



Improving the accuracy of self-reported sexual behaviour and adherence data in MDP 301

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Microbicides Development Programme - MDP301

Objective: To determine the efficacy and safety of two concentrations of “PRO 2000/5 Gel” compared to placebo in preventing vaginally acquired HIV infection

Primary outcome: Acquisition of HIV infection

Sample: 9673

6 Sites: Zambia, Uganda, Tanzania, South Africa (3)

Process: Feasibility → Pilot → Phase III

The problem

Interpreting the trial result may depend on sexual behaviour and adherence data

Self-reported data often unreliable

Key questions

- How do you know that your sexual behaviour data are accurate?
- How do you know whether women have used the product (properly)?

- How do you ensure that participants understand the categories and questions in the way you intend?
- How do you ask sexual behaviour questions across different cultures & vernaculars in a standardised way that enables meaningful comparison?

- Have they understood the information/consent process?
- Is the product acceptable?

MDP social science

- Social science integrated into the Programme
- Locally recruited social science teams at each site; central coordination

The strategy

- Clarify concepts, categories, etc. (spend time on developing instruments)
- Triangulate
 - In-depth interviews with women & partners
 - Coital diaries
 - Focus group discussions
 - Ethnography
- Resolve inconsistencies during the study (trust participants)
- Feedback into trial

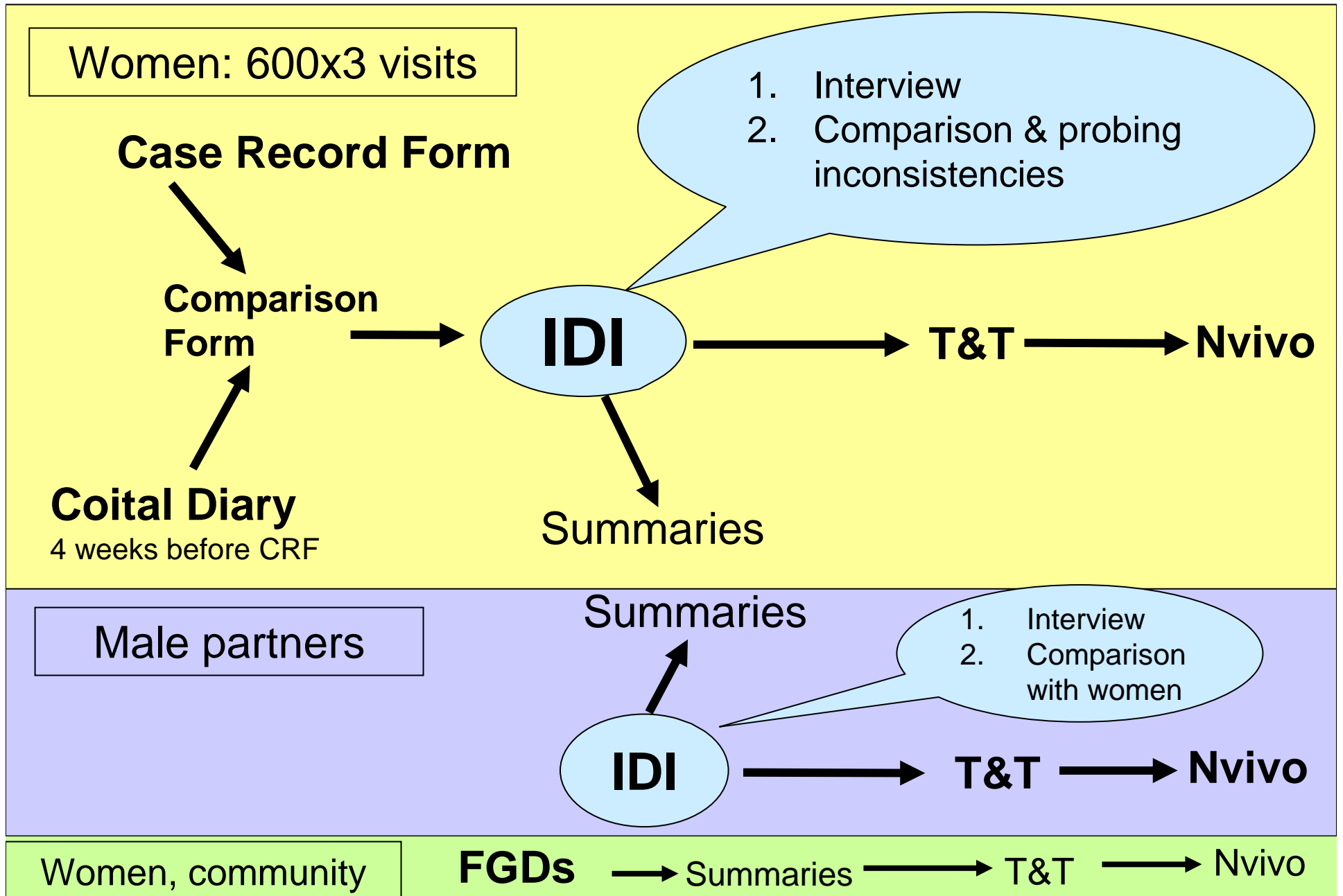
Explore & clarify standard categories & questions

- Almost all the central concepts in sexual behaviour research are ambiguous: marriage, partner types, anal sex, sex acts, condom use, etc.
- Ethnography (cultural & linguistic factors)
- Ask for use not meaning
- Use emic meanings

Triangulation

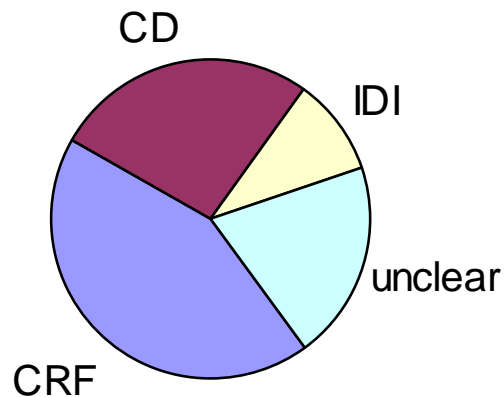
- Derived from surveying and navigation: Find position (single fixed point) by getting bearings on different landmarks
- In research: use different methods or kinds of information to determine the truth

THE MDP TRIANGULATION PROCESS



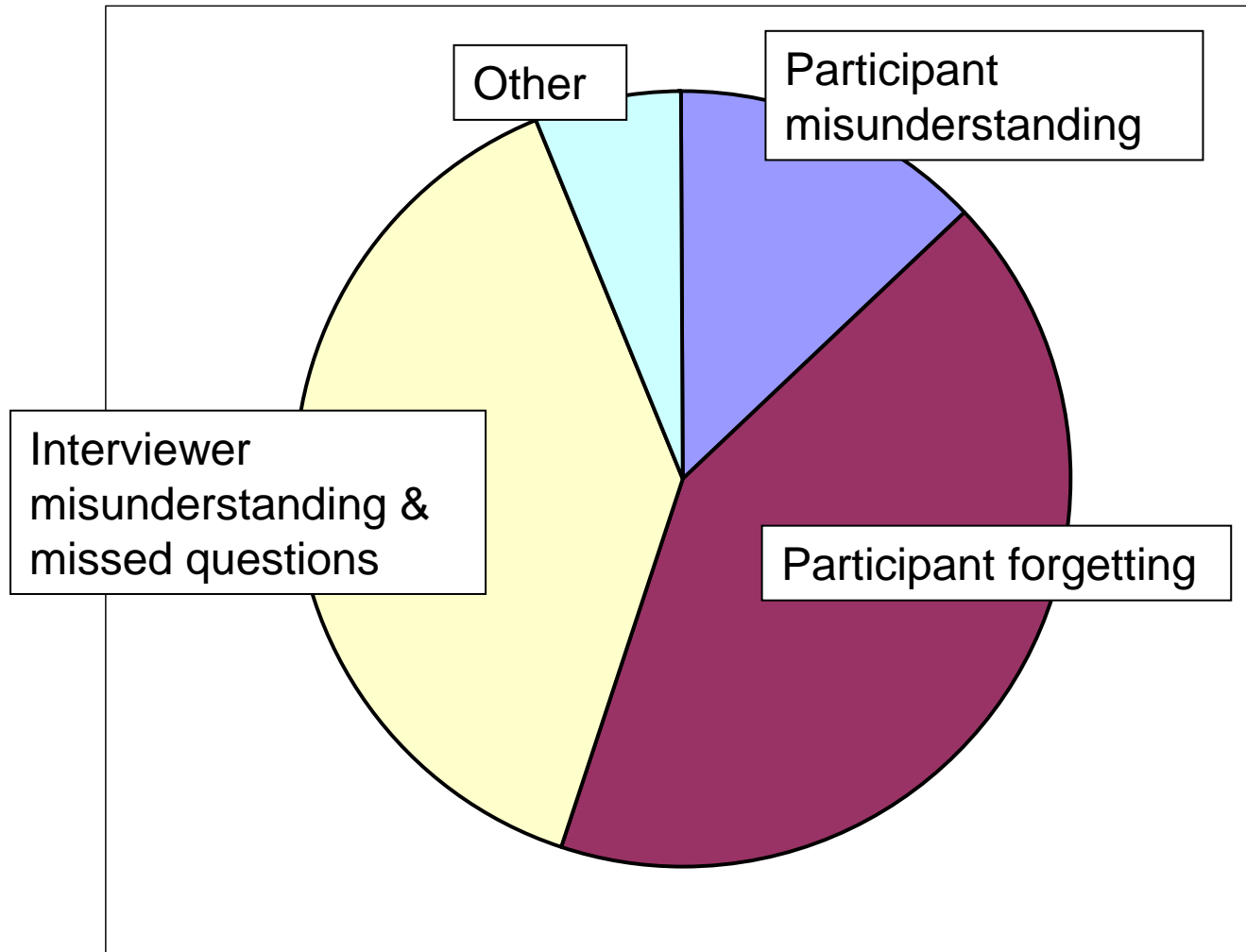
Consistency of CRF data

- In 52% (253/482) some inconsistency



- Mainly under-reporting sex, over-reporting gel use, & both over- & under-reporting condom use
- Most inconsistencies resolved during probing in IDI (80%)

Reasons for inconsistencies in CRF



Getting closer to the truth

- Adequately **fund** and integrate social science
- Invest a lot of time in design, **training**
- Clarify concepts and use **emic** meanings
- **Short recall**, memory aids
- Identify and **resolve inconsistencies** during the study
- Ensure continuous **feedback**
- Engage in **dialogue** with participants
- **Reflexivity**: study the research process
- **Ethnography**: study the context
- **Flexibility**: freedom to adjust methods & procedures

Constraints

- Differing epistemological assumptions between epidemiology and qualitative social science
- “Ethics”- The misplaced application of clinical trial ethics to social science research