Stakeholder Perceptions of Family Planning Services and Practices in HIV Prevention Trials

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Background

- Concerns about rates of pregnancy in early trials
- "Appropriate reproductive and sexual health counseling and ancillary services, including family planning, should be provided to trial participants" and "care and treatment practices should include reproductive health care for pregnancy and childbirth." (UNAIDS/WHO)
- Ever-increasing attention on fertility issues in ongoing and planned microbicide and PrEP trials

Source: UNAIDS/WHO. Ethical Considerations in Biomedical HIV Prevention Trials. Available at: http://data.unaids.org/pub/Report/2007/jc1399-ethicalconsiderations_en.pdf.

Aims

- To examine study-related practices and services related to pregnancy management and contraceptive care provided to trial participants in clinical microbicide and PrEP trials

- To assess current perceptions of practices and services related to pregnancy management and contraceptive care in clinical microbicide and PrEP trials, such as:
  - inclusion and exclusion criteria related to pregnancy and contraceptive use;
  - provision of contraception, counseling, and requirements for contraceptive use;
  - pregnancy testing;
  - pregnancy-related care; and
  - tracking and monitoring of pregnancies occurring during trials.

Methods

- Key Informant Interviews
  - performed Internet research to identify microbicide and PrEP trials meeting 3 criteria:
    - ongoing or planned
    - in phase II or III
    - enroll women of reproductive age
  - identified potential key informants for 12 trials
  - conducted phone interviews with 9 key informants who represented 7 trials
    - 2 microbicide (ongoing)
    - 2 PrEP/microbicide (1 planned, 1 ongoing)
    - 3 PrEP (1 planned, 2 ongoing)

Methods

- Online Quantitative Survey
  - distributed survey through 12 listserves
  - 800+ professionals working in HIV field
  - Questions assessed participants' attitudes regarding pregnancy and contraceptive issues
- N = 106

Online Survey Sample Demographics

Area of HIV Work	% (n) n=96
Advocacy	**22.9 (22)**
Policy	8.3 (8)
Ethics	00.0 (0)
Patient Care	8.3 (8)
Medical Research	18.8 (18)
Social & Beh Research	**27.0 (26)**
Biomedical Research	12.5 (12)
Pharmaceutical Research	2.1 (2)

Type of Org.	% (n) n=104
Govt	20.2 (21)
NGO	**47.1 (49)**
Private	4.8 (5)
Univ.	**27.9 (29)**

Prof Degree(s)	% (n) n=63
DrPH	6.3 (4)
JD	0.0 (0)
MD	31.7 (20)
MPH	**46.0 (29)**
MSW	4.8 (3)
PhD	**34.9 (22)**

Region of Work	% (n) n=100
North Am.	**63.0 (53)**
Latin Am.	8.0 (8)
E. Europe	4.9 (4)
W. Europe	7.0 (7)
N. Africa	1.0 (1)
Sub-Sah. Africa	**43.0 (43)**
S. Asia	9.0 (9)
S-E Asia	14.0 (14)
N-E Asia	2.0 (2)
Pacific Region	2.0 (2)
Mediterranean Region	0.0 (0)

Involved in HIV Prevention Trials	% (n) n=103
Yes	**54.4 (56)**
No	45.6 (47)

Key Informant Results

Criteria	# of PrEP Trials (n=5)	# of Microbicide Trials (n=2)
Exclude pregnant women	5	2
Exclude breastfeeding women	5	0
Exclude women with pregnancy intentions	5	2
Exclude women not willing to use effective contraceptive method	4	1
On site provision of contraception	5	2
Refer out for contraceptive methods not available on site	5	2
Record use of contraceptive methods by participants	4	2
Emergency contraception available on site	1	1
Provision of contraceptive counseling on site	5	2
Pregnancy testing at least once a month	5	2
Discontinue product use with positive pregnancy test	5	2
Continue most other study services during pregnancy	4	2
Permit participant to return to product use with negative pregnancy test	0	2
Permit participant to return to product use with negative pregnancy test and no longer breastfeeding	3	0
Refer participants testing positive for pregnancy to antenatal care	5	2
Provide participants testing positive for pregnancy with pregnancy options counseling	0	1
Track pregnancy outcomes	5	2
Track all infants past birth	1	0
Track infant past birth if abnormality detected	1	0

Online Survey Results: Pregnancy Issues

Overall, there was a strong belief that HIV prevention trials have a responsibility to address participants' pregnancy-related issues.

Statement	**Agree/strongly agree % (n)**
If a woman becomes pregnant during a trial, it should be the responsibility of the study to refer her to antenatal care services.	93.2 (69)
All trials should provide pregnancy options counseling to a woman who becomes pregnant during the trial.	85.3 (64)
All trials should monitor pregnancy and birth outcomes of participants who become pregnant during the trial.	87.7 (64)

Online Survey Results: Pregnancy Issues

Fewer respondents agreed with statements pertaining to frequency of pregnancy testing in clinical trials.

Statement	**Agree/strongly agree % (n)**
Pregnancy testing during trials should be conducted less frequently than once a month to help reduce detection of false or chemical pregnancies.	41.2 (28)
Pregnancy testing during trials should be conducted at least once a month to ensure that pregnancy is detected as soon as possible.	71.0 (49)

Online Survey Results: Pregnancy Issues

Those currently working on clinical trials were less likely than those not working on trials to believe that pregnancy testing during trials should be conducted at least once a month to ensure that pregnancies are detected as soon as possible.

Respondent	**Agree/strongly agree % (n)**
Working on trials	61.1 (22)
Not working on trials	81.3% (26)

Online Survey Results: Contraception Issues

Overall, respondents voiced strong agreement with statements related to offering contraceptive services to participants in trials.

Statement	**Agree/strongly agree % (n)**
Non-barrier contraceptive methods should be offered to participants at all trials sites.	94.6 (71)
All trial participants should be offered a long-term method of contraception.	86.3 (63)
Providing on-site contraceptive services and counseling to trial participants is a viable way to improve preventive care practices.	94.5 (69)
All trial sites should be linked or co-located with a family planning service or clinic	71.0 (54)

Online Survey Results: Contraception Issues

Fewer respondents believed that women should be required to use contraceptive methods if they wish to participate in clinical HIV prevention trials.

Statement	**Agree/strongly agree % (n)**
Non-barrier contraceptive methods should be required for participants in trials.	43.2 (32)
Participants should be denied participation in a trial if they refuse to use a non-barrier contraceptive method.	28.0 (21)
All trial participants should be required to use a long-term method of contraception.	12.5 (9)

Online Survey Results: Contraception Issues

Respondents currently working on trials were more likely than those not working on trials to believe that women should be denied participation in a trial if they refuse to use a non-barrier contraceptive method.

Respondent	**Agree/strongly agree % (n)**
Working on trials	40.0 (16)
Not working on trials	14.7 (5)

Stakeholder Perceptions

- 5 of 7 trials exclude women not willing to use an effective method of contraception
- Only 28% of survey participants agreed with this exclusion
- Of these:
  - 40% currently work on trials
  - 15% are currently not working on trials

Next Steps

- Further research to determine different stakeholder perspectives on pregnancy management and contraceptive care issues to better address disconnects between stakeholders.

- Expand opportunities for dialogue among different stakeholders to share knowledge and experiences that could enhance pregnancy management and contraceptive care practices in HIV prevention trials.

- Take proactive and thoughtful efforts to balance the safety and well-being of participants and their fertility choices with the needs of clinical trials.

Questions?