Challenges faced implementing an RCT and a cohort study evaluating new PMTCT interventions in South Africa  
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Background
There are serious deficiencies in PMTCT programmes across South Africa (Figure 1) with low uptake of HIV testing, low uptake of PMTCT, infant PCR testing rates of less than 30% at 6 weeks and almost no routine data recording PCR testing after the cessation of breast feeding. In addition 6 week Infant HIV positivity rates with dual therapy regimens remain between 6 and 10%. Effective provision of triple therapy has been shown to reduce vertical transmission to below 1% in the developed world. Absolute Return for Kids (ARK) will conduct two studies to evaluate a new model of care for PMTCT starting in February 2009.

Kraaifontein PMTCT RCT
Study Design : Randomised control trial.  
Randomisation: Simple randomisation using Tenalea software  
Enrolment start date: 23 March 2009  
Period of enrolment : 18 months  
Expected sample size: 450  
Intervention arm: Triple ART (AZT, 3TC & Kaletra) covering breast feeding + Patient Advocate+ Usual care  
Control arm: Triple therapy+ Usual care  
Primary objective: Investigate the effect of a PA on the rate of infant PCR testing at 6 weeks  
Secondary objectives: Effect of PA on ART adherence, infant feeding practices & Post weaning PCR uptake  
Comparisons : Between arms and to historical data  
Duration of follow up: Till 18 months post partum

Sundumbilli PMTCT study
Study Design : Prospective cohort study  
Expected enrolment start date: 10 April 2009  
Period of enrolment : 1 year  
Expected sample size: 1000  
Intervention arm: Triple (ART AZT, 3TC & Kaletra) covering breast feeding + Patient Advocate+ Usual care  
Control arm: No control  
Primary Objective : Investigate the effect of the intervention on vertical transmission rates at 6 weeks  
Secondary objectives: Effect of a PA on ART adherence, infant feeding practices & transmission of HIV through breast feeding  
Comparison: To historical data  
Duration of follow up: Till 18 months post partum

Ark PMTCT randomised control trial, Kraaifontein
PA vs. No PA

Figure 1: National averages of key indicators the PMTCT programme in South Africa (Health Systems Trust)

Conclusions
There is the need for significant improvement in the public sector PMTCT services in South Africa. The superior efficacy of triple ARV therapy should see it adopted as the standard of care for developing countries by the WHO in the future. These studies will contribute valuable information on the effectiveness and cost benefits of triple therapy and patient advocates in the provision of PMTCT care in South Africa which can be reviewed by future policy makers.

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INSTITUTIONS
1. Absolute Return for Kids  
2. KwaZulu Natal Department of Health  
3. Western Cape Department of Health  
4. Trials Unit Medical Research Council

Figure 1: National averages of key indicators the PMTCT programme in South Africa (Health Systems Trust)