It's not the result…

…it's what we do with it?

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MTN

I read the news today, oh boy…

2009: A Year in Review via the headlines

- *An AIDS vaccine is possible*
- *The future is ARV-based microbicides*
- *PrEP is our most promising new HIV prevention option; answers due next year*
- *Circumcision: latest anti-HIV weapon*

I read the news today, oh boy…

2009: A Year in Review via the headlines

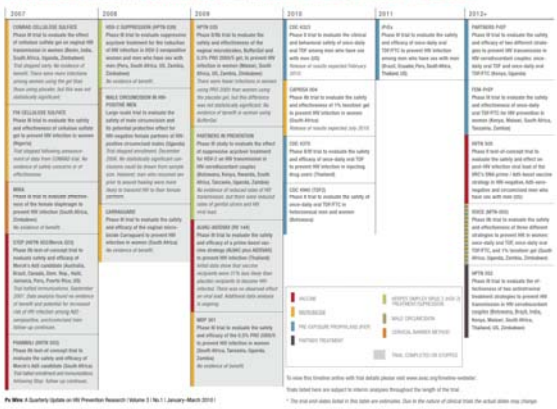
- *AIDS vaccine 'breakthrough' hopes dashed"*
- *Microbicide trials yield disastrous results*
- *PrEP trial can't recruit or retain participants*
- *The controversial cut*

2009: A Year in Review

- Feeling schizophrenic?
- So which is it? What is *the* truth?
- How did we get here?
- Where do we go?
- What will be the headlines of 2010?

There's a lot at stake

- For communities, it is never only about one trial; it is about a solution to the epidemic
- People – the public, community gatekeepers, those who need our interventions – are watching all of us – researchers, funders, advocates, media
- And the public perception and integrity of the HIV prevention research endeavor hinges on what they see
- But they are not only watching a single trial…



The Road Well Travelled: Selective 2009 Timeline

- 9 Feb 2009: HPTN 035 – non-statistically significant trend toward modest effect
- 8 May 2009: Partners in Prevention – no effect
- 24 Sept 2009: Initial announcement of RV 144 – statistically significant modest effect according to mITT
- 20 Oct 2009: Formal presentation and publication of RV 144 results – trend toward modest effect in all three analyses; only one of which is statistically significant
- 14 Dec 2009: MDP 301 – no effect
- 17 Dec 2009: CDC TDF2/Botswana PrEP trial – no longer able to detect effectiveness; now only expanded safety study

Trial results have issues

- What they tell us, and what they don't tell us
- How do we tell the story, to whom and when
- Ending a trial – and communicating results – is as hard (harder?) and as important (more?) as starting and implementing it – irrespective of the result
- Statistical significance ≠ community significance
- Timing is everything
- Lessons from the past help, BUT always new products, new trials, new challenges, new locations, new stakeholders

Bottom-line messages for the field

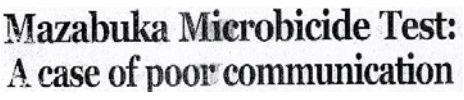
- We need large trials to answer the right questions
- Large trials are REALLY complicated to design, and even more complicated to implement and complete
- We can conduct – and support – scientifically-rigorous, high-quality, large clinical trials, even (especially?) in severely resource-limited settings
- Planning for communicating results begins before the trial starts and continues long past the initial announcement
- Not under the radar; not in a silo – what happens in one trial, with one product, in one community, happens to all of us

Success is…

- A clinical trial that produces a scientifically accurate result.
- It may not be the result we had hoped for, but it answers questions that help the field move forward.
- These trials need to be designed so that whether or not any particular trial finds efficacy, it at least produces clear results.
- Knowing what doesn't work (or what works marginally), may help us analyze results to understand why and what to do (or not do) next.
- Caveat – no trial will answer all the questions (duh)

"Failure" is/can be of the…

- Candidate – *MRK-Ad5; CS*
- Class – *Adenovirus vaccine candidates*
- Concept – *CMI-based vaccines; non-ARV-based products*
- Trial – *no result*
- Field – *not learning and applying results*
- Communications – Zambian *Sunday Times* headline:



We have many (sometimes conflicting) audiences

- Trial participants
- Researchers
- Policy makers
- "The Microbicide Field"
- "The HIV Prevention Research Field"
- "The AIDS Field"
- Media
- AIDS activists
- "General public"
- Future trial participants

What is "the media" these days?

- Mainstream media
- Science media
- Fringe media
- Niche media
- Listservs
- Bloggers
- Community Fora

And how should we interact with "the media"?

- Announce results to volunteers first or in scientific forum?
  - How much time between the two events?
- With whom and when to share information pre-embargo?
- Interact with "investigative" reporters?
- Try to correct facts in articles?
- Include multiple analyses in initial announcement?
- How to manage multiple countries, time zones and languages?

Good Participatory Practice Guidelines

Minimum elements for results dissemination:

- Development of a plan for results dissemination in simple, culturally appropriate language for the surrounding communities.
- Convening the community advisory mechanism to reflect on the validity of the data and, in particular, whether the findings reflect the lived experience of the target population.
- Reporting results of the trial to study participants and surrounding communities in clear, understandable language.

GPP on results dissemination

- "Researchers frequently plan to present preliminary findings at a scientific meeting, followed by submission of an article for peer review.
- "Dissemination meetings which present the findings to various stakeholders in country…must also be conducted, ***both as an obligation and as an opportunity*** to validate the findings and explore their potential implications."

Communicating research results

- Conclusive & clear interpretation at first announcement
- (Extreme) Caution on claims from indeterminate data
- Confidence in data interpretation is integral to public trust
- Multiple perspectives on the data and "the spin" are a given
- Coordinated approach involving multiple stakeholders, multiple audiences, multiple messengers, multiple channels – on *an ongoing basis* (and not only in crisis management mode)
- Plan, budget and staff these efforts like any other component of the trial

Communicating research results

- The absence of data/facts will be filled by someone
- Know your friends – and your "enemies" – well in advance
- No one trial answers all the questions
  - →Just as no one product or approach is "the" answer for AIDS vaccines, PrEP or microbicides
  - →Just as no single intervention is "the" answer to ending the epidemic
  - →It's all incremental – no magic bullets
- No matter how encouraging the results, "further study is required"

Challenges ahead

- Communications affect perception by the "field", the public and volunteers (past, present and future) – need coordination and collaboration
- Increase "literacy" of researchers, communities, donors, advocates, media, policy makers, other stakeholders
  - →Translate (increasingly) complex science to the "community"
  - →Translate complex community needs, perceptions, expectations, etc. to the scientific community
- Easy to say *what* should be done; hard to do it

Where to from here

- Maintain *openness* and *transparency*
- *Accuracy* – these are complicated issues; communicate more honestly and better articulate what a trial will – and won't – answer
- Exercise *balance, discipline*, *creativity*, *innovation*, *diversity*, *risk-taking*, *flexibility* especially in our decision-making processes
- *Sustain capacity* – scientific, clinical, trial site, community, policy, financial, communications
- *Manage expectations* – especially as they continue to evolve

Fasten Your Seatbelts: A Selective 2010 Timeline

- Q2 2010: Results from US PrEP Safety Study
- July 2010: CAPRISA 004
- July 2010: First DSMB review of HVTN 505 DNA/Ad5 vaccine study in MSM
- Q4 2010: First PrEP effectiveness data from iPrEx and Thai IDU trials
- Q4 2010: Results from PrEP expanded safety study in Botswana
- Q4: First results from first intermittent PrEP safety, acceptability and adherence studies
- ??????