Contraception In VOICE

VOICE

MTN Annual Meeting 2010

Pregnancies in prevention trials

- HPTN 035:
  - 3100 women enrolled
  - 323 pregnancies
  - 10.4%
- VOICE
  - Zimbabwe: 4 pregnancies/160 enrolled= 2.5%
  - Uganda: 1 pregnancy/ 85 enrolled= 1.2%
  - Durban-MRC: 0 pregnancies/65 enrolled= 0%

VOICE pregnancy details

- Ppt1: 303 (one full term delivery)
  - Started OCPs June 2008
  - Reported missing doses
- Ppt2: 303 (two full term deliveries)
  - Stared OCPs Jan 2006
  - Reported missing doses
- Ppt3: 312 (two full term deliveries)
  - Started OCPs March 2008
  - Reported missing doses

VOICE pregnancy details cont'd

- Ppt4: 304 (previous pregnancy)
  - Started OCPs January 2005
  - Reported missing doses
- Ppt5: 318 (two full term deliveries)
  - Started Depo Provera December 2009
  - Participant self reported last injection date

Surprising?

- One pregnancy on injectable
  - Risk of pregnancy on injectable
    - Among perfect users: .3%
    - Among typical users: 3%
  - Participant self reported last injection. Site administered injection possibly late
- Three of the four women who became pregnant after OCP use were long time users

Not Surprising?

- All appeared to be contraceptive failure due to missed doses (not method failure)
- Unintentional or Intentional?
  - 3/5 appear to be unintentional missed doses
  - 2/5 could be intentional missed doses based on site assessment

Voice Goal

- Prevent intentional pregnancies
  - Screening procedures
- Prevent unintentional pregnancies
  - Providing effective contraception
  - Offer contraceptive counseling

Why do we care?

- Participants must come off product during pregnancy and breastfeeding

- Time off product results in dilution of effect
  - If there really is a protective effect of study product, we may not be able to detect it because of time off product.

What have we done already?

- SOPs regarding verification of contraception and contraceptive counseling techniques
- Study-specific training on contraceptive counseling
- Feb 2010 Study Coordinators call to discuss contraceptive messaging, challenges

TODAY: Meeting to discuss strategies and share ideas between sites as to how we can improve contraceptive counseling, improve adherence, and prevent pregnancies among VOICE participants.

Review of study-specific training

- Protocol specified eligibility criteria for
  - Pregnancy intentions
  - Willingness to use an effective contraceptive method
- Site-specific methods for verifying surgical sterilization as part of eligibility determination
- Protocol-specified contraindicated methods
- Contraceptive methods available on site
- Contraceptive methods available through referral

Contraceptive Counseling During Screening

- Done at Screening Part 1, Screening Part 2, and before randomization on the day of enrollment
- Informed consent and contraception counseling sessions should
  - Explain which methods are acceptable for study purposes AND
  - Emphasize that women who cannot commit to using these methods for at least 24 months should not enroll in the study (this is part of their contraceptive choice)

Contraceptive Counseling During Follow-Up

- Continue client-centered approach each month
- If participant has no issues or problems with her chosen method, counseling sessions may be brief but
  - Always provide clear instructions for use
  - Always reinforce key adherence messages
- If participant has issues or problems
  - In some cases only counseling and reassurance may be required
  - In other cases, consideration of method switching may be indicated

Voice Goal

- Prevent intentional pregnancies
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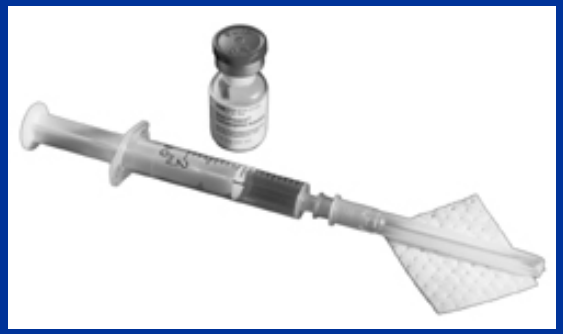
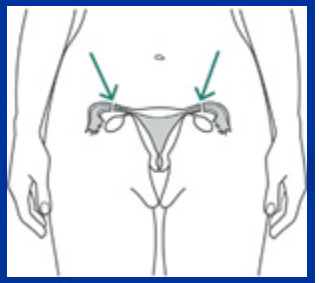
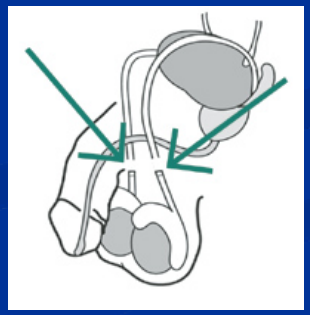
Issues to Consider

- The participant's actual pregnancy intentions
  - Not based just on what participant says
  - Need to consider all aspects of participant situation re: likelihood of pregnancy in next 24 months
  - Are we asking the right questions?
- Contraceptive method at time of enrollment
  - What documentation of contraception do we require prior to enrollment? Should we require more?
  - How can we manage transition from off-site to on-site provision of contraception without missing pills, doses, etc.

On-Site or By Referral?







Issues to Consider

- Adherence to oral contraceptives
  - How can we improve our counseling messages?
- Myths about injectables and intrauterine devices
  - Are participants choosing oral contraceptives because of their partner's or their own false beliefs about side effects or long-term effects of injectables?
- Counseling about back-up methods
  - Are we reminding participants to use a condom if even one pill is missed
- Do sites want more specific contraceptive training?

Let's Discuss