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[Home](#) > [Prevention](#) > [Oral Sex Roundtable](#)

Risk of HIV Infection Through Receptive Oral Sex

On March 14, 2003 HIV InSite convened a panel of San Francisco experts to discuss the data on risk of HIV infection associated with receptive oral sex.

Laurence Peiperl, MD (convener)
Director, UCSF Center for HIV Information

Tom Coates, PhD (moderator)
Director, UCSF Center for AIDS Prevention Studies

Participants: Susan P. Buchbinder, MD; Frederick M. Hecht, MD; Jeffrey D. Klausner, MD, MPH; Dennis Osmond, PhD; Kimberly Page Shafer, PhD, MPH; Eric Vittinghoff, PhD

Laurence Peiperl, MD: Welcome to the HIV InSite roundtable discussion on risk of HIV transmission by oral sex. Our goal today is to address three specific questions that have remained controversial throughout the AIDS epidemic. First, based on available scientific evidence, what is the risk of HIV transmission to an HIV-uninfected person who performs oral sex on an insertive male partner who is HIV positive? Second, what specific factors can affect this risk in a given situation? And finally, what advice is most appropriate for care providers and public health officials to communicate to people who have, or are thinking of having, oral sex?

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Based on available scientific evidence, what is the risk of HIV transmission to an HIV-uninfected person who performs oral sex on an insertive male partner who is HIV positive?

Our panel today includes San Francisco's leading researchers in sexual transmission of HIV, including Susan Buchbinder, who is the director of the HIV research section in the San Francisco Department of Public Health; Frederick "Rick" Hecht, who is an associate clinical professor at the UCSF Positive Health Program at San Francisco General Hospital; Jeffrey Klausner, who is the director of the STD Prevention and Control Services of the San Francisco Department of Public Health; Kimberly Page Shafer, who is an assistant adjunct professor at the UCSF Center for AIDS Prevention Studies; and Eric Vittinghoff, associate adjunct professor in the UCSF Division of Biostatistics. The discussion will be moderated by Tom Coates, who is professor of medicine and director of the UCSF AIDS Research Institute and the Center for AIDS Prevention Studies.

Thomas J. Coates, PhD: Thanks to everybody for joining us today. I think it might be useful to begin the discussion by trying to come to some consensus of what the scientific evidence says about the risk of HIV transmission to an HIV-uninfected person who performs oral sex on an insertive male partner who is HIV positive. In other words, what risk does one have of acquiring HIV by practicing receptive oral sex with or without ejaculation? We have various datasets and literatures that can play to that. So why don't we start by reviewing what those datasets. Kim?

Kimberly Page Shafer, PhD, MPH: I think it's appropriate that we refer to receptive sex on a male partner as "fellatio," since that is an appropriate and well described term for the act.

TC: Okay, fellatio with ejaculation. Who would like to start?

Jeffrey D. Klausner, MD, MPH: Perhaps we could get fellatio without ejaculation off the table and agree that's an extremely low risk exposure activity?

TC: Well, let's hear about that. Would everyone agree with that? Or, would there be anyone who disagrees with that?

Susan P. Buchbinder, MD: I think when we're talking about risk, we have to talk first about whether transmission has been reported to occur by that route and second, how frequently it occurs. What I would say about receptive fellatio without ejaculation is that there are case reports that it has occurred, but that it is exceedingly rare, and so the risk is very low for that type of exposure. That would be my opinion. I would say it does occur but very rarely and it is very low risk.

TC: Others?

Frederick M. Hecht, MD: Certainly in our Options study and other studies, there are clear reports of transmission through anal sex where there is not circulation, so I think oral circulation is potentially contagious. So that suggests that if oral sex transmission occurs, it potentially could happen without

ejaculation, so I think pre-ejaculate is potentially contagious. So that suggests that if oral sex transmission occurs, it potentially could happen without ejaculation. Having said that, though, while biologically plausible, I think it would be very unlikely. The data that's out there suggests that it is very low risk but I think there's not really good data to quantitate that. We have one report in the Options Project, one oral transmission case in which it's unclear whether there was ejaculation. It's possibly without ejaculation and I'm a little skeptical because of the exact way the report was made whether that's true. But otherwise, all the cases in which we suspect oral sex transmission included ejaculation. Our data again has a lot of limitations. We're not seeing cases, with one possible exception, that it can be a route of transmission.

TC: So we will say that fellatio without ejaculation can happen but it is exceedingly rare. It's not "no risk" but it's relatively low risk.

FH: I would say extremely low risk.

TC: Extremely low risk, okay.

JK: I think there has to be exposure to infectious substance or an infectious inoculum and no, HIV is not transmitted from skin-to-skin contact or skin-to-mucous-membrane contact without any deep cuts or breaks in squamous epithelium. If there is no infectious pre-cum, which is still a hypothetical route of transmission, and there is no ejaculate, there should be no transmission, there should be no exposure to virus.

SB: To follow up on that, there is some evidence that there is virus in pre-ejaculate, although probably low titer in a relatively small volume. One situation in which you might think that infection without ejaculation could occur orally would be, for instance, if someone had a urethral discharge. In cases of urethral gonorrhea or other inflammatory STDs or potentially ulcerative STDs—where you have an open wound on the penis—you could hypothesize that transmission could occur by that route. In the absence of those types of cofactors, I think I would agree with what Rick said, that transmission of HIV by receptive fellatio without ejaculation is exceedingly rare.

KS: The problem with the discussion, though, continues to revolve around the inability to quantify risk. And because these are cases or, in fact, even uncorroborated cases, of acquiring HIV from fellatio without ejaculation, besides saying "exceedingly low risk" or "very low risk," that's the best you can do. It is all still hypothetical.

TC: Umm-hmm. Well then, let's move to the case of fellatio *with* ejaculation and as you, from your various datasets, attempt to quantify the risk, it might be helpful to give a short description of the data upon which the estimates are made. Susan, do you have anything to say?

SB: I think that there's clearly biological plausibility that HIV transmission can occur from receptive fellatio with ejaculation and there are a number of types of databases that support that that occurs. One is animal data, which demonstrates that if you swab tonsillar tissue or expose macaques to SIV via oral mucosa, infection can occur ([Slide 1](#)). On the other hand, I think that the studies in which comparisons are made of the efficacy of SIV transmission through oral, anal, vaginal, and intravenous routes are potentially flawed. SIV is a different virus from HIV. In animal models, vaginal and rectal exposure are done atraumatically, which doesn't really represent what happens during sexual intercourse. So I wouldn't take away from the SIV models what the relative risks of various types of exposure are, but I would say that infection clearly occurs.

There also are data from animal models describing in detail the histology of tonsillar tissue, which is very similar to the histology of vaginal and rectal tissue, both in being rich in dendritic cells and also having these so-called M-cells that are similar to the MALT—or mucosal-associated lymphoid tissue—of the gut and the rectum. These cells are able to transport antigens to lymphoid tissue in the absence of trauma or inflammation. So I think that there's good basic science evidence that tonsillar tissue in particular should be susceptible to infection.

We also know that an average ejaculate in the absence of inflammation or STDs has about a million white cells. Now, we still don't know whether HIV is transmitted through free virus or cell-associated virus. But again, if a male partner is ejaculating into someone's mouth and into the area of the tonsillar tissue, the tonsillar tissue is receptive to becoming infected. We know there's HIV in semen. We know there are white cells in semen. It seems eminently reasonable to me that infection could occur by that route.

So then we're left with "what do the epidemiologic data tell us?" To try to briefly summarize, the difficulty quantifying risk, as Kim mentioned, is that some people have oral sex as well as other riskier practices like receptive anal sex, while other people just have oral sex. When you do cohort studies in people who are generally having multiple sexual practices, many studies suggest that having receptive fellatio with ejaculation does, in fact, confer some increased risk but that risk is relatively low, and in most cases no longer statistically significant once you control for other riskier factors, such as receptive anal sex. From data that we have—and I will let Eric describe it in more detail—laying out the per-contact risk of HIV, having receptive anal sex with or without ejaculation is probably on the order of 10 times riskier than having receptive fellatio with ejaculation.

So clearly, the riskiest practices can overwhelm our ability to look at the risk that is associated with having this lower-risk type of exposure. There are case series, which I think Rick will probably describe in greater detail, demonstrating that oral transmission occurs. We also have a cohort study of newly infected people in cities where people were followed prospectively in a cohort study. We had about a hundred seroconverters who were prospectively identified and were asked about their risk behaviors both prospectively—before their infection status was known—as well as retrospectively, when they were queried in great detail about all of their potential HIV exposures from three months prior to their last negative HIV test all the way through their first positive HIV test. In that study, 17% of the seroconverting men reported that their riskiest exposure was having unprotected receptive fellatio with ejaculation ([Slide 2](#)). Is it plausible that some proportion of those men under-reported higher risk practices, either because they misclassified the serostatus of their partners or were uncomfortable acknowledging their actual risk behaviors? Certainly. But I would say that the data from this study and others suggests that somewhere on the order of 5-15% of infections are caused by receptive oral fellatio.

Eric Vittinghoff, PhD: The analysis that I worked on was with data for people who were multiply exposed, to try to use multivariate methods essentially to tease out some estimate of the risk of fellatio with ejaculation ([Slide 3](#)). We worked on a large dataset of an 18-month prospective cohort with three follow-up visits. There were about 2,000 men, 59 seroconversions, and we came up with an estimate of 4/10,000—which was four one-hundredths of one percent—infection rate. One thing to emphasize is that this was lower by a factor of about 7 than receptive anal sex with HIV-positive or unknown sero-status partners, which was the same partner category that was used for the fellatio analysis. The other point to make is that the confidence interval for that estimate for fellatio with ejaculation was also quite wide. I mean, consistent with what Susan was saying about the difficulty of rejecting the hypothesis of finding a statistically significant result is that the information isn't very strong. So while the lower bound was very low, the upper bound was also high enough to be of some concern.

TC: Kim?

KS: To go back to where Susan started, the evidence is there that there is biological plausibility. Of the case reports--actually 28 published--some have multiple cases, so there are maybe over 40 in the actual literature. But I would emphasize that the number of case reports is extremely low when one considers the size and the duration of this epidemic and that, from a population perspective, should be kept in mind. The SIV data is also compelling and I think that probably more should be done with that animal model. The problem I have with the SIV model, and I think Susan addressed, is that it's not easy to extrapolate because in fact oral transmission of SIV, non-traumatic oral transmission, was easier to induce than anal infection in the SIV model. So I'm not entirely a believer in the SIV model vis-a-vis transmission routes.

I would argue that the epidemiologic evidence is actually overwhelming in showing that the risk is extremely low, and I go back to a paper published from the early cohorts. Roger Detels published a wonderful paper in which 232 men out of 2,915 MSM were followed and two of those reported no anal-genital sex in the seroconversion period in which their infection was detected, but in fact only one of those could be reliably reported as being inside the range of this infection period and so this very early data goes back and shows extremely low risk ([Slide 4](#)). Obviously, since the beginning of this epidemic, oral sex has been performed by a majority of folks, and not only gay men but heterosexuals. So it has always been a concern. But I don't think that the epidemiologic evidence in any way supports that it implies risk. In July of this last year, a group in Spain published an excellent paper from serodiscordant couples, who were heterosexuals, where they evaluated for risks of HIV transmission through unprotected oral sex, and in over 19,000 unprotected oral-genital contacts with HIV-infected partners, there was not a single case of seroconversion to HIV ([Slide 5](#)). This included both

infected women and infected men, but the majority of the population in this study was infected men. Our data in seroconverters that we've analyzed as well from pooling studies of seroconversion, did find a significant, an elevated risk. This is the study that we published in 1997, where we showed an elevated odds in a model controlling for anal sex, and actually this is what led me to begin to believe that there was increased oral sex risk, finding this elevated odds ratio in association with oral sex in seroconverters ([Slide 6](#)). The limitation of my study, which is clearly pointed out and which I come back to as I review more and more evidence, is that I could not ascertain that any of the men in this study did not also have anal sex and I believe that infectivity of anal sex is so high that I think it's almost impossible to unmask that. Eric's study was compelling and I think it was not only compelling because of the significantly low infectivity estimate associated with oral sex, but also, even though not significantly, insertive anal sex was of somewhat higher estimated infectivity, and protected receptive anal sex with a condom was of somewhat higher infectivity.

The data we recently published from my study designed to look at this question--and it may be the only study designed to look at the risk of oral sex--we published a study that showed that among 239 men who practice exclusively fellatio, not one HIV infection had occurred ([Slide 7](#)). To date, we've now interviewed over 363 men and again find no infections. This represents over 5,000 acts of oral sex, and preliminary infectivity estimates based on certain assumptions suggest an upper bound of less than what Eric published, which is 0.07%, so I think that our data--again this is a study designed to look at HIV infection in men who perform oral sex, as a means of unmasking the effect of anal sex--corroborate not only the previous studies but suggest extremely low risk. And I would say that, from the same time period and from the same population from which we recruited our participants, that HIV prevalence and incidence were extremely high in men who reported anal sex and in men who reported anal sex with a condom. These men were all recruited from HIV testing sites, who tend to be very high risk. There are likely to be certain differences in men who only practice oral sex compared to men who have a larger repertoire of sexual activities. But certainly consistently even in the 363 men, about 30% of them report having sex with HIV-positive partners and we still don't have any infections in this group.

The last thing I want to note about the epidemiologic studies, is that there are studies which report a high proportion of men who say that they got HIV infection from oral sex and in general, most of those studies rely on behavior which is recorded *after* folks know the results of their HIV test. And I think in the early years, 10 years ago, we knew that there was a recall bias in that. I would hypothesize, and this is only a hypothesis, and much of we're trying to do here today is based on hypotheses, but I would hypothesize that recall bias may be even higher nowadays. Twenty years into an epidemic after you have had a generation of safe sex messages, if after you get an HIV-positive result, you report that you've had unprotected anal sex, I'd say that there's probably a great deal of social and psychological trauma associated with that, as well as stigma. Keet published a really interesting paper in 1992 from the seroconverter study in Holland, in which 102 men seroconverted and 20 of them had reported having had only oral sex or fellatio in the period prior to that cohort visit. It was an awfully large proportion and in reinterviewing those men, 55% later did retract their initial story and in face-to-face interviews stated they had had higher risk exposures ([Slide 8](#)).

I'm going to conclude with the HOT study in which, again, we interview men who we screen and rescreen to ascertain that, in fact, their only risk is oral sex. So they are a special population and they are screened and rescreened and they get their HIV test and eventually we do another very in-depth interview and after three corroborating screenings, or two screenings and one interview in which they say they've only had oral sex, 25% later report a higher risk exposure--anal sex in the same time period--after we get them in another environment with a different questionnaire and a face-to-face interview, and this is after they've been told that, in fact, they're negative. And so we see this working many ways and they're like, "Whew! Well, now I can tell the truth." But in fact, of those 363 men, we estimate that up to a quarter of them probably weren't having only oral sex, and so I think that we have huge problems in terms of self-reported risk behavior when it comes to the oral sex question that will always plague us if we try to quantify risk.

TC: Rick, can you add anything from the perspective of the Options?

FH: Yes, I would add more. Can I ask one question before I forget this: When you say you have "5,000 acts of fellatio," is that with ejaculation or without?

KS: I haven't split that out yet. I've been sort of running these data quickly, but about 30% of them have partners who ejaculate.

FH: Okay, so...

SB: And about only 30% or so have a positive partner

KS: Right, only 30%, this...

FH: So, just to look at that, that's 5,000 acts which your data follows so far, only a third of those are with ejaculation, and then of those, the majority of people don't report a known HIV-positive partner?

KS: No. In fact, 30% report a known HIV-positive partner but then another 50% report a partner of unknown sero-status, which is often a black hole as well...

FH: Okay. The point is that of those 5,000 acts, the majority of those are probably not actual exposure to semen from an HIV-positive partner?

KS: At least based on self-report.

FH: Well, I can add a little bit of data from our Options cohort. I want to emphasize that this data is *not* looking at per contact risk. It is also *not* looking at population-attributable risk. What it's looking at is: In a cohort of men who are recently infected with HIV in San Francisco, how many of them do we think might have been infected through oral sex? What we did was look in detail at people who were enrolled in the study between June 1996 and August 1999, and in that time period, we had 102 men who were recently infected with HIV. We did a first step, which was to look at a baseline questionnaire that they did when they were enrolled that included a series of questions about how they might have been exposed to HIV. When we looked just at that initial questionnaire data of the 102 men, 19 of them or 18% reported only oral sex as the risk by which they might have become infected. We then did a series of follow-up steps which included a detailed interview with an epidemiologist, with a lot of permission to disclose other risks, a lot of ultra-detailed questions to probe and see if we could elicit any other kinds of possible exposures. And after that was done, starting from those original 19 people, we ended up with 8 of them who, after detailed and at least one—usually more, 2-3—additional interviews, did not look like they had other significant risks from history ([Slide 9](#)). And just to go over what happened with those other people who came up with other risks, 4 of those people on additional questioning revealed 1 incident of unprotected anal sex during the possible exposure period. Two of them reported there was at least some period in which they were "blackened out" in which they don't know of any other exposure but since we couldn't really rule out some other exposure, we took those people also out of this group of possible oral sex transmission. One person reported—actually from a partner who we brought in—one episode in which the condom broke and then one of those people reported multiple anal exposures that he had not previously revealed on the initial questionnaire ([Slide 10](#)). The basic point there is similar to what Kim is saying. There are people who are reluctant to disclose other risks or will not immediately disclose a risk that we might still consider something that would be a possible route of transmission. For example, the people who blacked out and can't be sure what happened to them, those are people that we didn't feel very confident were likely oral sex transmission cases.

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The next thing we did was look at those remaining cases and look at how good the evidence was and one of the problems here, like other people pointed out, is there really are not that many men who have sex with men who are only having oral sex. When we broke this down, one of those 8 people reported only oral sex and we could get a partner in who corroborated that, and they looked like two people who matched up and that transmission occurred, based on phylogenetic sequencing.

SB: How many?

FH: One. There was another person who reported only oral sex and no other exposures, and when I'm saying no other exposures, we're just taking a very broad period of time—a six-month period, up until the day they went for the first positive HIV test, or symptoms of potential acute HIV infection. That six-month window is probably much longer than actually would occur, but we took a wide period of time in order to rule out any other possible exposures. So a second person reported over a six-month period only oral sex exposure but we couldn't get a partner in to support the story. Four people reported as alternate exposures protected anal sex only, and one person reported one episode of unprotected anal sex but with a partner who we brought in and verified was HIV negative. So the bottom line here depends on how you construe the data. I think we had one very tight case of oral sex transmission. In some of the other cases, it is possible that transmission took place either through undisclosed risks or through condom failure that was not recognized by the participant. The bottom line though, is still that this suggests a series of cases in which HIV infection, we think pretty strongly, occurred through oral sex, or that was the most plausible route of transmission in this cohort.

TC: Thanks. So, Jeff, do you have anything to add to that?

JK: Well, I think that people ought to understand that the level of data—we're talking about the biological data, with the macaque model, epidemiological data—it's all weak. It's all got a lot of holes in it. When you talk about the macaque model, you talk about a sedated macaque that's anesthetized, that's swabbed for three 5-minute periods with infectious virus directly applied to multiple tonsillar areas. It's given a medication to prevent salivation. We know in human beings the presence of saliva and oral fluids has HIV-inhibitory properties, that there are mucosal antibodies, there are mucins, something called thrombospondin, something called secretory leukocyte protease inhibitor, that saliva itself is hypotonic, it doesn't support the replication of the virus. So just because a monkey can be infected from the application of an experimental swab, means—just that. But how does it translate into human experience, is still unknown. So you're left with epidemiological data and the history of epidemiological data comes from case

reports initially. So it's a time during the AIDS epidemic when people were extremely scared, frightened, appropriately so. There's a kind of energy to publish things based on individual interviews and what we call "publication bias" towards potentially sensational articles as Rick and as Kim pointed out. When relying on a patient history, it is often not really substantiated when you re-interview people. So I think we do have to accept that the biological evidence and the epidemiological data, until more recently, has been very limited. Recently, there have been two studies which have tried specifically to look at the risk of oral sex transmission. There was a Spanish study that Kim mentioned, which had measured specific episodes of oral-genital contact with known HIV-infected exposures and the total number of episodes was several thousand and the number of new cases of documented transmission was zero. In Kim's study, which is specifically looking at the risk for oral sex and oral exposure, she has not identified any new infections. Certainly, I have patients that I take care of, I have friends, I have colleagues that can tell me that's the way they got infected. So, I do believe that the evidence may be limited but that oral transmission can occur.

From a public health perspective at a population level, oral sex is a lower risk activity and the promotion of it on a population level could result in fewer HIV

Then the next question is, what is the frequency and what's really the public health impact of that? Certainly if we were able to eliminate all of the unprotected discordant anal intercourse, we would eliminate 95% of new HIV infections in San Francisco. So from a public health perspective at a population level, oral sex is a lower risk activity and the promotion of it on a population level could result in fewer HIV infections and actually result in a decline in the epidemic. Every time I mention that, someone says, "Well, you're willing to sacrifice an individual then for the good of the population." So I think, individuals still probably need to do what's reasonable—and that's to protect themselves from infectious exposure, which is exposure to ejaculate or semen – but similarly as responsible doctors and scientists, we should not be overplaying what the risk is because when it comes down to it, I think when we really

infections.

scientists, we should not be overplaying what the risk is because when it comes down to it, I think when we really look hard at the data, it's extremely limited.

TC: So that, would it be fair to say, then, it sounds like--sort of summarizing from everyone--that transmission by oral sex/fellatio with ejaculation, being the receptive partner, transmission is biologically plausible. We believe it occurs based on case evidence. It's a relatively rare event. It's somewhat difficult to estimate the exact per contact risk because of the imprecision of the estimates, both because of what people report and because of just the imprecise nature of what's trying to be estimated, and because oral sex gets confounded with other kinds of activities that people engage in.

Having said that, and sort of moving toward the public health message, if we thought about facilitating and inhibitory factors, what factors might facilitate transmission via oral sex? What factors might inhibit it?

KS: I'd just like to say, though, I think that Eric's work is really important work in terms of providing a number. And this is a segue into the message that we give because I talk to counselors, HIV test counselors, all over the country and the most frequent question that people get is "what is the risk of getting HIV from oral sex?" No one ever asks "what is the risk of getting HIV if I use a condom?" It's rarely asked. They want to know about oral sex. And Eric's work is very, very important work in that it gives us an estimate that we can hold onto for having had unprotected fellatio with an HIV-positive or unknown serostatus partner and to get to the bottom line for questions, because we don't know what the risk is if you have a positive partner but we do have an actual number that has been published in this well done work. So that needs to be put out there, that it's one out of 2,500.

EV: Well, I'd like to just comment on that but in some ways that's a frightening idea for me because I think that number is only interpretable in terms of a confidence interval and a lot of understanding about kinds of biases that could go into the estimation of that number.

JK: Could you explain how you got that number?

EV: Well, with a relatively, overly simple model, a so-called Bernoulli model, which assumes that there's a constant per-contact risk for this kind of exposure and that kind of exposure. So you can estimate a person's risk as a product of these various types of risks. So that assumes that we have good information on the numbers of contacts of each type, which is almost surely not entirely true. The model assumes that there is no heterogeneity across types of contacts, also untrue, although we did do a considerable amount of checking on the model to make sure that the results weren't badly biased by the heterogeneity factor. But it was done by a simple model.

JK: And that model uses real data or that model uses actual studies?

EV: No, the model certainly uses data which we have, self-report of sexual histories of sexual behavior from 2000 men over 18 months, of whom 59 seroconverted.

SB: And Eric, didn't you repeat the model actually using a new dataset, the HIVNET dataset, and find virtually the same numbers?

EV: That's right.

SB: Obviously the estimates are only as good as the data you collect. But these data were collected first in more than 2000 MSM and then in more than 3000 MSM in two separate studies and both models came up with virtually the same estimates. But this leads to two problems, and Kim, these problems also apply to the study you cited with sero-discordant couples. First, heterogeneity between partner pairs, and second, how people end up interpreting data for their own risk reduction strategies. When you look at studies of serodiscordant couples, you have to remember that they had to remain serodiscordant for some time before being identified. This means that they had sex for some period of time and managed to still have the negative person stay negative. So whatever they were doing may not be reflective of serodiscordant couples in which the negative person became infected relatively quickly, or of people who are having multiple partners. Similarly, my concern is that when you say that there's about a 1% risk of becoming infected per contact with receptive anal sex, with or without ejaculation with a known positive partner--and in Eric's study, it's 0.8%--sometimes people interpret this to mean "That's great news! I can do this 99 times and I'll be safe. It's only the 100th time that I have to worry about." So I think you have to be clear about the public health message and I know we're going to get back to that but I just wanted to put in that caveat.

KS: I want to come back to that because what's getting out to the public really has very little to do with anything that's published or anything that's known or anything that's been empirically shown. I have had counselors tell people to remove precum and semen from their mouth after oral sex by spitting, by gargling, by washing their mouth out with peroxide, with Listerine, with sucking lemons, with hot tea and with popsicles! I have heard counselors tell people--and we ask them all the time--it's a wonderful exercise that we do: "What is it that you tell people?" --"Don't floss or brush half an hour before or half an hour after, two hours before or two hours after, four hours before or four hours after." And I'm talking to counselors all over the country and sometimes the world. And it's only in this country, the U.S., that people worry about oral sex.

I have had counselors tell people to remove precum and semen from their mouth after oral sex by spitting, by gargling, by washing their mouth out with peroxide, with Listerine, with sucking lemons, with hot tea and with popsicles!

TC: Okay, so what's...Tell us the truth. What facilitates transmission via oral sex?

KS: We don't know.

TC: What inhibits?

SB: If the insertive partner has an STD that's either ulcerative potentially or certainly inflammatory, you're going to have more HIV in the ejaculate. It only stands to reason that it's plausibly going to increase the risk. And conversely, Jeff can perhaps comment on the rates that we're seeing right now of oral gonorrhea in the city in gay men, but they're relatively high. So I think that that could potentially increase the risk.

KS: I think there are at least six different cofactors, which may be involved in increasing or decreasing susceptibility to HIV infection through oral sex and they all appear in different contexts but all involve trauma, sores, inflammation, allergies, concurrent sexually transmitted diseases, ejaculation in the mouth, immunosuppression, and something

that is scientifically known as xerostomia or dry mouth. The first, genetic factors, may include CCR5 mutation or inherent factors in a host that may inhibit viral replication. Systemic immunosuppression, localized immune reactions, chronic allergies may activate the immune system. These are all hypothesized. Oral hygiene and health, gingivitis, certainly a large majority of case reports have speculated that gingivitis may play a role in increasing

hypothesized. Oral hygiene and health, gingivitis—certainly a large majority of case reports have speculated that gingivitis may play a role in increasing the risk of acquiring HIV orally. I think that this is unlikely because in fact the population prevalence of gingivitis is extremely high. Periodontal disease is hypothesized, oral health practices including mouthwashes and oral histories; some case reports report recent gum or oral surgery. Concurrent sexually transmitted infection, although I will also add that concurrent with our examination of oral sex and orally acquired HIV, concurrent oral STD testing has been going on in thousands of people at the AIDS Health Project, and we have identified cases of oral gonorrhea and other STDs, but not one had HIV. Other oropharyngeal infections—we also include this—and medications which affect the oropharyngeal mucosa or the production of saliva, anything that's anticholinergic may be a cofactor. Drug use, the route of administration—snorting, swallowing drugs. Many of these may either affect the mucosa or may affect salivary production. Certainly sexual behaviors are believed to be possibly cofactors. Anything that may involve trauma to the soft palate or to the tonsils. And behaviors that increase risk of blood contact are always a risk factor no matter what kind of sexual practices people have. And then obviously, partner infectivity—we haven't talked about that. It's possible that in the Spanish study, a large portion of those folks were on antiretrovirals and it's certainly hypothetically possible that many of them may have decreased infectivity because of decreased viremia, and so stage of HIV infection may be a very important component in this, too, that we don't know about. But certainly, people rarely go around asking their partners about their viral load, although they might nowadays. Acute viral syndrome is something that we think about, and so these are all possible cofactors and the HOT study was actually designed to look at those and we have failed to identify any because we failed to identify any cases of orally acquired HIV.

JK: We really need cases to measure the effect of cofactors. We haven't been able to measure their true effect because we haven't had any cases to

compare those with cofactors versus those without cofactors. It certainly makes sense to me that if oral sex transmission does occur, that something that would increase exposure to more virus—whether more ejaculate, more multiple exposure to ejaculate, more infectious ejaculate via STDs or a partner whose virus is not suppressed on antiretroviral regimen—will expose you to more virus, which would make you more susceptible. From the data, it looks like that there are certain T-cells, these MALT cells or lymphocytes in the tonsils, and STDs could increase the number of these inflammatory cells, although many of these STDs are without symptoms in the throat and we don't get a lot of people with frank tonsillitis or pharyngitis who are presenting with gonococcal infections of the throat. I still think it comes down to: a lot of it is unknown. I think it's okay to tell people that we really don't know.

FH: I think one of the important points here is that, in terms of factors that may facilitate oral sex transmission, they are all things that might be plausible, that we could suggest, but I would just emphasize that we really don't have the data to answer that question right now.

EV: If you can't estimate risks, and you can't estimate interactions.

FH: I also wanted to go over some of the data that we're starting from in estimating risk of oral sex transmission. I just want to emphasize again that while there may be certain weaknesses or limitations of the data that Eric has done, I think it's really the best place to start in terms of per-contact risk. I think we have some consensus on that. At least, I think from everyone I'm hearing except Jeff. I just want to go over it to see if we're really starting from that point.

JK: Well, let's say we start at a point where we accepted the risk was 1 out of 2500 per contact. Where would we go? Where would we go with a public health message? Where would we go with a prevention strategy around that? How do you translate that "1 into 2500" into health risk communications?

TC: Well, let's look at it a slightly different way and then we are segueing into number three: What advice for providers? What public health communications would we give? Assuming the point estimate is 1 in 2500. There are a couple of options and let's sort of push it to the extremes. The one option is to say, "Yes, it is plausible. Yes, it probably does occur. It occurs with relative infrequency. There are bigger fish to fry; there are more things to worry about." Then the other extreme is to say, "Well, if it's between 5-15% of infections, then that's a reasonable fraction of infections" and maybe we should be a little more assertive about saying, "Gee, people ought to think twice before they do this."

Dennis Osmond, PhD: Are we basing that number on what Susan said and what Rick said?

TC: Right.

DO: I've been following cohorts for 20 years and I still have yet to see what I think is really a documented case. The San Francisco Men's Health Study cohort had 46 seroconverters; and the San Francisco Young Men's Health Study cohort had 38, and there was one case of an individual who reports no risks at all. He seroconverted—so I was never able to get what I thought was a plausible story out of him. So I find it very hard to say that 10-15% of new infections are due to oral sex—I just don't see the evidence for it. I think the best evidence comes from the cohort studies for the reasons Kim points out. The cases who present to various clinics for various reasons come along with various stories and histories whereas in the cohorts, they are being questioned, prior to their tests, so you at least have that working for you. But you still have as everybody has mentioned a bias for underreporting risky behaviors, underreported risk. So I think even the 1 out of 2500 estimate is probably too high. I would apply my usual clinical correction rule which is to double it and say 1 in 5000. I'm being a little fussy. You're saying that's the upper limit?

TC: That's one point of view.

DO: That's one point of view. But anyway, I don't think we have solid evidence to say that 10-15% of new infections are due to oral sex. That's what I want to be on the record about.

TC: Susan?

SB: Based on data from our cohort studies as well as other published data with several very well-documented cases of HIV acquisition from receptive oral sex with ejaculation, I would estimate that oral sex contributes to 5-10% of new cases of infection. And we do have cohort data as well that does find that receptive oral sex to ejaculation, with a known HIV-positive partner is an independent risk factor for infection and that the attributable fraction is about 7%.

DO: But aren't some of those individuals having protected anal sex?

SB: That's a very important issue. In some sense, we're talking about the ways that misclassification can happen, either over- or under-attributing HIV

acquisition to receptive oral sex. But what I have to say is that in every case where people have both kinds of sexual practice, we automatically ascribe it to receptive or insertive anal sex. In Eric's data, what you see is that actually insertive anal sex and receptive oral sex with ejaculation have about the same per contact estimates. So I think there are situations in which we're probably underestimating the contribution of oral sex, as well as examples where we overestimate. So I come back to saying that 5-10% or if you want to be even more conservative, say even as few as 3% of cases of acquisition are due to oral...

JK and DO: Why not say 1%?

JK: ... which is what Kim's data, and Rick's data...

SB: I'm not sure that it's 1%...

FH: I'm not sure I necessarily construe my data as 1%. We need to talk more about limitations.

People draw their line in the sand in different places...they need to be armed with all of the information for them to make a personal decision about "How much is this particular practice worth versus the amount of risk that I take on?"

SB: But remember that attributable risk is a combination of what the absolute elevated risk is and also how common it is. So while I certainly think that we want to move people away from having unprotected receptive anal sex, and certainly want to counsel people that even if they have protected receptive anal sex, condoms sometimes fail and so there is some risk associated with that, I don't know that on the flip side we really want to say, "Go and have as much unprotected receptive oral sex with ejaculation as you want and you don't have to worry about it." What I come back to is that we need to consider both the public health strategy, which is very important, and, as Jeff has made the distinction, there are different issues that may come up in counseling the individual. I think we do individuals a disservice if we don't present them with the data that's available, and I think the data says, "Performing fellatio without ejaculation is exceedingly low risk. With ejaculation carries some risk, albeit relatively low risk but you need to know that there's some risk associated with it." One way to think about it is the risk relative to other kinds of practices. People draw their line in the sand in different places and I think they need to be armed with all of the information for them to make a personal decision about "How much is this particular practice worth versus the amount of risk that I take on?"

TC: Have we evolved, both in our public health messages and our individual counseling messages, from a point of view that I think we did hold at one point in time, that we really had to keep our safe sex messages simple, pure, clean--don't confuse people--to a position of saying, "Here's the information. Draw your line where you feel comfortable"?

We do individuals a disservice if we don't present them with the data that's available, and I think the data says, "Performing fellatio without ejaculation is exceedingly low risk. With ejaculation carries some risk, albeit relatively low risk but you need to know that there's some risk associated with it."

SB: I think it's patronizing not to do that. I think you don't want to make it exceedingly complex. I don't think you want to start throwing numbers and confidence intervals at people, but I think you can craft a fairly simple message that still doesn't dumb it down so much that you're not giving people the information with which they're going to make their decisions about their individual sexual practices. And I agree with Jeff that the goal from a public health standpoint is really to try to move people away from the highest risk sexual practices but I think that you want to do that by giving people all of the information, not just part of the information.

KS: What you run into, though, is if you say to a guy who comes in, "Well, it's very low" and then the next guy, "It's very, very low," they go out and it's "Well, what's very low compared to very, very low" and they say "Two 'verys' and one 'very'", and you could say, "Very, very, very low"...I mean, that's what people are hanging onto, which is a very difficult situation in terms of what actually happens in practice out there when people show up to get an HIV test and they want to know, how low is it? Well, it's very low. Well, *how* low is it?

FH: I think that those are challenges but one key issue is: do we say, "Oral sex is no risk" or do we say "It's low or very low risk"? I don't think it's right to say that oral sex is no risk. We need to craft some sort of message along the line of what Susan was saying, that says it's low risk or very low risk--and that's one of the number one issues--and

the second is, I think we have clear agreement that it's lower risk than, for example, unprotected receptive anal sex, and I think all of us would agree that you want to craft a message that says, "If you're trying to decrease your risk of getting HIV, it's definitely safer to have oral sex, even when someone comes in your mouth, than it is to be a bottom and not use a condom..." I think those are things we can clearly agree on. The more subtle things--how do you deal with that message about what the level of risk is--if you're going to get into that depends on whether people ask more questions about that. With the kind of data Eric has, you can give a ballpark. You have to say that this is really uncertain but to give someone an idea. If you do this 10,000 times, about four times you get infected. Or out of 2500 exposures, you might get infected once.

If you say to a guy who comes in, "Well, it's very low" and then the next guy, "It's very, very low," they go out and it's "Well, what's very low compared to very, very low?"

SB: Or the other way of crafting it, which I'd prefer, is to say, "You know, it's somewhere around 10 times less risky than being the bottom." So that helps you to decide, you know, and so you've got something to sort of hang it on, because again the thing I get concerned about is that people could also take this and say, "If you were the bottom, if you had receptive anal sex with a positive partner, about 8 times out of 1000, you'd become infected." I'd get concerned that people don't quite get that and they say, "Okay, then I could actually have unprotected receptive anal sex 992 times and I'm home free. I've just gotta be sure that 993rd time I use a condom." I think there are various strategies with which to...

DO: Do you take it a step further in using Eric's data and say, "It's less risky than being a bottom *with* a condom"? That's sort of what is being said, and I think my read of the literature agrees with that, that there is more risk just because of condom breakage.

SB: What's difficult about those estimates of higher risk with protected receptive anal sex is that these are probably a result of both condom failure and overreporting of condom use. But I do think that part of the message is: you've got to know that having receptive anal sex is the riskiest practice, and it can be risky even if you're using a condom. So here are the things we know about how to use condoms so they don't fail but you also just have to know that sometimes they do fail, and we have demonstrated relatively high rates of condom failure in multiple cohorts of gay men.

TC: So I think a principle that's evolving here, though, is that we really need to approach the at-risk population with great respect in giving out the

information and crafting a message that says, "Of course, this is the highest risk thing that you can do. Best to avoid it because it does have a much higher risk of having you contract HIV. There are other activities that are much lower risk, such as unprotected receptive oral with ejaculation, or protected anal, that could be of around the same magnitude or the latter may be of somewhat higher magnitude. So you just have to know that if you're engaging in those practices, there are ways to use condoms that might make it safer but there are occasions in which transmission does occur."

JK: You know, the principles on individual risk reduction have always been to move people along toward a safer part of the spectrum. So to move them from unprotected receptive anal, to receptive anal with a condom, to insertive, to insertive anal with a condom, to receptive oral with ejaculation, and if I was dealing on an individual level with a patient whose primary risk behavior was oral sex with exposure to ejaculate, I would counsel that individual to try to reduce their exposure to ejaculate. But from a public health perspective, I'm not going to spend a lot of effort trying to reduce the amount of exposure to ejaculate from oral sex because if the attributable risk on a population level is 1% or 2%, I'm going to spend much of my effort trying to work on that 99% or 95% of anal sex and anal exposure.

SB: I agree with what Jeff is saying, that from a population standpoint and from crafting public health messages, the focus should be on receptive anal sex. On an individual level, again, I think it's easy enough to say, "You know, the least risky thing you can do that's penetrative is to have fellatio and not let your partner ejaculate in your mouth. That's the easiest thing to do. If you're able to do that, that's the safest thing you can do." And then work backwards from this. People don't necessarily just need to move one step in the continuum but you do want to craft the message for where that particular individual *is* in the continuum and from a public health standpoint, you do want to focus your resources on the major portion of infections.

TC: Similarly, if they were exposed to cum through oral sex, would we offer them PEP?

JK: Would we offer them post-exposure prevention and post exposure prophylaxis with antiviral medications? So right now, at City Clinic, which is a public City STD clinic, we don't, because we have to prioritize our limited resources for the highest risk exposures and we don't have the resources to make available PEP for every possible type of exposure to HIV. But I've been in a lot of discussions and dialogues with other advocates and they say, "Well, oral sex is clearly an important exposure. You really need to serve that population and offer them PEP."

TC: Again, I don't think we'll achieve consensus on that. Some would say yes, some would say no. But I think our time is running out.

KS: But I think one of the things to consider there, though, and it is important, given what we know about people who underreported their risk, is that many people who come in and report a risk are actually seeking to confirm, they are looking for a way to get treatment or to get counseling about a higher risk exposure, which they don't feel comfortable disclosing and so it's always important for counselors to address the fact that even though people report only oral sex, many of them may have higher risk exposures and are not able to disclose those for one reason or another. And so we have to continue to promote responsible sexual behaviors, using condoms and reducing exposure to infected semen, no matter what practice they're having.

LP: Well, let me see if I can summarize the conversation and if everyone can agree or comment on the following statements. The first is that HIV acquisition by receptive oral sex without ejaculation is so unlikely, that we don't have any firm evidence even to show that it actually occurs.

SB: I'm not sure that I would say that. I think I would say that there are case reports—I can't really comment on the veracity of the reports—but they're on the order of case reports and it is exceedingly rare.

LP: Without ejaculation?

SB: Yes, there are reported cases.

FH: There are cases for it but I don't know how many.

KS: Oh, you mean without ejaculation?

SB: Without ejaculation. I can't say...

KS: I could count them!

SB: But you know, I think the thing also that we have to remember in thinking about counting case reports is that, after a certain point, people don't publish more cases of the same event. So I don't think you can count up the number of case reports and say that the number of cases reflects what's happening with the epidemic. I would just say, "While there are case reports, we think that the epidemiologic evidence such as it is suggests that that's a very rare event."

KS: An *exceedingly* rare...better than "very rare".

LP: Secondly, is it agreed that the risk of acquiring HIV from fellatio with ejaculation is on the order of 1 in 2500 per contact, but because people who have oral sex generally do it more than once, that receptive oral sex with ejaculation probably accounts for approximately 1-5% of HIV infection in men who have sex with men?

FH: I think that second part is going to be problematic and even though I think that might be true in some populations. I think the issues are (1) when you're really getting a population attributable risk the data is not really good; (2) it depends on what populations you're talking about. If there's very little other risk behavior and a lot of oral sex, I can see that being a high number. If there's a lot of unprotected anal sex, even with quite a bit of oral sex, it's not going to be as important a problem. So I think, again, it comes down to the kind of population that you're talking about and I think the data we have on that has weaknesses.

KS: I disagree. I think the data is overwhelming and when you look at the cohort studies that have accumulated over the past 20 years, especially the early ones, that 1% is what I would mark it at the highest, and I think that the cohort data is very, very good and inevitably, studies which report very high proportions of HIV attributable percent are in people who have reported their risk behavior after they have ascertained their HIV status.

SB: Well, I agree with what Rick said. I think that the early studies don't necessarily reflect current realities because there was a lot more unprotected anal sex early in the epidemic. As Rick points out, it doesn't necessarily reflect the current population attributable risk, which is driven by the relative

prevalence of various risk practices. And to address Kim's concern, our cohort studies assessed risk behavior before HIV infection status was known.

KS: But had they had anal sex?

SB: Some had and some hadn't, but that's what the multivariate models take into account. Multivariate models look at the independent contribution of each of the practices. So I think the bottom line is that probably we're not going to agree on what the population attributable risk is, and that it is in part going to be driven by the frequency of particular contacts in particular populations.

JK: I think we agree it's less than 5%, don't we?

SB: Uh,.... yes, I'd probably say it's--it may be less than 5%. I'd say 5% or less. But I wouldn't say 1% either.

JK: Well, 1% is less than 5%...(laughter)

KS: Well, I wouldn't say "5% or less"

SB: So I don't know that we're going to come to consensus on that.

TC: So we won't have agreement on that one.

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