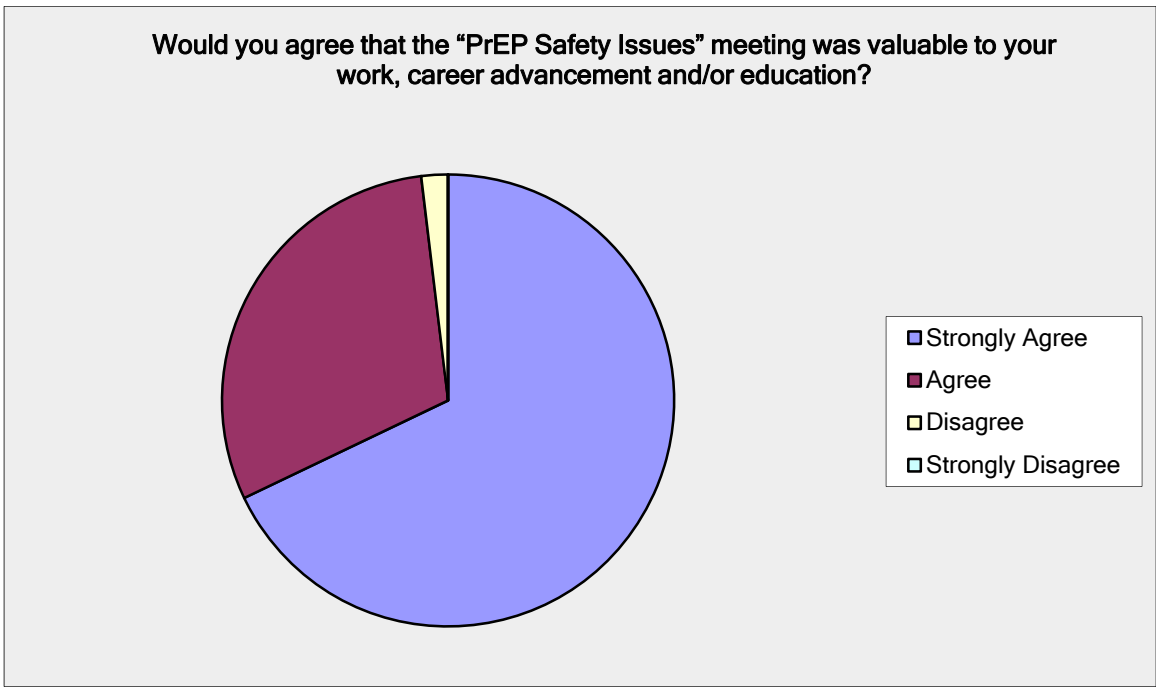
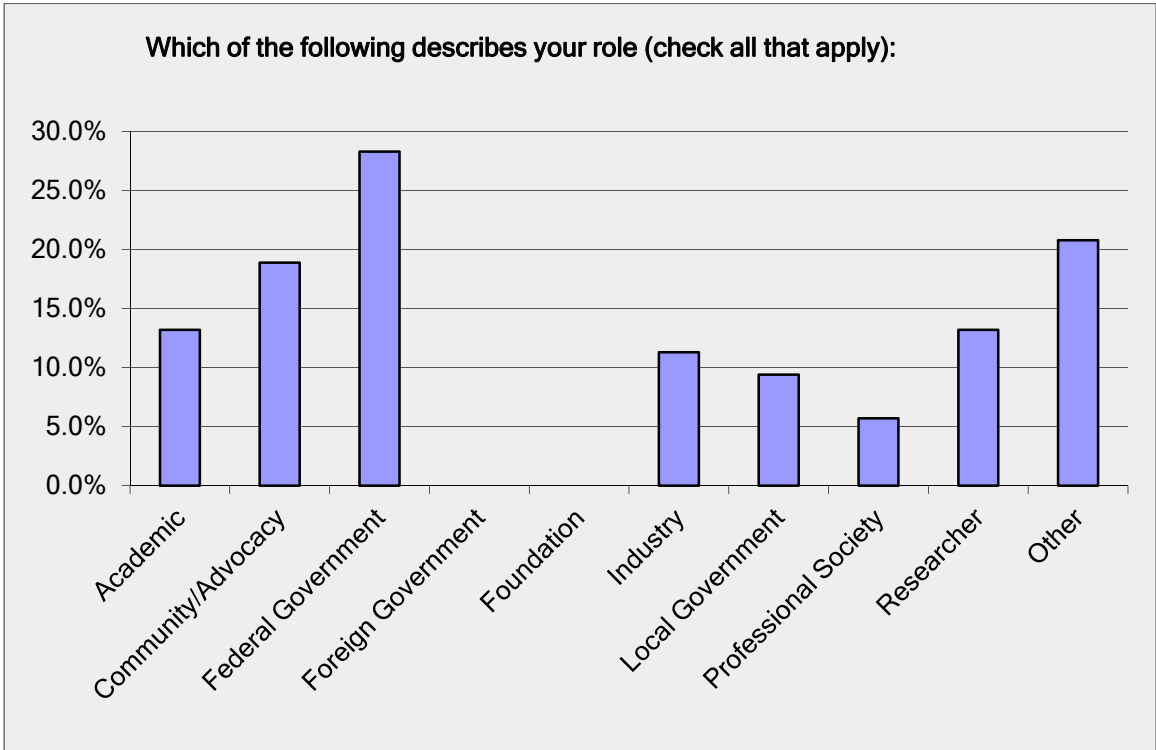


FORUM FOR COLLABORATIVE HIV RESEARCH

Safety Issues in Pre-Exposure Prophylaxis

Participant Evaluation

August 19, 2011



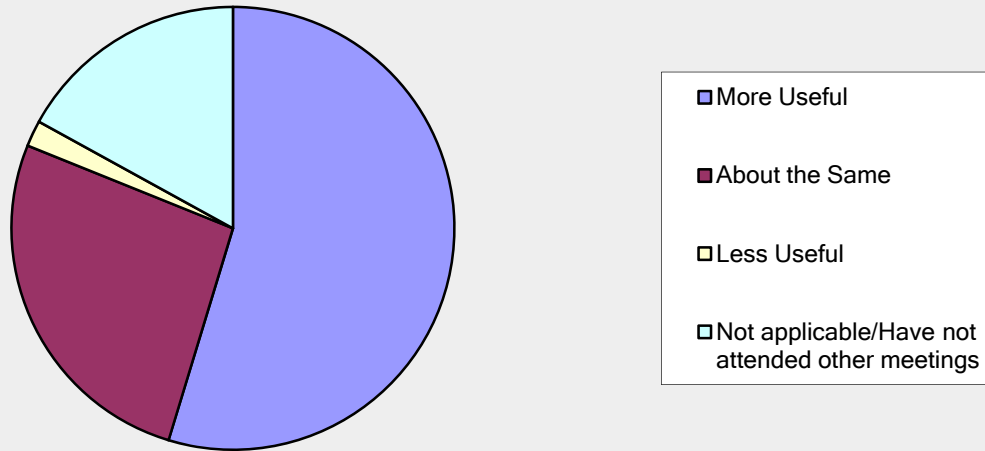
How will the information presented at the meeting assist you in the work you do?

- Underscores value of it.
- Very helpful for regulatory strategy and development of educational materials
- Clarified some of the implementation issues
- Will help in planning for some of our compounds and educating senior management
- This will help me to educate more people in the community I work in
- Provided important information to develop educational materials and to address advocacy related issues to foster better understanding of PrEP among community leaders.
- Further inform the development of and potential access to emerging prevention technologies for the community that I work with.
- Identified other partners to include in the ongoing dialogue regarding prevention research and implementation of PrEP
- I follow PrEP closely and will be deeply involved in both its progress toward FDA submission and approval and in the development and implementation of demonstration/implementation projects that move forward. I felt that the public dialogue moved forward several steps in this regard.
- The meeting presented updates and planning issues relevant to HIV PrEP.
- There was a discussion of issues that need to be addressed in future research.
- It will inform our discussion on policy
- This meeting helped to clarify critical safety questions relevant to my organization's constituents & stakeholders in thinking through PrEP implementation issues.
- I am with the Division of Antiviral Products and will be responsible for managing the regulatory review of the application and the forum was very informative.
- Assist FDA in carefully considering this important public health issue and optimum consideration of challenging and interconnected issues for safe use of ARV products.
- Informs me on the issues so that I can inform our members.
- Provided background and opinions that will be useful in review of applications
- It addressed certain challenging questions, particularly related to implementation.
- The meeting provided information on the range of safety issues of concern to different stakeholders. This info will be useful in crafting public health policy and determining what additional studies are needed to safely use the products for this indication.
- Help inform policy
- Primarily it gives me an idea of how the health care providers and federal regulators perceive this issue.
- It provides perspective and background to someone who is new into this field
- Support planning activities for education regarding PrEP throughout the community.
- The information will be helpful in giving guidance to grantees regarding inclusion of PrEP in education and training of clinicians caring for PLWHA and those at risk for HIV infection.
- It provided key elements about potential difficulties in the future implementation
- I will use information and contacts to prepare educational calls and sessions for the community.
- The updated information on PrEP trials and the next steps will help my organization plan our future steps and chart our work on the timeline. It was also very helpful to learn about the various demonstration projects occurring so we can monitor their success and utilize the information gathered.
- The information has allowed to identify some specific gaps in HIV research and considerations for moving the field forward.
- I enjoyed the panels providing various perspectives on issues for implementation research as well as informing the ongoing debate regarding the possible negative impact on treatment drugs if bad outcomes when drugs used for PrEP in uninfected. Informs strategies for new drug development and clinical trials
- Vital preparation for community town hall meetings on prevention as treatment
- Better understanding of the issues concerning other parties
- Information updated my knowledge base and applying the information to HIV prevention program implementation domestically and internationally.
- Understanding USA context of global discussion on safety and practicality of oral PrEP
- Planning for trials with combination prevention methods.
- Helps me to better understand the educational requirements for patients and providers.
- It will guide future research
- Planning PrEP demo project
- Potential to inform future policy and programming.
- Help inform our work to roll out PrEP through our county health department
- Already had a meeting about convening a meeting in my community in order to inform the community.

How will the information presented at the meeting assist you in the work you do?

- New information and insights into the US epidemic and health care system
- Feedback from a variety of stakeholders
- Opportunity to hear multiple positions related to implementation of PrEP
- A lot of this has been discussed before. The most helpful was getting insight from the FDA as well as some of the insurance providers.
- Better education on PrEP Safety Issues
- A good understanding of the range of issues that the FDA may address and the regulatory framework.
- An opportunity to further explore and understand the issues surrounding next steps with PrEP development
- Excellent forum to discuss complex issues related to PrEP implementation
- Information on REMS and how it could be dealt with in practice.
- An opportunity to listen to the opinions and interpretations of the various studies by influential thought leaders and to look at the issue of PrEP safety from different perspectives, especially in regards to how this might fit into how the FDA traditionally regulates other similar products.
- It gave me a sense of who was getting involved in decision-making following release of positive results from clinical trials.
- Ability to hear diverse thoughts on the issues
- A sense of what people are thinking about roll-out of PrEP in the US.
- It provided many valuable perspectives, data and input to frame the PrEP discussion
- The meeting provided diverse perspectives on the future of PrEP and key areas for further implementation research.
- up to date information on the status of ongoing trials and demonstration studies
- A very well-rounded look at a multi-faceted and complicated issue.
- Validation of some of our current thinking
- Varied points of view from different disciplines. I found the discussion very lively and informative.
- It provided opinions on whether PrEP should be restricted.
- Information from the sources
- A lot of really interesting and important information.
- A good understanding of the consensus thoughts on the potential safety issues of PrEP
- The significance of proper education and case management of patients on PrEP as part of a prevention package.
- It clarified some of the concerns about PrEP, while still leaving many unanswered questions. This is still a topic 'in progress'.
- Feedback from different constituencies about the complexities faced to implement the strategy
- A more in-depth understanding of the issues/challenges of PrEP, as well as optimism that these challenges are being anticipated and planned for.
- Some relief that over the course of the day most of my concerns were raised, so I know others have the same thoughts about the philosophical, political and financial issues surrounding PrEP.
- The meeting provided me with valuable updated information and insight about where others are in the PrEP progress
- Specific details regarding the safety issues of PrEP and considerations to scale-up and/or roll out PrEP in a 'real' community.
- opportunity to see people and learn about issues in the United States
- Better understanding and appreciation for the ethical issues
- Exposure to other interested parties
- Increasing different perspectives on PrEP and its application in different setting.
- An insight into USA domestic concerns and challenges of rolling out oral PrEP in USA context
- Some details of the safety issues and how they are being followed.
- Helpful perspectives from a wide range of stakeholders.
- Ideas for future research projects
- opportunity to meet leaders in PrEP field and have rich discussion on key issues in PrEP implementation
- Introduction to a wide area of issues; raised awareness of safety issues--particularly those facing adolescents and young people.
- Networking, and the opportunity to hear multiple experts on the clinical, regulatory and practical aspects of implementing PrEP
- Background review and future issues overview

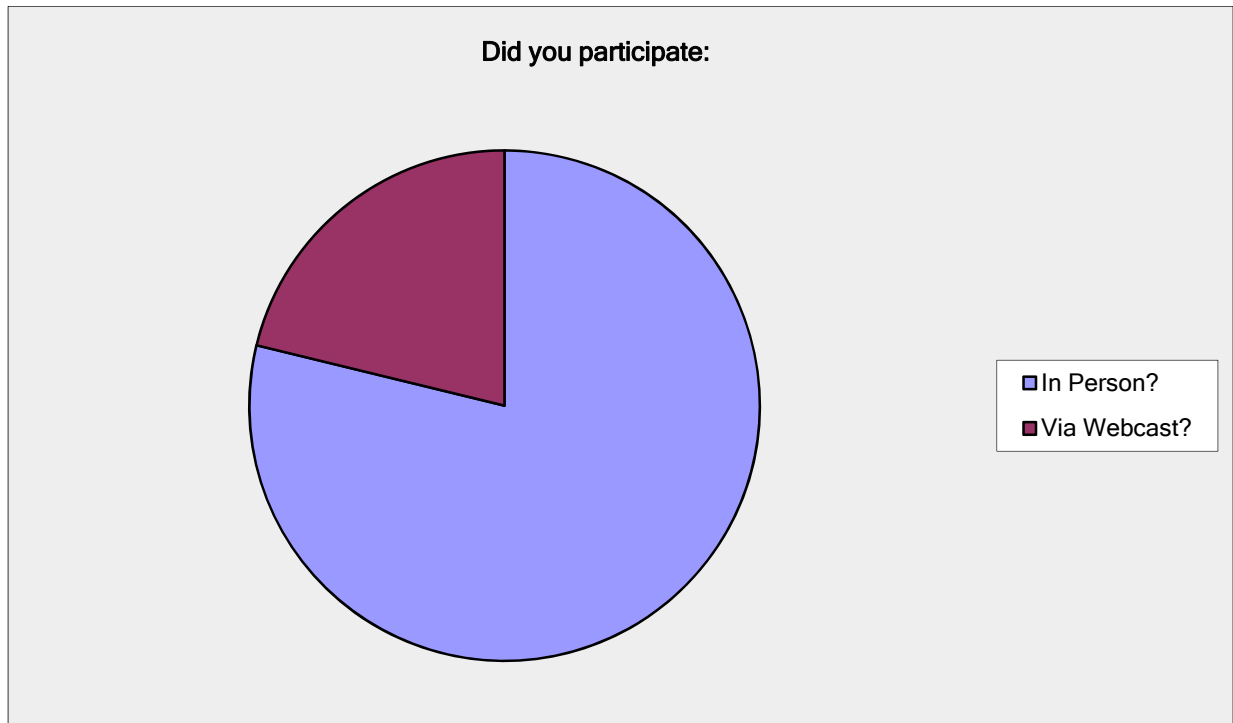
How does the "PrEP Safety Issues" meeting compare to non-Forum sponsored meetings that you have attended for learning and sharing information in the field of PrEP research?

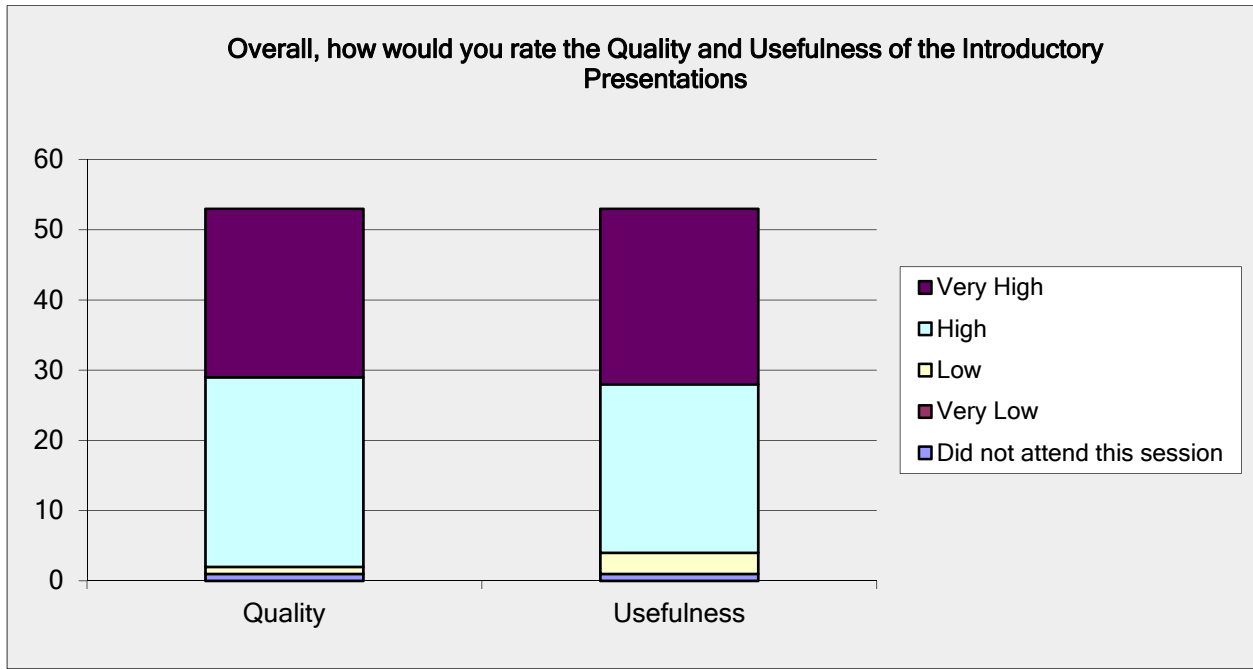


Are there any aspects of the meeting that you believe could have been improved?

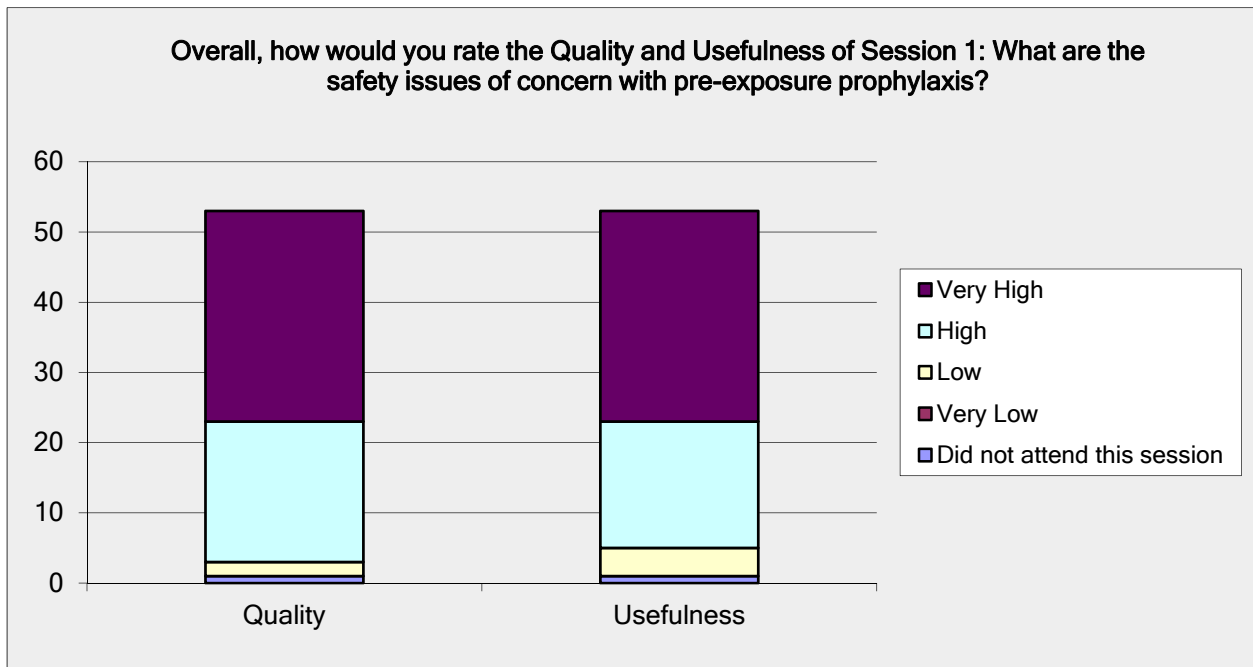
- It could have been a day and a half meeting. Some of the topics could have used some more time for discussion.
- Being able to use your computer
- Creating consistency in audience Q&A and comment period.
- The overview of the safety data at the beginning of the meeting was rushed. It would have been helpful to have more time for the speakers to present this information.
- I think the agenda was overly ambitious. Time is money, and as such it is the case that conference conveners often can't bring people together for as long as is needed to fully flesh out key issues. In this case, I felt that more could have been accomplished in regards to "solutions" to safety issues and toward best practices in implementation if we'd had at least another half-day.
- Interactions with remote attendants. I personally typed in a question (twice), and it was neither answered nor acknowledged by the chairperson.
- I would have liked to hear more from some of those in attendance, It almost needed to be a 2 or at least day and a half long meeting
- Timing was a bit off to start the day due to delays in arrival of coffee. Many people seemed to expect there to be pastries or something to eat to start the day so better dissemination of information on exactly what to expect and what to provide for yourself would be helpful.
- No
- I found the morning panels overall were more informative than the afternoon panels.
- I think there should have been 15 minutes set aside to answer questions that were submitted on the sheets and online.
- No
- The panels were wonderful, and so were all the presentations. Well done meeting. Would like to see some of the presentations available afterwards. Perhaps a transcript.
- No
- Include more of the negative opinions about use of PrEP
- No
- More networking and/or small group discussion opportunities.
- The meeting was very good, potentially it would have benefitted to have some more time to interact with speakers and other attendees to discuss this topic.
- Panel with questions formulated by the audience could be more useful
- There was a large emphasis on men who have sex with men and their use of PrEP. Future panels could be improved by discussing both the effect on men and women and different methods to address the issues we are anticipating will arise.
- More time for audience participation.
- It would have been helpful if the title of the meeting indicated that it was focused on PrEP for the U.S. The speakers were mostly international researchers, and thus it was not clear that the meeting would center on U.S. issues with regard to PrEP.
- Audio pertaining to questions from the audience was poor.

- I could not hear the questions asked by members of the audience, and the moderators did not repeat the questions.
- Questions/issues raised by people on the webcast were not addressed. I could not identify a single question asked online that was passed to the panel
- The early morning section on presenting the data should be lengthened.
- Poor sound system (or maybe speakers did not use microphones properly)
- A short "take Home" list of the safety issues and what needs to be considered for different groups of people, e.g., adolescents, pregnant women, people with hypertension.
- The agenda was very ambitious, but the moderators did a good job of staying on schedule. It was a little bit hard to hear sometimes.
- Session on "remedies and their pros and cons" seemed less structured than others. Could have been strengthened to address issues more directly.
- I thought it was a great meeting.

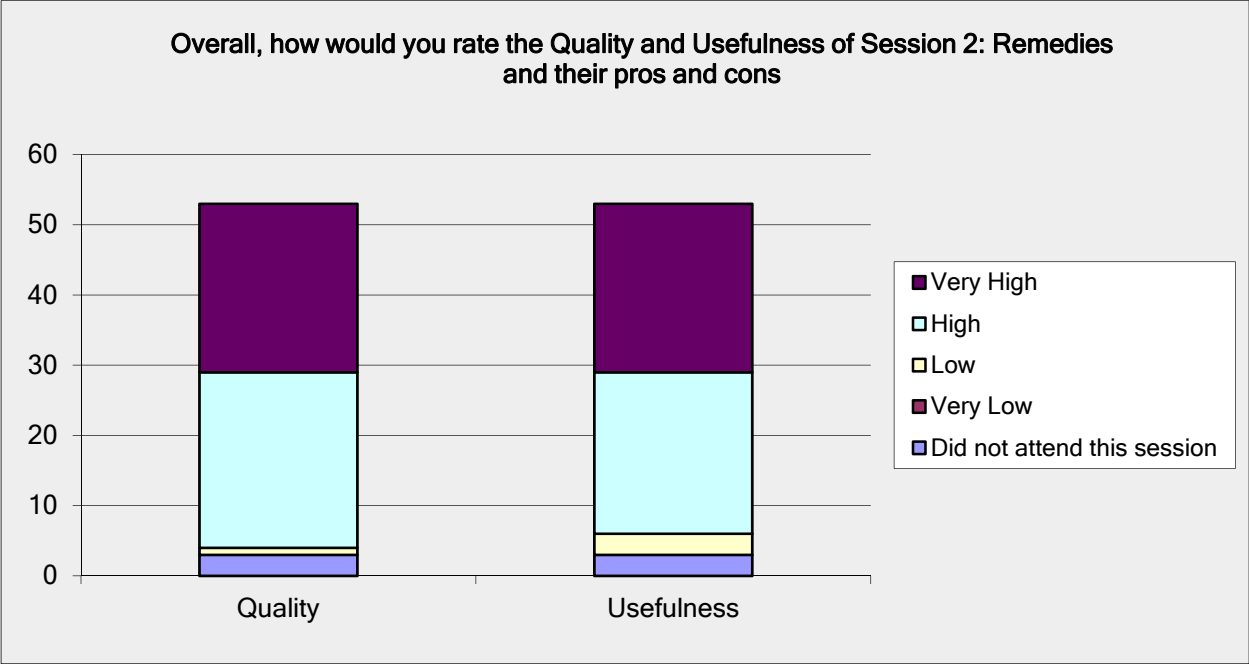




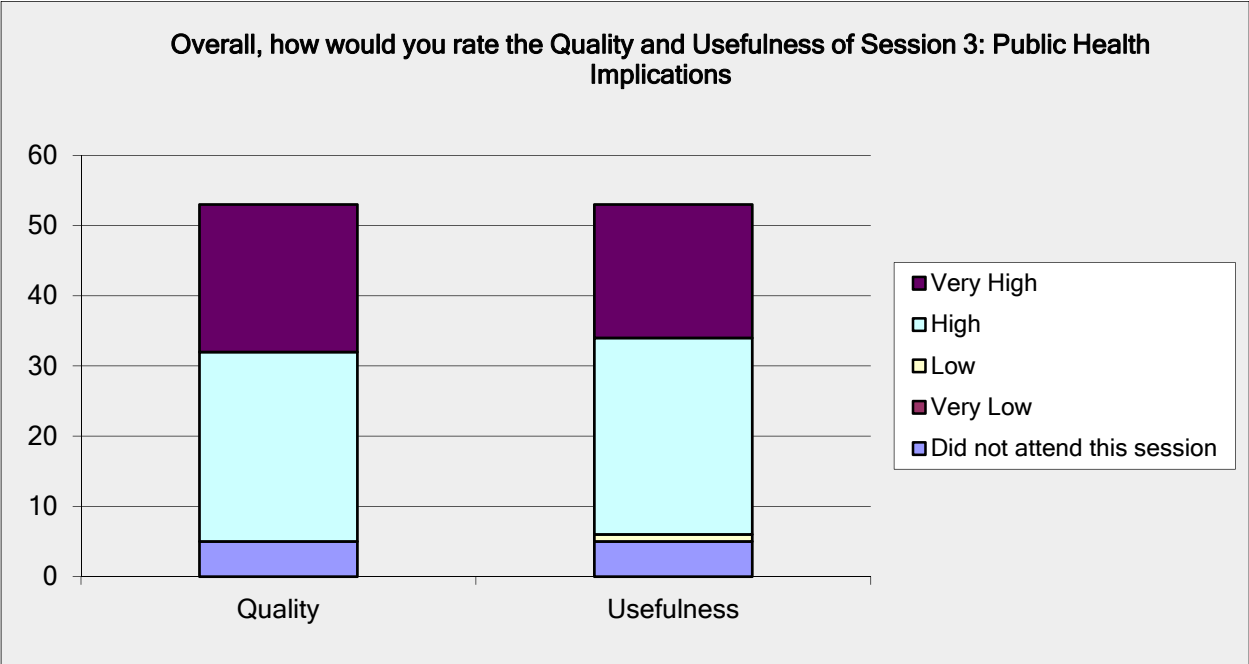
- I would have liked a little more time assigned to the description of the studies (perhaps another 5 min per presentation) so that the presentation of data was not so rushed
- I haven't participated in a day long meeting over the web before. It was a pleasant experience. I have participated in webinars...this was much better. Maybe because I was interested in the content.



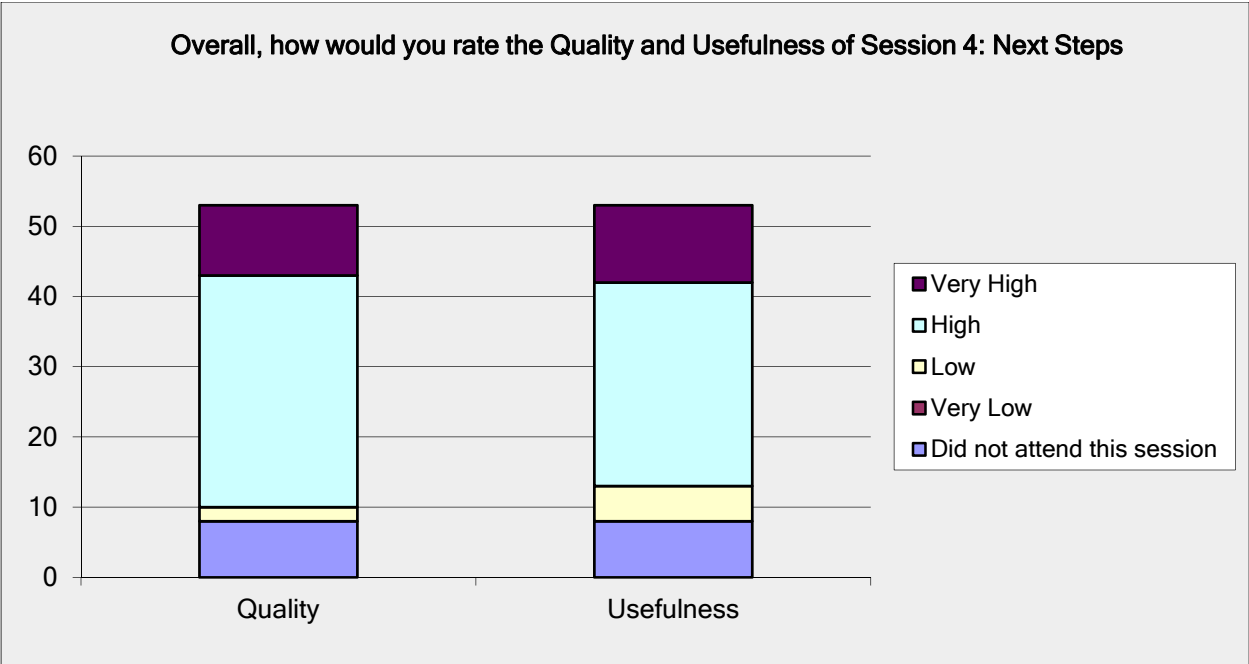
- Great info
- Excellent panel discussion, very thoughtful comments from seasoned individuals in the field.
- The discussion did overlook some studies that have indicated that the antiretroviral drugs have mitochondrial toxicities. However it centered on Truvada primarily.
- Good moderator and panelists
- I would have liked a little more science discussion but realize time was limited.
- Noted the concerns about intermittent PrEP and drug sharing issues that I hadn't heard about before.



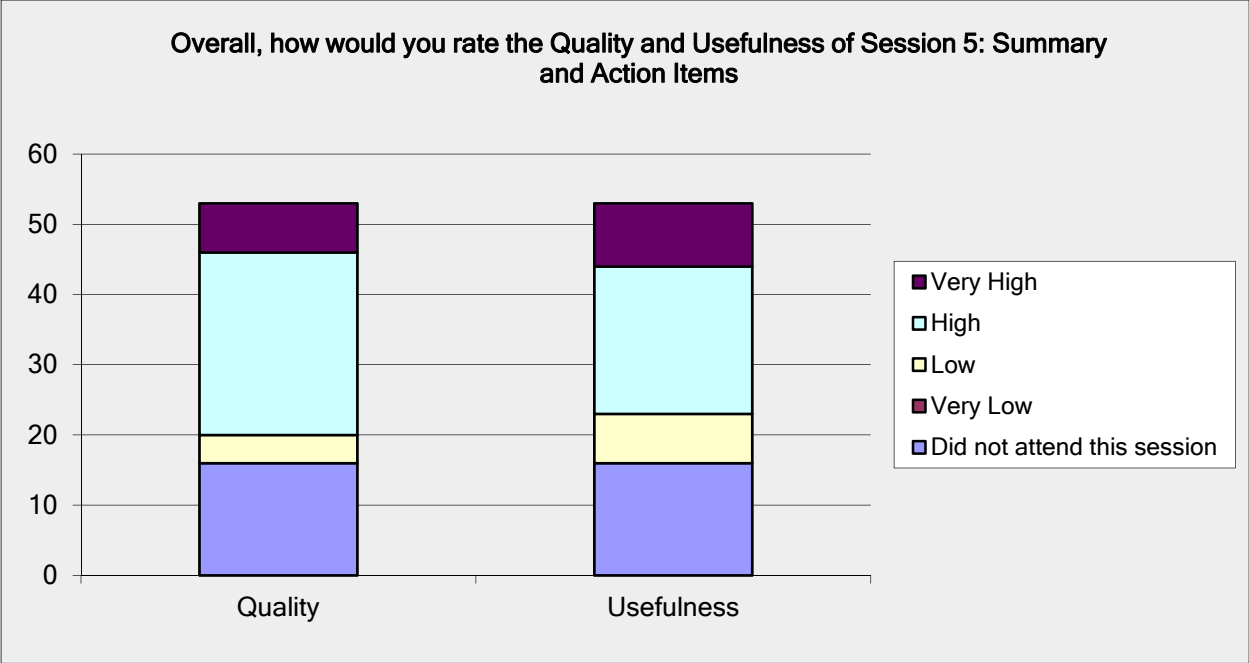
- I appreciated hearing diverse points of view.
- Here the presence of department of health from cities implementing test and treat strategy could be good as a way to expand this intervention linked to that



- Having an unbiased discussion, without special interest was very useful, to hear from others their take on the implications for public health.

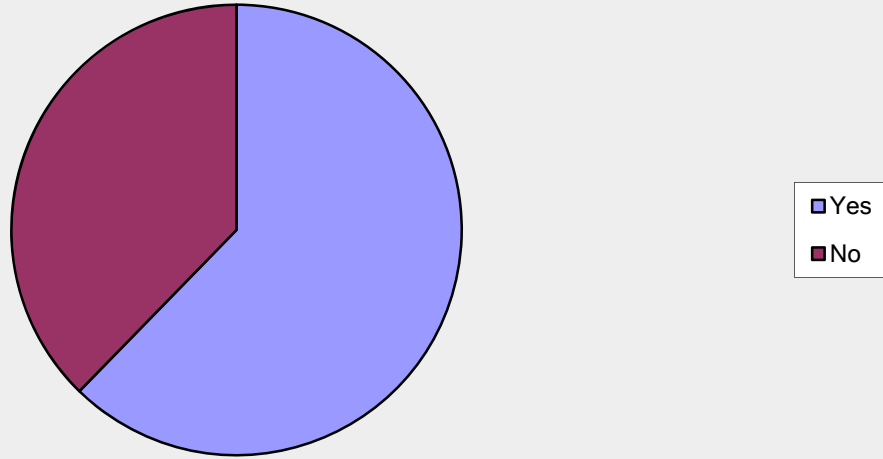


- Funding for prep in poor populations not discussed realistically today.
- Perspective of insurance companies was very enlightening and first time I have heard this.
- I actually would have rated the usefulness as "moderate." It was a good start, but was too short to be of great usefulness.
- Would have liked the insurance representatives to include the coverage of education, training, and counseling in their discussion.
- A better outline of where studies are already ongoing that will address some of the issues raised.

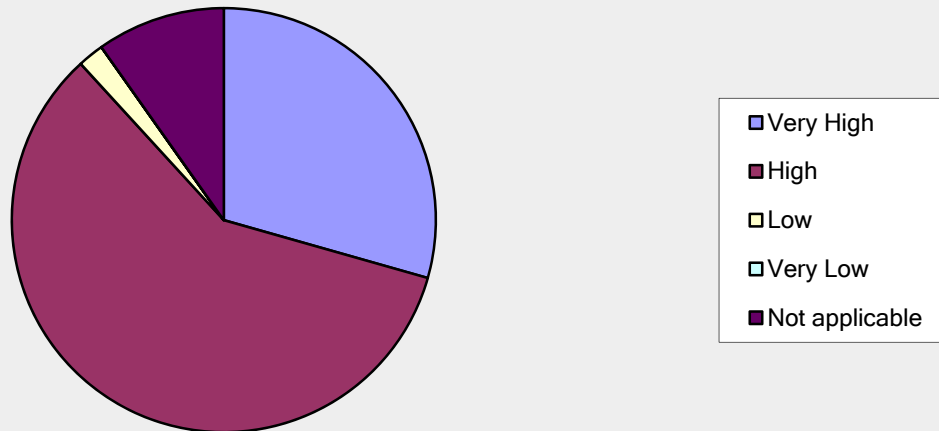


- Unfortunately, the session was rushed.
- Would have rated both as moderate. I think some of the presentations were a little off and not entirely reflective of the dialogue that occurred. I'm also not sure that it was the right mix of individuals.
- Enjoyed the variety of perspectives.
- One of the things that was not discussed was "Why hasn't there been more clamor for the drugs already."

Will this meeting facilitate new collaborations with individuals/organizations that you have not collaborated with before?



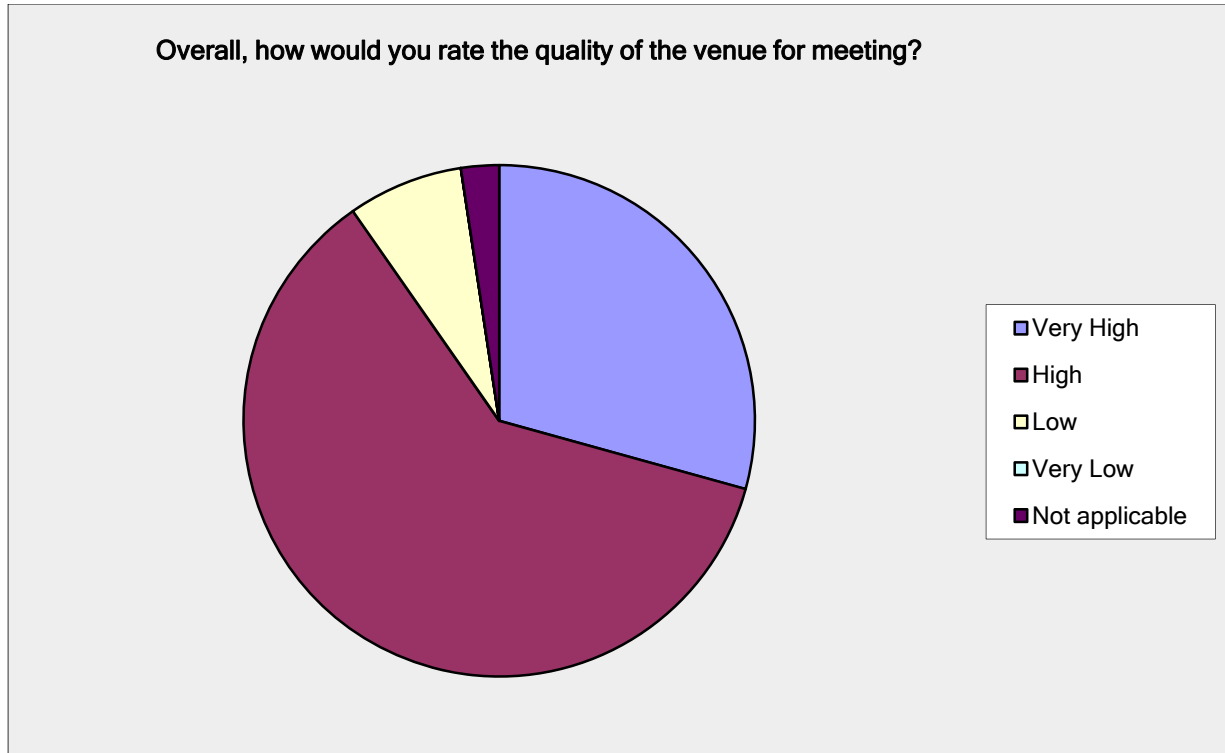
Overall, how would you rate the pre-meeting logistics (including such things as the registration process, arranging hotel and travel if needed, provision of relevant meeting info such as directions and agenda)



Do you have any comments on the pre-meeting logistics that would help us to make future meetings a greater success?

- The forum staff were extremely helpful.
- Flight arrangements always seem to be made "too late" with the best flight choices already sold out.

- Difficult to make travel arrangements and get required pre-approvals because of late notification of registration acceptance.
- Everything was well planned and clear.
- Appreciated that it ended early, but wish it could have started later.
- Despite limited time for audience participation, I enjoyed the format and layout and felt the lack of formal presentation allowed for a more fruitful discussion.
- Easier access to the Webcast link. I had a last minute change in travel plan. It took additional query to contact the event organizer.



Do you have any comments on the venue that would help us to make future meetings a greater success?

- Wifi password, difficult to leave the room without interrupting the meeting.
- Think this meeting could have used a larger venue.
- Would be nice for everyone to be at a table.
- Poor sound system
- Very convenient to metro
- The room was very wide and tightly packed...audio quality was tough at times. It was an "OK" venue and I am sure it was cost effective.
- Would be very helpful if room was wi-fi equipped
- The room was freezing so warming up the room a bit would be nice. Also, having hot water and tea available for non-coffee drinkers would improve the experience at the meeting.

Do you have any comments about the webcast that would help us to make future meetings a greater success?

- Pay more attention to webcast attendants' comments. I personally typed in a question (twice), and it was neither answered nor acknowledged by the chairperson.