

The sustainability of care beyond HIV prevention trials: An evaluation of the MIRA Standard of Care programme

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Background

The Methods to Improve Reproductive Health in Africa (MIRA) trial

- Conducted 2003-2006
- Phase III randomised controlled trial, to evaluate the effectiveness of the diaphragm and Replens[®] lubricant gel in preventing heterosexual acquisition of HIV among women in South Africa and Zimbabwe
- Diaphragm and gel were found to offer no added protective benefit for HIV prevention when provided in addition to condoms and a comprehensive package of services (HIV VCT, risk reduction counselling, treatment for curable STIs) [Padian et al. *Lancet* 2007]

Care for study seroconverters

- Ethical obligations to provide ongoing healthcare to seroconverting participants have increased as treatment options in Southern Africa have expanded
- National ARV treatment programmes in South Africa and Zimbabwe were not yet operational when MIRA trial started but developed rapidly as the trial progressed
- During the trial, the donor and the investigators developed the MIRA Standard of Care (SOC) programme to ensure sustainable care for women who became HIV-positive during MIRA

The MIRA Standard of Care (SOC) programme

- The programme was implemented October 2006 – May 2007 and had two objectives:
- Inform and educate all HIV-positive participants of locally-available clinical and psychosocial care
- Actively facilitate participants' entry into available services to ensure appropriate and sustainable care at the closure of the trial

SOC locations

- The SOC programme was offered at the three MIRA site locations:
- Harare, Zimbabwe (UZ-UCSF)
- Durban, South Africa (MRC)
- Johannesburg, South Africa (PHRU)



SOC programme components

- Direct care (varied by site):
- CD4 and other HIV-related blood work
- STI testing and treatment
- Pregnancy testing
- Pap smears
- Individual and/or couples counselling

- Referrals:
- Sustainable care at local wellness and treatment programmes
- Research studies offering continued care

Benefits of the SOC

- Personally facilitated and tracked referral and entry into public healthcare programs and other research studies
- One-on-one case management, including follow-up of care
- CD4 testing (where available), which allowed participants to 'jump the queue' at government treatment programmes
- Extended direct care at the MIRA clinics for five months after trial close-out in December 2006

Purpose

We performed an analysis of the uptake of optional services during the SOC programme period (October 2006 – May 2007) and an evaluation of the programme's strengths and limitations.

Methods

Participant re-contacting

- Starting October 2006, MIRA staff attempted to contact all 327 women who seroconverted during the MIRA trial to provide information about the SOC programme
- Most women had already exited the study by the time of re-contacting
- Staff were required to document a minimum of three contact attempts by telephone and/or home visit

Data collection and analysis

- Monthly reports of SOC programme uptake per site
- Case reports for every eligible woman
 - Coded to classify participants into three categories: accessed care, declined care, and unable to be re-contacted



MIRA clinic in Chitungwiza, Zimbabwe

Results

Sample description

- During the MIRA trial, 327 HIV infections were identified among 5039 participants
 - 125 in Harare, Zimbabwe
 - 53 in Durban, South Africa
 - 49 in Johannesburg, South Africa
- Four of these 327 participants died prior to the implementation of the SOC programme

SOC programme statistics

	Harare, Zimbabwe	Durban, South Africa	Johannesburg, South Africa	Total
PROGRAMME OVERVIEW				
Total number of seroconverters*	123	151	49	323
Accessed some SOC service during program period	89	70	20	105
Declined SOC services	11	36	10	57
Unable to be recontacted/reconnected	23	39	19	81
LINKAGES TO OUTSIDE SERVICES				
Public-sector opportunistic infection programs and facilities				
Referred	85	36	21	142
Enrolled	60	21	9	90
Other research studies				
Referred	13	31	5	49
Enrolled	0	31	4	41
Private-sector care	0	2	1	3
ARV TREATMENT				
Received CD4 test at MIRA clinic				
CD4 <200	9	2	0	11
CD4 201-350	25	2	1	28
CD4 >350	53	25	6	84
Initiated ARV treatment via public sector (includes single-dose Neutrapine)	9	3	4	16
Waitlisted for ARVs at end of data collection	3	0	0	3

*: Four seroconverters died prior to the initiation of the SOC programme and are not included in this table.

SOC uptake among MIRA seroconverters (N=323)

- 57% (n=185) accessed some form of follow-up care at least one time
- 18% (n=57) received information about the programme but declined or never reported accessing additional care
- 25% (n=81) were lost/unable to be re-contacted after at least three contact attempts

Access to care

- Direct care:
- 38% (n=123) received at least one CD4 test at MIRA clinics
- 5% (n=16) initiated ARV therapy via public facilities
- Referral care:
- 44% (n=142) of all seropositive MIRA participants received referrals to public health facilities; 63% of these (n=90; 28% overall) enrolled in a programme of sustainable care in the public sector
- 13% (n=41) enrolled in other clinical trials

Conclusions

SOC programme limitations

- Difficult to re-contact and locate women for SOC since programme began after most women had exited the trial
- Reasons why 18% of women declined additional care were not systematically recorded
- Prevention trials identify early-stage HIV disease, and participants may not be physically or emotionally ready to accept additional care
- At the onset, there was no precedent or model programme of standard of care for HIV prevention trials
- Difficult to design and manage a single care program across three sites with varying resources and relationships with local facilities

Recommendations

- Develop plans for caring for seroconverters when designing prevention trials
- Fully integrate SOC programmes into prevention trials and implement simultaneously from outset
- Provide essential services (i.e., CD4 testing) that allow clients to skip lengthy queues at government programmes
- Incorporate quantitative and qualitative assessment tools to better understand why some HIV-positive individuals decline additional care

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