

HIV Pre-Exposure Prophylaxis and Sex Work in Canada 2016

#SWPrEP

HIV Pre-Exposure Prophylaxis and Sex Work in Canada 2016

Record of a national consultation at
the Dalla Lana School of Public Health,
University of Toronto, October 19-20

Organized in partnership with Triple-X Workers'
Solidarity Association of British Columbia

Funded by Elton John AIDS Foundation



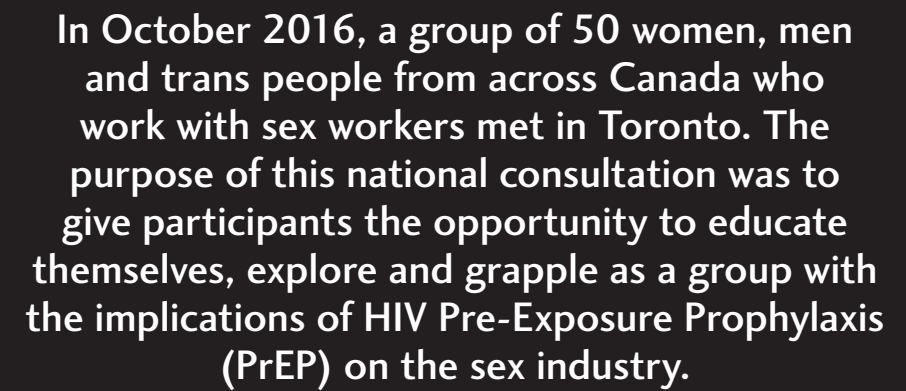
UNIVERSITY OF TORONTO
DALLA LANA SCHOOL OF PUBLIC HEALTH



Biindigen (BIN-deh-gay) I would like to honour
the caretakers of the traditional territories of
the Wendat (WHEN-dat), Anishinabek
(ah-nish-NAH-beck) Nation, the Haudenosaunee
(ho-den-ah-SHOW-nee) Confederacy, the
Mississaugas (miss-iss-AH-gahs) of the New
Credit First Nations, and the Métis (may-TEE)
Nation. This land is beautiful and provides
everything we need to survive. By caring for this
land, these Nations have gifted us with a home
for our families. Now it is our responsibility to be
the caretakers for our future generations.

~ Aqua Nibii Waawaaskone





MENU

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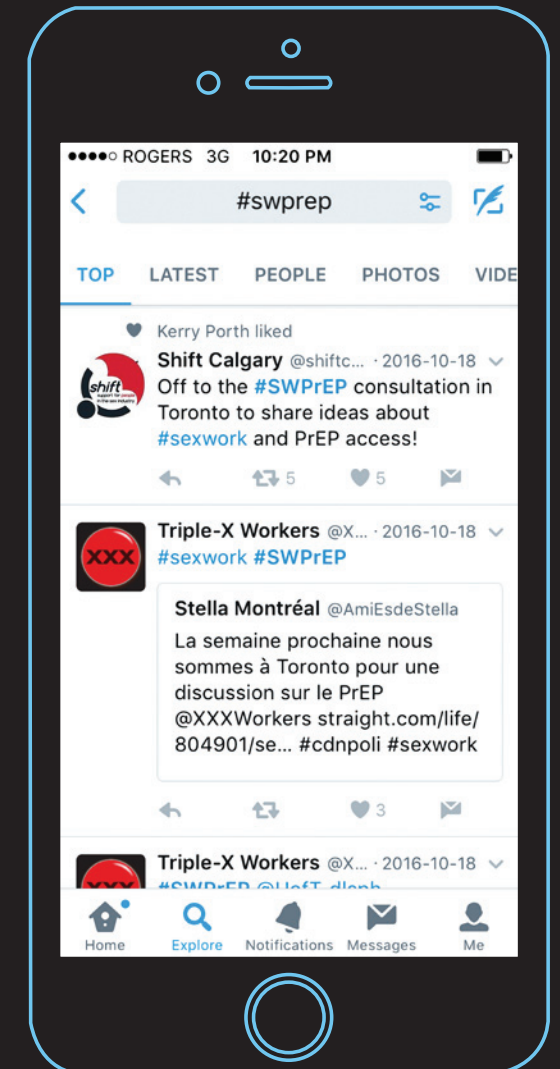
MENU

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WHY WE ARE HERE

Background for a national consultation

Andrew Sorfleet, Triple-X Workers' Solidarity Association of B.C.

Hi everybody. My name is Andy Sorfleet and I'm from the Triple-X Workers' Solidarity Association of B.C. If you don't know a lot about Triple-X, we started in 2012 and our goal was to form a kind of like a before a union — a proto-union of sorts. And we gathered together some friends with a lot of sex work experience and we joined up with some friends from the actors' union. And our goal in the last four years has been to put together all of the legal paperwork and proper documentation to make us a proper registered organization — a society, an association. The reason we did that is we felt that sex workers don't really have a voice to represent their concerns. The way we look at it is, we are not really here to represent all sex workers or their voices. We're trying to build something that could represent the voices of our members — the way that the actors' union represents the voices of the actors when they have to negotiate with producers.



So we're about four years in and we're very close to having everything, all our "t"s crossed and our "i"s dotted. We are just waiting now for our right to certify — to have a certification mark. So that's where that's at.

In terms of this particular gathering: A year ago May I was looking around on Facebook and I found a set of guidelines that came from the B.C. Centre for Excellence in HIV/AIDS research, and it suggested reasons why people would be prescribed PrEP. And one of the risk factors it listed was involvement in commercial sex. This may or may not be true, but what really bothered me about it is that there had been no opportunity for consultation or input from sex workers. There'd been no — as far as I could see — no attempt at doing that. So I put out a call on the friendly Internet and two people here today both responded right away to help. That was Dan Allman from the Dalla Lana School of Public Health, who I've done projects with over 20 years. And Cheryl Overs who I've known for a very long time from the beginning of the Network of Sex Work Projects — NSWP.

Dan started by working tirelessly writing grant applications for us, and then Elton John gave us a grant! That's how we were able to make this happen. We've had our trials, but we have tried to do as much preparatory stuff as possible. It's really hard because the momentum behind the great PrEP machine — it's been hard to keep up. It's an awful lot of information, there's demonstration projects, and research constantly churning out new data which we tried to stay up to date with. So we have come together here because there was also a lot of concern — internationally and here at home — about how PrEP might affect the workplace. Because it's very different when we are talking about our intimate relationships than it is when we are talking about work.

There were some fears and some concerns and we thought it was important for people to come together and share those. One of the things I want to say is while I think that it is good for us to come up maybe with recommendations or with guidelines or with goals, I do not see this as, like, this is the end. That we're going to create this end product that we are going to give Health Canada. That's not what I see here. What I want to see is that this is the beginning of the



road to talking about these things. And really what we produce out of these two days is all up to you. It's what you want out of it. We will do our very best to produce that, to take what you give us and synthesize it into something that you will then see and you will approve—even if that means we just want to meet again. So that's the introduction from my side.

Dan Allman, Dalla Lana School of Public Health

Hi everyone. Thank you for coming first of all. I can't believe how many hours collectively of journey we have here. It's been a long road. I'm really happy to see you all here. I'm a professor here in the Dalla Lana School of Public Health. In a bit of a way I'm a teacher. I teach. I teach some of the students walking by here. I come from a family of teachers. And even though there are some elements of what we will do here that might seem "researchy" I just want to make it clear that this is actually not research. It is education and capacity-building. We will ask about your thoughts on our ability to record what is discussed here today. That recording will be used to inform the reporting—not to contribute to research. We all, I think, have experience of research in our community, that's not what we are doing here. Elton John AIDS Foundation doesn't fund research. We got top-up money from Gilead—the maker of Truvada® PrEP—and they would not fund research either. They just wanted to fund our education.

The other thing I want to say is this. This is what we're here talking about. These pills. Now I went to Gilead, and I said, you know, "can we have some pills?" It's just, otherwise it's so abstract. Here we can pass them around. So, I asked Gilead if we could have some of these for a demonstration and they said, "No, no you can't." I had to go on the black market. But I did that. No, I cannot divulge how much they were. So, on a certain level that is what we are here to talk about today. This is meant to be the new condom—in some people's eyes. I mean it won't prevent you from getting pregnant. And, it won't prevent you from becoming infected with syphilis for example—transmitting syphilis or gonorrhea or anything else. But HIV? You know, by and large... I think a lot of us were pretty suspicious originally at the beginning, but the evidence does seem to suggest that despite its side-effects—and there are some, for instance we're going to hear about that.

We have people who are going to come here and talk about that—give us a little more education, a little more knowledge about how these things work. What they're good for, and what they're not good for. It is something that arguably can be added to the sex worker's toolkit. Doesn't mean that anybody has to use them. I don't know if I would use them, but anyway that's neither here nor there.

The other thing I want to talk about is the consent process around recording what you say today so I'll just get the form back here so I'll know what it is that I am saying.

Keeping in mind that this is not research, it's an education and capacity-building consultation, we have a form here that asks for your consent. The form is two parts. One, it asks for your consent. It informs you about what is going down here, and in fact we could hand this out so that people could read it as we go along. If we could hand out two copies to every person so that people—whether they want to sign or not have a copy or two to take with. It tells you what the consultation is. Let me read it because it's important.



CONSENT TO PARTICIPATE

PrEP in the context of sex work: possibilities and limitations

- The purpose and goal of the consultation is to educate and build the capacity of sex workers and organizations that work with them about HIV pre-exposure prophylaxis (PrEP) in Canada.
- You will be asked to discuss issues related to sex work, sexuality, health, education, HIV, and pre-exposure prophylaxis (PrEP).
- The discussions will be audio recorded, and a transcript will be made from the recordings in order to report what has been discussed. Elements of the consultation will be photographed and video recorded and photographs and video will contribute to reporting what has been discussed. Only people who say it is OK (consent) will have their pictures or video taken. Only photographs and video of people who say it is OK (consent) will be used to report what has been discussed.
- Your identity will be protected during the consultation. Only members of the consultation team and staff will have access to information that could identify you personally unless you provide permission otherwise.
- All information collected in the consultation will be kept confidential. All members of the consultation team will be asked to sign an oath of confidentiality. Participants in the consultation will also be asked to sign an agreement on confidentiality.
- The decision to participate in this consultation is entirely voluntary. You have the right to refuse to participate in any or all activities. You can withdraw at any point during the consultation process. All identifying information related to your participation will be destroyed where information shared by you in the consultation up to the point of withdrawal can be identified and separated.
- The HIV status of individuals is not a topic that we are seeking to discuss, but we are aware it may be information which you may voluntarily want to share.





GROUPS PARTICIPATING FROM ACROSS CANADA

Action Santé Travesti(e) et Transexuel(le)s
du Québec, Montréal

Agincourt Community Services, Toronto

Butterfly Migrant Project, Toronto

Coverdale Women's Centre, St. John

HUSTLE, Vancouver

Maggie's, Toronto

New Hope, Prince George

PACE Society, Vancouver

Peers, Victoria

REACH 2.0 Trans Research Program

RÉZO, Montréal

Sex Professionals of Canada

SHIFT, Calgary

SHOP, St. John's

Stella, Montréal

Stepping Stone, Halifax

Sunshine House, Winnipeg

SWANS, Sudbury

SWAN, Vancouver

SWAP, Regina

SWUAV, Vancouver

Triple-X Workers' Solidarity Association of B.C.

Winnipeg Working Group

CONVERSATIONS THAT MATTER

Welcome from the Dalla Lana School of Public Health

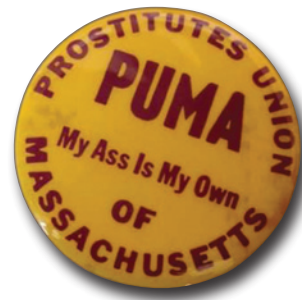
Dr. Howard Hu, Dean

There's really just a couple of things I want to say. First of all, congratulations on obviously having a very productive, incredible workshop on a topic that's absolutely critical for health, public health and population health. Congratulations to Dan Allman and our other faculty who are involved in this.

We are dedicated to addressing inequities, marginalized populations — that is part of the ethos and DNA of this school. I'm very happy to endorse that to the fullest. And these kinds of conversations that you have had are some of the many difficult conversations that have to happen in the school of public health. In fact, we call them “conversations that matter” and creating safe spaces for you and others to conduct these kinds of conversations, we believe, is critical.

The second thing I wanted to say is it's very ironic—I find it ironic—to be able to greet you for this. Now, let me just tell you a little bit of a story of my own. In 1986, I had finished training in internal medicine and was training in occupational medicine and epidemiology. And, we were required to do a research project. And at that time, having trained at Boston City Hospital, we were all very excited about the new tools that were available to identify those infected with HIV.

Myself and Don Craven, who was the head of infectious disease at Boston City Hospital at the time, created a project in which we would look at HIV risk factors among Boston sex workers, borrowing the new term that was just created in San Francisco, and we had hired a case worker to work with Boston sex workers in the so-called red-light zone in Boston. We worked with the Prostitutes Union of Massachusetts, PUMA, developed a questionnaire, got funding from Elizabeth Taylor's AIDS foundation, and we were all set to go when a state-legislator from Western



Massachusetts submitted a bill that called for mandatory testing of all sex workers — prostitutes — in Boston, and jailing those who were HIV positive. This was 1986. Our study immediately collapsed. Our subjects said, “Look, we know you said all this stuff about informed consent and protecting confidentiality, but we just obviously can't take this risk.” And I ended up doing something completely different. So I know something about this space and how important it is to get it right. And once again, congratulations, Dan, and your colleagues on forming this workshop. We are 110% behind you and we wish you the best of luck.

Questions & Answers

Q This is my big fear for PrEP, is that, yes, it will prevent a person, most likely, from getting HIV. But, when many people are using PrEP, the prevalence of gonorrhea, chlamydia, and syphilis will increase. Drastically. According to the World Health

Organization, chlamydia and gonorrhea are rapidly becoming antibiotic resistant. If sex workers and gay men are going to be put on PrEP, and we can't get clients to use condoms, are we not creating a basis where the antibiotic-resistant STIs will become a public health disaster?

A First, let me just say that we have lots of researchers in our school who are probably more expert than I am in responding to your question. But let me try to give you a general answer. First of all, you are right, the emergence of anti-microbial resistance has become a global public health challenge that's now recognized at the very highest levels of the scientific establishments of countries and of course the World Health Organization.

In public health, we are advancing the notion that all of these challenges have to be looked at from a system-wide perspective. We have to get out of this siloed thinking of simply attacking one infectious disease without thinking about all the others. Or, thinking about it as a purely infectious disease problem without considering behavioral issues. This is the only way to avoid unintended consequences such as creating Truvada®, thinking that you are now going to reduce the epidemic of HIV, but then actually fostering new behaviors that create new infectious epidemics of other microbials that we may not have the proper anti-microbials to attack them with. That's what public health does. We try to work across these different disciplines and look at population health as a whole, and anticipate those kinds of trends including unintended consequences. So I think you're asking the right questions. I hope our researchers are anticipating as well as you, and some of your colleagues are. This is precisely why we need to have these kinds of discussions and have researchers and folks on the ground in the same room so we can anticipate these questions.

Q It's just the nature of public health that quite often you are going to be doing research with marginalized populations. Obviously any well-designed research is going to have institutional ethics review boards and all of that. My concern is: Do you have a framework in place to make sure your researchers are not marginalizing populations further? Because, ethics review boards may not necessarily be people who have the lived

experience, so maybe they can't pick up on problematic things in a study design. Is this something you consider?

A That's a really good question. I think we have the privilege of making sure we have some of our own faculty on the ethics review boards. They are, in a sense, the sentinels if you will, to pick up on some of the cultural nuances that might actually lead to unintended consequences in an ethics review board. Fortunately, I think we have one of the largest critical mass of social science researchers in this area who have their antennae up as to what is going on around the school and elsewhere in the university. But ultimately, each one of these processes depends on people, and people aren't necessarily selected for committees or for grant approvals based on the factors that might be most important for preventing unintended consequences with regards to marginalized people. It's a very good point. I'll be very interested in hearing from our colleagues here about whether in fact we need more safeguards on that regard.

Q From a public health perspective, I think the best intervention that we could do is to decriminalize sex work. So, in this school of public health as an institution, do you feel you're doing everything you can to support this? And, do you plan on doing more as we're fighting for this in the next year or so?

A We have a school council and on all matters of major policy for the school, they are the governing body to essentially vote on questions that relate to school-wide recommendations for policy statements. So far, schools of public health in general are pretty famous for coming out, collectively, against things like tobacco research, making statements regarding nutrition, et cetera. But sex work is an area that our school has yet to make a school-wide position statement about. Certainly all individual faculty members have the academic freedom to say whatever they want, but we do have a mechanism by which these kinds of proposals can be put forward. So I'm all ears, basically. I would love to hear what others in our faculty community would like to propose. We have a whole governance process for bringing policy recommendations up for school council and perhaps this might emerge as one that our faculty would embrace.

A HISTORY OF COMMUNITY-BASED HIV PREVENTION RESEARCH IN CANADA

Presentation from the HIV Social, Behavioural and Epidemiological Studies Unit

Ted Myers, Professor Emeritus

I'm going to talk about community-based research and how it came to be involved with HIV in Canada; and a little bit about myself. I came out of a background in community work—in social work. Then I did my PhD in Scotland before ending up in Toronto at the beginning of the HIV/AIDS epidemic. There was a group of us in an organization called Gays and Lesbians in Health Care. We would sit around a table in this one individual's living room, and every article that was published would come to this group for discussion. This was 1983. There wasn't much written. At that point in time they didn't even have the name 'HIV.' It was called GRID—Gay-Related Immune Deficiency.

So HIV was seen as a gay man's issue. At that time, gays were a very marginalized population. And so it was very easy sort of. Maybe one day a month we sat around to go through all that had been written in the past month. If you sit down with what is being written today you could fill this room 10 times over, and probably fill it once over again each year with what is coming out now. So, there has been an explosion of information.

I came from the community. At that point in time there was the odd physician who was treating HIV, and involved with it, but, the politicians weren't doing anything about HIV. There was no funding for community groups. Jack Layton of the City of Toronto proposed the budget be increased four times and he was certainly a leader in that area. But, most of the leadership, and the mobilization that happened came from the community. I was working closely with the AIDS Committee of Toronto—in fact I became involved prior to the formation of the AIDS Committee of Toronto. The group Gays and Lesbians in Health Care broke apart. Half of us went to work with Casey House hospice and the other group went to work with the AIDS Committee of Toronto. The group Gays and Lesbians in Health Care dissolved.



It was a real organic movement that took place. Because I had the research expertise, I was asked if I could help do a survey. I did a survey with the City of Toronto called, "The Condom Give-Away Survey," where we wanted to learn about people's attitudes toward condoms. I conducted the first study of gay men in Canada—a community survey in bars and bathhouses. I worked extremely closely with the educators in the community, who had many great ideas. At that time I was within the university. I then left the university and worked with the City of Toronto and became a volunteer at the AIDS Committee of Toronto.

I proposed a research project and on that project I had a community investigator. This was unheard of prior to that time. Community wasn't involved in research except perhaps being the subject of research. And, as I worked I recognized that what we were doing had been done elsewhere in Canada in other fields of research. Particularly in provinces such

as Saskatchewan, where the agricultural movement, and the poverty that was taking place in the country, led to a cooperative movement. Basically, doing research on, and with, the community, to mobilize community to be able to respond to the issues.

It was very early in this stage that I coined the term in the HIV and AIDS field as “community-based HIV research.” I’m very proud to have done that because no one ever thought of involving community. Research was all so biomedical. We had this young student who was looking for a bit of extra cash, and his name was Dan Allman. So “Dan,” I said, “we’ve got to document this, and we’ve got to develop a document.” So Dan actually sat down and wrote a very comprehensive document about community-based HIV research. And in that he demonstrated that it can mean many things, and many different things to different people. But, primarily, community-based HIV research is focused on action and mobilization and participation in various forms.

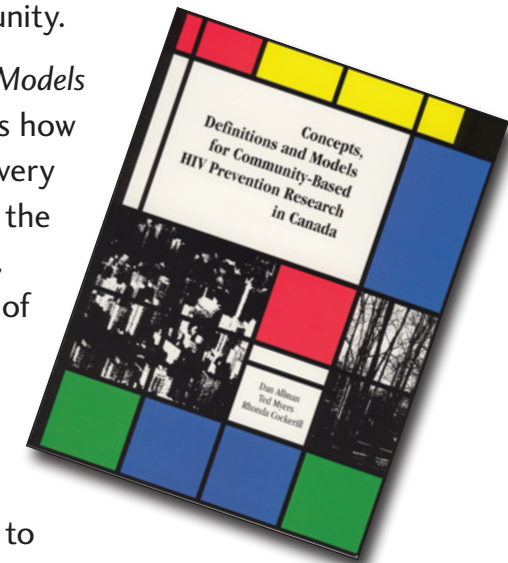
Interestingly enough, community-based HIV research has moved beyond that. There was always a distinction between what is research, and what is community participation and community development. The two go very closely together, but in different combinations. Now, we have individuals in this country who think, “well this is community-based research, so this is what is required.” But I think it’s important to understand the organic nature of how this happened.

Some of you may remember people like Kevin Orr, who was extremely involved in activism and mobilizing it. Kevin had a very good mind. He knew what questions to ask, and that helped me as a researcher to work and to help him with the research skills that I had to move things forward. What we did in Toronto led to how things were done elsewhere in Canada and across the country. I did a number of other studies that were national in scope. Then, we have seen different models of organizations doing their own research, and bringing in researchers. So, I think that rather than co-opting individuals to this sort of thing, it is important to have this organic nature, and I think in that spirit Dan and Andrew have brought together this group.

You may not know it, but part of it is we’re here — Dan and Andrew are here — to get your knowledge and wisdom and the questions that you bring. Also, there’s some expectation that you have skills to take and use the knowledge that might come out of research to move things forward. And I think it’s an expectation that if there is any research done at any point in time, people will use it. There is always the need to implement and use the knowledge. In my experience, much of the research that I have done has been used by organizations when they’re putting in proposals. Proposals for programs which support the need, or address lack of knowledge, or proposals for some other research project that they might want to do on a smaller basis in their own community.

So that document that Dan wrote [*Concepts, Definitions and Models for Community-Based HIV Prevention Research in Canada*] shows how relationships within community-based research can be very, very varied. There are always issues. Some of the issues vary with the size and scope of a project. Like a national study—it’s very, very difficult to come up with one definitive answer in terms of what should be done because there are regional differences. There are differences in terms of the populations that are affected. There are differences in the way services are delivered. To come up with a single conclusion as to what might happen can be very problematic. Sometimes it’s good to keep things small and contained, but sometimes you want to have it large to see how things evolve in different ways; how one community can do something one way, and another can do something another way. And working in synchronicity, the ultimate goal or outcome might happen.

I think it’s also important—you’ve heard Andrew talk about this today—the importance of building trust between researchers and between community, and to recognize that the skills of the community and the researcher might be quite different. And the skills of all individuals in this room with regards to community-based research might be also very, very different. So individual roles in research can vary immensely. I think that’s all I really



want to say about community-based research. We've had a lot of successes. I think we've also had some failures where things get bogged down in the politics and where individuals' interests might compete or conflict with another individual's interests. But for the most part, I think there has been progress.

Dan Allman, Assistant Professor

I guess what I would add is this, you know, specific to research that is done about sex workers and research that is done with sex workers, different places in Canada have approached it differently. And, I don't want to province-bash or institution-bash. I want to be diplomatic. Because I am on camera. And that, you know, if you get me in a hall somewhere, or you get me in a bar somewhere, you might get a very different story. But what I would say is that our work in universities is a product of our environment, and the environment that the University of Toronto finds itself in, in Ontario, is very different than the environment that, for example, the University of British Columbia, in British Columbia, finds itself in. And, the ways in which research is funded — and the ways in which research careers are rewarded — have a lot of bearing on the different models of community-based research that we'll find. It's one of the reasons that the kind of community-based research that we see in Ontario might be different from the kind of community-based research that we would see in a province like British Columbia or other provinces.

You see, in 1969, Arnstein described this “Ladder of Participation.” [Originally published as Arnstein, Sherry R. “A Ladder of Citizen Participation,” *JAIP*, Vol. 35, No. 4, July 1969, pp. 216-224. -Ed.] And, her Ladder of Participation came out of that whole kind of Sixties movement around women's liberation and around ethno-cultural liberation and around the anti-war protests, and in part, were spurred by the kinds of liberation that the birth control pill brought to the world. And it's a whole other conversation, the relationship of the birth control pill — of that era — to PrEP, to pre-exposure prophylaxis and today's “blue pill.” It's a whole other conversation.

But what I want to say about Arnstein's Ladder of Participation is that for her there were these gradients of participation. And you could call it “participation,” but the genuinity,



or the authenticity of that participation could be very variable. For example, in some places you could have a community advisory board and that would be seen as being participatory and community-based in one way, whereas in other places you could have community members leading the research and actually doing the research and that could be participatory in other ways. As things went on — as we saw at Health Canada and at the Public Health Agency of Canada — they started to get this idea. They started to twig that it wasn't just about who was doing what, but it was about who held the money — who had the money, right? Because money was power.

That is in part why Health Canada and then the Public Health Agency of Canada fostered this community-based research funding where communities could hold funding for research. This variability in participation is one way of understanding the difference

that we see across the country. That early on in Ontario we saw the value of not just using community as a form of *entrée* — of access — but a way of improving the research. Because, when communities ask the questions — when communities tell us what it was that they want to learn, and tell us the kinds of things that they would like questions developed about — then they don't need to necessarily have PhDs in methodology or in questionnaire design. They could say, "This is what we need answers for, now you methodologists, you go off and do the boring stuff and leave us to the fun stuff."

And that is one way of interpreting what happened in Ontario. It's not that Ontario is so exceptional. I mean, in Manitoba we saw great things happening in part because of the Prairie's history with solidarity movements and with agricultural movements. We saw that. In Québec, we saw really good things happen in part because of some of the discourses around separatism and language issues. In the Maritimes, we saw good things happen as well. And I don't want to province bash — we've seen some good things happen out west, as well, in British Columbia.



But you know, all of this is really to take us to the next stage, or the next activity that we want to delve into. And that is to have this national discussion — this unprecedented national discussion — about the kinds of answers that you would like, and about questions that you may have.

Dr. Myers is a Professor Emeritus in the Dalla Lana School of Public Health, University of Toronto. Dr. Myers has extensive experience in socio-behavioural and behavioural-epidemiological research with marginalised populations including aboriginals, gay and bisexual men and drug-using populations. He has particular interests in geographic and cultural analyses of sexual and risk behaviour. He has undertaken a number of province-wide and national community-based studies of behaviour and service delivery.

Dan Allman is Assistant Professor at the University of Toronto's Dalla Lana School of Public Health, Acting Director of the School's HIV Social, Behavioural and Epidemiological Studies Unit. He is a founding member of the CIHR Social Research Centre in HIV Prevention (SRC) and the Canadian Network on Hepatitis C (CanHepC). A sociologist and public health researcher, Professor Allman's scholarly work focuses on the social and structural production of risk and well-being, particularly for those considered marginal, vulnerable or peripheral to a society's core. At the University of Toronto, Professor Allman is recipient of the Robin Badgley Award for Teaching Excellence (2015) and the John Hastings Award for Excellence in Service to the University and the Community (2016).

- *Concepts, Definitions and Models for Community-Based HIV Prevention Research in Canada and a Planning Guide for the Development of Community-Based Prevention Research.* Dan Allman, Ted Myers, Rhonda Cockerill, HIV Behavioural and Epidemiological Studies Unit, Faculty of Medicine, University of Toronto, 1997
- *La recherche communautaire en prévention du VIH au Canada : concepts, définitions et modèles.* Dan Allman, Ted Myers, Rhonda Cockerill, HIV Behavioural and Epidemiological Studies Unit, Faculty of Medicine, Université de Toronto, 1997

BASICS OF PrEP: QUESTIONS & ANSWERS

Presentation from Canadian AIDS Treatment Information Exchange (CATIE)

Camille Arkell, Knowledge Specialist, Biomedical Science of Prevention
Lara Barker, Regional Health Education Coordinator, Pacific Region

Camille: We were asked to do an informal presentation on PrEP, to kind of be here as you guys kick off your two days of talking about PrEP, to answer any questions that you might have and make sure that everyone is on the same page. We are from an organization called CATIE. My name is Camille Arkell and my title is “Knowledge Specialist for Biomedical Science of Prevention,” so I do a lot of work with PrEP. I’ve been with CATIE for less than a year, but I am quite familiar with the research on PrEP and what people are saying about it so hopefully I will be able to answer your questions adequately.

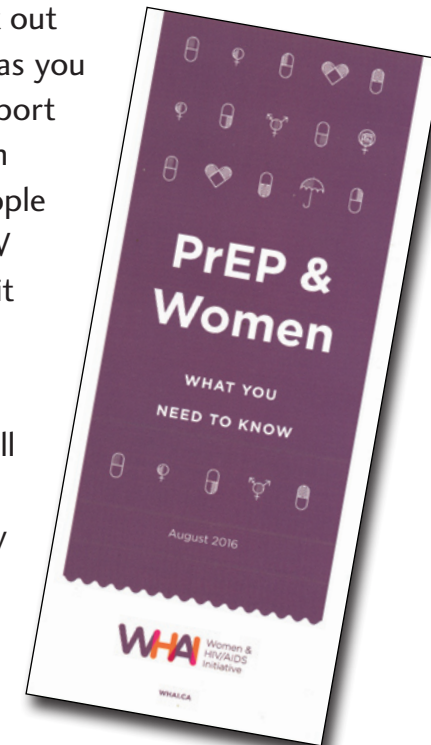
Lara: I’m Lara. I’m really happy to be here and to see that there’s so many west-coasters here. I work primarily in B.C. with CATIE. We’re a national organization, but I work out on the west coast partnering with local organizations there to offer CATIE’s educational courses, workshops, and conferences.

For those of you who have never heard of CATIE, we’re a national non-profit organization. We’ve been around for over 25 years, and our whole mandate, essentially, is to provide really easy to understand HIV and Hep C information to service providers and to the general public in both French and English. A big part of what we do is offer educational opportunities, so conferences, workshops. A lot of the conferences that happen in different provinces across the country will bring together folks who are working front-line to attend—to bring a community voice to the conference, and then help them to carry that information back to their communities and share that information far and wide.



Another part of what we do, you might have heard of the CATIE ordering centre. We have several hundred resources like this: brochures, info sheets, stuff that you can use in your education outreach work in community. I encourage you to check out our ordering centre. Everything is free so you can order as many as you like and they get shipped to your address. It’s a great way to support the education work that I know a lot of you are doing. Other than that, we also have an information line. It’s a 1-800 line where people call us from all across Canada toll-free with their questions on HIV and hep C. Our email address is info@catie.ca. So that’s a little bit about what we do.

Camille: So, we’re assuming everyone here knows at least a little bit about PrEP. I brought this great new resource out that’s a small booklet called, “PrEP and Women: What You Need to Know,” created by the Women and HIV/AIDS Initiative [WHA]. It’s pretty much brand new, but it’s one of the only client resources that we have on PrEP right now—which is kind of strange. It can be a great tool for just explaining the basics on PrEP and things that are specific to women. There’s lots on our website about PrEP as well. You can find resources developed by CATIE and many that we’ve compiled from other organizations.



Q Is that resource only for cisgender women?

A Camille: Yes, the information is mostly specific to cisgender women. For example, there is a point about how PrEP takes longer to accumulate in the vagina versus the rectum. So that would be specific to cisgender women.

Q What kind of vagina? Sorry. Like a regular vagina? It’s important for me to know.

A Camille: Yes, the vagina of a cisgender woman. There’s not a lot of research on trans women. There’s really no research on what you might call a surgically constructed vagina and how PrEP works in that bodily tissue. There is a great resource made by an American

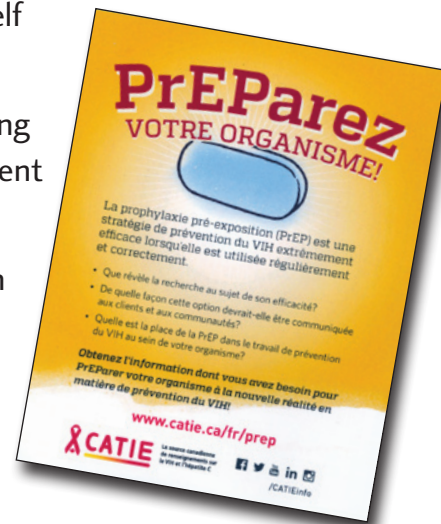
organization called Project Inform. They have a booklet for trans women. As well as booklets for gay men and other men who have sex with men and cisgender women.

Lara: Project Inform has a number of good resources on their website. You can also watch videos. I definitely encourage you to check it out. They're a good example of differences between the Canadian PrEP landscape and the American landscape. The discourse and dialogue in PrEP research and promotion in the U.S. is further ahead, it seems.

Camille: So, let me just do a really quick overview: basically PrEP stands for Pre-exposure Prophylaxis. And, what we're talking about—right now anyways—is oral pre-exposure prophylaxis—something that's taken in pill form. It's a pill that's called an antiretroviral drug and it's used for HIV treatment in people living with HIV. It's approved in Canada to be used also as PrEP for preventing HIV. This means that it is taken by an HIV-negative person on a daily basis, before being exposed to HIV and continuing afterwards. So, it's for someone who may be having ongoing exposures to HIV and it's a way to protect themselves from becoming infected with HIV. And it works. The way that it works is you take this drug orally once a day—every 24 hours—and the drug then builds up in your body. It becomes present in your bloodstream. It becomes present in different bodily tissues, so in the vagina, in the penis, and in the rectum. Then if a person is exposed to HIV and it enters into the body, the presence of PrEP in those cells and tissues helps to stop HIV from being able to infect cells and reproduce itself within the body.

Q When you said, “daily dosing” do you mean daily dosing because that's the Canadian guidelines? Because intermittent dosing is also considered to be effective.

A Camille: Daily dosing is what the bulk of the research is on and it's what is currently recommended by Health Canada. The forthcoming Canadian guidelines will present intermittent PrEP as an option that can be considered for men who have sex with men and transgender women who



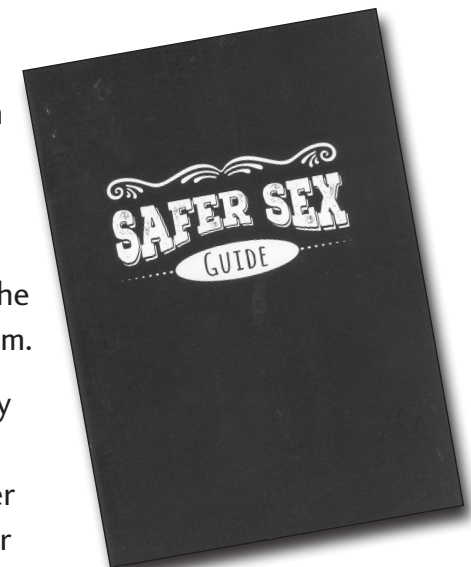
have sex with men. There are biological differences that explain why for cisgender women, intermittent dosing is probably not an option for them. If they are having mostly vaginal sex, they will have less reliable protection—or possibly none—using intermittent dosing because PrEP accumulates more slowly in the vaginal tissue and drug levels do not get as high as in the rectum.

Another point I want to make is that oral PrEP—predominantly daily oral PrEP—has been tested in multiple populations, including heterosexual cisgender men and women and cisgender men who have sex with men, as well as a little bit in transgender women who have sex with men. And one study of people who use injection drugs. It's found to be effective in all of the populations that have been studied, but the key detail is that the more adherent you are, the better it works, the more likely it is to work. They found that people who have been taking the drug most consistently have the greatest level of protection.

Q Are there any substances that are available that people could be taking that could possibly interact with PrEP? Or enhance negative side effects? Because substance use is prevalent in a lot of demographics that we're talking about today, that also do sex work.

A Camille: There isn't any research that has looked specifically at different people using different substances and whether or not that puts them at greater risk while taking PrEP. However, it doesn't seem to be an issue in terms of PrEP effectiveness. You know, the data has consistently shown that as long as you are taking PrEP, and as consistently as possible, it can work well. Basically people who have been found to be the most adherent based on PrEP levels in their blood have the greatest protection, regardless of anything else, in the research that's been done so far.

When it comes to negative side effects, a person may have interactions with other substances, and that's why it's really important to have regular medical check-ups and monitoring for side effects and drug toxicity while taking PrEP.



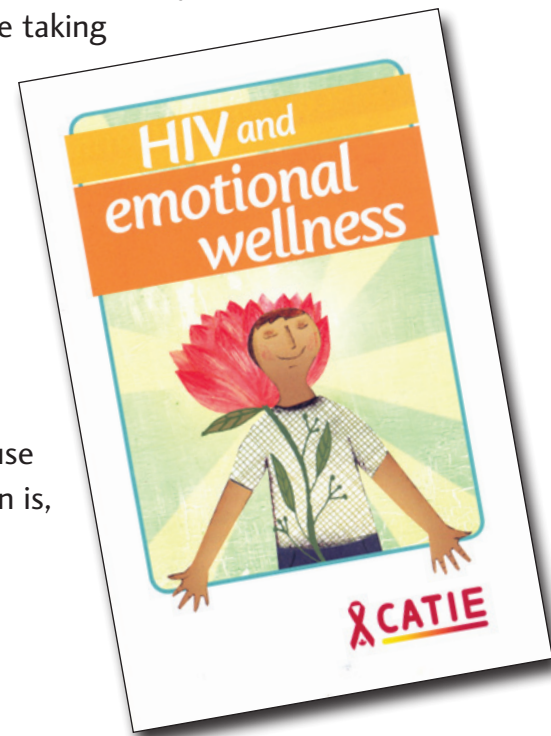
Q So there's no contraindications with say, birth control pills? Chemotherapy? Or...?

A Camille: Chemotherapy I'm not sure, but in terms of birth control pills, women have been included in large PrEP studies and presumably many of them were taking oral contraceptives and it is not contraindicated. PrEP is a combination of two antiretroviral drugs—called Truvada®—and this combination has been used in people living with HIV for over 10 years. Truvada® was approved for PrEP—so to be used in HIV-negative people—in 2012 in the United States. And since then it's taken a long time for the rest of the world to kind of catch up. It was only approved this year in Canada.

Q So, I am positive, and I do have Truvada® as one of my medications along with two others. My concern has always been the long-term effects of taking this drug. I mean, I don't have a choice, I have to take it every day. But for other people who want to take this drug, I wonder about safety.

A Camille: There are a few safety concerns associated with taking Truvada® long-term. They've done studies in people taking Truvada® as PrEP and in HIV-positive people who have been taking Truvada® as their HIV treatment—and as you said—these are people who don't have a choice and they're taking Truvada® for many years. This research has found that it does have an impact on kidney function, as well as bone development.

Q I have that problem. In the last couple of years, I've broken my wrist and broken my arm. So, they tried to change my medications to something that's more bone-friendly, but unfortunately I have too many side effects from it. I'm not comfortable taking medication for the rest of my life that is going to cause long-term side effects from it. And my other question is, who pays for this?



A Camille: I'll just finish on your first point. In people taking PrEP who are HIV-negative—we know that 1% to 10% of people experience some kind of side effect, whether it be gastro-intestinal or these more severe side effects that affect kidney function and lower bone density. In people taking PrEP, they found that in the people who have experienced those kinds of side effects, if they then stop taking PrEP the changes were reversed. So their kidneys can improve, they can get back to normal function and their bone density can improve.

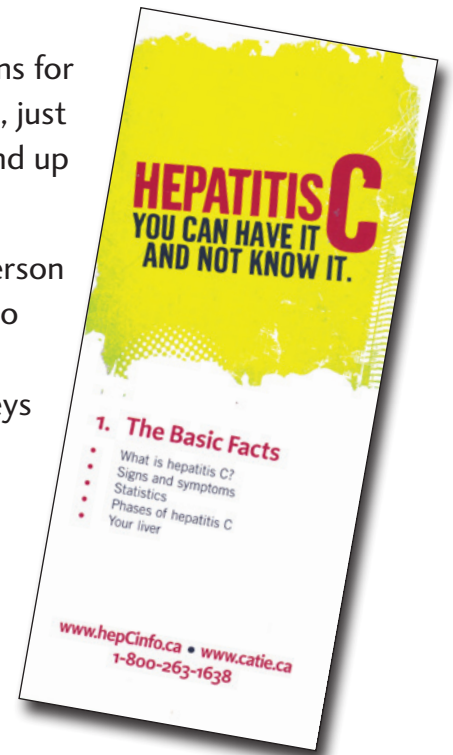
Q I take medications for stomach problems, I take medications for an overactive bladder, and I take medications for my bones. So, just kind of seems like along with that medication you eventually end up taking a whole bunch of other medications, too.

A Camille: Yeah, which is not ideal. If that happened in a person taking PrEP, they would likely have to stop taking it. There's also a new formulation of Truvada® that's just been approved for treatment and it's supposed to have less of an impact on kidneys and bones. I don't know if that might be an option for you moving forward.

Q Can I just quickly interrupt there to say that it's really important that we understand how the drug industry works? The reason Gilead has created a new drug is because that the current recipe of Truvada® goes "off-patent" in about 18 months from now, so what costs hundreds of hundreds of dollars now will go down to costing very little, so they'll put a new one on the market that costs a lot.

Q I'm interested to know how long they've been doing research around the side effects. I'm interested to know how diverse the research was as well.

A Camille: Basically I've been talking about a body of research that has looked at multiple populations that are at risk of HIV and might want to take PrEP. And every study



looks at safety and side effects. So, across the board, it's about 1% to 10% of people experience some side effect. The most common is gastro-intestinal.

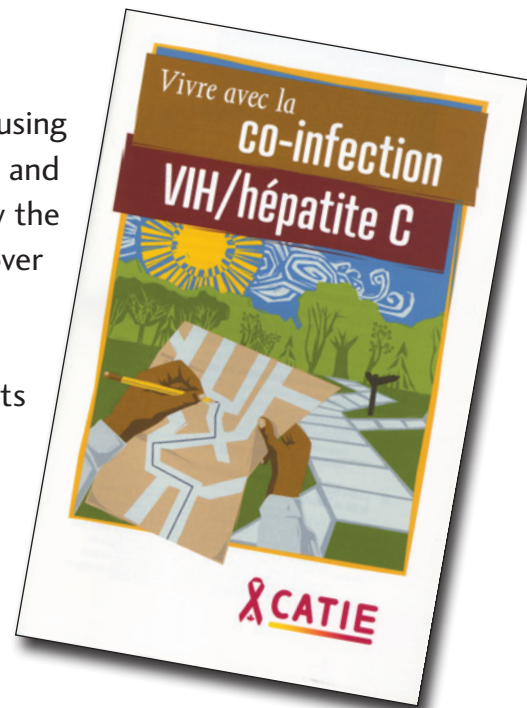
Q But how long have they been researching it? Five years?

A Camille: In 2010 the first research on oral PrEP was released, so I guess, since 2004 or 2005 is when they started the research. It's considered to be a significant body of evidence, and Truvada® is considered to be fairly safe and well-tolerated, for the most part. But it's true, most HIV-negative people taking PrEP—it's so new—haven't been taking it long term so we're not really sure. I would say that it's acknowledged within the research community that it's a safe drug to take, for most people. But ongoing monitoring is really important to identify and deal with any negative side effects.

Q Are you aware of any ongoing longitudinal studies right now of people who are taking PrEP—HIV-negative versus HIV-positive folk who have just been taking the Truvada®? Because I've heard, anecdotally, from folks who were taking it, often side effects happen when people are first taking drugs—whether it's the gastro-intestinal or whatever. But the things like renal issues or the bone loss stuff, that comes with long-term use. Sure, if you're first taking it can be reversible, but what about long-term?

A Camille: Right now, the studies are ongoing. Lots of researchers are trying to study PrEP in more “real world” settings, outside of the clinical trial setting—like people using PrEP in local clinics—and every study is looking at safety and every study wants to be able to say something about how the drug is affecting the people who are taking it. So I think over the long-term we will know more, but right now, what we know is that it's relatively safe. There may be longer-term effects, but, in the short-term, at least, any negative effects appear to be reversible when the drug is stopped, too.

Q So, for example, my man has got hep C, and say for example I have HIV, so he's going to start taking the PrEP



pill. Now, at the same time, he's going through the new drug for hepatitis C treatment. How's that going to affect everything? And on top of that, there's also a question of taking the HPV vaccine which is another six-month, three-times deal, so can you combine all of those things with a drug like Truvada®?

A Camille: I would suggest he talk to his doctor or care provider.

Q If I could interrupt. My partner's just finished sofosbuvir. He's just cured of hep C. Really, really amazing. We went into the research about—it's a rather lovely word—“pharma-co-kinetics.” This is the word for drugs combining, so the pharmacokinetics of Truvada® and the pill etc. And the pharmacokinetics of sofosbuvir and interferon had not been studied because we looked completely into it to see about what Truvada® means. Medical science doesn't know if you can take Truvada® with the hep C medication, so if your GP down the corner says he knows, he's not telling you the truth. There is no answer. [“Coadministration of tenofovir disoproxil fumarate and Harvoni® (ledipasvir/sofosbuvir) has been shown to increase tenofovir exposure.” *U.S. FDA MedWatch*. Feb. 2016. -Ed.]

Q When I see the words, “Cameroon” and “Cambodia,” I'm wondering how many Caucasian people took this drug. I find this a very distressing subject because a lot of birth control is tested on third world women. I'm just saying over the years I've seen how pharmaceutical companies have used vulnerable human populations. I'm kind of wondering, Cambodians, Africans, and who else has really taken this drug?

A Camille: It has been tested in a number of countries including the U.S. and the U.K. and countries in Africa, Asia, and South America. So, there has been a pretty diverse sample with all the research pooled together.

Q How many of the studies were conducted by the drug company themselves versus independent studies?

A Camille: None of the studies up to now were conducted by the drug companies. However, Gilead, the pharmaceutical company that makes Truvada®, is about to start a study looking at a new formulation of oral PrEP, which was mentioned earlier.

Q One of the side effects that I find doesn't get talked about very much is drug resistance. It seems to never get mentioned and there was certainly a very famous case here in Toronto where somebody was taking their PrEP every day—they had to double-check—and it turned out it was a multi-drug resistant form of HIV. And, some of us who are older know that HIV is kind of a tricky. That some of the older ARVs stopped working. And I've also been reading—even in *Xtra!* here—that adherence is an issue—that if you have a lot of trouble with adherence you're way more likely to catch HIV in that situation. And, if you do, then Truvada® won't work as treatment. And I'm wondering how much data there is about that, because we don't ever hear about it.

A Camille: So there was this one instance of a man in Toronto. He was incredibly adherent to PrEP, they found that he was taking it every day for two years. And he became infected with HIV despite being on PrEP. This is the one very well-documented instance of that happening, and it turns out the strain of HIV he was infected with was resistant to both of the drugs in Truvada®. In that case, Truvada® is not going to protect you if the strain has evolved to become resistant to these drugs. So that is a concern, but considering how many people are taking PrEP worldwide, that's an incredibly rare case.

The other issue is the idea that if you are taking PrEP and you are not super adherent and you become infected with HIV but you don't know and you keep taking Truvada®, there's a chance that the HIV that you've become infected with will then mutate to become resistant to Truvada®. At that point, Truvada® won't work for your treatment. So, in the research, they have found that it can happen. It's also very rare.

It's more likely to happen if you start taking PrEP when you are, in fact, already HIV-positive. So, that's why it's very important to make sure you are HIV-negative before starting, because if you are already HIV-positive—and you don't know it—and then you start taking PrEP you are more likely to develop a resistance to that drug. However, in the other scenario that I described first where you are HIV-negative, you start taking PrEP but you're not super adherent and you happen to become infected, you are less likely to become infected with resistant HIV in that scenario. In both cases, this highlights the importance of regular monitoring and HIV testing before starting and while taking PrEP.

Q We know HIV monotherapy interrupts and reduces the efficacy of HIV multi-therapies. That's known. It doesn't even need to become resistant. I'm talking about clinical outcomes for HIV patients who have had previous monotherapy. And, it's clear that if you've had monotherapy that multi-therapy afterwards is compromised. It might not be a huge deal, but I just don't think we can say it's fine, stop taking PrEP and everything's OK, you can just go onto taking combination therapy if you become HIV-positive and it will be OK. I'm not sure that's right.

Q Someone said, "Who is paying for this?" I work with a lot of youth in the city—a lot of queer and trans kids, and a lot of youth that use, and a lot of youth that are sex workers. When it comes to the availability and actually purchasing it, will it always be covered by ODSP [Ontario Disability Support Program] or OW [Ontario Works financial assistance]? And, will any future variations be that you have to pay out of your pocket? And if you do, where else would we be able to get that is available for free?

A Camille: Basically right now it's just not covered in most provinces unless you have a private insurance plan that may cover it. Québec's public plan does offer some coverage, and it appears that First Nations and Inuit people can access PrEP under the Federal Non-Insured Health Benefits [FNHIB] program.

Camille Arkell works in knowledge exchange at CATIE, Canada's source for up-to-date, unbiased information about HIV and hepatitis C. In her role as CATIE's Knowledge Specialist, Biomedical Science of Prevention, she shares research evidence on PrEP and other HIV prevention tools with frontline service providers. Camille has a Masters of Public Health degree in health promotion, and has been working in HIV education and research since 2010.

Lara Lise Barker holds an M.Sc. Public Health from the Berlin School of Public Health. Lara started at CATIE in 2006 and has also worked in HIV/AIDS policy and advocacy at the European AIDS Treatment Group in Brussels. In her role as CATIE's Regional Health Education Coordinator for British Columbia, she currently works with partner organizations in B.C. to deliver educational trainings on HIV and hepatitis C to front-line service providers across the province.

PATHWAYS TO INCREASE ACCESS TO PrEP

Presentation from University of Toronto Clinical Research Unit on HIV Prevention

Dr. Darrell Tan, Director

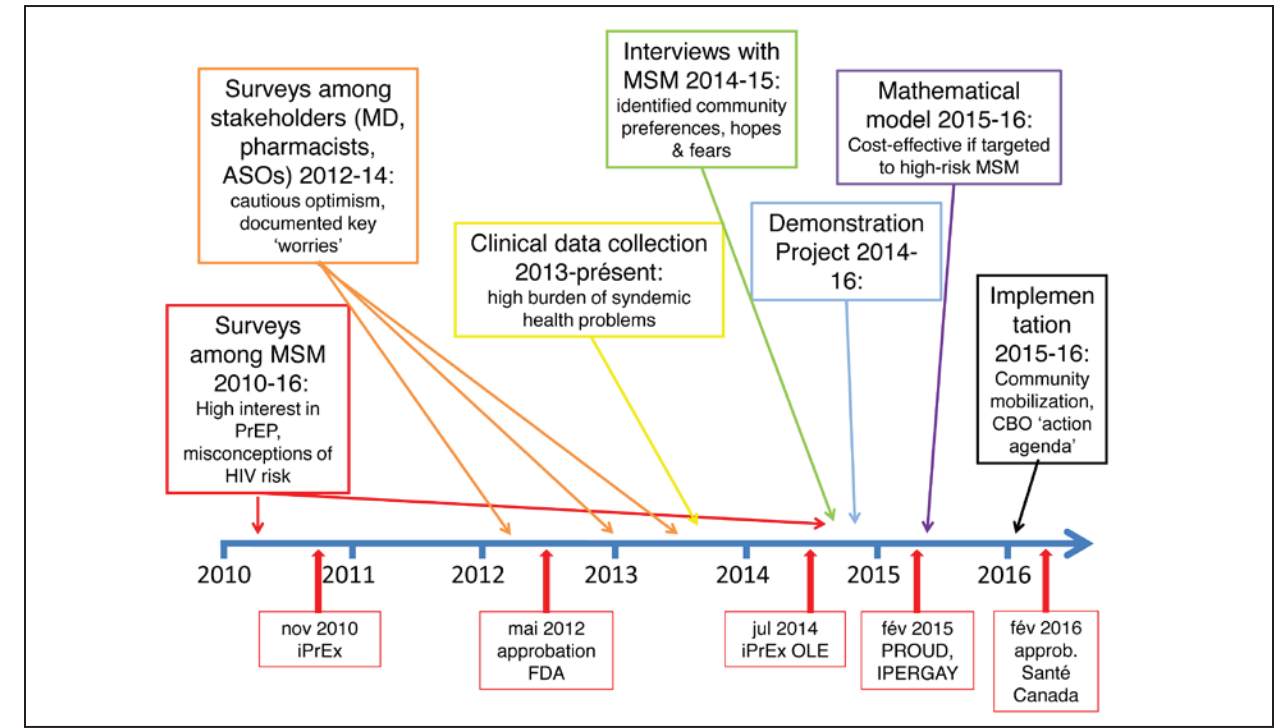
The first problem that remains is the need for widespread access to the drug for those who need and want it.

The second problem is the need for a different pathway for figuring out who is going to be using PrEP. I use the term “candidates” here, that may not be the best term. But we need to figure out who should be, or wants to be, and is appropriate for using PrEP, and who it may not be the best choice for. There are a lot of different ways we can arrive at that sort of decision.

The third and the really challenging problem that I myself see as a clinical provider is the need for knowledgeable — and what I would call culturally competent — providers to prescribe this. I can’t tell you how many times I get a referral in the clinic from a family doctor from the community and the person comes in and says: “I’m so glad to finally be here because I’ve tried, like, two or three doctors, or a bunch of walk-in clinics, and every time I ask about PrEP the doctor was like, ‘What’s that? I have no idea. I can’t do that. Go somewhere else.’” That’s a big problem.

The fourth problem is we must not forget that PrEP is one intervention that needs to be thought about as part of a broader combination approach to HIV prevention. We can talk that talk for a long time, but exactly what that means and how to truly, truly operationalize that I think is a big unknown still. And then as a researcher — myself as well — just thinking logically about it, I think it’s really imperative that no matter what we’re doing as a community, we need to be monitoring what we’re doing, studying it, so that we can learn from our experience and constantly be thinking about how to improve upon it.

So, here’s a timeline — starting at 2010 or so to approximately the present day — to give you some of the major events in the recent history of PrEP. So, 2010 was when the first



major research studies were published which suggested that PrEP actually worked for gay, bi, and other men who have sex with men, and in a small number of transgender women who participated in those studies, with few side effects. PrEP got approved in the United States by the FDA not that long after that, in May of 2012. Then in 2014 and 2015, there were some other major trials published. And then four full years after U.S. FDA approval, we finally got Health Canada’s approval in February of this year.

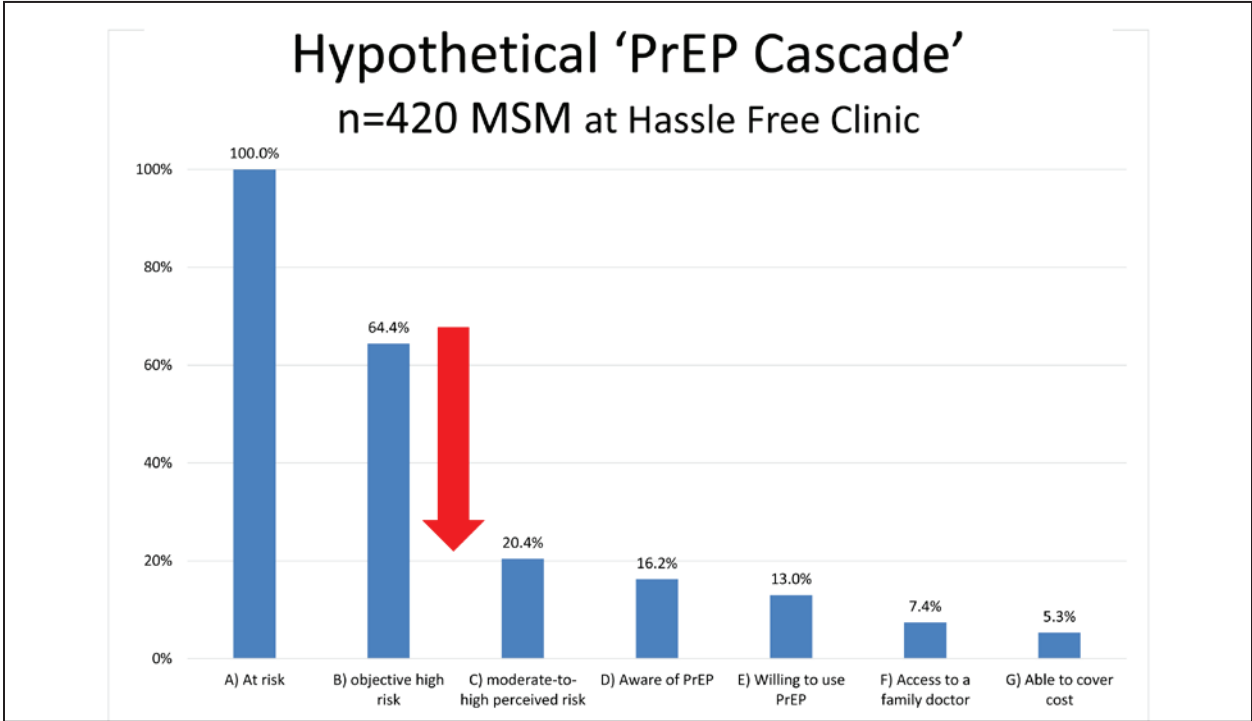
So over that time period, my own group has been thinking about this a little bit. We started to do some surveys with different stakeholder groups, physicians, people who work at AIDS service organizations across the country. I’ll show you some of our findings in a moment. We started to collect our own clinical data about just what was happening in our own clinic, working primarily with gay men to begin with. We got a wealth of qualitative work interviewing guys about what they thought about PrEP, and their hopes and fears with respect to PrEP in Toronto.

We started our first demonstration project in 2014. It was a small project just for 50 guys that we were able to study here in Toronto and we're just wrapping up the analysis of that project right now. And then we started to think more on a systems level. I work with some great people who know a lot about mathematical modeling — cost effectiveness studies — and we've been able to start to generate some local cost effectiveness data. And then, finally, some implementation science so when the day is over, we know that this works. It's been proven very clearly. How do we make this happen? That's what we try to think about as well.

Let me just show you some little snippets of data that we got out of that. Again, a lot of this has really been focused on gay, bi, or men that have sex with men, just because that's the focus that we started with. I'm really interested to think with you about how this applies, or how this is relevant, or how they differ from considerations from different categories of sex workers. So the first thing is that we surveyed these guys who were coming into a sexual health clinic for HIV testing about what they thought about PrEP — what they knew about it.

We hypothesized that if someone needs to get on PrEP to help prevent HIV infection, there's a whole bunch of steps that have to happen in order to make that a reality. They have to be at some HIV risk — and actually for PrEP to be worthwhile, it should be a significant amount of risk. They need to be aware of that risk. They need to know about PrEP and be willing to use it. They need to have access to a prescriber and have access to the drug in order to successfully start taking the thing. A whole cascade of steps. What we did was we asked about 400 guys questions in a survey that look at these various issues. What you can see is that all of the guys [column A] were at some risk by definition because they were coming in to the clinic for an anonymous HIV test.

If you apply a scale that's been published that looks at how we quantify risk for HIV in gay men, 2/3 of the men would be in column B. Most people would agree that, yes, PrEP is something they should seriously consider. But what you can see is that there was a big drop off in this column, C: Did that guy perceive himself to be at at least moderate,



if not high, risk of HIV? And, we found that this was the biggest drop off in this cascade, suggesting that one of the biggest challenges is this pathway for finding candidates or people who could benefit from PrEP. There's a lot of work that might need to be done to help them understand their own level of risk.

Questions & Answers

Q Under the B column: Because there is this pretty large drop off, I'm wondering, when you guys were quantifying objective high risk, was it a matter of you having perceived high-risk categories and it was only if someone had two or more then you have objectively high risk? What is the cut off between moderate and high in your formulation?

A That's a great question. We had to come up with some definitions. What we chose to do for this particular analysis is, there's a paper that's generated out of the Centers for

Disease Control in the States where they've taken huge cohorts of gay men and looked at predictors of HIV infection in those cohorts. They came up with a risk score, and if you score greater than 10 on this scale that goes from zero to 48—you can go as high as 48 on that scale—then they would say that is significant enough risk that the person should be at least thinking about considering PrEP. That's what we used for column B. And with column C, we asked the guys: "What do you think the risk is for getting HIV? Is it zero? Is it low? Is it moderate? Or high?" Just however people interpret those words. And that's the "moderate" or "high."

Q I'm also interested in how would you define risk in terms of sex workers? Earlier we heard that, in Canada, anyone exchanging sex for money—doing sex work—is considered at risk. That's clearly not anything grounded in research, because sex workers in Canada have not been at high risk for getting or transmitting HIV, since the whole thing began. So what is the high risk? And does it ever involve a vagina?

A Honestly, I don't know the answer to that question. And I think that's why I'm actually really happy to be in this room with you, because I'm very interested in what your perspective is. In terms of how do we define high risk? How we define high risk in this particular one study doesn't really matter. With respect to your question, the bigger question is: how are we going to use that concept of "risk" on a case-by-case, individual basis—and in some cases a collective basis—to decide where should we use PrEP? I don't know the answer to that question. There's lots more data for gay men, just because this is the population that has always had the highest incidence and prevalence of HIV infection in Canada since the beginning of the epidemic. And, if there are data gaps that we need to fill in terms of understanding how risk is perceived; how it's acted on; what it actually is—even logically—with sex workers in Canada, then I think that's an actionable fact to find out what the data gaps are that we need to fill in order to figure out what we need to be doing next.

Q What do you think needs to happen to address this? What can we do?

A I think one piece of it is advocacy, right? The reason that this bus ad exists, to me, it's symbolic of a lot. To walk down the street and see a big ad celebrating something like this, and to have the name on it that's doing it be the city—the public health authority of the city—that says a lot. That's a big commitment. That's a public show of leadership, and unfortunately that's been relatively absent in Canada for a bunch of reasons.

Q When it comes to risks—both in the study and risk in general—does ethnicity factor into it? Because I do know within the cis queer black community, HIV status is not something we talk about. And that does relate to Caribbean culture. You don't go to the doctor unless you're really hurting. You don't talk about things like that you're ill, because it's viewed as shameful, and it's something that you're supposed to take on yourself. So in certain communities, PrEP is an elusive idea because we don't disclose—about partners, about status... I talk to a lot of youth of colour and it's hard to even get them to go for testing. So, is that factored in at all? And, if not, how can it be? Because that is a big determining factor.

A I think you're absolutely right about that. It's not unique to PrEP, as you are pointing out. It applies to testing as well, engagement, all kinds of care as well. It's a related issue, absolutely. The way I see my own small role in all of this is, which hat do I wear? On this one I'm a researcher so I'm wearing that hat. One project that we've initiated in the last year—and we just got a small seed grant to do—is to work in partnership with



organizations like Women’s Health in Women’s Hands here in Toronto, and [Black CAP](#), to do some qualitative and some quantitative research with folks in the Ontario African, black, or people of colour communities to say, “Hey, there’s this thing called PrEP. Have you heard of it? What do you think?” — just to try to apply it to them. I totally agree with you. It’s a huge thing.

Q I wanted to quickly make a comment about gender. When you say there’s been only this research on men and that’s just the way it is, but you girls will be alright and it’ll work for you too, so come along in... In terms of medical research, this is utterly unacceptable. And, in terms of thinking about sex work and PrEP, the idea that we should be joining gay men and demanding access when FEM-PrEP was closed because of lack of efficacy for women. So when we’re talking about research in a data environment, it’s not only incomplete — things are being drawn from these samples of men around sexual and reproductive health issues for women. Then sex workers as another layer on top of that. I really have to say, we need to be thinking about women’s sexual and reproductive health in a much more holistic way than just HIV prevention. If you’re a middle-class white gay man, HIV’s a big thing for you! You know, if you’re a woman, unwanted pregnancy as to all that is right up there. And, that’s not coming through in the discourse we’re getting about PrEP from the medical authorities, and indeed from those advocating on our behalf at the highest policy levels.

A I think you’re naming it like it is, right? I mean, I agree. When I see women in the clinic who come in to ask about PrEP — it hasn’t happened very often — the database that I can draw on to counsel that individual is limited. It exists, though. There was the Partners PrEP trial that was done in East Africa. There was the TDF2 trial that was done in Botswana. Partners PrEP was done in the context of heterosexual serodiscordant or sero-different couples [one partner is positive, one partner is negative], and they were all heterosexual partnerships. In Botswana — this is the second highest HIV prevalence in the world — a general population of any sexually-active adult was eligible for that trial. There’s a report from pregnancy and outcomes of the pregnancy from Partners PrEP. So, there is good data from those two sources on outcomes of PrEP in women. It’s true that it’s not as large

as the database on gay men. And certainly one big gap is that it’s Africa — two different countries with very different studies, actually, both of which are very different from Canada in many ways. But I’m on the same page as you. There’s a big data gap.

I’ll tell you one little anecdote about how we at least tried to struggle with this issue right here in Canada. There’s a project that we just started to put together here in Ontario. We actually started the conversation to partner with colleagues in B.C. and Québec to build cohorts of those who are on PrEP for whatever reason, to understand this better in real life. A lot of the evidence base that we’re drawing on is randomized placebo-controlled trials — which are really tightly regulated as to who gets into those trials, et cetera. Not necessarily a good reflection of real life. So, we’re trying to build something closer to real life by building cohorts where we can follow those over time and answer lots of detailed questionnaires, et cetera.

In Ontario, when we tried to build this, one of the things that we did is that we went to the Ontario priority population networks. The GMSH [[Gay Men’s Sexual Health Alliance](#)] is the one representing gay men, there’s the Women’s HIV and AIDS Initiative [[WHAI](#)], there’s the African and Caribbean Council on HIV/AIDS in Ontario [[ACCHO](#)]. We said, “If we’re going to do this together...” That was the intent, make it a community initiative. “Let’s try to reserve spots within this cohort for women and for trans women, and for black people, specifically because there is no data.” And one of the challenges we had when we were trying to figure out how to achieve this, and how to write down our plans was that we asked around: “So, what’s the number of women that we know of who are on PrEP in different settings in Ontario?”

It was really hard to come up with very many at all. So, that in turn made us say: “Well maybe what we need to be doing alongside this program is more outreach to raise awareness, and to go out to different sorts of settings where women might want to hear more about PrEP and consider it for themselves.” And that’s now become a part of the project plan. I tell you that anecdote to illustrate how we immediately came upon this challenge of, “Let’s enroll women who are on PrEP into our study, where are they?”

We need to do more work to raise awareness so that there can be some women on PrEP to even start to study, at least in our study.

Q But isn't that sort of putting the cart before the horse? I mean we don't know if this drug is safe. And, we already do know that loss of kidney function can be pretty serious for women. So, to get more women on PrEP, to see if it's safe, is kind of, I don't know. I don't like it.

A We can spend more time talking about the safety. I feel like there is a pretty large evidence base on the safety of TDF [tenofovir]. The company that manufactures it, paradoxically has, I fear, been successful in trying to convince us that it may be less safe than they tried to tell us it was a few years ago. I don't know whether this was brought up earlier. Did anyone talk about TAF? We should maybe talk about that. Let's just talk about what's coming up. OK, Truvada® is a combination of two things: TDF plus emtricitabine [FTC] in one pill. We've been using that pill in HIV therapy for years and years and years. We have a very good understanding of what the safety profile is. And, like I was mentioning before, I would say more than 2/3 of folks who are living with HIV who are in-care—and I'm talking about Canada—are using TDF and FTC as part of their regimen because the safety has been so high. Although, we did know that there was a renal signal.

There have been some rare issues with kidney function, it was a known issue and the company has been trying to say: "Don't worry about that. It's not a big deal. It's very rare, don't worry about it." The drug, TDF—you heard earlier—is going "off-patent" next year. A few years ago, the company said: "You know what? There's this other version of tenofovir that we've got coming out, and it's called TAF [tenofovir alafenamide]. We're going to package it together with FTC in a pill." That will be like a version 2.0 of Truvada®. And the advantage of it, for a bunch of biological reasons that we don't need to get into, is that it's safer from the bone and kidney perspective. They've done clinical trials and the drug is now licensed in Canada. We are already able to prescribe it and many of us are doing so. It's safer from a bone and renal standpoint and that's great for everybody, but the thing that it's there to replace was pretty damn safe, too. That's my personal opinion.

Q I feel concerned about hearing safety talked about as the same for treatment as for prevention. In medical ethics you have an entirely different standard for prevention. I'm prepared to live with bone density problems and kidney problems and whatever else because the alternative is death. But, to put that drug into a healthy body is a different thing. It's the discourse I have a problem with. The discourse is: "tenofovir is safe." I want to hear about tenofovir safety for prevention and tenofovir safety for treatment very separately, because we've talked about 16-year-old healthy kids who are at risk of unwanted pregnancy, STIs, HIV, a whole lot of stuff. To put tenofovir into a 16-year-old HIV-negative body is very different from a 60-year-old HIV-positive body. We're hearing "it's safe." Well, for who? Medical ethics says safety for preventative stuff really has to be the absolute highest.

A Yes I agree—I was trying to emphasize that there is a lot of data on the safety of Truvada® as PrEP including in women earlier, when speaking about the Partners PrEP trial and TDF2 trial, as well as the safety of Truvada® as treatment in men and women living with HIV.

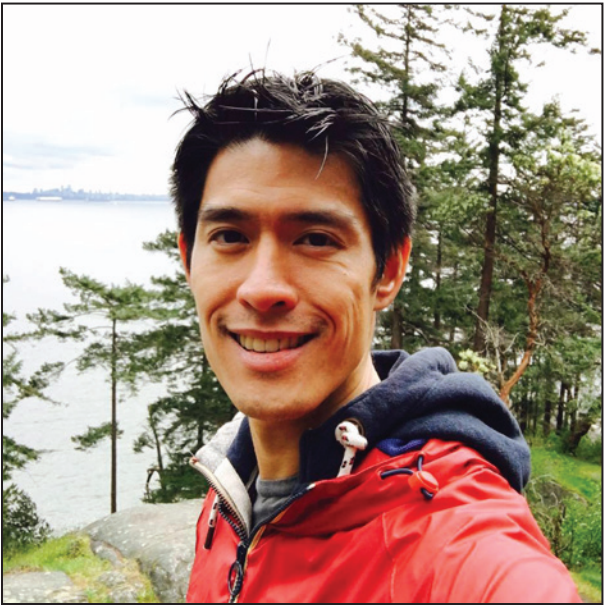
Q In terms of pregnancy, let's say there was a youth or a young adult who was a sex worker who became pregnant. What would happen to that person's pregnant body, as well as the unborn body if that person chose to go on PrEP? Or if they were on PrEP? Any information you could give me to pass along to either warn or reassure?

A So, information is limited. The best thing that I can think of comes out of that Partners PrEP trial I was talking about in east Africa—Kenya and Uganda. So there's context issues. Like in Kenya, again, a population maybe different from Canada in many ways. I think if I remember the data correctly there were a couple hundred pregnancies and they were able to show the rate of successful live births and the gestational age which is another model for health of the pregnancy. The numbers were similar between those taking Truvada® and the trial group who were receiving a placebo. Out of interest, they looked at the flip-side of the scenario: if the person whose sperm resulted in the pregnancy was taking PrEP and there was no difference.

The other thing to say—the earlier comment about treatment and prevention being entirely different scenarios is well taken—as a marker of what happens in a pregnancy where the fetus is exposed to TDF-FTC during the course of that pregnancy, the rate of birth defects is no different than the general population.

Q I can't even remember what my question was, but I did want an answer about pregnancy. I can only get search results for tenofovir, but it's at least at U.S. FDA Category B for pregnancy. ["There are no adequate and well-controlled trials in pregnant women. Use during pregnancy only if clearly needed." [Truvada.com](#). -Ed.]

Dr. Tan is an infectious diseases physician, clinician-scientist and Canadian Institutes of Health Research (CIHR) New Investigator whose research focuses on clinical trials in human immunodeficiency virus (HIV) prevention and HIV-sexual transmitted infection (STI) co-infection. As Director of the University of Toronto Clinical Research Unit on HIV Prevention and co-leader of the CIHR Canadian HIV Trials Network Biomedical Prevention Working Group, he is leading multiple efforts to optimize the implementation of HIV pre- and post-exposure prophylaxis (PrEP and PEP) in Canada. These include Canada's first demonstration project of daily oral TDF-FTC-based PrEP in Toronto MSM, the development of national Clinical Practice Guidelines on PEP and PrEP use, exploration of the relationship between syndemic health problems and clinical outcomes of PEP and PrEP, studies of nurse-led PEP and PrEP, and evaluations of novel antiretroviral PEP regimens.



snapshot: PrEP TRIALS

Randomized clinical biomedical HIV prevention research

Trial Phases

Clinical trials are conducted in a series of steps, called phases—each phase is designed to answer a separate research question.

Phase I Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

Phase II The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

Phase III The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

Phase IV Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

~ [Clinical Trial Phases FAQ](#), U.S. National Library of Medicine

Country Codes		Study Drug Codes	
BW Botswana	MW Malawi	TFV tenofovir	
BR Brazil	NG Nigeria	TDF tenofovir disoproxil fumarate	
KH Cambodia	PE Peru	FTC emtricitabine	
CM Cameroon	ZA South Africa	More Information on PrEP Trials	
CA Canada	TZ Tanzania	• Ongoing and Planned PrEP Demonstration and Implementation Studies , AVAC 2016	
EC Ecuador	TH Thailand	• ARV-Based Prevention Pipeline , AVAC 2016	
FR France	UG Uganda		
GH Ghana	US United States of America		
KE Kenya	ZW Zimbabwe		

PrEP Trial	Years	Countries	Women	Men	TransW	Study Drugs	Trial Phase	New HIV+ on Drug	New HIV+ on placebo	Effective preventing HIV+
Viread® PrEP	2003-2004	KH	960			TDF placebo	II	N/A	N/A	N/A
“researchers ... halted ... the placebo-controlled trial after ‘a verbal directive’ from the Cambodian Prime Minister, Hun Sen, that the trial violated human rights” [No TDF dispensed.] <u>Trial of antiretroviral for HIV prevention on hold.</u> Khabir Ahmad, Lancet 2004 Oct;4(10):597										
Viread® PrEP	2004-2005	MW		500		TDF placebo	II	N/A	N/A	N/A
“three PrEP trial protocols that were refused ethics approval in Malawi between 2004 and 2009” <u>Saying ‘No’ to PrEP research in Malawi: what constitutes ‘failure’ in offshored HIV prevention research?</u> Kristin Peterson et al, Anthropol Med. 2015 Dec;22(3):278-94										
Viread® PrEP	2004-2006	CM, GH, NG	936			TDF placebo	II	2	6	N/A
“did not achieve statistical significance ... owing to premature closures of the Cameroon and Nigeria study sites” <u>Tenofovir Disoproxil Fumarate for Prevention of HIV Infection in Women: A Phase 2, Double-Blind, Randomized, Placebo-Controlled Trial.</u> Leigh Peterson et al, PLOS Clin Trial 2(5): e27.										
Bangkok TDF	2005-2010	TH	489	1924		TDF placebo	III	17	33	48.90%
“enrolled volunteers from 17 drug-treatment clinics in Bangkok, Thailand ... who reported injecting drugs” <u>Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial.</u> Kachit Choopanya et al, Lancet 2013; 381: 2083–90										
CAPRISA 004	2007-2010	ZA	889			TDF-FTC gel placebo gel	IIB	38	60	54%-64%
“tenofovir gel reduced HIV infection by an estimated 79% in the group of women who had a high median applicator use” <u>Adherence in the CAPRISA 004 Tenofovir Gel Microbicide Trial.</u> Leila E Mansoor et al, AIDS Behav. 2014 May ; 18(5): 811–819										
iPrEx	2008-2010	BR, EC, PE, TH, US		2133	366	TDF-FTC placebo	III	36	64	44%
“blood levels [of drug] strongly correlated with the prophylactic effect” “nausea was reported more frequently during the first 4 weeks in the FTC–TDF group than in the placebo group” <u>Pre-exposure chemoprophylaxis for HIV prevention in men who have sex with men.</u> Robert M. Grant et al, N Engl J Med. 2010; 363:2587-2599.										
Partners PrEP	2008-2010	KE, UG	1796	2962		TDF-FTC TDF placebo	III	(13+17) 30	52	75% 67%
“protective effects of TDF–FTC and TDF alone against HIV-I were not significantly different” <u>Antiretroviral prophylaxis for HIV prevention in heterosexual men and women.</u> J.M. Baeten et al, N Engl J Med. 2012; 367:399-410.										
TDF2	2007-2011	BW	557	662		TDF-FTC placebo	II	9	24	62.20%
“the long-term safety of daily TDF–FTC prophylaxis, including the effect on bone mineral density, remains unknown” <u>Antiretroviral pre-exposure prophylaxis for heterosexual HIV transmission in Botswana.</u> Michael C. Thigpen et al, N Engl J Med. 2012; 367:423-434.										
FEM-PrEP	2009-2011	KE, ZA, TZ	2120			TDF-FTC placebo	III	33	35	N/A
“the study was stopped early ... because of lack of efficacy” <u>Pre-exposure prophylaxis for HIV infection among African women.</u> Lut Van Damme et al, N Engl J Med. 2012;367:411-422.										
VOICE	2009-2012	ZA, UG ZW	5029			TDF-FTC TDF TFV gel placebo placebo gel	IIB	(52+61+61) 174	165	FTC-TDF -4.4% TDF -49% TFV gel 14.5%
“no significant difference in the rate of HIV-I seroconversion between a group receiving any study product and the group receiving the corresponding placebo” <u>Tenofovir-Based Preexposure Prophylaxis for HIV Infection among African Women.</u> Jeanne M. Marrazzo et al, N Engl J Med. 2015;372:509-18										
IPERGAY	2012-2014	CA, FR		400		TDF-FTC placebo	IV	2	14	86%
“the use of TDF-FTC before and after sexual activity provided protection against HIV-I infection in men who have sex with men” <u>On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-I Infection.</u> J.-M. Molina et al, N Engl J Med. 2015;373:2237-46										
PROUD	2012-2014	UK		544		TDF-FTC	IV	3	20*	86%
* “participants were randomly assigned (1:1) to receive daily [TDF-FTC] either immediately or after a deferral period of 1 year” [Not a placebo-controlled trial.] <u>Pre-exposure prophylaxis to prevent the acquisition of HIV-I infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial.</u> Sheena McCormack et al, Lancet 2016; 387: 53–60										

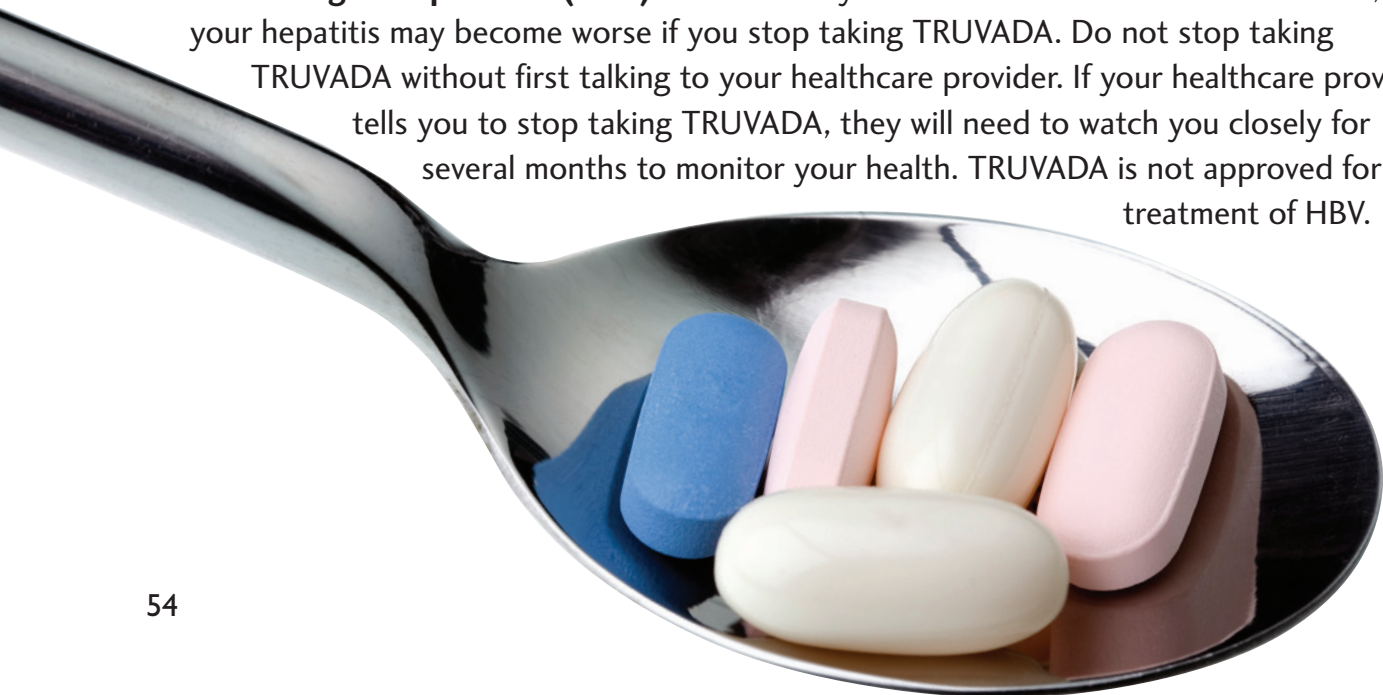
TRUVADA® CAN CAUSE SERIOUS SIDE EFFECTS

Factsheet from [Truvada.com](https://www.truvada.com)

- **Too much lactic acid in your blood** (lactic acidosis), which is a serious medical emergency. Symptoms of lactic acidosis include weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, nausea, vomiting, stomach-area pain, cold or blue hands and feet, feeling dizzy or lightheaded, and/or fast or abnormal heartbeats.
- **Serious liver problems.** Your liver may become large and tender, and you may develop fat in your liver. Symptoms of liver problems include your skin or the white part of your eyes turns yellow, dark “tea-colored” urine, light-colored stools, loss of appetite for several days or longer, nausea, and/or stomach-area pain.

You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight (obese), or have been taking TRUVADA for a long time. In some cases, these serious conditions have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.

- **Worsening of hepatitis B (HBV) infection.** If you also have HBV and take TRUVADA, your hepatitis may become worse if you stop taking TRUVADA. Do not stop taking TRUVADA without first talking to your healthcare provider. If your healthcare provider tells you to stop taking TRUVADA, they will need to watch you closely for several months to monitor your health. TRUVADA is not approved for the treatment of HBV.



Serious side effects of TRUVADA® may also include:

- Kidney problems, including kidney failure. Your healthcare provider may do blood tests to check your kidneys before and during treatment with TRUVADA. If you develop kidney problems, your healthcare provider may tell you to take TRUVADA less often, or to stop taking TRUVADA.
- Bone problems, including bone pain or bones getting soft or thin, which may lead to fractures. Your healthcare provider may do tests to check your bones.
- Changes in body fat, which can happen in people taking HIV-1 medicines.
- Changes in your immune system. If you have HIV-1 infection and start taking HIV-1 medicines, your immune system may get stronger and begin to fight infections. This may cause minor symptoms such as fever, but can also lead to serious problems. Tell your healthcare provider if you have any new symptoms after you start taking TRUVADA.

Common side effects in people taking TRUVADA to reduce the risk of getting HIV-1 infection include: stomach-area (abdomen) pain, headache, and decreased weight.

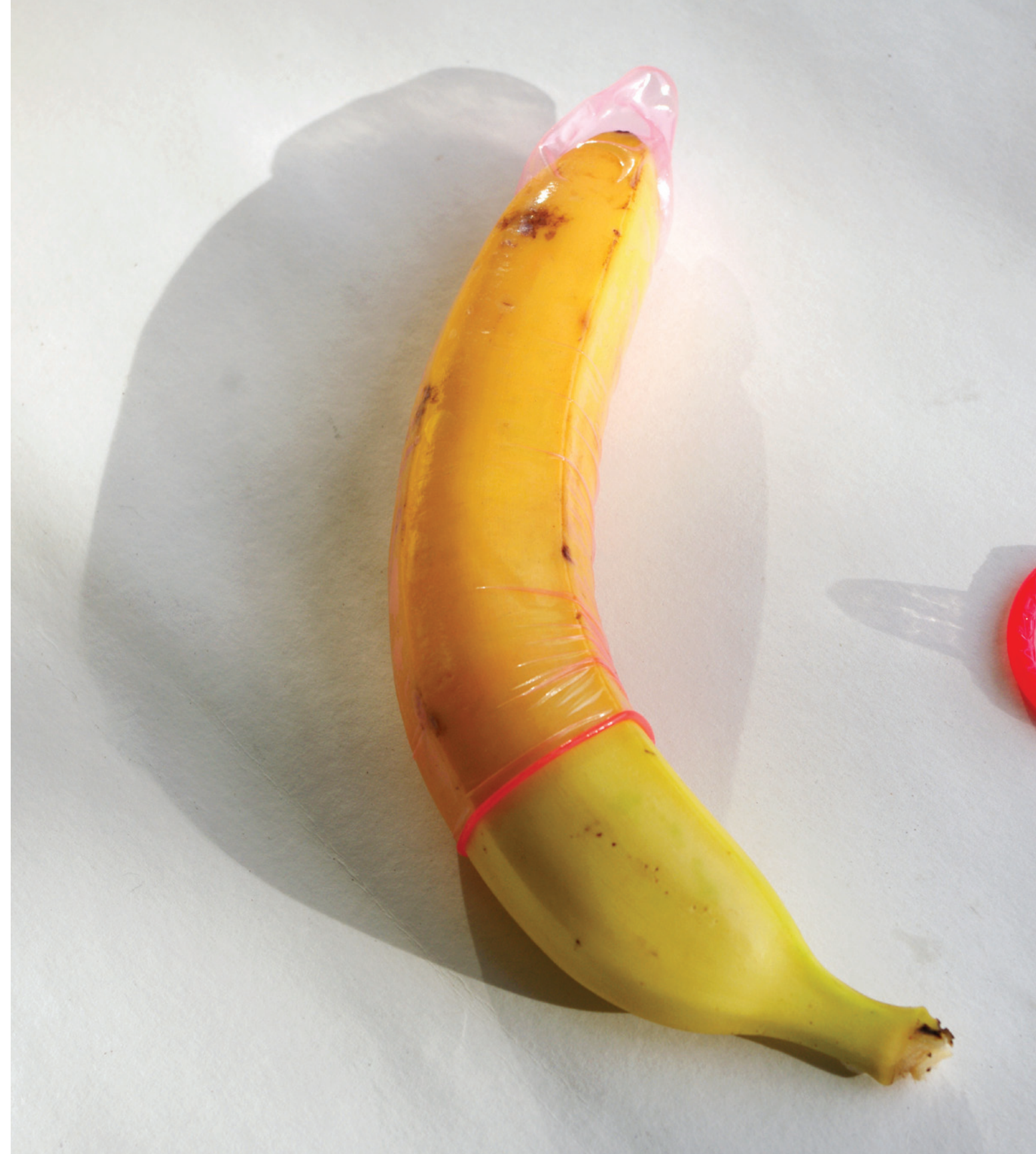
What should I tell my healthcare provider before taking TRUVADA®?

- **All your health problems.** Be sure to tell your healthcare provider if you have or have had any kidney, bone, or liver problems, including hepatitis virus infection.
- **If you are pregnant or plan to become pregnant.** It is not known if TRUVADA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking TRUVADA. If you are taking TRUVADA to reduce the risk of getting HIV-1 and you become pregnant, talk to your healthcare provider to decide if you should keep taking TRUVADA.
- **Pregnancy Registry:** A pregnancy registry collects information about your health and the health of your baby. There is a pregnancy registry for women who take medicines to treat or prevent HIV-1 during pregnancy. For more information about the registry and how it works, talk to your healthcare provider.

- **If you are breastfeeding (nursing)** or plan to breastfeed. Do not breastfeed. The medicines in TRUVADA can pass to your baby in breast milk. If you have HIV-1 or if you become HIV-1 positive, HIV-1 can be passed to the baby in breast milk.
- **All the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TRUVADA may interact with other medicines. Keep a list of all your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.
- If you take certain other medicines with TRUVADA, your healthcare provider may need to check you more often or change your dose. These medicines include: didanosine (Videx EC), atazanavir (Reyataz), atazanavir with cobicistat (Evotaz), darunavir (Prezista), darunavir with cobicistat (Prezcobix), lopinavir with ritonavir (Kaletra), or ledipasvir with sofosbuvir (HARVONI).
- You already have HIV-1 infection or if you do not know your HIV-1 infection status. If you are HIV-1 positive, you need to take other medicines with TRUVADA to treat HIV-1. TRUVADA itself is not a complete treatment for HIV-1. If you have HIV-1 and take only TRUVADA, your HIV-1 may become harder to treat.

You must stay HIV-negative to keep taking TRUVADA to reduce your risk of getting HIV-1:

- Know your HIV-1 status and the HIV-1 status of your partners.
- Get tested for HIV-1 at least every 3 months or when your healthcare provider tells you.
- If you think you were exposed to HIV-1, tell your healthcare provider right away. If you do become HIV-1 positive, you need more medicine than TRUVADA alone to treat HIV-1. TRUVADA itself is not a complete treatment for HIV-1. If you have HIV-1 and take only TRUVADA, your HIV-1 may become harder to treat.



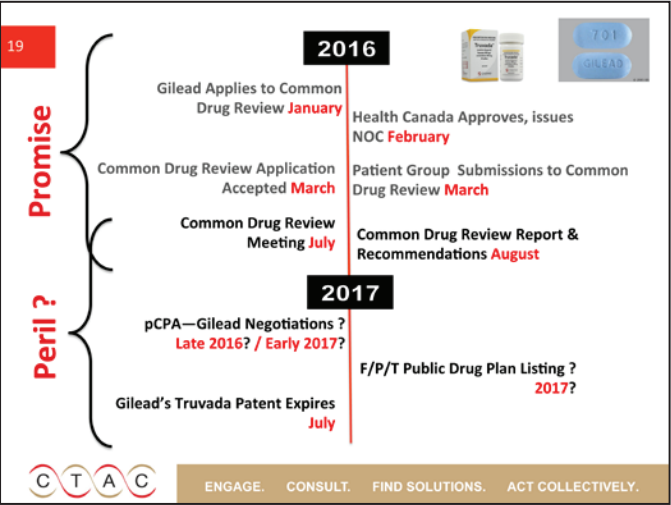
PROMISES AND PERILS OF PrEP

Regulatory aspects of Truvada® as HIV PrEP and pathways to reimbursement under public drug plans in Canada

Glenn Betteridge, HIV & AIDS Legal Clinic Ontario

It's great to be here. I was so happy to be invited to present. Basically, I'm here for you, to answer your questions and have a discussion about access to PrEP in Canada. We're going to focus on public access to PrEP, so I'm going to walk through some of the regulatory steps the drug goes through on its way to being publicly listed, or listed for reimbursement. Reimbursement of some — or all — of the costs via public funding.

I've been doing a lot of work in terms of Truvada® and regulatory stuff in my job at CTAC [Canadian Treatment Action Council] which advocates for access to HIV and hep C meds. Canada approved Truvada® for PrEP in February of this year, so not that long ago. Truvada® to treat HIV had been approved for going on 10 years, and has been the backbone in a lot of HIV treatment regimens. My presentation is called, "The Promises and Perils of PrEP" and so it was with great fanfare and a lot of promise that Truvada® was approved, because advocates had been asking for a long time for Gilead to actually bring it to Health Canada for approval.



One of the common themes throughout this regulatory process is, although it's a public process, it's driven by the manufacturer. The manufacturer has to apply, at every step of the way, for approval, for listing, to negotiate with the public payers. So it's largely driven by Gilead, and in Canada that's Gilead Sciences Canada. They're a "branch plant" of the big multi-national, and in

particular, the U.S. office. So, in terms of the promise of greater access — because we heard from a lot of people, "My doctor won't prescribe Truvada® for PrEP because it doesn't have that indication, it's not been approved for that purpose" — this seemed to solve that problem. People can now go to their doctors and say, "It's now approved for PrEP, you can't fight me on that one." And, Health Canada approval is the key

first step in getting it on insurance in Canada, both public and private. That's because insurance plans, writ large, are not going to cover a drug that hasn't been approved for a particular indication. That's a really big generality, but it sort of holds. Except in exceptional circumstances. We saw this playing out in B.C. with some of the insurance companies. People who had been covered for PrEP were subsequently denied coverage because they made "a mistake," because it hadn't yet been approved.

So, were we prepared? I think it's fair to say that Gilead wasn't prepared for this. It happened more quickly than they thought on their regulatory timeline. And, I don't think the Canadian community as a whole was prepared for this. We kind of had our head in the sands a bit, and we relied heavily on government funders, and I don't think government funders had been terribly interested in PrEP. It had been quite controversial in the gay male community, and some other communities, and they just didn't want to touch it.

So we're playing catch-up now, and we're in a period when a lot of folks don't have money for PrEP work, especially front-line organizations. It's just one more thing that they need to counsel people about, talk about, promote, advertise, and think about policy implications. So we're in a bit of a catch-up period, but without the resources to do it.

Public cost coverage: Where are we in October, 2016? As of today? Well, Québec's universal public drug program has covered Truvada® for PrEP for years now, before Health

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Steps along the pathway

1. Health Canada = approved safe & effective

2. Common Drug Review = list on public plans

3. pan-Canadian Pharmaceutical Alliance = public plans negotiate price structure

4. Federal, provincial & territorial government programs = individual plans enter into contracts, set limits on access

5. People who need it get Truvada for HIV PrEP ?

C T A C

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Daily Truvada for PrEP:
According to Health Canada

- When prescribing Truvada for HIV PrEP, **healthcare providers must:**
 - Prescribe as part of **comprehensive HIV prevention**, because Truvada not always effective
 - Counsel** about need for **strict adherence**
 - Confirm **HIV 1-negative status** through diagnostic testing prior to prescribing
 - Screen for HIV-1 every 3 months**

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Canada approved Truvada® for PrEP. In Québec, any drug that’s on the public drug program also has to be covered under private drug programs. They have a quasi-universal drug coverage system, and because Truvada® had been on the general list for treatment of HIV, people were able to access it for prevention—i.e. PrEP—both under public and private drug insurance plans.

As you know, we have a significant

colonial legacy in Canada with our Indigenous populations, and so there’s separate health programs and separate responsibilities in that regard. The federal government operates the Non-Insured Health Benefits program which has a separate formulary of drugs, and so Truvada® is covered under this formulary. My colleagues and I found that out because we happened to be at a meeting about PrEP where people from that program were present and said, “Oh yeah, we covered it.” And I said, “Well where’s that written?” “I don’t know if it’s written anywhere. I’ll ask around.” And so it wasn’t written. It was some decision, or sort of the reverse of a decision, just, “Oh, I guess we do.”

Q Does that mean Indigenous people have more access to PrEP than others in Canada?

A Access has many facets. On one hand, the insurance program that covers certain Indians and Inuit people —and I’m going to use those terms because those are the terms that are used in the legislation which underpins this health program, or this program flows out of that legislation — notionally they have access under that program. Whether they have access to the health services, the doctors, and pharmacists and support services that can make them aware of this, is another question. So for example, I had an email around this issue from a doctor who works with a trans client base in downtown Vancouver — one of the epicentres of the HIV epidemic in Canada — who has a lot of Indigenous folks who

did not know about this. So, to answer your question, notionally yes. But in practice, access is structured by many determinants of health — cost being one of them.

So this is on the public side. This is where we stand today. A little proviso about Ontario, some people have been able to get public cost coverage of PrEP in Ontario through the Trillium Drug Program which people with HIV successfully advocated for many years ago and have been relying upon for a long time. That’s a program for people who are working and have income, but their drug costs are enormous. So rather than forcing people to go on social assistance to get free drugs, this program allows people to work and to pay part of their drug costs based on their income.

Q In terms of access —youth access—is it going to be covered under Ontario Works or ODSP [Ontario Disability Support Program] anytime soon? Would there be a separate way in which you can navigate that for youth?

A So, these two social assistance programs —one disability and one general social assistance — come with a drug card. And the drug card gives people access to all the drugs that are on the provincial public program formulary. Truvada® is on the formulary. But, there’s a note that states a person can only get it from a doctor who is part of the facilitated access mechanism —which is a list of over 500 doctors—that I had to make an access-to-information request to get. The list would give you the doctors’ names and tell you where they were geographically located. So, as an advocate, if I had someone who wanted to know if Truvada® for PrEP is going to be rolled out, and only these doctors on the list are going to be able to prescribe it, where do these doctors practice? So, what is access going to look like? Currently the general rule is that nobody is getting PrEP publicly funded in

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Communities of interest

If taken correctly and consistently, PrEP is up to 99% effective in reducing your risk for HIV.

PrEP - Canada: Rethinking HIV P...

Associated with grassroots Advocates for PrEP Access in Canada (APAC), website a work-in-progress (www.Prepnow.ca)

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Ontario. There are exceptions through the Trillium Drug Program and I'm not aware of any other ones. But there may be.

Other cost coverage exists outside of these public programs: private insurance. People with jobs — good jobs nowadays, people who work at universities and big institutions often have private drug coverage. And some people have money to pay 1,000 bucks a month out of pocket for meds. Odds are people are combining these two things, because increasingly private drug insurance has deductibles. You have to pay 20%, 30%, 40%, 50%. So if you had to pay 50%, that's over 6,000 bucks a year from your after-tax income. So people pay that, or, combine different insurance, so they have insurance with their employer and then they buy insurance on the market — on the open market.

Q So, am I getting it clear here? It's a 1,000 dollars a month?

A More or less, in Canada, if you were to go to the pharmacy. That's the retail price.

Q Is that the new one that Gilead is putting out or is that the old one?

A No. Descovy® — the new one — hasn't even been trialed for PrEP. So we're many, many, many years likely away — if the trials prove it's not inferior to Truvada® — for it actually coming onto the market as PrEP. And there's probably going to be a lot of conflict and activism around the trials for Descovy®.

5

Advocacy for public access

GETPrEPED

One preventable HIV transmission is one too many. Tell our leaders: We want access to PrEP in BC now!



Affordable PrEP Access Now!

In February 2016, Health Canada approved the use of daily Truvada as PrEP for reducing the risk of sexual transmission of HIV. However, PrEP is not yet available in BC. With reduction in risk for HIV, negative individuals who take the pill every day as directed. According to the most recent BC Centre for Disease Control (BC CDC) surveillance report, 1,000 people and other people who have sex with men (MSM) continued to acquire the virus.

We are asking our provincial government to list Truvada as PrEP on the general formulary of British Columbia's provincial drug plan (aka Pharmacare). Listing Truvada as PrEP on the general formulary means the cost of Truvada as PrEP would be covered in part or whole by the province.

You can help by sending a letter and sharing this call to action with others!

Email Terry Lake, the Minister of Health & Social Services BC

100 people want

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Canada. You're not legally allowed to import drugs in. So, mail, courier, those type of things tend to get stopped at the border. They're not going to be allowed through. But if you can get a P.O. box down in the States, get a 'script, go online, order it from an Indian or a Thai generic producer, have it come to the States and go pick it up. Some people have had success bringing it back across the border.

Q With the make-up of the generic Truvada®, is there any significant difference in terms of the way it affects your system? Can certain generic elements be harmful for your body?

A There shouldn't be any difference. If you ask name-brand pharmaceutical companies they'll routinely say that generics are inferior products. If you ask the World Health Organization — in the context of HIV, TB, and malaria — they have pre-approved certain pharmaceutical companies that provide generic versions. They are basically the pharmacy to the world — South African, Brazilian, and broadly Indian generic manufacturers. So if you go with one of them, it's basically a manufacturing facility that's been approved by the World Health Organization to provide generic drugs.

People have also enrolled in clinical trials, which there have been few in Canada, who have also been able to access PrEP.

There's great advocacy for public access. Let me just stop here and say, I'm talking about advocacy focusing on the regulatory process and trying to affect that, as opposed to community building, capacity development, fostering conversations of the type we're having here. The Women's HIV/AIDS Initiative [WHAI] in Ontario has done some great work around increasing conversations and information, and bringing information to people. The next few slides are going to talk about people doing work with a view to

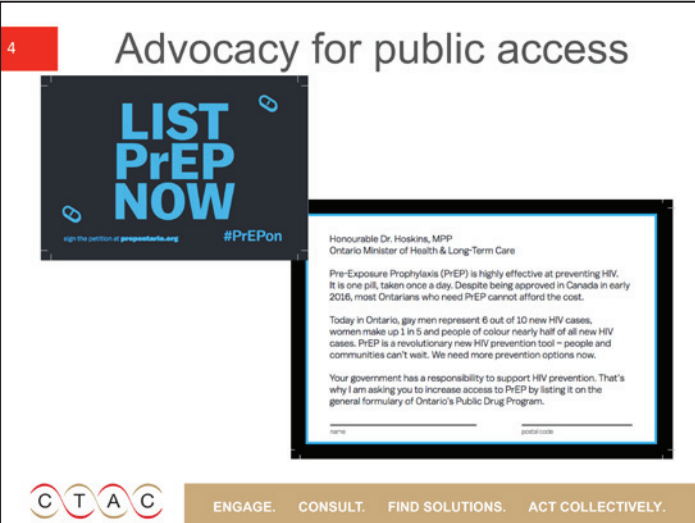
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CanPrEP advocates working on..

- Initial in-person meeting in October 2015
 - Agreement to work together on project-by-project basis; focus on work, NOT building an organization or institution
 - Adopted Basecamp communication platform in January 2016
 - Cross Canada representation, community, HCPs, PHAs, local
- Activities in progress (May 2016)
 - PrEP prescriber referral list (local list, possibility of national?)
 - Request for meeting with Gilead to discuss pricing, access, patent expiry and product support for Truvada (by end of May 2016)
 - Regional/provincial support and co-ordination
 - Ontario kicking off postcard and sticker campaign to coincide with LGBTQ2S Prides and other summer festivals in Ontario; request for meeting with Ontario Public Drug Program; campaign launch and physician support in Fall 2016
 - NS investigating lay of land
 - Alberta discussions and organizing involving community and HCPs
 - BC community education, awareness, web-site development, social media work, and early stages of communicating with BCCF, BCCDC, MoHealth, community, PAN

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affecting the regulatory process which is ultimately going to dictate price and access, and conditions on access.

There's this "List PrEP Now" campaign going on in Ontario currently which targets the Minister of Health and long-term care saying, "List PrEP now and make it open listing." So, put it on the formulary and let any doctor prescribe it—if that doctor feels confident to do so. There's a campaign in B.C.:

Email Terry Lake, the Minister of Health and your local MLA. Same thing. They're asking for cost coverage, and a pretty broad listing. There's a question in B.C. about how—and if—Truvada® for PrEP is going to be distributed. As you know, there's something called the B.C. Centre for Excellence in HIV/AIDS. They have a common pharmacy which provides HIV medications to people for free. Universal access. They also have a public drug program that would provide things like medications to treat STIs. Where is Truvada® going to end up? The B.C. Centre has not been particularly outspoken on the issue and isn't perceived to be advocating very strenuously for access to PrEP.

Q They also receive a lot of money for using information about who is taking the medication for research—long-term studies.

A Yeah, they're a research outfit. It's unclear whether they're actually interested in PrEP in a significant way. They moved their attention onto treatment-as-prevention in the hep C world, and don't seem to be giving as much attention to PrEP.

Meanwhile we have Edmonton Men's Health Collective. They've done a really extensive survey on PrEP. I think they've had over 400 responses; they're crunching the data. They've been meeting with members of the legislative assembly in Alberta including the Minister of Health to talk about PrEP access. There's stuff going on across the country.

So, the pathway to public listing: CTAC where I used to work has a great video on their website—which is ctac.ca—about five minutes long. It's a really great video that sort of walks through from clinical trials to pills in people's bodies and what that process looks like. It's really complex and simplified. The complexity comes from—if for no other reason—the fact that we have 18 public drug programs in Canada. 18 public drug programs! So what people have access to in Newfoundland, on reserves, in downtown Toronto, in the Yukon, varies greatly. A person living with HIV or living with diabetes or living with... they might have access to different public funding for medications solely based on where they live. It's a big mishmash of programs.

So what's the pathway? Health Canada approved, safe and effective. Check. That's done. Then there's something called the "Common Drug Review," which is basically the first step in evaluating value-for-money for drugs. And value-for-money versus everything other drug that's out there that does that same thing. There's a pan-Canadian pharmaceutical one. We live—if we listen to our government—in very lean times. And health care is a huge expense that is growing, and prescription drugs are a huge part of that huge expense. So, this is a mechanism where all the provincial ministers of health got together—Québec came later—to negotiate as a block with drug manufacturers, because in the past, drug manufacturers had gone province-by-province, and all the agreements they reach are confidential. You could have two provinces side by side, and one paying vastly more than the other. If you get economies of scale together you're going to get all the provinces bargaining together. They believe that they could get better deals.

Once the distribution structure and the price structure is negotiated then it's up to each federal, provincial, or territorial government program to decide whether



or not to list and enter into a contract with the drug-maker— Gilead in this case. Then, notionally people who need it can get Truvada® for HIV PrEP.

Steps along the pathway: These five steps determine private access, but more importantly determine public drug plan access. So: Who? Under what plan or program? How long before will they be able to get it? What are the administrative rules, procedures, hurdles, and hoops they have to jump through? Who pays when and how much? What percentage—is it full cost coverage? Is it co-pay? Does the public plan pay up front to the pharmacy, or do you have to carry the costs on your credit card or something else until you can submit your bills and get paid back by the public drug plan?

Promise and peril. The promise: a large meta-analysis of studies of PrEP for all populations—determined that Truvada® for PrEP was safe and effective, highly effective in all populations. Let’s get to some of the perils in a second.

First, we’ll just go through a timeline. Gilead applied to the Common Drug Review in January, a month before Health Canada approved the drug. That’s just a regulatory timing issue that is not worth getting into. Common Drug Review: Is this product good value for money and should public programs pay for it? The application to have it reviewed made by Gilead was accepted in March, and patient-group submissions were invited. Basically, patient perspectives are on whether this drug is good value for money and should be

covered. The Common Drug Review folks—the experts—met in July and then they made the recommendation in August, about whether public drug programs in Canada should fund Truvada® for PrEP.

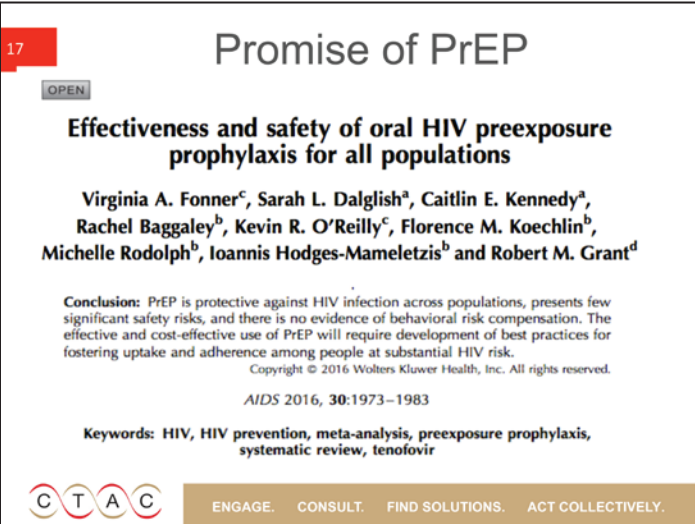
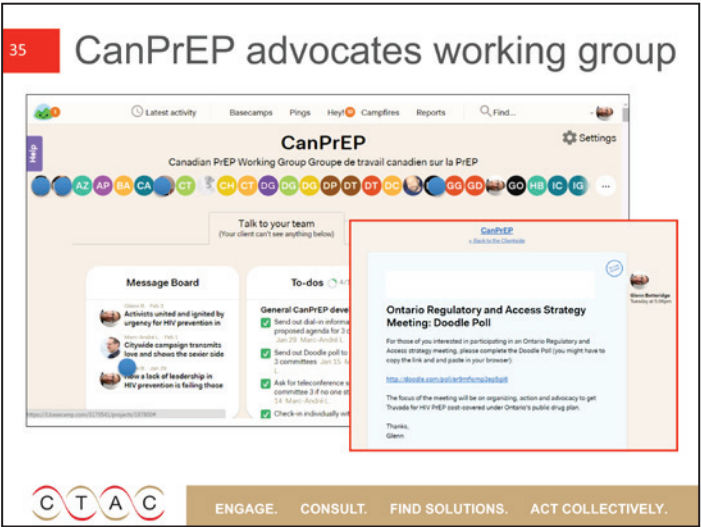
What lies ahead? Pan-Canadian Pharmaceutical Alliance: This is where all the provinces and the other drug plans get together and bargain with Gilead—

bargain or negotiate. Late 2016 and late 2017 looks like the timeline. Then, after that, public drug plans—the individual ones—have to enter into agreements with Gilead if they want to publicly list the drug in their province/territory or on their public drug plan.

Here’s the confounding factor: Gilead is working against a relatively short timeline to maximize their profit, because the patent—the Canadian patent on Truvada®—expires in July 2017. Large question: Are there any generic manufacturers interested in bringing generic Truvada® to market? And it’s unclear, in part because nobody’s had the time to look at this issue and approach generic pharma and say, “Are you going to produce it?” Truvada® is an old drug. It has a not great side-effect profile. Not awful, but there are better medications, arguably. Gilead now says their new medication Descovy® is better. And the market for PrEP is unknown. How many people are eligible under clinical guidelines for PrEP? We just don’t know. It’s hard to tell whether a generic manufacturer is going to enter the market—they are for-profit businesses. Is there a business case for manufacturing and marketing generic Truvada®? And, it’s been estimated in the Canadian context to bring a drug through these five steps for a generic company costs \$4,000,000 for each drug. So can they recover that money? Gilead has had the market, developed its brand, spent money, et cetera.

Q For the U.K., there are national guidelines called NICE (National Institute for Health and Care Excellence) guidelines. They’re the instructions from government about who qualifies to get this drug. So, for example if selling sex qualifies you for the drug—even though there’s been no research—who decides the who-needs-PrEP category?

A It’s unclear. The government, as a unitary government, is not going to decide individual access. It’s unclear because there is no unitary guideline setting in Canada.



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Daily Truvada for PrEP: According to Health Canada

- Following factors **may** help to identify a **person at high risk of HIV infection**:
 - partner(s) known to be HIV-1 infected, **or**
 - engages in sexual activity within a high prevalence area **or** social network, **and** one or more of the following:
 - inconsistent or no condom use
 - diagnosis of sexually transmitted infections
 - exchange of sex for commodities (e.g., money, food, shelter, drugs)
 - use of illicit drugs or alcohol dependence
 - incarceration
 - partner(s) of unknown HIV-1 status with any of the factors listed above

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that’s not the way it really happens, in terms of how a drug is approved. So, here’s what the drug Truvada® for HIV PrEP is approved for under current Health Canada rules: Daily use in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 infection in adults —because all the studies were in adults—at high risk. OK? Adults at high risk. So it is a group, but it’s a very large group and all the other groups don’t really figure in terms of a straight-up medical assessment according to this indication. The indication or the product monograph says: “Look at the following factors to determine if a person is at high risk of HIV infection.” So partners of people living with HIV. Or, the people engaged in sexual activity within a high prevalence area —geographic area, community, neighborhood, social network. So geographic area or social network, and one or more of the following: Inconsistent or no condom use. Diagnosis of STIs. Exchange of sex for commodities —money for shelter, drugs. Use illicit drugs, or alcohol dependence. Incarceration. Or, partners of unknown HIV status with any of these factors listed above. So it doesn’t go through and do what we so often do in HIV: name key populations or target populations. It’s just not the way the regulatory system works in terms of providing drugs.

Q I just have a quick question: when you say a partner who has HIV, this includes people who have an undetectable viral load?

Doctors have a great deal of discretion to interpret guidelines when prescribing. The ultimate question is can you get it paid for?

Maybe I can address something about populations, talking about whether Truvada® is going to be indicated for, or whether sex workers are going to be identified, or whether X population is going to be identified as appropriate for Truvada® for HIV PrEP. In Canada,

A That would depend on the doctor’s discretion. We have a doctor here. What would you counsel a sero-different couple —one person is HIV-positive, one negative—and the person living with HIV has an undetectable viral load? Is PrEP something you would suggest?

Dr. Tan: From all the research that has been done, we know, that if someone is truly zero viral load, that the risk of sexual transmission is extremely low. The way I like to phrase it when I’m talking to folks is to say: “It’s really close to zero, but I’m not a 100% certain in October 2016 that it is equal to zero.” The big question is: How close to zero is it? And that gives people a sense of perspective. Some people are more comfortable with that risk than others. Another factor that is always challenging is that every relationship is different. When one person is trying to make a decision about their personal health based on the health status and actions of another human being —albeit their partner—because that partnership can be quite different from partnership to partnership. That factors into it as well. They may still choose to make a decision quite independently because of uncertainty about what’s happening with their partner. Or, they may be completely confident in what’s



happening with their partner. That's another factor. Of course other considerations are costs, and side-effect profile which is minimal. And, the inconvenience of having to come in and see a doctor all the time — get blood tests done all the time. That's another factor. I think many practitioners in the field would discuss those with their patients and then together try to reach a decision. I think most practitioners would not actively recommend PrEP and say, "I really think this is something you should do." But, I think many of us would also not block and say, "You should not do this."

Glenn: One final point for illustration: Presuming that Gilead and the Pan-Canadian Pharmaceutical Alliance can arrive at a cost structure everybody can live with, then it's up to each province or territory or public drug plan to figure out: "How will we list it?" The presumption is that they go on to enter into an individual agreement and then they have it listed. In Ontario, there's an executive officer of our public drug program and it's her decision, ultimately, whether or not to list drugs. She's got a lot of choices ahead of her. And, each one of these choices has different implications for access. Is it going to be as broad as possible access by listing the drug on the general formula? This might



also be broad, distributed through public health or sexual health services — programs administered by public health units, of which there are 36 in Ontario. Or, general formula limited use: Paperwork for every 'script and approval via the Exceptional Access Program. That group of 500 or so doctors — pre-approved for the Exceptional Access Program for HIV meds — are they going to be the ones who have access on behalf of their patients? Although, that program is very loose and porous nowadays. It's not only those docs who can prescribe HIV meds. There's a whole range of different ways that this might end up being listed on Ontario's public drug program, and ultimately, that will likely have implications for who gets PrEP funded by the government. So... this is just a snapshot of a very complex, inconsistent, incoherent, maddening system for prescription drug regulation, and our lack of universal prescription drug coverage in Canada.

Glenn has volunteered and worked in health, human rights and advocacy for over 20 years. Much of his work has focused on promoting the health and well-being of people living with and at risk of HIV and hepatitis C, low income people and other people systematically excluded from full benefit of laws and social programs in Canada. He learned a great deal from sex workers as lead author of the full-length 2005 report, Sex Work Rights: Changing Canada's criminal laws to protect sex workers' health and human rights, and by working alongside sex-worker advocates to support law reform. Glenn recently returned to practicing law at the HIV & AIDS Legal Clinic Ontario after working as a policy analyst, researcher, consultant and PhD student for the past 13 years.

- Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. Virginia A. Fonner *et al*, *AIDS* 2016, 30:1973-1983.



HISTORY OF SEX WORK, HIV & ACTIVISM

Presentation from Michael Kirby Centre for Public Health and Human Rights

Cheryl Overs, Researcher

Officially the modern secular state creates laws to protect people from “that which is injurious or offensive” rather than impose morality as was formerly the case. On that basis it usually bans soliciting, operating sex businesses, et cetera. This same shift from imposing morality to protecting people has driven an important change in emphasis from trying to prevent women selling sex into protecting public health. One of the consequences of that shift is the resources for similar programs and advocacy are all now almost exclusively tied to health. Albeit, the health of others. And that’s called “public health.”

The health approach isn’t bad for the sex workers of course. Sex workers have always struggled with health issues and improving access to health care is of course crucial. But public health law can also underpin criminalization, quarantine, unethical research,

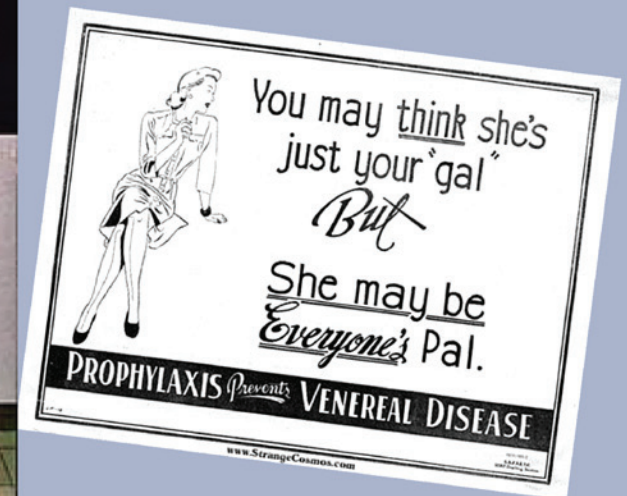
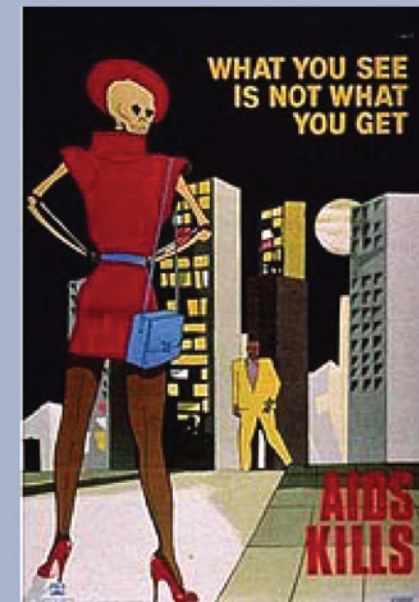
containment of sex workers, forced testing of sex workers, and registration. So while the wider world think of health for sex workers as a good thing, sometimes the term “health” sets off alarms for sex workers.

The role of stigma in access to health and health as a human rights risk can’t be overstated of course. Sex workers were always stigmatized — that got worse when HIV arrived. And, that stigma was soon played out in public health by images such as this one that portray sex workers as AIDS carriers stalking the streets. It’s important to recognize that public health folks who absorbed stigma into unhelpful AIDS programs are not against sex work. Most support decriminalization. Stigma was so pervasive and so powerful that challenging it within HIV programs was a high priority in the late 1980s.

The sex workers’ rights movement existed before HIV, including here in Canada. In 1985 we developed the World Charter for Prostitutes’ Rights at a conference in Amsterdam run by ICPR — the International Committee on the Rights of Prostitutes. It won’t surprise you to know that white sex workers from wealthier countries were over-represented at the



Sex workers were always stigmatised, and then came HIV



conference. For the public health authorities sex work in Toronto or Melbourne was of less interest than in Africa and Asia where HIV epidemics were taking off. They were totally and absolutely caught out, knowing programs would be needed, but without any idea of what they should look like. Those of us already doing sexual health work among sex workers were able to go into that space and function in that space as both activists and service providers. I even got a job in Geneva at the World Health Organisation for a while.

Our top priority was to challenge the fact that sex workers were being blamed for spreading HIV. Traditional epidemiology methods identified sex workers, gay men, injecting drug users as “core transmitters” using mathematical algorithms. “Transmitters” categories became “high-risk groups.” We had to protest against that. And, against the traditional response to “core transmitters” which is to locate and treat or isolate them to prevent ongoing transmission.

As effective HIV medication became available we also had to protest about lack of access to medication.

The programs sex workers set up were the origins of methods that are now known as peer education, community outreach and harm reduction. In reality that often involved nothing more than putting out pamphlets to fellow workers. I always feel nostalgia for a time with fewer meetings, trainings, conferences, monitoring and evaluation.

For those of us working internationally it was important that we make more global contacts with sex-worker groups throughout the world. At the time, we had the ICPR but to get public health funding and embed ourselves in the response to HIV we created the international Network of Sex-Work Related HIV Projects [later the [Global Network of Sex Work Projects](#)]. An unintended consequence of this was that the sex workers’ rights-oriented global network, ICPR was no longer viable.

Over time, the influence of the human rights activists became evident. Epidemiological tools were revised and science gradually caught up. In policy documents the view of sex workers as vectors of infection who should be identified and stopped was replaced by harm reduction and systems for testing and distributing drugs improved. And, the legacy

of these enormous shifts is that we now have a medical model which is more grounded in human rights. In this context sex workers’ role moved from protesting and from doing that first, very basic, reactive work I spoke about a moment ago.

From protesting against the public health paradigm we moved to participating in it. But as science caught up, so did politics. The space that we could operate outside of those limits I have described, was contracting. By the turn of the century, instead of a few sex work organisations taking HIV work upon ourselves, sex workers were applying for harm reduction posts in organisations funded by governments and other donors.

Having set up one such organization myself I want to reflect critically on what that meant. Even though we were all cheering for harm reduction because it was so much better than what preceded it, it’s worth recognizing that the ideas that underpin it cast the sex worker and client as vulnerable to HIV and in need of protection from it. This, and the funding configuration I mentioned earlier, entrenched disease prevention as the highest priority of the sex workers’ rights movement.



Now I look at how the sex-worker community was incorporated into the HIV response and wonder if some of the consequences have improved on the older style programs that overtly violated human rights. Here is an example.

Community-based HIV testing is an idea created by UNAIDS in Geneva to increase sex workers' access to HIV services. This is what it looks like in a sex venue in Cambodia. There's no protection of confidentiality; the women drawing blood is a sex worker peer educator. Its happening in a venue where clients and brothel owners can watch, where violence is absolutely over the top, and where alcohol — large amounts of alcohol is consumed.

Here is another public health intervention created by a Swiss local government. These are sex boxes that sex workers and clients can use legally. They are staffed by social workers who supervise the sex workers and test them for HIV and STIs. The government made it illegal to work elsewhere and then wondered why the sex boxes are hardly used.

In Mongolia, the Global Fund pays for VCT — Voluntary Counseling and Testing. But,

Imperfect

Switzerland. Local government built drive-in sex boxes, put health/social workers there and made it illegal to solicit elsewhere. They told the press it's decriminalisation. Sit back and wonder why they are hardly used.

Mongolia. The Global Fund pays for VCT. In police stations. Of arrested sex workers.

Asia and Pacific. A handful of sex workers endorsed a 'unique identifier code' despite years of the movement opposing registration.

Germany and New Zealand have made it illegal to sell or buy sex if no HIV protection is in place.



“Community-based” HIV testing in a sex venue, a programme designed by UNAIDS & funded by the U.S. government. Worthy of George Orwell?



UNAIDS

outreach workers who test sex workers for HIV are accompanied by police who arrest and take anyone who refused a test back to the police station for post-arrest testing. We have argued for years against registration, right? Don't want sex workers all named with numbers and registered and cards and all that. Well, that's exactly what NGOs right through the Asia Pacific are doing. It's called a “Unique Identifier Code” [UIC] and because it's not the government that's doing it, it goes unnoticed. When I mentioned this to a staff member of an organization paying for this she said, “NGOs that support sex workers are issuing the UICs to help them. You don't have to have it! It's not compulsory! It's not mandatory!” But, those who don't have the number get no health services whatsoever from the NGO. Which makes VCT: “Virtually Compulsory Testing.”

One last example of the disconnect between sex workers' rights and public health — Germany and New Zealand have made it illegal to sell sex if no HIV protection is there.

Most sex work in New Zealand is decriminalized, but, sex workers and clients can still be arrested if they have sex without a condom—although the law says “protection” which means it can be updated to PrEP. It worries me slightly if the sex work activists who advocate for the New Zealand model all over the world accept the idea that criminal laws drive HIV prevention in the sex industry. Perhaps they do not know about it since they rely on organisations funded through public health programs.

Now that PrEP is changing the HIV-prevention guidebook again we need to reflect back on sex workers’ rights in the context of public health. The introduction of PrEP is the perfect stage to play out power dynamics between sex workers and public health authorities.

Most, if not all, of the rights-based social action that has spun off the HIV industry will be de-funded in favour of providing ARVs either as treatment for the HIV-positive, or as PrEP for the HIV-negative. In this context of re-medicalization of HIV it’s important to distinguish inclusion or cooperation in public health and to make sure it’s not co-option.

When we think about PrEP, rather than thinking in the language of harm reduction for public health we should be thinking in the straightforward terms of sex workers’ rights: We are not vectors of disease. Don’t stigmatize us. Don’t coerce us. Don’t expose us to arrest. Don’t ignore clients. Don’t violate our privacy. Don’t expect health services to work properly while the threat of arrest and discrimination hangs over us.

To this I would like to add—stop providing sex workers with ‘below the waist’ rather than holistic health care. For me ‘below the waist only’ healthcare is clear evidence that sex workers are still treated as vectors of sexual disease.

Because at this stage, the most important thing that can be said about PrEP and sex work is that more research is needed. We need to also reinforce the need for decent research. We have seen so much rubbish. It’s improved slightly since we protested against it at the AIDS Conference in Montreal almost three decades ago, but the principles haven’t changed. And, we’ve still got to push back against the public health paradigm which continues to cast sex workers as vehicles of disease.

Valerie: Because we had nothing to lose. There were meetings at city hall about quarantining gay men and sex workers. We weren’t afraid.

Cheryl: Valerie’s point there can’t be over emphasized. We didn’t expect *them* to even speak to us. The fact that they let us into their conferences was amazing. And, we didn’t care who we offended. I was reminded of just how much sex workers spoke truth to power and of the anger and determination of ACT UP [AIDS Coalition To Unleash Power] at the 1989 AIDS Conference.

Just as those of us at the International AIDS Conference in Montreal in 1989 challenged how sex workers would be treated in at the outset of the HIV pandemic, contemporary activists have a complex terrain of public health and human rights to navigate that includes PrEP. In some ways it’s easier now because there are more of you and technology is better. But, in some ways it’s more difficult than in 1989 when unruly sex workers leapt into that gap created by a virus that had everyone confounded. Public health institutions have become stronger and have co-opted those parts of the sex workers’ rights agenda that suit unchanged public health aims. The Empire always strikes back.

Cheryl Overs is a founder of Australian sex-worker rights organisations the Prostitutes’ Collective of Victoria (PCV), the Scarlet Alliance and the Global Network of Sex Work Projects (NSWP). Between 1986 and 2010 she worked with sex workers in more than 20 countries and wrote about sex worker led, rights based programming. Since 2010 she has been a researcher with the Michael Kirby Centre for Public Health and Human Rights at Monash University in Australia and at the Institute of Development Studies in the U.K. In that time she has worked on establishing a legal service for sex workers in Cambodia; studies of legal and economic empowerment of sex workers in Myanmar, Ethiopia, Malaysia, Cambodia, and Fiji; an electronic database of academic publications on sex work (PLRI); and a global map of sex work law. In 2012, Cheryl was a member of the Global Commission on HIV and the Law and delivered a keynote address at the International AIDS Conference.



PrEP TRIALS IN CAMBODIA & CAMEROON

How activism led to 'Good Participatory Practice' in clinical trials

Melissa Ditmore

Thank you for including me today. I was really happy to be able to come back to Toronto. I've only been here every few years. The last time I was talking about trafficking. I'm going to go through some history. My first visit to Toronto was 10 years ago for the International AIDS Conference here. Two years prior there were protests sponsored by Women's Network for Unity. This organization, during one meeting, planned the demonstrations that they held with ACT UP Paris at the AIDS conference in Bangkok over the treatment of sex workers in clinical trials for tenofovir for PrEP that were started in Cambodia.

Sex workers were recruited. They did not understand what the trials involved. They were given information in English rather than their native Khmer or Vietnamese. They were

offered, as an incentive, almost enough money to cover their transportation back and forth to the research site. So, that's not really an incentive. There were no provisions made for long-term care for people who became HIV positive, or who suffered side effects like renal problems and broken bones from a lack of bone density. No one in this room, I think, would participate in clinical trials under those sorts of circumstances. I wouldn't. And, I'm presuming that people here with some education, perhaps higher literacy levels, would not.

We can understand how necessary their protests were to change these conditions. Their protests stopped a clinical trial and this is important. I will go through a little more history to demonstrate how much of a milestone that was. Another trial, under similar conditions, was stopped in Cameroon by local sex-worker organizations, just like they did with the sex workers from Cambodia. A third trial in Nigeria was also halted. The closures of these unethical trials were cause for celebration because they demonstrated the power that organized sex workers working with allies and strategically using resources can leverage.



Time to Deliver Sex Workers' Rights! at XVI International Conference on HIV/AIDS, Toronto, August 2006. © HimYSyed-photopia



NSWP Booth at XV International Conference on HIV/AIDS, Bangkok, July 2004. © Jenni Gamble, South Australia Sex Industry Network

This is the booth from the Network of Sex Work Projects during the 2004 AIDS conference in Bangkok. These are banners: “\$36/year cannot buy a sex worker.” “We are human beings not animals.” Their perspective of how they’ve been treated like lab animals is well grounded. But after the trial closures everyone except ACT UP Paris and sex workers seemed to turn on sex workers for not carrying on with these trials. Western gay men, people in serodiscordant relationships, and most notably, pharmaceutical companies — particularly Gilead, which makes Truvada® — lambasted and attacked sex workers. A transgender sex worker activist in Cambodia asked why sex workers should do this for humanity when humanity, in her experience, had shunned sex workers, attacked sex workers, and now wanted to treat sex workers like lab animals.

That is a room in a small brothel in Cambodia. Just bare walls. The only cushion was the mattress. This was a place where someone lived and worked. A fairly prosperous person—not terribly prosperous—that was her own place, working in her own room.

Medical history has a lot to answer for. The history of medical research and sex work is hideous and gives me nightmares. Sex workers were intentionally infected with syphilis and also gonorrhea for doctors to observe the progression of each disease. This was part of the identification of the bacteria that causes gonorrhea. That was a century before the Tuskegee study of syphilis in the U.S. in which African American men were not told that they were being tested for syphilis, and then not treated to watch the progress of the disease. In the 1940s and '50s, in Guatemala, the U.S. government infected prostitutes in secret experiments to test penicillin as prophylaxis for syphilis. Though it may not be in history books, sex workers were used in nightmare-inducing experiments involving exploration of the female reproductive system and genitals. Sex workers were victims of Nazi war crimes in the form of



Time to Deliver Sex Workers' Rights! at XVI International Conference on HIV/AIDS, Toronto, August 2006. © HimYSyed-photopia

medical experiments, unethical practices that actually contributed to the development of standards for research ethics after World War II.

This is the cover of a recent publication from sex workers in Europe: *Sex Workers Speak. Who Listens?* At the 2006 AIDS conference here, there was a panel featuring sex workers who described their treatment by Gilead, the pharmaceutical company behind the tenofovir trials and the trial staff. And while this was not the first time the sex workers had spoken quite clearly about this, including in publications, it was the first time that the AIDS industrial complex listened.

One of the responses to this was the development of “Good Participatory Practice,” in addition to good clinical practice, to promote the meaningful inclusion of research participants, and to prevent flaws leading to the closure of any future trials. Dan Allman was part of the development of “Good Participatory Practice.” He and I both have



critiques of it. It's limited, but he and I asked people for what we believe is important input, from people who were sought for trials including sex workers and people who use drugs. Meanwhile, tenofovir, one of the medicines in Truvada® and the PrEP trials moved forward with enthusiastic participation from gay men in the west. It seemed that half of the New York gay community was on PrEP when they started including western men in the trials. And PrEP is now already being rolled out. What will new prevention technologies bring us?

We've made some progress in treatment of people during clinical trials. But we're here to talk as much about the roll-out and how this is going to be used. How are these new technologies, not limited to PrEP—vaginal rings,

microbicides, and maybe someday vaccines? Lots of women are really accustomed to long-term pharmaceutical consumption. A daily dose of birth control or an injection for long-acting contraception, or an IUD with hormones that get into your system over the next seven years. There are probably people in this room who have had every single one of these birth control technologies. We're pretty comfortable with them. But, there are lessons in there.

And gaps, as the PrEP trials have primarily focused on men. Dosage and efficacy may not be the same across gender. How will this affect transgender people? And, in sex work conditions in which people may have sex multiple times daily with multiple partners, what does this mean? And will the roll-out be coercive? The fact that we're having this meeting in response to a lack of consultation with sex workers when it was proposed that PrEP be prescribed to sex workers by a health organization on the west coast of Canada, is very, very important to keep in mind. This consultation is a reaction to the same shit. We talked

a little bit about PrEP and birth control and the lack—the seeming lack of information on pharmacokinetics, or side effects based on the drug interactions.

What about emerging resistance? We talked a little bit about that. These are issues not only for Canadians who may or may not choose to use PrEP, but sex workers everywhere. Right now, condoms are the most efficacious and easiest prevention method, not only for HIV, but other STIs and pregnancy. They might be the simplest prevention, but there are real obstacles to their use including in sex work settings. People talk about violent people posing as clients. We know that STI rates are rising.

And, PrEP is expensive. How is this all going to be financed? There may be gaps in coverage—particularly for youth—perhaps for people not covered by public health insurance; perhaps some of those people are migrants or undocumented, or have some sort of irregular status here in Canada. These are important issues and they're the same issues we see in the rest of the world—expensive medicines often experience stock-outs, expensive medicines like the next formulation of Truvada® as old PrEP becomes affordable. It's important to think about the financing of pharmaceutical industries. Most of that research is funded by your government, the U.S. and the French government, some Australian. Our governments are paying for that research. When drug companies start to go on about, "Well how will we recoup the cost of research?" that has been recouped. We've paid for it. There wasn't that same expenditure. So, you may not see particular stock-outs here in Canada, but you will see gaps in access, and what does that mean for people who want PrEP?

While regulations and interventions have been attempted—about STIs, moralities—trying to address nuisances like noise, traffic, litter—litter! Litter and property values. The whole trafficking-in-persons mess. And, we've also tried empowerment, and it seems to be that the rights-based approach is the right approach. All of these efforts have been justified by STIs and have affected access to testing, diagnosis, and treatment for STIs. Rights violations can occur in programs that look good. We talked about Cambodia. Before, during, and after the tenofovir trials there was a program called 100% Condom Use Program, which sounds not bad. It looks good on paper: everyone uses condoms in

the brothels, but then it was enforced with extreme coercion. HIV-positive sex workers who were known to be HIV-positive were out of a job. And it just became a bribe scheme for the police who were the people in charge of enforcing this—sometimes by looking for condoms in wastebaskets. People do things other than penetrative intercourse in sex work. Periodic presumptive treatment—which is giving people doses of antibiotics regularly rather than testing—has real problems: coercion, antibiotic resistance, and lack of diagnosis resulting in the wrong treatment.

Rights-based programming starts with consulting sex workers about their needs and what they want, which is what we're doing here today. Offer services in a non-judgmental environment. This is all what people in this room have said: "Don't coerce people. Don't link services to criminalization and expect them to work. Address abuses by police, by vigilantes, by others, including researchers." But how would we apply this? What do we ask for? What do we demand with new medical interventions that are coming? We need to prepare.

Melissa Ditmore is a freelance consultant specializing in issues of gender, development, health and human rights, particularly as they relate to marginalized populations such as sex workers, migrants and people who use drugs. Her past and current clients include the Asia Development Bank, AIDS Fonds Netherlands, and the Sex Workers Project at the Urban Justice Center. She has extensive experience working on projects in the United States and in Asia and Africa.

- *Sex Workers Speak. Who Listens?* Edited by P.G. Macioti and Giulia Garofalo Geymonat, COST European Cooperation in Science and Technology 2016
- *Good Participatory Practices: Guidelines for biomedical HIV prevention trials.* Joint United Nations Programme on HIV/AIDS (UNAIDS) 2011



Time to Deliver Sex Workers' Rights!
Demonstration CN Tower 8.16.06

flashback

1989

our bodies our business



VIDEO: OUR BODIES OUR BUSINESS

Prostitutes' rights activists at the 5th International Conference on AIDS 1989

Our Bodies Our Business was produced for the 2016 national consultation on PrEP and sex work at Dalla Lana School of Public Health in Toronto. Edited and directed by George Stamos with video shot by ACT UP New York filmmaker Catherine Gund, *Our Bodies Our Business* showcases activists Danny Cockerline and Valerie Scott from the Canadian Organization for the Rights of Prostitutes (CORP), as well as Cheryl Overs from the Prostitutes' Collective of Victoria (PCV), Carol Leigh —The Scarlet Harlot from COYOTE, San Francisco and Toronto activist Tracey TieF.

Our Bodies Our Business documents the resilience, artistry and power of prostitutes' rights activists as they confront stigma and prejudice head on in actions throughout the conference, including panel sessions full of HIV researchers who study prostitutes. They challenge dangerous myths that fuel violence about sex workers spreading AIDS.

Since the emergence of AIDS in the early 1980s, prostitutes, like gay men, were scapegoated for the spread of AIDS. By 1989, public hysteria regarding HIV-positive prostitutes erupted in several places, sparking calls by government officials for mandatory HIV testing and even quarantine, despite the fact that such legislation would contradict national AIDS strategies. In 1987, the B.C. Minister of Health introduced amendments to the Health Act which would have enabled Medical Officers of Health to order HIV-positive individuals, whose sexual practices were considered "unsafe," into "isolation, modified isolation, or complete quarantine."

In 1989, Ontario Minister of Health, Richard Shabas called for legislation to quarantine HIV-positive people who continue to have sex — even with condoms — or who share needles. A study by the B.C. Civil Liberties Association documented AIDS discrimination including human rights complaints that involved solitary confinement for HIV-positive prisoners, and quarantine of an HIV-positive sex worker in an emergency shelter in Vancouver. In Australia, Health Minister Peter Collins called for HIV-positive persons to be banned from working in the sex industry. This moral panic fueled increased stigma and violence against people working as prostitutes.



Valerie Scott from Canadian Organization for the Rights of Prostitutes

We're here to protest the fact that drug companies and condom companies can go in there in the trade floor and sell their wares, but we can't sell safer sex. In Canada there's a law called "communicating for the purposes of prostitution." They don't define what "communicating" is. In fact, one guy in Vancouver was arrested for revving his car engine at a girl. We're not allowed to wear buttons that say "Safe Sex Ho," we can be arrested for that. Escort agencies are not allowed to talk about sex on the phone, let alone safer sex. And they're putting these laws on us all over the world. It's not just Canada.



So, what's happening now is they're using the AIDS issue to justify these laws against us. It's a perfect issue to scapegoat us with, as if we're trying to infect the middle-class, which we're not. Whores are safe sex pros. We're the ones who put the condoms on the guys. We're the ones who do the education. And what do we get for it? At conferences like this all we get is shit on. "Prostitutes are spreading AIDS." That's bullshit! As I said the other day, if that were true, half the government would be dead already.

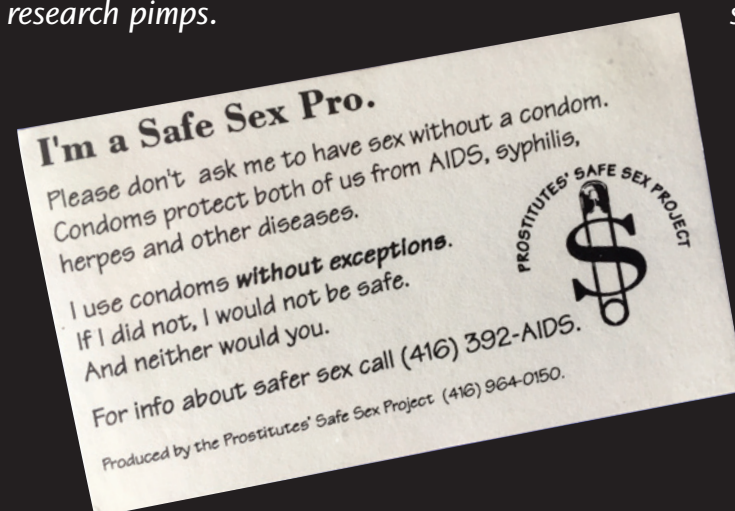
So we're here, and we're being loud, we're being obnoxious. We're going into the trade floor. We're going to announce our prices and our services. And we need your help. We need you to stand up for us. Thank you.





Cheryl Overs from Prostitutes' Collective of Victoria, Australia

They talked the whole time about prostitutes, prostitutes, and you start to wonder who prostitutes have sex with? Other prostitutes? Because all they can think about is the minority of people who participate in the sexual exchanges—that is, the workers. The majority of people involved in the sexual contacts are men. And they didn't even get a mention—except they were all sitting there. They are research pimps.



Danny Cockerline from Toronto Prostitutes' Safe Sex Project

Actually, I'm really pleased that these for the most part these people are not prodding and researching and studying and fingering and prying into the lives of male prostitutes the way they have been with female prostitutes. I think that all prostitutes and all people need safe sex education, but we don't like being singled out as the only group that's in need of it.

It's like the whores and tarts and the sleazebags and the harlots and the whole lot of us we're responsible too. And we're just going to take our little goods inside and ply them around the trade floor. You're all welcome to come along for the show.



Andrew Hunter from Prostitutes' Collective of Victoria, Australia

Seeing programs from people who obviously read the stuff that's come out of the sex-worker controlled programs three or four or five years ago and then pretending like it's some fabulous new model. It's just a load of shit.



Carol Leigh, The Scarlot Harlot from COYOTE, San Francisco

We are here to oversee the kind of information that's being put out about prostitutes. Obviously there's a lot of blaming and scapegoating. Prostitutes are seen as vectors of HIV in most of the workshops that are being presented. They're studying prostitutes because prostitutes are registered in some countries—in Senegal, I just attended a workshop about the registration. And of course that's a violation of our rights to force us to be licensed by the government. That makes the government a pimp.





Danny Cockerline from Toronto Prostitutes' Safe Sex Project

I'm here because I'm tired of hearing prostitutes being blamed for the spread of AIDS. I mean like at the opening reception all we heard was that jerk, Jonathon Mann talking about the number of female prostitutes that were infected in various countries as though the only women in the world who were at risk of being infected were prostitutes. I mean it's just a really ridiculous and dangerous message to be sending out to people all the time. And not only that, all they're concerned about is that the prostitutes might be spreading it to someone else. They don't give a damn that the prostitutes are infected. And have you ever noticed the fact that you've got hardly any customers infected and a whole lot of prostitutes infected? It's obvious that



the tiny little bit of customers infected are infecting the prostitutes, not the other way around.

There's a prostitute in Toronto right now being detained. They arrested her for being a common nuisance for endangering the health of others and they keep her in jail. Why? Because she's HIV-positive and she was charged with soliciting. Well, soliciting doesn't mean having unsafe sex.

Cheryl Overs: *The virus doesn't travel on cash. The virus travels in sperm. It doesn't stay on an American Express card or on money.*

Danny Cockerline: *And I've never heard of a prostitute holding a gun or a knife at a customer and saying, "you have to have sex with me without a condom." But I have heard of the reverse.*



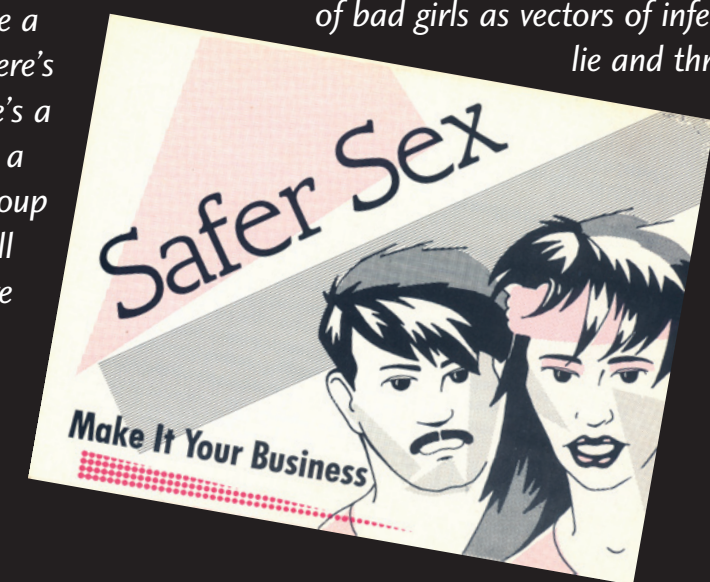
Valerie Scott from Canadian Organization for the Rights of Prostitutes

It seems like this Fifth International is all about whore-bashing, this particular conference. So many studies are coming out where they don't have control groups, where they haven't really done the research. But it seems to not matter when you're studying prostitutes you can say whatever the hell you want and everybody will believe you. And that's happening quite a lot here. So fortunately there's a lot of groups here. There's a group from San Francisco, a group from Australia, a group from Sweden and us as well and there's some voice here finally. And naturally we have to protest all this shoddy research shit. That's what we're here for.



Tracy TieF, Toronto Activist

Prostitutes and our supporters call for the decriminalization of prostitution — not legalization which amounts to state pimping and furthers the violation of our human rights. Governments are criminalizing the most effective safer-sex workers and all people will pay dearly. Less than one per cent of North American prostitute women are HIV positive. Less than your so-called "general population." The stigmatization of bad girls as vectors of infection is a lie and threatens all women.





**Carol Leigh, The Scarlet Harlot
from COYOTE, San Francisco**

We are one of the original organizations actually, that developed a plan, "Prostitutes Prevent AIDS." This is information about how prostitutes are actually preventing AIDS. How we do outreach, education. This is a California-based organization but there are outreach programs in Canada. In Toronto there's an outreach program. In Victoria, Australia there's an outreach program. And of course it's necessary to find prostitutes and ex-prostitutes to staff these programs and to provide outreach. I think the number one thing to know is that we shouldn't be forced to work as a prostitute, and we shouldn't be kept from working as a prostitute. We need our sexual freedom in both ways.



**Cheryl Overs from Prostitutes'
Collective of Victoria, Australia**

Our group actually started well before AIDS. Our group started in 1975 as a feminist-based prostitutes' rights group. And so when AIDS came along that changed our agenda to the extent that AIDS is an occupational health and safety issue for women in the sex industry. AIDS became an issue in Australia in about '83, so we started, we took out our outreach programs in '83.

Our membership is a few hundred, we have eight staff and a few volunteers. We do all the safe sex workshops and we do a big needle exchange we go through maybe 5,000 needles a week. And we have a big drop-in centre, which the women use during the day which is fun. Which really hops.



SEX WORK SESSION

PrEP in the context of real life

M Moderator: So, we want to talk a little bit about real life situations and PrEP. We know that—well at least where I come from—a lot of people are up to date among the gay community including people who sell sex for PrEP, and we know that there's some pressure not to use condoms for everybody. I worry that PrEP will increase that pressure a lot. And, I worry that people who might rely on PrEP might have unintended pregnancies, have STIs, and may not get the best care for everything that they're dealing with.

S Speakers (various): And for youth, access to everything is problematic, especially if they've left home. The shelter system is a huge issue. You would think you'd be in a system that would facilitate stuff but it doesn't. A lot of them are abstinence-based shelters for example, Covenant House. These are specifically for youth. And that means abstinence from sex or abstinence from selling sex.



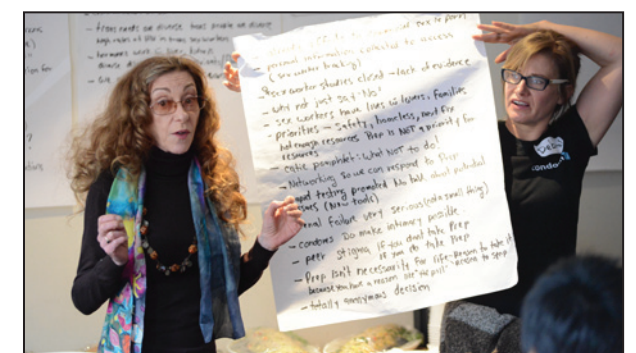
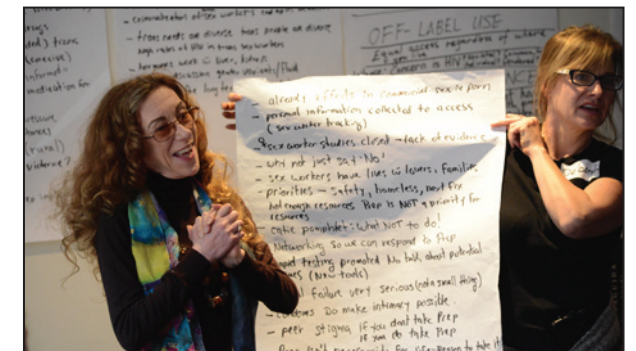
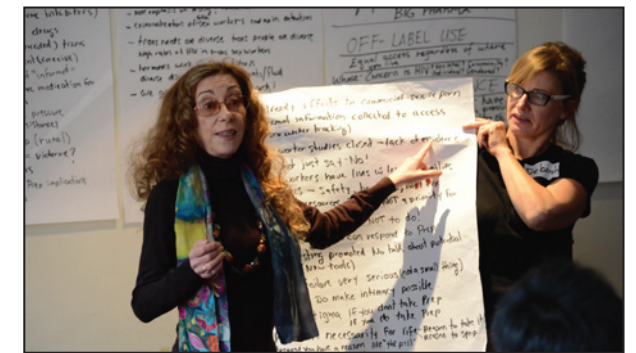
S Does that include trans people?

M Some of the issues for trans people, we don't know about pharmacokinetics with hormones and androgen inhibitors. I think transgendered people frequently get substandard medical care simply because doctors may be uncomfortable with that, and doctors may be less familiar with the health needs of different bodies.

S Not all doctors work with us people, like they don't know how to work with us. I don't know. At least, in Montreal, medical resources for trans people.

S But that's a problem in and of itself. I mean, I can't count how many times I've gone into a doctor to get, like, a prescription renewed for something that's completely unrelated to my care as a trans person and had that doctor say, "Oh, I'll just give you a month for that until you see your specialist." I transitioned ten years ago. This has nothing to do with my hormones, and at this point my hormones are exactly the same as my mother gets for her menopause. You don't need a specialist for me.

S I think of people who are not in a stable lifestyle. So people who are using recreational drugs.



S Well I have concerns especially for people that live and breathe in the downtown eastside of Vancouver. Even when they did the hep C treatment, a lot of times it was stipend-based and they would give the person a stipend to receive their medicine. And, I'm afraid that this is going to maybe happen again. I don't think it's a good thing because I don't think it's ethical to tell you the truth. I wonder, too, if they do try to engage in a population that lives more in poverty, or doesn't have a telephone and doesn't have different things, whether they consent to something but it's not truly informed consent. Especially when stipends and money is attached to it. That happens over and over again in different populations in Vancouver. It's not really truly free and informed consent, right?

S We already see this in Vancouver with the B.C. Centre for Excellence. Basically offering medication to people who are HIV positive but under the guise of treatment as prevention and using that as a giant research study. The people who are participating in it don't know that they're participating in research. Nothing's free, but you're getting the medication for free.



S I think that if sex workers anywhere are forced, whether it be the government or health care to take PrEP, clients of course are not going to want to use condoms. So, then it's a vicious circle. How will this play out in the post-antibiotic world? We are almost at the post-antibiotic world right now.

M So you're talking both about STIs and antibiotic resistance, and then super STIs like multiple drug resistant gonorrhea?

S I'm actually just talking about regular gonorrhea, regular syphilis, and regular chlamydia. WHO — the World Health Organization — says that syphilis, chlamydia, and gonorrhea are rapidly becoming antibiotic resistant. There are super gonorrheas out there, but we're talking about regular gonorrhea now and if sex workers and other groups are forced to take PrEP? Instead of in five years where we're post-antibiotic, we're going to be post-antibiotic in two.





S I worry that if we see a shift in the expectations around condom use in the sex industry—and so pressure towards that—what about inequitable access for people who live in rural areas and for people who are not covered under drug plans such as MHP [Manitoba Health Plan]. Because, there’s generally no HIV services in rural areas. And, Indigenous people just tend to get fucked over on health care in general.

S OK, so when talking about pressuring sex workers to not use condoms during sex, also this can possibly facilitate further violence because it’s like you’re taking PrEP so there’s no reason why you should not bend to my will and have sex with me without a condom. At that pressure they say, “No, because I also care about myself at the end of the day, it’s my body, my choice.” That could facilitate anger because it’s like, “I’m paying this person, they’re not doing what I want.”

M I have a question, in response to this, which is now that condoms became fairly standard and then expectations are changing, do people still do dick checks and look for visible sores for syphilis and drip from gonorrhea for example? You haven’t been taught to, because it’s not often we think of a formal work situation.

S I was on the board of directors for a sexual health clinic when I was 15 and I did it.

M It’s not good for everything. Some things are asymptomatic. A lot of times chlamydia doesn’t have any symptoms; gonorrhea now often doesn’t have any symptoms. And HPV?

S But it’s good for things like herpes, or even something like pubic lice. That is also still a thing.

S I’m kind of wondering does this drug have implications for the health of the vaginal tract?

M All drugs do. This goes back to some of what the people from CATIE said about different mucus membranes—the vagina versus the rectum and the absorption. But also, could vaginal gels like these create lesions like nonoxynol-9 was found to do?

S Which increases risk for other STIs, right?

M For other STIs, for HIV, for genital irritation.

S We've already seen it in adult film where, you know, just like years ago you could get blacklisted for doing a scene bareback in some major studios. Now, lots of those major studios do bareback scenes and lots of those studios are now big spokespeople for PrEP. I don't think we have to ask whether or not it's going to happen with sex work, it's already happened in the sex industry.

S One of the things, of course, was a new prevention technology that came out and that was the rapid HIV test which was able to be used in a home-based study and we've seen, similarly with sex workers, we've seen that happening in brothels who are offering GFE ["Girl Friend Experience"], so you can do a rapid test of the client, rapid test of the worker, say, "OK, both of you are clean," so then you can charge a lot more to give a more intimate experience. I think more women would use condoms if people didn't feel really confident in the testing.

S There's still that six-week window.

M During which, people are most infectious regarding HIV when they have first acquired the virus themselves. That is when they are most likely to transmit. Your body is just replicating the virus so much it's at a very high level even though you may be asymptomatic. That is the point in time when you do not know—when a person has recently contracted the HIV virus—that is when they are most likely to share the virus with other people. So, this is really important about the window period.

S I'm afraid of the way that you would get the drug. To get the drug, you have to give your name, probably your social insurance number, your medical card number, all that. Is that going to be a whackadoo tracking system of sex workers? It could fold into that, and I'd be very afraid if it starts to be something like that because that could be easily done.



M How many of you are open with your healthcare providers about your work in the sex industry, and do you feel like that is confidential?

S Never.

S 41% never disclose. We did a study on youth in 2014. 41% of the women never, ever disclosed to a healthcare provider.

M I certainly wouldn't, but I live in a very different legal system.

S So, what happens is, if you have a special program to make sure sex workers get PrEP, then you have to declare your sex worker status? That is a big barrier, right?

S I guess my concern is that we're even having this conversation. I mean, I came into this already thinking that this medication is not good, not knowing too much of the details. And, after the presentation this afternoon and the mere fact that—correct me if I'm wrong—but three studies that were done on women were shut down.



M There have been more studies that were done on women. But three studies on sex workers in Africa and Asia were closed.

S OK, so I mean, for myself, because of lack of evidence, period, it shouldn't be promoted. I just feel like it's a "no" for me that I would ever promote this medication at all. And, I think that we could all spend the rest of the day talking about why it's wrong, but I think we know. So, I'm just kind of wondering like, what are our expectations coming out of here? Because I think we all know that this is wrong for a lot of different reasons. Like, unless we're here to say, "This is no and this is why."

M Well, I would not advocate PrEP for people in the sex industry for use then. It has been very useful for people in serodiscordant relationships with one person who is HIV-positive and one person who is HIV-negative. That has been really effective for the person who is negative to remain negative. So, that's a situation that some people in this room might be in.

S But we're here representing sex workers, right? We're not here representing that group.



S As sex workers we are not just sex workers, we are women with children, with husbands, with lovers. So, it does encompass all of those things.

M Your point is we have many roles, and some people may choose to use PrEP for some situations, but not to make it part of their sex work expectations. But, there was the point raised earlier that some people are already working without condoms. PrEP could be important for them.

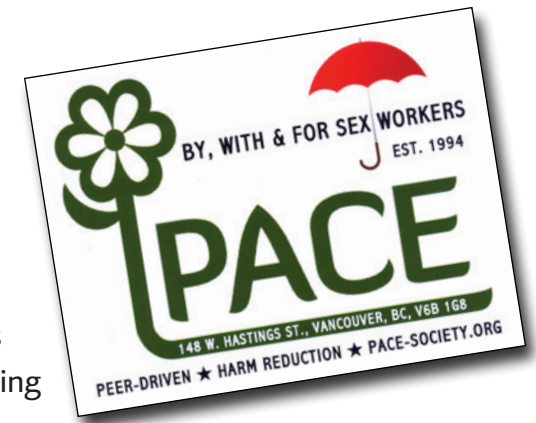
S What about those places with the rapid test, you know, parlours where that's already happening, the rapid tests are happening?

M That's still very dangerous.

S It is still risky because there is a window period. If you're a sex worker who is already in that scenario PrEP might be really appealing.

M Let's go back to what are the expectations for today. First, Andy and Dan were very clear that today is supposed to be educational. For us to have all of the information possible to talk about—in a short period of time. We've got 10 hours to share so that we have as much data and evidence and information to share with the people we work with, to tell them why PrEP might not be helpful in some situations, or in some cases why it might be. I asked the same thing when I got the note from Andy, "What do you expect to come out of this?" And he said, "Well, there's no expectation about a document or something," but it sounds like some people may want a summary, like a front-and-back information sheet about what we know. If that's appealing.

S Andrew: Well, while we were in Winnipeg we did a planning session and the first thing that came up is, we did an eight-page response to the draft guidelines. So, the fact is that the draft guidelines for the country are already being drafted. They're being drafted by a group who are not empowered in any way. It's an ad hoc committee. There's no idea who will authorize these guidelines and so we wrote an eight-page

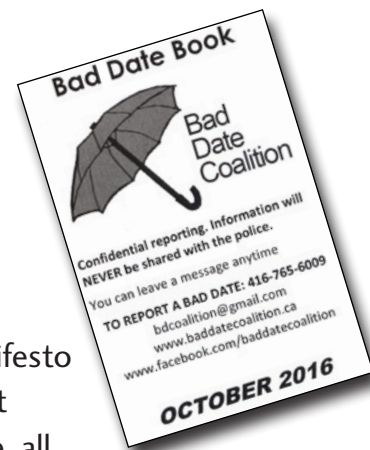


letter of a lot of things which included, like, information must be in many languages. Like in Vancouver, we definitely have a huge population of people that speak Chinese. Even the City of Vancouver puts everything in Chinese and Punjabi, because of the number of people in the city who speak those languages first.

The other thing is, if we wanted to, we could make a sort of a manifesto or recommendations to Health Canada. We might say, “Do not put sex workers in your guidelines.” Like, from my personal perspective, all healthcare is a private choice. The drugs we take are none of your damn business and I don’t need to tell—that’s part of the problem. There was this doctor—he’s on this committee—he was prescribing PrEP to a few female sex workers. I recently read an email from him that said they all stopped taking it because of presumed “peer stigma,” he called it. So, what exactly is that? Why do your peers even know what drugs you’re taking, right? So, it was kind of strange. But, on the other hand I have seen ads for male escorts who are definitely, in code, saying that they are on PrEP and that safe sex is kind of negotiable. These are \$500 an hour escorts, and I don’t want to have to say, “You can’t do that.” But, maybe we want the industry to self-regulate? If you are a member of Triple-X, one of our conditions is that you must offer services with “protection appropriate to the service” is how it’s worded. So then you have the little XXX logo in your ad and everybody knows, “OK, that sex worker is providing protection appropriate to the service.”

S Where I’m from in Regina, which is in Saskatchewan, we have a very high rate of HIV, higher than the national average. But, the way that it’s transmitted there is through IV drug use and sharing needles predominantly. So, where I’m coming from, the priorities are different. People’s priorities are: “Where are we sleeping tonight? How am I going to get my next fix? How am I going to bring home money to the guy that I’m working for? How am I going to keep myself safe?” There’s a lot of missing Indigenous women. So, I just don’t see this as being a priority for the people.

M So, this is low on the list of priorities like food, shelter?



S It would take a lot of energy, time, money, in order to try and convince people to take something like this. And, I think that could be better used somehow.

M So prioritizing the resources that we have, for the organization you work with, this is not a priority. That makes perfect sense when you’re dealing with people who are in survival situations. I hope you have naloxone distribution as a high priority.

S So, I just wanted to point out, because I noticed people picking this little pamphlet up. There’s some very, very wrong information in here. They say it is 90% to 96% effective, and this is directed at women. Those are the numbers for men who have sex with men. The numbers for women are very hard to pin down because of the various data that exists. The latest number that I had was about 60%. So, we’re working with very different numbers. If you take this flyer, use it only as an example of what not do. It talks about why it’s important to have PrEP, and there’s this little bubble as if someone is saying this but no one is really quoted, and it says, “I see it as being valuable for sex workers and women in abusive relationships.” So, we have people that are making these documents,



essentially speaking for us and making these really, really messed up assumptions and not even putting their names at the bottoms of these quotes. So, yeah, I think that's why it's really important for us. I would like for us to have some sort of common discourse; it doesn't have to be a manifesto or a document, but I would like for all of us to leave here and for those of us who have the time and the energy to put together something so that in every province we can respond to whatever a public health agency is going to come at us with.

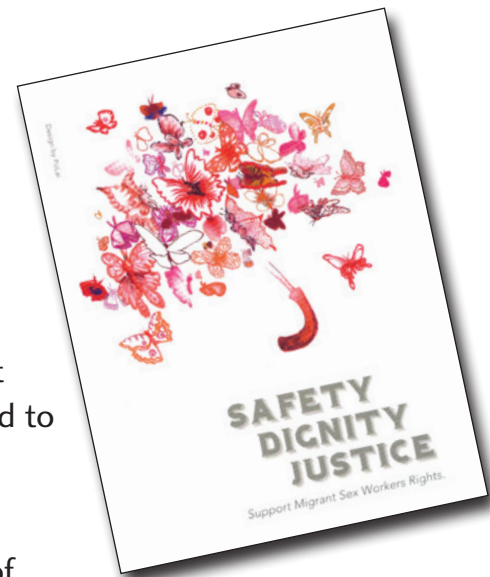
You mentioned rapid testing before and I think it's really important, because—in Québec at least—we're members of various organizations that represent all of the HIV organizations, and this question: "Make rapid test readily available everywhere for free for anyone under any circumstance," is really strong. I was at a meeting on this to develop messaging and there was very little talk of the potential issues that that might bring. I'm not saying that I'm against having rapid testing. I think it's great, but in sex work there are different considerations. So, to me, those are two issues that we need to link up—that go together in terms of new tools for HIV prevention, et cetera. So, I would like to include that.

S I've talked to a doctor that I know and really trust as a resource person about what other doctors are doing, somebody that I respect very much. He's curious with what's going on with PrEP because of the effect that it can have on people's kidneys. And, everybody kind of minimizes, "Well, it could cause a bit of a kidney problem." Well you know, having a kidney problem is not like having a broken fingernail. You can die from it. Have your life really wrecked and die.

M A lifetime of dialysis or...?

S Like, people are not considering that. Especially if they're trying to push PrEP.

My other point is, people have been doing safer sex education for years. We're trying to promote the idea of condoms being sexy and fun and in my work I often use rubber gloves



and my clients will say, "Oh, do you think I've got a disease?" and I'm like, "No, no, it's just rubber gloves just feel so good together with lube, they feel really good."

Part of our job is promoting the safe sex and making it fun. And, even something that Dan said recently. He said something about that condoms can be a barrier to intimacy. I would have to argue with that, because I'm in love with this guy who I only see, like, once a year. And, if it wasn't for condoms we wouldn't even have any intimacy at all. So, I just say we have to keep pushing condoms as something wonderful and beautiful and fun.

S I think condoms can be great. I have a whole way of doing it so that the guy doesn't know. It's not always a 100% smooth. But, I have had guys say they know what I'm doing, but they'll say, "But, you're very smooth." A little trick goes a long way, right?

And, further to what you were saying about kidneys, it's medically understood that in healthy people, over the age of 60, the kidney function decreases. So, I think that PrEP is just going to make it more rapid and even worse. And, pardon me, we all know women that are menopausal and post menopausal now know how important bone density is.



M We haven't talked about why are we talking about a daily pill to prevent the need to take a very similar—if not the same—daily pill? I suppose the implication is that people will get over this phase of promiscuity or... I'm not sure. That is how it was presented to gay men in the trials. But, the men I know who were in the trials were in their 20s through their 60s, so this idea of a temporary thing, you might be taking a pill to prevent having to take a pill for a long time.

S I want to just pick up on two things: I really want to pick up on the bone density thing because they're really pushing this at youth, and teenagers are still growing their bones and nobody really puts those two pieces together enough.

M Are they really pushing that on youth?

S Honestly, that's all we talk about. I work at several youth shelters, PrEP is constantly talked about. We arrange trips for our residents to go to workshops. We have people coming to talk who are in peer roles. PrEP is everywhere.

M So, it really is being pushed.

S That's one of the reasons I came here, because I walked in thinking PrEP is great. It's just this one pill that you take, and like, goodbye HIV. And, you don't think about the fact that if you choose not to take this pill you will get stigmatized.

M So, you've got peer stigma both ways. Peer stigma if you take it, and peer stigma if you don't.

S I've heard people say, like, "Oh, fuck condoms, I'm just going to go on PrEP and not worry and that's it." That's the conversation they have with their friends, with the service providers, and then it ends at that.

S I was just going to pick up on the point you made about taking a pill before and taking the pill after. One of the things



I find really annoying about the propaganda is they say, "Well, if you prevent an infection, then that's a whole lifetime of treatment which is X millions of dollars, and this is only costs this million." But actually, because you prevented HIV once, here, it doesn't actually mean that you prevented HIV for an entire lifetime.

S We're going on the premise, it seems to me, that if you start taking this pill, you're going to be taking it until the end of your days or something. But really, can't we look at it in a different way? Where, OK, you don't want to use it for sex workers, but maybe you do want to use it in your private life? Well now you broke up with dude, so take a break, eh? What's to say you can't go on and off the medication as long as you give it the requisite time that it takes to adhere to your cells?

M We're starting to see data about intermittent use. So, there may be new information.

S Sure. Just like women, we go off the birth control pill for periods of time to allow our system to heal, or whatever. Any doctor will even tell you, "Oh, you've been on it 10 years, you better get off it." So I mean, this pill, is this really necessary? It's almost like you take it every day, every year of your life, like for the rest of your life. Is that what they're promoting? Because I don't think that's necessary to promote. Why not promote it in different contexts and let a sex worker decide for herself? And, it ought to be a totally anonymous decision between her and her doctor. What the hell's it got to do with anybody?

M Your point about the pill is really good because it also highlights other issues. So, the pill was developed in the 60s—so 50 years ago. We've had the pill for 50 years and dosages started very high, and then they've been changed and there are formulations for people at different ages so that usually between 35 and 40, people get a lower dose; if you don't use other forms of birth control you get pregnant. I know a lot of women who had babies from that moment in time. They attended to their hormone level.

S Also, a lot of women had heart attacks. I was a perfect example of that. I was 22 years old. I'd been on the pill since I was 14. They had me on it. So, by the time I was in my 20s,



the doctor was saying, “I think you should come off it, you’ve been on it since you were this big.” So, I went off it and six months later had a heart attack directly as a result of the pill. This is back in say, ’78, ’79. So, that’s right. That’s why they started changing it because women were having horrendous results — pulmonary embolisms, all that kind of thing. So, that’s why they started juggling and fudging with it.



M This is what we’re going to see with HIV medicine — one place we’re paying attention to is the effects on women’s bodies. Once that’s tracked, once there’s data, once we get that data, you have to pay attention to it.

S I really want to echo what was said about this blurb here because I started reading the pamphlet, and it’s ripe with stigmatic assumptions. And, that’s one of the biggest barriers we face, ongoingly. I think that if the health networks continue to do this, their language — which isn’t near on par to how we’re treated — still has us as victims and we need to be safe. All this high-risk kind of stuff, too. And, I don’t have any confidence that they’re going to change soon. So, that to me is a huge red flag because it just feeds the fire of this stuff and we need to do the opposite.

S I just want to say that what you said about taking one pill now versus taking a lot of pills later, in my mind, it just kind of goes back to safe practices. People need to really be aware of the long-term effects of taking these pills because they’re very real. So, you’re not actually taking one pill now and three pills later, you’re taking one pill now and eventually taking all kinds of other pills because of all the side effects that it’s going to cause your body. So I just wanted to say that. Also, I had my appointment at the HIV clinic only about a week and a half ago. So I asked my doctor her thoughts on it. And her thoughts were, “Well, if there was more emphasis put on education, testing, for example, because once you are on a medication your viral load goes down to probably undetectable and your risk of transmission is very low.”

S So, this isn’t a fully formed thought, but just on the topic of youth who are under 18 and selling sex and the criminalization



of them, like, if they want PrEP and need to disclose that they’re doing sex work, then mandatory reporting is required for service providers and then youth land in care or detention.



S Well, I have concerns about this concept. When I asked, like, what kind of woman are you talking about here, obviously we have trans women here. But, there is nothing about trans women in the pamphlet. Also, we are talking about trans identities. Like, it’s not the same thing talking about transgender persons, as gay, bisexual, et cetera. There are trans women with penis, trans women with vagina, and we don’t have to transition, right? There is no rule how it is to be a woman, right? Or, how it is to be a trans woman or a trans man. So, basically, I mean, the discourse about like men and women, but specifically, trans needs are different. It’s so diverse.

Trans men sex work, transgendered people sex work, transsexuals sex work. What kind of transsexuals? Those who have penis, those who may have vaginas. I mean, it’s important for people because also we have been marginalized for all these years, and stigmatized.



It's not enough to be transsexual, that's stigmatized. You're a sex worker, and there are big numbers of HIV in the trans community — trans women living with HIV. Like, big numbers. And, it's hard work and it's difficult to keep informed in the street. I mean we probably have similar experiences, but I think, also, they should be consulting trans sex workers because we have different bodies and also different backgrounds. Many women who I work with — sex workers — they have different intersections in their immigration processes, languages. They have yet to include other languages, which is amazing, because there is all this information. Anyways, I think it's important for the discourse to keep the diversity. Not only, you know, man, woman and binary. Also, in the trans community, in the big umbrella, there is gender diversity, like gender fluid, non-conforming people and it's important.



PROGRAMMING SESSION

PrEP in the context of providing services for sex workers

M Moderator: So, when we think about what makes for a positive experience in taking PrEP and we think about collective health and safety standards...

S Speakers (various): It's replacing a thing that anybody can go up and buy without giving a name or anything, with something that you have to go every three months, be tested, for HIV, liver, kidneys, the whole lot. It's a huge shift.

S I just think my point about agency and empowerment should be there, because on the flip-side, there's always that, "Oh, c'mon we don't want to use a condom, don't need to use a condom," and that's that pressure. PrEP is a potential relief of pressure for somebody. At the very least — not counting all the other STIs and other things that can happen — at the very least I know that I protected myself against HIV. I don't have to



necessarily cave to the pressure — or even have it affect my mental health — the pressure of not wanting to use a condom.

S That point also applies in terms of private relationships, because for lots of sex workers you're primed to use condoms at work and you will probably want to use condoms at work even if there was no HIV or pregnancies or anything just because it gives you a sort of a psychological distance from the client. That's why people don't like to use them in their private lives.

S I work for a gay men's health organization and so we have our own PrEP campaign. And, anecdotally, a lot of men who are having sex with men talk about feeling that relief of pressure of not having to worry about HIV status. It's not about HIV status anymore, and you take that out of the equation somewhat and then it's freedom. Like, there's a lot of freedom; freedom of choice, freedom not to always have to have that discussion as part of the sexual negotiation of the attraction or the encounter. It de-medicalizes it a bit and brings it back to something positive.

S I want to say this: You're talking about his behavior, not status. He's talking about status, you're talking about behaviour.

S They're not mutually exclusive.

S No, I'm talking about PrEP. I'm talking about practices in a workplace. And, I just wanted to point out, has anyone looked at the male sex work ads? Is PrEP in all of them here? Yeah? In London, in the U.K., 80% of the male sex worker ads say, "I am on PrEP," that means...

S "Come and get it."

S That means you don't have to use a condom. So, I actually think we should think very seriously about the prospect of condomless brothels for women or men; a condomless sex



industry is a very serious thing. For the medical profession — or whoever we are — to be creating for the sex industry... We sort of talk about individuals, the patient that goes to the doctor, but when we start wanting to reform the sex industry so that condoms are not a feature of it—and they're not in the male sex industry in the U.K. now, at all. That's a big thing.

S I just want to say that already exists. You know what I mean? There are and always will be escorts or sex workers who are going to offer sex without condoms whether PrEP is on the table or not, too.

S But once you start advertising it... I guess my point is if you want to do that, fine, you take the risk. But, if you work next to me and you start advertising it, you're putting risk onto me and that's where the workplace analysis becomes important because your actions will reduce my income unless I also decide to have condomless sex.

S With the people that we work with who are on the street living in active addiction, we see those kinds of things happening more all the time as well. So, I think they already exist.



For example, for certain people that we work with, PrEP is a really positive thing, because they are the kind of people who, even with their best intentions after a few days being up — they usually at some point end up not using a condom or whatever. And then it's anxiety and then it's stress et cetera. Or, they use so much they're blacking out and they don't even know. So for some people, like in those contexts PrEP is a safeguard as well.

S I think we're very supportive of options, right? Obviously, we're supportive of PrEP as a viable option for guys that are having sex with men. One of our signature programs is our condom packaging distribution program throughout the city and it continues to be really important. So, I take your point of, like, one replacing the other and the messaging that gets out there. We've got to get onto that messaging, "Oh, now we don't have to use condoms anymore because we have this pill." That in itself is problematic. It's not an either/or situation. I would like to see equal weight and promotion. Let's keep the condom messaging going. Condoms are still effective.

S Maybe what might work for one person will not work for another person. Also, it doesn't have to be either/or, it can be an "and" option for people, right? I think so. Let's keep the condom messaging strong about that advantage.

S Absolutely. And, the thing that would mark that up for sex workers is clients. It's very different when you're talking about MSM population of people having sex with each other. Clients and sex workers — it's quite different.

S Like in the situation where I've accompanied someone through the whole getting PrEP and so forth. Somebody who never used condoms, who was very much into their addiction, and was going to the pharmacy every day for other reasons. Being able to get PrEP every day and for that individual, the anxiety that was relieved was immense. Like, this was his worst fear—was contracting HIV. That was his specific case and we evaluate that.

S Is he scared of getting syphilis?



S Well, I think that's where we need to educate, yes, because things that are treatable, it's less scary for certain people.

S Syphilis is no picnic.

S And HIV is treatable.

S Yes, yes, yes, I agree a 100% on that. But I think that when you're giving the person the options and seeing that they're less stressed or less anxious—when they're already in survival mode, I mean, every day...

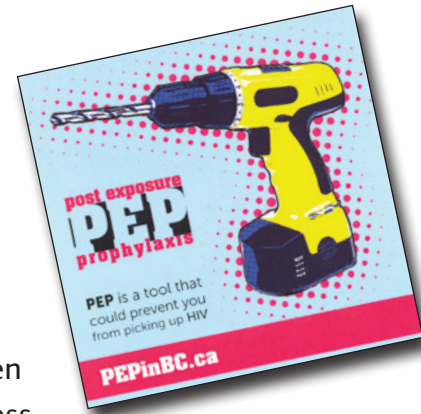
M What's interesting is it brings up this point about stigma around AIDS or HIV versus herpes for example, or syphilis, right? So, for somebody who is street-involved—or a lot of us—HIV is that big fear. But, living with herpes is no picnic either.

S People are still saying, "AIDS—I don't want to have AIDS. I'm worried to get my AIDS result." You still see that, but that's where we come in with the education.

S It does have a huge amount of stigma. Yeah, if somebody says, "Well, if I get syphilis I go, I get my double shots, that's it." But, if I get HIV, "Oh, it's chronic." And, so even though it's chronically manageable, they're thinking AIDS, they're thinking, you know, the worst case scenario, right? Even though we've come a long way.

S Criminalization plays into this big time.

S Just being in this room has really made me think. When I heard some of the conversations here, I'm thinking drug companies have now created drugs to facilitate human trafficking in vulnerable populations. Because, actually, more people might be hurt, really, by this, if it's implemented improperly. Because of things of like stigma, you know—youth and stupidity versus age and experience and that involves other factors. I think it's really hard to tell a person who is just turning 19 and has been pretty bullet proof and fantastic—even if they're strung out on a whole bunch of stuff—that their termination date is much sooner. We can't really portray that to a person. You want to be able to



convince a young person who is relatively healthy now to stay that way. HIV is one way to zap your health, so they're not open to getting other things which is what happens.

S Well, if you say, "Look, take this pill so you don't get a disease that'll make you have to take this pill." How does that work? It's the same pill.

S I'd take that pill.

S OK, what I'm saying is this: There's Western communities which are fairly affluent and there's other communities where a certain level of socio-economic disparity. I'm always suspicious of drug companies. Sex workers taking this drug in a third-world country and in oppressed economic conditions is going to be a different situation than for a person who is in say, Melbourne or London or New York or Toronto.

M Can I summarize what you're saying in thinking about social location? You're talking about age and social location where somebody may have a pretty hopeless perspective on the future, right? So, the concern is that PrEP could possibly help them through, you know, years of poverty. But they may not see it as an advantage to.



S If there's health concerns, and they've got another thing, if they've got hepatitis C, if they have hepatitis B — I mean, all the things that can happen.

M I think what I'm hearing was a concern of somebody telling somebody else whether they should be on PrEP or not?

S Qualified. So, what's essential in asking those questions, about being a sex worker in Thailand, a sex worker in another community where there's not as many options? When a person says: "Well listen, we have this pill here and it's a barrier to exposure to HIV." Now in that situation, once the word gets out to the clientele...

M So, this connection to agency and empowerment. What would make a positive experience of PrEP would be feeling like you have the option for what works best for you, is that fair?

S Let's not forget that we have sex workers from those countries working in Canada. Our organization works with migrant and immigrant sex workers. And, I've started to



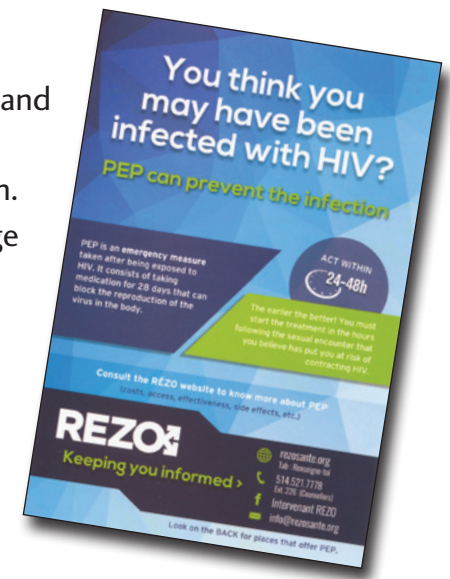
think about this. I see how PrEP can have pros for some women, and cons for others. So, for some women — especially with language barriers — most of the women we work with do not speak English. It can be a negotiating tool because they don't have the language to negotiate the interaction. And, also working in a new context and a new country, it takes time to figure out. So, in those ways, I think it can be pros, but on the other hand, I see a lot more cons because these women, due to immigration issues that they're faced with, when we go to doctors they always want to use a pseudonym and oftentimes they don't have the money to pay. And, I can just imagine what a nightmare these intake forms would be, because we encounter these receptionists all the time. They have their boxes and if you say anything that's outside that box they just can't handle it. It just draws more attention to the person that's trying to access the service. And also, within those populations as well, it's going to be really, really challenging for us to figure out how to do this work because the sex work stigma is so deep and so strong, and then we bring on the conversation about HIV and PrEP and then you've got that added HIV stigma as well. So it's going to be incredibly difficult. Layers. Yeah.

S I think this is going to be a complex passing point on the survey. I think it's going to be another year of research.

S Internal mobility — how much internal mobility of sex workers is there in Canada? How much do people move around? Do medical records move easily with people? Do you have a national system?

S Ontario and Québec are side by side, but they have totally different systems. And, if you need help, and you're in Québec, there's more likelihood that you'll want to live in Ontario.

S East coast to west coast.



S Oh! That's really serious. I didn't realize that. Australia is a federal system, like Canada. But your medical records — the health is federal.

S You have to request a medical record province to province. If you move from your province then you have to request your medical records.

S In Québec, you have to live three months before you can have access.

S Also, I don't know if it was mentioned, there's the cost. Like how much PrEP costs. It's quite, like — depending where you live, it's quite expensive. So, for sex workers to have that additional financial burden.

S And, we had a really terrible example as well. It's not sex work specific, but shows how very real these concerns are. They're not just perceptions. There was a health authority last year, just outside of Vancouver, that was referring undocumented patients to Canada border services for non-payment.

So, if you were undocumented and you ended up in the hospital and you weren't able to pay, your name was being forwarded by the financial department of the health authority directly to Canada border services, and then Canada border services was coming and standing over your bed and saying, "Let's go." So, fortunately we — some groups did some work and that has ended. So, this perception about not being able to pay and how your non-payment, connected with your healthcare or health services makes its way to immigration is a very real concern.

M We put the assumption out there that street-based sex workers are at risk. Those are the ones who are at highest risk. But do we have our algorithms correct? Well, we have our own self-perceptions about risk, right? We think we're at risk or not, doesn't matter what other people think. What kinds of sex you do will inform what your actual risk is.



Just because you're street-based doesn't mean that you're having risky sex. Even if you had a lot of sex — *without condoms* — if there's a low seroprevalance in the environment in which you're having sex, i.e. the other people that you're having sex with — your social network — then that risk will be much lower. How are people under 16 getting access to PrEP when they're not comfortable with their disclosure of their sex work activity? What would be the messaging around condoms if PrEP is broadly available? How will we keep peddling condoms?

Then we asked what would make for a positive experience of taking PrEP? Well it would be one where you are informed about the risk; you'd have done your own assessment, and you're working with somebody in the system who is skilled at facilitating the discussion and helping you think things through rather than somebody who is pressuring you into taking it or not taking it. You would have some knowledge about PrEP from its physical impacts, in a variety of ways — big pharma, that kind of thing; you would feel that you had the agency and were empowered enough to negotiate the sex you wanted. And that would be both in your professional



and in your private relationships. You could choose to work in an environment where you were more comfortable, i.e. maybe an environment where everybody is using PrEP, or in an environment where nobody is. You would feel that you had options available. Because you were low socio-economic, or you had a certain community or family that you were not excluded from accessing PrEP. You would have a medical system where the records were moving with you as you moved.

S That's not necessarily a good thing, though. It can be. It can be, but it can also be a very bad thing.

M I think that's something like, "I can't get rid of this moniker," right?

S But, we need something in there about confidentiality. Is that coming? I can't see it. And decriminalization of HIV transmission. Hello?

M Does that cover most of what you were talking about?

It's affordable, it doesn't create undue hardship. HIV is non-criminalized.



What are the emotional and mental health impacts of PrEP—the environment around PrEP? We had industrial health and safety standards across the board. What is the collective effect of replacing condoms with PrEP. What's the effect of the power dynamics between clients and sex workers? Will there be a pressure for condomless sex? What will the impact of that be on our mental health?

Perhaps PrEP will create the possibility of not worrying about your status or having anxiety about what your status is in every sexual encounter. How will we feel to work in a condomless brothel or environment? PrEP in the context of the HIV stigma: how will reduced HIV impact—how does that impact the stigma of STIs? Or, are we just overly focusing on HIV even though it's a treatable infection? PrEP in the context of people with chaotic substance use, realities. We talked about the addiction stuff. New immigration, not insured, may feel uncertain or fearful in the medical environment. How will that impact the ability to get access to PrEP, or even feel comfortable enough to bring it up? And, then being undocumented and the impact of that. Again, it comes back to that fear of your immigration status and being afraid of being criminalized because of not being able to pay for your PrEP. Ouch. What else have we not included? Anything?

S The only thing that hasn't come up is referred to as the black market for PrEP that exists, that people are selling it, using it without being followed, misunderstanding; people who don't have access to it so they're buying it off their friends or whatever.

S Linking PrEP to good messages—messages and services.

S People who are positive who are selling their antiviral medication.

S Or, who get a prescription for PrEP but then sell it. So we see that a lot. Or, also, like an example someone had told me too, having a client who is a doctor who prescribed it to them, but they don't actually have a proper follow up.



S And, there's the flip-side benefits from generic importation. So, generic importation is happening for a fraction of the cost, being funneled through the States, and then you go down to the States and you pick it up. You can bring over a three-month supply on your person, so there's pathways that are being propagated.



S I'm a little unhappy about the under 16. We've stated it as how will they get access to PrEP if they're not comfortable with disclosure. Well I'm not sure lack of comfort with disclosing you're a sex worker is the only barrier. I would've thought there'd be dozen of barriers.

S And, especially the involvement of child protection I think needs to be added to that, as well.

S It should be disclosure of exchange of sexual services at the very least. It shouldn't be their involvement in sex work—it's exploitation.

S Yeah. I'm really uncomfortable with calling children who are under 16 sex workers. The men who are...

S It's a form of exploitation. They may not consider it exploitation, but it is.

S It seems to me, that you'd want to do a whole raft of research before you could work out how best to address the issue. There's a concrete recommendation: you could get a whole lot of money to do some.

S We like that.

M So, a bigger question comes up about if the client population that you're working with is underage folks that are being exploited or involved in the sex trade, how will Children's Aid Society insert themselves on that situation if they disclose? What are the real impacts of PrEP on younger persons? How do you recommend that?

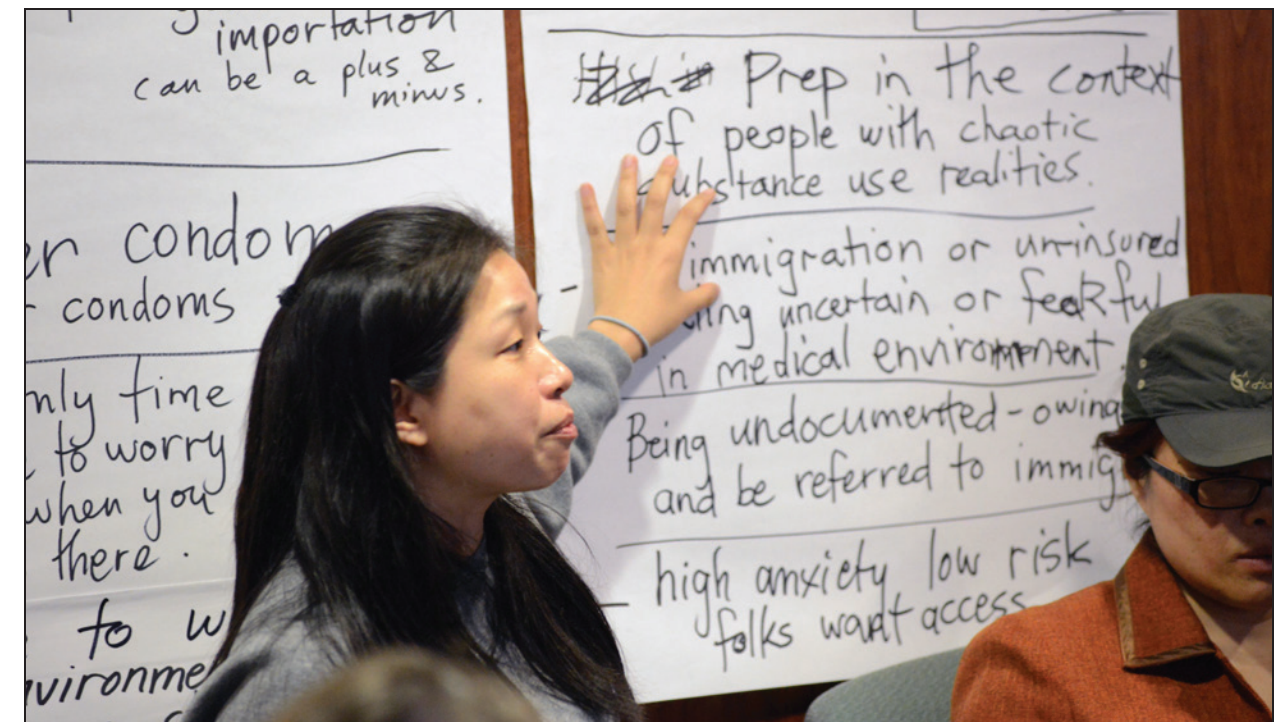
S Well you know what's amazing? They can get a morning after pill no questions asked, but something like this is going to be very, very difficult.

S In fact, I think people have forgotten the value of PEP in a lot of the talk of PrEP. A lot of people talk about PrEP, when actually what they're saying could apply to PEP. Morning after—which is much lower dose, much less intrusive. In fact, people have stopped talking a lot about PEP.

S I don't know, correct me if I'm wrong, what I've heard is PEP more difficult for some people to actually follow the whole treatment because it's a month-long treatment and as well the side effects?

S The side effects are a lot greater in the short term. It's a very rigorous dose, so that is a factor.

S Yeah, but if you're 16 and someone is telling you to take Truvada® for the rest of your sex life, I mean, that's big impact stuff, too. This idea... PrEP's not Aspirin®.



S I think that they'll probably get into more about the doses that you can take. Because — this is more for the MSM — PrEP is something you can take before — not every day. Like, those options.

S Well we don't know about intermittent dosing.

S Does anybody here know what the statistics are for HPV? No, nobody knows about it? Because I was thinking how many women — young women — are getting HPV?

M I actually have got one. I did work in a sexual health clinic.

And, some people would come in with very high anxiety and very low risk. So in terms of these assessments, there's going to be people that have sex once every five years. Like, it's amazing. And, they're going to want to be on PrEP every single day. So, what do you do for those ones where it is a mental health concern? Does everybody get access to it even when the risk is low? I don't know.

S Well, if you know how many days before you take it and it builds up in your system and then you can have good sex, and then when you stop having the sex you stop taking the pill.

M I'm talking about people that maybe had sex once with a sex worker. They have no sex, they live with their parents, but they have sex once, and it's five years later and they still need it.

S There's also people that take all the precautions, but it's still not enough and they still want to get tested. Every two weeks, "I have to get tested." Right? And, they're doing everything right but it's just so futile.

S Yeah, that's so true. Oh no, that's why it's so tempting for people to say, "Give it to whoever wants it," it's like, whoever wants it is going to be the wrong people.



S The careful people; the conscientious people. People who take their vitamins every morning.

S That's right.

S Can I just say though, most people that I have talked to over the years that are less careful in their personal life and a lot more careful in their professional life and I'm one of them. And I've got some Hs — and I don't want to discuss which ones — but I'll tell you something right now: If you can convince people to use more condoms, more condoms, more condoms, have fun with condoms, play movies with condoms, do pornography full of condoms and inflated condoms! Huge condoms!

S And also on that point, to improve the condom. We've seen millions go into drug research and we're still, you know, mucking around with these bits of rubber. Surely.

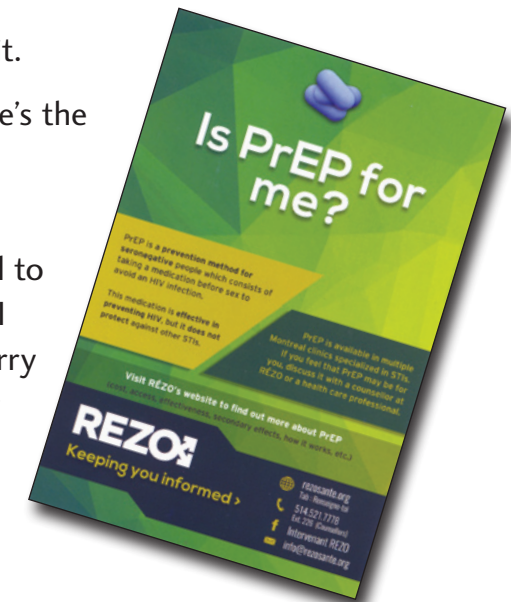
S And they don't look that fun.

S Surely they could've improved condoms. They have a bit.

S And where's the messaging? Condom messaging? Where's the messaging?

S I've got something I want to share: I saw the best HIV message recently. I loved it. It was, "The only time you need to worry about HIV is when you don't know it's there." Which I thought was a great revised message. You don't have to worry anymore about HIV. The only scary thing is you don't know it's there. It's a testing message.

S And the reality of undetectability. Right? Undetectability, it means non-transmission.



appendices



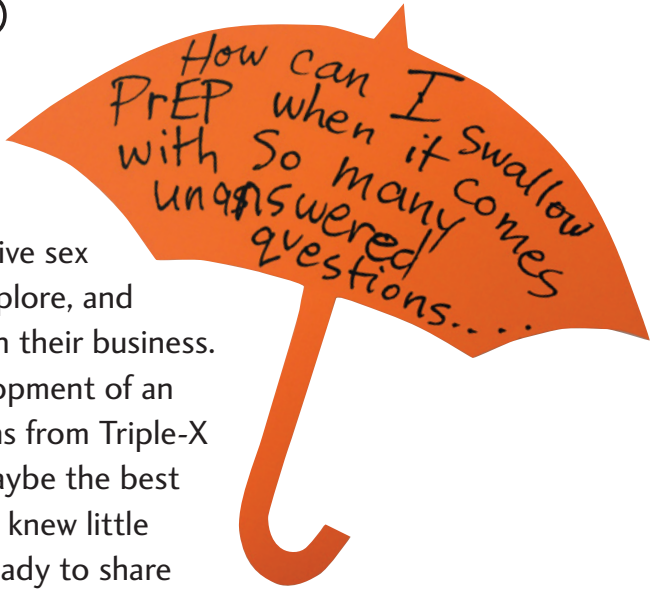


SEX WORKERS PrEPARED

Facilitator’s summary

Deborah Waddington, Sexual Health Promoter, Toronto Public Health

The purpose of this national consultation was to give sex workers an opportunity to educate themselves, explore, and grapple as a group with the implications of PrEP on their business. The desired result of the consultation is the development of an online survey for sex workers and recommendations from Triple-X to inform Health Canada policy guidelines. But, maybe the best outcomes are that most of the folks who attended knew little about PrEP, and went away feeling informed and ready to share this information in their workplaces.



Concern about unintended consequences of PrEP

- Would there be an overall increase in STI rates, such as herpes, HPV, drug-resistant gonorrhea, and especially syphilis — which has an increased susceptibility and deleterious effect on people living with HIV?
- If PrEP was broadly distributed would the result be increasing numbers of drug resistant strains of HIV? What would be the impact for folks who caught HIV and were unable to manage it effectively because drug resistance?

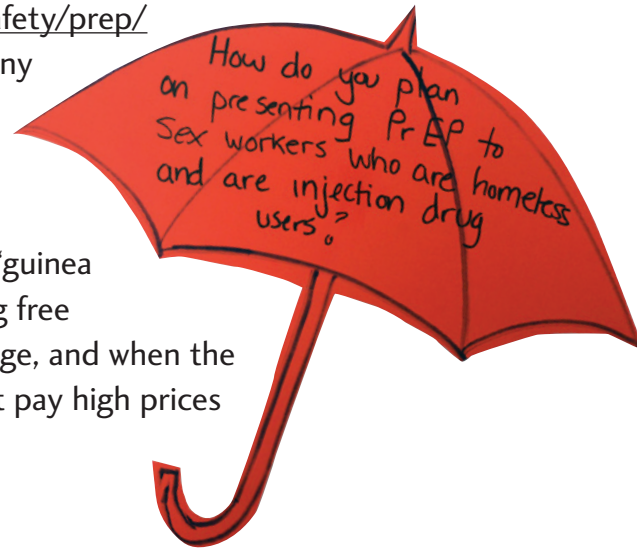
Public health policy regarding access to PrEP

- There was a strong sentiment that increased access to PrEP based on being a member of a “target population” (e.g. a sex worker) was wrong-headed. Not all sex workers are equally vulnerable to contracting HIV. As stigma about sex work is high among health care providers, asking for PrEP because you fall into a “target population” is highly problematic.

- There was a strong feeling that access to PrEP should be made available to people who engage in risky behaviours (only some sex workers engage in risky sex; others do not).
- As well, access to PrEP should be based on the “viral load in the community” where risky behaviours take place. For example, in some communities, rates of HIV are high and few community members are currently accessing HIV treatments. In these communities, people who engage in risky behaviours potentially stand to benefit from being on PrEP.
- The sex workers at the consultation expressed anger about medical and public health establishments which they felt perceived them as a “target population” with the target being their genitals! They are whole beings, with a variety of aspects and experiences, and they need health care that is holistic.

Unethical research practices regarding sex workers and PrEP

- A concern was expressed that early research by pharmaceutical company, Gilead Sciences, to get PrEP ready for market was unethical. In particular, it was referenced that a Gilead PrEP study on sex workers in Cambodia was halted after compensation was demanded for those people who contract HIV during their participation. Another example of an unethical research was experiments carried out on sex workers in Guatemala in the 1940s. (See triple-x.org/safety/prep/ for more on this research). On the whole, many marginalized communities have very little trust in research and the motives of large pharmaceutical companies.
- It was noted that sex workers have acted as “guinea pigs” for pharmaceutical companies, receiving free medication when it is in the development stage, and when the drug is reissued with modifications they must pay high prices for it.



Gaps in research

- There was a concern that much of the research was conducted on men. It is uncertain how well women’s, and trans womens’ bodies will respond to PrEP over time.
- It is felt that there is a need for more information about drug interactions with PrEP. There is a website that lists the side effects of Truvada® with many common drugs, but there is a need for a greater understanding of the use of PrEP with street drugs, psychiatric drugs, and those that treat lifestyle diseases which disproportionately affect those at the lowest end of the socio-economic ladder.

Concern about down-playing the side effects of PrEP

- The two main side effects of taking PrEP over the long term are stress on the kidneys and bone density loss. Older sex workers in the room wanted to emphasize to the younger group that these are not minor side effects. These side effects can have a big impact on your health and wellness as you age.

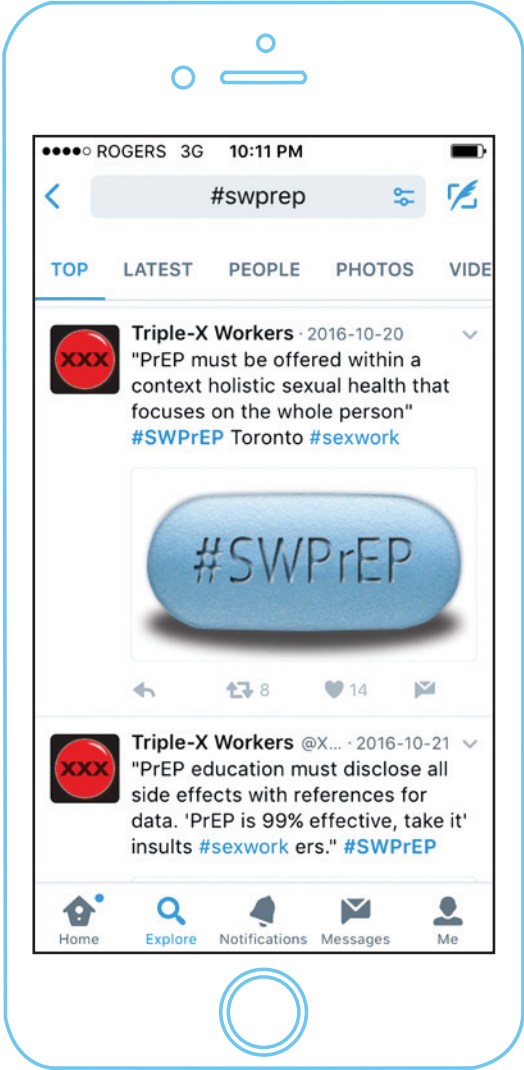


Informed decision-making

- There was a lack of confidence that sufficient time would be available in doctors' offices, or sexual health clinics, to give people a full understanding of the ramifications of this drug before it was prescribed.

Access to PrEP

- Many trans women feel their basic health needs are not currently being recognized, taken seriously, and often they are not covered by our current medical system. Many trans folk feel their relationships with the medical establishments are already challenged so there is not a lot of confidence that having PrEP on the plate will improve things.
- With new immigrants, in particular non-status sex workers, the concern is that there is no money to pay for PrEP, nor will they be able to openly disclose to medical authorities that they are sex workers. (We were told about a situation in Vancouver where non-status immigrants were sent to Canada Border Services Agency because of non-payment of their medical bills.)
- People who worked with the most marginalized sex workers were concerned that these people would not be fully informed about all aspects of PrEP before they were prescribed it by medical folks. Some of these people have very little personal agency and true informed consent is unlikely to happen in a medical clinical setting.



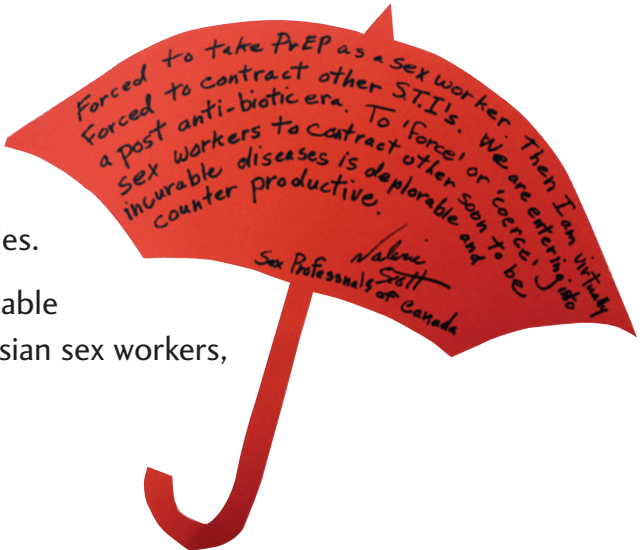
- There are some sex workers who live with impulsivity, or chaotic lifestyles that will make adherence to a strict daily regime of PrEP very challenging—which may increase their chance of contracting a drug resistant strain of HIV. In some situations it may be possible for the people to pick up PrEP when they go to the pharmacy to get their methadone.

Adherence to PrEP

- It was noted that when people have ambivalence about a medication, their willingness to tolerate side effects and their adherence is low. This could increase the potential for drug resistant forms of HIV to develop and mean that, if they did catch HIV, Truvada® could not be used to treat it.
- It was noted that new versions of PrEP—like a three-month injectable PrEP—are currently being developed. This mode of taking PrEP may be more viable for folks with chaotic lifestyles.

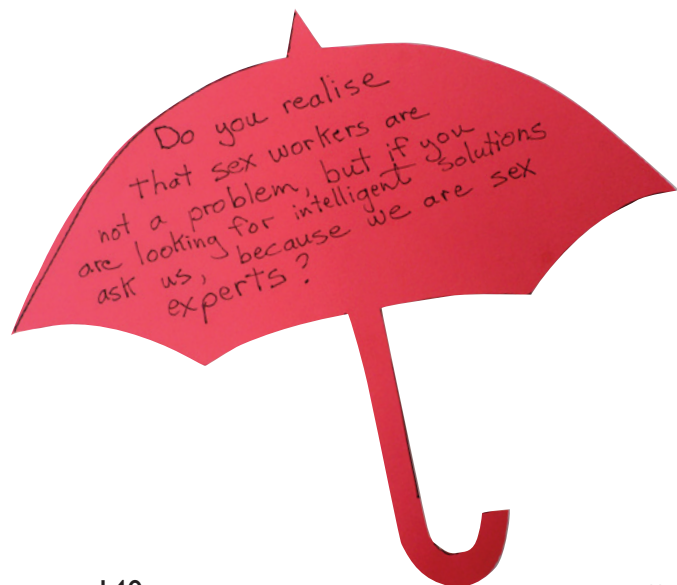
Lack of awareness and information among some peoples

- It was noted that gay men are generally well-informed about PrEP, and many are currently accessing it through their doctors or the black market. AIDS service organizations have produced information about PrEP. However, most of the women sex workers, and service providers working with women, knew very little, or had no knowledge at all. There needs to be simple but accurate information available in all communities before PrEP is rolled out in various communities.
- Many of the print materials are currently available only in English and French—those, such as Asian sex workers, do not have good information on this drug.



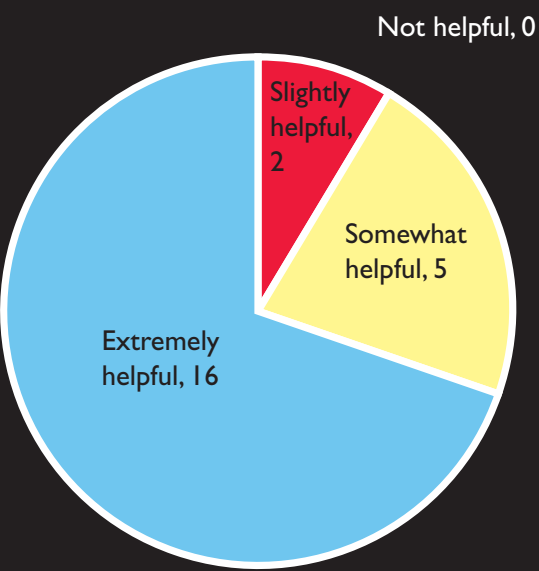
PrEP in the context of sex work

- Adherence to PrEP may become a health and safety tool within the working environments of sex workers. For example, at a brothel sex workers may be required to take PrEP as a condition of their working there, and then these brothels may use adherence to PrEP as an advertising ploy.
- If everyone takes PrEP in a workplace, sex workers may have less leverage with clients that they use condoms. Not every sex worker is in a position of power that they can demand condom use.
- There is a concern that PrEP will create division among sex workers, pitting sex workers who are on it against those who are not and increasing stigma in the community.

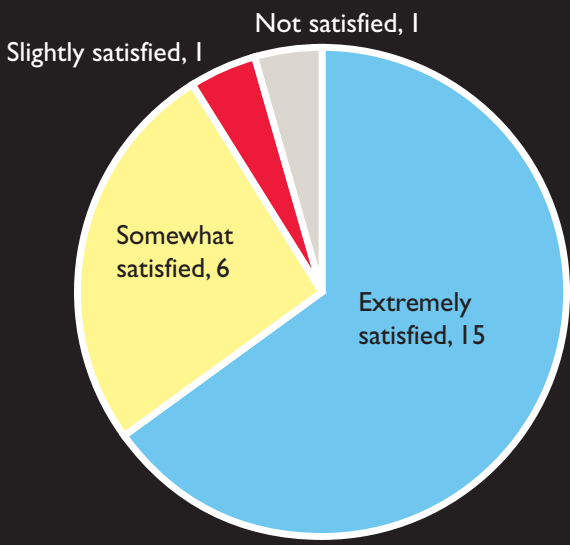


#SWPrEP PARTICIPANT FEEDBACK

1. How helpful was the consultation?

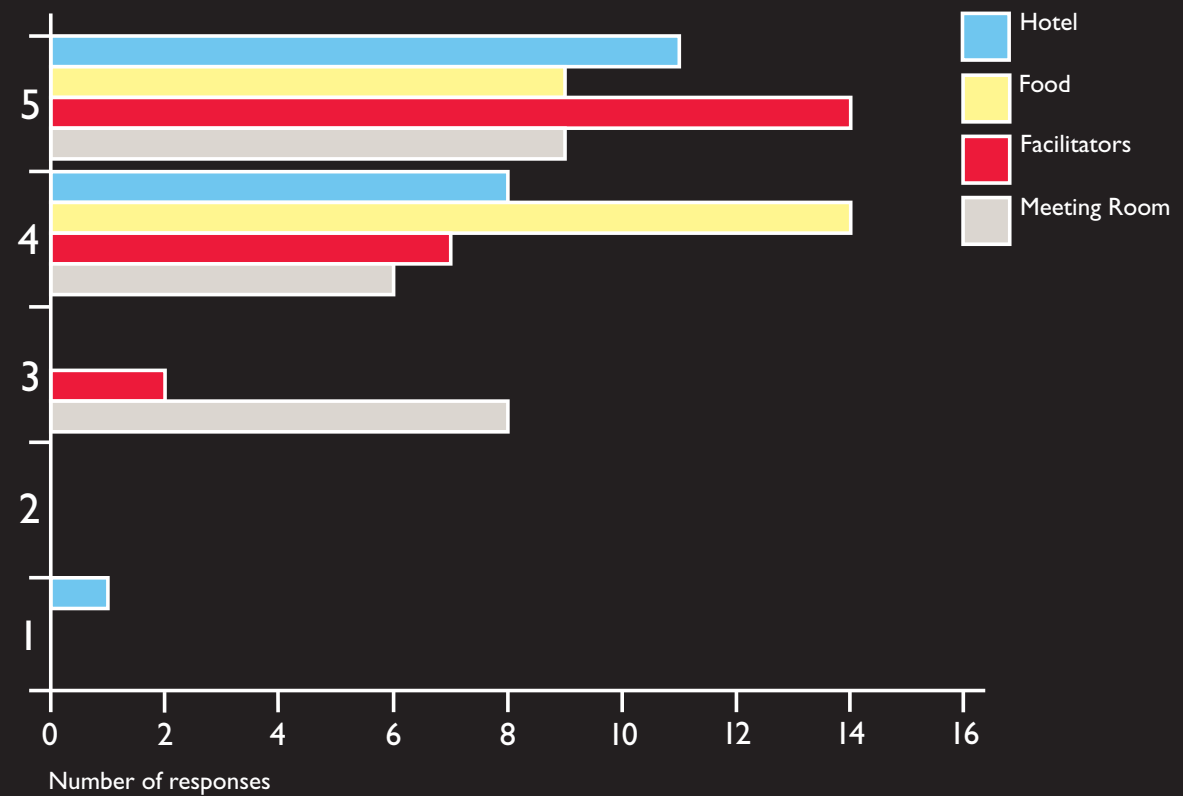


2. How satisfied were you with the consultation?



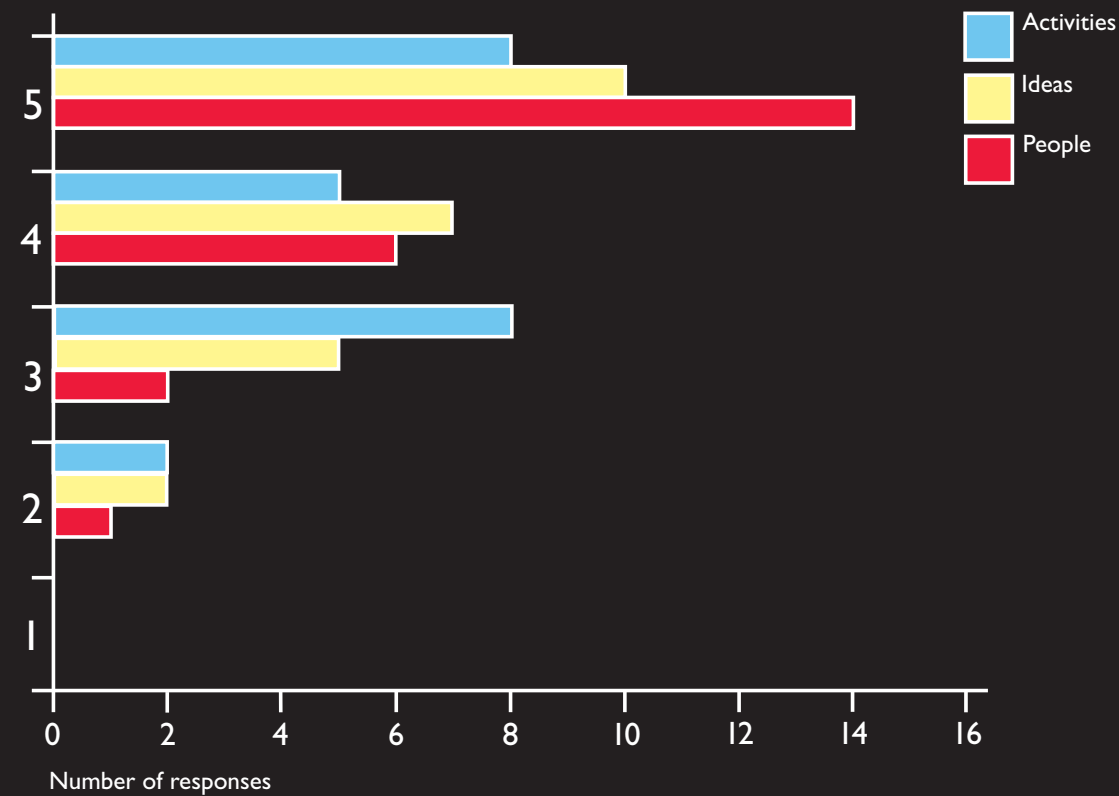
Survey Results
23 responses

3. Rate the consultation (1= Poor, 5= Excellent)

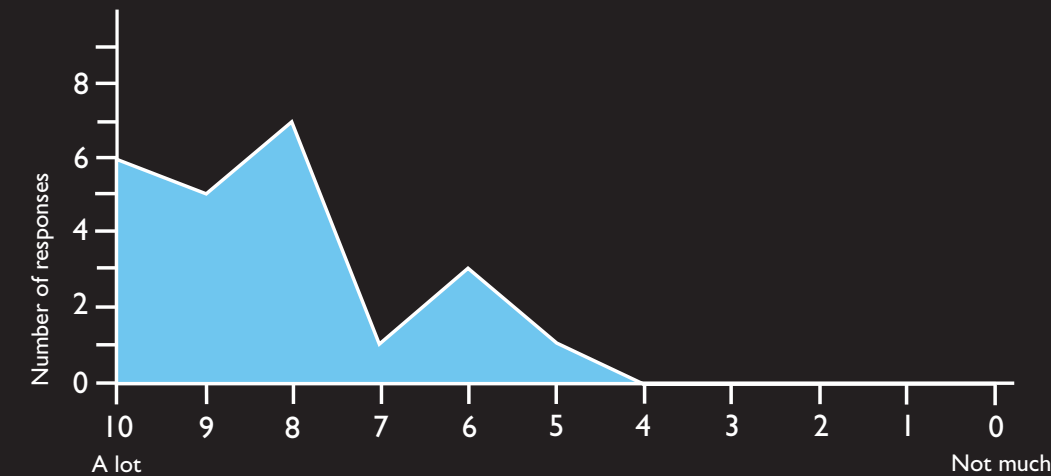


#SWPrEP PARTICIPANT FEEDBACK

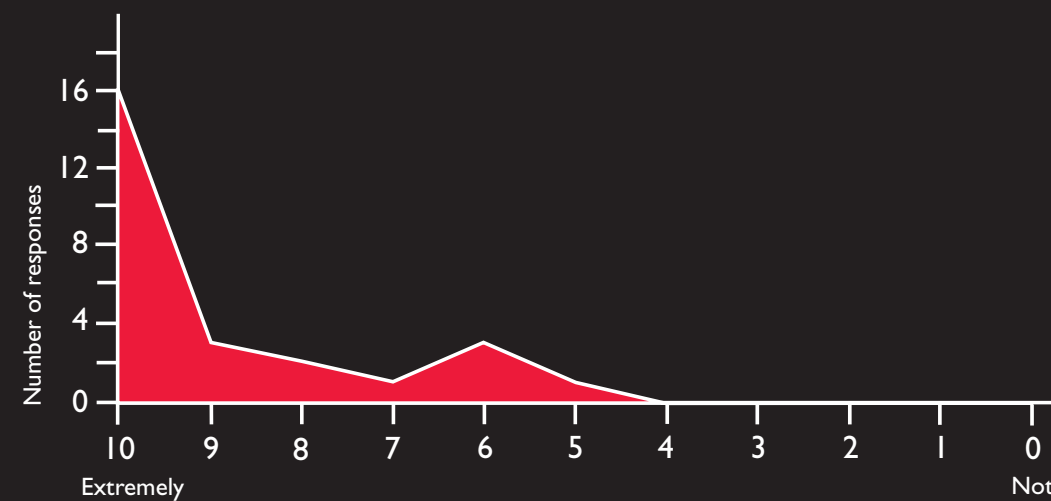
4. Rate the diversity (1 = Poor, 5 = Excellent)



5. How much did you learn about PrEP in the context of sex work?



6. How likely is it you will tell others in the context of sex work about PrEP?



#SWPrEP PARTICIPANT FEEDBACK

7. What worked well?

(Comments presented here represent key themes identified by respondents.)

- “Respectful and safe environment.”
- “Open forum for everyone to share.”
- “National representation of sex workers and sex work organizations.”
- “Great discussion, really thought the presentations were helpful in understanding what PrEP is.”
- “The facilitation was great.”
- “The balloons!”



8. What experience did you value the most?

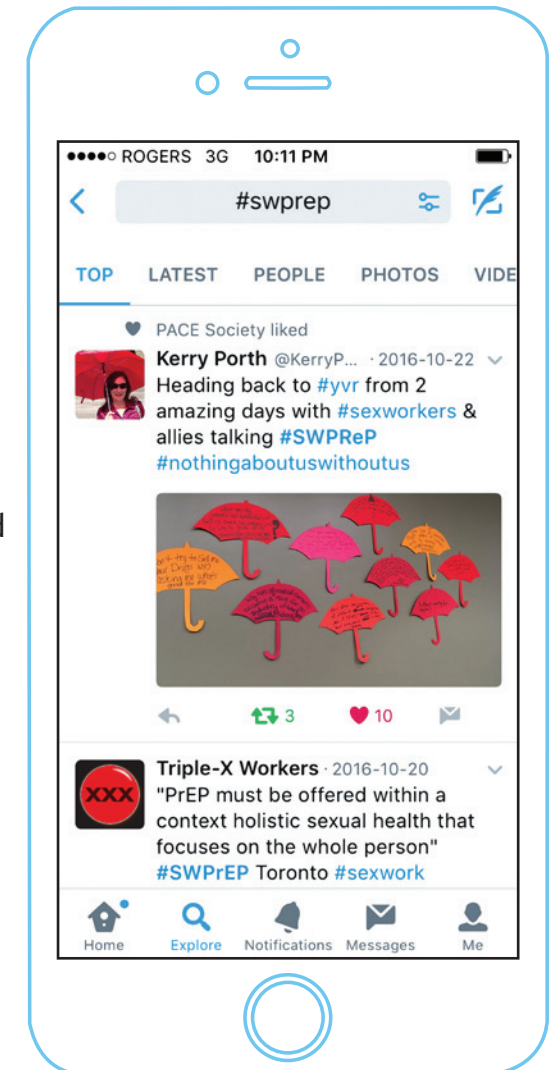
(Comments presented here represent key themes identified by respondents.)

- “Sharing stories, laughs, smudging.”
- “The ability to speak freely among my peers.”
- “Frank discussion about people’s behaviour, including risks.”
- “Being enlightened on concerns about PrEP and sex work that hadn’t crossed my mind.”
- “How respectful people were to one another, including to the experts and during times of differences of opinions.”
- “Aqua.”

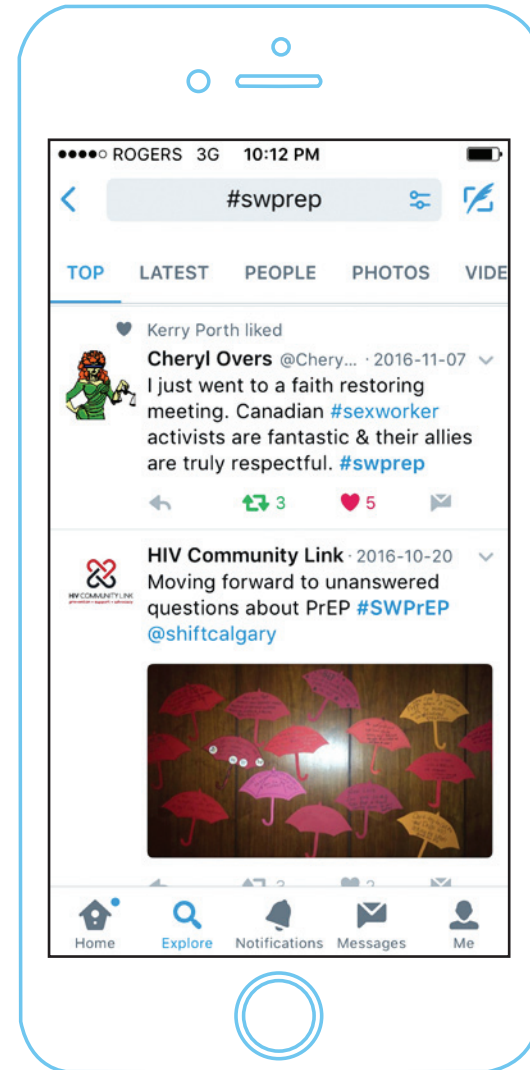
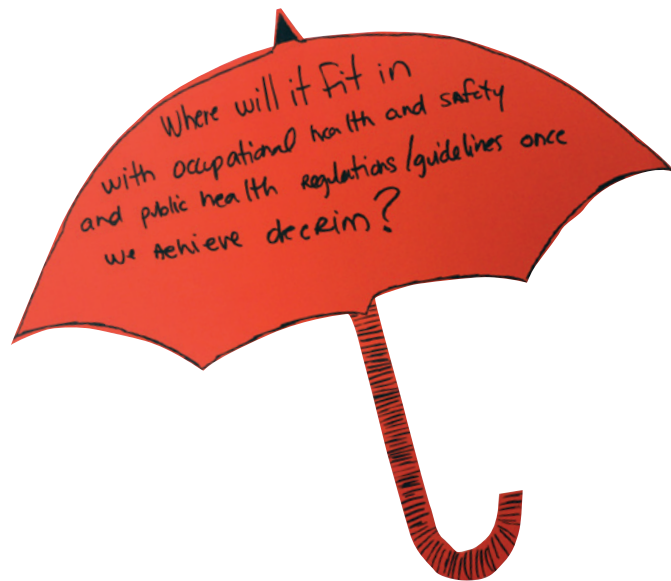
9. What could the organizers do better?

(Comments presented here represent key themes identified by respondents.)

- “Bigger space to allow for movement.”
- “Have more presentations by sex workers rather than ‘experts’.”
- “Take more time to get to know conference participants. To know who is who and what they are up to, their struggles, challenges and successes.”
- “Guide the conversation a bit better.”



- “If we could have had the opportunity to break into smaller groups I feel their would have been more opportunity for those who listen more than speak to become more comfortable within the group.”
- “I don’t feel like clear next steps were identified.”



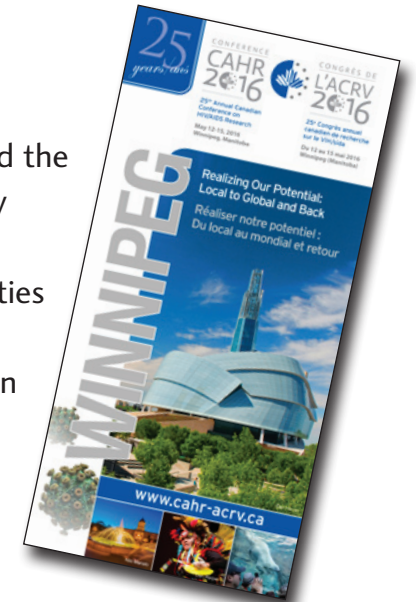
PLANNING FOR PrEP IN THE CONTEXT OF SEX WORK

Winnipeg planning meeting, CAHR Conference, May 12, 2016

Synopsis Summary

Creating meaningful involvement for sex workers in discussions of PrEP

Triple-X Workers’ Solidarity Association of British Columbia and the HIV Studies Unit, Dalla Lana School of Public Health, University of Toronto held an invite-only planning session for a national consultation called, “PrEP in the Context of Sex Work: Possibilities and Limitations” that was attended by 12 participants from organizations that work with sex workers. Draft planning session notes were reviewed and 353 individual points were identified. The points were re-organized, condensed, synthesized and repetition removed to produce these recommendations.



1. Leadership role

Sex work is an occupation not an identity. Sex workers are safe sex professionals. Historically in Canada and elsewhere, sex workers have been leaders in safe sex promotion and education. Emerging treatment and prevention technologies such as Pre-Exposure Prophylaxis (PrEP) offer opportunities to organize, consult and ensure that sex worker voices represent the interests of the sex industry.

2. PEP for sex workers

Sex worker sexual health and safety should include timely access to Post-Exposure Prophylaxis (PEP) on demand.

3. The science of PrEP for women and trans people

PrEP science has focused primarily on the efficacy on gay men. Women and trans people have specific requirements that must be addressed in order to access PrEP.

4. Sexual health and safety

Promotion of new technologies for preventing HIV transmission alone is too narrow in scope, and is likely to have negative impact on other proven prevention methods such as condoms. To date, PrEP promotions have focused primarily on marketing rather than education.

5. Impact on the sex industry

The sex-industry context differs significantly from other contexts such as people's personal sex lives or public health responses geared for various communities.

Distinct pressures related to PrEP and the sex-work marketplace can be identified, including:

- workplace sexual health and safety practices
- confidentiality of workers' private health status
- competition among workers
- shifting expectations from clients and employers
- being HIV-positive and continuing to work
- legal requirements to disclose one's HIV-positive status to sexual partners

6. Education

The promotion of new HIV-prevention technologies raises concerns over the lack of basic understanding about sexual infections including HIV among workers. A focus on access to health care and public health regulation and sex work is required.

The complexity of legal, medical and scientific explanations regarding HIV is a barrier to workers. Education strategies require:

- clear explanations about basic concepts (free of legal and scientific jargon)
- accessible formats beyond text such as infographics, audio and video
- gender-based information on the impact of medical technologies
- multiple languages
- culturally-sensitive and context-sensitive material for ethnic and migrant workers

7. Access

In the context of workplace sexual health and safety, sex workers face specific issues regarding access to sexual health treatment, including:

- limited universal healthcare coverage for low-income workers
- high cost of prevention technologies (beyond condoms) and treatments
- requirement to disclose sex worker (risk-group) status in order to be eligible
- needs being assessed based on assumptions attributed to risk-group status
- physical access to PrEP and PEP
- follow-up testing and surveillance requirements
- implications of public health regulations concerning HIV status



8. Regulation

- a. Due to federal, provincial, territorial and local government jurisdiction, policy and regulation related to sex work and healthcare are a patchwork across Canada. This makes documentation, comparison and education a big challenge.
- b. When informing sex workers who are seeking prevention technologies, testing and treatment, extra considerations need to be taken into account:
 - implications of a diagnosis of sexually-transmitted infection, including HIV, on one's livelihood
 - contact tracing, where one is required to provide names of sexual partners
 - records of past sexual infections being used against you
 - sex workers may be ordered to stop having sex
 - positive test results for reportable diseases are recorded in provincial government databases
 - moving within Canada to different legal regimes
- c. Public health authorities are responding to new technologies by creating new policies, which raises concerns that include:
 - emerging public health regulation of sex work generally



- perceptions that the sex industry puts the public at risk
- public health authorities targeting sex workers through seek-and-treat programs
- potential for workers individually or as a group to be forced to use condoms or to take PrEP

9. Advocacy

- a. It is important to help inform people's opinions so that they can think and answer for themselves. Sex workers have the capacity to be involved in advocacy; the process to include them needs to take this into account, and:
 - focus on clear communication
 - explain what is being asked and why
 - provide information in a way that can be taken back to their communities
- b. To get sex-worker input on government policy, sex workers need to be connected to discuss concerns:
 - many sex workers are connected through service organizations
 - include sex workers from smaller centres and make space for their voices
- c. Rally nationally and provincially to:
 - resist pressures for enforced condom-use and PrEP
 - make HIV and STI testing and treatment more accessible

10. Recommendations

Overall

1. Do not replace empowerment with biomedical prevention.
2. We need a better and more robust model of peer-empowered education in order to discuss PrEP and other new HIV-prevention technologies.

3. PrEP resources for women sex workers must be a priority.
4. Hepatitis C and other sexually transmitted infections need to be included.
5. New safer-sex guidelines that include HIV-prevention technologies are needed.
6. Talk about the problems that the PrEP environment can create in terms of other sexually transmitted infections, as PrEP may instill a false sense of security among sexually-active people.

PrEP education

7. Basic science for antibody testing, HIV, ART and PrEP—as well as their efficacy should be provided.
8. Education should include access to multiple sources of information.
9. Information about PrEP and PEP availability and access needs to be included.
10. Education should also include experiences of people taking PrEP.

Consultation planning

11. Meeting should be well located geographically.
12. Who should be included:
 - a. industry perspectives, not just activists' perspectives



- b. more involvement from trans people including trans men
- c. consider inviting a range of PrEP experts
- d. an expert that is critical of PrEP
- e. don't have anyone from the drug company

13. Engage workers in meaningful consultation:

- a. provide basic education in order to get an informed response
- b. use scenarios to explain contexts
- c. ask questions that arise from scenarios to elicit opinions
- d. break the questions down
- e. find facilitators who can provide learning experience that is not intimidating
- f. small group stuff (crayons, Post-it notes and flip charts)



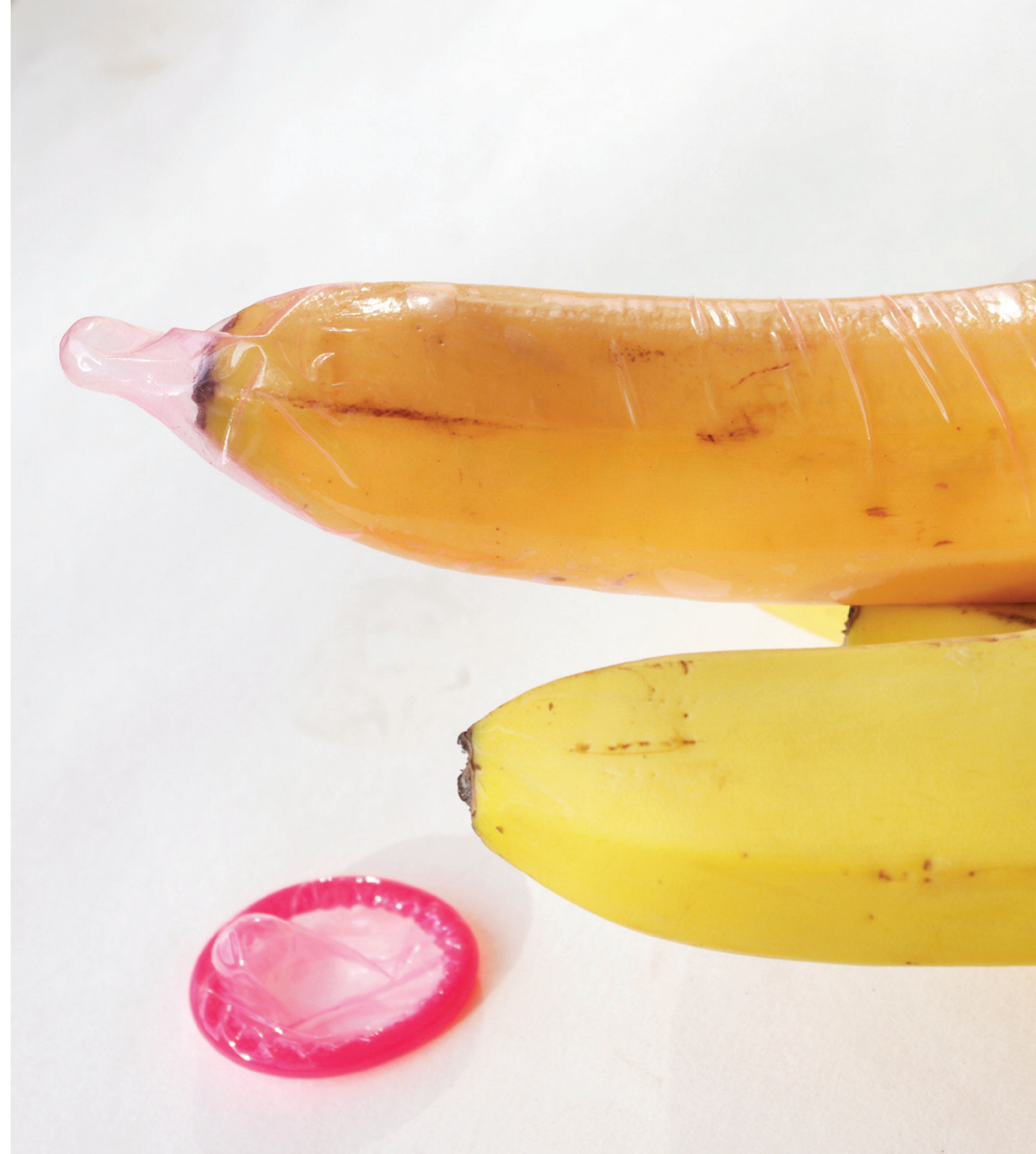
Triple-X secretary Kerry Porth and president Andy Sorfleet at The Tallest Poppy, Winnipeg, May 15 2016. Photo: Dan Allman

- g. find tools that capture ideas for PrEP education
 - h. foster, ignite and educate around PrEP
 - i. collect questions about PrEP
 - j. not everyone will necessarily be prepared beforehand
14. Use Guidelines for the Inclusion of Drug Users, L'ADDICQ, a project of the Québec Association for the Promotion of Drug Users' Health (AQPSUD).
 15. Current sex workers should be paid for their time.

Outcomes

The outcome of the consultation must not be a final recommendation.

16. Plan for the possibility of future input.
17. Develop talking points that sex workers may want to discuss with a clinician.



#SWPrEP FINANCES 2016

#SWPrEP Revenue Actuals 2016

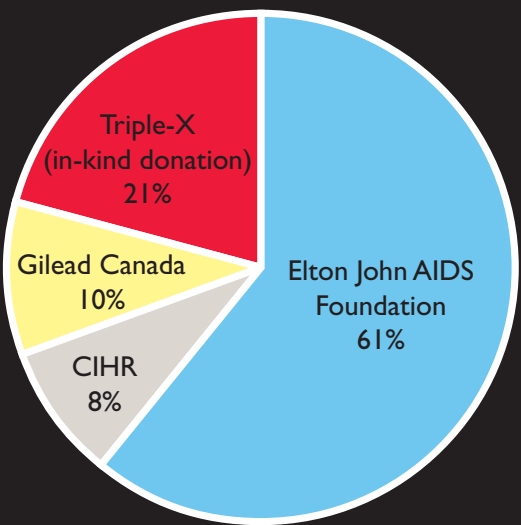
Elton John AIDS Foundation Grant	105,360
Canadian Institutes of Health Research - Planning & Dissemination Grant	14,984
Gilead Sciences Canada Inc. Financial Support	16,720
Triple-X Workers' Solidarity Association of B.C. (in-kind donation)	36,000
Total Revenue	C\$173,064

#SWPrEP Expenses Actuals 2016

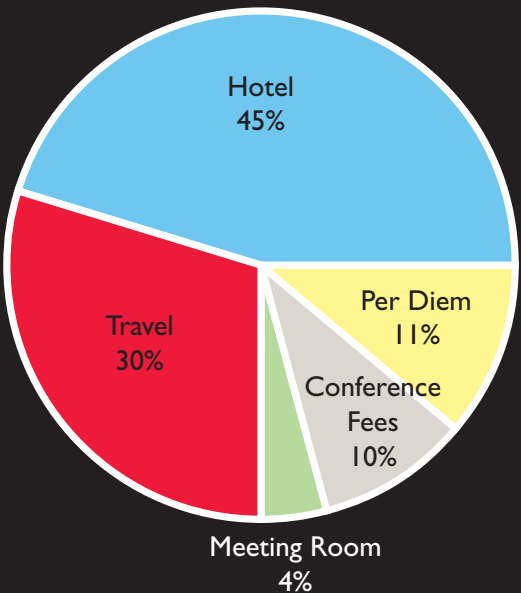
Winnipeg Planning Meeting - May 12, 2016	
Travel	5,925
Hotel	9,031
Per Diem	2,172
Conference Fees	1,945
Meeting Room	800
Sub-Total	19,872
Toronto Consultation - October 19-20, 2016	
Travel	17,409
Hotel	20,568
Per Diem	5,163
Participant Fees	10,250
Catering	4,636
Supplies	3,396
Services	2,863
Video and Photography	17,947
Triple-X - Administrative Support	13,486
Triple-X - Professional Design Services (in-kind)	36,000
Sub-Total	131,718
Total Expenses	151,589
Balance*	21,475

*Note: Project granted extension to June 30, 2017. Balance to be applied to 2017 production expenses for knowledge mobilization tools and events.

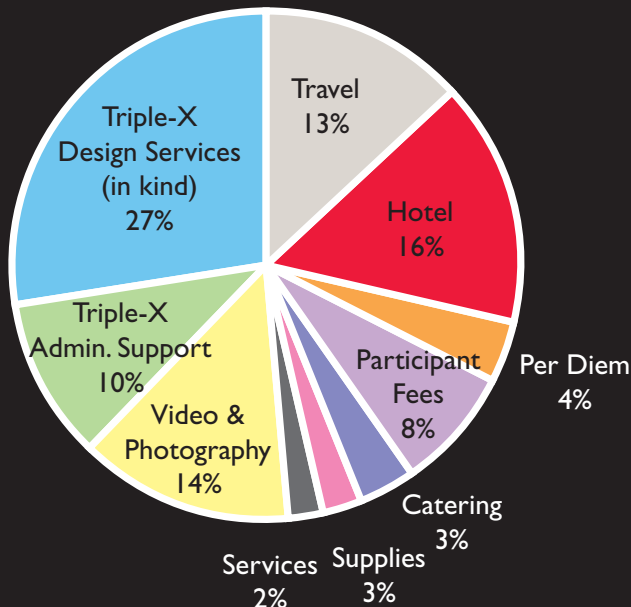
#SWPrEP Revenue 2016



Winnipeg Meeting Expenses



Toronto Consultation Expenses





Thank you from Triple-X & the
Dalla Lana School of Public Health

TO: All the participants for their time and their thoughtful
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represented for their support. All the presenters who
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(AVAC), Canadian AIDS Society, Canadian Public Health
Agency (CPHA) and Canadian AIDS Treatment Exchange
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All of the contributors to this book, including:

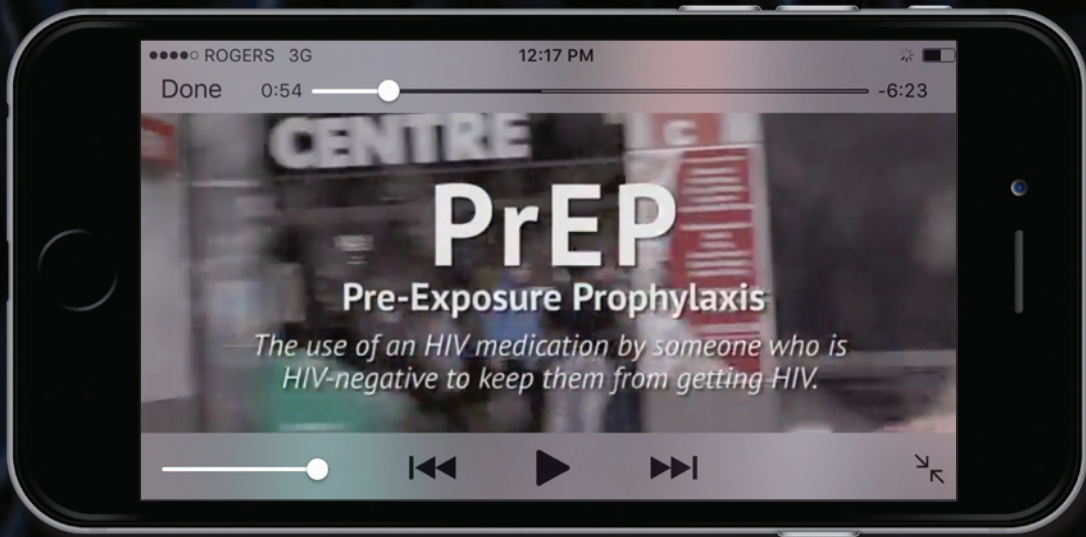
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Blessings: [Aqua Nibii Waawaaskone](#). Excellent note-taking:
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Fine Foods](#). Conference videographer: Richmond Obeng
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Our Business](#). International guests, Cheryl Overs and Melissa Ditmore for coming and helping out. The
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Thank you all.

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<http://triple-x.org/safety/prep>



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for HIV prevention education at the national sex work consultation. Determining
content for the consultation and selecting attendees and speakers were responsibilities
of the Dalla Lana School of Public Health, University of Toronto and Triple-X Workers' Solidarity
Association of B.C. Gilead Sciences Canada, Inc. had no input in these areas.



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