Low acceptance of early antiretroviral therapy (ART) among postpartum women in 14 countries across the globe

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1. PROMISE TRIALS

BACKGROUND

PROMISE was a randomized controlled trial conducted in 14 countries around the globe (Fig 1) that began in 2010. The aim was to determine the optimal antiretroviral strategy to prevent vertical transmission of HIV and maintain maternal and infant health:

- 1077HS in countries where the standard of care was highly active antiretroviral treatment (ART) and formula feeding to prevent vertical transmission of HIV, at study initiation
- 1077FF/BF in countries where other antiretroviral strategies were standard plus formula feeding (FF) or breastfeeding (BF), at study initiation

STUDY TREATMENT

Eligible HIV-infected pregnant women (1077BF/FF) or postpartum women (1077HS and 1077BF/FF) who did not meet local criteria to initiate ART were randomly assigned different antiretroviral strategies to assess prevention of vertical transmission during pregnancy and post-delivery, infant safety, and maternal health:

- 1077HS: stop or continue maternal triple ART after the risk for transmission was over
- 1077FF/BF:
  - —Zidovudine prophylaxis versus triple ART in pregnancy
  - —Maternal triple ART versus infant nevirapine prophylaxis during breastfeeding
  - —Stop or continue maternal triple ART after the risk for transmission was over

2. START TRIAL

WHAT IT MEANT FOR PROMISE

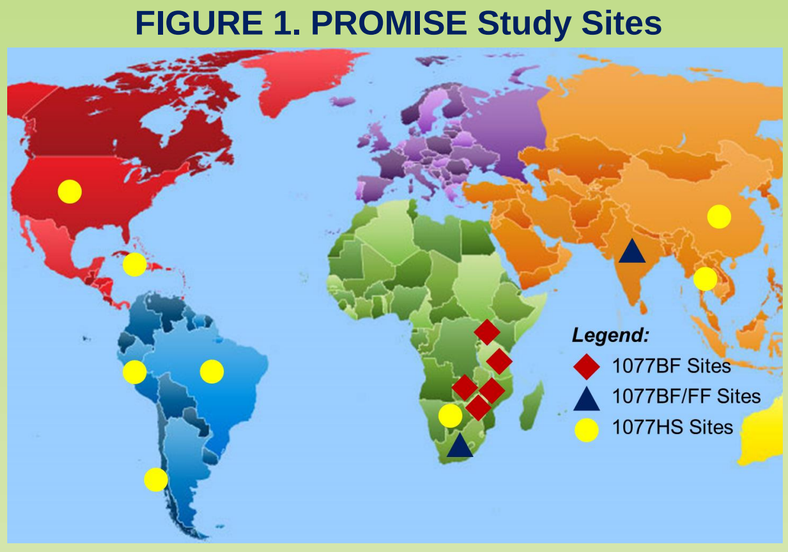
In June 2015 the START study results were announced, demonstrating that early ART initiation regardless of CD4 count reduces the risk of HIV disease progression.

The PROMISE study team rapidly informed active participants of these results and strongly recommended that women not receiving ART at that time immediately initiate treatment to optimise their own health.

Treatment initiation carried no financial cost for the participant. Their decision did not determine continued participation in the PROMISE studies.

We summarize PROMISE participants' responses to these recommendations and their reasons given to either accept or decline the offer of early ART.

FIGURE 1. PROMISE Study Sites



1077BF (14 sites in India, Malawi, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe)
1077BF/FF (4 sites in India and South Africa)
1077HS (52 sites in Argentina, Botswana, Brazil, China, Haiti, Peru, Thailand, and the United States)

3. METHODS

APPROACH

A mixed methods approach was used to gather both qualitative and quantitative responses from PROMISE participants who received the START information.

PROMISE study staff actively contacted participants to return to the clinic.

At clinic visits, staff delivered START results, utilising a structured script in a language chosen by the participant and then assessed comprehension.

The talking points included information about the START trial aims, study location and results that were announced:

"Now that the START study has shown that it is better to start ART earlier, we recommend that all women in PROMISE take ART."

Women not on ART were advised to accept the offer to initiate ART, during a client-centred counselling session.

The information-giving and counselling sessions were documented in real time by staff completing closed and open-ended questions on a data form.

Women selected their primary reason for accepting or rejecting the offer of ART from a set of closed options.

We report the uptake of early ART and the primary reasons given in support of their decisions among PROMISE participants.

4. RESULTS

ENROLMENT AND EARLY ART UPTAKE

Across all PROMISE studies, 5398 women enrolled:

- ➢ 4,513 women were in active follow-up at the time of the START results communications, with a median follow-up of 2.8 years (range 8 months to 6 years)
- ➢ 4,192 (93%) women were traced and underwent the START results session
  - ➢ 1,483 (35%) women were not on ART → All were advised to initiate early ART
    - ➢ 984 (66%) accepted early ART at initial session
    - ➢ 499 (34%) declined early ART at initial session

Acceptance rates varied by country, with all women accepting ART in Peru to 37% accepting in Tanzania (Figure 2).

"I'm not yet ready to commit myself to life long ART at this time."

"I am staying with many people who I don't want to know my status."

REASONING BEHIND DECISIONS MADE

The primary reasons given for <u>accepting</u> early ART were concern about health (45%) and because of the recommendation given by the protocol team (36%).

Reasons were similar between 1077BF/FF and 1077HS sites (Table 1).

The primary reasons given for <u>declining</u> ART were wanting more time to consider (40%) and feeling well and knowing CD4 count was high (18%), with a minority expressing concerns about potential side effects of ART (8%) (Table 2).

FIGURE 2. Early ART Acceptance Rates per Country

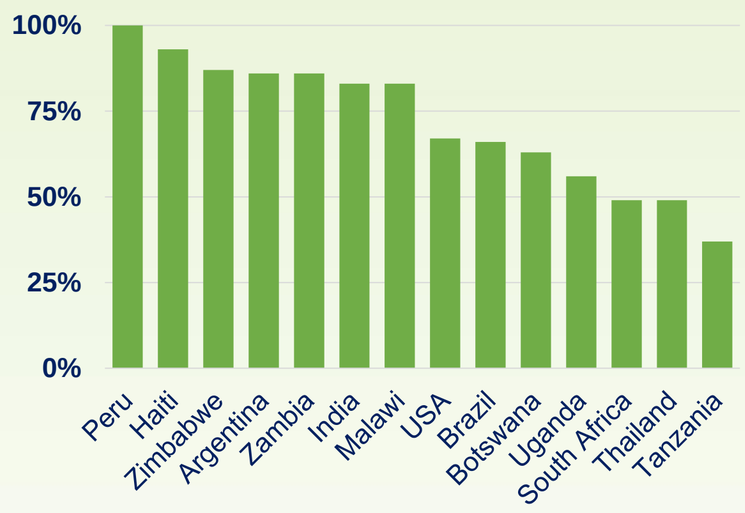


TABLE 1. Primary Reasons Given for <u>Starting</u> Early ART

Reason	1077BF/FF	1077HS
Concerned about health	46%	43%
Understands treatment is now recommended	35%	36%
Concerned about CD4 count	16%	13%
Other reason	2%	7%

TABLE 2. Primary Reasons Given for <u>Declining</u> Early ART

Reason	1077BF/FF	1077HS
Wants more time to consider	44%	33%
Feels well/knows CD4 count is high	13%	28%
Concerned about HIV disclosure	9%	3%
Concerned about commitment to life-long ART	9%	4%
Concerned about potential side effects	8%	8%
Other reason	7%	14%
Knows treatment not indicated per current local guidelines	6%	0%
Too busy with child care or other responsibilities	2%	5%
Concerned about adherence	1%	5%

5. CONCLUSIONS

WHAT THESE DATA SHOW

These data from a large sample recruited across a wide variety of settings demonstrate that a substantial number of women were not willing to initiate early ART after an initial counselling session.

Despite prior exposure to intense ART education and HIV monitoring within a highly-resourced clinical trial setting, more than one third of women still needed more time to consider the offer to start early ART for their own health.

WHY THIS IS IMPORTANT

This finding is of importance to ART programme implementers as they develop communication materials for the Treat All strategy.

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