

# *On the Horizon for Health Department Consideration: Biomedical Advances for Prevention*

Tyler A. TerMeer, MS

Joy Mbajah

2011 NASTAD Annual Meeting

Wednesday, May 25, 2011

**BRIDGING SCIENCE, POLICY AND PUBLIC HEALTH**

- Readiness activities vs. implementation activities?
- What skills and arguments do we have to develop as administrators to be prepared for biomedical advances?
- How do we help the community prepare?
- What additional education is needed at both the client and provider level?
- Where do biomedical interventions fit into the portfolio?

- Do we have the capacity for PrEP implementation?
- Is PrEP even feasible?
- Will people take a pill consistently?
- What about drug resistance and HIV testing?
- What are the long-term safety issues?
- What about other populations?
- How much will it cost and who pays?
- What about PrEP in other prevention trials?
- Where do vaccines trials fit in this conversation?

- What does a trial result mean?
- How good is “good enough”?
- When will there be access to the product?

## Key messages

- No single trial will provide a definitive answer about ARV-based prevention.
- A positive result would require further exploration.
- A trial result that shows no effect from one ARV-based strategy cannot be extrapolated to other trials of the same or similar strategies.

## How good is good enough?

- Great question!
- For what? (Licensure, normative guidance, label change, off-label use, additional studies)
- For whom? (Specific populations, risk groups, countries, communities)
- According to whom?

## Are more PrEP trials needed?

- Are more trials needed?
- Is there clear ownership and leadership of the product development pathway?
- Is there political will, buy-in, community engagement, enabling environment?
- Is there money?

## Remaining questions after current trials

- Are there dosing strategies other than ongoing, once-daily dosing that could be used with oral PrEP drugs to reduce risk?
- Can PrEP strategies be developed for adolescents and pregnant women—two groups not included in current effectiveness trials?
- Can other compounds be developed as PrEP drugs?
- What are the long-term safety consequences of PrEP use?
- What are the rates of drug resistance associated with individuals using PrEP who seroconvert?
- How does this impact future treatment options?

\*Keep in mind that only 10 percent of iPrEX data has been analyzed to date.

# Can we deliver on the promise?