

Final Study Report:
Feasibility and Acceptability of Pre-exposure Prophylaxis (PrEP)
and Non-occupational Post Exposure Prophylaxis (nPEP)
for HIV Prevention

***A Qualitative Research Study Sponsored by The
Los Angeles City AIDS Coordinator's Office***

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EXECUTIVE SUMMARY

- Three focus groups and five key informant interviews were conducted to assess potential barriers to the acceptance and use of biomedical HIV prevention strategies. A modified grounded-theory approach was used to analyze the interview and focus-group data.
- Focus group participants were sixteen self-reported HIV-negative men who have sex with men in Los Angeles. Key opinion leaders were recruited from local CME activity rosters.
- Participants appear to invoke a complex decisional balance in the consideration of HIV prevention. This decisional balance seems to parse into two distinct decision-trees.
 - The first is whether HIV still poses credible threat to health, well-being, and longevity in the current era of effective antiretroviral treatment.
 - The second balances novel prevention strategies including biomedical prevention against routinely available male condoms. The decision to use any prevention strategy at all is dependent on the participant's perceived risk for HIV infection.
 - The most striking finding of the study was the conception of novel HIV prevention strategies as alternatives to condoms, and a highly motivating desire for such alternatives.
- Future efforts need to be directed toward community based literacy around HIV natural history, prevention, and treatment.
- Study findings are limited by the absence of a concrete product for participants to evaluate for biomedical prevention.

BACKGROUND

Epidemiology

Currently, over 1 million persons with HIV/AIDS live in the US, and prevention efforts have been largely unsuccessful in stemming the ongoing rise in incident infections in men who have sex with men (MSM).¹ Approximately 50% of new annual diagnoses of HIV in the US continue to be attributable to sexual contact between MSM² who represent 76% of prevalent AIDS cases in Los Angeles County (LAC).³ LAC represents 3.5% of the US population and 27% of the population of California, yet disproportionately contributes 40% of California-incident HIV infections. A protective HIV-vaccine is still far from realization.⁴ New scientific approaches for prevention of HIV transmission need to be tested and evaluated for safety, efficacy, acceptability, and impact on risk behaviors.

Prevention Strategies

While male condom use remains the cornerstone of HIV prevention, behavioral interventions have had limited success in impacting disease incidence. Other methods of questionable benefit for reducing risk of HIV acquisition include serosorting,⁵ the attempt to only partner sexually with ipso-serostatus individuals (i.e. negative with negative, and positive with positive), strategic positioning (choosing to exclusively be the insertive partner for anal intercourse to reduce the chance of HIV acquisition),⁶ withdrawal prior to ejaculation,^{6, 7} and selecting partners based on report of an undetectable viral load.⁷

There is increased interest in the use of HIV treatment medications as prevention tools, and these parse into 3 large categories. Post-exposure prophylaxis (PEP) is a strategy of administering HIV antiretroviral medications to HIV-negative persons in the wake of a known or suspected exposure to HIV-infected blood or genital secretions. This is standard-of-care for healthcare workers after occupationally-related exposures,⁸ estimated to reduce the risk of acquiring HIV after such an exposure by more than 80%,⁹ and is increasingly recommended to the general public after sexual or injection drug use exposures to HIV,¹⁰⁻¹² despite a paucity of efficacy data for its use in this context. Safety, feasibility, and non-promotion of high-risk behaviors have been documented in domestic and international programs.¹³⁻¹⁸ Pre-exposure prophylaxis (PrEP) employs HIV

antiretroviral medications taken in advance of an exposure to HIV, not unlike taking daily birth-control pills to prevent unwanted pregnancy. PrEP studies are currently being conducted to evaluate the safety, efficacy, feasibility, and impact on risk-behavior of such a strategy.

Knowledge and use of these so-called biomedical prevention strategies is limited in MSM populations.^{19, 20} Reasons for limited uptake by both providers and potential consumers of biomedical prevention services are poorly understood, and are likely multifactorial. The most concerning of proposed explanations is an alleged acceptance of risk by some groups of MSM,²¹ which has been argued to remove compelling momentum from attempts to mitigate or abrogate ambient risk of seroconversion.

The Current State of Pre-Exposure Prophylaxis Research

Ongoing clinical trials of PrEP are studying HIV antiretrovirals which are currently FDA approved for treatment of chronic HIV infection. Two agents are currently under investigation: Viread (Tenofovir), a nucleotide-analogue reverse transcriptase inhibitor (NRTI), and Truvada (Tenofovir/Emtricitabine), a fixed-dose combination tablet of two such similar agents. Data from the HIV therapeutics literature suggest that the addition of emtricitabine does not substantially increase the toxicity of the regimen, and that two agents are more effective at inhibiting HIV replication than is a single agent.²² Animal models also suggest impressive efficacy of the combination of tenofovir and emtricitabine for pre-exposure prophylaxis,²³ and that two-agent treatment may be more effective than single-agent treatment.²⁴ Studies are currently being designed which will establish the pharmacokinetic parameters of less frequent dosing of these medications, and perhaps lend insight into the implications for less-than-optimal medication adherence should PrEP become widely implemented. Studies investigating the utility of alternative/additional agents with attractive mechanisms of action for prevention strategies are likely to follow the initial wave of tenofovir and Truvada-based studies.

Major concerns about the use of prolonged antiretroviral treatment in HIV-negative populations include the potential for nephrotoxicity and bone mineral density loss (both toxicities associated with tenofovir use²⁵) flares, sometimes serious or life threatening, of Hepatitis B upon cessation of PEP medication in chronic HBV-infected patients,²⁶ the potential for development of resistance to the PrEP agents should HIV infection occur

despite the use of antiretroviral prophylaxis²⁷, and the as-yet-undefined behavioral implications of PrEP use: That is, will individuals increase their risk taking behaviors in the context of perceived protection against HIV acquisition?²⁸ Even relatively small increases in risk taking behavior, in mathematical models, appear to have the potential to abrogate protective effects of PrEP use on incident infections at the population level.²⁹

METHODS

Study Design

This was a qualitative study of knowledge, attitudes, beliefs, and perceived barriers to implementation of biomedical prevention strategies among MSM in metropolitan Los Angeles, California. Three focus groups comprised of sixteen unique individual participants were conducted at the UCLA Center for Clinical AIDS Research and Education between April 2008 and June 2008. Additionally, five key informants were interviewed individually. Three interviews were performed face-to-face, and two were performed via telephone for participant convenience. The UCLA IRB approved the study and its documents.

Study Population

MSM in metropolitan Los Angeles were recruited via Craigslist (www.craigslist.com), newspaper/magazine advertising, and palm-card and flyer distribution at MSM-focused locations including bars, restaurants, dance clubs, and commercial sex venues. Twenty men responded to advertising and were scheduled for three focus group dates; 16 men presented for focus group participation. Key Informants were recruited on a first-responder basis from a master list of HIV providers and community based organization staff and activists who attend UCLA HIV-related symposia and events. Each participant (focus group and key informant) was compensated \$20 for their time.

Study Procedures

Participants were given a Research Information Sheet, as the IRB deemed no formal informed consent to be required. Participants then completed a de-identified demographic assessment prior to focus-group participation, and were allowed to use a name of their choosing, including a pseudonym for the focus-group exercise. Focus groups were conducted by study staff (RJL, MNC and SL), and were digitally audio-

recorded. Audio recordings were transcribed by a transcription services and then edited and re-reviewed by the study team (MNC and RJL) for accuracy and fidelity based on field notes and personal recall from the source focus group. Transcripts were coded using line-by-line open coding in the manner of Strauss and Corbin. The interviews were independently coded by two of three individuals (RJL, MNC, and SL) and discrepancies in coding resolved utilizing the third coder. “Core categories” were identified iteratively, and when a core category was selected, axial coding was developed to delimit future coding and make connections between a category and its subcategories.³⁰⁻³² To identify categories, participant transcript segments with the same label were grouped and analyzed for similarities and differences, using the technique of constant comparative analysis.³³ Categories were coded to saturation and then sorted manually in the manner of Lincoln and Guba,³⁴ in conjunction with field notes and memos made during data collection, and assembled according to a constructed visual scheme. From this, a model was assembled based on central tenets of the Health Belief Model.³⁵⁻³⁷

RESULTS

Focus Group Participant Demographics

Of the sixteen participants, twelve provided demographic information. Four (33%) participants were African-American, two (16%) were Hispanic/Latino, and six (50%) were Caucasian. Five (42%) identified themselves as bisexual, and seven (58%) identified themselves as gay. Nine (75%) reported sex with a male in the last two months, and one (8%) reported having sex with a transgendered person in the last two months. Six (50%) reported receptive anal sex in the last two months, and of that group, five (83%) reported that condoms were used. Seven (58%) reported insertive anal sex in the last two months, and of that group, six (86%) reported condom use. Two (17%) reported insertive vaginal sex with a woman in the last two months, and two (100%) reported condom use. Two (17%) of participants reported that they had been told that they have an STD in the past two months (STDs reported were Hepatitis B and Genital Herpes). Twelve (100%) of participants reported a negative HIV test, which was an inclusion criterion for study participation. Over the last two months, eight (67%) participants reported heavy alcohol use, one (8%) used amphetamines, two (17%) used nitrates, two (17%) used ecstasy, one (8%) used GHB, and one (8%) used Viagra. One (8%)

participant had injected drugs with a needle in the last two months, and reported using a new needle that had never been used before.

Are Sexually Transmitted Infections a Threat to Me?

All of the focus group participants acknowledged the threat of HIV infection in their lives, although their perceptions of the severity of this threat varied. MHC, (Caucasian male) abstained from intimate relationships altogether based on his fear of HIV infection, noting “I don’t feel like I have the freedom to have sex like I used to. I had to drastically change my habits just out of fear because I didn’t – I mean I believe in the safety of a condom, but it still feels scary.” He continued, “I think there might be a lot of people out there, that they’re not normal because they don’t have a normal sex life because of fear of exposure, the same category that I’m in...” A Caucasian male, DBW also noted, “[There are] plenty of people who are ‘retired’ now because of just fear.”

Several participants recounted situations in which they discussed the issue of HIV status with their potential partners, and were uncertain as to whether their partners were being honest. KLA, a Caucasian male, stated, “I’ve been in a situation afterward where at first I thought the guy was negative, and then by the end I thought, you know what? Different things will kind of make me think, I don’t know, I think he might have been positive.” Many agreed that they felt safer assuming that a casual partner was HIV-positive, and taking the precautions to prevent HIV infection. GNY, a Latino male, described his philosophy about protecting himself sexually, saying, “[PrEP] could be something against HIV but not against the rest of the STD’s – there’s no fun going through all those STDs, even though there is a cure, there is no fun just to go through that, and to get those. How about if you get herpes? As far as I know, so far, it’s not curable. So you get herpes, great. I don’t have HIV but I’ve got the herpes for life. I am Mr. Positive about everything in life, but we have to be – we have to face [it]. It’s just my opinion. In the world that we live, I hope that we would never have to think about condoms. But we can’t. We just can’t. We have to face it. It’s just my opinion. That’s it.”

The sexual patterns and frequency of partnerships of the participants weighed heavily in their thoughts about the risk of HIV infection. Several participants were either currently in serodiscordant relationships with HIV-positive partners, or had been in a serodiscordant relationship in the past. In considering biomedical interventions, TJJ, an

African American male, said, “I guess if I was... with a partner who was HIV positive, it would be less... tedious. I don’t want to think of it as tedious, but I’m like... because I think okay, if I did slip, oops, there, I can get the PEP and let that be it. As a single gay man, I wouldn’t be that interested in PrEP on a daily basis, because I would just say, ‘why?’” SER, a Caucasian male is currently in a serodiscordant relationship. He said, “When I was single, I don’t think I probably would’ve been interested in this, even if it were more than 75 % [effective] just because I wouldn’t want to be taking something everyday on the off chance of this weekend, I might hook up... but now I have this daily sort of, it’s around all the time, which – even if we’re not anywhere near that, if it were 50% or whatever just as long as it was something, another weapon in the arsenal to combat.” TJJ (African American male) discussed a sense of complacency about HIV that he developed while in a relationship with an HIV-positive partner. He said, “When I was in a relationship for three years and my partner was positive, I was the receiver – you get to the point where you get just so stupid, you’re just like, fuck it, you just say, forget it, infect me! And I just – then when you break up, you’re just like, thank God I didn’t get it, but I think you see like the positive ones in a relationship being a little bit more responsible...”

A common theme in the discussions about partners and risk was the difference between knowing that a regular partner is HIV-positive, and having casual sex with partners of unknown serostatus. Those who were constantly at risk through their HIV-positive partner had a different perception of risk than those who had sex casually. SER (Caucasian male) appeared more eager than other participants to try biomedical interventions, and he pointed out, “I think that’s part of already knowing that he is positive, or another set of issues, you’re single and you’re going out and you hook up with somebody and he may or may not be, and then all of the sudden, that’s a different set of risks than knowing that he is – it’s a whole different set of things.”

Participants noted that although HIV still poses a threat, it is not the same threat that it was earlier in the course of the HIV epidemic. MHC (Caucasian male) said, “The fear isn’t as dominant now as it used to be in people my age or even a little younger because when AIDS first came about, it was terrifying and most of the people my age remember how frightening that was, and it’s really been played down a lot now, tremendously compared to what it was... it was an epidemic that was going to kill the world.” Younger

participants may not have experienced the same fear that older participants have surrounding the risk of HIV infection. MNO, a Caucasian male, described his assessment of his risk: “Yeah, people don’t die of AIDS like they were dying in the 80’s, people die of cancer now, cancer is the big one, everyone is freaked out about cancer. AIDS is, from what I’ve heard, is a sustainable disease, it’s a manageable. A lot of people, I know, it’s like, they don’t think of AIDS, if they get it as being traumatic and horrible and they cry for a couple of weeks about it but they get on with their lives.”

What are my choices for HIV prevention?

While participants recognized the threat of HIV infection, many also expressed a desire for spontaneous and meaningful sexual experiences. They noted that concerns about HIV often interfered with the passionate, care-free sex that they wanted to have. KLA (Caucasian male) summarized this dynamic, saying, “By always stopping and saying, ‘you better put a condom on, you might get gonorrhea, you might get syphilis, you might get this, you might get that.’ I think as gay men particularly... yes, we’re cognizant of that, and mindful of it, and I certainly am... [But] if you allow that to become such a dominant theme in how you view sex, it kind of, for me at least, it changes what the experience should be. Which is something really pleasurable and exciting and spontaneous and all of those things.” RMR, a Latino male, agreed, saying, “You want to enjoy sex, you want to enjoy your partner, you don’t want to have that fear. That’s what we’re striving for.” DCL, a 30 year old African American man, said that his concerns about HIV restricted the types of men he could have sex with. He recalled a trip to a bath house on his birthday in which, “All the people who wanted to have sex with me were porn stars who had sex with everybody in there, and I would’ve done it if I didn’t have to worry about stuff, and, so I didn’t because I was like, ‘well, they’re having sex with everybody so I have to worry about HIV.’” It appeared that he wanted to be able to have sex with men he was attracted to, even if they appeared more promiscuous and therefore at presumed higher risk for HIV infection.

The discussion revealed that many participants were not content with condoms as their sole method of protection. DCL (African American male) complained about the interruptions that condoms can cause, saying, “Condoms aren’t perfect, they keep distracting them from the sex... When you’re having sex with a condom on, your penis goes down, and then, that’s it. You can’t use it again, you know, you’ve got to find

another condom, you've got to unwrap it, you've got to do all this stuff, you've got to get it back up, all this stuff. It's not like it's so smooth, it's not seamless." DBW (Caucasian male) also described the fallibility of condoms, noting, "Condoms can break, condoms can come off, and the thing is, once that happens, all bets are off. That happened enough times to me to make me condom militant." DCL (African American male) noted the difficulty of condom adherence, even with culturally pervasive messages encouraging condom use. He said, "It's always a message that we're supposed to always use condoms. I've taught people to always use condoms, and I don't." KLA (Caucasian male) agreed, pointing out, "I have been in that situation where I was in a relationship with a bottom who was positive, I didn't always use a condom." This additionally points out the known tactic of "strategic positioning" – making decisions around being the insertive partner (rather than the receptive partner) for the exclusive reason of perceived lower HIV transmission risk.

Sex on Alcohol or Drugs

Drugs and alcohol appeared to have an impact on many participants' decision-making, and some participants noted that they wanted to be able to have sex while under the influence of alcohol or drugs without having to worry about the status of their partners. DBW (Caucasian male) pointed out the difference between sober thinking, and the mentality during a night of polysubstance use, saying, "In these rooms, thinking rationally, logically, thinking do I want to add on anything else to my regime, my daily regime – weekends, being nice, high and horny, fuck, forget it." DCL (African American male) agreed, pointing out that although many men are now meeting over the internet, alcohol is still an important factor in encounters between sexual partners. His view was that a biomedical intervention would need to be free of adverse effects if used with alcohol or drugs, as, "Until the internet takes over everything, I think people still hook up at clubs and it would be good to believe that's not adversely affected by alcohol. That's really important. And um, until people – until as a community we really get control of this... meth, really ... that maybe, if it didn't interact with that, that'd probably be best." For SER (Caucasian male), a biomedical intervention could serve as an added layer of protection when normal attitudes about HIV prevention are affected by alcohol and drugs. He said, "I'm not going to go out and get crazy, but there is that thought in the back of your head, well, you know what, I'm at least this much more, 80 % protected than I was before, so regardless of – the front of my brain says don't, but you know what,

if you're in a party and you've been drinking, that might be one of those moments like, 'well, I'll roll the dice.'"

Risk Acceptance

Between the threat of HIV infection and the sex lives that focus group participants desired, most had found a place in which they accepted their current level of risk in exchange for the benefits they received from their sexual encounters. SER (Caucasian male) cited oral sex as an example, saying, "You put on a rubber to have oral sex, people look at you funny. Because that's one of those deals that they've made with themselves, that's a risk I'm willing to accept." The level of acceptable risk varied greatly among participants, and affected their willingness to consider biomedical interventions for HIV prevention. Some reported 100% condom adherence. For KLA (Caucasian male), who had expressed interest in spontaneous sexual encounters, he described his strategy saying, "It is great to have the conversation, but... I assume, honestly, if I'm having casual sex, I assume they are [HIV positive]. I just do and take the precautions."

Biomedical Prevention

In discussing pre and post-exposure prophylaxis for HIV prevention, participants had a variety of considerations in determining whether biomedical interventions would work for them. A major factor for several participants was the frequency of their sexual encounters. When asked how effective a biomedical intervention would have to be to consider using it, DBW (Caucasian male) responded, "Oh, it really wouldn't matter. I'd have to be more sexually active than I really am right now for it to matter." TJJ (African American male) agreed, saying, "What if I'm spending, you know \$50 a week on medication, I'm going through a dry spell, like what the hell!" MNO's (Caucasian male) view was that, "When you're sexually active and still going out, well, you're concerned enough to [be] doing the PrEP." Several participants shared the sentiment that a PrEP regimen would only be "worth it" if they were more sexually active than they currently were. Recalling his younger and more sexually active days, TJJ (African American male) said, "I would've taken PrEP earlier because I mean I would go do a lot of drugs, go to a lot of bath houses, sex clubs, so then, because I'm like, you know, what is it 2-3 [partners] a week? 2-3 a night might've been more like it! But yeah, I would've taken it... then because, yeah, but now it's kind of like, you know, if I see them, if it works out,

boom.” DCL (African American male) said, “Taking it on a daily basis reminds you of how much sex you’re not having and that would be really annoying for guys.”

Side effects were a concern to many participants. SER (Caucasian male), the participant in a serodiscordant relationship, described his partner’s antiretroviral regimen, saying, “The drugs are not very nice and he has one that he takes, he has to take it at night because it makes him really loopy and it knocks him out, he says, ‘you don’t want to do that – on a maybe it might work,’ and I said, we’ll go see, but that would come back to it. If there were no bad side effects, I really wouldn’t worry about it, I’m not afraid of taking pills.” CBT, an African American male, agreed with the importance of side effects in his decision to use biomedical preventions, stating, “For me it would depend on the nature of the side effects. I know that most pharmaceuticals have some degree of side effect. And even if they’re not known, you may experience, you know, a ‘new’ side effect, and so I think that it would probably make me think about it, and further investigate the nature of the side effects, and probably, or ultimately if it were only a side effect, it probably would not change my enthusiasm for taking on that course.” After the group discussed potential side effects, KLA (Caucasian male) said, “I mean... the things you’re describing – yeah, they’re not pleasant, but if you weighed that against doing nothing, you know, and just roll the dice... I would roll the dice and... with the odds that are more in my favor.” He continued, “If you’re talking about that or your life, potentially or ultimately a fatal illness, side effects aren’t pleasant but I’m assuming they’re temporary, like once you stop taking it, they go away. That’s nothing, like for 28 days, you can put up with that. I could.”

The participants had a range of opinions regarding the administration of a biomedical intervention. Some did not take issue with a regimen of pills. MNO (Caucasian male) said, “Once you get used to it – a regime, I mean it’s not that [much] harder than taking a multi-vitamin, which a lot of us do, or taking a dietary supplement or something like that, so no, I don’t think that would be a concern.” TJJ (African American male), on the other hand, was less interested in taking pills. He said, “I’m 42 now. So am I interested in taking one more pill each day? I’m more interested in something that’s going to be like – I was hearing that it could be some sort of a vaccine. You know, a shot to take once a quarter, like birth control.” DBW (Caucasian male) was also interested in alternative

methods of administration. He suggested, “They now have transdermal patches, and if they could come up with an administration for the cocktail of pills because I think it would be very tedious to have to, everyday add another regimen of medication, because I’m just bored of it. You know, you’ve got your blood pressure meds, your this, your that, your allergy, whatever.”

Finally, participants had wide-ranging opinions on how PEP or PrEP would fit into the greater HIV prevention landscape. Some of the participants noted that with the added protection of a biomedical intervention (given some assumed efficacy), some people’s level of acceptable risk would change, but many say they would continue to use condoms unless the efficacy of the regimen was very high. DBW (Caucasian male), who described himself as someone who “uses condoms religiously,” said that a PrEP regimen would be, “like a carpet with scotch guard, I mean to put it in a commercial sort of way. I think if somebody, especially if it had a high rate of over 50 % effectiveness, it would give people who were say, maybe out of the social circuit... common sense prevention, that would feel very empowered and say, hey, you know what? This has a 72 % success rate, I have not missed a dose in six weeks, I am going to Palm Springs, damn it!” In describing his own acceptable risk level, participant RXC (Latino male) said that he would be comfortable having sex without condoms if he were taking a PrEP regimen with at least a 95% protection rate. He said, “I’d still wear condoms at 75%. 95%, then we’re talking something – and then I would consider it because I know there’s going to be side effects. For me to just be able to have sex, not having to think twice about anything... 95 % of the time? I mean I’m willing to take, you know, the 5 % risk. The 5 % that I’m risking is with the benefits that he just stated for me.” He felt that, “Anybody who’s going to take this, it’s going to decrease their hardly existing desire to use condoms.” With that caveat, he also said, “I think any prevention is better than none.”

Key Informant Interview Results

Five separate interviews were conducted with key informants working in the field of HIV in Los Angeles County. These key informants discussed existing protocols for non-occupational PEP and pre-exposure prophylaxis. They also discussed barriers to successfully implementing biomedical interventions at their facilities in Los Angeles, as well as recommendations for future work in PEP and PrEP.

Biomedical Intervention Protocols in Place

Key Informant 4, a physician, described the post-exposure prophylaxis protocol in place at his large Southern California-based HMO. In order to establish PEP, his group “set up a program where, at every medical center, every primary care provider, especially emergency, urgent care- everyone knew about it and contacted the ID doc whenever a patient came along who was eligible... We also went through the logistics of what happens if... [an HMO] member who is HIV-positive, presented with their partner, who is not [an HMO] member... eligible for PEP, and we basically said that our policy, never written, never formal, but the policy was that we would, for compassionate reasons... give a three day supply to that person... and we’d then have them get [the rest] from their regular provider.” He continued, “We really drummed it into people, and we basically said, knowing that people who are outside HIV, you know, PEP might be a concept that they hear about once, they’re not going to really remember it when it happens- call ID, call ID, call ID- 24/7... and the ID docs agreed to be awakened at 4:30 in the morning, to discuss with an ER doc, a patient who comes in saying, ‘I just had unprotected sex’... The ID doc will stratify and handle it.”

Key Informant 1, an administrative analyst in an HIV epidemiology group, described an instance in which a friend of his was able to access non-occupational PEP through a pilot study at a community service provider. He says, “He had gone to get a test, and he was really worried and upset, and thinking he had been exposed, and he had never heard about it, but the HIV counselor at the [community center] mentioned there was possibly something they could do. It had been within that 72 hour period, and so they... referred to him to a medical person at the [community center] who spoke with him about PEP, what it was thought to do in terms of lessening the chance that he would be come infected, and he was very excited about that, nervous of course. So he was given the PEP and he was given about a month to take it, and he tested I think weekly at the [community health center], and he didn’t seroconvert.”

Key Informant 5, a physician, reported that while there is an occupational PEP program at their site, “We officially do not have a non-occupational post-exposure prophylaxis, and that was actually a conscious decision... because they did not have funding to provide medications to all the patients, and because all the other affiliated locations also

did not have a protocol for non-occupational PEP. And so they did not want to attract patients from all over the county to come to our clinic and deplete all of our funding.” KI5 explained that if a patient needed nPEP, “Non-occupational patients will be seen in the ER... and I was told that for a single fee, I don’t know how much that fee is, I’ve heard it was something like \$50- that pays for both their care that day, as well as a three-day supply of whatever medications the doctor... decides to give that patient. These patients can be followed up in primary care within our own system, if they don’t have a doctor, but even within our system, currently, only doctors who are infectious disease-trained- if you’re not on the list of doctors, the county pharmacy will not dispense whatever’s on your prescription if it’s an HIV drug... And patients who have not been confirmed to have HIV cannot be seen in our HIV clinic.”

Barriers to Implementation of Biomedical Interventions

Participants identified numerous barriers to successfully implementing PEP programs, and many believed that these barriers would hold true for a potential PrEP intervention. Barriers exist at the provider, patient, and administrative (or logistical) levels.

At the provider-level, Key Informant 4 (physician) brought up the fact that with a large per-diem physician pool, it was difficult to maintain provider education about the PEP protocol, even though it existed. He said, “A lot of the people who came into an urgent care, again on a weekend night... They’d be seen more likely by a per diem, and the per diem pool is moving so quickly, that to keep people continually educated, we figured it would be not insurmountable but really difficult. There are just too many protocols and rituals in the system.” Even among the full-time providers, KI4 noted that, “Provider overload is a phenomenal problem and who when you ask, ‘is there a curriculum we could develop, a PEP flyer, a mini curriculum, and email it to every one of 3,500 physicians in the region... Can we make them pass a test?’ No. At his small community clinic, Key Informant 3, a physician assistant, described the difficulties in taking on research trials. He said, “I’m always interested, but the thing is, we’re under funded, under staffed, under-everything and usually everything that has to do with a trial is labor intensive. There’s a lot of paperwork that goes with it, and everybody here already wears several hats.” Key Informant 2, a community-based treatment educator, even had experience with patients who attempted to obtain PEP through proper channels, but were turned away because the clinic staff was not properly educated. He

says, “[I received] all these calls, and finding out peoples’ stories that were situations that shouldn’t happen, where they were getting turned away from ERs and losing a day or two days of just waiting or being sent from one place to another, going to County Public Health and being told, ‘We don’t do that, we don’t offer that.’- going to the ER, the ER saying, ‘You know, you’re using up our time and resources, we don’t do that, go to public health.’ So you have this ping pong where they have no answers.”

Barriers also exist on a patient level. At Key Informant 4 (physician)’s site, even with a comprehensive nPEP protocol in place, it was not considered successful because it had a low level of patient uptake. He said, “We did not keep a log... and there was a time where we actually tried to figure out how many patients [we saw for nPEP], and we got a very paltry number, that over the span of the year, maybe a dozen patients around the region, which is highly unlikely.” He estimated that, “We would’ve done, at least one a month, so maybe a dozen a year, so that we extrapolate to more than one hundred to two hundred per year [across the entire HMO].” He also echoed the effects of competing information for patients, saying, “I do think people in our world, in general, are just dealing with overload, and it’s hard to get any new message into people.” Key Informant 3 (physician assistant) discussed the major issues facing his most difficult patients, including low education levels and poverty. He said, “Our population is, for the most part, uneducated... I think most of our patients just aren’t aware of things that are out there, plus it’s a real conservative area... It’s just not on people’s radar.” In line with their socioeconomic status, insurance or lack thereof plays a major role. Key Informant 2 (treatment educator) noted that for an uninsured patient, the cost can be tremendous. “One would have to assume that a triple combination regimen is probably around \$1,500 for a 28-day supply.”

Logistical and administrative barriers can also inhibit effective biomedical interventions. Key Informant 5 (physician) discussed the logistical difficulty of prescribing PEP or PrEP to a patient who is not HIV-positive. “If you’re not on the list of [infectious disease or HIV specialists], the pharmacy... will not dispense whatever’s on your prescription if it’s an HIV drug. One of the doctors who works in our HIV clinics Tuesdays nights is internal medicine trained and certified in HIV, so his name is on the list of doctors whose prescriptions for HAART will be dispensed. So currently the only way that a[n HIV negative] patient can get HIV medicines... is through him.” She continues, “He’s got

administrative duties, vacation, et cetera- so there's no way he can see every patient that walks through his doors." Another logistical barrier is filling prescriptions outside pharmacy hours. One of Key Informant 2 (treatment educator)'s patients needed to access PEP in the evening. The clinic "provided some counseling and they did give him a prescription, but they didn't give him any kind of starter pack... The pharmacy was closed, but the whole idea of PEP is getting on these drugs as soon as you can... he would've had to wait for over twelve hours to actually access the drug." Key informant 4 (physician) discussed a plan to add a prompt about PEP and PrEP into the medical center's computer system. However, he notes, "our electronic health record was so... clunky that to get one specific request in, when you have thousands of requests fighting for, not even center stage but peripheral stage, was really impossible."

Recommendations for Future work in PEP and PrEP

The key informants all had strong opinions as to how to implement a program for biomedical interventions in Los Angeles. Geography is one important consideration. Key Informant 1 (administrative analyst), whose friend accessed PEP two years ago, noted the benefit of being able to access PEP at a familiar clinic. He says, "[The clinic he went to] is a place he always goes to get his STI and HIV test, I think he felt comfortable with them. Because it was part of the menu of items that was sort of offered... it made it that much easier to access for him. In terms of going out and driving some place that would be less convenient... it's hard to speak for other folks- I'll speak for myself. It would be less likely." Key Informant 5 (physician) shared her patient's geographical considerations, saying, "I wouldn't place [a PEP/PrEP clinic] at a gay and lesbian place, because a lot of my patients who are straight will not go there. A lot of my straight people won't go any place in West Hollywood... But then I thought, how about something in the middle, but I have patients who don't want to go downtown. There are patients who refuse to travel; they'll die before they go to the other side of town."

In discussing how best to implement an intervention, community buy-in and an educational campaign were the most common elements seen as necessary for an effective program. Key Informant 3 (physician assistant) explained that at his own site, influential community members were the ones who attended the weekly support group. He said, "We have a group that meets... and that group takes care of themselves, for

the most part, and are vocal, so if they start talking about something, or they see something as advantageous, then they kind of spread the word... They'll disseminate the information." Key Informant 4 (physician) talked about two religious leaders who have influence with his patients. "Every African American patient I know with HIV knows both of them, and speaks as if they know them personally. I don't know if that's really the case, but they have- it's an MLK kind of phenomenon." Key Informant 1 (administrative analyst) echoed the influence of the church in the African American community in Los Angeles, but noted that, "you may have to overcome... the frankness of the sexuality. It may be a problem in some of those venues, that's an issue."

Advertisements and a community education campaign were identified as another important component to promoting biomedical interventions. Key Informant 1 said, "What may work in West Hollywood is a kind of high tech, kind of snazzy marketing ad campaign that includes video, that includes palm cards, that would include perhaps a person or a group of people coming into Here Lounge or The Abbey, or giving a power point presentation. He also suggested using HIV testing sites as a place to spread knowledge about prevention. "In HIV testing and counseling centers, if you had some video, some general informational video, when people are waiting to get their services they could be distracted easily. If you have something for them to watch that's educational and may be appropriate for them, I think that could be a brief educational intervention while they're waiting."

The target population for PEP and PrEP varied across the different key informants. Key Informant 3 (physician assistant) worked with numerous heterosexual couples, and was interested in targeting serodiscordant couples. He said, "If you're in a long-term relationship, I think that the PrEP makes much more sense... Even though it's an addition to condoms, not only are you covered when the condom breaks, you're covered to some extent when you don't have a condom... People are going to do what they're going to do, but they're going to get some protection." Key Informant 1 (administrative analyst) noted, "It would be really difficult to choose the right populations, because when you mention drug users, it may be difficult for them to follow that regimen... I'm thinking that drug using communities would probably be least compliant in a study such as this, because of other things that come before this. So perhaps [a better target would be] high risk people who are highly motivated and highly educated." Key Informant 5

pointed out a key challenge, which is that, “People on the Westside are more in the know, they’re more proactive, they’re up on data and what’s going on in HIV more than people in the East Side. But the people who need it are the ones who won’t ask for it the most.” She continued, “A lot of them who... are at higher risk, know other people who are at just as high risk. And I don’t know if there’s some other way to... trickle out to those other people, because they have access to people that we won’t.”

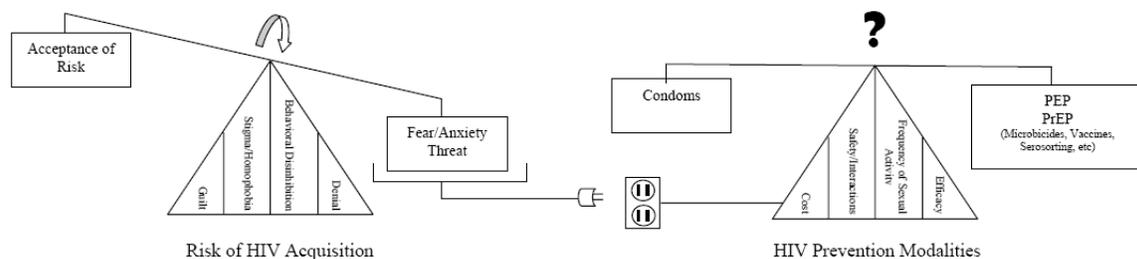
Discussion

In the conduct of focus groups and key informant interviews of HIV-negative MSM in Los Angeles, important and novel information has been brought to light. Such data will inform the process of paving the way for clinical trials involving biomedical interventions as well as the ultimate implementation process, should clinical trials validate the appropriateness of wide-spread use.

The qualitative data accrued from the three focus groups appear to suggest a series of two complex decisional balances, the second dependent on the first (Figure 1).

The first decisional balance is a very concerning one: It appears that MSM in Los Angeles are titrating their assessment of the importance of the threat of becoming HIV infected against their acceptance of that risk. Participants seem to lend voice to other

Figure 1. Model of serial decisional balances for the use of biomedical prevention strategies



health concerns (i.e. cancer) as something that they fear more than HIV acquisition. While the reasons for this deprioritization of avoiding HIV acquisition were not explored in depth, participants pointed to pharmaceutical advertising and anecdotal reports for the

perception that HIV infection is an ever-more-manageable chronic disease state. They expressed only limited appreciation of the complexities of HIV care and treatment.

The importance of this finding cannot be underestimated: Our model is based on the Health Belief Model (HBM), one of the primary models guiding research into HIV prevention behavior modification.³⁵⁻³⁷ The central tenets of the HBM include a balance between an individual's expectations of benefit from a behavior change and the perception of adversity ("threat") as an outcome of no-behavior change. The "threat" component is composed of an individual's development of "worry," or "perceived vulnerability" and a belief in their own ability to adopt HIV-prevention strategies. Secondly, the reward-to-cost ratio of behavior change must be favorable.³⁸ It has been argued that until perceived "threat" (in this case fear of HIV acquisition) is sufficiently elevated, expectations (in this case, risks and benefits of, and self-efficacy to implement a prevention intervention) do not enter into the equation for behavior change to avoid the "threat."³⁹ Thus, in order for consideration of the use of an HIV prevention strategy to be relevant, *enhanced education and outreach must be directed at the at-risk communities for reinforcement of concepts around the importance of avoiding HIV transmission/acquisition.*

We found 4 central themes which ran through the focus groups highlighting the components of the decisional balance regarding assessment of HIV risk. These were (in no particular order) denial, behavioral disinhibition, stigma/homophobia, and guilt.

Denial

The most remediable hinge-point of the HIV-risk assessment is the denial of risk. Ethnically, linguistically, and culturally appropriate educational programs emphasizing risk behaviors and strategies for risk avoidance are paramount to these educational interventions. This will be a particular challenge as "scare" campaigns are unlikely to be effective. Key informant interviews suggest that public health alliance with key community leaders may be a more effective strategy to design campaigns which will be well received by the relevant communities.

A major challenge in this regard is that actual numeric estimates of the per-coital or per-injection drug sharing risk of HIV transmission may sound surprisingly benign, and

therefore undermine the importance of safe sex and safe needle use messaging. Emphasis on the binary nature of an exposure outcome (i.e. a given individual gets infected or doesn't get infected based on a given exposure, thus setting up a real-life "Russian roulette" situation) is lost in the surprise of the low per-contact transmission risk data. Thus the very act of sharing the actual data, although aimed at building trust in communities through transparency, appears to have the opposite effect.

It is unclear how to appropriately balance the realities of HIV infection and its acute and chronic health effects while appropriately counseling infected patients that the disease is manageable and not the "death sentence" that it was in the 1980's and 1990's. To not appropriately acknowledge the latter is to perpetuate misinformation and encourage stigma (see below).

Behavioral Disinhibition

By the very fact that HIV does not appear to be as threatening a diagnosis to receive as it has in the past, it appears that many MSM are re-experiencing a renaissance of sexual freedom.⁴⁰ Increased rates of "bare backing," rising rates of STIs, and detailed public health reports all confirm these assertions. This bodes poorly for the at-risk population being willing to tolerate significant complexity to participate in HIV prevention. If the sexual caution enforced by the visions of those dying of AIDS and AIDS-related complications in 1980's and 1990's is either long erased, or never imprinted in (particularly) youth MSM, reigning in sexual freedom is a non-trivial task.

It is clear from the focus group results that the ability to maintain sexual freedom, pleasurability, and even numbers of partners is a priority to the sexual identity and well being of many MSM. This raises important concerns for any biomedical prevention strategy. For many, acceptance of their current level of HIV risk from the behaviors that they choose will obviate the utility of any prevention strategy. There simply is not enough threat or fear of acquiring HIV to balance the ferocious nature of the need/desire for sexual freedom. For those who have limited concern or feel some threat from HIV infection, perhaps a well-tolerated, simple prevention strategy will be acceptable and worthwhile in their decisional balance, although the majority will turn to condoms, the tried-and-true standard of care. For those who perceive serious threat from HIV

acquisition, universal condom use is likely already part of their routine practice – and any use of biomedical prevention strategies will be adjunctive.

While it is likely to be a dramatic oversimplification to parse all MSM into one of the three above-mentioned categories, it remains to be seen where in the spectrum of HIV-threat or fear is the inflection point whereby the impetus to use any prevention modality (or modalities) tips the proverbial balance towards action. And subsequently, what subset of those individuals will seek out or be interested in technology other than condoms.

Perhaps the most direct impact of behavioral disinhibition within the MSM community is the behavioral disinhibition induced by substance use – alcohol, methamphetamine and other stimulants, marijuana, nitrate inhalants, and prescription medications. The altered risk-benefit equations induced by substance use clearly err on the side of increased risk-taking, and have been associated with increased risk behavior in prospective studies, as well as STI and HIV outcomes. There are many layers on which interventions can be augmented to address these specific issues, from increased counseling services, to funding of novel programming and research for dependence on a variety of substances used by the MSM community.

Stigma/Homophobia

Although parsimoniously addressed by focus group participants, key informants cited stigma and homophobia as critical forces in decisions about the threat of HIV and the decisional balance of whether HIV infection risk is, in fact, worth attempting to mitigate. Arguments are somewhat circular regarding how stigma and homophobia impact HIV prevention efforts.

The first is an external homophobia, which comes into play in assessing the impact that perceived protection, conferred by a prevention strategy, has on risk behavior. The level of judgementalism which pervades many assessments of risk behavior implies that having sex on the part of MSM is something which ought not to be encouraged – an intrinsically homophobic tenet. Thus the discussion of whether and if public funding should be used for HIV prevention, and indeed previous United States Government administrations' policies on the limitations to uses of such funding, further the discriminatory overtones which seem to punctuate these discussions.

Perhaps more insidious is an internal homophobia, propagated in part by a lack of more general public acceptance (as evidence by ongoing civil equality struggles faced by homosexuals across the country), which may contribute to a more community-wide lack of protective instinct, or, worse, tendency towards self-destructive behavior.

While it is beyond the scope of prevention programming to address or remedy these overwhelming issues, it is important to recognize them and the context into which they force risk behavior – and understand the limitations these conditions place on the efficacy of any intervention operating within them.

Guilt

Treading similar paths as internalized homophobia, guilt and guilt-related anxiety are powerful forces in HIV avoidance decision making. The focus of the guilt may be varied, from feelings around disappointing parents or other authority figures, to survivor guilt if other friends or partners have acquired HIV already. However, guilt and guilt-related anxiety are a large impetus to self-medication with recreational prescription and non-prescription medications, as noted above. Increased mental health services to address underlying guilt and/or guilt-related anxiety may be important interventions for HIV prevention, and should be seriously considered for formal study as HIV prevention tools.

There are likely many additional contributors to the primary decisional balance involved in HIV-prevention strategy uptake: we only captured four. What appears quite clearly in the narratives is that if there is not sufficient perception of fear of HIV infection, or at minimum a perception that HIV-acquisition is a threat in some way, further consideration of ways to avoid HIV is obviated. It is likely that an individual's precise threshold is fluid over time, and certainly not likely to be the same for different individuals. It is unclear if such thresholds segregate across demographic lines or racial/ethnic lines – our analysis was unable to make such distinction based on small numbers, but further social research and development of instruments to measure such thresholds might contribute importantly to understanding barriers to prevention efforts.

If there is some sufficient threshold of threat, it seems that a second decisional balance becomes relevant (Figure 1). In this triage decision, various considerations contribute to weighing the use of condoms against the use of an alternative prevention strategy.

It should be first noted that perhaps the most salient and disturbing finding from our focus-groups was that the majority of participants felt that any new prevention strategy was first and foremost weighed as an *alternative* to condoms. It was clear that this was the primary motivator for consideration of novel prevention technologies, even when it was emphasized that such modalities were being investigated to be an adjunct to condoms, not as an alternative. This raises significant concerns about the potential impact of biomedical prevention strategies on rates of unprotected intercourse. While it has been definitively shown in two large studies that having access to post-exposure prophylaxis (PEP) does not appear to increase rates of high-risk behavior^{15, 41}, conceptually Pre-exposure prophylaxis (PrEP) or microbicides are quite different: The impact on high-risk behavior taking is likely to be substantially different when an individual has the prophylactic agent “on-board” in the context of decisional balances relating to planned exposures compared to those same decisional balances made knowing that a preventive agent was available after-the-fact.

Frequency of Sexual Activity

Almost all participants noted that in order for a systemic intervention such as PrEP to be worthwhile to them, there would have to be some threshold level of sexual activity. What the precise threshold would be varied greatly between participants, some noting 2-3 partners per week, whereas some would require 2-3 per night. Some even noted that continuing such a prevention strategy during a period of time of relative sexual inactivity would be a constant reminder of that current lack of activity - - which would perpetuate a sense of despondency and poor self-esteem (see homophobia/stigma, and guilt, above).

Again, it is unclear if there is an age-related, race/ethnicity-related, or socio-economic status-related difference in what the threshold might be for decisions around “sufficient” frequency of sexual activity to warrant consideration of pharmacologically-based chemoprophylaxis. Research directed towards development standard scales for evaluation and subsequent assessments in diverse groups would significantly inform these questions.

Efficacy

It is not surprising that efficacy was a substantial factor in decisions around use of biomedical prevention strategies. The discussion of a hypothetical drug to be used in biomedical HIV prevention is intrinsically problematic, as there are an infinite number of variations in efficacy, safety, cost, pill burden, side effect profile, and implications of treatment failure that it becomes impossible to make useful predictions of acceptability. This is particularly noticeable in this study's discussion of PrEP efficacy – wherein some participants were willing to accept a 50% or greater efficacy (anything better than the flip of a coin seemed advantageous), whereas the majority would demand a 90-95% efficacy level before considering such an intervention worthwhile. This, of course must be viewed in light of the proposed context of use: as an alternative to condoms. Attempts to refocus the groups to define an acceptable level of efficacy if biomedical strategies were to be used in conjunction with condoms were unsuccessful – again emphasizing the perspective of this particular sample as uniquely seeking an alternative to condoms.

Safety/Drug Interactions

Perhaps surprisingly, the most common safety concern cited after general “side effects,” were interactions with recreational drugs and alcohol. While it is well documented in the literature that MSM have baseline rates of drug and alcohol use which are higher than the general population, concern about interactions of an HIV prevention medication with recreational drugs and alcohol reference prior enunciated concerns about medicating feelings of guilt and/or stigma and homophobia with such substances, and also raise the specter of “planned risk taking.” Planned risk taking is particularly problematic, as it implies that risk-to-benefit balance assessments have been completed and fallen on the side of risk-taking - - in a very premeditated way, which will involve further mitigation of judgment and/or reasoning with alcohol and/or drugs. This is in notable contrast to the “unplanned risk taking” which has been documented to characterize those who access PEP, where the typical exposure candidate is someone who most often practices safer sex, and had an aberrant event – for which they are presenting for treatment.¹³ It is a charge to behavioral scientists to consider the concept of “planned risk taking” and how best to intervene on this construct.

Some participants were very sophisticated in their understanding of biomedical HIV prevention strategies, noting that the clinical, immunologic, virologic, and resistance implications of seroconverting despite biomedical prevention use would need to be carefully examined - - others raised concerns that their bodies would become “immune” to the medications. This latter, although slightly misguided in terms of biologic mechanism, demonstrates an awareness at multiple levels of understanding that there could be consequences which might impact future treatment options should seroconversion occur despite the use of such strategies.

Cost

It is not at all surprising that cost would enter into the equation for the use of biomedical prevention strategies. However, this was not mentioned as frequently as the other inputs noted above; there appeared to be an assumption that insurance would cover prescription costs and doctors' visits, as well as requisite lab tests. Some participants did raise concern that, should efficacy and safety be demonstrated, that biomedical prevention strategies be made available to all at-risk persons without regard for their ability to pay for it - - however, the majority of participants did not focus attention on cost issues as much as the study staff anticipated that they would. One potential explanation for this limited attention might be a sampling bias in that the majority of participants seemed to have adequate access to healthcare and prescription coverage (although this was not systematically assessed), and therefore was not an issue which they had been forced to navigate in other contexts. Another, more unsettling potential explanation is merely one of entitlement: that is, should biomedical prevention strategies be demonstrated safe and efficacious, then it is “someone's” responsibility to provide such treatment to at-risk populations. Further inquiry into this particular topic is warranted in future studies.

Conclusions

While there appears to be significant interest in the use of biomedical HIV prevention strategies among HIV negative MSM in Los Angeles, there are numerous barriers to further study and implementation of such interventions.

Treatment and prevention literacy remains low in high-risk populations, and HIV is not always considered of sufficient threat to warrant excessive energy expenditure to avoid.

It is only in groups in whom serious threat to health, well-being, or quality of life is perceived that prevention strategies in general appear to gain traction.

The use of biomedical prevention strategies was predominantly of interest as an alternative to condom use. In the absence of a concrete product to evaluate, hypothetical estimates of safety, efficacy, cost, availability, and tolerability make it extremely difficult for potential consumers to evaluate their enthusiasm for such a strategy.

These findings will be presented to the community at two community advisory board meetings: The UCLA Center for Clinical AIDS Research & Education CAB, and the Network for AIDS Research in Los Angeles (NARLA) CAB, both of which are open community advisory boards for their respective organizations.

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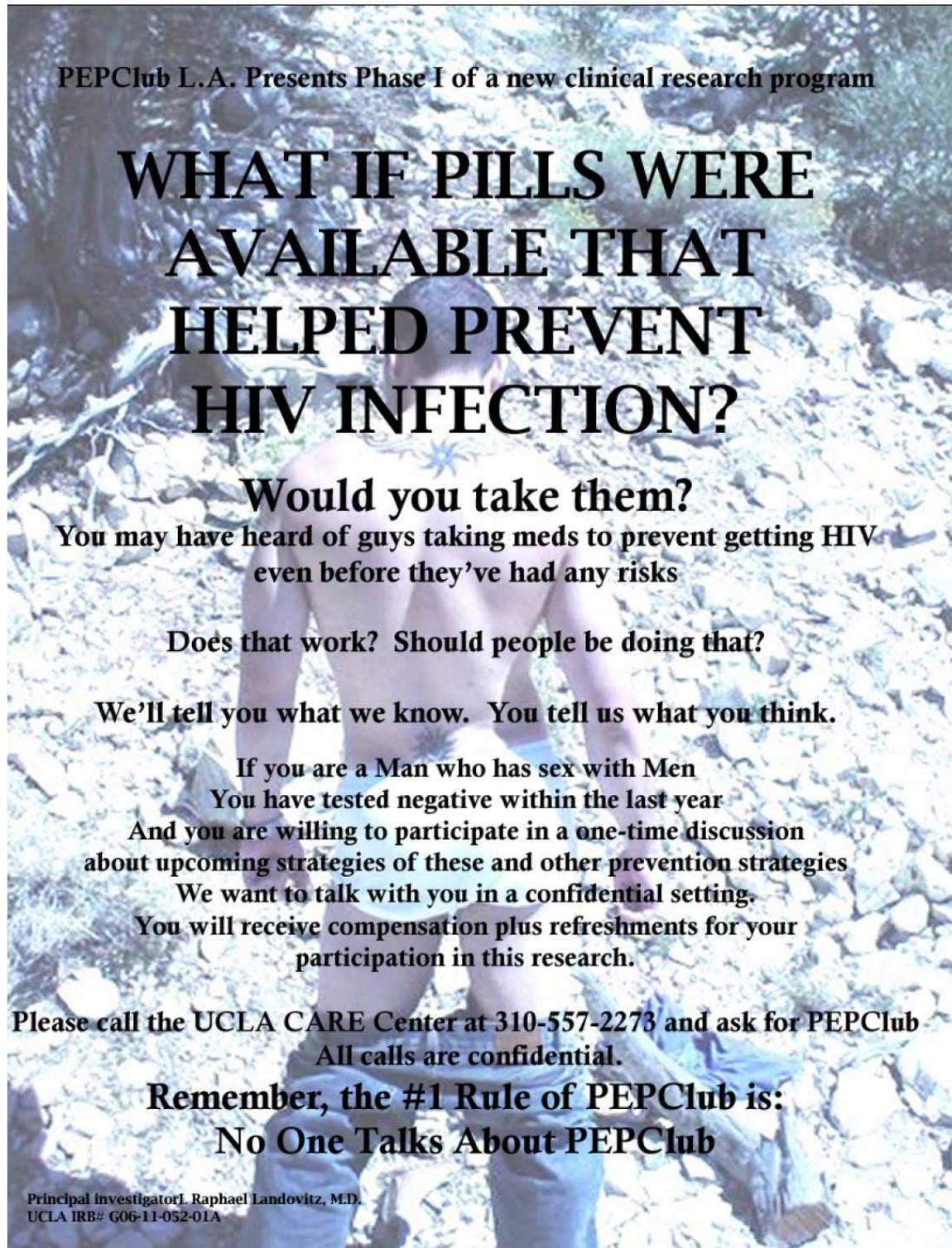
Appendix A. Focus Group Probes

- What do you or your friends know about biomedical (the use of various medical treatments like those listed below) HIV prevention?
 - Vaccines?
 - Microbicides (foams or gels inserted rectally or vaginally before sex)?
 - Pills?
- Did you know that you could take pills *after* risky sex to prevent getting HIV?
- Have you or your friends ever taken a pill either *before* or *after* sex to prevent HIV?
 - If so, which one(s)?
 - Who gave it to you?
 - How long did you take it?
 - Have you ever been offered a “one time” pill at a party or concert to prevent HIV?
- What do you think about the idea of taking HIV medicines *before* sex as a way to prevent HIV infection (PrEP)?
 - What are your main concerns?
 - (Cost, Long term toxicity, Resistance, Behaviors, Changes in the way HIV would affect you if you got infected after taking pills before? other?)
- What do you think your partner(s) would think about you taking a pill *before* sex to prevent HIV?
 - What would you think if they were taking a pill to prevent HIV?
- What do you think would happen to your willingness to take sexual risks (having sex without a condom or barrier) if you were taking a pill *before* sex that might prevent HIV?
 - Oral sex?
 - Anal sex?
 - Extreme sex? (Fisting/Watersports?)
 - Do you think it might affect your willingness to take party drugs which might make you lose control of your willingness to have risky sex?
- What do you think your peers might think about taking a pill *before* sex to prevent HIV?
 - What concerns might they have about such a prevention method?
 - Do you think it would be acceptable?
 - Would it make you or your friends less attractive as sexual partners?
 - Would you feel bad or sad if you took it?
- Who do you think might benefit most from this specific strategy of HIV prevention ?
 - Drug users?
 - Gay men?
 - Bisexual men?
 - Women who date bisexual men?
 - Women who date drug users?
 - Some or all of the above?

- Others?
- What do you think of a randomized comparative trial of PEP (taking pills *after* sex), facilitated PEP (using starter packs kept at home to start quickly *after* sex) and PrEP (taking pills continuously *before* sex), all in combination with behavioral counseling and condom provision?
 - What problems do you see?
 - Would you and/or your friends be interested in participating?
 - What would help you or your friends stay in the study?

Appendix B. Key Informant Interview Probes

- How many years have you been using HIV medications:
 - To treat HIV?
 - To prevent HIV, i.e. with Post Exposure Prophylaxis (PEP)?
- Have you talked with your patients about whether or not they or their negative partners have used HIV medications as prevention (PEP)?
 - What is the range of responses?
 - Which patients seem to be most informed about PEP?
- What is your understanding of the cost/benefit for providing HIV medications as HIV prevention?
- What are your concerns (if any) about potential adverse experiences to using HIV medications as HIV prevention
 - Cost?
 - Transmission of Resistant Virus?
 - Toxicity?
 - How much follow-up would you want before you considered the safety database adequate?
 - Would an outcome registry similar to the Pregnancy Registry be helpful?
 - Encouraging risky behavior?
 - Efficacy?
 - What sort of data would you want to see before implementing this?
 - What if that data were not available?
 - What if that data were NEVER going to be available?
- What sorts of issues would you and/or clinicians in your medical group would be concerned about if you were to provide HIV medications to high-risk negative individuals as HIV prevention?
- How would you suggest making these interventions available to MSM and MSM/W or heterosexual women who are from communities usually excluded from access to cutting edge medical treatments (if you feel comfortable providing this care at all)?
 - What sites would you use to provide the care?
 - Are there individuals who should be consulted within these communities (e.g., key opinion person) who can provide support to providing this type of HIV prevention to these communities?
 - Who should fund this?
- How long do you think is a reasonable period for continuing HIV medications using PrEP?
- What do you believe will happen to the risk behaviors of those who receive biomedical HIV prevention using PrEP?
- What sort of behavioral counseling do you think would be appropriate for this intervention?
 - Should behavioral counseling be an obligatory part of PEP or PrEP?
- What laboratory monitoring should be included in someone on PrEP?
 - At what intervals?
 - Who should fund this, if the patient is uninsured?
- What do you think of a randomized comparison of PEP, Facilitated PEP (with starter packs), and PrEP, looking at behavioral outcomes?
 - Do you see any barriers to implementing such a trial?
 - Who do you think would be most interested in participating?
 - What can be done to maximize retention?
 - What locations do you think would be best in recruiting for such a trial?



PEPClub L.A. Presents Phase I of a new clinical research program

WHAT IF PILLS WERE AVAILABLE THAT HELPED PREVENT HIV INFECTION?

Would you take them?
You may have heard of guys taking meds to prevent getting HIV
even before they've had any risks

Does that work? Should people be doing that?

We'll tell you what we know. You tell us what you think.

**If you are a Man who has sex with Men
You have tested negative within the last year
And you are willing to participate in a one-time discussion
about upcoming strategies of these and other prevention strategies
We want to talk with you in a confidential setting.
You will receive compensation plus refreshments for your
participation in this research.**

**Please call the UCLA CARE Center at 310-557-2273 and ask for PEPClub
All calls are confidential.**

**Remember, the #1 Rule of PEPClub is:
No One Talks About PEPClub**

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