

Medication diaries do not improve outcomes with highly active antiretroviral therapy in Kenyan children: a randomized clinical trial.

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Abstract

BACKGROUND:

As highly active antiretroviral therapy (HAART) becomes increasingly available to African children, it is important to evaluate simple and feasible methods of improving adherence in order to maximize benefits of therapy.

METHODS:

HIV-1-infected children initiating World Health Organization non-nucleoside reverse transcriptase-inhibitor-containing first-line HAART regimens were randomized to use medication diaries plus counselling, or counselling only (the control arm of the study). The diaries were completed daily by caregivers of children randomized to the diary and counselling arm for nine months. HIV-1 RNA, CD4+ T cell count, and z-scores for weight-for-age, height-for-age and weight-for-height were measured at a baseline and every three to six months. Self-reported adherence was assessed by questionnaires for nine months.

RESULTS:

Ninety HIV-1-infected children initiated HAART, and were followed for a median of 15 months (interquartile range: 2-21). Mean CD4 percentage was 17.2% in the diary arm versus 16.3% in the control arm at six months ($p = 0.92$), and 17.6% versus 18.9% at 15 months ($p = 0.36$). Virologic response with HIV-1 RNA of <100 copies/ml at nine months was similar between the two arms (50% for the diary arm and 36% for the control, $p = 0.83$). The weight-for-age, height-for-age and weight-for-height at three, nine and 15 months after HAART initiation were similar between arms. A trend towards lower self-reported adherence was observed in the diary versus the control arm (85% versus 92%, $p = 0.08$).

CONCLUSION:

Medication diaries did not improve clinical and virologic response to HAART over a 15-month period. Children had good adherence and clinical response without additional interventions. This

suggests that paediatric HAART with conventional counselling can be a successful approach. Further studies on targeted approaches for non-adherent children will be important.