

IMPROVING PEDIATRIC OUTCOMES THROUGH RESEARCH: THE PESS STUDY

SOUTH AFRICA

Background and Rationale:

While great progress has been made scaling up HIV care and treatment services for adults, expanding children's access to HIV care continues to lag. It is estimated that, of the 2.6 million children living with HIV in 2014, only 32 percent were receiving antiretroviral therapy (ART). Infants and young children infected with HIV have a very high risk of mortality and, without treatment, approximately half will die before the age of two. Research is needed to better understand the care children are receiving in HIV programs—as well as the gaps in that care—and the effects late ART initiation has on pediatric patients.

Study Overview:

From 2012–2015, ICAP collaborated with the Centers for Disease Control and Prevention (CDC) and health provid-

ers at five health facilities in South Africa's Eastern Cape province to conduct the **Pediatric Enhanced Surveillance Study (PESS)**, a prospective cohort study examining outcomes of children enrolled in HIV care. The PESS study enrolled 397 HIV-infected infants and children eligible to start ART (see box) and followed them for 12–24 months as they received routine care at five health facilities and enhanced laboratory and developmental monitoring for the study. The study aimed to examine clinical, immunologic, virologic, metabolic, psychosocial, and behavioral outcomes of enrolled children.

Key Findings:

Preliminary analyses indicate that, among the first 272 children enrolled in the study:



- More than half of those between five and 12 years of age at enrollment had not been diagnosed with HIV until they were over five years old.
- High proportions of children were hospitalized at enrollment and/or had a history of hospitalization prior to ART initiation. Among children under 12 months of age at study enrollment, 41 percent were hospitalized at enrollment and 18 percent had a history of hospitalization.
- Among children between two and nine years of age, 60 percent of caregivers reported at least one developmental delay or difficulty, and 35 percent reported two or more.

Box: Characteristics of the children enrolled in PESS:

- Children ranged in age from one month to 12 years of age
- At enrollment, 60 percent were three years old or younger
- 48 percent were female
- The mothers of 51 percent of the children were on ART at the time of enrollment
- The child's primary caregiver was:
 - The mother, in 72 percent of cases
 - The grandmother, in 14 percent of cases
 - Another family member, in 10 percent of cases

months old, 11 of whom had high viral loads ($\geq 100,000$ copies/mL).

- Almost half of children were delayed in starting ART due to adherence concerns of the health provider, including lack of a treatment supporter or incomplete adherence counseling.

Implications:

The study's findings provide critical information about gaps in the care being provided to children living with HIV in resource-limited settings. Findings indicate that many HIV-infected children continue to go undiagnosed and that many are not started on ART until they have reached advanced stage of disease. Only half of the children under 12 months of age enrolled in the study started ART within seven days, as required by South Africa's national fast-track guidelines, indicating that urgent action is needed to ensure that health workers are adequately trained and supported to rapidly initiate HIV-positive infants on ART. The study's findings also provide new and previously undocumented information about the way perceived adherence challenges can cause delays in ART initiation among children, including those with high viral loads and at greatest risk for disease progression and mortality.

An examination of ART initiation among the 354 enrolled children who were alive and attending study visits after three months:

- 76 percent, 84 percent, and 89 percent had initiated ART at 30, 60, and 90 days, respectively, after being identified as eligible for ART.
- Only half of the 85 children under 12 months of age initiated ART within seven days, as recommended in South Africa's 2013 national ART guidelines.
- Of the 40 children (11.3%) who did not initiate ART within 90 days, 31 (78%) started ART at a median of 119 days (range: 91-519), while 9 (13%) never started at all. Among the 40 late starters, 13 children were under 12