Aspiring Toward Efficiency- Streamlining without Sacrifices

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MTN Regional Meeting 2012
Efficiency Definition:

- Literary definition: “skillfulness in avoiding wasted time and effort”

- VOICE definition: Was in terms of shortening participant visit length at research sites
  - Focus: 7 deadly wastes in improving clinic flow

- ASPIRE: “Efficiency is everything”
  - Per visit retention right from accrual stage, every effort to promote product adherence, safety & quality data
We MUST win on all “The Big Five”

Accrual

Adherence  Retention

Clinical and Laboratory Participant Safety

Data Quality and Timeliness
Why efficiency is important

We’re at crossroads for HIV prevention among women in developing countries

- Low level efficacy with TDF gel (39%)
- Oral PrEP didn’t work in high risk women in VOICE (TDF) & FemPrEP
  - ? Biologic/Adherence challenges for VOICE
  - Adherence was low in FemPrEP
- The “Ring” is our best chance to prove efficacy if it indeed biologically works
Adherence seems critical to ART based approaches to prevention

<table>
<thead>
<tr>
<th></th>
<th>Efficacy</th>
<th>Adherence*</th>
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<tbody>
<tr>
<td>Partners PrEP</td>
<td>75%</td>
<td>82%</td>
</tr>
<tr>
<td>iPrEx</td>
<td>44%</td>
<td>51%</td>
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<tr>
<td>Fem-PrEP</td>
<td>6%</td>
<td>26%</td>
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* Based on tenofovir levels in non-seroconverters

Baeten CROI 2012, Abstract 29
Donnell CROI 2012, Abstract 30
Grant NEJM 2010
Van Damme CROI 2012, LB32
Potential ‘drivers’ of adherence

- Adherence may reflect risk perception & patterns of sexual behavior
  - Baseline HIV risk assessment
  - Local HIV statistics matter (New HIV infections per day)
    - “Knowledge is Power”

- Per visit retention rates (NOT overall retention) counts
  - Missed visit = month of zero adherence

- Good Participant Rapport is going to be “KEY”
  - Staff must love what they do
  - Participants ought to feel a sense of belonging
What will it take to efficiently conduct ASPIRE?

- Community outreach must have its “ear to the ground” approach
- Participant discussions ought to change their perception of study participation to altruism
- Efficiencies in visit flow will be critical
- We have to “KNOW OUR PARTICIPANTS”
  - As messengers, we must be fully committed to the message
  - Examine if any inefficiencies will mar our ability to answer research question
We’re all part of the same team…

- No one knows how to do this perfectly
  - We will need to keep an open mind….
  - Cross-site, cross-team sharing is important
    - Some of our ideas: job-specific list-servs, biweekly calls with FHI360, regular protocol team meetings that focus on site-led presentations
    - We need to constantly talk with each other…
We shall need to keep an open mind…

- Every CRS is different
- There is “no once size fit all” message, but the guiding principles to efficiency improvements are the same:
  - Regular internal audits of your systems
  - Listen to your participants
  - Keep open to evaluating new ideas
  - Every step or process needs to add value
General impressions from early assessments:

- Enthusiasm about running ASPIRE is high. KEEP IT UP!
- The outreach teams are making great effort to recruit women at highest risk of HIV acquisition
- Within research experienced communities like Durban, research naïve participants have been recruited to date
- Attention being paid to retention early on
- Data collection is streamlined and CRFs easy to use
- Sites have embraced a contraceptive method mix (Implants, IUCD’s, Pills, Injectable all provided on site).
Efficiencies Related to Accrual

- The right number, the right women
  - Modest site sample sizes = achievable number of recruitments
  - Critically evaluate each potential participant
    - Is she likely to return each month for a year+?
    - Is she motivated to use the study product? Why?
    - What is her risk level? Her risk perception?
    - Seeing this critical evaluation taking place at sites visited
  - Being selective at screening can save a lot of time and energy for the team down the road
Efficiencies Related to Retention

- Focus here is both staff & participant retention
  - Good trained staff not easy to find (and training takes time)
  - Modest achievable sample sizes imply greater focus on quality enrollees (risk perception & retention)
  - Efficient clinic flow enhances overall retention (get in and get out)
  - Efficiency challenges when dealing with specific IRB requirements- more systems/procedures adds to length
Efficiencies Related to Visit/Binder Flow

- Periodic visit and data flow assessments are necessary
- Sites already engaging in visit flow adjustments to lead to more efficient flows, reducing screening visits by hours
- Efficient visit flow procedures allows for time for effective QC during the visit
- Efficient movement of binders through QC1/QC2/DF ensures that timelines for faxing are met
Efficiencies Related to Adherence

- What it takes to get women to come, contribute to the study, and honestly report their experience
  - Critical for staff to promote comfort and openness in discussing ring experiences
  - ACE Approach- motivating and supporting the participant to develop strategies to improve adherence; allowing non-perfect adherence to be OK
  - High retention: Missed visit = month of zero adherence
    - The ‘retention loop’ as a key component to adherence counseling
Efficiencies Related to Data Quality

- Documentation systems:
  - Duplication → takes more time and more opportunity for discrepancies
    - Are there additional sources for this information? Can they be eliminated or reduced?
  - There must be value addition for every chart note
  - Using checklists and other source docs to document procedures done and less interactive processes (ID, co-enrollment verification, blood draws, test results, counseling procedures)
Chart-noting:

- Depending on the site, 1.5-6 pages of chart notes for a screening visit. Keys to efficiency:
  - Focus on what needs to be documented in the chart notes per Source Doc SOP - otherwise it’s duplicative.
  - No need to rewrite what is in the site SOPs.
  - Document interactions with the participant, not the procedures conducted.
  - These are unique to the visit, not found elsewhere, help clue next staff member in to ‘who’ she is/what her experiences are.

- EXAMPLE: Post IC, nurses may address some residual questions about the ring or post BBA staff may address some of the worries she reported before randomizing.
Post-test and Risk Reduction

12:06 Counselling done, Pat's readiness for HIV test result assessed. She was ready therefore HIV negative result disclosed. Pat was happy to receive such result. Importance of maintaining her status discussed and how she can achieve that explained and emphasised. Partner testing and counselling offered. 20 study male condoms dispensed.
<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>07 SEP 12</td>
<td>PPT IDENTITY CONFIRMED WITH SA</td>
</tr>
<tr>
<td>09:13</td>
<td>ID DOCUMENT: Co enrollment</td>
</tr>
<tr>
<td></td>
<td>DATABASE CHECKED PPT is NOT Co enrolled</td>
</tr>
<tr>
<td></td>
<td>PPT REGISTERED FOR SCREENING VISIT. AGE is</td>
</tr>
<tr>
<td></td>
<td>CONFIRMED PPT is 33 years OLD. PPT is NOT ON MENSES.</td>
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<tr>
<td>07 SEP 12</td>
<td>SCREENING IC OBTAINED AND IC</td>
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<tr>
<td>10:00</td>
<td>COVER SHEET WAS COMPLETED AS PER STUDY SAP.</td>
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Things to Share…

- Peer Educator Model:
  - Former VOICE ppts aiding recruitment in some sites
    - Sites talking about utilizing this model for IUCD promotion as well
  - Waiting room support from participants who have had the ring inserted- ‘I can’t feel it!’

- Cross-pollination within CRS, CTU & across CTU’s
  - Interaction with ppt on ring use/experiences at various cadre ship levels of staffing
  - Between Clinicians/Nurses/Counselors/RA’s
  - Forum for exchange of successes & challenges
We will now call upon…

Doeriyah Reynolds, Emavundleni CRS

- Share site experience around promoting efficiencies in the IC process
- How this system translates into greater participant ‘participation’ in the trial-comprehension, willingness/openness to use the produce, come to clinic etc
ASPIRE TEAM

Malawi College of Medicine – JHU Research Project

UNC Project - Malawi