

Integrated Next- Step Counseling

PREX

OLE

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Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

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	FTC/TDF Events Incidence	Placebo Events Incidence	Efficacy (95% CI)	P-Value
By Primary Cutoff May 1, 2010	36 2.2/100py	64 3.9/100py	44% (15–63)	0.005
By End of Treatment	48 2.3/100py	83 3.9/100py	42% (18–60)	0.002

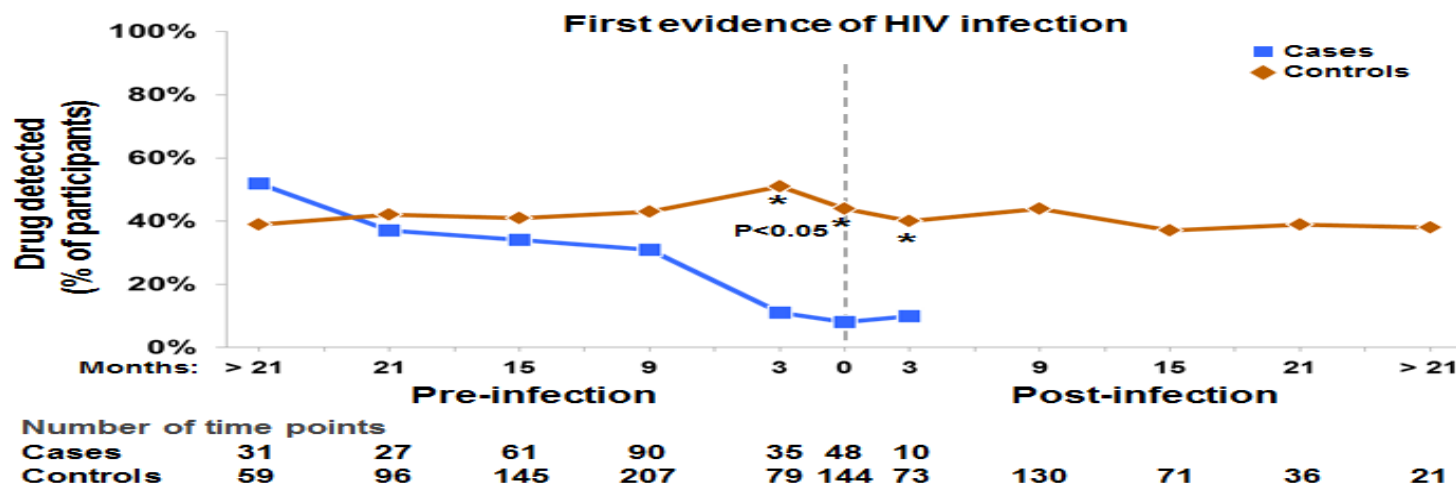
Learned from the RCT...

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

94% reduction in HIV risk
(95% CI: 79 to 99%)



Any Drug Detection by Group and Time



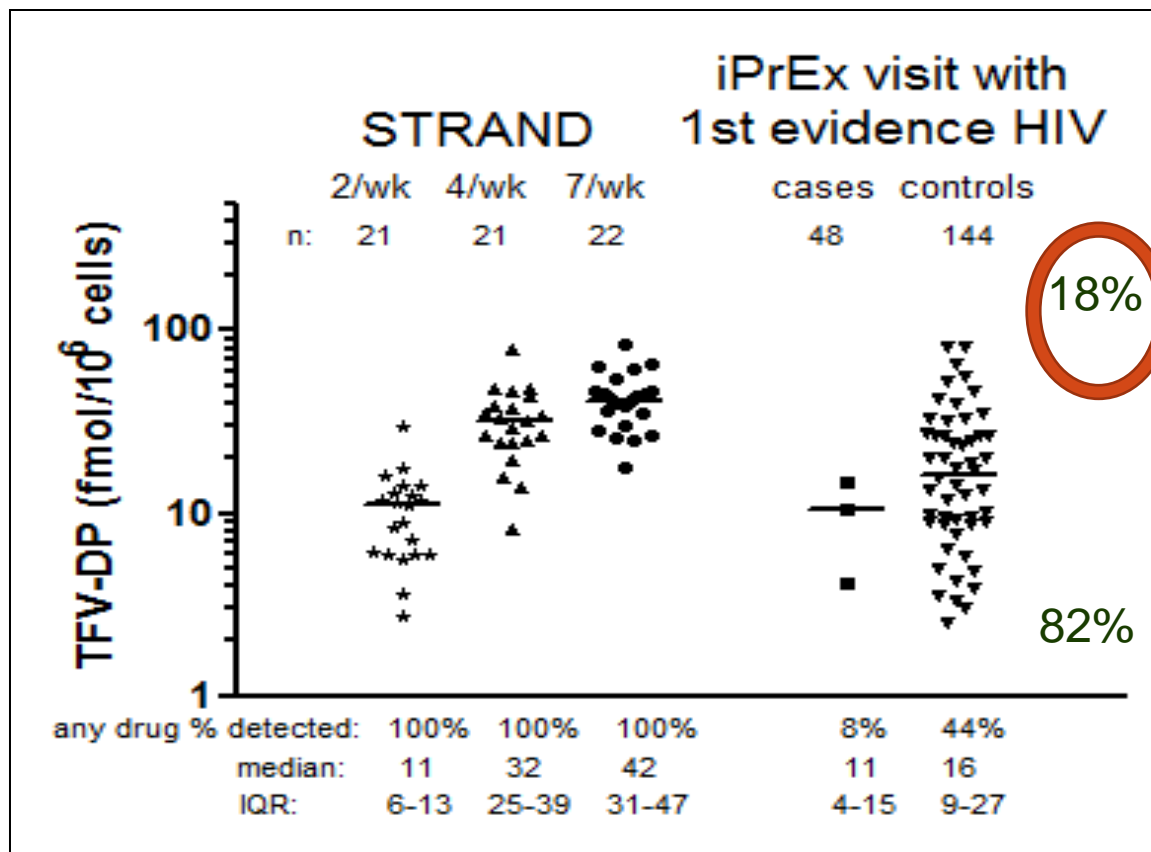
Anderson et al, 2012

18

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
- Multisite [11] international [6]

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*

INTEGRATION CHALLENGES

The behaviors (behavioral risk reduction strategies and PrEP adherence) are very different and yet share similarities

- Unique

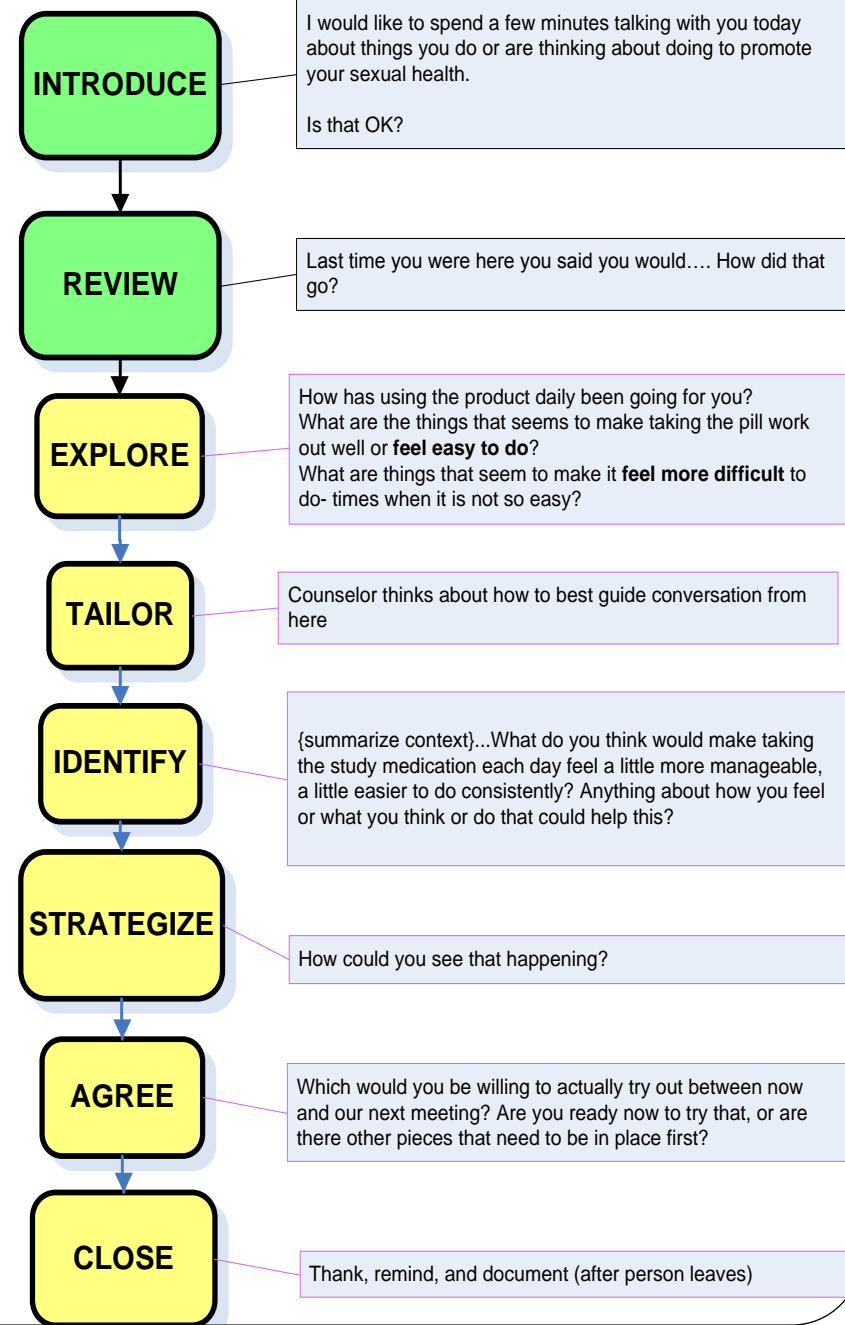
- Specific strategies differ
- Context of implementing difference strategies differ
- Information, aspects of motivation and skill set for each discrete behavior differ

- 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



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

INTRODUCE

REVIEW

EXPLORE

TAILOR

IDENTIFY

STRATEGIZE

AGREE

CLOSE

SAMPLE: DO NOT FAX TO DATAFAX

DFinet (iPrEx) 100

(SHPC) 101

☐ off PrEP☐ on PrEP☐ seropositiveVisit
Week . CRF not administered ☐

Participant ID:

Site

Participant Number

CRF

Visit Date:

dd

MM

yy

Sexual Health Promotion Counseling - iNSC

1	INTRODUCE: Introduction to session provided?	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n/a
2	REVIEW: Were the participant's experiences/decisions in the study reviewed?	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n/a
	2a. Transition provided?	<input type="checkbox"/> yes	<input type="checkbox"/> no	→ Go to item 3.
3	EXPLORE: Facilitators <input type="checkbox"/> Not discussed			
	3a. Categories: mark all that apply:			
	<input type="checkbox"/> being well informed	<input type="checkbox"/> confidence in negotiating strategies with sexual partner(s)		
	<input type="checkbox"/> partner(s) supports strategies	<input type="checkbox"/> personal commitment (motivation) to staying HIV negative		
	<input type="checkbox"/> having intimacy with my partners	<input type="checkbox"/> fits well into what I do sexually		
	<input type="checkbox"/> other, specify: _____	<input type="checkbox"/> none could be identified		
	EXPLORE: Challenges <input type="checkbox"/> Not discussed			
	3b. Categories: mark all that apply:			
	<input type="checkbox"/> not feeling well informed	<input type="checkbox"/> specific incentives to not use strategies (pay or trade)		
	<input type="checkbox"/> partner(s) unwilling/reluctant/afraid to practice strategies	<input type="checkbox"/> fearful of rejection or missed opportunity (ruining the mood)		
	<input type="checkbox"/> thinking partners are HIV-negative without really knowing their status	<input type="checkbox"/> interferes with intimacy		
	<input type="checkbox"/> feeling down/beat (not caring about protecting self)	<input type="checkbox"/> not thinking that getting HIV would be bad		
	<input type="checkbox"/> drug or alcohol use (making decision making difficult)	<input type="checkbox"/> caught up in the moment		
	<input type="checkbox"/> other, specify: _____	<input type="checkbox"/> none could be identified		
4	TAILOR: Level of engagement in this part of counseling:	<input type="checkbox"/> low	<input type="checkbox"/> medium	<input type="checkbox"/> high
5	IDENTIFY needs: (What) <input type="checkbox"/> Not discussed			
	5a. Categories: mark all that apply:			
	<input type="checkbox"/> feel better informed	<input type="checkbox"/> be assertive/confident		
	<input type="checkbox"/> have access to strategies (condoms, HIV testing, lube)	<input type="checkbox"/> have strategies that are brought into sexual life		
	<input type="checkbox"/> feel more motivated	<input type="checkbox"/> have better concrete skills around negotiating strategies with partners		
	<input type="checkbox"/> social support	<input type="checkbox"/> basic living needs met (housing, food, safety)		
	<input type="checkbox"/> other, specify: _____	<input type="checkbox"/> none could be identified		
6	STRATEGIZE: Strategies discussed?	<input type="checkbox"/> yes	<input type="checkbox"/> no	
7	AGREE on: Strategy and Action Plan			
	7a. Strategy selected?	<input type="checkbox"/> yes	<input type="checkbox"/> no	→ End of item.
	7b. Action Plan?	<input type="checkbox"/> yes	<input type="checkbox"/> no	

Completed by: _____ (initials/date)

SAMPLE: DO NOT FAX TO DATAFAX

DFINET (iPrEx) 100

(SPC) 100

☐ off PrEP
☒ on PrEP
☐ seropositive

 Visit Week .
 CRF not administered ☐

 Participant ID: - -
Site Participant Number CRF

 Visit Date: / /
dd MM yy

Study Pill Counseling - iNSC

1	INTRODUCE: Introduction to session provided?	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n/a
2	REVIEW: Were the participant's experiences/decisions in the study reviewed?	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n/a → Go to Item 3.
	2a. Transition provided?	<input type="checkbox"/> yes <input type="checkbox"/> no
3	EXPLORE: Facilitators <input type="checkbox"/> Not discussed	
	3a. Categories: mark all that apply:	
	<input type="checkbox"/> mobile/carry tools (e.g. pill boxes)	<input type="checkbox"/> match with routine/event
	<input type="checkbox"/> commitments (protecting self or others)	<input type="checkbox"/> memory aids/tools (e.g. calendar, alarm)
	<input type="checkbox"/> access	<input type="checkbox"/> social support (family, friends, partners)
	<input type="checkbox"/> other; specify: _____	<input type="checkbox"/> none could be identified
	EXPLORE: Challenges <input type="checkbox"/> Not discussed	
	3b. Categories: mark all that apply:	
	<input type="checkbox"/> partying/drugs/alcohol	<input type="checkbox"/> medication (too big, tastes bad)
	<input type="checkbox"/> disruption in routine	<input type="checkbox"/> forgetting/no doses available
	<input type="checkbox"/> side effects	<input type="checkbox"/> lack of privacy
	<input type="checkbox"/> other; specify: _____	<input type="checkbox"/> none could be identified
4	TAILOR: Level of engagement in this part of counseling:	<input type="checkbox"/> low <input type="checkbox"/> medium <input type="checkbox"/> high
5	IDENTIFY needs: (What) <input type="checkbox"/> Not discussed	
	5a. Categories: mark all that apply:	
	<input type="checkbox"/> access (have available)	<input type="checkbox"/> remember
	<input type="checkbox"/> motivation	<input type="checkbox"/> manage side effects
	<input type="checkbox"/> privacy	<input type="checkbox"/> social support
	<input type="checkbox"/> other; specify: _____	<input type="checkbox"/> none could be identified
6	STRATEGIZE: Strategies discussed?	<input type="checkbox"/> yes <input type="checkbox"/> no
7	AGREE on: Strategy and Action Plan	
	7a. Strategy selected?	<input type="checkbox"/> yes <input type="checkbox"/> no → End of form.
	7b. Action Plan?	<input type="checkbox"/> yes <input type="checkbox"/> no

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

PROCESS VARIABLES

- 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.....

SexHealth

EXPLORE [facilitators] (99%)

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

2% None

53% Personal commitment

42% Well informed

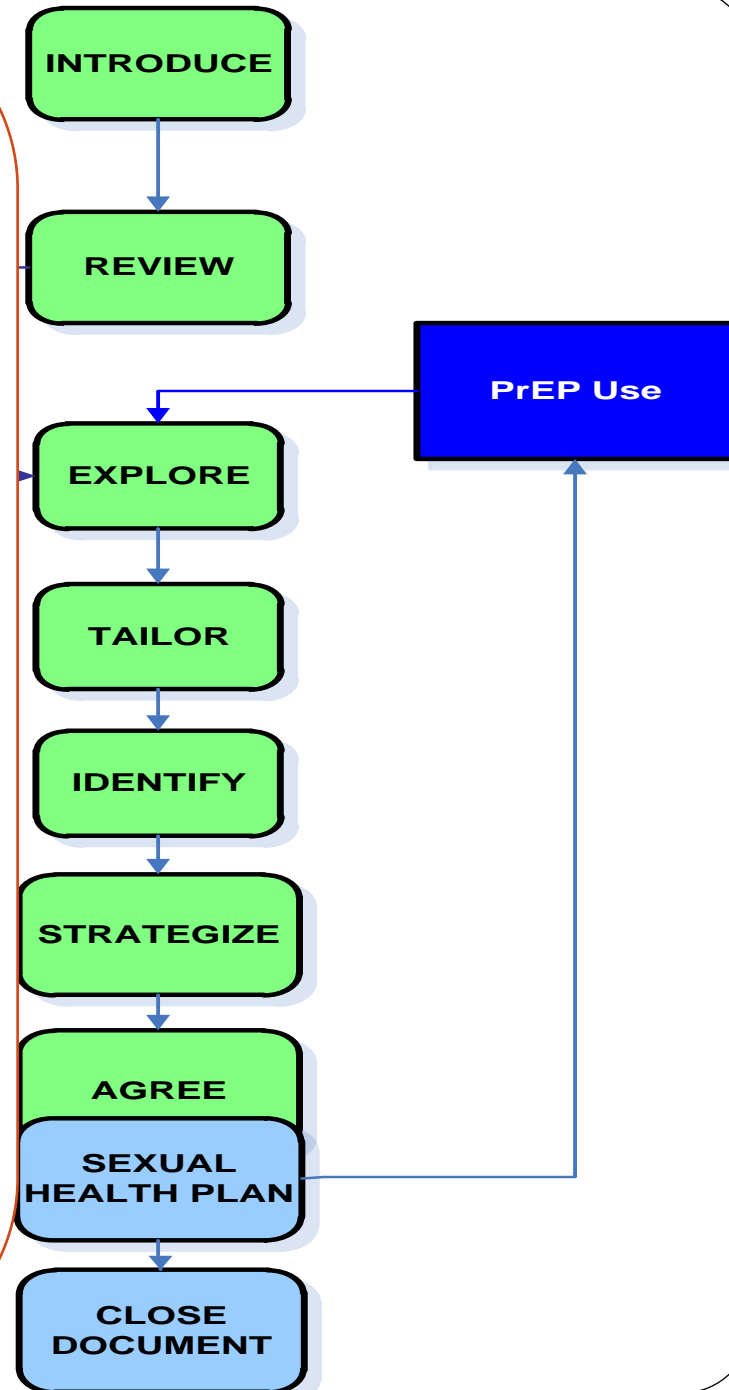
31% Confidence

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

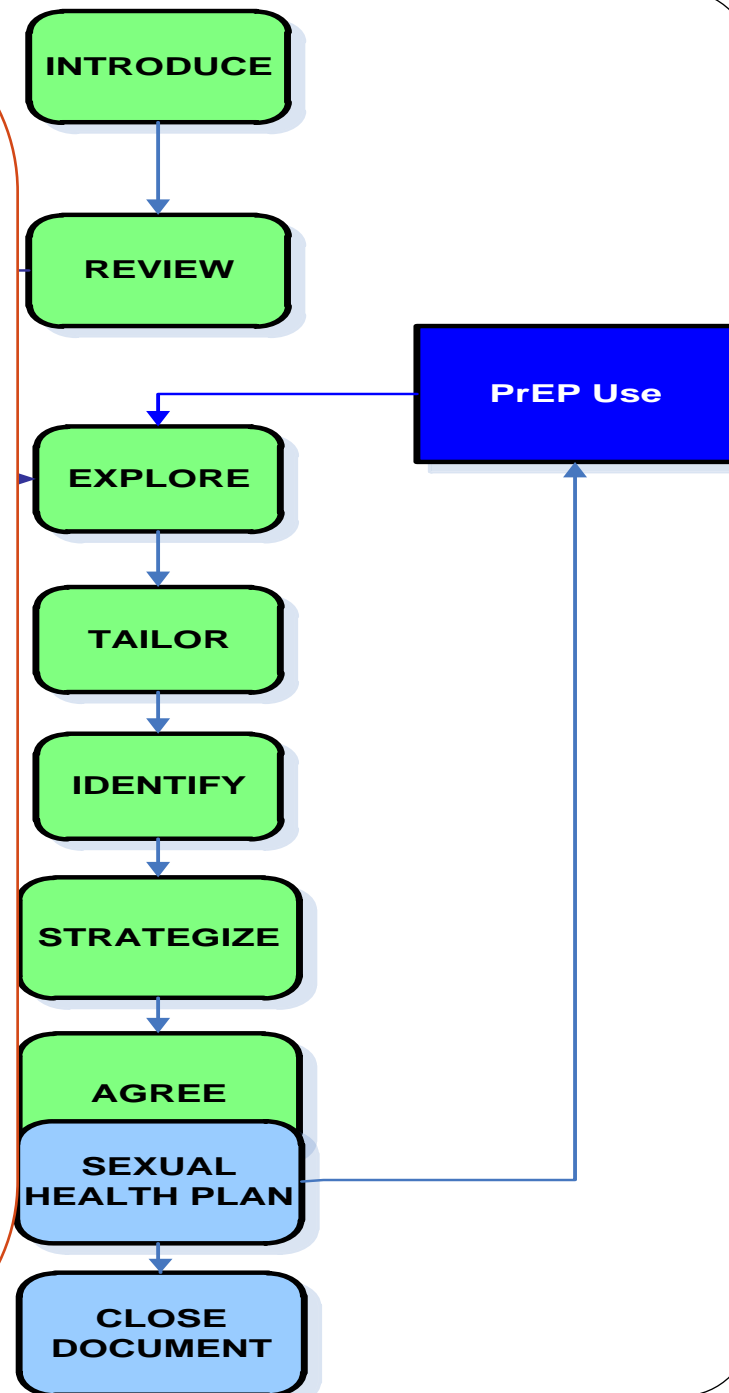
2% Lacking Information

2% Low neg value HIV infection

2% Neg affect

1% Spec incentives (trade)

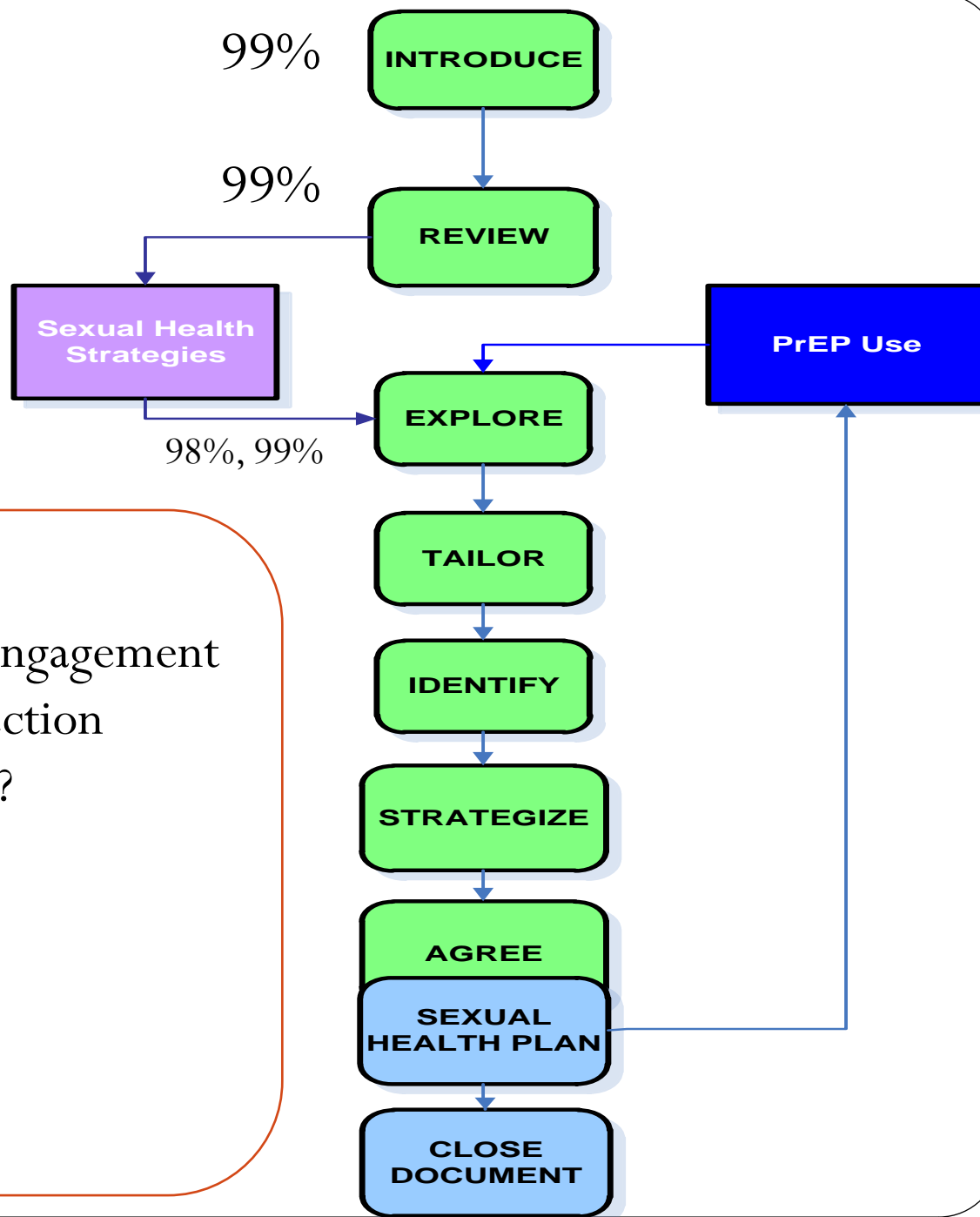
10% Other



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

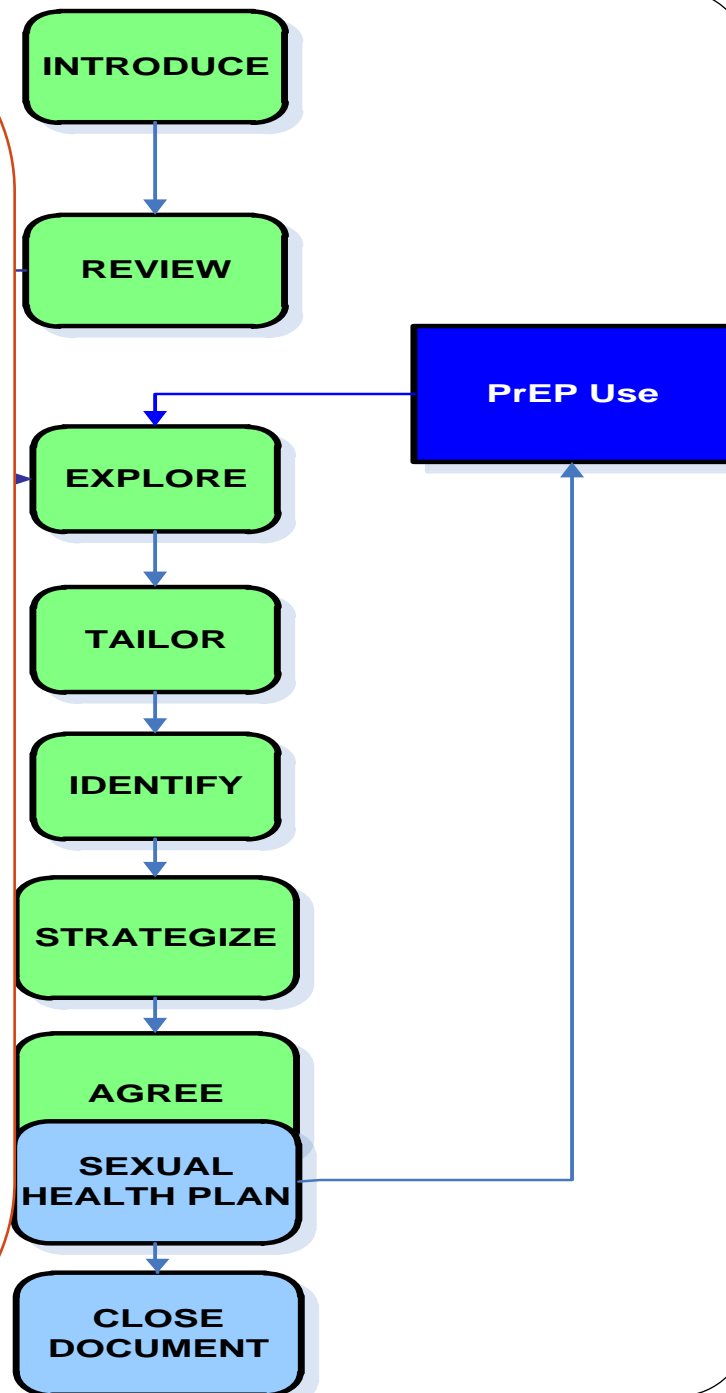
8% More/better Information

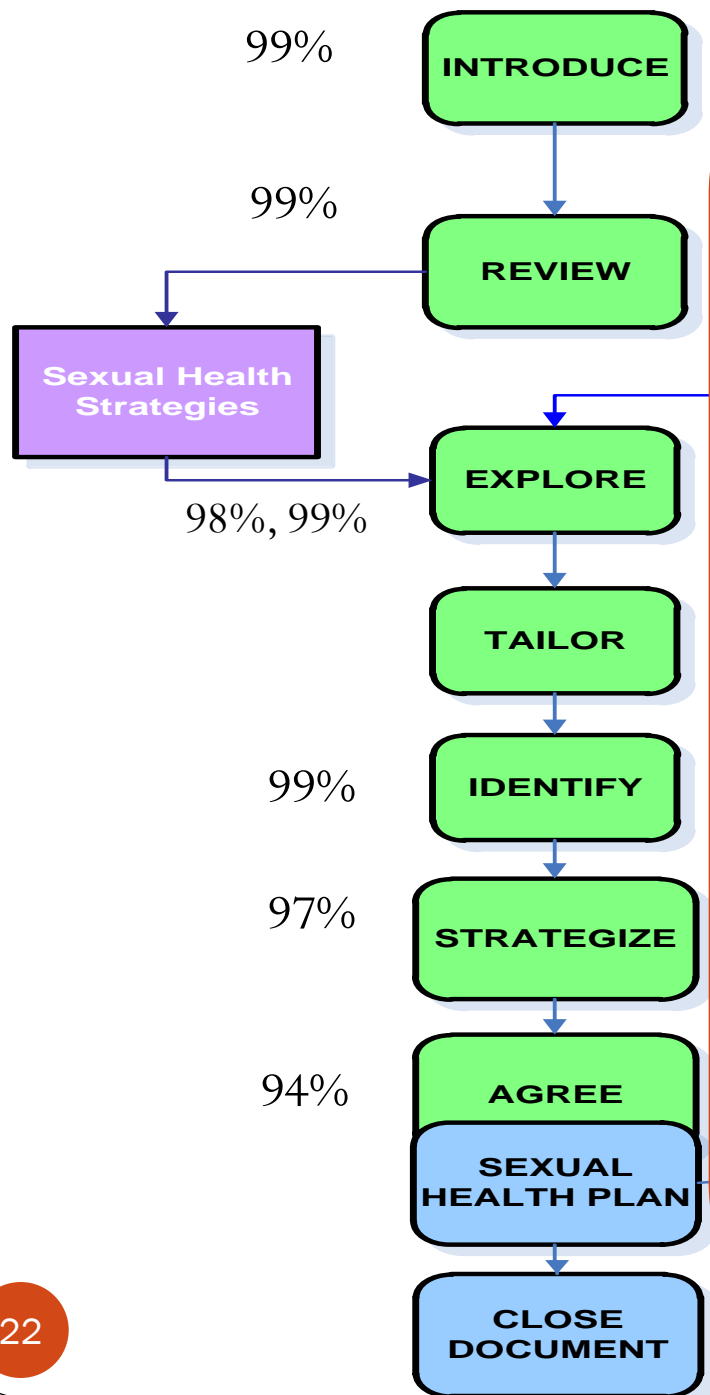
6% Negotiation skills

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

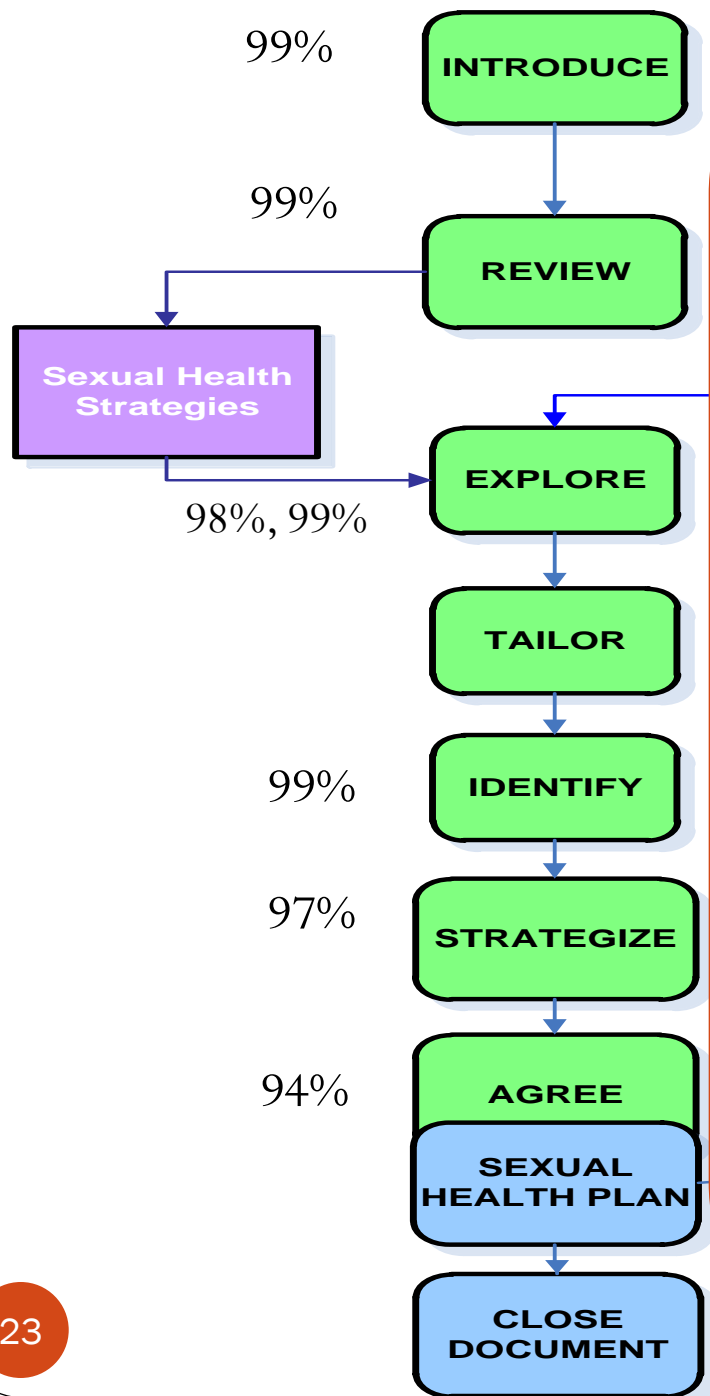
17% Memory aids/tools

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

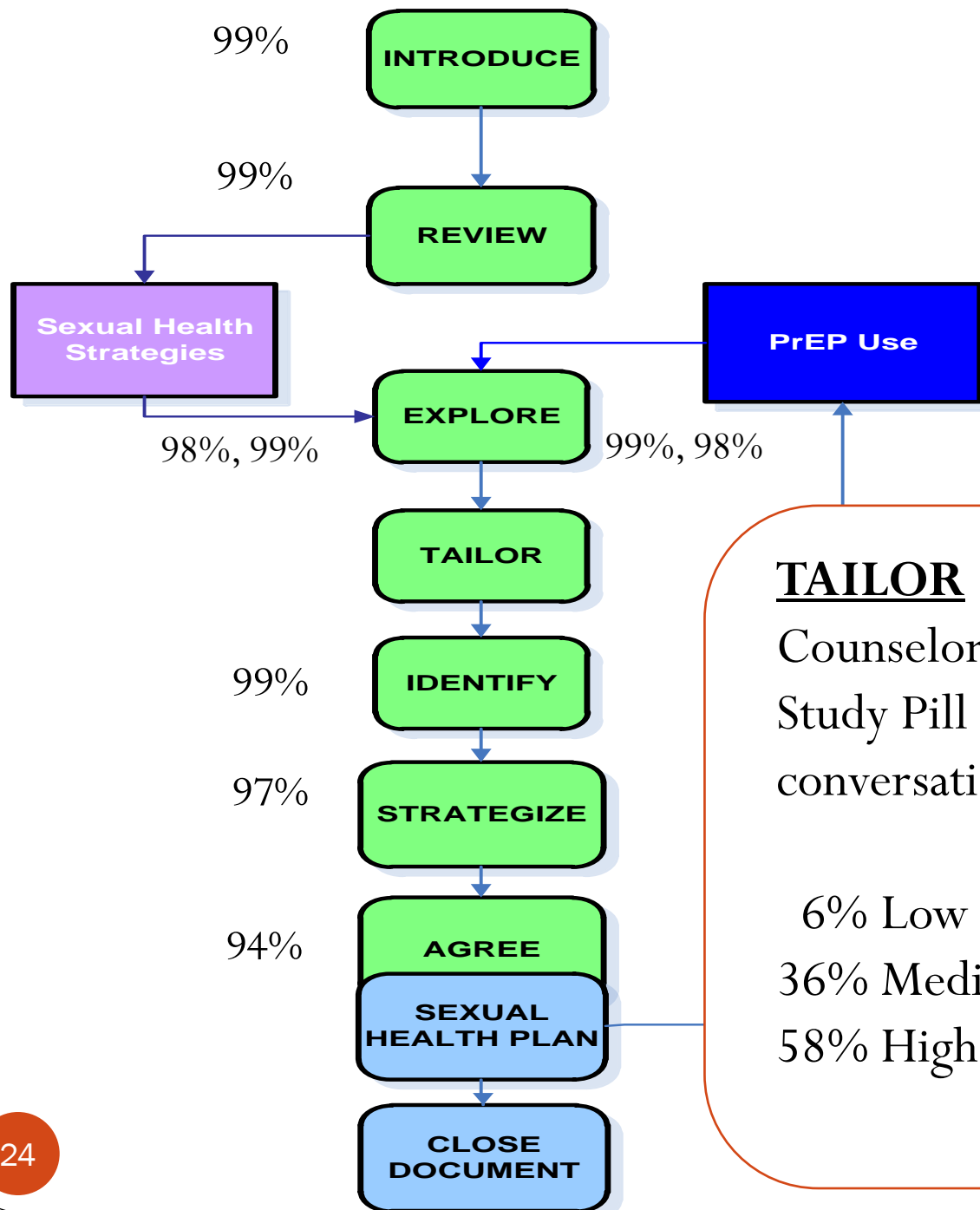
9% Side effects

8% Drug/Alc use (partying)

2% Lack of privacy

1% Characteristics of meds

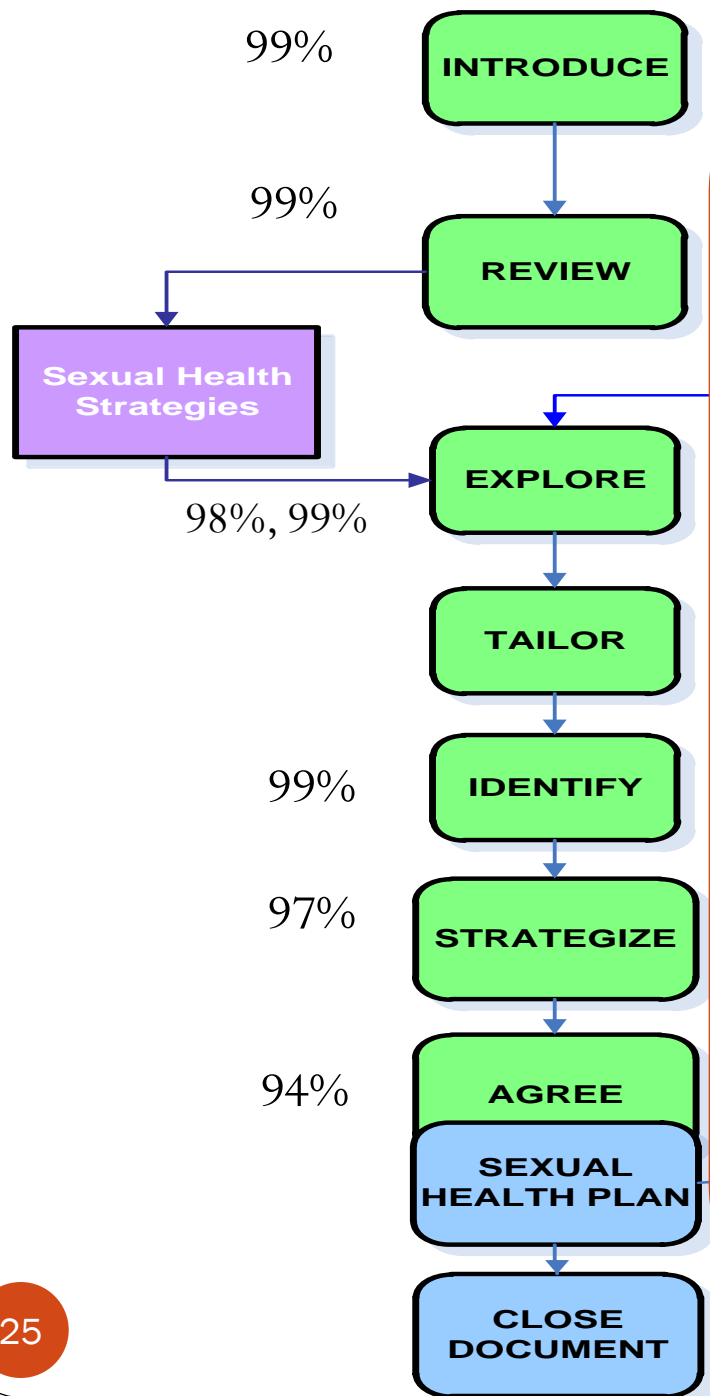
2% Other



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

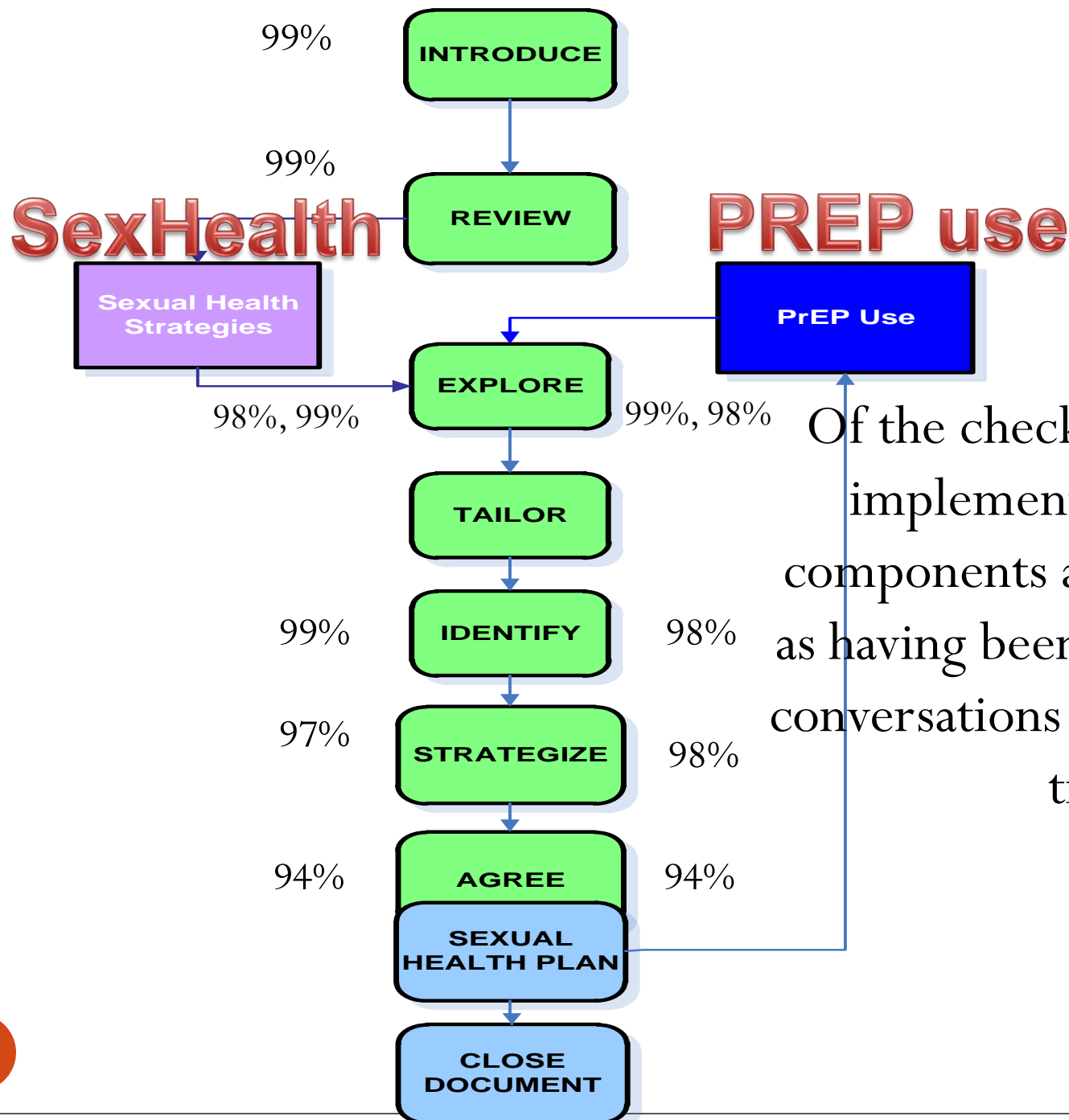
8% Side effects management

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

SUMMARY

- 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

Top 3 most common	Behavioral Strategies	PrEP adherence
Facilitators	<ol style="list-style-type: none"> 1. Personal commitment/motivation (53%) 2. Feeling well informed (42%) 3. Confidence (31%) 	<ol style="list-style-type: none"> 1. Match to existing Routine (81%) 2. Carry doses (22%) 3. Personal commitment; memory aids (17% each)
Barriers	<ol style="list-style-type: none"> 1. Caught in moment (21%) 2. Assuming partner is HIV neg (14%) 3. Drug/Alc; Interference with intimacy (11% each) 	<ol style="list-style-type: none"> 1. Forgetting dose time or to bring doses; Routine disruptions (31% each) 2. Side-effects (9%) 3. Drug/alc use (8%)
Needs	<ol style="list-style-type: none"> 1. Consistent/better access (41%) 2. More confidence (15%) 3. Motivation; Fit (12% each) 	<ol style="list-style-type: none"> 1. Remember/cue (46%) 2. Consistent/better access (27%) 3. Side effects management (8%)

CONCLUSIONS

- 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



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Susan Buchbinder
Albert Liu



Esper Kallás



Mauro Schechter



Valdilea Veloso



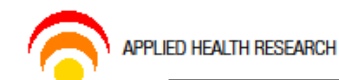
Linda-Gail Bekker



Peter Anderson
Lane Bushman



Brian Postle



K. Rivet Amico



Howard Jaffe
Jim Rooney



David Burns



Grace Chow
Ana Martínez



The iPrEx Study: Safety, Efficacy, Behavior, and Biology



Create, empower, and promote open collaborations