



MTN-042

Summary and Next Steps

Sharon Hillier, PhD

Stakeholders Consultation
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Major Feedback Received

- General support for the MTN-042 study
- General agreement that more data is needed to support the safety of oral PrEP
- General agreement that the dapivirine ring should be studied in pregnant women, and the time is right to move forward
- Lots of specific suggestions:



Major Feedback Received

- Consider extending access to prevention products at least through 6 weeks post-partum (oral PrEP only?)
- Include as an eligibility criteria the intention to carry the pregnancy through to delivery
- Consider longer follow up of infants through a year of life- should this be integrated into the 042 protocol or should we stay with the current model of enrolling women into the pregnancy registry?

Major Feedback Received

- Integrate a section justifying the inclusion of young women ages 18-21 since there was no clear protection associated with ring use in women less than 21 years of age.
- Harmonize the definitions of maternal and neonatal outcomes with the standardized definitions developed for use in maternal vaccination studies
- Estimation of gestational age should be standardized across the sites; ultrasound?

Major Feedback Received

- Need a plan for community/stakeholder sensitization about the study
- Social harms associated with using an HIV prevention product need to be considered
- Need strong linkages with care providers to ensure that “influencers” are aware of the study and do not advise women not to use study products
- Provide clear plan for when ring should be removed at labor

Major Feedback Received

- Consider whether women having their first pregnancy are the ideal candidates for participation
- Consider mental health evaluation as part of the health evaluation of the women
- Will need to ensure that participants receive clear guidance about seeking care sooner than later when labor is suspected.
 - Could provide a brief flyer or brochure for women to give their providers

Thanks to all of you!

- We appreciate all of the perspectives and input into the MTN-042 protocol over the past two days.
- We will integrate as much as possible your suggestions after discussing these suggestions with our funders and the full protocol team
- If you think of other issues you want us to consider but did not have an opportunity to bring to us, please follow up with us

Acknowledgements

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