Integrated Next-Step Counseling
Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

Robert M. Grant, M.D., M.P.H., Javier R. Lama, M.D., M.P.H., Peter L. Anderson, Pharm.D., Vanessa McMahan, B.S.,

<table>
<thead>
<tr>
<th></th>
<th>FTC/TDF Events Incidence</th>
<th>Placebo Events Incidence</th>
<th>Efficacy (95% CI)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>By Primary Cutoff May 1, 2010</td>
<td>36</td>
<td>64</td>
<td>44% (15–63)</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>2.2/100py</td>
<td>3.9/100py</td>
<td></td>
<td></td>
</tr>
<tr>
<td>By End of Treatment</td>
<td>48</td>
<td>83</td>
<td>42% (18–60)</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>2.3/100py</td>
<td>3.9/100py</td>
<td></td>
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</tbody>
</table>
Learned from the RCT...

- Drug levels were highly related to reductions in risk of HIV-infection

94% reduction in HIV risk (95% CI: 79 to 99%)
Learned from the RCT...

- But estimates suggested low overall rates of participants with any drug detected
  - iPrEx 44%

18% Estimated to have taken PrEP Daily
Learned from the RCT...

- Risk behavior did not increase as a result of being in the study or being assigned to active arm.
iPrEx RCT

• In a nutshell
  • PrEP can be effective if you take it
  • Taking it close to daily had high protection
  • Generally, people did not take a blinded study pill of unknown content or protective benefits at these rates
  • Generally, people did not increase their risk behaviors over course of participation
Unknown...

- Will adherence be the same when people have the chance to get an effective product?
- Who would want it?
- Will sexual risk taking change as a result of open label PrEP?
iPrEx OLE

- Open Label Extension
  - Prior iPrEx trial participants were offered enrollment in an 18 month extension where:
    - FTC/TDF daily
    - Participate in other aspects (HIV testing, condom provision, STI screening) of the study but not PrEP

- Started in June 2011 and is ongoing
HOW TO SUPPORT SEXUAL HEALTH PROTECTION?

• Address both behavioral strategies and PrEP use in a single, brief, person-centered conversation

• Advantages
  • Models comprehensive sexual health protection approach
  • Models “compendium” thinking
  • Targets prevention synergies

• Efficiencies
  • Participants receive pre/post HIV-test counseling at study visits - integration saves time
  • Commonalities in conversations allows merging them to reduce redundancy
The behaviors (behavioral risk reduction strategies and PrEP adherence) are very different and yet share similarities

• Unique
  • Specific strategies differ
  • Context of implementing difference strategies differ
  • Information, aspects of motivation and skill set for each discrete behavior differ

• Common
  • Motivation, commitment or desires for protecting sexual health may be shared
  • Perceived risk for acquiring HIV is consistent; as are perceived benefits of remaining HIV negative
  • Using behavioral strategies and PrEP are part of one’s sexual health protection “plan”
Leverage NSC

- Brief theory based check in
- Draws from MI and other client-centered strategies
- Identify facilitators, barriers, needs and strategies

INTRODUCE
Is that OK?

REVIEW
Last time you were here you said you would…. How did that go?

EXPLORE
How has using the product daily been going for you? What are the things that seem to make taking the pill work out well or feel easy to do? What are things that seem to make it feel more difficult to do- times when it is not so easy?

TAILOR
Counselor thinks about how to best guide conversation from here

IDENTIFY
(summarize context)...What do you think would make taking the study medication each day feel a little more manageable, a little easier to do consistently? Anything about how you feel or what you think or do that could help this?

STRATEGIZE
How could you see that happening?

AGREE
Which would you be willing to actually try out between now and our next meeting? Are you ready now to try that, or are there other pieces that need to be in place first?

CLOSE
Thank, remind, and document (after person leaves)
Frame check in as focused on sexual health protection

Review goals from last check in

All the things you are doing or thinking of doing besides PrEP to protect your sexual health

How things are going with taking PrEP daily to prevent HIV
### Sexual Health Promotion Counseling - iNSC

#### 1 INTRODUCE: Introduction to session provided?
- [ ] yes
- [ ] no
- [ ] n/a

#### 2 REVIEW: Were the participant's experiences/decisions in the study reviewed?
- [ ] yes
- [ ] no
- [ ] n/a

2a. Transition provided?
- [ ] yes
- [ ] no

#### 3 EXPLORE: Facilitators
- [ ] Not discussed

3a. Categories: mark all that apply:
- [ ] being well informed
- [ ] partner(s) supports strategies
- [ ] having intimacy with my partners
- [ ] other, specify: ____________________________

3b. Categories: mark all that apply:
- [ ] not feeling well informed
- [ ] partner(s) unwilling/reluctant against to practice strategies
- [ ] thinking partners are HIV-negative
- [ ] without really knowing their status
- [ ] feeling down (not caring about protecting self)
- [ ] drug or alcohol use (making decision making difficult)
- [ ] other, specify: ____________________________

#### EXPLORE: Challenges
- [ ] Not discussed

#### 4 TAILOR: Level of engagement in this part of counseling:
- [ ] low
- [ ] medium
- [ ] high

#### 5 IDENTIFY needs: (What)
- [ ] Not discussed

5a. Categories: mark all that apply:
- [ ] feel better informed
- [ ] have access to strategies (condoms, HIV testing, lube)
- [ ] feel more motivated
- [ ] social support
- [ ] other, specify: ____________________________

5b. Categories: mark all that apply:
- [ ] be assertive/confident
- [ ] have strategies that are sexy/fit into sexual life
- [ ] have better concrete skills around negotiating strategies with partners
- [ ] basic living needs met (housing, food, safety)
- [ ] other, specify: ____________________________

#### 6 STRATEGIZE: Strategies discussed?
- [ ] yes
- [ ] no

#### 7 AGREE on: Strategy and Action Plan

7a. Strategy selected?
- [ ] yes
- [ ] no

7b. Action Plan?
- [ ] yes
- [ ] no

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**Version 1.0, 01-APR-11**

Completed by: ____________________________ (initials/date)
**Study Pill Counseling - iNSC**

<table>
<thead>
<tr>
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<th></th>
</tr>
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<tbody>
<tr>
<td>1 INTRODUCE: Introduction to session provided?</td>
<td>□ yes □ no □ n/a</td>
</tr>
<tr>
<td>2 REVIEW: Were the participant's experiences/decisions in the study reviewed?</td>
<td>□ yes □ no □ n/a</td>
</tr>
<tr>
<td>2a. Transition provided?</td>
<td>□ yes □ no</td>
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<tr>
<td>3 EXPLORE: Facilitators</td>
<td>□ Not discussed</td>
</tr>
<tr>
<td>3a. Categories: mark all that apply:</td>
<td></td>
</tr>
<tr>
<td>□ mobile/carry tools (e.g., pill boxes)</td>
<td>□ match with routine/event</td>
</tr>
<tr>
<td>□ commitments/protecting self or others</td>
<td>□ memory aids/tools (e.g., calendar, alarm)</td>
</tr>
<tr>
<td>□ access</td>
<td>□ social support (family, friends, partners)</td>
</tr>
<tr>
<td>□ other, specify:</td>
<td>□ none could be identified</td>
</tr>
<tr>
<td>EXPLORE: Challenges</td>
<td>□ Not discussed</td>
</tr>
<tr>
<td>3b. Categories: mark all that apply:</td>
<td></td>
</tr>
<tr>
<td>□ partying/drugs/alcohol</td>
<td>□ medication (too big, tastes bad)</td>
</tr>
<tr>
<td>□ disruption in routine</td>
<td>□ forgetting/no doses available</td>
</tr>
<tr>
<td>□ side effects</td>
<td>□ lack of privacy</td>
</tr>
<tr>
<td>□ other, specify:</td>
<td>□ none could be identified</td>
</tr>
<tr>
<td>4 TAILOR: Level of engagement in this part of counseling:</td>
<td>□ low □ medium □ high</td>
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<tr>
<td>5 IDENTIFY needs: (What)</td>
<td>□ Not discussed</td>
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<tr>
<td>5a. Categories: mark all that apply:</td>
<td></td>
</tr>
<tr>
<td>□ access (have available)</td>
<td>□ remember</td>
</tr>
<tr>
<td>□ motivation</td>
<td>□ manage side effects</td>
</tr>
<tr>
<td>□ privacy</td>
<td>□ social support</td>
</tr>
<tr>
<td>□ other, specify:</td>
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<td>7a. Strategy selected?</td>
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<tr>
<td>7b. Action Plan?</td>
<td>□ yes □ no</td>
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**Version 1.0, 01-APR-11**

Completed by: ______________________ (initials/date)
INSC IS IN CONTEXT OF OTHER PIECES

- Education
- INSC
- single time drug detection feedback
INSC TRAINING AND SUPPORT

- As of June 1st 2012
  - 11 sites on 4 continents have participated in a ½ to 1 day workshop on iNSC

PRINCIPLES
- Client-Centered
- Comprehensive (Multi-targeted)
- Counselor Guided
- Context-Driven
- Genuine
- Recognizes Limited Role

SKILLS
- Active listening
- Elicit-Provide-Elicit
- Open-ended questions
- Paraphrasing
- Pausing
- Process comments
- Reflective listening statements
- Reframing
- Summarizing
- Third-personing
- Ventilation and Validation
• 4371 sexual health promotion sessions have been documented (1274 unique participants, ave 2.7 sessions)
• 3345 PrEP Use discussions occurred in combination with these (964 unique participants, ave 2.6 sessions)

• Data available to date on implemented sessions.....
**EXPLORE [facilitators] (99%)**

98% Any facilitator ($M = 2$);

2% None

53% Personal commitment

42% Well informed

31% Confidence

29% Partner Support

12% Intimacy with partner

11% Strategies fit well

15% Other
EXPLORE [challenges] (98%)
51% Any barrier ($M = .8$);
49% None

21% Caught in moment
14% Presuming status of partners
11% Drug/alc use
11% Intimacy interference
8% Partner Unwilling
3% Rejection/missed chance
2% Lacking Information
2% Low neg value HIV infection
2% Neg affect
1% Spec incentives (trade)

10% Other
TAILOR
Counselor estimated engagement in Sexual Health Protection
Check in conversation?

5% Low
39% Medium
55% High
IDENTIFY NEEDS? (99%) 
[facilitating conditions] 
71% Any identified; 29% None

41% Access
15% Confidence
12% Motivation/Commitment
12% Sexy/Fit
8% More/better Information
6% Negotiation skills
6% Social support
1% Basic needs

9% Other
PrEP Use

EXPLORE [facilitators] (99.6%)
99% Any facilitator ($M = 1.6$);
1% None

81% Routine match
22% Carry/mobile tools
17% Memory aids/tools
17% Personal commitment
14% Access
5% Social Support
2% Other
EXPLORE [challenges] (98%)
61% Any barrier ($M = 0.8$);
39% None

31% Forgot/no access
31% Routine disruptions
 9% Side effects
8% Drug/Alc use (partying)
2% Lack of privacy
1% Characteristics of meds

2% Other
TAILOR
Counselor estimated engagement in Study Pill Use Check in conversation?

6% Low
36% Medium
58% High
IDENTIFY NEEDS? (98%)
[facilitating conditions]
70% Any identified; 30% None

46% Memory aid
27% Consistent Access
  8% Side effects management
  7% Motivation/Commitment
  2% Privacy
  2% Social support

6% Other
Of the check in discussions implemented, all iNSC components are documented as having been included in the conversations 94 – 99% of the time.
Nearly all iNSC sessions are documented as containing the key “ingredients”.

Preliminary data is suggesting that combining prevention practices that are behavioral with PrEP use in a single conversation on sexual health protection is feasible and acceptable.

More sessions focus on enhancing and maintaining developed strategies than on removal of barriers.

Differences and similarities in key components of NSC discussions.
## SUMMARY

<table>
<thead>
<tr>
<th>Top 3 most common</th>
<th>Behavioral Strategies</th>
<th>PrEP adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Facilitators</strong></td>
<td>1. <strong>Personal commitment/motivation</strong> (53%)&lt;br&gt;2. Feeling well informed (42%)&lt;br&gt;3. Confidence (31%)</td>
<td>1. Match to existing Routine (81%)&lt;br&gt;2. Carry doses (22%)&lt;br&gt;3. <strong>Personal commitment; memory aids</strong> (17% each)</td>
</tr>
<tr>
<td><strong>Barriers</strong></td>
<td>1. Caught in moment (21%)&lt;br&gt;2. Assuming partner is HIV neg (14%)&lt;br&gt;3. <strong>Drug/Alc; interference with intimacy</strong> (11% each)</td>
<td>1. Forgetting dose time or to bring doses; Routine disruptions (31% each)&lt;br&gt;2. Side-effects (9%)&lt;br&gt;3. <strong>Drug/alc use</strong> (8%)</td>
</tr>
<tr>
<td><strong>Needs</strong></td>
<td>1. <strong>Consistent/better access</strong> (41%)&lt;br&gt;2. More confidence (15%)&lt;br&gt;3. Motivation; Fit (12% each)</td>
<td>1. Remember/cue (46%)&lt;br&gt;2. <strong>Consistent/better access</strong> (27%)&lt;br&gt;3. Side effects management (8%)</td>
</tr>
</tbody>
</table>
Using a general approach that allows for flexibility so that “local” and tailored content can be incorporated appears feasible.

Implementing the approach calls for a range of adaptations from current standards of care and practice for promoting HIV-prevention strategies.

Workshops, training and support need to flexibly respond to diversity in participant population and study team needs.

Combining behavioral and PrEP prevention practices in a single conversation does appear to provide multiple efficiencies.
LIMITATIONS

- No objective characterization of session content or process
- Fidelity and drift not monitored
- Counselor report may present over-estimate of use of key components
- Data collection is on-going: Main conclusions may change with more data gathered on sessions and with more sessions contributed from other sites and over time
- Data regarding drug level feedback or participant experiences with any of the support check-ins not yet available
FUTURE DIRECTIONS

- Need a better understanding of what is implemented (vs. what is recommended or trained on)
- How PrEP use compares to rates of study product use is of interest:
  - Can help guide us in terms of how intensive or blanketed integrated approaches should be
- While efficacy of iNSC will not be established in iPrEx OLE, we are planning to learn about
  - PrEP adherence needs
  - Rates of actual use
  - Perceptions of what would be most helpful in supporting open discussions about prevention strategies
  - Experiences with drug level feedback
Create, empower, and promote open collaborations