CASE STUDY:
Media relations issues following the closure of the Cellulose Sulphate Trial
Experience from Durban, South Africa

Gita Ramjee
30th January 2007
- study closure
- Inform BREC, MCC, National and Provincial DoH

31st January 2007
- Face-to-face meeting with BREC Chair

6th February 2007
- Face-to-face meeting with Health Minister

13th February 2007
- Sponsor and P.I present interim analysis to BREC

20th February 2007
- Present to Parliamentary Health Portfolio Committee

21st February 2007
- Face-to-Face meeting with Provincial DoH

Press Release
“…cellulose sulfate could lead to an increased risk of HIV infection in women who use the compound.”

4th February 2007
First negative press article
“guinea pigs contract HIV”
“hundreds of women…feared to have contracted the virus”
[participants] “…are bitter, feel used and misled…”
“We were told [by recruiters] to visit drinking spots…and make ourselves available when men approach us”
“…encouraged to sleep with as many people as possible.”
STATEGY TO PROTECT OTHER TRIALS (CS EXPERIENCE)

29 January 2007
CS CLOSURE

Trial closure announced to Investigators

South African P.I

PRIOR TO PRESS RELEASE

CS SITE  ETHICS  MCC  DOH  COMMUNITY

PRESS RELEASE & NEGATIVE PRESS

2 DAYS
STATEGY TO PROTECT OTHER TRIALS (CS EXPERIENCE)

IMPACT ON TRIAL SITES

CONRAD CS

POP COUNCIL

MDP 301

HPTN 035

ISSUES/CONCERNS RAISED

• Product use was questioned
• Women threatened to withdraw from trial
• Recruitment and retention affected

COMMUNITY UPROAR

• Meeting with local community
• Meeting with Ward Councillors
• Meeting with Political Councillors

ACTION TAKEN

• Intensive counselling
• Partner counselling
• On-going local community meetings
• Emergency Toll-free number
• Suggestion boxes at sites
• Peer Educators workshop

Initiated within first week, intense for 3 weeks post closure and ongoing
IMPACT ON CLINICAL TRIALS

CS closure impact on other microbicide and vaccine trials:

- Researcher’s honesty and transparency questioned
- Loss of community trust
- Distressed staff
- Local and national Department of Health questioned ethics of microbicide trials
Involve site investigators and community in drafting press releases and communication strategies- prepare scenarios in advance

Inform outcome to Ethics, MCC, local and national DOH prior to press release

Engage press prior to press release- if possible press conferences concurrent in participating countries- sponsors, DOH, investigator reps.

Underscores the need for effective community and stakeholder partnership