Evaluation of the Acceptance of Patient-Delivered Partner-Therapy for Incubating Syphilis Among Men who have Sex with Men in San Francisco, CA

April 2, 2004

EXECUTIVE SUMMARY

Background

The purpose of the evaluation reported here was to determine barriers and facilitators to the acceptance of patient-delivered partner therapy (PDT) for incubating syphilis in the San Francisco City STD Clinic (SFCC) from the perspective of patients, Disease Control Investigators (DCI), community leaders, and private medical providers who see a high volume of syphilis cases in San Francisco. A secondary objective was to assess the feasibility of the provision of PDT by private providers. The evaluation was conducted by Cathleen Walsh (Senior Health Scientist) and Waimar Tun (EIS Officer) from the Health Services Research and Evaluation Branch of the Division of STD Prevention (CDC, Atlanta) in July, 2003.

Early syphilis cases have increased dramatically in San Francisco since 1998. In order to control the syphilis epidemic among men who have sex with men (MSM), the San Francisco Department of Public Health (SFDPH) introduced an additional intervention ("Syphilis Partner Packs", referred to in this report as 'PDT packs') at the SFCC where many of the syphilis cases have been identified. The PDT packs are offered to the syphilis-infected patient to be given to his sex partner(s) and to his network of social contacts. The packs include patient education material on syphilis, information on where to seek medical care, if warranted, condoms, and a 1 gram dose of azithromycin, a prophylactic drug used to treat incubating syphilis infection in exposed partners. This prophylactic drug has been recommended by San Francisco's Infectious Disease Society as a means to prevent syphilis transmission in an epidemic situation. The PDT packs are not meant to replace the need for clinical evaluation and syphilis testing. The pack functions to speed the delivery of treatment for incubating syphilis to those who may not seek care in a timely manner, or to those who may not access care.

Since the intervention's inception in July 2002, the PDT packs have had low acceptance by patients (approximately 10%) but the reasons for low acceptance are not clear. Hence, the objective of the evaluation was to determine the reasons for low acceptance and to identify ways to increase the acceptance if SFDPH decides to continue the program. Additionally, given that private providers diagnose and treat over 50% of the early syphilis patients in San Francisco, a secondary objective of the evaluation was to determine the feasibility of the provision of PDT packs by private providers in San Francisco.

In consultation with staff at SFDPH and SFCC, the evaluation team developed a protocol to conduct focus groups (FG) with syphilis-case patients, sex partners and social contacts of syphilis-case patients and sex partners, and key informant interviews with DCIs at SFCC, community leaders involved with gay/bi-sexual health in San Francisco and private medical providers who see a high volume of syphilis patients in San Francisco. Focus group participants were asked about their views on barriers to and facilitators of acceptance of the PDT packs. To protect the confidentiality of focus group

participants, all questions regarding PDT were posed in a hypothetical fashion so as not to reveal the syphilis infection and exposure status of the focus group participants to each other. The focus group sessions were conducted by Better World Advertising and key informant interviews were conducted by the CDC team between July 1 and 11, 2003.

MAJOR FINDINGS AND RECOMMENDATIONS

The findings from the evaluation suggest that while there are many individual and community level barriers to the acceptance of PDT by the high-risk MSM community and the medical community, there are ways to improve its acceptance. The evaluation revealed important barriers to and facilitators of the acceptance of PDT by MSM that were related to i) syphilis-case patients', sex partners', and social contacts' perceptions of PDT and syphilis, ii) the nature of the relationship between case-patients and sex partners, iii) the method of PDT pack delivery at SFCC, iv) social responsibility, v) the packaging and contents of PDT packs, vi) the potential for increased high-risk sexual behaviors, vii) the pharmacological features of azithromycin, and viii) the importance of clinical evaluation. Key informant interviews with private providers regarding barriers to the provision of PDT in the private provider setting revealed barriers relating to i) medical liability and responsibility, ii) the lack of financial benefit for their health plans, and iii) the missed opportunity for a clinical evaluation if PDT is offered to sex partners.

Major findings from interviews with case patients, sex partners and social contacts, community leaders, DCIs, and private providers regarding the acceptance of PDT by case patients, sex partners and social contacts included the following:

1. A few sex partner focus group participants mentioned that the novelty of the concept of bringing medications to sex partners would make it difficult to offer the PDT packs to others. These participants indicated that they would be more likely to take the PDT packs for their sex partners if they had learned of this intervention from a credible source or if they knew others who had used the PDT packs.

2. A few community leaders and private providers indicated that community norms of being concerned about sex partners' health and taking responsibility for high-risk behaviors are lacking in the MSM community. They felt that this kind of thinking would be needed to increase acceptance of PDT.

3. A few community leaders felt that endorsement of the PDT intervention by recognized medical sources was lacking. They expressed that because of PDT's novelty, the MSM community would be more accepting of the intervention if it were to be supported by an entity that MSM deem credible, such as the Gay/Lesbian Medical Association.

4. Some DCIs, private providers, and community leaders felt that there was a lack of consistency in the messages regarding the benefits and value of PDT coming from clinicians, public health personnel, and community leaders regarding the value of

PDT. Some felt that hearing inconsistent messages about PDT from these groups made it more difficult to promote PDT.

5. A few private providers indicated that implementing the PDT intervention alone may not be enough to control the syphilis epidemic. They felt that PDT must be part of a comprehensive STD prevention program for it to be successful.

6. A few case patient, sex partner, and social contact focus group participants indicated that their attitudes towards and feelings for their sex partners would influence their willingness to offer PDT to sex partners. Participants indicated that they would be less willing to give PDT to sex partners that they do not personally care about, know well, trust, or partners they are not emotionally close to.

7. Some of the social contact focus group participants expressed concerns about negative repercussions of informing their sex partners of syphilis and offering medication. They fear the sex partner may get angry or blame and accuse them of transmitting syphilis.

8. Many case patient, sex partner, and social contact focus group participants indicated PDT packs would be difficult to deliver to sex partner due to the anonymity of many sex partners. Given this social environment where high-risk sexually active MSM do not know even the basic identifying information such as name, phone number, or address of their sex partners, they would not know how to contact their sex partners to deliver the packs.

9. Social responsibility was mentioned by some participants of the case patient and sex partner focus groups as a factor that would compel them to give PDT to recent sex partners. They felt that it was "the right thing to do".

10. Many of the community leaders, case patients and sex partners felt that there was more stigma around syphilis than around HIV, which may make it more difficult for patients to approach sex partners about syphilis and PDT. While there may be more fear around HIV than syphilis, many felt the stigma was greater for syphilis.

11. Some private providers indicated that the urgency of the syphilis epidemic does call for creative interventions such as PDT, even though the PDT intervention may not be ideal. They indicated that although there may be some negative consequences of such an intervention, they see that the PDT pack intervention is one of multiple interventions that SFDPH is trying in dealing with an emergency public health situation.

12. Some case patient and sex partner focus group participants firmly believed that only health care providers should dispense medications to people. Although the PDT is being given out by health care professionals to the patients, many still felt that it was not appropriate for non-healthcare providers to offer medications to others, when they do not know the health status and history of the PDT recipients.

13. Some case patients and sex partners indicated that awareness of the PDT pack option at the beginning of the clinic visit may facilitate acceptance of the PDT packs. They expressed that learning about the option would allow them to think it over more carefully.

14. Some of the sex partner and social contact FG participants, as well as some private providers, community leaders and DCIs expressed concern that the PDT packs may prevent PDT recipients from seeing a healthcare provider for clinical evaluation and syphilis testing. They felt that the packs may make it too convenient for PDT recipients to not seek care.

15. A few case-patients and sex partners from the focus groups, as well as some private providers and community leaders indicated that the PDT packs may reach some sex partners who may not otherwise seek healthcare for a variety of reasons, including lack of health insurance, lack of time, and embarrassment about STDs.

16. The majority of the private providers, community leaders and DCIs pointed to some of the positive features of azithromycin that would facilitate acceptance of the PDT packs: single-dose, safe, and well-tolerated.

17. Some participants from all three focus groups indicated they may not trust the legitimacy of the medication packet. Some of the features they indicated would be necessary for their acceptance include a tamper-resistant, official and professional looking package with contact information to verify the integrity of the packet.

18. Nearly all focus group participants indicated a need for some critical information to be contained in the PDT packages in order to feel comfortable giving them to sex partners. They would want information regarding syphilis disease, and the medication, including side effects and contraindications. They also wanted additional resources such as contact numbers for questions and answers and for emergency, and website addresses for more information.

19. Some private providers, DCIs and sex partner focus group participants expressed concerns about PDT intervention promoting promiscuity and high-risk sexual behaviors. They felt that the packs may promote the idea that syphilis is easy to treat.

20. Another related concern expressed by some DCIs, case patients, and sex partners was the unintended consequence of hoarding of medication by case-patients for their own use before the next time they have unprotected sex. They were concerned that some people may either ask for extra PDT packs, or keep the ones they took from SFCC rather than give the packs to their sex partners.

Major findings from in-depth interviews with private medical providers regarding the acceptability of providing PDT in the private practice setting to their patients included the following:

1. The primary concerns of PDT delivery in the private practice setting that the majority of private providers expressed was the potential legal liability of treating someone whom providers have not clinically evaluated was identified as a major barrier to delivering PDT in the private provider setting. Private providers expressed concern about providing treatment for someone whose medical history they do not know because of the potential adverse drug reactions, in particular allergic drug reactions and interaction with other medications. In addition to the legal responsibility, most of the private providers expressed concern about the medical responsibility of the sex partners once he takes the medication. Some felt that it was unclear who was responsible for the medical care of the sex partner, and others felt that the sex partner becomes their responsibility once the sex partner takes the medicine that originated from the provider's office.

2. Some private providers expressed concern about their provision of PDT not being in the health plan's (or their practice's) financial interest. From a purely business perspective, they felt there was no benefit to their plan or practice because of the cost of the medication, cost (time and money) of treating people who are not their patients, and other associated costs.

3. Some providers were concerned that they would miss the opportunity to clinically evaluate potentially infected sex partners if PDT were implemented in their practice. Providers were concerned that sex partners would not seek care and be clinically managed for other STDs.

4. A few providers expressed concern about under-treatment of sex partners. They were concerned about sex partners who may already have active disease since 1 gram of azithromycin will not treat those who are already infected with syphilis.

RECOMMENDATIONS

If SFCC wishes to continue the PDT program, they may wish to consider the following individual and community level interventions to increase acceptance among MSM syphilis patients, sex partners and social contacts:

1. Community Awareness Campaign

A community-wide campaign to raise the awareness of PDT for syphilis prevention is a critical component to i) increasing the legitimacy of and trust in the PDT packs, ii) facilitating discussions around syphilis and PDT packs, iii) changing the community norm to being responsible for the health of the community.

2. Private Provider Education

This would be critical to better inform providers of the pros and cons of PDT, regardless of whether providers were to offer PDT packs in their own practice or simply refer their patients to SFCC for the PDT packs. Additionally, providers will need to be well-informed about the PDT packs as PDT recipients may call their private providers with questions regarding the PDT packs.

3. Public Health Personnel Education

To help prevent inconsistencies in the messages coming out from physicians, public health personnel and community leaders regarding the value of PDT, it may help to review the rationale, process and implementation for this intervention with organizations and interested personnel in an attempt to generate support.

4. Patient Counseling

Patient counseling on PDT by DCIs should specifically address barriers including credibility and liability issues, and fear of negative repercussions from sex partners. Additionally, the facilitating concepts and perceptions of social responsibility, having the opportunity to offer a solution to a problem, clearing one's conscience, and having high regard for people who do notify their partners may be effective in developing counseling messages that DCIs can employ during their counseling sessions with the patients.

5. Packaging and Contents of PDT Packs

To reduce the suspicion and increase the legitimacy of the PDT packs, the packs should be tamper-resistant, official looking, and professionally packaged. It will also be important to ensure that the advertising in the community accurately represents packages given out at the Clinic.

6. Provision of PDT at SFCC

While DCIs should continue to be responsible for the comprehensive discussion of PDT at the end of the visit, it may be valuable to have PDT mentioned throughout the patient's visit to the City Clinic. Posters and pamphlets about PDT for syphilis should be made available in the waiting room.

7. Clinical Evaluation and Testing

Given the importance of getting a clinical evaluation and syphilis test done for sex partners, regardless of whether one takes the azithromycin in the PDT packs, there should be easier access for the evaluation and testing. Case-patients should be given information about the availability of the new on-line syphilis testing program so that they can tell PDT recipients to access it in case they may be interested (http://www.dph.sf.ca.us/sfcityclinic/syphilistesting/). The City Clinic may want to consider having a 'Fast Lane,' where exposed sex partners attending the clinic can come in just for a syphilis test rather than spending hours at the clinic for a complete evaluation.

8. SFCC Staff Training and Involvement

All staff at the City Clinic should be well-informed about the PDT packs to be equipped to answer questions patients at the clinic or persons who call on the phone may

have. It will be important to have a consistent message being conveyed to the community. DCIs should be involved in any changes to the PDT protocol since they have significant insight into barriers and facilitators of PDT from the perspective of the patients and their sex partners.

Recommendations regarding PDT provision in the private practice setting

The following recommendations should be considered by SFDPH if SFDPH is interested in having private providers offer PDT in their practice to their patients.

1. Resolution of legal issues

If it is clear that the risks do outweigh the benefits of PDT packs, then it may be useful to consider bringing together a group of lawyers specializing in medical malpractice (medical legal experts) to discuss possible ways to protect private providers against negative legal consequences.

2. Resolution of financial issues

In order to know if there are financial benefits for health plans or not, some economic data and analyses would be required (i.e., direct and indirect costs of untreated syphilis, complications from syphilis, cost of packs, savings from prevention of syphilis in health plan's members, etc…) and the pros and cons would have to be weighed. Additionally, SFDPH may want to consider subsidizing for the cost of lab test and/or medications.

3. Private provider education

A private provider education campaign would be extremely important to increase private provider support for implementing this intervention in their practice.

In summary, we identified barriers to patients', sex partners' and social contacts' acceptance of PDT that were related to i) their perceptions of PDT and syphilis, ii) the nature of the relationship between case-patients and sex partners, iii) the method of PDT pack delivery at SFCC, iv) social responsibility, v) the packaging and contents of PDT packs, vi) the potential for increased high-risk sexual behaviors, and vii) the importance of clinical evaluation. However, if SFCC wishes to continue the PDT program, they may wish to consider individual and community level interventions to overcome these barriers. The following sections provide details of the above findings with suggested recommendations.

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Evaluation of the Acceptance of Patient-Delivered Partner-Therapy for Syphilis, San Francisco, CA

INTRODUCTION

San Francisco has experienced recent increases in early syphilis (primary, secondary and early latent), from 41 cases in 1998 to 525 cases in 2003. The increase in cases was especially dramatic in the past two years, with increases of 160% from 2000 to 2001 and 167% from 2001 to 2002. Over three-quarter of early syphilis cases occurred among men who have sex with men (MSM) since 1999, and the majority (60%) of these cases are among MSM who are also HIV-infected. Most of the case-patients acquired their infection through sex with multiple anonymous sex partners, including partner they met through the internet, at sex clubs and large parties where sex with many anonymous partners occur. One of the traditional pillars of syphilis control has been partner management, which includes partner elicitation, contact tracing and partner notification and rapid evaluation and treatment of recent sex partners by health department staff. Between July 2002 and March 2003, approximately 4,500 sex partners were reported by 399 case patients with early syphilis. However, case patients were able to supply contact information for only 12% of the reported sex partners. With the high number of sex partners and the anonymity of sex partners, innovative new strategies to provide treatment for sex partners were necessary to control the growing epidemic.

In order to increase the number of exposed sex partners who receive prophylaxis to prevent the development of active syphilis infection, the San Francisco Department of Public Health (SFDPH) added patient-delivered partner therapy (PDT) intervention ("syphilis partner packs") at the San Francisco City STD Clinic (SFCC), where many of the syphilis cases have been identified. This strategy was initiated after consultation with and support of infectious disease experts at the University of California in San Francisco as an emergency epidemic control measure, and is endorsed by the San Francisco Infectious Disease Society. Note that while California statute permits Chlamydia-infected patients to deliver therapy to their sex partners, there is no such statute for syphilis.

The traditional partner management services continued to be offered in conjunction with the PDT intervention. The partner packs are offered to syphilis-infected patients to be given to their sex partner(s) or social contacts who are at high-risk of syphilis exposure. The partner packs include patient education material on syphilis, information on where to seek medical care, condoms, and a 1 gram powder sachet dose of azithromycin, a prophylactic drug used to prevent incubating syphilis infection in exposed partners, directions for taking azithromycin, and information on safety and side effects of the drug; the contents are packaged in an informal brown paper bag. *[See Appendix 1A-1C for patient education material contained in PDT packs.]* The PDT packs are not meant to replace the need for clinical evaluation and syphilis testing. The

pack functions to speed the delivery of treatment for incubating syphilis to those who may not seek care in a timely manner, or to those who may not access care.

The use of 1 gram azithromycin prophylactic drug is supported by the Division of Infectious Diseases at the San Francisco General Hospital as a means to avert the development of syphilis in exposed persons ("incubating syphilis") and thus, prevent syphilis transmission in an epidemic situation. This recommendation was based on data from a published clinical study showing that a 1 gram dose of azithromycin was highly effective in prophylaxis of syphilis in exposed partners.[1] While there is evidence that suggests 2 grams of azithromycin is efficacious in treating primary and secondary syphilis [2], there is no evidence that a 1-gram dose would be sufficient to treat early syphilis. A recent study has also shown that azithromycin delivered in the "field" is a more cost –effective method for managing exposed sex partners than is traditional partner management. [3]

Since the intervention's inception in July 2002, the partner packs have had low acceptance rates by patients (approximately 10%) but the reasons for low acceptance are not clear. During a recent assessment of the programmatic response to the syphilis epidemic of MSM in San Francisco, the SFDPH STD Program Director requested an evaluation of the syphilis partner pack program. Cathleen Walsh (Senior Health Scientist) and Waimar Tun (EIS Officer) from the Health Services Research and Evaluation Branch of the Division of STD Prevention conducted this evaluation in response to that request.

METHODS

The CDC evaluation team made an assessment trip, which included a visit to the SFDPH to meet with key staff involved with PDT program, and SFCC to meet with clinicians, and DCIs. The purpose of the pre-evaluation assessment was to gather initial background information, determine the focus of the evaluation, determine the needs of the stakeholders with regard to the evaluation, and initiate the development of a protocol for the evaluation. The initial assessment also included observation of clinic flow at SFCC and the development of a logic model for the PDT intervention, which served as a tool for the program evaluators to help identify the various activities involved in the implementation of the PDT intervention, and how they are related to the goal of PDT. *[See Appendix 2 for logic model.]*

To identify barriers and facilitators of the acceptance of patient-delivered partner therapy (PDT) by case-patients, sex partners and social contacts, the evaluation utilized a non-experimental approach, using qualitative methods to collect data. Data collection involved focus group sessions with syphilis-case patients, sex partners and social contacts of syphilis-case patients, and in-depth, semi-structured individual interviews with disease control investigators at SFCC, community leaders involved with gay/bi-sexual health in San Francisco and private medical providers who see a high volume of syphilis patients in San Francisco.

Three focus groups, each consisting of 5-9 participants of MSM, were conducted: 1) Syphilis case-patients attending SFCC; 2) Sex partners of case-patients; and 3) Social contacts of case-patients and sex partners. For the recruitment of case-patients, all MSM diagnosed with syphilis at the SFCC and patients who were diagnosed by private providers and contacted by DCIs in June 2003 were asked to participate in the focus groups by the DCIs at the end of the counseling session. For the recruitment of sex partners, all MSM who were referred to come into SFCC by their sex partners or sex partners who were identified by an original case patient and contacted by DCIs in June were recruited to participate. Additionally, case-patients diagnosed with syphilis in May 2003 and sex partners contacted by DCIs in May 2003 were recruited by telephone by a DCI; they were selected by the DCI from a list of patients diagnosed with syphilis and sex partners of original case-patients seen in May, starting with the most recent date. For the recruitment of social contacts, case-patients and sex partners interviewed by DCIs in June were given a flyer about participation in the focus groups and asked to recruit their social contacts (not sex partners) for the focus groups. All participants for the focus groups had to be sexually active MSM. DCIs were aware of the sexual behaviors of case-patients and sex partners from the partner elicitation interviews. When focus group participants were recruited, they were told that they were being recruited to discuss a new program to control STDs in San Francisco; there was no mention of syphilis or PDT. [Note that case-patients and sex partners should have been offered PDT packs by the DCIs.] Focus group moderator's guide was developed jointly by the CDC evaluation team, SFDPH staff and Better World Advertising, who conducted the focus group sessions.

The purpose of the focus group sessions was to elicit views on barriers to and facilitators of acceptance of the PDT packs. Questions were related to their knowledge of syphilis, attitudes toward PDT, reasons for accepting or refusing PDT if they were offered PDT and views on the packaging and content of the PDT packs. All questions regarding PDT were posed in a hypothetical fashion so as not to reveal the syphilis infection and exposure status, or familiarity with PDT of the focus group participants. For example, questions regarding PDT were introduced as *"Imagine that you have just been diagnosed with syphilis, and you are at the SF DPH City Clinic…"* The questionnaires for all three focus groups were identical in order to protect the confidentiality of focus group participants.

The focus group sessions were held during the evenings of July 1-2 at Consumer Research Social, a private facility designed for focus group sessions. Each session lasted approximately 2 hours and focus group participants were reimbursed $70 for their participation. Sessions were audio-taped, of which the participants were informed, and participants signed a consent form at the beginning of the session.

Five of the six DCIs at SFCC were available for interview. To recruit community leaders, SFDPH provided a list of community leaders and 5 out of 11 were available for interviews. These community leaders were selected by SFDPH as they have worked with these community leaders and their affiliated community-based organizations on MSM

STD-related issues. Community leaders were selected for participation in the evaluation based on their availability.

Given that private providers diagnose and treat over 50% of syphilis cases in San Francisco, it was important to understand their perspectives on barriers and facilitators of the acceptance of PDT. Additionally, SFDPH wanted to learn the concerns private providers had regarding the implementation of PDT in the private practice setting, in the event that they ask private providers to participate in the provision of PDT packs. We interviewed 9 private providers, who were selected from a list of 20 providers that reported the highest number of syphilis cases in 2002. While these providers do not exclusively treat MSM, the patient population they serve is primarily MSM.

Separate questionnaires were developed by the CDC evaluation team for in-depth interviews with the community leaders, DCIs and private providers. Questions were related to barriers to and facilitators of the acceptance of the PDT intervention. Private providers were asked additional questions regarding the delivery of PDT in the private practice setting. Interviews lasted approximately 1 hour. [See Appendices 2-5 for questionnaires.]

All focus group sessions and key informant interviews were transcribed. The CDC team reviewed the transcripts and developed codes and sub-codes for major themes. Transcripts were manually coded and themes were abstracted from the interviews by an analyst.

FINDINGS

ACCEPTANCE OF PDT BY PATIENTS, SEX PARTNERS AND SOCIAL CONTACTS

The following are findings from focus group (FG) interviews with case-patients, their sex partners and social contacts, and in-depth interviews with DCIs, private providers, and community leaders regarding barriers and facilitators to the acceptance of PDT packs by case-patients, sex partners and social contacts. This section is organized by major themes: i) perception of PDT, ii) nature of relationship between case-patient and his sex partners, iii) social responsibility, iv) perception of syphilis, v) method of PDT provision at SFCC, vi) importance of clinical evaluation, vii) pharmacological features of azithromycin, viii) packaging and contents of PDT packs, and ix) potential to promote high-risk sexual behaviors.

Perception of PDT

1. **A few sex partner FG participants mentioned that the novelty of the concept of bringing medications to sex partners would make it difficult to offer the PDT packs to others.** These participants indicated that they would be more likely to take the PDT packs for their sex partners if they had learned of this intervention from a credible source or if they knew others who had used the PDT packs.

   "It's weird enough to have someone tell you "Guess what, I might have exposed you to syphilis." It's another thing for them to go "I've got this thing [PDT pack] here, I'm connected." It's a little strange." [Sex Partner 1]
   "Anything new at first could be." [Sex Partner 2]

   "I'd be questioning first, when did they [the health department] start this [offering PDT]?" [Sex Partner]

   "If this was something that was FDA approved or something that was new I probably still would go to my healthcare professional…she would have all the information." [Sex Partner]

2. **A few community leaders and private providers indicated that community norms of being concerned about sex partners' health and taking responsibility for high-risk behaviors are lacking in the MSM community.** Community leaders and private providers did not feel that this kind of thinking was part of the mindset of MSM engaging in high-risk behaviors and they felt that such community norms may be needed to increase acceptance of PDT.

   "I think the bigger picture…is to have a shift in the community norm around gay men taking care of each other and their partners. Then we use that message - a sound bite…it's to get the community to take care of,

first, to care about yourself enough to take care of your body…then to care about your sexual partners enough then to care about the community enough." [Community Leader]

"It encourages a sort of sense of responsibility for people…it sort of gets people in a different mindset that there's a long term communication that's important…in the long term, people will start thinking about this and say 'Maybe I should get your name and number just in case something comes up.'…They try to be responsible. They just need some options for what that means." [Private Provider]

"If it is a fully globalized integrated program of buddy packs, education, and population awareness, yes, I mean 20 years ago we didn't think we could do it with HIV. I mean how would you change people's basic sexual response? And we created the safe sex guidelines... kind of a household icon. Ask anybody, what's safer sex? Oh, then up comes a condom." [Private Provider]

3. **A few community leaders felt that endorsement of the PDT intervention by recognized medical sources was lacking.** They expressed that because PDT is an unusual and new intervention, in order to increase the credibility of the intervention and consequently improving the acceptance by MSM, the MSM community would feel more comfortable with the intervention if it were to be supported by an entity that MSM deem credible, such as the Gay/Lesbian Medical Association.

4. **Some DCIs, private providers, and community leaders felt that there was a lack of consistency in the messages regarding the benefits and value of PDT coming from clinicians, public health personnel, and community leaders regarding the value of PDT.** Some felt that hearing inconsistent messages from these groups about PDT made it more difficult to promote PDT. There seems to be uncertainty among these groups about the effectiveness of the dose of azithromycin used, as well as uncertainty about the effectiveness of the PDT intervention.

   "Even among doctors, private providers, they are unsure about the effectiveness of the medicine. So they're not really completely on board when it comes to giving zithromax [azithromycin] as a partner pack. If the doctors…the medical community really wants this to be successful, you really need to get them on board. Otherwise, you're just fighting." [DCI]

   "…the State of California STD branch isn't really excited about those packets and …the city people are big proponents of it and the state people say it doesn't work. So the average person in the street hopefully is not hearing that debate…I think that state staff is not really saying it doesn't work, they're just saying it's not enough." [Community Leader]

"My other big problem is that…there's difference of opinion [among public health practitioners] as to the efficacy and the risk. The more that's publicly done, the more challenging it is for people to hear a clear message." [Community Leader]

The inconsistency in message was illustrated by the fact that some of the private providers did indicate that there were a number of medical and economic issues regarding PDT that were either unresolved or that they were lacking knowledge in, resulting in their hesitation in fully promoting PDT to their patients. These include the potential for the development of antibiotic resistance at the individual and community level, efficacy of 1 gram versus 2 grams azithromycin for incubating syphilis, under-treatment of already-infected sex partners, effectiveness of PDT as a disease control strategy, and the cost and cost-effectiveness of the intervention.

"The other thing that I don't know much about … is azithromycin resistance in the community. There's about 30% now documented in the city…I think it's strep pneumo, that is resistant to azithromycin, and that's because of our use… overuse… So I don't know what 1 gram of azithromycin does to increase that number but it's already certainly an alarming number." [Private Provider]

"If they are already late, then they've already gone past their primary and secondary…So is a person like that better off getting half treated or no treatment for syphilis? That's a real important question that would be worth knowing, and therefore maybe the question is whether we should be treating with 2 grams." [Private Provider]

"My concern is the missing of people who have active disease…They're thinking that they are adequately treated and they never get medical attention. Of course, chances are, those people weren't going to get medical attention anyway." [Private Provider]

"I'm just wondering if it's economically feasible…The cost certainly is an issue when we have budget problems galore here." [Private Provider]

Some providers indicated that provider education would be critical in making PDT more acceptable to their patients, as well as to providers themselves. The more informed private providers are about the intervention, the better they will be able to present it to their patients and counsel them about it.

"I think number one, you have to be convinced that the physician knows what the pros and cons of it is. So that has to be worked out. And you have to transmit that to the patients and then the patient has to be convinced that it's the right thing to do… there's a lot of education that has to happen. You can't just say take this and give this to your partner." [Private Provider]

5. **A few private providers indicated that implementing the PDT intervention alone may not be enough to control the syphilis epidemic.** They felt that PDT must be part of a comprehensive STD prevention program for it to be successful. They felt that the PDT intervention should occur in conjunction with other educational and counseling interventions, both at the community and individual levels.

   "I think it's anything we can do to decrease this [syphilis epidemic], I think, is great, because I know that it's in conjunction with other educational, interventional kind of harm reduction approaches." [Private Provider]

   "If it is a fully globalized integrated program of buddy packs [PDT packs], education, and population awareness, yes [it could control the epidemic]." [Private Provider]

Nature of Relationship between case-patients and sex partners

6. **A few participants from all three FG indicated that their attitudes towards and feelings for their sex partners would influence their willingness to offer PDT to sex partners.** Participants indicated that they would be less willing to give PDT to sex partners that they do not personally care about, know well, trust, or partners they are not emotionally close to. Some FG participants indicated that they have sex partners with whom they have little to no emotional investment and attachment. They are less comfortable approaching a partner about a potential syphilis infection and offering PDT to them if they do not know the partner well enough. For example, they indicated they would offer PDT to their boyfriends but not to sex partners with whom they do not have a close relationship because they feel less responsibility towards the latter sex partners to inform them of potential syphilis exposure and offer PDT to them.

   "I think it's probably easier to give it [the PDT pack] to people you know and trust. The less you know your partners the less you trust them, the less likely you are to give it to the person and the less well-received it would be by the recipient." [Sex Partner]

   "If it's your boyfriend, really that will be clear and you will take it home to your boyfriend." [Sex Partner]

   "If it's a one night stand, you probably don't know that person good enough to go there. You would probably give City Clinic their phone number and have somebody else contact that person. I do believe that if you feel comfortable with the person you had sex with, you'd probably do that – bring them a pack." [Case Patient]

"I really wouldn't be comfortable taking it or giving it to anyone except my boyfriend. Literally just the one person." [Sex Partner]

"I guess it depends on who the person is. I don't give a damn if it's Joe Blow or whatever, but if it's somebody that I actually care about, yes, I would bring it to them." [Social Contact]

7. **Some participants in the social contacts FG expressed concerns about negative repercussions of informing their sex partners of syphilis and offering medication.** They fear the sex partner may get angry or blame and accuse them of transmitting syphilis. Some FG participants said they themselves have gotten angry when they were informed by a sex partner about a possible syphilis exposure and some have also experienced partners getting angry at them and blaming them.

"I've had people that I was really surprised get really pissed off." [Social Contact]

"They [sex partners] could be grateful but also get mad about it." [Social Contact]

"…if you do know their names and they find out that you've given it, most people get angry." [Social Contact]

"I'd get pissed…" [Social Contact 1]
"Pissed at what?" [Social Contact 2]
"That they gave it to me." [Social Contact 1]

8. **Many participants from all three FGs indicated PDT packs would be difficult to deliver to sex partner due to the anonymity of many sex partners.** Given this social environment where high-risk sexually active MSM do not know even the basic identifying information such as name, phone number, or address of their sex partners, they do not know how to contact their sex partners to deliver the packs.

"There's also plenty of people out there who sleep with people and don't know how to contact them afterwards." [Sex Partner]

"I've been with a guy for a few years and I'm still not sure what his name is, so how am I going to call him?" [Social Contact]

"There's also that little group orgy thing, where you're invited and there's 6 or 7 other guys. I don't have any way to reach them." [Social Contact]

<u>Social Responsibility</u>

9. **Social responsibility was mentioned by some participants of the patients and sex partner focus groups as a factor that would compel them to give PDT to recent**

sex partners. They felt that it was "the right thing to do" and that it was a social obligation.

> *"I think that's a cop out. You know their phone number and their name, and you don't call them yourself – you're just not being a man about it." [Case Patient]*

> *"I feel obliged to tell [my] partners…It's a social obligation. Human concern and it's for your own peace of mind. You want to make sure that it [the disease] doesn't repeat." [Case Patient]*

> *"I would do it for many reasons…If you give it [syphilis] to the person, you kind of feel guilty and you want to try to make it as easy for others as possible." [Case Patient]*

Some sex partners FG participants also mentioned that telling their sex partners about their possible infection and about PDT allowed them to clear their conscience -- they possibly gave something that was harmful to the partner, i.e., infection with syphilis, and the PDT is an opportunity for them to offer a solution.

> *"If there's a potentially easy way to cure it, then why not dispense it." [Sex Partner]*

> *"I potentially have dispensed syphilis to others so it might be nice to potentially dispense a cure also and then let people take it from there. But at least my conscience is clean." [Sex Partner]*

Further, many of the sex partner FG participants expressed respect for those who do contact and inform their sex partners about their potential exposure to syphilis. Some of the participants in the sex partner focus groups who had been contacted by their recent sex partners telling them of their potential exposure did express how grateful they were when they were the ones contacted and told by their partners of their exposure to syphilis. Many expressed how much they respected the people that contacted them.

> *"I've been called by men that I came across. They called me themselves and I kind of respected that actually." [Sex Partner]*

> *"I was so grateful to the person that notified me…I said 'Thank you! Thank you so much. You have no idea. I'm so happy to hear that.' I would much rather hear that than never hear anything." [Sex Partner]*

> *"I would appreciate being told if they had it so I could go get checked out." [Social contact]*

"I'm thankful to the guy that called me…he was responsible and kind enough to call me to let me know." [Sex Partner]

Perception of Syphilis

10. **Many of the community leaders, case patients and sex partners felt that there was more stigma around syphilis than around HIV, which may make it more difficult for patients to approach sex partners about syphilis and PDT.** While there may be more fear around HIV than syphilis, given that HIV is a more serious disease, and lacks a cure, many felt the stigma was greater for syphilis. Some of the case patients and sex partners indicated that there may be more stigma with syphilis because it is visible.

"I think there's a culture around being HIV positive that doesn't exist around having syphilis, that there's been historical, political and cultural activism around being HIV positive so that…stigma is tempered by the services that are available…you know there is a community of support around being HIV positive. I think having syphilis…I think it denotes…it's like dirty…I think people see that as that you're really being slutty, that you're somehow unhygienic." [Community Leader]

"Around STD? Yeah, there's still a lot of embarrassment. I know men who are much more comfortable with saying they have HIV than…an STD. There's still a value judgment. I think it's because we've had 20 years of messages that says HIV isn't necessarily a value-based disease. And for 20 years, up until 3 years ago, we've essentially down-played STDs overall." [Community Leader]

"The stigma is that, you know, HIV happens and you know there's 6,000 people living with HIV…Syphilis still feels like the dirty little secret…they are still somehow believing that syphilis is something that happens to somebody else." [Community Leader]

"There's more of a stigma with it [syphilis compared to HIV] because you can see it." [Sex Partner]

"The person I was exposed from, he had the rash all over his arm…I think anytime you can see it, there is definitely more of a stigma." [Sex Partner]

"I would say that there's a much greater stigma [with syphilis than HIV]. I'm very open with a partner about HIV…When I was hired for the current job that I have, I had no problem telling them that I was HIV positive. However, about a month ago, I had this incidence with the high syphilic count…I didn't want it to be called 'syphilic meningitis' because there is a whole stigma attached to it. In my opinion, a lot of people view it as dirty sex." [Case Patient]

11. **Some private providers indicated that the urgency of the syphilis epidemic calls for creative interventions such as PDT, even though the PDT intervention may not be ideal.** They indicated that although there may be some negative consequences of such an intervention, they see that SFDPH is dealing with an emergency situation and the PDT packs is one of multiple interventions that SFDPH is trying.

    "I think if we realize that this isn't the optimal way, and I say that right up front, this is not the optimal way to control an epidemic which …can be prevented by using a condom… This is a piss poor substitute for practicing safe sex but guess what, we have to get reality of life." [Private Provider]

    "In many settings, these interventions, pharmacological ones, are a harm reduction strategy. It's not ideal. They're not saying that this is the best way. They're just saying 'When judgment's impaired, in the setting of these club drugs and when people are having lots of sex, then you make a decision whether to try and reduce the risk of syphilis and HIV transmission.'" [Private Provider]

Method of PDT Provision at SFCC

12. **Some case patients and sex partners firmly believed that only health care providers should dispense medications to people.** Although the PDT is being given out by health care professionals to the patients, many still felt that it was not appropriate for them as non-healthcare providers to offer medications to others, when they do not know the health status and history of the PDT recipients. Many felt that it was the responsibility of the health care providers to do a medical evaluation, and only then prescribe the appropriate medications.

    "… you should never get medicine unless it's from a doctor. There are very specific reasons for it…It's prescribed by a doctor for specific people. It's on an individual basis." [Sex Partner]

    "I wouldn't do that [take medication to sex partners]. I have no ability to take medication to anyone. I would tell them to go get the medicine on their own." [Case Patient]

    Closely linked to this issue is the opinion some sex partner focus group participants expressed about being held liable if the PDT recipient has an adverse drug reaction. Some felt that they do not want to be held liable if the PDT recipient should have an adverse health reaction.

"So if it was dispensed in packages, but still the liability because you don't know that person. How does the Health Department know that person's health and what they're allergic to. What could happen? If you did something like that, not only would you be liable but the person could get sick, go into shock, go to the hospital." [Sex Partner]

"You're putting the middle man in liability. If the person takes it anyway, they can still come after the middle man, and after the doctor and after the clinic if they have some sort of reaction." [Sex Partner]

13. **Some case patients and sex partners indicated that awareness of the PDT pack option at the beginning of the clinic visit may facilitate acceptance of the PDT packs.** They expressed that learning about the option early in the encounter would allow them to think it over more carefully. They suggested that PDT should be mentioned by intake staff or clinical staff earlier during the clinic visit. This would allow case-patients to have some time to weigh their options. In fact, some DCIs thought that City Clinic clinicians mentioning PDT packs during their time with the patient helps improve acceptance of PDT packs by patients.

    "I can almost see a scenario where I went in and the intake guy explained that that [PDT pack] was an option maybe. Then they do their intake procedure and let you know that's an option and what it would involve. Because the whole experience could be overwhelming where you then might have time to think about it and then either at the outtake or when you go to get your treatment and then you say, 'OK, I'll take three.' And then they hand them to you and maybe answer any medical questions you have." [Sex Partner]

    "I'm just thinking that for me it might make it a little more comfortable to have a little time to think about it, to know it's an option." [Sex Partner]

    "Don't tack it [offering of PDT packs] on to the end of the visit because by the time you've been there, you've been there for an entire afternoon." [Social Contact 1]
    "They should do it in the waiting room while you're waiting." [Social Contact 2]

    However, it was not clear from case-patients, sex partners or social contacts who should offer the PDT packs to them at the SFCC. There were a variety of responses, including nurses, doctors and counselors.

<u>Importance of Clinical Evaluation</u>

14. **Some of the sex partner and social contact FG participants, as well as some private providers, community leaders and DCIs expressed concern that the PDT**

packs may prevent PDT recipients from seeing a healthcare provider for clinical evaluation and syphilis testing. They felt that the packs may make it too convenient for PDT recipients to not seek care, especially when seeking care would be a good idea to get testing or clinical evaluation.

> *"I think the concern might be people who take it as a way of avoidance of any clinician. I think these are the people who are ashamed of their behavior, so they need more counseling." [Community Leader]*

> *"I think that if you give someone a pill, you are giving them a real easy way of not going to the doctor and really find out about maybe a lot of shit that would need to be checked out. A lot of people don't like to go to the doctor and that's going to make it real easy for them to say 'Oh cool, I'll take a pill.'" [Social Contacts]*

> *"If the person who exposed me brought the medicine to me, number 1, I do trust them so that's a big factor. But I would have been really happy to take a pill and not go down to City Clinic and wait two hours and get two really painful shots." [Sex Partner]*

Many DCIs, private providers and community leaders emphasized the importance of a clinical evaluation and testing for STDs regardless of whether PDT recipients take the medication from the PDT packs. Additionally, many of the focus group participants from all three groups indicated that they would want to get tested first if they got the PDT pack from their sex partner or that they would tell their sex partners to consult a doctor first before taking the medications.

> *"I would probably suggest to the people that I've been with to get tested. If it [PDT pack] was available to give to them, I would give it to them, but I would still suggest that they get tested. It's only 10 – 20 minutes out of the day to get tested and know for sure before you start taking antibiotics that may or may not make you feel not very well." [Case Patient]*

> *"I would probably not take it [the medication] until I got tested first to see if it was even necessary to take it." [Case Patient]*

> *"I think that if I trust the person, I will take the medication but I will still go to City Clinic." [Case Patient]*

> *"If I were the recipient of it [PDT pack], I would probably take it and then get myself checked out right away." [Sex Partner]*

However, while PDT packs may make it too convenient for some to avoid seeking healthcare, it was also brought up that the PDT packs may reach some sex partners who may not otherwise seek healthcare for a variety of reasons, including lack of health insurance, lack of time, and embarrassment about

STDs. A few case-patients and sex partners from the focus groups, as well as some private providers and community leaders indicated that offering the packs at no charge for the patients to deliver to the sex partners would be beneficial for sex partners who do not have health insurance. Additionally, it would be convenient for those who did not have the time to see a healthcare provider immediately, or are embarrassed to go to an STD clinic or see their provider. While many participants believe that PDT recipients should get a clinical evaluation and STD testing, regardless of whether they take the PDT medication, a few case-patients, sex partners, private providers and community leaders indicated that the packs may reach those who would not otherwise get treatment.

"If a sex partner doesn't have insurance and they are not sort of connected with a provider, it makes it easier for that person to get treated. Maybe the sex partner is embarrassed to visit their own primary care physician for this sort of thing. Some partners maybe don't want to be tested, reported and called. And then, you know, have to sort of go through the whole thing. This way [with PDT] they can get treated." [Private Provider]

"In the non-ideal world when a lot of people really aren't going to come in, at least you've gotten the dose into them." [Private Provider]

"I think we live in a society that is busy,…I think partner packs [PDT packs] is a community effort that says, 'We value your time and we know that in some cases, if you do not have a painful discharge, you do not value sitting at a clinic or your doctor's office.'" [Community Leader]

"I think the main benefit would be – there's a short little window there that you have to be treated in…I think that it must be treated aggressively and quickly." [Sex Partner]

"I know that for a fact that a lot of people aren't going to go down to South of Market [to the STD Clinic] and want to go in and feel comfortable…Those who have health care, a lot of times…they don't want to tell their doctor every four months, 'I've got syphilis again.'…And so if there is something with information and all that, that could help them, then I think it's a responsibility that I would definitely take on." [Case Patient]

Pharmacological Features of Azithromycin

15. The majority of the private providers, community leaders and DCIs pointed to some of the positive features of azithromycin that would facilitate acceptance of the PDT packs: single-dose, safe, and well-tolerated.

Packaging and Content of PDT Packs

16. **Some participants from all three focus groups indicated they may not trust the legitimacy of the medication packet.** They need to know that the medicine is legitimate and indicated a desire to be able to verify the integrity of the packet. Many expressed that they would want to have a contact number they can call to verify.

    "If it's down in the Muni stops and we know that this is out there and the next week I happen to hook up with Philip and he says, "Oh by the way, I've got one of those pills that they came out with last month, do you want one?" And it's in the wrapper that I saw on the Muni bus, sure." [Case Patient]

    "What else are you making in your basement besides this? I wouldn't take anything unless it was given to me by my doctor. I would go to my doctor and have it checked out." [Sex Partner]

    Additionally, consistent and professional packaging and marketing of the PDT packages would be critical elements that would strengthen their belief in the legitimacy of the medicine packet, and consequently may increase the likelihood of PDT recipients actually taking (swallowing) the medication. They felt the package must look official and the medication should be tamper-resistant in order for them to have confidence that the medicine is legitimate.

    "…something that does come across looking very pharmaceutical… very clinical in its approach. Right now the buddy packs are kind of cool, but the buddy packs come in a brown paper bag and it's one of those bottles that you pee in that they put the pills into. The pills are sealed but they need to improve the current delivery mode." [Case Patient]

    "It depends if it's something novel that's well spun by an advertising firm. If it's this nifty little packet that you get that has some call to action to get in touch with the Department of Health, and make it more interesting than a packet of Zithromax, then you might actually get some action out of it." [Social contact]

    "I wouldn't give it to somebody unless it was packaged properly…It would have to have the right explanation." [Social Contact]

17. **Nearly all FG participants indicated a need for some critical information to be contained in the PDT packages, as well as preferences for the presentation of the package itself, in order for them to feel comfortable taking it from City Clinic and giving them to sex partners.** FG participants indicated they would find the following information valuable in the PDT packages:
    i. Syphilis symptoms, disease progression and prognosis;

ii. Allergic reactions and what to do in case reaction occurs;
iii. Side effects;
iv. Contraindications;
v. Emergency contact information;
vi. Phone number to call for more information;
vii. Website address for more information; and
viii. How the medication works.

Some community leaders and private providers indicated that pictures of syphilis symptoms have worked well in getting the message across to patients. Additionally, short simple bulleted information should be used. However, it should be stressed in the information sheet, as is currently done, that if they see these signs of syphilis infection, a 1-gram dose of azithromycin will not be sufficient to treat the infection and that they must seek care from a health care provider.

Potential to Promote High-risk Sexual Behaviors

18. **Some private providers, DCIs and sex partner focus group participants expressed concerns about PDT intervention promoting promiscuity and high-risk sexual behaviors.** They felt that the packs may promote the idea that syphilis is easy to treat. They are concerned that if MSM believe that simply a pop of a pill will cure the disease, they will be more likely to engage in high-risk sexual behaviors. Some of the private providers believed that people should take responsibility for their actions and that a solution should not be as easy as 'just pop a pill'.

"…in our population [their private practice patient population], we do see a lot of attitude around that kind of stuff…expectation that treatment should be quick and easy and the more quick and easy it is, the more behaviors seem to not be careful… you know, not change." [Private Provider]

"…'Oh well, I can just fuck around and they just give you this packet, so really it really doesn't matter' and theoretically we're increasing unsafe sex practices because we're giving the wrong message out." [Private Provider]

"I'd want to have a better sense of 'Is this [PDT intervention] going to contribute more to the spreading of HIV disease, while it might be lessening the incense of syphilis…I'm thinking more in terms of the HIV negative person who is playing around at this party circuit, who is putting himself at greater risk to get HIV and whether he will put himself at greater risk knowing that he has been prophylaxed against syphilis." [Private Provider]

> *"What it suggests to me is that there is an easy cure so that potentially men may not be as cautious about it [sex] because they know there's a quick fix." [Sex Partner]*

Another related concern expressed by some DCIs, case patients, and sex partners was the unintended consequence of hoarding of medication by case-patients for their own use before the next time they have unprotected sex. They were concerned that some people may either ask for extra PDT packs, or keep the ones they took from SFCC rather than give the packs to their sex partners. In fact, one patient indicated that he kept some PDT packs for his own use.

> *"They asked me how many [PDT packs] I needed and I only had three people I had fucked and I kept a couple. And people actually called me and said, 'Do you still have one of those things? I think I need it.'" [Case Patient]* (In this quote, the participant was most likely referring to PDT for Chlamydia as he referred to 'pills'.)

> *"What this suggests to me is that there's an easy cure…It's like, 'Oh great. I'll just keep this stuff [PDT pack] for myself. Once a week, I'll just use it and then I won't ever need to get tested.'" [Sex Partner]*

These findings regarding the potential for MSM to believe syphilis is easy to cure with just a pill and the possibility to keep medication for their own use function as barriers from the perspective of DCIs and private providers in that they may contribute to DCIs and private provider's hesitation to provide and promote PDT packs to case-patients. However, they may also be factors that facilitate acceptance of the PDT packs from the perspective of patients, sex partners and social contacts, albeit for the wrong reasons. Therefore, program planners will need to address these unintended consequences of the PDT program.

Private Providers' Views of PDT Provision in Private Practice Setting

Private medical providers serving a large volume of at-risk MSM in San Francisco were asked to express their views about the advantages and disadvantages of the delivery of PDT in their practice. This section focuses specifically on private providers' perspectives on the delivery of PDT in the private practice setting.

1. **The primary concerns of PDT delivery in the private practice setting that the majority of private providers expressed were medical and legal responsibilities. Most of the private providers expressed concern about the medical responsibility of the sex partners once he takes the medication.** Some felt that it was unclear who was responsible for the medical care of the sex partner, and others felt that the sex partner becomes their responsibility once the sex partner takes the medicine that originated from the provider's office.

   "…I would have some concern about writing prescriptions out with my name and all that to someone I don't know exactly… and not take responsibilities."

   "Whose responsibility is that patient [the sex partner] from there forward if they don't have a doctor dispensing?"

   "Whose responsibility do we undertake by giving a partner pack to a patient who's not part of our practice? If they have an allergic reaction, what happens? What are the liability issues around that? What if there is a drug interaction? ...This is a patient that's not a patient of ours. So it's not clear what our obligations and responsibilities, both clinically and legally, are from this approach."

   Many felt that the potential legal liability of treating someone whom providers have not clinically evaluated was a major barrier to delivering PDT in the private provider setting. Private providers expressed concern being held legally liable for providing treatment for someone whose medical history they do not know.

   "Dealing with the nature of the obligation for the partner pack and dealing with the potential legal liability issues, if any, around that would be necessary before we would consider changing what we do and how we do it here."

   "…I have no doctor-patient relationship with the partner. And if he's taking medication under my prescription, I'm wide open to any sort of liability which the public health department presumably is not."

   "Is there an implied consent of care if we give something to somebody who we don't know? What have we done by initiating that action? And aside from the legal aspect of that, is there some ethical, moral, medical,

you know, have we entered into a contract with this person? I don't know the answers to those questions. I think that by giving medicines to patients, we do initiate some sort of an obligatory relationship."

Most private providers reported not providing treatment for sex partners unless the partner is also a patient of the practice. But some providers did express willingness to help SFDPH with PDT by introducing the concept (not the PDT packs per se) to their patients and referring their patients to SFDPH for the PDT packs:

"…at least if we know that it's [PDT] out there, we can educate our patients. And that's a step further than I usually go."

"I think that everyone who I reported with a positive RPR was going to get this conversation [about PDT], then when I tell them that… you are going to get a conversation possibly about treating your contacts [from the health department], I think it's a good thing…a couple of sentences might actually help in the percentage of the poor responders who just don't buy into it."

2. **Some private providers expressed concern about their provision of PDT not being in the health plan's (or their practice's) financial interest.** From a purely business perspective, they felt there was no benefit to their plan or practice because of the cost of the medication, cost (time and money) of treating people who are not their patients, and other associated costs.

"…obviously syphilis is never cheap and we've had some really bad cases of secondary syphilis where a few of them had to be hospitalized with oral ulcers and all sorts of things, so preventing a case might actually be productive in the long run, but the health plans have a hard time seeing that."

"The last thing we need, given how busy we are, is to have everybody's partners call in and say I need a partner pack. Not only are we not going to have a chart, but we're not going to know that patient and we're going to have to be doling out care that we're not getting anything back for."

3. **Some providers were concerned that they would miss the opportunity to clinically evaluate potentially exposed and infected sex partners with early syphilis if PDT were implemented in their practice.** Providers were concerned that sex partners would not seek care and be clinically managed for other STDs.

"I think maybe about 70% of our syphilis cases are in HIV-infected individuals, so that means that 30% are not. So do we miss the opportunity to do some HIV testing, if we are just treating people out there with antibiotics?"

"But there are some people who, if told to go to the doctor, would, but when given that [PDT pack], think they don't have to…So they say 'Oh, I'm given the treatment…now I don't have to go to the doctor.'"

"So you have to get around the law of doing good faith physicals…because no one is examined and determined if this person should have this prescription drug."

4. **A few providers expressed concern about under-treatment of sex partners.** They were concerned about sex partners who may already have active disease since 1 gram of azithromycin will not treat those who are already infected with syphilis.

"So that's the other risk. What if somebody has actually, they have late late syphilis already? Then you are going to under-treat them.… So is a person like that better off getting half-treated or not treated for syphilis? That's a real important question that would be wroth knowing and therefore maybe the question is whether we should be treating with 2 grams, the treatment dose instead of just an incubation dose."

"But my only concern is the missing of people who have active disease… They're [the sex partners] thinking that they are adequately treated and they'll never get medical attention."

Other Recommendations to Control the Syphilis Epidemic in San Francisco

The following is a list of recommendations mentioned by community leaders, DCIs and private providers about ways to control the syphilis epidemic in San Francisco. [The suggestions were made by the type of interviewee indicated in brackets.]

1. Consider giving prophylactic azithromycin to people who are repeatedly tested positive for syphilis so that it could be taken before unprotected sex to prevent future syphilis infection. This was suggested due to the doubling in the percentage of this group of people. [Community leader]

2. One private provider mentioned not prescribing Viagra to a patient until the patient has been counseled by a health educator on safer sex. [Private provider]

3. Healthcare providers should routinely offer a standard set of STD tests to MSM. As the patient is waiting to be seen, he should be given a list of tests that the patient is recommended to get on a regular basis. Then the patient can check off the ones that he has not been tested for. This would be a way to offer the tests in a potentially less embarrassing way. Additionally, all HIV care providers should do syphilis screening of their HIV positive patients. [Community leader]

4. To help with the reporting of partners, private providers can give to their syphilis-infected patient a form from the Health Department that asks them to list their previous sex partners and their contact. The belief was that the patient may be more willing to give up sex partner names since they would be more trustful of their provider than the health department. If the provider recognizes someone on that list as one of his/her patients, then the sex partner could be contacted by the provider for treatment. However, the provider would not contact listed sex partners who were not his/her patients – that would be left to the health department. This would not be a counseling session as the private providers would not have time for it, but this form would simply be introduced by someone in the clinician's office for the patient to complete while in the office and it could faxed or mailed back to the health department. [Private provider]

5. Implement STD control and prevention interventions at emergency rooms and urgent care centers. They were indicated as places where many of the private provider patients were accessing, particularly on the weekends when other clinics are closed. [Private provider]

CONCLUSIONS AND RECOMMENDATIONS

The primary finding of the focus group and key informant interviews was that while many of those interviewed were in favor of PDT packs and understood the need for them, case-patients, sex partners, social contacts, and private providers identified barriers to the acceptance of PDT that prevented them from immediately embracing the intervention. However, if SFCC wishes to continue the PDT program, they may wish to consider individual and community level interventions to overcome these barriers. Other barriers may be more difficult to overcome or may require data collection and feedback, or long-term interventions to address the barriers. This section details individual and community level recommendations for interventions to address some of the barriers identified by the evaluation team based on the evaluation findings and recommendations made by evaluation participants.

Recommendations

Community Awareness Campaign

A community-wide campaign to raise the awareness of PDT for syphilis prevention is a critical component to i) increasing the legitimacy of and trust in the PDT packs, ii) facilitating discussions around syphilis and PDT packs, iii) changing the community norm to being responsible for the health of the community. While changing community norms is a more challenging and long-term objective, a number of community leaders and private providers felt that it was a necessary component to increase acceptance of the PDT packs. The following information sources were mentioned by focus group participants as accessible and credible, and should be utilized for the community awareness campaign:

ii. Ads and articles in the gay press;
iii. Ads at bus stands and other public transportation sites;
iv. Healthy Penis Campaign - Since the majority of MSM interviewed were familiar with the Healthy Penis Campaign, the PDT campaign should take advantage of this and PDT should be promoted through this means;
v. Interviews with Jeff Klausner[1] - Many MSM, as well as healthcare providers, have read articles from interviews with Dr. Klausner or have accessed "Ask Dr. K" on the internet. In addition to the ad campaigns, it would be worthwhile to do interviews, whereby the PDT packs can be explained in greater detail and some of the concerns of both the medical community and the gay community can be addressed;
vi. City Clinic website and the Healthy Penis Website - Information on PDT should be made available through these websites;
vii. Internet - Advertise through chat rooms and other internet-related methods since many high-risk MSM find information and sex partners on-line; and
viii. Community organizations - Information about City Clinic's PDT program should be distributed through health-related community organizations, including Magnet, Walden House, AIDS Health Project, API Wellness

[1] Jeff Klausner: STD Director, SFDPH.

Center, STOP AIDS Project so that at-risk MSM community members can become familiar with PDT.

One of the community leaders suggested utilizing outreach workers (whether from SFDPH or from community-based organizations) to distribute information about PDT packs in strategic venues (gay bars, sex clubs, Castro, South Market and Polk).

The campaign should incorporate and emphasize some of the factors that may influence someone to take PDT packs for their sex partners as identified by focus group participants. Factors that facilitated acceptance according to focus group participants include social responsibility, having the opportunity to offer a solution to a problem, clearing one's conscience, and having high regard for people who do notify their partners.

The community awareness campaign should try to increase community exposure to and familiarity with people telling their sex partners about their potential syphilis exposure and offering PDT to sex partners. It must address the stigma around syphilis, in particular that it is a 'dirty' disease that only a few promiscuous people get. This may help reduce the discomfort people have about confronting sex partners about syphilis and the PDT packs. One community leader recommended that the campaign incorporate the theme of taking care of one another's health and well-being so that it can become a community norm. In the long-term, a community awareness campaign would ideally and ultimately shift the social norm to where people are able to approach casual or intimate sex partners about the PDT packs with minimal discomfort.

The campaign should also incorporate symptom recognition and awareness of the syphilis epidemic, which in turn could reinforce the notion that syphilis is not so rare in San Francisco now. HIV positive gay men need to be aware that while syphilis may be relatively rare overall in San Francisco, the rate of disease is much higher among HIV positive gay men. They need to know that it is not rare among their peers.

Additionally, the campaign must inform the community that the medication in the PDT packs does not treat syphilis if you are already infected with syphilis. Therefore, it must be emphasized that the medication does not replace clinical evaluation and testing for STDs. Thus, the real aim is to speed up the delivery of treatment to persons with incubating syphilis or get treatment to persons who would not otherwise seek care. This goal of the program is worth emphasizing not only to the community but also to DCIs, SFCC staff and private providers.

Given the difficulty of reaching the population who are unable to be identified by their sex partners, media messages through the community awareness campaign may be the best avenue to inform high-risk MSM that they are at risk, to advise them of early symptoms, and to encourage them to seek health care promptly.

Private Provider Education

Given that private providers diagnose and treat over 50% of syphilis cases, a provider education campaign would be critical to better inform providers of the pros and cons of PDT, regardless of whether providers were to offer PDT packs in their own practice or simply refer their patients to SFCC for the PDT packs. Additionally, providers will need to be well-informed about the PDT packs as PDT recipients may call their private providers with questions regarding the PDT packs.

The provider education efforts should inform providers of PDT pack availability at SFCC, and address concerns about PDT, including concerns about potential for increased promiscuity, the development of antibiotic resistance at the individual and community level, efficacy of 1 gram versus 2 grams azithromycin for incubating syphilis, under-treatment of already-infected sex partners, effectiveness of PDT as a disease control strategy, and the cost and cost-effectiveness of the intervention. While many of these issues cannot be presently resolved, they should be addressed over time. It may be useful to acknowledge that, while there may be some issues that remain unresolved, faced with this epidemic, decision makers need to explore the PDT intervention as a supplemental strategy to traditional partner management. It would also be useful for private providers to receive some information about the PDT intervention's progress and performance from the past year of PDT implementation, (e.g., information on acceptance rates, treatment failures, estimated costs incurred).

Additionally, SFDPH should inform providers that the PDT pack intervention is occurring in conjunction with other STD/HIV prevention interventions (i.e., it is part of a comprehensive STD/HIV prevention program). Providers need to be reassured that PDT is not replacing other behavioral change programs and that there is an extensive patient educational and counseling component to the intervention, both at the community and individual levels.

Private provider education should be conducted regardless of whether SFDPH asks private providers to dispense PDT packs, or if SFDPH simply asks providers to refer their patients to SFCC for PDT packs. If private providers do not participate in directly offering PDT packs to their patients, SFDPH should encourage private providers to mention City Clinic's PDT program to their syphilis-infected patients. Having private providers initiating a discussion with and counseling syphilis-infected patients about PDT packs, and referring them to the City Clinic for the PDT packs may facilitate the acceptance of the packs by patients.

Education efforts with private providers should be conducted in person by a clinician from SFDPH. Additionally, SFDPH may want to consider including some educational messages for providers in the SF Monthly STD Report. Some providers indicated that they liked receiving these reports electronically in PDF format. Receiving the reports electronically made it easy to forward them to other clinicians in the practice. Lastly, the educational campaign for providers should be focused on a group of private providers who see a high volume of syphilis patients.

Public Health Personnel Education

To help prevent inconsistencies in the messages coming out from physicians, public health personnel and community leaders regarding the value of PDT, it may help to review the rationale, process and implementation for this intervention with organizations and interested personnel in an attempt to generate support.

Patient Counseling

Given that some patient's unwillingness to give PDT to sex partners stems from discomfort in bringing up the topic or not knowing how to approach a sex partner about PDT, especially with partners he is not close to, it may be worthwhile to have DCIs counsel and coach patients on how to approach sex partners (casual or intimate), what to say, and how to deal with negative reactions. Role playing exercises may be valuable.

If, however, the DCI can determine that the patient's unwillingness to give PDT to sex partners is due to fear of negative repercussions or accusations and blame by the sex partners, then traditional partner notification may be more appropriate for these situations.

Again, the facilitating concepts and perceptions of social responsibility, having the opportunity to offer a solution to a problem, clearing one's conscience, and having high regard for people who do notify their partners may be effective in developing counseling messages that DCIs can employ during their counseling sessions with the patients.

Since many focus group participants expressed concerns regarding non-clinicians distributing medications, liability if sex partners have adverse drug reactions, and the need for sex partners to get a clinical evaluation and testing, DCIs should stress the following during counseling sessions with patients even though many of these are already stated in information sheets contained in the PDT packs:

i. Patients should tell partners to seek medical evaluation regardless of whether they take the medication or not;
ii. Patients should tell their sex partners to call the City Clinic with any medical questions;
iii. Giving PDT to their partners gives the partners the option to decide for themselves if they want to take it or not and that taking the medication does not preclude them from getting a medical evaluation;
iv. Stress that azithromycin has very few side-effects; and
v. The value of preventing potential syphilis infection in the partners is greater than preventing adverse reactions from treatment with azithromycin from PDT packs.

DCIs should also try to counsel patients on ways to contact anonymous partners they met through the internet. Although these sex partners may be anonymous, it may still be possible to reach some of these partners. For example, they may still have e-mail

addresses of those partners they met on-line or could find them again at venues where they made initial contact. Therefore, should either counsel patients on how to reach anonymous partners through these means or obtain e-mail addresses of these partners whom the patient met on the internet. Additionally, if patients had sex with anonymous partners at a party, it may be possible for the DCI to obtain contact information of the party organizer. If the party organizer is willing, he/she could contact guests about their possible exposure to syphilis and that they should see their doctor. However, if the organizer is not willing to contact guests, then it may be possible to work with him/her to have some educational material about syphilis and PDT available for future parties.

Packaging and Contents of PDT Packs

Effort must be made to satisfy the needs and preferences of MSM patients with regard to packaging style and content of the PDT packages. To reduce the suspicion and increase the legitimacy of the PDT packs, the packs should be tamper-resistant, official looking, professionally packaged as focus group participants indicated. It will also be important to ensure that the advertising in the community accurately represents packages given out at the Clinic.

The following information should be included in the PDT packs:

i. Syphilis symptoms, disease progression and prognosis;
ii. Allergic reactions and what to do in case reaction occurs;
iii. Side effects;
iv. Contraindications;
v. Emergency contact information;
vi. Phone number to call for more information;
vii. Website address for more information; and
viii. How the medication works.

It should also be stressed in the information sheet that it is critical to seek care and treatment regardless of whether or not they see signs and symptoms of primary or secondary syphilis infection since they may miss the signs. Information must also emphasize that the 1-gram dose of azithromycin contained in the PDT pack will not treat syphilis infection. Additionally, it may be necessary to include in the information sheet the negative consequences of taking too much azithromycin unnecessarily, especially at the individual level in order to prevent hoarding of medications.

The lot number of the azithromycin packets that are distributed in the PDT packs from the City Clinic should be recorded in a log so that PDT recipients can call to verify that they have a legitimate packet of azithromycin.

Provision of PDT at SFCC

While DCIs should continue to be responsible for the comprehensive discussion of PDT at the end of the visit, it may be valuable to have PDT mentioned throughout the patient's visit to the City Clinic. Some of the focus group participants indicated that they would like to receive information on the PDT option from the beginning of the clinic visit because it would allow them time to think about whether that option would be

appropriate for him or not. Posters and pamphlets about PDT for syphilis should be made available in the waiting room. The staff registering the patient can give a pamphlet on PDT to patients who come in with syphilis-related chief complaints. Additionally, the clinician can also encourage the patient to take PDT packs for their sex partners. And finally, the patient can be counseled about the PDT packs in detail by the DCI.

Clinical Evaluation and Testing

Given the importance of getting a clinical evaluation and syphilis test done for sex partners, regardless of whether one takes the azithromycin in the PDT packs, there should be easier access for the evaluation and testing. Case-patients should be given information (both verbally and in the information sheet contained in the PDT packs) about the availability of the new on-line syphilis testing program so that they can tell PDT recipients to access it in case they may be interested (http://www.dph.sf.ca.us/sfcityclinic/syphilistesting/). Although those who test positive are followed up by DCIs for counseling, and to ensure that they have been appropriately treated, it should be stressed to these people that if they do get a positive test result, the 1-gram dose of azithromycin from the PDT pack will not be sufficient to treat syphilis infection and that they should seek appropriate treatment from a healthcare provider. Information about Magnet, a community sexual health services center, should be included in the PDT pack as another venue for syphilis test (as well as other STD tests). These information on alternative testing sites may also be useful for the case-patients themselves should they want to access it in the future.

The City Clinic may want to consider having a 'Fast Lane,' where exposed sex partners attending the clinic can come in just for a syphilis test rather than spending hours at the clinic for a complete evaluation. A coupon could be included in the PDT pack that would allow the PDT recipient to access the 'Fast Lane'. This would be a time-saving option for those PDT recipients who wanted to get tested first.

SFCC Staff Training and Involvement

All staff at the City Clinic should be well-informed about the PDT packs to be equipped to answer questions patients at the clinic or persons who call on the phone may have. It will be important to have a consistent message being conveyed to the community.

Staff persons who answer the phone line that is included as the contact number in the PDT packs should be well informed of the PDT packs for syphilis and should be able to answer specific questions about azithromycin and syphilis. It may be valuable to develop scripted responses to common questions, which would be provided to staff answering the telephone line. Staff members who respond to these calls should keep a log of questions they get from callers. DCIs should also keep a log of questions they receive from patients about the PDT pack. These questions should be brought up at Clinic management and staff meetings so that there will be a standard set of answers for these questions. A list of "Frequently Asked Questions" should be compiled, along with the answers and should be distributed to all involved with the PDT provision (directly or indirectly), as well as to other key members of the community so that they can

appropriately respond. *[Questions from patients encountered by DCIs have been included in Appendix 6]* Staff members who should be knowledgeable about the PDT packs include support staff, clinicians, nurses, DCIs, and community outreach workers.

DCIs should record the reasons the patient did not accept partner pack. These issues should be discussed at staff meetings to determine ways to overcome some of these barriers. DCIs should be involved in any changes to the PDT protocol since they have significant insight into barriers and facilitators of PDT from the perspective of the patients and their sex partners. Feedback from the DCIs on the progress, problems, facilitators and obstacles should be an integral part of this program.

It may be useful to consider using some kind of a feedback system whereby DCIs are informed of the number and rate of uptake of the PDT packs on a weekly basis. Tracking the trend of uptake by patients on a regular basis may increase DCI's enthusiasm for the intervention, which might be passed on to the patients and consequently increase uptake

Additionally, SFCC may want to consider including a phone number that calls into a recorded telephone message that provides basic information about PDT, with an option for additional assistance. Additionally, it may be useful to have DCIs give out his/her business card along with the PDT pack (one for the patient as well as additional ones for each pack given to the patient). One DCI reported giving out his business card along with the PDT pack. This allowed the sex partner receiving the pack to have direct access to a counselor who could answer any questions on syphilis, as well as the PDT pack.

Recommendations regarding PDT provision in the private practice setting

The evaluation also revealed barriers regarding the provision of PDT packs (or endorsement of SFCC's PDT intervention) to patients in the private clinic setting from the perspective of private providers. The following recommendations should be considered by SFDPH if SFDPH is interested in having private providers offer PDT in their practice to their patients.

<u>Resolution of legal issues</u>

The primary reasons for private provider's unwillingness to provide PDT packs in their practice were legal liability and medical responsibility. If it is clear that the risks do outweigh the benefits of PDT packs, then it may be useful to consider bringing together a group of lawyers specializing in medical malpractice (medical legal experts) to discuss possible ways to protect private providers against negative legal consequences.

If PDT will be offered in the private provider setting, it would also be useful to clarify beforehand the source of the medication - the Health Department or the private provider. Should the PDT packet be considered something that is coming from SFDPH via the patient who happens to be the patient of the private provider (i.e., is the private

provider serving as a middleman) or is the private provider serving as the primary deliverer of the PDT packet? This may be important to consider for legal purposes.

Resolution of financial issues

One of the concerns raised by some providers was that it was not in the financial interest of their health plans to pay for such an intervention. In order to know if there are financial benefits for health plans or not, some economic data and analyses would be required (i.e., direct and indirect costs of untreated syphilis, complications from syphilis, cost of packs, savings from prevention of syphilis in health plan's members, etc…) and the pros and cons would have to be weighed. Additionally, SFDPH may want to consider subsidizing for the cost of lab test and/or medications.

Private provider education

A private provider education campaign would be extremely important to increase private provider support for implementing this intervention in their practice. [See "Private provider education" section above.]

Limitations

These findings should be considered in light of some limitations of the evaluation. First, these findings are based on only focus groups and in-depth interviews with a small group of key stakeholders, and hence have some limitations. First, these focus group and key informant interviews are not generalizable to the respective reference groups from which participants were selected, but represent one set of opinions. Therefore, the views we elicited may not be representative of the entire community. Additionally, this evaluation is not meant to be generalizable to other settings that are experiencing syphilis outbreaks, as the local context of the epidemic and public health law in San Francisco is very unique.

Secondly, there may be some bias in the selection of community leaders. Since community leaders we interviewed were sampled using convenience, rather than systematic methods, from a list of community leaders with whom the SFDPH works closely, these community leaders may be more likely to be proponents of the intervention. However, this was likely minimal as we did receive both positive and negative views regarding the intervention.

Thirdly, there may be a Hawthorne effect in that participant's knowledge of the evaluation may have influenced their responses in a more positive way. However, this was most likely minimal because, as mentioned earlier, all participants spoke about both the pros and the cons of the intervention.

There may also be some recall bias among case patient and sex partner participants of the focus groups, as we did not conduct the interviews immediately following their visit to SFCC.

Despite these limitations, the present evaluation revealed important findings to guide efforts to improve the acceptance of PDT among at-risk MSM and among private providers if SFCC wishes to continue this intervention. It is important to keep in mind that this evaluation assessed the process rather than the outcome. In other words, we did not evaluate the long term outcome of the reduction in syphilis morbidity due to the intervention. Indeed there are complex and challenging methodological issues in investigating the effectiveness of the intervention; however, it is a question that will need to be answered.

APPENDIX 1A

City and County of San Francisco Department of Public Health

Preventive Medicine and Syphilis

You have been diagnosed with syphilis and will be treated for syphilis today.

As you may know syphilis has been epidemic in San Francisco gay men, increasing from 41 cases in 1998 to 491 cases in 2002.

While traditional methods of syphilis control rely on partner notification and rapid evaluation and treatment of recent sex partners, many conditions currently make this difficult. We still continue to perform partner notification but also rely on a new strategy to reduce the spread of syphilis.

To enhance the control of the current epidemic, doctors and other clinical staff in the San Francisco Department of Public Health have begun offering preventive medicine for syphilis patients to give to sex partners and friends who may be at risk for getting syphilis. By giving sex partners and at risk friends preventive medicine, we hope to break the cycle of the continued spread of syphilis in the gay community.

The preventive medicine works well and is safe for everyone to take. In a recent study, none of 40 patients given preventive medicine developed syphilis. In another study in Africa in persons given preventive medicine, the frequency of syphilis declined by 20%.

The preventive medicine we are providing is called 1 gram of azithromycin. It is a powder taken by mouth after mixing with water. Some patients may get a mild upset stomach or nausea after taking the medicine, but that does not last long. Azithromycin does not interact with other medications and is safe for persons taking other medications. The medication is prescribed by Dr. Klausner, a Deputy Health Officer and Director of STD Prevention and Control Services in San Francisco. Patients are delivering medications and not prescribing medicine. Only doctors can prescribe medicine.

Please speak to your counselor about how many preventive medicine packets may be right for you. Giving your sex partners and at risk friends preventive medicine may be the best way to control this epidemic. Only you can make that difference.

Thank you.
Sincerely,

Dr. Jeff Klausner	Dr. Joe Engelman	Dr. Will Wong	Stefan Rowniak, NP
Director	Senior Clinician	Clinician	Senior Nurse Practitioner

APPENDIX 1B

San Francisco Department of Public Health

You have been given AZITHROMYCIN medication because you may have been exposed to syphilis and need to receive preventive treatment.

Prior public health research regarding transmission of syphilis shows that sexual partners or social contacts of syphilis cases are at increased risk for syphilis infection.

San Francisco has been experiencing an increase in the number of new cases of syphilis, especially among men who have sex with men. Approximately 60% of new syphilis infections have been found in HIV positive men and 40% in HIV negative men. This is of particular concern because HIV positive men co-infected with syphilis are better able to transmit HIV during sex while syphilis in HIV negative men makes it easier to acquire HIV. Syphilis in HIV positive men may also cause fever, headaches, night sweats, weight loss, skin rashes, eye and ear problems, often associated with HIV related illnesses, thereby, making the diagnosis more difficult and possibly delaying treatment.

The traditional method employed by health departments to control and prevent syphilis has been to ask persons with syphilis to name sex partners so that they may be given preventative treatment. While this remains the preferred method for notifying partners, the increasing number of infected individuals who cannot name their partners requires different methods to prevent syphilis. Azithromycin is a very safe medication that was given to you to prevent syphilis. Azithromycin may be taken with or without food.

Although azithromycin is very effective in preventing syphilis, it is not the best medication for people who already have syphilis. The best medicine for people with syphilis is penicillin given as an injection by a doctor. If you have any of the symptoms described below, do not take the azithromycin. Instead, come to the City Clinic (or see your doctor) right away.

SYMPTOMS OF EARLY SYPHILIS
➢ SORES ON THE PENIS, ANUS, OR IN THE MOUTH (PAINLESS OR PAINFUL) ➢ SKIN RASH INCLUDING A RASH ON THE CHEST, BACK, PALMS OF THE HANDS, SOLES OF THE FEET, OR ON THE GENITALS ➢ WHITE/GRAY PATCHES IN MOUTH, ON LIPS OR ANUS

If you are not comfortable taking azithromycin without a prior medical evaluation for syphilis, you should visit City Clinic at 356 Seventh Street, between Folsom and Harrison; (415) 487-5500; www.dph.sf.ca.us/sfcityclinic/. No appointment is necessary. During your visit, you will be checked for syphilis and other sexually transmitted diseases such as gonorrhea, chlamydia, herpes simplex and HIV as indicated.

Thank you for your attention to this serious health issue.

APPENDIX 1C

DIRECTIONS FOR TAKING AZITHROMYCIN 1 gm
PLEASE READ THIS VERY CAREFULLY

BEFORE YOU TAKE THE MEDICINE, PLEASE READ THE FOLLOWING

The medicine is very safe. However, **DO NOT TAKE THIS IF:**

- You ever had a bad reaction, rash, or allergy to Azithromycin or Zithromax®, Erythromycin, Clarithromycin or Biaxin®;
- You have kidney, heart, or liver disease;

If you have any of these conditions, you should talk to your doctor or come to City Clinic before you take this medicine.

To take this medicine:

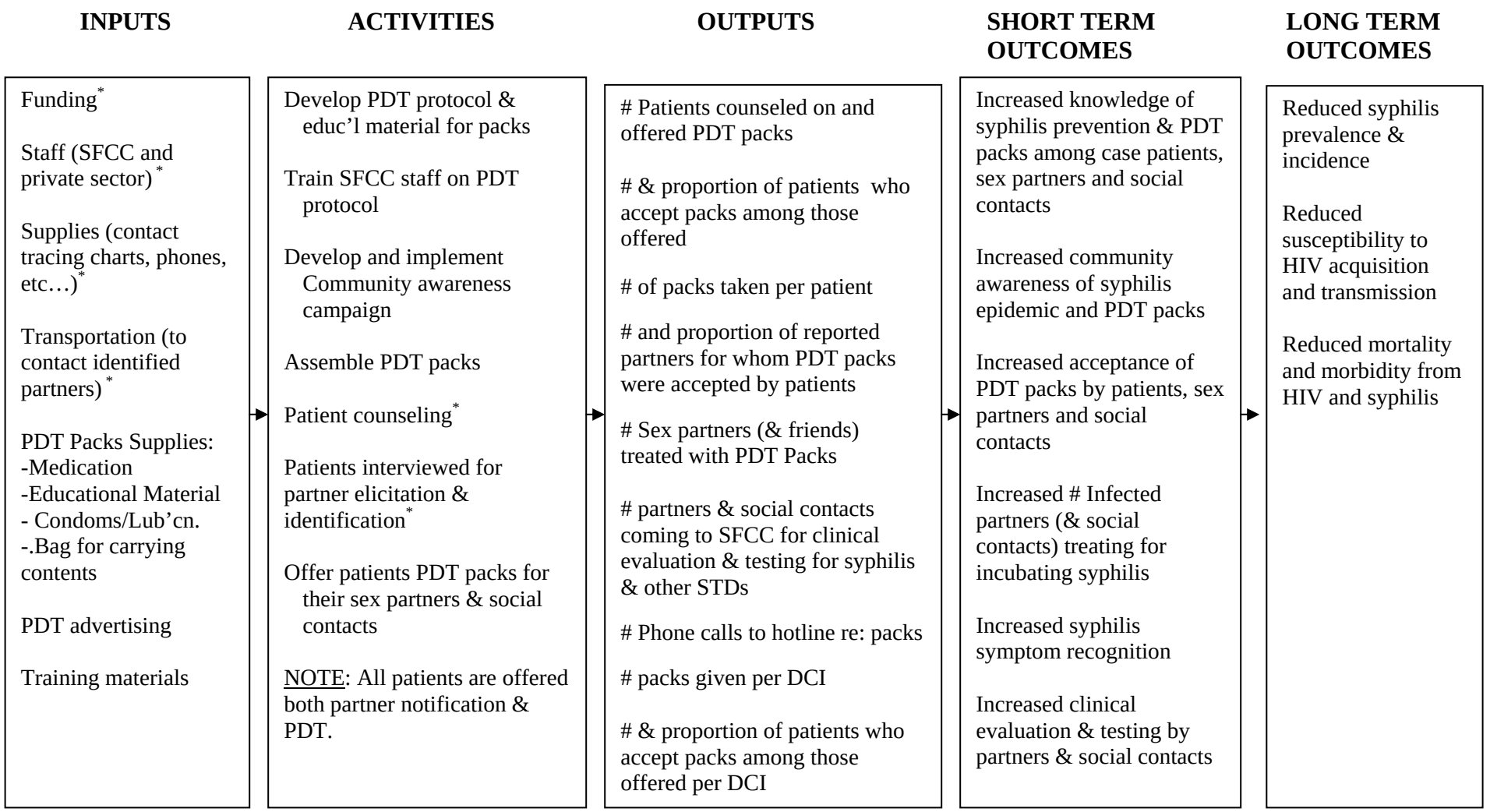
- Open the packet and pour all of the powder into the cup
- Add water to the black line
- Shake vigorously
- Drink all of the medicine
- Fill the cup with water again to the black line and drink
- Take this medicine with food and lots of water

- Some people get a mild upset stomach after taking this medicine. This doesn't last long.
- Don't share or give this medicine to anyone else.
- Do not have sex for the next 7 days because it takes 7 days for the medicine to prevent ***syphilis***. If you have unprotected sex during the 7 days after taking the medicine, you could still pass the infection to your sex partners.

If you have any questions about the medicine or about ***syphilis***, please call (415) 487-5500 between ***8:00 am-4:00 pm Mon., Wed., Fri., 1:00-6:00 pm Tues., 1:00-4:00 pm Thurs.*** All calls are ***CONFIDENTIAL***. You can also come into ***City Clinic, 356 7th Street (between Folsom St. and Harrison St.), San Francisco***, for a free STD exam, testing, and medicine. No appointment is needed. Website: www.dph.sf.ca.us/sfcityclinic/

APPENDIX 2

Situation: Approach to manage and treat sex partners of syphilis case-patients among MSM in San Francisco using Patient-delivered partner therapy (PDT).



External Factors: Community norms, endorsement of PDT by clinical community and community leaders and organizations, locatability of anonymous sex partners.

APPENDIX 3

Focus Group Discussion Guide

Partner Pack Syphilis Treatment Kit Exploratory
San Francisco Department of Public Health
July 1-2, 2003

You have been invited here because you identify as gay/bi men willing to talk about your health needs. The DPH wants to better understand your needs so they can improve their services to you. In the next few weeks we will be talking to many people like you through such groups.

My role is to keep the conversation moving along, so if I interrupt you or change the subject it is only because we have limited time and a lot of questions we'd like your feedback on.

Ground rules:

Say anything, one at a time.	There are no 'right' or 'wrong' answers.	Bathroom location.
Stays inside this room. Comments cannot be traced back to individual.	Recording audio just to help us write our report later.	You'll receive a gift at the end.

Introduction: Name and how long you have lived in SF. (20 minutes)

1. General Awareness / Knowledge of STD's

Q What diseases / illnesses are you most concerned about getting?

Probe: for HIV/AIDS
Probe: for Syphilis

Q What about these diseases makes you afraid?

Probe: fears/stigma associated with getting HIV
Probe: fears/stigma associated with getting Syphilis
Probe: what are the differences between HIV and Syphilis

2. Syphilis Awareness / Knowledge

Q I want to talk a minute about syphilis. Does anyone think it's a problem? What would make you think that syphilis is a problem in your community?

Probe: sources of information (friends, partners, DPH, other)

Q Right now at this moment, how would you rate your own knowledge about syphilis? How you get it, what are the symptoms? Use 1-5 where 5 is a high level of knowledge and 1 is not much at all. Raise your hands all together, make fist, and at the count of 3 hold them up.

Q Those who said 4/5, can you describe the symptoms of syphilis? Is it difficult or easy to spread? How to cure it?

Probe: easy to cure with antibiotic

3. Key Questions (60 minutes)

Now let's imagine that you have just been diagnosed with syphilis, and you are at the SF DPH City Clinic. There is a good chance that your recent sexual partners may also have it, but they may not know about it. The health department has a program where they can give you medicine (an antibiotic) to give to your sexual partners and friends.

ATTITUDES

Q Do you think the idea of a package with a single dose of medicine that you can give to your friends and lovers is a good idea?

Probe: knowledge of partner notification (process) vs. partner packs, other ways to treat/inform

Okay, you've just been treated for syphilis, and someone from the health department is offering you a package with information and medicine that you can give your sexual partners.

Q How would it make you feel to be offered this thing?

Probe: stigma, blame or neutral or positive

USAGE

Q What are some of the things that would prevent you from taking these packages and giving them to your partners?

Probe: blame/awkwardness, comfort level talking about syphilis, ability to contact partners (anonymous, causal), lack of interest, not comfortable giving medicine,

Q What are some of the reasons why you would WANT TO give this to your partners?

Probe: care about partners, responsibility

Q What do you think are some reasons why your partners would NOT take the medicine you are giving them?

Probe: trust issues, believability, lack of symptoms, knowledge of syphilis

Q How would you feel if someone you recently had sex with contacted you and wanted to give you such a medicine? Would you be open to taking it?

Probe: lack of credibility, resentment for infection, hassle, fear that contact info was given to DHP,

Q Do you think it is a good idea to give this to your friends, people who you don't have sex with?

Probe: would not want my friends to know I got syphilis, risk level of friends, difficult to talk about

PRODUCT DESCRIPTION (25 minutes)

Let's now go back to the City Clinic. We have just been treated for syphilis and someone from the health department is offering you some treatment packages to give your partners. How should such a package be presented to you?

Q What is the setting that would make you feel most comfortable?

Probe: Counseling room, examination room, lab room

Q Who should be the person offering it to you?

Q What would make you trust this person? Not trust?

Q What sort of information do you want them to be telling you about this partner treatment?

Q Tell me what this package should look like. What should be inside it? What kind of information? How much information?

Probe: contact info to DPH, other, safety seals, endorsement by physician or DPH, instructions for use, info about syphilis, medicine effectiveness and side effects, use by date, size, shape

APPENDIX 4

Community Leader Discussion Guide

Briefly mention the recent outbreak of syphilis among MSM, and possible cite some figures from SF that show the increase.

The reason I wanted to speak with you today is because you, as a community leader, can provide us with some insights into some of the perceptions, beliefs and norms, with regard to STDs and in particular syphilis, among gay and bi-sexual men in San Francisco. The DPH wants to better understand their needs, so they can better tailor their interventions to control the syphilis outbreak.

1. **Before we start talking about the partner-delivered therapy for syphilis, can you first give me a brief description of what your organization does in terms of the population you serve and the services you provide? I am particularly interested in any programs you may have on STDs and HIV for the gay/bi-sexual community.**

2. **Have you added any new programs or services to address the recent outbreak of syphilis in San Francisco?**

In the next questions that I'm going to ask, I'd like you to think about the perspectives of your community *constituents* when you answer the questions.

3. **What diseases/illnesses do you think your constituents are most concerned about getting?**

   ____ HIV/AIDS
   ____ Syphilis
   ____ Hepatitis
   ____ Others: Specify:

4. **Do you think the fears associated with getting HIV and syphilis are the same, or more for one disease than the other, for gay men?**

   ____ Same for both
   ____ Fear HIV more than syphilis
   ____ Fear syphilis more than HIV, Why?_____

5. **How about the stigma? Do you think stigma associated with getting HIV and syphilis is the same, or more for one disease than the other, for gay men?**

____ Same for both
____ Stigma worse for HIV than syphilis _____
____ Stigma worse for syphilis than HIV_____

6. **Do you think gay/bi-sexual men in San Francisco see syphilis as a problem in the community?**

___ Yes, What might be making them think that syphilis is a problem?

____ No, Why would they not think that syphilis is a problem?

Now, let me tell you a little about what the SF City Clinic started doing about a year ago to try and get sexual partners of syphilis patients treated for syphilis. They've been offering a one-dose packet of an antibiotic to the patient to give to their sexual partners, as well as their friends.

7. **From your perspective, do you think this is a good way to get sexual partners of men treated for syphilis?**

____Yes, Why?

____ No, Why?

8. **What do you think might influence men who are infected with syphilis to take these packets for their sexual partners?**

____ care about partners
____ consider it their responsibility
____ Other. Specify:

9. **What factors do you think might prevent them from taking these packets for their sexual partners?**

____ embarrassment in admitting to others he has syphilis
____ blame/awkwardness
____ discomfort talking about syphilis
____ inability to contact partners (anonymous, causal)
____ lack of interest
____ not comfortable giving medicine
____ Other factors. Specify:

10. Do you think offering men the option of giving the packets to their friends, people who they don't have sex with, is a good idea?

____ Yes, Why?

____ No, Why?

11. Do you think distributing these packets at other venues, such as sex clubs, gay bars, and bath houses is a good idea?

____ Yes, Why?

____ No, Why?

12. Can you think of any other ways in which we could get medications to men who are sex partners of syphilis-infected patients?

13. What else do you think we need to know about your opinion of this intervention that we haven't discussed today?

Distribute your card, and invite them to call you if they think of something else that they would like you to know.

APPENDIX 5

DCI Discussion Guide

Thank you for agreeing to speak with me. As you know, we are evaluating the syphilis partner pack intervention. We're specifically trying to understand what some of the key positive and negative features are in terms of its' acceptance by patients and their contacts. Since you, as a DCI, play a critical role in the delivery of these packs, we feel you can provide us with some critical insights into some of the pluses and minuses of the program.

1. **First, I'd like to know what type of instructions you were given before you implemented the partner pack intervention with patients.**

   PROBES:

   a. Were the instructions written or verbal?
      ___ Written
      ___ Verbal

   b. Who gave you the instructions?

   c. Describe the kind of training, if any, that you got?

   d. How much time was spent on the training, or on the instructions, before you implemented the partner pack procedures?

   e. Did you have any input into development of the procedures?

      ___ Yes, How much?

      ___ No, Should you have had input? ___Yes, ____ No

      How would your input have improved the intervention?

2. **We'd like to get your thoughts on whether DCIs are supportive of this intervention.** (Let DCI respond before proceeding.)

   a. What features of the intervention do you think the DCIs like?
   - ___ Allows patients to take more control of their own health.
   - ___ Allows patients to reach people who we would not be able to reach through regular partner notification.
   - ___ Prevents partners from having to contact HD or doctor
   - ____ Other: Explain

   b. What features of the intervention do you think DCIs do not like?
   - ___ Hinders the DCIs from doing the traditional partner notification.
   - ___ I wouldn't know if the sex partner is infected or not
   - ___ Don't think the patients will give to partners.
   - ___ Don't think the partners will take the medicine.
   - ___ HD won't know if partner takes medicine.
   - ___ Patients will not come in for care.

   c. What do you think should be done about the problematic features you just mentioned?

3. **Do you think most of the DCIs follow the procedures for giving out the syphilis partner packs?**

   ___ Yes,

   ___ No, Why not?

   PROBES:
   a. What makes it hard or easy for the DCIs to implement this intervention?

   b. What do you think could be done to make it easier for the DCIs to implement this intervention?

c. What are some specific ways in which the procedures may not be followed?

4. Tell us what you do when you present patient-delivered partner therapy to syphilis-infected patients.

5. We want to get a better understanding of why patients' don't accept the partner packs. What are some reason(s) they give you for not accepting the medication?
(Let them answer before proceeding.)

PROBES:

a. What type of questions do you get about the partner packs (if any) from the patients?

b. Do patients want to discuss it further (i.e., how they can bring it up with their partners)?
___ Yes
___ No

6. From your perspective, do you think this is a good way to get sexual partners of men treated for syphilis?
___ Yes, Why?

___ No. Why?

7. What do you think is the best way to get medications to sex partners of syphilis-infected men?

8. Do you think offering men the option of giving the packets to their friends, people they don't have sex with, is a good idea?
___ Yes, Why?

___ No, Why?

9. **Do you think distributing these packets at venues such as sex clubs, gay bars, and bath houses is a good idea?**

   ___Yes, Why?

   ___No, Why?

10. **Is there anything else that you think we need to know to better understand patient-delivered partner medication here in the SFCC?**

Give DCI your business card and invite them to call you if they think of something else that they would like us to know.

APPENDIX 6

PMD Discussion Guide

- Discuss recent outbreak of syphilis among MSM, and possibly cite some figures from SF that show the increase. [1999: about 40 cases of early syphilis reported; 2002 increased to over 500 cases. 90% of these cases are among gay/bi-sexual men and 2/3 are HIV positive. End of June 2003 = at least 300 early cases.]

- SFCC has been trying to control the outbreak for past year. Some of the things they have done is:
  - Make an effort to make everyone aware that we are dealing with an outbreak of syphilis among gay men in SF, and we hope you have been made aware of the problem. And,
  - One of the new things the health department has done at the City Clinic is to offer a one-dose antibiotic to a man who has tested positive for syphilis to give to his sex partners (partner-delivered therapy).

- So we are evaluating this partner-delivered therapy intervention to learn if this is a good way to get sex partners treated and how we might do it better.

- Since more than two-thirds of the cases are diagnosed in the private practice setting, it's important for us to hear your thoughts on this intervention.

<u>Physician Experience with STDs and Syphilis</u>

1. **Before we start talking about partner-delivered therapy for syphilis, can you first give me a brief description of the patients you see in your practice, in terms of some basic demographic and medical conditions? [Mostly gay men?]**

2. **Can you give me some sense of the risk profile of the patients who are contracting syphilis and where they may be contracting the disease?**

   ___ Men who frequent bathhouses
   ___ Men who frequent sex clubs
   ___ Men who have several partners
   ___ Men who are HIV-positive
   ___ Other: Explain:

3. **How do you ensure that sex partners of your patients with syphilis get treated? [Practice-wide policy?]**

___ Treat sex partners yourself (If yes, does the patient ___ or physician's office ___ contact the partners)
___ Ask patient to refer his sex partners to a medical provider or to the City Clinic
___ Other: Explain

Opinions on Partner Pack

[Briefly describe SFDPH's Partner Pack intervention at the City Clinic, and show them an example of what would be given to the patient.]

5. **Before today, were you aware that the City Clinic was doing this intervention?**

___ No

___ Yes, How did you hear about it?_____

6. **What is your opinion about this intervention?**

7. **What features of this intervention do you think makes it effective in getting sex partners treated?**

____ Allows patients to take more control of their own health.
____ Allows patients to reach people who health department would not be able to reach through regular partner notification.
____ Prevents partners from having to contact HD or doctor
____ Other: Explain:_____

8. **What features of this intervention would prevent it from being effective in getting partners treated?**

____ Concern about legal implications of providing medication to a person not your patient
____ Concern about potential adverse drug reactions in partners
____ That partners don't come in for an evaluation
____ Don't believe patients will give to sex partners
____ Other: Explain:_____

9. **If these packets were given to your patients with syphilis, do you believe they would be 1) able and 2) willing to give them to their sex partners?**
(Note: Make sure response addresses both.)

1) Able:
____Yes
____ No: Why not?

2) Willing
___ Yes
___ No, Why not?

10. What is your opinion about the effectiveness of this intervention as an epidemic control strategy for San Francisco?

11. How do you think it compares to the traditional partner notification, whereby the health department staff locates the sex partners of infected patients and brings them to the City Clinic for evaluation and treatment?

12. Would you be willing to provide these packets to your patients with syphilis?

____Yes, What would you need to implement this intervention?

____ No. Why?

13. What else do you think we need to know about your opinion of this intervention that we haven't discussed today?

14. Do you have ideas about other things the SFCC might do to increase the number of infected men who receive treatment in time to avoid disease.

Give Provider your card and invite them to call you if they think of something else that they would like us to know.

APPENDIX 7

Frequently Asked Questions

Scripted answers should be prepared for the following list of common questions. It will be important to have consistent messages being conveyed to the community. Questions should be added to this list as they come up. These questions and answers should be distributed and used for training staff involved with the distribution of the PDT packs (whether they are directly or indirectly involved). Additionally, they should be distributed to key community leaders as well.

1. How long will the medicine last in my system and protect me from getting syphilis?

2. I don't know if I'm allergic to azithromycin, erythromycin, clarithromycin or biaxin. Should I still take it or not?

3. I know people have gotten shots for syphilis. Why am I drinking this medicine?

4. Is zithromax going to cure me of syphilis?

5. Can I save the zithromax medicine and take it before the next time I go out to play?

6. Can I just slip the medicine into my partner's drink?

7. Is it OK to take this medicine after I've been drinking (alcohol)?

8. I did some drugs last night (ecstacy, crack, viagra, poppers, etc…). Is it OK to take the medicine?

9. I am on a whole bunch of HIV medications. Is it OK to take it with these other drugs?

10. What do I do if I think I have symptoms? Can I just take this medicine?

11. Do I have to come get tested for syphilis?

Reference List

1. Hook EW, III, Stephens J, Ennis DM. Azithromycin compared with penicillin G benzathine for treatment of incubating syphilis. Ann Intern Med, **1999**;131:434-437.

2. Hook EW, III, Martin DH, Stephens J, Smith BS, Smith K. A randomized, comparative pilot study of azithromycin versus benzathine penicillin G for treatment of early syphilis. Sex Transm Dis, **2002**;29:486-490.

3. Blandford JM, Gift TL. The cost-effectiveness of single-dose azithromycin for treatment of incubating syphilis. Sex Transm Dis, **2003**;30:502-508.