.7	9.2
Total number	26,656	31,606	27,527	23,615	16,527	12,324	8,755	7,426

NOTE: Percentages may not add to 100 due to rounding errors.

the staff in an on-line format. In what follows, we present highlights of the data captured for 1992–1999 through this method.

TYPES OF CALLERS

One of the key data elements collected is the type of requestor (e.g., HIV-positive person, health professional, general public). These data are shown in Table 2, which indicates that there have been some changes in the types of callers contacting ACTIS over the years of the operation of the service. In 1992, a high percentage of calls were from people self-disclosing HIV-positive status (45.9% of all inquiries). In 1999, only 27.9% of the callers identified themselves as HIV-positive, a decrease from the 1992 percentage. In 1992, 17.1% of callers indicated that they were health professionals, the original target audience for this service as mandated by the HOPE legislation. By 1999, the percentage of health professionals calling the service had decreased to 12.7%. However, the calls from "institutions" or organizations, possibly serving as intermediaries for either health professionals or patients, increased from 5.7% to 9.2%. From 1992 to 1999, the percentage of calls from the general public more than doubled, from 20.6% to 43.7%.

GEOGRAPHIC LOCATION OF CALLERS

Over the years, calls have come to the service from all 50 states. However, most callers who mentioned a state (more than 60%) were from only 10 states. The states in the top 10 and the proportion of requests from those states remained virtually the same in 1999 as in 1992. These states closely mirror the jurisdictions with the highest HIV/AIDS prevalence rates. In 1992, the 10 jurisdictions with the highest numbers of cases of HIV infection and AIDS were California, New York, Florida, Texas, New Jersey, Illinois, Pennsylvania, Georgia, Maryland, and Massachusetts.[4] In 1999, the 10 jurisdictions with the highest numbers of cases were New York, District of Columbia, California, Texas, New Jersey, Pennsylvania, Georgia, Illinois, Maryland, and Massachusetts.[5]

SUBJECTS OF QUESTIONS

Table 3 compares the subjects of questions asked in 1992–1999. The most frequent questions posed by callers focused on trials. Questions on drugs (e.g., specific drugs, side effects) were the second most common type of questions asked in 1992 (27.1%), but the percentage dropped steadily, down to 15.2% by 1999. Other changes in subjects are reflected in the data in Table 3: questions about AIDS-related opportunistic infections dropped from 7.3% of the total in 1992 to 2.8% in 1999; questions about vaccines dropped from 11.2% in 1992 to 4.2% in 1999; and inquiries about ACTIS services and requests for patient education materials rose from 9.3% in 1992 to 33.0% in 1999.

IMPACT OF MEDIA COVERAGE ON SERVICE USE

Throughout the entire period of operation, the volume of telephone requests to ACTIS appears to have been heavily influenced by media coverage of HIV/AIDS-related research. Major media stories have frequently been followed by sharp increases in calls to ACTIS on those specific topics, and announcements in the press concerning new data, new studies, and new drugs and vaccines have been followed by increased interest in HIV/AIDS clinical trials in general and requests for information specific to the topic of coverage. For example, in 1994, the results of a clinical trial (ACTG 076) showed a decrease in perinatal transmission with the use of zidovudine (AZT) during pregnancy.[6] In the month following the announce-

Table 3. Subjects of calls to ACTIS, 1992–1999

	Percentage of calls							
Subject	*1992*	*1993*	*1994*	*1995*	*1996*	*1997*	*1998*	*1999*
Clinical trials	31.8	36.1	38.0	30.2	30.0	30.8	26.9	28.1
Drugs	27.1	29.3	20.0	26.8	23.5	22.1	17.2	15.2
Services and educational materials	9.3	9.2	21.4	25.0	23.8	20.1	29.2	33.0
Specific populations (e.g., women)	6.5	5.5	7.7	6.9	9.8	11.0	8.2	5.5
Treatment	6.8	6.4	4.8	4.8	7.2	8.8	10.1	11.2
Opportunistic infections	7.3	6.0	5.1	4.7	4.1	4.2	3.7	2.8
Vaccines	11.2	7.5	3.0	1.6	1.6	3.0	4.8	4.2
Total number	29,345	41,193	45,146	49,768	38,080	28,107	19,715	14,969

NOTE: Percentages may not add to 100 due to rounding errors. Data on questions about subjects that are outside of ACTIS's mission are not shown.

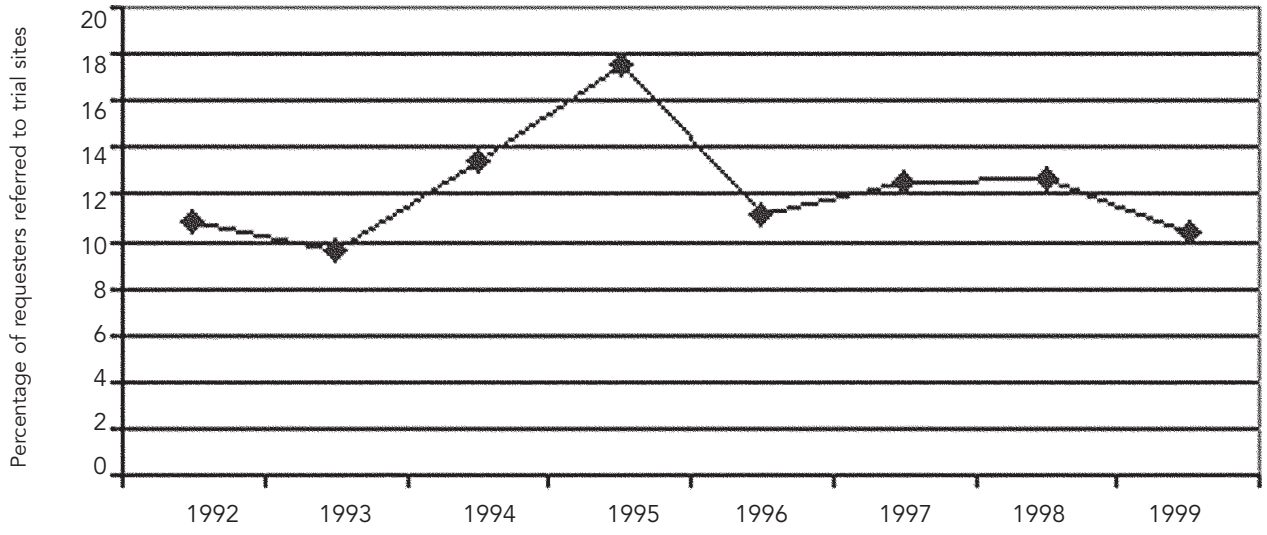
ment of trial results for ACTG 076, inquiries about trial results in general more than doubled and inquiries about ACTG 076 increased sevenfold. Requests from HIV-positive pregnant women or family and friends on behalf of HIV-positive people also showed an increase compared to the previous month.[7]

In 1996, following media coverage of FDA approval of ritonavir and indinavir, some of the first drugs in the new class known as protease inhibitors, 1,930 requests were made to ACTIS for information about ritonavir and indinavir, just under 12% of information requests for the entire year. And in a more recent example, when results for a study on interleukin-2 (IL-2) were published in the lay press in 1998, for the next month requests for information about IL-2 increased fivefold over the previous month, and the number of referrals made by ACTIS to clinical trial sites (for both interleukin trials and other trials) almost doubled.[7]

REFERRAL TO CLINICAL TRIAL SITES

The Figure shows the annual percentages of ACTIS callers referred to clinical trial sites during 1992–1999. While the actual number of referrals decreased over the years, coinciding with the decrease in overall call volume, the percentage of total callers referred to trial sites has remained about the same. With the availability of contact information for trial sites on the ACTIS website, however, users can communicate with study

Figure. Requesters referred to clinical trials, 1992–1999



staff on their own without the help of a telephone information specialist. This makes it impossible to quantify the total number of referrals to trial sites that result from the use of ACTIS resources.

No data are available to assess what percentage of ACTIS requestors referred to trials actually participated in a trial. In fact, there is a general paucity of research into the association between knowledge of a specific trial and participation in that trial. In a 1996 survey of users of the National Cancer Institute's Cancer Information Service, callers were contacted by telephone three to six weeks after their use of the service. During a five-week period, more than 12% of the callers who had sought information on clinical trials reported that they, or another person for whom they had requested information, had enrolled in a study. Another 34% of callers reported that they or another person had considered a trial and had talked with their doctor about it.[8]

IMPACT OF THE INTERNET

When ACTIS started and for several years thereafter, on-line access to HIV/AIDS clinical trial information was limited. While the AIDSTRIALS and AIDSDRUGS databases were available through the NLM on-line system, the search language was complex and until 1994 there was a fee for on-line access. As a result, these databases were used primarily by health professionals and librarians. Once the fees were eliminated in 1994, on-line use through the NLM service increased dramatically. The Web has since made using on-line information much easier. As access to the Internet became widespread, more users were able to find information about HIV/AIDS clinical trials without assistance. As discussed above, these changes have profoundly influenced use of ACTIS.

It is clear that the ACTIS website has experienced greatly increased overall service use. Although telephone requests for information from ACTIS have declined sharply as use of the website has increased, there may continue to be a need for personalized assistance from trained information specialists. Research has shown that telephone services have the potential to provide high-quality, accurate data[9,10] tailored individually to the needs of the person contacting the service.[11] Information transmitted during such contacts often reassures callers and influences their willingness to participate in clinical trials.[12] This may be due in part to the caller's increased understanding of clinical trials in general and how participating in a trial provides additional options in their overall treatment regimen, and may also be due in part to the anonymity possible in the encounter,[13] an important consideration for those with concerns about discrimination.[14]

Access to the Internet is still far from universal. According to a report from the National Telecommunications and Information Administration of the Department of Commerce, although the number of people with Internet access is increasing, a digital divide continues to exist.[15] Throughout the course of the epidemic, it has been important for information on HIV/AIDS clinical trials to reach underserved populations. This has become an even greater priority as HIV transmission patterns in the U.S. have shifted in the last few years to affect certain underserved populations more heavily.[16] With this goal still high on the national public health agenda, a telephone service will continue to be a key information resource.

Because of the complexity of clinical trial information, even those with Web access frequently require assistance in identifying appropriate trials and in understanding the information in the trial summaries. Many people seek information on HIV/AIDS trials after other therapies have proven unsuccessful. They often require assistance in sorting through their options. Explaining clinical trials is a complex task[17] and the one-on-one discussion and expert database searching that information specialists can provide helps potential participants to understand all the issues involved.[8] Information specialists provide callers with sufficient information to enable them to work with their own health care providers to plan their actions for the future.[8,12] However, telephone services are expensive to maintain, and the relationship between phone and Web use will need careful monitoring as more and more households obtain Internet access.

FUTURE PLANS AND RECOMMENDATIONS

Integrating HIV/AIDS services

As ACTIS continues into its second decade of operation, its government sponsors are examining ways to better integrate ACTIS and its companion service, ATIS, with other HIV/AIDS services as well as to continue to provide seamless linkage for users to all of the DHHS HIV/AIDS and clinical trials information services. In 1997, Section 113 of the Food and Drug Administration Modernization Act (FDAMA) required DHHS, through NIH, to establish a registry of clinical trials for serious or life-threatening diseases or conditions.[18] As a result, in February 2000, NIH, through NLM, developed *ClinicalTrials.gov* to provide patients, family members, health care professionals, and members of the public easy access to information on clini-

cal trials for a wide range of diseases and conditions. The site currently contains descriptions of thousands of clinical studies sponsored by NIH, other federal agencies, and the pharmaceutical industry. The summaries for HIV/AIDS-related trials available on that site include links to relevant information in English and Spanish on the ACTIS site.

Although the provisions of the original HOPE Act of 1988, which established ACTIS, are very similar to those of Section 113 of FDAMA, the focus has shifted from technical data for health care professionals to information accessible to the general public. HOPE envisioned medical providers and scientific researchers as the intended audience. Under FDAMA, the focus is on patients, and the new law specifically requires that information provided under the Act be in lay language.

Developing new clinical trials resources

In keeping with the priorities described in the *NIH Strategic Research Plan to Reduce and Ultimately Eliminate Health Disparities*,[19] which outlines the Department's commitments in this area for 2002 to 2006, ACTIS will continue to add to its collection of resource materials that explain, in easy to understand language, what it means to participate in a clinical trial and the complex medical information included in trial descriptions. New resources and strategies to address increasingly diverse cultural and linguistic needs are essential to ensure that clinical trials truly represent the entire spectrum of the U.S. population. The Spanish-language version of the ACTIS website is a step in that direction, but the need for resources for other language groups and for other specialized populations, such as those with low literacy levels, is an important future priority.

Need for research on the roles of telephone services and the Web

In the last five years, the Internet has changed communication in ways that are barely understood. Traditional information services such as ACTIS have experienced a major shift from the telephone to the Web, affecting staffing levels, the expertise needed by staff, and the technologies employed to provide and track responses. To help determine the role of telephone services vis-à-vis Web information services, research needs to be conducted to study the information-seeking behavior of Web users with respect to complex medical topics. This will include examination of the use of new call center technologies that enable users to move seamlessly from the Web to a telephone service. As the research proceeds, ACTIS will continue to respond to users' expressed preferences for receiving information via the Web by fine-tuning the website to ensure that it is as user-friendly as possible and that it takes advantage of multimedia capabilities and communication options such as on-line chats, which can be available beyond traditional telephone service hours. Another area for exploration is the integration of Web and wireless technology (cell phones and personal digital assistants) to bring rapidly changing information directly to the user.

CONCLUSION

In the past decade, thousands of people infected with HIV have participated in critically important clinical trials, and many more participants will be needed in the future to develop effective therapies and methods of preventing the spread of HIV. The success of clinical trials ultimately depends on the patients who are willing to enroll in studies of experimental therapies, on their loved ones who support their decision to enroll, and on medical professionals who encourage their participation. As new treatments are developed and vaccines are tested, clinical trials will continue to play a key role in the nationwide effort to combat the devastating effects of HIV infection. There is a corresponding need for the federal government to continue to provide information on clinical trials as part of its on going HIV/AIDS information programs and to make that information available as widely as possible.

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