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Successful Techniques for Retaining a Cohort of Infants and Children Born to HIV-Infected Women: The Prospective P²C² HIV Study

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Abstract

Retaining subjects from disadvantaged populations in long-term studies is necessary to obtain high-quality data. This article presents cumulative retention rates from a 5-year prospective cohort study, the Pediatric Pulmonary and Cardiovascular Complications of Vertically Transmitted HIV Infection study. It also presents results of a cross-sectional qualitative survey about factors that induced caregivers to stay in the study. Although the repeated study visits were long and uncomfortable, cumulative retention among the 298 HIV-infected children was 80%. Incentives considered important by the caregivers included phone contact with nurse coordinators, nurse coordinators accompanying the caregiver and child during visits, phone reminders for appointments, help with scheduling, meals and transportation, access to health care, and relationships with staff. Thus, the high follow-up rate was in part due to nurses' efforts to reduce the study's burden on the families, provide tangible and intangible incentives, and establish personal relationships with families.

Keywords

retention; pediatric HIV; AIDS

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Retaining subjects from poor and disadvantaged populations in long-term cohort studies is a difficult task, but it is crucial to obtaining high-quality, generalizable data. Retaining inner-city families affected by pediatric HIV disease may be particularly challenging.

For these reasons, retention was a top priority in the Pediatric Pulmonary and Cardiovascular Complications of Vertically Transmitted Human Immunodeficiency Virus (P²C² HIV) Study, a prospective cohort natural history study initiated by the National Heart, Lung, and Blood Institute in 1989 to study the heart and lung complications of infants and children born to mothers infected with HIV (The P²C² HIV Study Group, 1996). Interventions to increase retention were conducted by the nurse coordinators. Such interventions were considered important because this study, initiated before the advent of protease inhibitors or highly active antiretroviral therapy, offered families no treatment or intervention that might serve as an incentive to remain with the study. Furthermore, the study was onerous for families, who were asked to visit the hospital several times a year for a full day of testing.

This article has two purposes. First, we contribute to the relatively sparse literature on long-term retention rates among HIV-infected children by reporting the cumulative 5-year retention rates for our cohort. Second, we report qualitative results from an exit interview administered to the children's caregivers at the end of the study to determine why they remained on study. We describe the retention-promoting services that these caregivers identified as most helpful.

Background

HIV disease has effects that may make families unlikely to remain in a research study. Like any serious illness, HIV disease places both child and family at risk of depression and social isolation (Mellins & Ehrhardt, 1994). Many patients hide their HIV status from even close friends and family and thus may be at especially high risk of isolation. Families affected by HIV are also under additional stress from the multiple illnesses and deaths caused by HIV and frequently also from poverty and social factors (Mellins & Ehrhardt, 1994). Families affected by HIV disease may have risk factors associated with failing to keep appointments or dropping out of longitudinal studies, including minority race, youth, poverty, low educational level, and stressful life events (Cattlet, Thompson, Johndrow, & Boshkoff, 1993; Senturia et al., 1998). However, there is no strong consensus on the factors that increase the likelihood of attrition; the Women's Interagency HIV Study reported that African American race lowered risk of loss to follow-up; youth and unstable housing increased risk; and unemployment, low educational level, and substance abuse had no effect (Hessol et al., 2001).

The demands of a research study itself often constitute barriers to retention, particularly if the study requires patients to visit a medical facility regularly. Such barriers may be particularly high for natural history studies, which offer no curative medical therapy for the illness. Not surprisingly, patients are less likely to keep appointments for nonurgent medical care (routine care or screening) than for urgent care (Cattlet et al., 1993). This implies that patients may also be less likely to keep appointments that are scheduled for a natural history

study than they would be to keep appointments for a clinical trial that offered treatment directed at the disease.

Awareness of barriers to patient participation can lead to creative solutions and incentives that increase retention rates (Morse, Simon, Besch, & Walker, 1995). For example, research nurses can provide a variety of psychosocial incentives for patients to join and remain in a study. Previous researchers have found that HIV-positive women place high value on having personalized, caring relationships with their health care providers and want to be able to talk to them about the problems of living with HIV (Meredith, Delaney, Horgan, Fisher, & Fraser, 1997). Caregivers of HIV-positive children report that their most important psychosocial needs are professional support, family support, respite care, and assistance in communicating with health care professionals (Mellins & Ehrhardt, 1994). Such psychosocial needs are common to other groups; in a recent inner-city asthma trial, parents who felt “involved and valued” by the study were more likely to remain in the study, even in the face of logistical difficulties (Janson, Aliota, & Boushey, 2001).

Nurse coordinators can thus have a positive impact on patient retention through their emotional commitment to patients as well as through persistence, flexibility, and creativity (Cohen et al., 1997; Xanthos, Carp, & Geromanos, 1998). In a 1-year HIV prevention study among 164 low-income women, counseling that “took the form of a listening ear” was credited for helping to improve retention (Brown-Peterside et al., 2001). A multifaceted outreach must also include careful collection of contact information, well-organized tracking efforts, good training and support for study staff, material incentives, and confidentiality, all of which have been shown to increase retention rates (Brown-Peterside et al., 2001; McKenzie, Tulskey, Long, Chesney, & Moss, 1999).

Quantitative data on long-term retention rates from HIV-infected infant cohorts is relatively sparse. The Women and Infants Transmission Study (WITS), with a median follow-up of 24 months, had a 2-year retention rate of 50% (Diaz et al., 1998). A study of HIV-infected children enrolled in Pediatric AIDS Clinical Trials Group (PACTG) clinical trials of antiretroviral drugs had a 3-year retention rate of 89%, but this figure is not directly comparable to the present study because it focused on children participating in drug trials, and the opportunity to receive experimental drugs was itself an incentive to remain in the study (Gortmaker et al., 2001). A group of uninfected PACTG infants exposed to zidovudine in utero or in the neonatal period was followed for a median of 4.2 years after birth to determine the effects of the drug; this group had an 86% retention rate (Culnane et al., 1999). The study was a follow-up to a randomized trial of zidovudine, and parents’ desire to find out whether the children had been affected by the medication may have provided an extra incentive to remain in the study.

Retention rates for cohorts of different types of patients provide some context for findings in the present study. At the 5-year point of a 10-year longitudinal study, the Women’s Interagency HIV Collaborative Study Group reported an 82% retention rate among a cohort of 2,628 women (78% of them HIV-infected) (Hessol et al., 2001). This study was similar to the present study in that it required subjects to come to the study center regularly for a

physical exam and an interview, although these visits occurred twice a year, rather than 3 to 4 times a year as in the present study.

Finding comparable data from other studies is often difficult because “retention” in the literature is sometimes defined as success in reaching subjects by telephone or locating data about subjects, rather than as a cumulative rate of patient participation. For example, in a cohort of HIV-infected men, vital status was determined for 89% of subjects at 9.5 years, but only 72% completed study visits regularly during the study (Dudley et al., 1995). In a cohort of inner-city asthmatic children and their families, 89% were contacted by telephone at 3, 6, and 9 months, but only 42% completed symptom diaries regularly during the study (Senturia et al., 1998).

Method

P²C² Study Design

In the P²C² HIV study, a prospective cohort of 816 infants born to HIV-infected mothers was recruited at five clinical centers in different parts of the United States (The P²C² HIV Study Group, 1996). Recruitment began in the summer of 1990 and ended in January 1994, and patients were followed through January 1997. Institutional Review Board approval was granted from each institution, and written informed consent was obtained from each infant’s parent or guardian.

Group I (the older cohort) enrolled 205 infants and children with documented vertically transmitted HIV infection who were older than 28 days and born after April 1, 1985. Some children born before this date were included when vertical transmission of HIV infection could be documented with reasonable medical certainty.

In Group II (the birth cohort), HIV-infected mothers agreed to enroll their infants before the infant’s HIV status was known. The 611 infants were enrolled either during gestation ($n = 443$, 72.5%) or before 28 days of age ($n = 168$, 27.5%). After HIV status was determined, this group was found to include 93 HIV-infected, 463 HIV-uninfected, and 44 HIV-indeterminate infants, plus 11 fetal deaths.

The infants and children in Group I (the older cohort) were seen every 6 months, and the infants in Group II (the birth cohort) were seen every 3 months until age 2 years and every 6 months thereafter. The visits included respiratory and cardiac examinations, laboratory tests, chest radiographs, electrocardiography, 24-hour Holter monitor assessments, pulmonary function testing, and echocardiography (The P²C² HIV Study Group, 1996).

Interventions to Increase Retention

In any longitudinal study, it is important to increase the benefits to participants while minimizing financial and emotional costs and inconvenience (Weinert & Burman, 1996). The nurse coordinators and the nursing staff at each P²C² center explored a wide variety of interventions to reduce the burden of the negative aspects of the study and to provide tangible and intangible benefits for the participants.

Ways to reduce costs to families—Costs of transportation and meals were reimbursed or paid directly, and in some centers, families were given public transportation tokens or cards.

The nurse coordinators also worked with various hospital departments to coordinate clinical tests and reduce waiting time between tests. Visits could be scheduled for evenings or weekends to accommodate caregivers' work schedules. Study children and their siblings were given opportunities to play during each visit, and caregivers had access to rest areas and free time while the nurse coordinators provided respite care. The P²C² staff also helped coordinate the care-givers' own medical appointments so that they could be completed during the child's P²C² visit and provided free babysitting while the parent/caregiver attended support groups, substance abuse treatment, or medical appointments and programs.

The nursing staff was also instrumental in adjusting the study protocol to require fewer (although longer) visits. One important innovation was to schedule pulmonary function tests and echocardiograms consecutively during the same visit, so that only single-dose sedation was required.

Nurses called patients routinely to remind them about upcoming appointments, plan transportation to the study visit, and discuss health issues. In addition, families themselves were invited to call the nurse coordinators with any questions or concerns.

Ways to increase benefits for families—The study staff hosted parties to celebrate holidays, Mother's Day, birthdays, and other events. They obtained corporate donations of coupons, diapers, clothes, child furniture, formula, school supplies, and age-appropriate toys to be distributed at P²C² study visits or parties. A less tangible benefit was assigning a nurse coordinator or staff member to accompany the family on the trip through the hospital from one test to the next. Personal relationships were also fostered by regular telephone discussions, which also gave parents/caregivers a chance to discuss the health status of the child.

Occasionally, more creative benefits were offered. Some of the centers that participated in the General Clinical Research Center (GCRC) Program allowed the mother and child to stay overnight at the GCRC. The center was viewed more as a hotel than as a hospital floor, so even though the stay included patient testing, it was experienced as a vacation. Also, at some centers, the study staff routinely dispatched a car service or taxi to pick up families for their visits and sometimes treated the families to limousine rides. To make the Holter monitor more appealing to the children and families, one nurse designed decorated child-sized vests to hold the device and recruited a church volunteer group to sew a collection of the vests.

Access to medical care—Although P²C² did not provide treatment for the children or their families, it did increase their access to medical care in several ways. First, the routine screening tests helped monitor the child's health and may have identified problems early. Second, the nurse coordinators provided education for families about health issues and helped them learn about the health care system and their own medical options. Third, nurse coordinators frequently helped families arrange for medical and social services that they

may not have known about or known how to find for themselves, including helping to enroll the children in clinical trials when appropriate.

Tracking—Study staffs were aggressive in tracking missing participants. Methods of finding missing families included repeated telephone calls to any telephone number associated with the family or their relatives, asking staff from other departments for information, and following up leads from social workers and home care nurses who had dealt with the family. Tracking became less arduous as caregivers established relationships and commitment to the study.

Exit Interview

At the conclusion of the P²C² study, the nurse coordinators conducted exit interviews with the caregivers of the HIV-infected children, using a multiple-choice questionnaire plus several open-ended questions. The questionnaire was designed to examine (a) the characteristics of caregivers of HIV-infected children, (b) the usefulness of retention-promoting incentives offered by the centers, (c) the reasons why caregivers participated in the study, and (d) the perceived benefit of their participation to their children and the community.

Statistical Analyses

The Kaplan-Meier method was used to estimate cumulative retention rates. Because previous work had shown that race might affect retention (Cattlet et al., 1993; Hessol et al., 2001; Senturia et al., 1998), the research team study performed log-rank tests to determine whether race/ethnicity affected retention among patients. To determine whether it was necessary to control for geographic location, which often affects retention (see, e.g., Hessol et al., 2001), the research team also compared retention rates in the five centers with log-rank tests. Proportions were compared using the chi-square or exact chi-square test. Continuous variables were compared with the Kruskal-Wallis test. Statistical tests were two-sided. A *p* value of less than .05 was considered statistically significant.

Results

Retention Rates and Demographics of Children

The study included 298 HIV-infected children, of which 205 were from the older cohort (Group I) and 93 were from the birth cohort (Group II). Median follow-up was 46 months (range 0.1 to 78 months). Most children were members of minority groups (49% Black, 33% Hispanic). Fifty-one percent were male. At the start of the study, 79% of caregivers were biologic parents.

The 5-year cumulative retention was 79.6% (95% CI, 74.5% to 84.7%) (see Table 1). Ethnicity did not significantly affect retention rates; the 5-year cumulative retention rates were 78.7% for Blacks, 82.0% for Hispanics, and 71.4% for White participants (*p* = 0.29). Cumulative retention rates were similar for all five clinical centers (*p* = 0.18).

Characteristics of the Children's Caregivers

Of the 298 children, 100 died during the course of the study and 42 were lost to follow-up, leaving 156 who were alive and still in the study in January 1997. Exit interviews were conducted with 112 of the 156 caregivers (72%). Fifty-five of the 112 (49%) were the children's biologic parents (see Table 2).

Approximately 60% of the interviews were conducted in person by nurse coordinators; the remainder were conducted by telephone. The remaining 44 caregivers did not participate. Thirty-four of them were at a center that was unable to participate in the exit interview study because of insufficient staffing. Other reasons recorded for not participating included the following: a visit could not be scheduled, the parent/caregiver was too ill to be interviewed, the caregiver was out of the country, or no interpreter was available.

Forty-six (41%) of the 112 caregivers reported being employed. 50% ($n = 56$) had less than a high school education, and 48% ($n = 54$) had a high school diploma, college education, or college degree. Only 30 (27%) caregivers used a personal car to drive to appointments. Most of the rest used public transportation or P²C²-provided car or taxi services.

The time taken to reach the P²C² study centers may have been an obstacle for some families. Fifty (45%) reported that travel time was less than 30 minutes, 42 (38%) reported that it was between 30 and 60 minutes, and the remainder ($n = 18$; 16%) said it took longer. The P²C² study site was the site of the child's primary health care for 80% of children ($n = 89$).

When rating the list of services provided by the study, 75% or more of the caregivers reported that they particularly valued phone contact with the nurses, the nurse coordinators accompanying the caregiver and child during visits, phone reminders for appointments, assistance with scheduling and rescheduling, and meal coupons used during the hospital visit (see Table 3).

In answers to the open-ended questions about why they stayed with the study, a number of common themes emerged. Most common was the answer that the study provided access to health care, careful monitoring of the child's health, and reassurance about the child's health status. Caregivers frequently said that they also appreciated learning more about HIV and their child's condition.

Less commonly, caregivers cited altruism, saying that the study gave them a chance to help other children and contribute to the fight against AIDS. Some caregivers said that they were fulfilling a previous commitment to the study, and some foster parents said they were fulfilling a commitment made by a mother who had died. Personal relationships with the study personnel were sometimes cited as benefits, as were free transportation, meals, and the other material incentives.

When asked about the least attractive aspects of the study, many caregivers said the visits were difficult for children because the procedures were painful or uncomfortable, took a long time, and involved waiting and sedation. The chloral hydrate used as a sedative was bitter in taste and sometimes caused vomiting. Children recovering from sedation were frequently irritable and disoriented. The Holter monitor, pulmonary function test, and

echocardiogram were cited as particularly difficult for the child because of the duration of these tests.

Discussion

Retaining a large proportion of the cohort for many years was crucial to obtaining longitudinal data for this natural history study. On the surface, the obstacles to retention were serious; the P²C² study offered few concrete benefits to patients and their caregivers while exacting a high price in terms of time, inconvenience, and discomfort. For example, the study provided no drugs or therapies to the patients; patients could participate in clinical drug trials such as the PACTG without enrolling in or remaining with P²C². Also, each P²C² study visit was time-consuming for the family (lasting from 2 to 6 hours) and uncomfortable for the child. Pulmonary function tests and echocardiograms necessitated sedation for the younger infants.

Another challenge with this cohort was parental illness because the biological mothers were all HIV-infected. Family poverty, substance abuse problems, incarceration, and the fact that many children were in foster care posed additional problems to follow-up.

Despite these obstacles, our study had a 2-year cumulative retention rate of 88% and a 5-year cumulative retention rate of 80% among the HIV-infected cohort.

The key to retaining patients and families appears to have been the nurse coordinators' persistence, flexibility, creativity, and emotional commitment to the patients (Cohen et al., 1997; Xanthos et al., 1998). The top reasons given by the caregivers to explain remaining in the study involved their personal relationships with the nurse coordinators: the regular telephone calls and the presence of a companion nurse coordinator during each visit (see Table 3). These personal friendships and connections were particularly important to the parents who were hiding their health status from their friends and family. Holiday parties helped foster these relationships and allowed staff and families to get to know each other in a nonmedical context. Individual nurse coordinators also took additional initiatives to build their relationships, such as taking Spanish-language classes to learn to communicate with Hispanic families.

Our observations also suggest that the P²C² study empowered mothers and caregivers to become more active partners in their own and their children's health care. For example, the study provided many indirect health benefits such as education about HIV and about health care and social services as well as personal support from the nurse coordinator in navigating the health care system and sometimes social service agencies as well. Active patient participation has been linked with improved nurse coordinator-patient communication, fewer patient complaints, a diminished feeling of powerlessness on the part of the patient, and in general, improved quality of life (Cahill, 1996).

The strategies used by the nurse coordinators were part of a multifaceted outreach that included careful collection of contact information, well-organized tracking efforts, good training and support for study staff, material incentives, and confidentiality, all of which have been shown to increase retention rates (McKenzie et al., 1999).

Limitations

Demographic data were not collected from caregivers at baseline, and the caregiver population changed substantially over time. Many children entered the care of relatives or of foster or adoptive families after the parents died from HIV disease, were incarcerated, or became unable to care for their children for other reasons. In addition, no data are available from caregivers of children who left the study or who died. As a result, the data represent those families who were retained in the study. Nevertheless, the perspective of this group is helpful in planning for future studies.

A second limitation is that the exit interviews were administered by the nurse coordinators rather than by a third party unknown to the caregivers.

Third, the nursing interventions were not completely standardized, and they varied between sites. However, the annual P²C² HIV coordinator meetings, quarterly conference calls, and monthly newsletters offered opportunities to share ideas, so that most sites adopted a similar set of incentives and interventions (as shown by the last column in Table 3).

It should also be noted that retention of the uninfected children (not discussed in this article) was substantially lower than retention of the infected children (50% at 5 years). These patients were offered the same range and intensity of nursing interventions, but two reasons may have contributed to their higher attrition. First, the children were generally healthy, thus their caregivers may not have valued routine health screening. Second, the HIV-infected mothers of these uninfected children suffered from the same physical and socioeconomic difficulties as the mothers of the infected children. In sum, the barriers to remaining in the study were the same, but the children were not HIV-infected. Different approaches may be needed to retain healthy children in natural history studies.

Conclusions

The 5-year retention rate of 80% was obtained in a multicenter study of the pediatric pulmonary and cardiovascular complications of vertically transmitted HIV infection in which there were few concrete benefits and considerable inconvenience with respect to time and discomfort for enrolled families. Active and creative engagement by the nursing staff was critical to the high retention rates in this cohort of HIV-infected children. In this longitudinal study, the high follow-up rate appears to be attributable in part to the nursing staff's efforts to reduce the subject burden for the families by establishing personal relationships and providing both material and intangible incentives to increase access to the health care system.

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References

- Brown-Peterside P, Rivera E, Lucy D, Slaughter I, Ren L, Chiasson MA, et al. Retaining hard-to-reach women in HIV prevention and vaccine trials: Project ACHIEVE. *American Journal of Public Health*. 2001; 91:1377–1379. [PubMed: 11527761]
- Cahill J. Patient participation: A concept analysis. *Journal of Advanced Nursing*. 1996; 24:561–571. [PubMed: 8876417]
- Cattlet AT, Thompson RJ, Johndrow DA, Boshkoff MR. Risk status for dropping out of developmental follow-up for very low birth weight infants. *Public Health Reports*. 1993 Sep-Oct; 108(5):589–594. [PubMed: 8210257]
- Cohen HL, Davis L, Hunter J, Carp D, Geromanos K, Sunkle S. for the P²C² HIV Study Group. Coordinating a large multicentered HIV research project. *Journal of the Association of Nurses in AIDS Care*. 1997; 8:41–50. [PubMed: 9085248]
- Culnane M, Fowler M, Lee SS, McSherry G, Brady M, O'Donnell K, et al. Lack of long-term effects of in utero exposure to zidovudine among uninfected children born to HIV-injected women. *Journal of the American Medical Association*. 1999; 281:151–157. [PubMed: 9917118]
- Diaz C, Hanson C, Cooper ER, Read JS, Watson J, Mendez HA, et al. Disease progression in a cohort of infants with vertically acquired HIV infection observed from birth: The Women and Infants Transmission Study (WITS). *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*. 1998; 18(3):221–228. [PubMed: 9665498]
- Dudley J, Jin S, Hoover D, Metz S, Thackeray R, Chmiel J. The Multicenter AIDS Cohort Study: Retention after 9½ years. *American Journal of Epidemiology*. 1995; 142(3):323–330. [PubMed: 7631636]
- Gortmaker SL, Hughes M, Cervia J, Brady M, Johnson GM, Seage GR III, et al. for the Pediatric AIDS Clinical Trials Group Protocol 219 Team. *New England Journal of Medicine*. 2001; 345(21):1522–1528. [PubMed: 11794218]
- Hessol NA, Schneider M, Greenblatt RM, Bacon M, Barranday Y, Holman S, et al. *American Journal of Epidemiology*. 2001; 154(6):563–573. [PubMed: 11549562]
- Janson SL, Aliota ME, Boushey HA. for the Asthma Clinical Research Network. Attrition and retention of ethnically diverse subjects in a multicenter randomized controlled research trial. *Controlled Clinical Trials*. 2001; 22:236S–243S. [PubMed: 11728627]
- McKenzie M, Tulsy JP, Long HL, Chesney M, Moss A. Tracking and follow-up of marginalized populations: A review. *Journal of Health Care for the Poor and Underserved*. 1999; 10:409–429. [PubMed: 10581885]
- Mellins CA, Ehrhardt AA. Families affected by pediatric acquired immunodeficiency syndrome: Sources of stress and coping. *Journal of Developmental and Behavioral Pediatrics*. 1994; 15(3):S54–S60. [PubMed: 8063921]
- Meredith K, Delaney J, Horgan M, Fisher E Jr, Fraser V. A survey of women with HIV about their expectations for care. *AIDS Care*. 1997; 9(5):513–522. [PubMed: 9404394]
- Morse EV, Simon PM, Besch CL, Walker J. Issues of recruitment, retention, and compliance in community-based clinical trials with traditionally underserved populations. *Applied Nursing Research*. 1995; 8(1):8–14. [PubMed: 7695360]
- Senturia Y, Mortimer K, Baker D, Gergen P, Mitchell H, Joseph C, et al. Successful techniques for retention of study participants in an inner-city population. *Controlled Clinical Trials*. 1998; 19:544–554. [PubMed: 9875834]
- The P²C² HIV Study Group. The pediatric pulmonary and cardiovascular complications of vertically transmitted human immunodeficiency virus (P²C² HIV) infection study: Design and methods. *Journal of Clinical Epidemiology*. 1996; 49(11):1285–1294. [PubMed: 8892497]
- Weinert C, Burman M. Issues in clinical nursing research: Nurturing longitudinal samples. *Western Journal of Nursing Research*. 1996; 18:360–364. [PubMed: 8693728]
- Xanthos GL, Carp D, Geromanos KL. for the P²C² HIV Study Group. Recognizing nurse coordinators' contributions to the clinical research process. *Journal of the Association of Nurses in AIDS Care*. 1998; 9:39–48. [PubMed: 9436166]

Appendix

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NOTE: A complete list of study participants can be found in The P²C² HIV Study Group (1996).

* = principal investigator.

Table 1Cumulative Rates of Retention in the P²C² HIV Study for 298 HIV-Infected Children

Time ^a (Months)	HIV-Infected Children			
	<i>n</i>	L	%	<i>SE</i>
6	276	12	95.9	1.2
12	257	20	93.1	1.5
24	220	33	88.2	1.9
36	192	42	84.4	2.2
48	143	49	80.9	2.5
60	87	51	79.6	2.6

NOTE: *n* = number remaining in study; L = cumulative number lost to follow-up; % = cumulative percentage retained on study; *SE* = standard error.

^aTime since enrollment for Group I (205 HIV-infected children recruited after 28 days of age), age in months for Group II (93 HIV-infected infants of the birth cohort).

Baseline Demographics of 298 HIV-Infected Children and Their Caregivers

	Total (<i>n</i> = 298)						Study Completers Who Completed Survey ^d (<i>n</i> = 112)				Study Noncompleters			
			Study Completers (<i>n</i> = 156)						Lost to Follow-up (<i>n</i> = 42)					
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%		
Race of child														
White Non-Hispanic	43	14.4	25	16.0	14	12.5	10	23.8	8	8.0				
Black Non-Hispanic	130	43.6	66	42.3	43	38.4	18	42.9	46	46.0				
Hispanic	114	38.3	57	36.5	48	42.9	14	33.3	43	43.0				
Other	11	3.7	8	5.1	7	6.3	0	0	3	3.0				
Caregiver														
Biologic parent—Yes	236	79.2	116	74.4	84	75.0	36	85.7	84	84.0				
Biologic parent—No	58	19.5	37	23.7	27	24.1	5	11.9	16	16.0				
Unknown	4	1.3	3	1.9	1	0.9	1	2.4	0	0				
	<i>n</i>	median	<i>n</i>	median	<i>n</i>	median	<i>n</i>	median	<i>n</i>	median				
Age of mother at enrollment (years)	266	29.1	138	29.7	99	28.8	35	27.9	93	29.6				
CD4 percentage of mothers at enrollment ^b	78	23.5	45	24.0	38	23.5	8	28.0	25	21.0				

^aData from this group were collected via the end-of-study survey. Data for the other groups were collected at baseline.

^b CD4 tests were performed on mothers of the infant cohort (Group II) only.

Table 3
 Caregivers' Assessment of Retention-Promoting Services Provided by P2C2 Clinical Centers ($n = 112$)

Type	<u>Very Helpful</u>		<u>Somewhat Helpful</u>		<u>Not Helpful</u>		<u>Service Not Provided</u>	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Phone contact with the study nurse coordinators	93	83.8	13	11.7	0	0.0	5	4.5
Accompanying the caregiver and child during visits	90	81.1	13	11.7	1	0.9	7	6.3
Calling to remind caregiver about appointments	89	80.2	11	9.9	1	0.9	10	9.0
Assistance with scheduling/rescheduling	88	80.0	13	11.8	2	1.8	7	6.4
Coordinating child's appointments	87	79.8	12	11.0	2	1.8	8	7.3
Meal coupons	84	77.8	11	10.2	4	3.7	9	8.3
Transportation to study visits	75	68.2	9	8.2	6	5.5	20	18.2
Stickers	70	63.1	22	19.8	4	3.6	15	13.5
Availability for transportation	67	62.0	8	7.4	2	1.9	31	28.7
Activities to occupy the child during the visit	59	53.6	24	21.8	4	3.6	23	20.9
Toys	55	49.5	11	9.9	0	0.0	45	40.5
Coordinating child and mother's appointments	42	48.3	6	6.9	2	2.3	37	42.5
A rest place for moms during visits	53	48.2	10	9.1	4	3.6	43	39.1
Parties	41	39.4	9	8.7	2	1.9	52	50.0
Reimbursement for travel/parking	31	31.0	7	7.0	1	1.0	61	61.0
Assistance with other forms (WICS, camp, etc.)	23	22.3	9	8.7	1	1.0	70	68.0
Clothing	22	20.2	7	6.4	1	0.9	79	72.0
Child care products	18	16.4	6	5.5	1	0.9	85	77.3
School supplies	15	14.2	2	1.9	1	0.9	88	83.0
Coupons for food stores	9	8.8	2	2.0	1	1.0	90	88.0
Coupons for retail stores	2	1.9	0	0.0	1	1.1	100	97.1