

## **Clinical Trials Project: Progress Report 5**

Vera Institute of Justice  
October 2006

This report is the fifth in a series of quarterly progress reports describing the Vera Institute of Justice's review of issues related to the enrollment and monitoring of foster children in clinical trials of HIV and AIDS treatments.<sup>1</sup> The report covers the quarter running from July 1, 2006, to September 30, 2006. The current report describes:

- Progress in implementing the research design,
- Additions to the list of files that the Administration for Children's Services has asked Vera to review,
- Institutional Review Board review of child and caregiver interviews,
- Outreach,
- Next steps, and
- Updated analysis of Child Care Review Service administrative data that includes new cases.<sup>2</sup>

**Summary:** Vera staff continue to review the files of children who the Administration for Children's Services (Children's Services) believes participated in HIV/AIDS clinical trials. By the end of September, of the approximately 465 cases forwarded to Vera by Children's Services, our child welfare document review team had examined 235 case management files and 170 case planning files.<sup>3</sup> The medical document review team had looked at 149 case management files and 165 case planning files. Efforts are ongoing to locate 26 case management files and 58 case planning files that Vera had planned to review during this quarter.

In the course of reviewing these documents, Vera staff and staff at Children's Services identified 61 additional children who had participated in clinical trials while in foster care, bringing the total number of known cases to 526. Project staff briefed Vera's Clinical Trials Advisory Board, the Children's Services' HIV/AIDS Health Care Advisory Board, the New York City Mayor's Office, and the City Council on these additions. Just after the close of the quarter, Vera's Institutional Review Board approved the protocols for interviewing children who had participated in the clinical trials and their caregivers.

### **Section 1. Implementing the research design**

Vera's research team continued its formal file review begun earlier this year. This process is expected to reveal why children came into care, how medical decisions were made for them, the

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<sup>1</sup> In the spring of 2005, New York City's Administration for Children's Services asked Vera to explore issues related to the enrollment of approximately 465 foster children in clinical trials of HIV and AIDS treatments during the late 1980s and 1990s. In conducting this review, Vera staff will identify the established processes for enrolling and monitoring these children, determine whether those procedures were followed, and report on the condition of the children today. Vera signed the contract to do this work on June 28, 2005.

<sup>2</sup> The Child Care Review Service is an administrative database kept by Children's Services that contains records of the movements, legal activities, permanency planning goals, and other information about children in foster care.

<sup>3</sup> Case management files refer to files kept at Children's Services as part of its oversight responsibilities for managing the care of foster children. Case planning files refer to files housed at agencies that are under contract with Children's Services. Because children can move through different agencies during the course of their involvement in the city's foster care system, they may have multiple case planning files but have only one case management file. In addition, child welfare and medical document reviewers look for different aspects of a child's case but review the same files. For more information, see Progress Report 2.

consent process for participating in clinical trials, and the child welfare and medical outcomes for these children and their families. For more information, see Progress Report 3.

About 45 nonprofit agencies were under contract to New York City's child welfare agency to provide case planning and services to foster children who were participating in the clinical trials. Three agencies provided services to nearly half of the children: Saint Vincent's Services, Leake and Watts Services, and Catholic Home Bureau (now merged with Catholic Guardian Society). Each of these three agencies had a specific program to address the special needs of children who tested positive for HIV.

Vera began its file review process by reviewing the case files of the children who received services from these three agencies. We have completed the review of files from the original list of known cases at two of these agencies—Saint Vincent's Services and Leake and Watts Services—as well as at Little Flower Children and Family Services. We are still reviewing files at Catholic Home Bureau and Catholic Guardian Society, including those of children who were cared for by the Incarnation Children's Center when it was under the auspices of the Catholic Home Bureau.

By the end of this quarter, our child welfare document review team had completed 235 case management files (which are housed at Children's Services) and 170 case planning files (which are retrieved by storage companies for each contract agency and reviewed by Vera staff at the agencies themselves).<sup>4</sup> Meanwhile, our medical document reviewers had completed 149 case management files and 165 case planning files. As noted in previous progress reports, the medical file review team is smaller and more specialized, so medical review lags somewhat behind the child welfare review. We are hiring and training additional members for both review teams in the next quarter.

In the course of our work, Vera staff planned to review an additional 26 case management and 58 case planning files. However, they were not available. Of the 58 case planning files, we learned that 26 were lost in a severe fire that destroyed a storage company warehouse on May 19, 1997.<sup>5</sup> Sixteen of the case management files cannot be found by Children's Services. Efforts to retrieve the remaining case management files and case planning files are ongoing. As mentioned in Progress Report 4, we continue our efforts to review additional types of documents.

We are also working to update the database that will store the information collected during this project. Collecting, entering, and analyzing the data will take many more months. To provide a full and fair assessment of the information we collect, Vera will limit the release of preliminary analysis until we have a complete data set.

During the past quarter, we conducted 11 key respondent interviews. These included interviews with physicians who were principal investigators on the clinical trials, child welfare specialists, and community activists. For more information on our key respondents, see Progress Report 3.

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<sup>4</sup> The large volume of case planning files made copying and storing files at Children's Services impractical due to the cost of duplication, risks to confidentiality in the copying process, and limits on space at Children's Services.

<sup>5</sup> For a description of this event, see Michelle Seaton, "For the Record" *NFPA Journal*, March/April 1998.

## **Section 2. Additions to the list of cases that Children's Services has asked Vera to review**

Vera, Children's Services, and the Children's Services' HIV/AIDS Health Care Advisory Board expected that Vera's file review might produce additional participants in clinical trials. Without a central database to keep track of clinical trial enrollments, the original list of names produced by Children's Services relied on paper records available from its Pediatric AIDS Unit (PAU). These files, as is generally known, were in disarray when the clinical trials issue arose in 2004 and 2005. Vera's contract with Children's Services assigns responsibility for identifying additional children who may have participated in clinical trials to Children's Services. When those cases are identified, Children's Services asks Vera to review them. However, when Vera identifies a child who participated in a trial while in foster care, but who is not on the original master list of cases, we request that Children's Services add that name to the list. The threshold for adding a child to the list for Vera to review is low—any evidence that a child may have participated in a clinical trial qualifies that child's case to be added to the master list.

Identifying additional children who participated in clinical trials may take place in several ways. As Vera's team reviews files, the reviewers make note of names of children who appear to have participated in clinical trials but who are not on the original list. Sometimes these names are found in letters that are in an individual file. Occasionally the Vera team reviews lists of clinical trial participants associated with a particular institution, agency, or clinical trial that are in an individual file. In some instances, veteran staff at foster care agencies remember children who were in trials but whose names do not appear on Vera's list of children from those agencies. In each case, these names are compared with names on the original lists of trial participants provided by Children's Services. When additional names are found, we forward the names to Children's Services staff to check if these children were in foster care or if other information is available.

Checking names is an arduous process for many reasons. Like many children in foster care, some of the children who participated in clinical trials were known by two or more names. Sometimes these names are similar (fictional example: Michael Jones was also known as Mickey Jones), and in other cases they have no obvious connection (Michael Jones was also known as Peter Smith). Twins who have similar names or nicknames are often difficult to distinguish, as they have the same date of birth and the same Children's Services case number. Some names may be misspelled by medical, child welfare, or social services staff, and some names may be shared by many kids who spent time in foster care (fictional example: there are many children with the name Juan Gonzalez). Children's Services staff have developed detailed procedures and alias lists to sort out these problems.

Over the course of the past year, Children's Services conducted a review of all of the files—including individual documents and folders—from its Pediatric AIDS Unit, which was created prior to 1990. This review led to the identification of additional children who participated in clinical trials. Children's Services added these names to the list of cases for Vera to review.

Table 1 summarizes the results of these activities. As of September 30, 2006, the number of children on Vera's master list of cases is 526. It is possible, even likely, that during the course of

our work we will identify additional children who participated in clinical trials while in foster care.

**Table 1: Sources of newly identified foster children who participated in clinical trials**

<b>Source</b>	<b>Number of children</b>
Original list provided by Children’s Services	463
Additions made by Children’s Services staff through July 26	4
Additions suggested by contract agency staff	4
Children’s Services review of Pediatric AIDS Unit records	37
Vera document reviewers	18
<i>Total</i>	<i>526</i>

Children’s Services is continuing its efforts to identify any additional children who participated in clinical trials while in foster care. The agency’s staff have identified groups of children who are likely to have been enrolled in clinical trials, such as children who died of AIDS while in foster care or children who were HIV positive and living in the same foster home as another child who participated in a clinical trial. Children’s Services staff will review these files to identify additional children who may have participated in clinical trials. Any additional participating children who are identified will be added to the list of children for Vera to review.

**Section 3. Institutional Review Board review of interviews**

Because this project involves human beings as research subjects, it is being reviewed by Vera’s Institutional Review Board (IRB), which is composed of people trained in the rules and ethics of research protocols. In this quarter, we submitted our protocols to Vera’s IRB for our interviews with children who participated in clinical trials and their caregivers (birth parents, kinship foster parents, foster parents, and adoptive parents). Just after the close of this quarter, on October 4, the IRB reviewed and approved the process for conducting these interviews.

**Section 4. Outreach**

There are a range of views on what happened when children were enrolled in clinical trials in the past and how the child welfare system should handle similar circumstances in the future. We feel it is important to hear and understand this range of opinions so that we can take diverse perspectives into consideration as we do our work. Below are highlights of our outreach efforts during this quarter.

- In July, August, and September we met several times with members of Children’s Services’ HIV/AIDS Health Care Advisory Board, which is composed of community-based health service providers and advocates and chaired by Debra Fraser-Howze, chief executive officer and president of the National Black Leadership Commission on AIDS, and Gail Nayowith, executive director of the Citizens’ Committee for Children. The Health Care Advisory Board meetings focused on the additions to the list of children’s files that Vera will review and on Children’s Services’ draft policy for enrolling foster children in clinical trials.

- In September, Vera staff briefed the New York City Mayor's Office, members of the City Council's General Welfare Committee, and Children's Services managers on this project's progress and the additions to the master list.
- We continue to have regular discussions with Dr. Robert Johnson, chair of Children's Services' Medical Oversight Committee. We have also had meetings with Children's Services' Office of Child and Family Health to discuss the organization of the case files and the logistics of reviewing those files.
- We met with members of the community to hear their concerns and to better understand their expectations for our final report.

### **Section 5. Next steps**

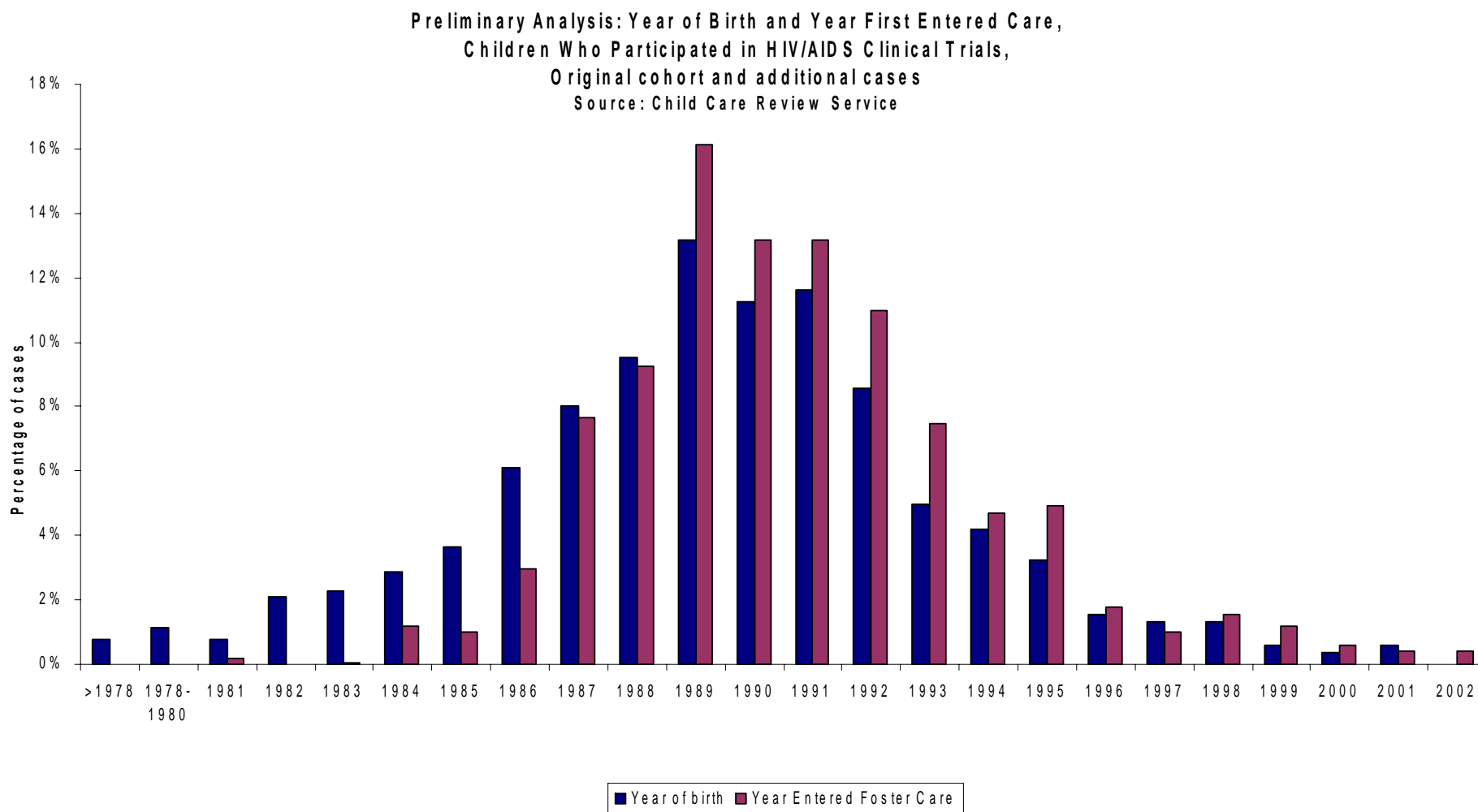
We have engaged in all the next steps identified in our last progress report with two exceptions. Due to scheduling issues, our IRB review of children and caregiver interviewers took place four days after the quarter ended instead of during the quarter. In addition, we have not finished construction of the database that will store the data we have collected. We expect that work to be completed in early November.

In the next quarter, we plan to do the following activities:

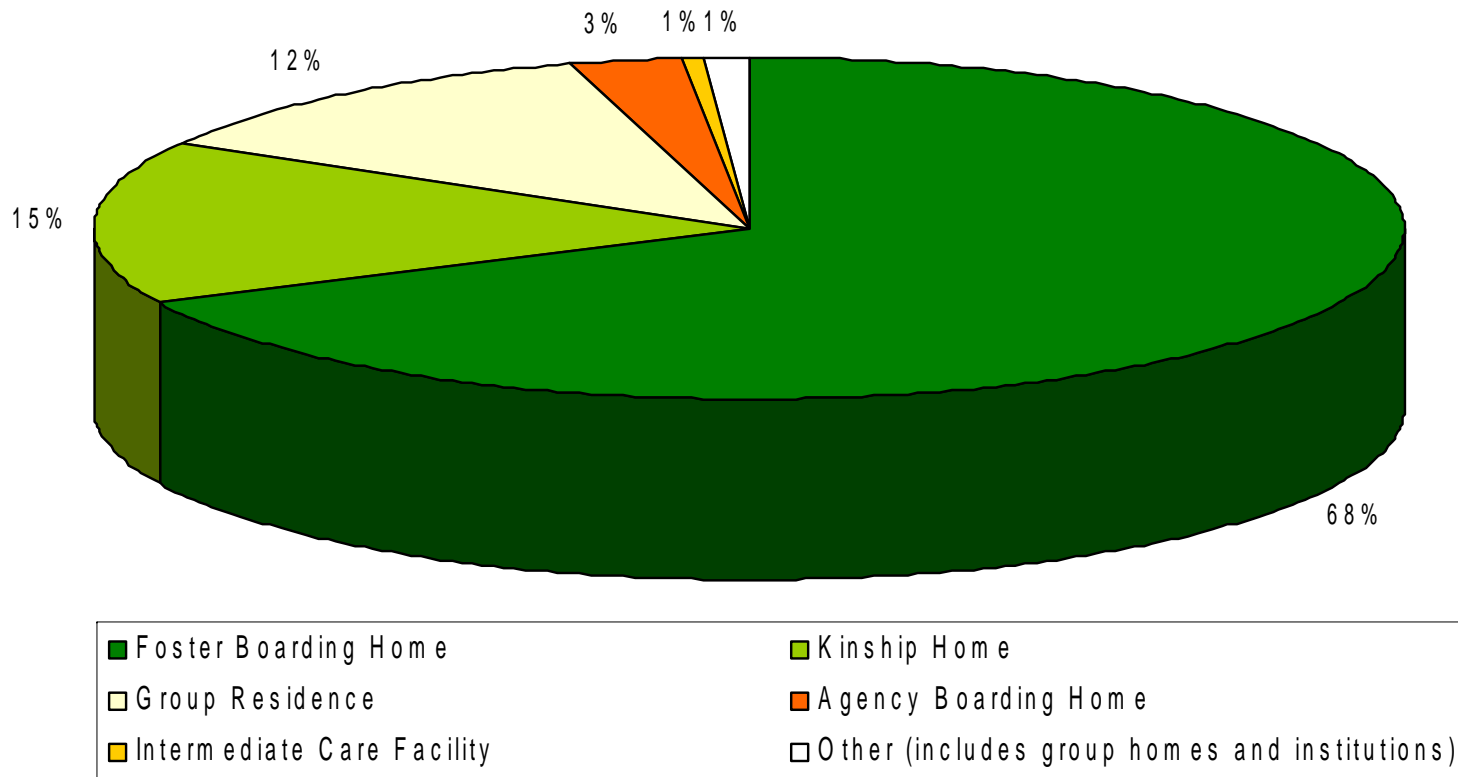
- Continue analyzing administrative data,
- Continue the case file document review,
- Hire additional document reviewers,
- Continue key respondent interviews,
- Begin children and caregiver interviews,
- Finish construction of the database that will store the data collected on this project,
- At the request of the City Council and Children's Services, continue our participation in the development of Children's Services' new clinical trials policy, and
- Receive documents requested under the Freedom of Information Act on an investigation of research practices involving foster children at Columbia-Presbyterian Medical Center conducted by the federal Office for Human Research Protections.

## Appendix 1: Characteristics of children who participated in HIV/AIDS clinical trials while in foster care

At our December 20, 2005, testimony to the New York City Council General Welfare Committee, Vera indicated that if the general characteristics of the children who participated in HIV/AIDS clinical trials while in foster care changed, we would provide new numbers and update the charts and graphs presented in Progress Report 1. The increase in the number of cases that Vera will review discussed in section 2 above changes the overall numbers, but in percentage terms, the new group is similar to the group of children already identified. Updated charts and graphs are below.

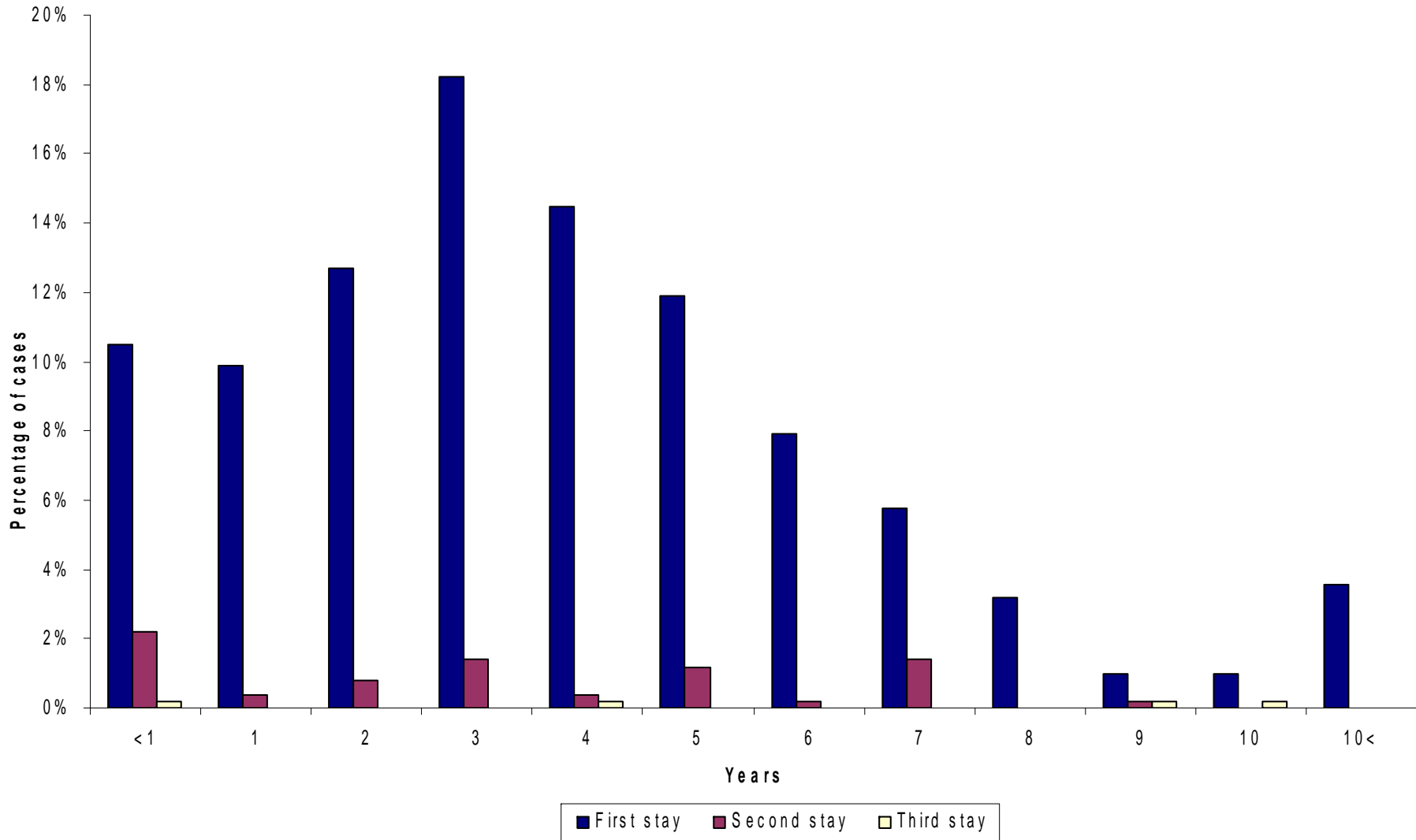


**Preliminary Analysis: Initial Placement  
 Children Who Participated in HIV/AIDS Clinical Trials,  
 Original cohort and additional cases  
 Source: Child Care Review Service**

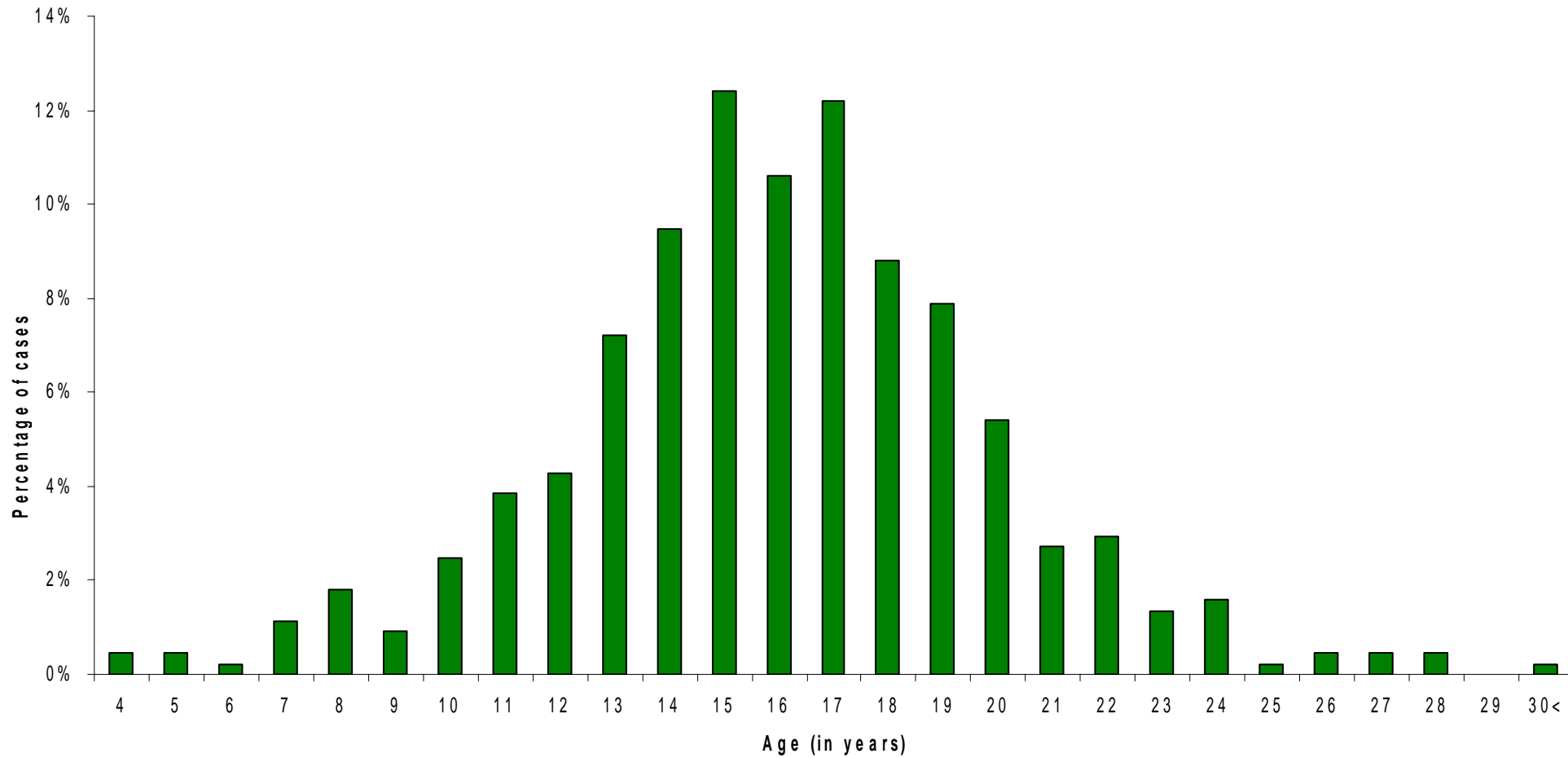




**Preliminary Analysis: Length of Stay in Foster Care**  
**Children Who Participated in HIV/AIDS Clinical Trials**  
 Original cohort and additional cases  
 Source: Child Care Review Service



**Preliminary Analysis: Age as of October 2006  
(Not including those that passed away while in care)  
Children Who Participated in HIV/AIDS Clinical Trials  
Original cohort and additional cases  
Source: Child Care Review Service**



Preliminary Analysis: Final Discharge  
 Children Who Participated in HIV/AIDS Clinical Trials,  
 Original cohort and additional cases  
 Source: Child Care Review Service

