

International Rectal Microbicides Working Group (IRMWG)

Monthly Teleconference

May 10, 2007

Present:

1. Marc-André LeBlanc (IRMWG SC Secretary, Global Campaign for Microbicides, Canada),
2. Robert Reinhard (USA),
3. Shaleena Theophilus (Canadian AIDS Society/MAG-Net, Canada),
4. Jessica Terlikowski (AIDS Foundation of Chicago, USA),
5. Trina Nelson (AIDS Foundation of Chicago, USA),
6. Roy Wadia (IRMWG SC member, BC CDC, Canada),
7. Latifa Boyce (Alliance for Microbicides Development, USA),
8. Bindiya Patel (GCM, USA),
9. Jim Pickett (IRMWG Chair, AIDS Foundation of Chicago, USA),
10. Elena (USA),
11. Alex Carballo-Diequez (Columbia University, USA),
12. Edd Lee (AVAC, USA),
13. Manju Chatani (SC Member, AMAG, Ghana),
14. Tim Farley (WHO, Switzerland),
15. Emily Rigmont (AIDS Action Committee, USA),
16. Doreen Hardy (USA),
17. Julie Davids (SC Member, CHAMP, USA),
18. Nick Myers (USA),
19. Rowena Johnston (SC Member amfAR, USA),
20. Cindra Feuer (USA),
21. Charles Price (UCLA, USA),
22. Courtney Mulhern-Pearson (SF AIDS Foundation, USA),
23. Judy Auerbach (SFAF, USA),
24. Ian McGowan (UCLA, USA),
25. Anna Ford (AIDS Action, USA),
26. Helenka (AIDS Vancouver, Canada),
27. Peter Anton (UCLA, USA),
28. Steve Wakefield (HPTN, USA).
29. Sean Barry (CHAMP, NY)

1. Jim welcomed participants and thanked UCLA for sponsoring this call as well as Dr. Tim Farley for presenting.

2. Dr. Farley presented on heterosexual anal intercourse in developing countries, using his slides as guide. Supplementary information to the slides is included below.

Slide 13: Reflects HIV shedding vaginally. We may need to verify that a similar pattern occurs rectally, but this is highly likely.

Slide 14: When it mentions risk associated with male-to-male transmission in anal intercourse, it refers to the risk for the receptive partner when the insertive partner is positive. We need data on the risk for the insertive partner when the receptive partner is positive.

Slide 16 shows that the increase is primarily in condom use among young single sexually active women, not married women.

Slides 17 and 18 shows that condom use did not increase as much among married women, and that may be because most condom use was motivated by the wish to avoid pregnancy.

Slide 20: when dealing with marketing, we need to ensure that this is not done in a way that will stigmatize the product among populations where it could have a significant impact.

Slide 21: When considering the type of partner with whom AI (anal intercourse) is practiced, we must keep in mind that while it is more frequent with commercial sex workers than with regular partners, presumably regular sex partners by definition have sex more frequently, possibly leading to an actual greater number of AI/sex acts in those relationships.

Discussion

Ian asked whether we should be concerned about UAI (unprotected anal intercourse) affecting the outcome of late stage microbicides trials. Dr. Farley explained that given these are double-blind randomized trials, this will help to diminish the potential effect, presumably, or at least somewhat equalize the effect across arms, so this is good. However, it is entirely possible for UAI to dilute the effect of a potentially effective product, and thus have it show up as not effective in a trial.

For example, for the sake of illustrating this point, if a given trial population engages in AI 10 times less frequently than vaginal intercourse, but that AI is 10 times more likely to lead to infection (and thus an equal number of infections are attributable to UAI and UVI), and the product being tested reduces risk by 50%, then you will really only see a 25% decrease in infection, since it only reduced the infections that occurred vaginally, not anally.

Add to this a product that actually INCREASES risk through UAI, and you may very well completely erase your ability to see the protective effect in the trial.

We should also keep in mind that these trials are being conducted in high-risk populations, often the very same ones that report the highest rate of AI.

Some study teams try to take all of this into account by trying to collect data on AI in trials, but all are frustrated by the lack of reliability of that data.

3. Announcements:

- Many thanks again to UCLA and Tim for this call!!!
- Our next call in June will feature the authors of the report from the International Gay and Lesbian Human Rights Coalition, *Off the Map*, looking at the unmet prevention needs and context for work with people engaging in same-sex acts in Africa.