

PREVALENCE OF ANAEMIA IN WOMEN AT SCREENING AND FOLLOW-UP IN A MICROBICIDE PHASE III TRIAL

Hasinah Asmal, Dinesh Singh, Gita Ramjee

HIV Prevention Research Unit, Medical Research Council of South Africa.

BACKGROUND

- MDP 301, an international phase III multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 microbicide gels for the prevention of vaginally acquired HIV infection is conducted at 2 sites in Durban : Tongaat and Verulam.
- The first 500 women enrolled have routine FBC's (full blood counts) done at their screening visit.
- Anaemia is a common medical condition in the general population.
- The prevalence of anaemia in African females in South Africa varies between 10 – 25 %.
- Due to lack of regular screening, most anemias go undetected until symptomatic

Map of Kwazulu-Natal

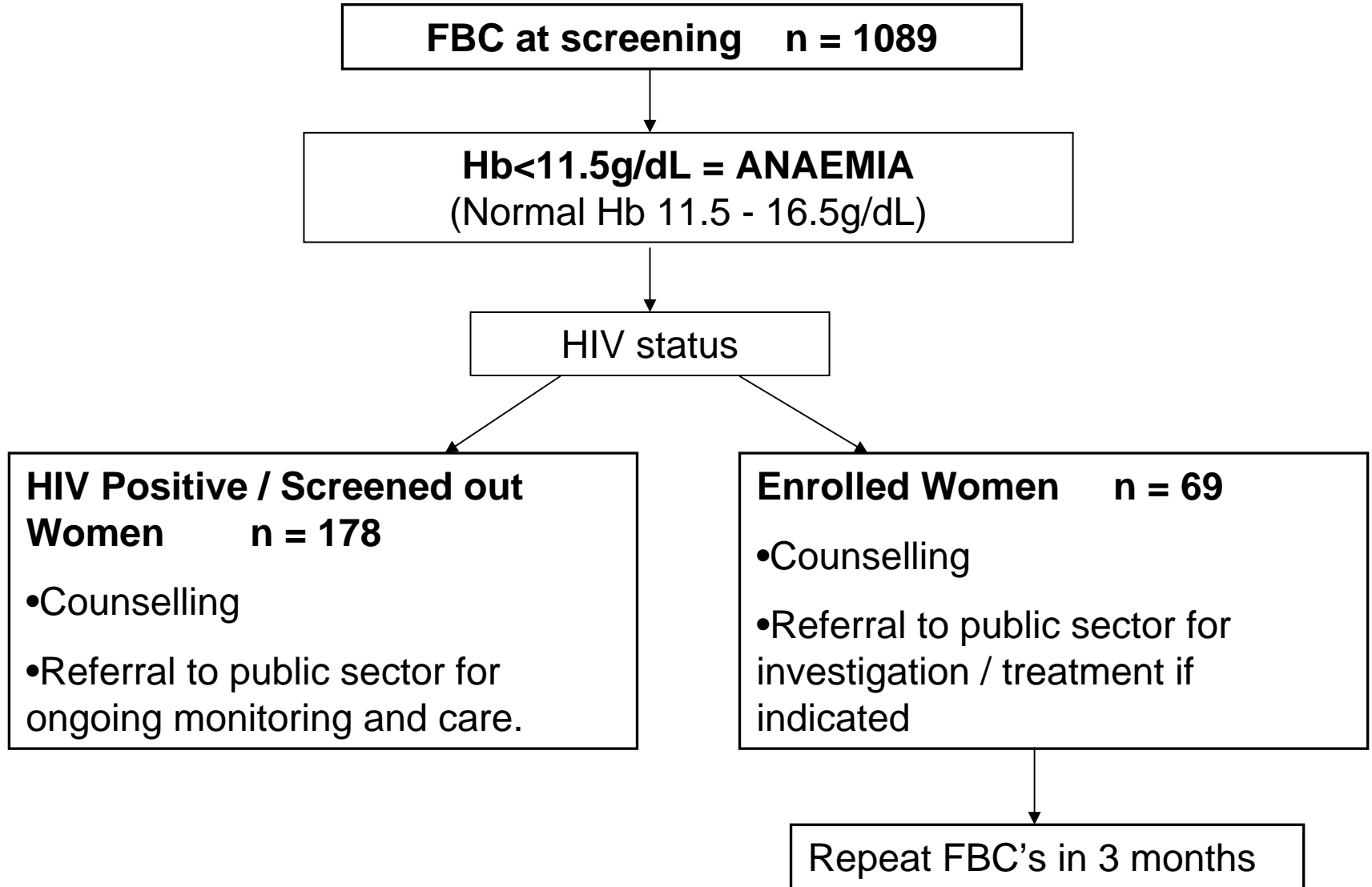


OBJECTIVE

A sub study was undertaken as part of the Phase III trial to ascertain the prevalence of anemia among women recruited and followed up in the microbicide trial.

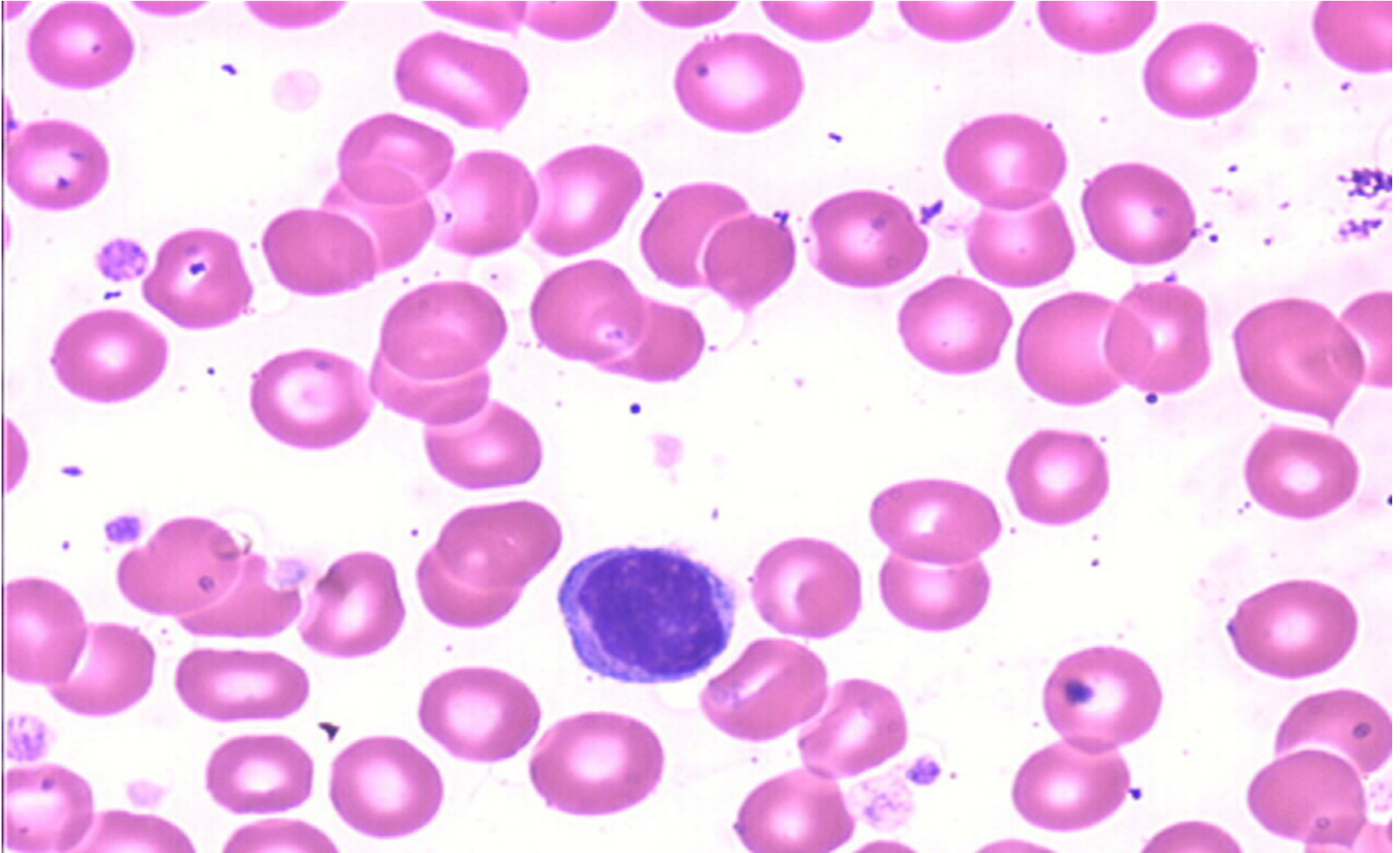
METHODOLOGY

Full blood counts (FBC's) routinely collected at screening between 06/02/06 to 28/07/06.



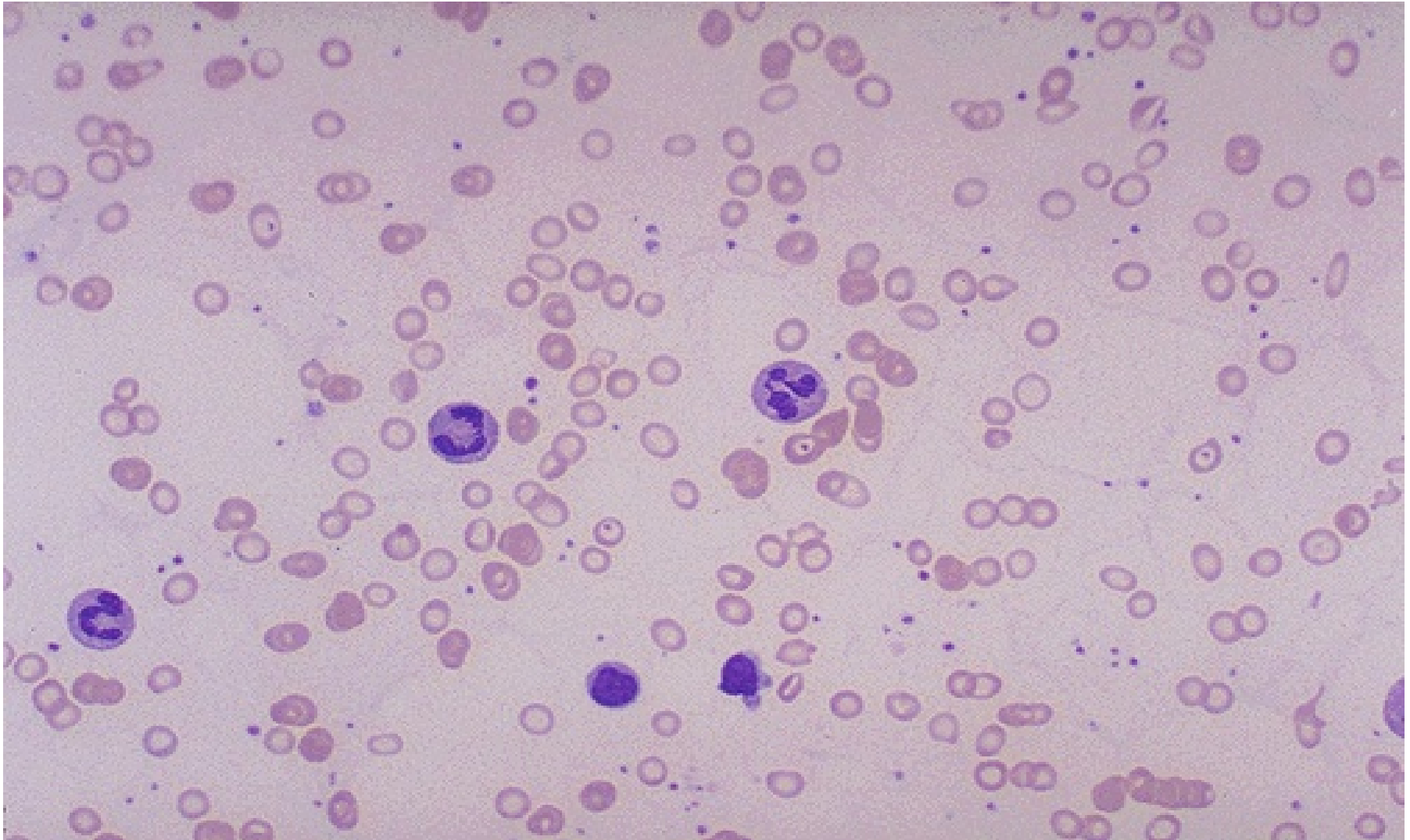
Normal Peripheral Blood Smear

showing normal size red blood corpuscles and normal haemoglobin content



Abnormal Peripheral Blood Smear

showing decreased size red blood corpuscles and decreased haemoglobin content



RESULTS

FBC at screening n = 1089

Hb < 11.5 (ANAEMIA)
n = 247
prevalence = 22.7%

Hb > 11.5 (NORMAL)
n = 842

**HIV POSITIVE /
SCREENED OUT WOMEN**
n = 178

**HIV NEGATIVE
ENROLLED WOMEN**
n = 69

- Counselling
- Referral to public sector for ongoing monitoring and care.

- Counselling
- Referral to public sector for investigation / treatment if indicated

continued

- Counselling
- Referral to public sector for investigation / treatment if indicated

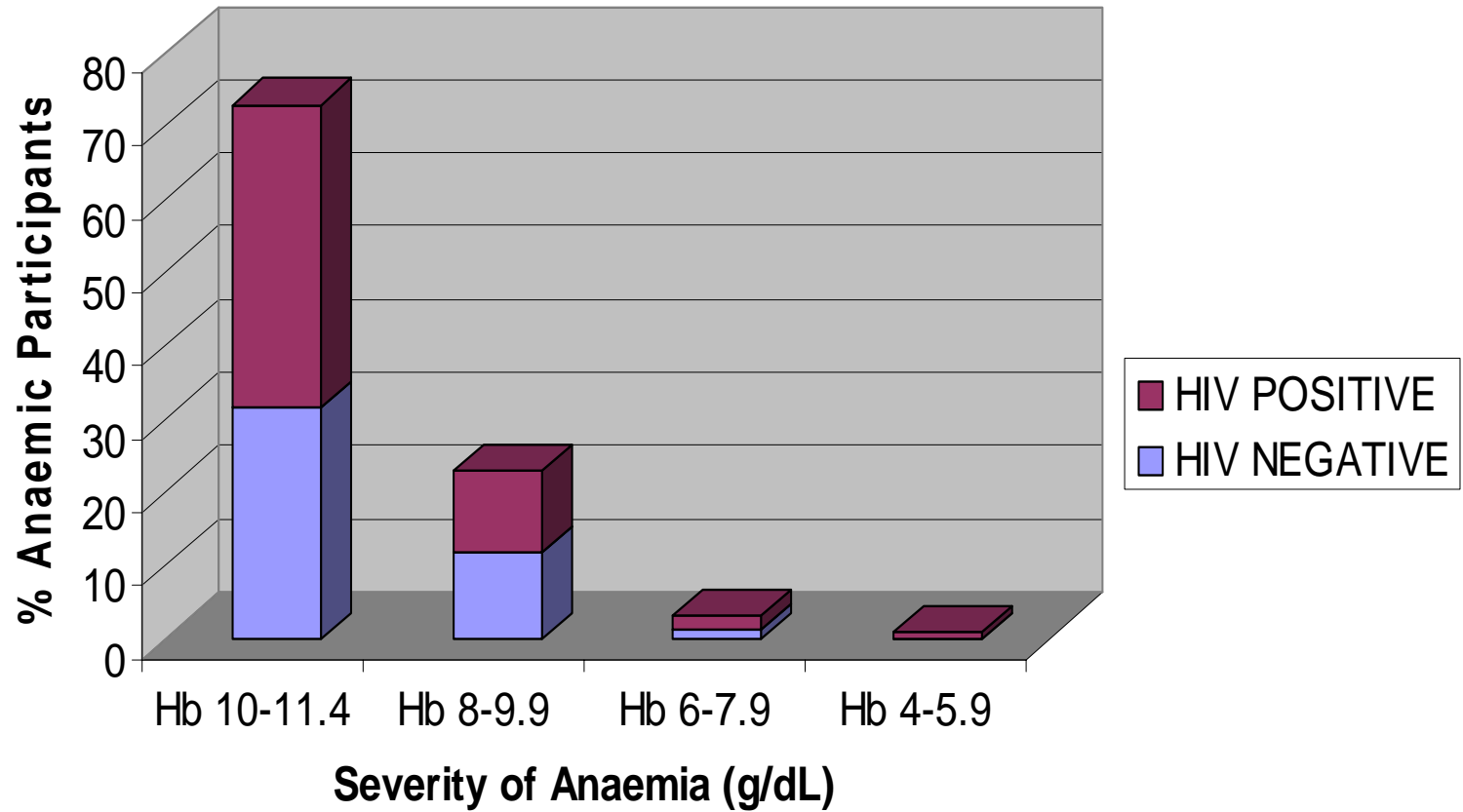
Follow-up at week 12
Repeat Hb

68%
(n =47)
IMPROVEMENT in Hb

43%
(n=30)
Hb NORMALISED
Through a combination of factors including :

- Counseling
- Improved diet
- and/or Referral for investigation / treatment

HIV STATUS AND SEVERITY OF ANAEMIA



CONCLUSIONS

- Through the screening process of an HIV prevention trial, women with anaemia were identified and followed-up.
- This is an additional public health benefit as without the trial in the community, this condition would have gone unrecognized.
- Clinical trials should consider investing in treatment such as haematinics (ferrous sulphate, folic acid) as a standard of care to improve follow-up and outcomes in such women.

ACKNOWLEDGMENTS

Participants of the study

Medical Research Council

MDP (Microbicides Development Programme)

Department for International Development (DFID)

Contact Information

Hasinah Asmal

HIV Prevention Research Unit

Medical Research Council

Tel. +27 (0)31 242 3600

hasinah.asmal@mrc.ac.za