The Bophelo Pele project Orange Farm (South Africa)

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Male Circumcision and HIV Prevention: Operations Research Priorities
An International Consultation
1- 2 June 2009
Safari Park Hotel, Nairobi, Kenya

Bophelo Pele Male Circumcision Project

Orange Farm (South Africa)

ANRS-12126

Aim

- To fulfil an ethical obligation from the ANRS 1265 Male Circumcision Trial – by offering free and safe MC to the community (Orange Farm, South Africa) where the trial was done
- To establish a MC program in a community
- To evaluate the impact of such program on:
  - Knowledge, attitudes and practices towards MC
  - Existing prevention strategies like sexual behaviour change, condom use, STI treatment seeking behaviour and VCT attendance
  - The spread of HIV and HSV-2

Objectives

Offer free and safe MC in a community (OF)

- **Measure uptake**
- **Effect on HIV (time) among men and women**
- **To study risk compensation**
- **To monitor use of other prevention strategies, like condom use**

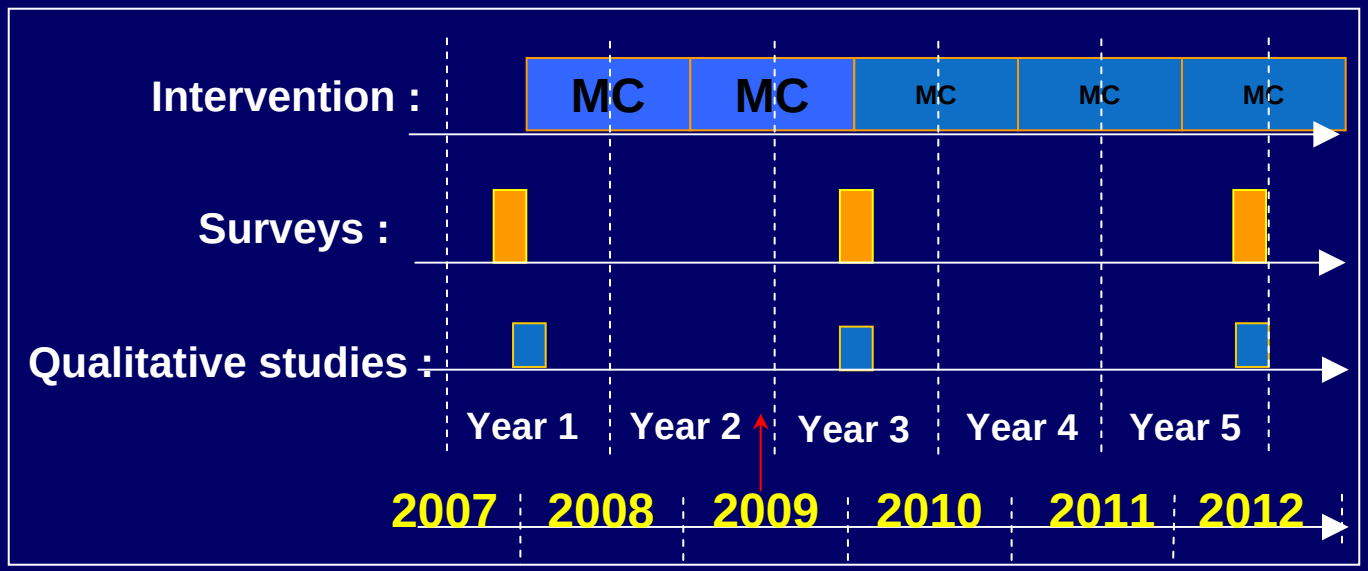
Does MC work in a real world setting?

Objectives

OR objectives:

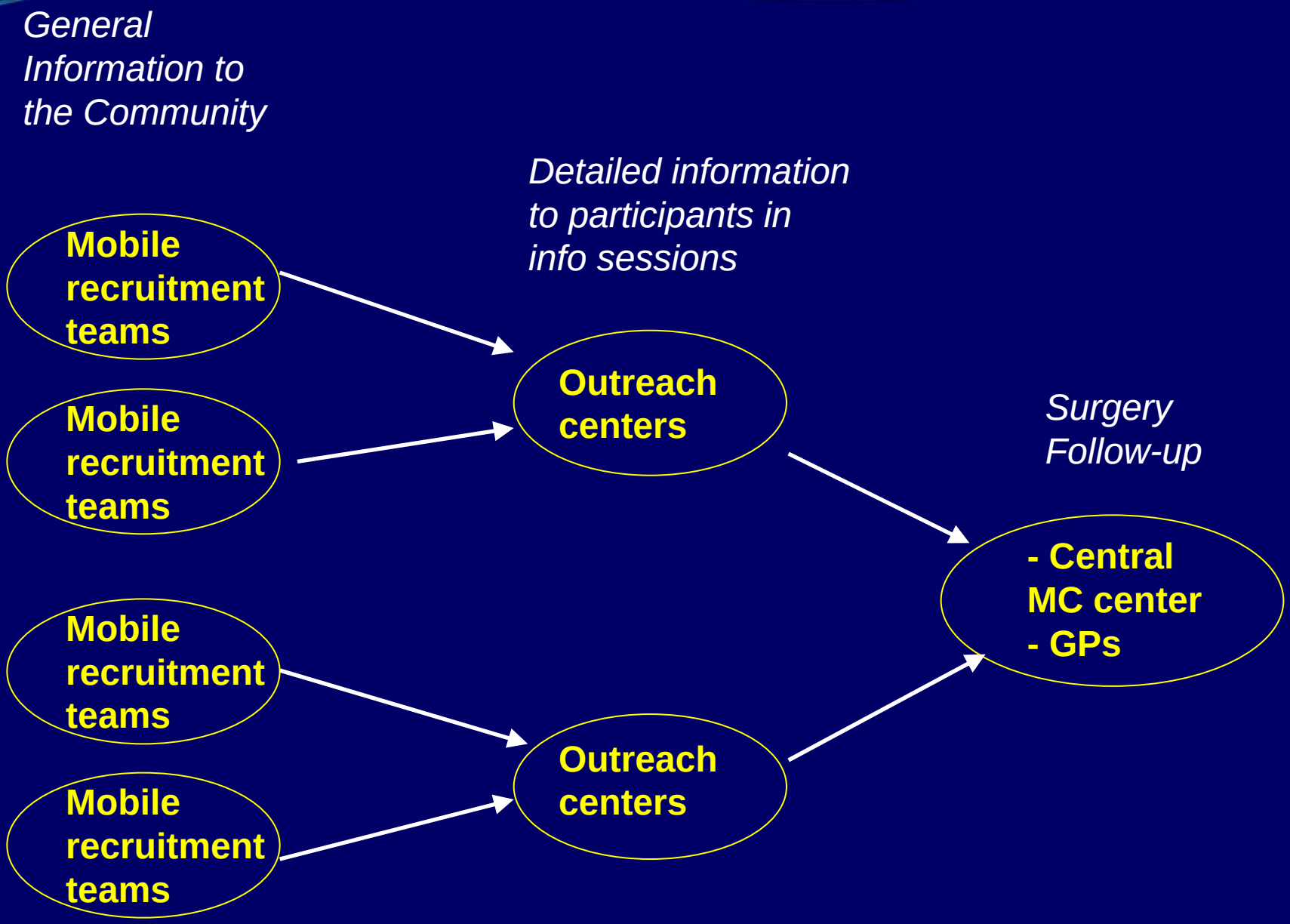
- Our first question was: "How could we make MC work as an intervention strategy"
  - What would the uptake be?
  - In an ideal situation?
- Measure uptake from specific outreach activities
  - What would convince young men to be MC
- Formulating a minimum package for roll-out
- Design a large scale surgical facility
- Test feasibility of task shifting
- Study communication messaging
  - What are we telling men and what do they hear

Bophelo Pele MC Project



2007-2012

5 000 000 Euros
67 people


General Information to the Community
Detailed information to participants in info sessions
Surgery Follow-up
Mobile recruitment teams
Mobile recruitment teams
Mobile recruitment teams
Mobile recruitment teams
Outreach centers
Outreach centers
- Central MC center
- GPs

General information to the community

Community advisory board

CAB: Local NGO's, Political structures, local leaders, scientists, interested parties

Community meetings

Recruitment
Outreach activities

- Schools, churches, community leaders
- Local radio station: Thetha FM
- Community outreach activities: all households
  - “What women should know about MC”
  - “What men should know about MC”
- Community stakeholder workshops i.e. loveLife
- Local GPs
- In the clinics (STI patients)

Local radio

Door-to-door outreach

Inclusion activities at Outreach centres

- Information session, anyone can attend, parents, spouses, partners
  - → Safe sex messaging
  - → Section on MC
    - Partial protection for men only
    - 6-week period of abstinence
  - → Individual counselling
- VCT is recommended and offered
- CD4 count test (on site) → ARVs
- Paper work (minimum) for Inclusion, including Informed consent

Wait 3 days before surgery!
(7 days for smokers!)

So what have we found out so far?

Finding for most important questions are preliminary and study is ongoing

Findings: Uptake

Among "Uncircumcised":

If MC was done by a doctor and free of charge would you be willing to become circumcised?

82.1% 709/864

Among those willing to become circumcised:

Went for circumcision:

72.1% 511/709

Among "Uncircumcised":

Uptake 59.1% (55.8 – 62.4%) 511/864

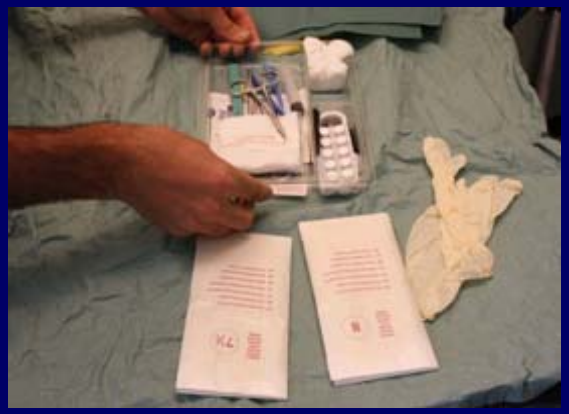
Surgery: previous model

One doctor operating with one nurse ie conventional surgical setup was too slow

We needed a high volume high quality models

Surgery: current model

- 4 surgical bays per doctor
- Forceps guided method
- Operative assistants (nurses) to block and help suture
- Use of electrocautery
- Friendly MC kit
- Simple paper work (MC card)
- Cost has been reduced to ZAR 300 (~US$ 35) per circumcision



Surgery: current model

A surgical team is composed of

a) 1 surgeon to apply the forceps, cut the foreskin, control the bleeding and supervise staff
b) 5 nurses to administrate local anaesthesia, assist during surgery and complete the suturing
c) 4 beds

→6 - 10 MC per hour

→with an average surgeon time of 7-8 minutes per MC

→Total procedure time of 20 minutes.

Cosmetic results
Forceps guided method

Immediate post-operative

After two months

After one year

Adverse events

After more than 7000 MC:

No deaths
No permanent injuries due to adverse events
8 (0.14%) participants were hospitalised for adverse events.

The total complication rate, including minor complications such as pain, bleeding, local infection and swelling, is 2.7%.

External quality control using the WHO Quality Assessment Toolkit is organised regularly (at the moment)

Surgery
WITS Urology Department Study Site

- There is a **follow-up** visit 2-3 days after surgery
- Second follow-up visit have been introduced, attendance of this second visit low
- **Emergency response** for participant after surgery

Next steps

- Intervention: To increase the MC prevalence 15% → ?%
  - We still don't know what the overall uptake will be
  - We need to refine our communication strategies
  - Create maximum demand
  - Study risk compensation over time

- To assess the effect of the project
  - Sexual behaviour
  - Prevention strategies
  - HIV & HSV-2

- Methodology:
  - To repeat cross sectional surveys
  - Nested studies

Next steps

- **To create an example of what could be done to roll out MC in Southern Africa**
  - **Refining a minimum package for roll-out**
- **South African policy (policy by April 2009)**
  - **How will that effect the uptake and our project**
- **Quality assurance of service delivery**
  - **Maintain low AEs**
  - **Include Traditional surgeons**
  - **Task shifting should not compromise**
- **Feasibility of neonatal MC**

Acknowledgments

Orange Farm community
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Thank you for your attention