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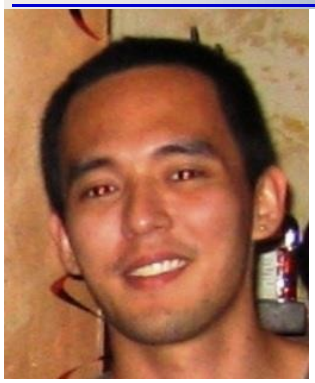
NEWS & VIEWS

Look Who Joined The Client Advisory Committee (CAC)



Name: Albert Aguirre

How long have you been a client of Open Door? Almost a year now.

When did you join the CAC? I joined CAC a few months ago.

What types of things do you want to see done on the CAC? I want the CAC to be the bridge between the clients and the clinic. To be able to give feedback and make changes that impact the clients that will make them care for themselves and be aware that we can live normal lives.

Describe your family (define family however you want)? Family for me are the people I keep close to my heart. The ones that care for you and bring you up when you are down and accept you for who you are with out any questions.

What do you enjoy doing in your free time? I like to read, watch movies, eat good food and travel if possible.

Where is the farthest place from home you have ever been? I grew up in the Philippines so I am already half way around the world from home.

What is your favorite food? I don't have anything particular favorite I eat depending on how I feel but sweets would always be on top of my list.

What one thing do you want to do that you haven't done yet? I have a bucket list and slowly doing what I want to do. I want to travel more, see different places and meet new people and be lost in a different culture and learn a new language.

Who is the most impactful person in your life or most impactful person on humanity (dead or alive)? Anyone who tries to survive despite the odds against them or anyone who tries to make a difference or help someone impacts me every day and inspires me to do something with my life.

What have you hope learned while being on the CAC? I hope I would learn how to hear other people's concern implicitly and explicitly. To make things better for everyone.

INSIDE THIS ISSUE

"Undetectable": Safe or Not?

From TheBody.com
August 28, 2013

This article originally appeared on PositiveLite.com, Canada's Online HIV Magazine.

Positive people, on effective treatment, with an undetectable viral load and healthy immune system, still don't know if they can or can't pass on the virus to their partners. New UK developments suggest that official conclusions may already have been reached.

Recently, the idea that people on HIV medication who are also undetectable (where your viral load is measured at less than 40-50 copies of HIV in every milliliter of blood) might also be non-infectious to others with similar tested levels and a healthy immune system, has naturally got everybody in that situation very excited. There is however, still no definitive proof and although we're assured that proof either way is being worked on, it's going to be some time before that news emerges from behind the locked doors of the research labs.

In the meantime, people with an undetectable status see proven non-infectiousness as a possible, instant solution to many sorts of stigma. If, after indisputable proof, it is widely reported that people on successful treatment are not in danger of passing on the virus, then there is no reason for every sexually active person on the planet not to get tested and if necessary treated because treatment will make you a safe person to have sex with. This is discounting other STDs of course but then you're just as much at risk as any sexual partner of contracting those. If successfully proved, people living with HIV will be seen as living with a chronic illness that is no danger to their partners, pretty much like diabetes patients, cancer patients and others. The world will change overnight, not only for positive people but for LGBT society as a whole. They won't be able to point accusing fingers at us anymore, claiming we're "unclean," "disease spreaders" and a "danger to society."

It's almost a utopian idea but it may well be only a large-scale research study away. Doctors, scientists and HIV-specialists are already giving the idea some credence; politicians and other social groups ... not so much. The idea that people living with HIV can safely have sex with anyone in the community again, sticks in many a craw, including, astonishingly enough, many HIV organizations, who see it as subversive to all the work they've been doing to promote condom use and safe sex!

The word "undetectable" has already been abused and misused to the point where many claim it to be meaningless. Proof
that undetectable means non-infectious, or even proof that undetectable means the possibility of transmission still exists, is essential and you have to ask why research groups across the world aren't moving heaven and earth to get an answer one way or the other. Maybe they are but nobody's telling us.

That all said, there has been a breakthrough in the UK this month which gives a remarkable insight into the way health authorities and government ministries there are currently thinking.

The current ban on health workers in the UK who have HIV, carrying out certain procedures involving possible exposure to blood and fluids, has been lifted! It even hit the breakfast news and made national headlines the same day but it is the reasons behind the decision that have enormous implications for all people living with HIV.

So why has the ban on HIV+ health workers working normally with patients been scrapped?

Remember, this means that HIV positive health workers can deal with contact situations in the same way as all their colleagues and this includes surgery and dentistry. It's a decision that can't have been taken lightly because the ramifications of an HIV transmission from nurse to patient are enormous. You might reasonably assume that they must be sure of their facts.

Both on television and in the press, Professor Dame Sally Davies, England's chief medical officer (second only to the minister responsible for health) explained the decision in refreshing detail, stating that science had moved on and "outdated rules" should be scrapped. She went on to say that modern treatment means that HIV is mostly a chronic condition where people can live long and normal lives. Nothing new so far you might think; but the revolution in thinking is in the details and as she explained:

"At the moment we bar totally safe health care workers who are on treatment with HIV from performing many surgical treatments, and that includes dentists."

Professor Davies continued in a more HIV-friendly tone than we may be used to:

"What we want to do -- and want to get over -- is how society needs to move from thinking about HIV as positive or negative and thinking about HIV as a death sentence, to thinking about whether they're infectious or not infectious."

People with HIV "... are leading lives that are normal in quality and length. With effective treatment, they are not infectious."

The new rules are very straightforward. HIV positive people with a job in health care must have an undetectable viral load; be on an effective combination therapy and must be regularly monitored by their own specialists (every three months). There is a non-obligatory responsibility for medical carers to get themselves more frequently tested if they feel that have been once again exposed to the virus but again, the professional is being trusted to do the right thing. There will be a confidential (barring memory sticks being left in taxis!) register of infected workers lodged with Public Health England but this registered proof of status is as much to protect the health worker as the patient. No excessive government control or checks; no unreasonable demands and no uncertainty as to what the ruling actually means ... refreshing or what!

It was also pointed out that there have only been 4 cases worldwide of health carers infecting patients, with none in the UK and to hammer home the point, it was suggested that people have more chance of winning the state lottery than being infected by an HIV+ medical health worker. Professor Davies went even further to educate the public:

"Many of the UK's HIV policies were designed to combat the perceived threat at the height of HIV concerns in the 1980s and have now been left behind by scientific advances and effective treatments ... It is time we changed these outdated rules which are sometimes counterproductive and limit people's choices on how to get tested or treated early for HIV. system that continues to protect the public through encouraging people to get tested for HIV as early as possible and that does not hold back some of our best health care workers because of a risk that is more remote than being struck by lightning. The risk is absolutely negligible, we are talking about people being treated so they are not infectious." What we need is a simpler How often do we hear such sensible conclusions from government, or health organizational sources? Little wonder that this decision has been welcomed

Continue on Page 6

Should HIV Serodiscordant Couples Always Take Preventive Measures? Experts Debates

You're in a long-term, committed, monogamous relationship with a loving partner. You are not HIV infected, but your partner is. However, your partner is on stable antiretroviral therapy and has had a fully suppressed HIV viral load for several months.

Should the two of you still take measures (condoms, pre-exposure prophylaxis [PrEP], etc.) to reduce the risk of HIV transmission? Or is unprotected sex "safe enough"?

This is the question faced every day by thousands of couples in the U.S., and many thousands more throughout the world. It was also the issue vigorously debated by two prominent HIV clinician-researchers at a session entitled "Clinical Controversies" at IDWeek 2013. Roy "Trip" Gulick, M.D., took to the podium to argue the "pro" position in favor of continued prevention measures, while Paul Sax, M.D., was the standard-bearer for the "con" position.

The Argument for Continuing HIV Prevention Efforts

"What does suppressed HIV RNA really mean?" Gulick asked rhetorically. "The fact is, it does not mean that there's no virus in the blood." On the contrary, Gulick said, research has shown that HIV is still potentially present in the blood plasma of patients with an "undetectable" viral load (the term typically applied to a viral load below the level of detection in blood using widely available assays, usually less than 50 copies/mL), and that in fact cases of transmission have indeed occurred in this setting.

Further, Gulick added, virus has also been found to potentially be present in the tissue, semen and cervicovaginal fluid of patients with an undetectable plasma viral load, suggesting a very real risk of transmission during activities that traditionally expose an individual to HIV. He cited two examples, in published research, of HIV transmission from an infected partner with an undetectable viral load to a previously uninfected partner. (One was a case report from 2008; the other was a case report from 2012 involving an elite HIV controller.)

It is these sorts of data that feed into an HIV risk calculation model that was published in The Lancet in 2008, which found a small per-sexual-act risk of HIV transmission from females to males (1 in 50,000), males to females (1 in 25,000) and males to males (1 in 2,500) -- risks that appear remote until one takes into account that the average couple engages in sexual intercourse 100 times per year, Gulick said.

In addition, HIV is not the only transmissible pathogen that couples should be concerned about, Gulick noted. Hepatitis C, gonorrhea, herpes simplex (and other herpes viruses), and human papillomavirus are just a few examples of additional, harmful microorganisms that can bring potentially severe consequences to the HIV-infected and uninfected partner alike -- and against which safer sex is the best protection.

Gulick also took a cynical, if realistic, approach on the nature of human fallibility and relationships. Citing results from HPTN 052 and the Partners PrEP studies in which extra-relationship transmission of HIV occurred despite partners saying they were in a "committed" union, Gulick questioned the value of a public health approach based on a trust between partners that was often broken. "Do we really want to advise our HIV positive patients to have unsafe sex?" he asked.

To which Sax responded: Absolutely.

The Argument for Stopping HIV Prevention Efforts

Sax's counterargument largely revolved around a desire for what he considered a more realistic approach to prevention set within the modern context of the epidemic. In the early 1990s, when Sax and Gulick were both fellows at Massachusetts General Hospital, AIDS was a leading cause of death among youth and one of their mentors "basically made us feel that having unprotected sex was the equivalent of a death sentence," according to Sax.

"What Trip is telling you is that he's a product of his time," he said. But what the data show -- "in humans ... not in laboratory experiments, not in models" -- is that the actual HIV transmission rate from a virologically suppressed, HIV-infected person to an HIV-uninfected partner is "essentially zero," Sax asserted.

Sax cited a systematic review of 11 cohort studies that found zero cases of HIV transmission from an HIV-infected partner to an HIV-uninfected partner when the HIV-infected partner's viral load was below 400 copies/mL -- even if the partner was not on antiretroviral therapy.

Sax also referred to the well-known "Swiss statement," a landmark 2008 publication by highly respected clinician-researchers in Switzerland that unequivocally supported the argument that HIV cannot be transmitted sexually by an HIV-infected person who is fully compliant with therapy, is monitored by an attending physician, has had an undetectable viral load for at least six months, and has no other sexually transmitted diseases. "Precision, orderliness ... those are some of the things that come to mind when you say 'Switzerland.' You do not think, 'Oh, they are going to give irresponsible statements about public health,'" Sax said. "And you'll note that the people on this statement were people who are leading figures in our field of HIV research."

Sax also called attention to the 2011 publication of results from HPTN 052, which he suggested may be the most important HIV prevention study to date. That study (a randomized investigation comparing HIV transmission rates in early versus late treatment initiators who were in serodiscordant relationships)

Continue on Page 6

New HIV Prevention Technologies on the Horizon

A vaginal ring that delivers both tenofovir for HIV prevention and levonorgestrel for contraception, a gel containing the experimental antiretroviral IQP-0528 designed for both vaginal and rectal use, and a gel combining tenofovir and the anti-herpes drug acyclovir were among the new HIV prevention technologies presented at the **American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition** this week in San Antonio.

The field of biomedical HIV prevention has seen major advances in recent years. Pre-exposure prophylaxis (PrEP) using oral tenofovir or **Truvada** can dramatically reduce the risk of HIV infection, but it only works with good **adherence**. Researchers are exploring other delivery methods that may be more convenient and encourage better adherence than daily pills. Multipurpose prevention technologies -- for example, combining protection against HIV and other sexually transmitted infections, or HIV protection and contraception -- is another way to encourage consistent use.

*Vaginal ring containing **tenofovir** and levonorgestrel (image: AAPS)*

Vaginal Ring for HIV Prevention and Contraception

Patrick Kiser from Northwestern University, Meredith Clark from **CONRAD**, and colleagues are working on an intravaginal ring designed to deliver a combination of tenofovir and the hormonal contraceptive levonorgestrel for 90 days.

Studies have already shown that a 1% tenofovir vaginal gel applied before and after sex decreases HIV infection risk for women. Putting tenofovir in an intravaginal ring would allow it to be left in place longer. This type of ring was **shown to protect monkeys** from vaginal exposure to an HIV-like virus. Adding a contraceptive could address two needs at once.

"We saw the urgent need to make this dual-protection intravaginal ring because a majority of the world's unintended pregnancies occur within resource-poor regions where the HIV/AIDS pandemic is most prevalent, such as sub-Saharan Africa," Clark explained in an **AAPS press release**.

But putting tenofovir and levonorgestrel together in a ring is tricky because they have different release rates and biochemical properties: Tenofovir is hydrophilic, meaning it attracts water, while levonorgestrel is hydrophobic, or naturally repels water. (**This article from MIT explains the difference**.)

To solve this problem, the researchers developed a segmented polyurethane ring with separate reservoirs that can deliver both drugs simultaneously. Using tubes of different lengths to change the amount of drugs released, they were able to achieve target levels of both tenofovir and levonorgestrel. After optimizing segments for each drug, they tested the combination rings in rabbits and sheep, showing that tenofovir levels in vaginal tissue and fluid were similar to those obtained with 1% tenofovir gel in human clinical trials.

"Products only work when they are used," said CONRAD's David Friend. "By having a ring that can remain in the body for up to 90 days, our hope is that this ring will offer a solution to increase adherence, and therefore provide greater protection against HIV while also preventing **pregnancy**."

CONRAD and collaborators expect to start Phase 1 clinical trials in early 2014 using the combination ring and one containing tenofovir alone.

DuoGel Vaginal and Rectal Microbicide

In another presentation, Anthony Ham and colleagues from ImQuest BioSciences described the development of DuoGel, a **microbicide** gel containing IQP-0528 -- an experimental antiretroviral that acts as both an **NNRTI** and an HIV entry inhibitor -- that is designed for both vaginal and rectal use.

"It is recognized that both vaginal and rectal intercourse occur during the same sexual act, so a single product that is safe for both compartments makes sense in terms of convenience, which is likely to result in higher compliance," Ham explained in another **AAPS press release**. "In addition, these DuoGels will be much safer products for HIV prevention in males practicing receptive anal intercourse."

The researchers developed various IQP-0528 gel formulations using excipients (inactive carrier compounds) approved for both vaginal and rectal administration. They tested the gels' biochemical properties, drug release, toxicity, and anti-HIV activity in laboratory cell cultures and cervical and rectal tissue explants (tissue samples kept alive in a lab). The best DuoGel formulation showed no toxicity to cells or normal vaginal bacteria at the highest concentration tested, and caused no loss of viability in cervical or rectal tissue.

Acceptability and adherence are now being evaluated using a placebo DuoGel without the active ingredient. The researchers are preparing the current gel for animal studies and hope to begin Phase 1 human clinical trials in early 2015. In the next stage, they plan to create a multidrug DuoGel that contains IQP-0528 plus tenofovir.

Vaginal Gels for HIV and Herpes Prevention

Finally, researchers from SRI International reported on the development of a vaginal gel combining tenofovir and acyclovir, which is used to treat and prevent outbreaks of **genital herpes**.

The team developed gels made with different combinations of two polymers, Pluronic F-127 and Noveon AA1. One gel, dubbed SR-2P, retained its structure when diluted with fluids and subjected to "mild simulated coital stress." It showed good adhesion to pig vaginal tissue and caused little or no irritation in a mouse model.

Because tenofovir is compatible with Noveon AA1 while acyclovir is compatible with Pluronic F-127, the researchers are working on a dual syringe that can administer the two drug/polymer mixes from separate compartments.

Holiday Party 2013

On December 14th 2013, Open Door's Client Advisory Committee (CAC) hosted their 2nd annual Holiday Party for the clients and families. There was music, dancing, great food, gifts, and a visit from Santa.

This is just one of the many events the (CAC) hosts or co-hosts . This allows the clients to come together and socialize with other clients and provide a sense of community and support.

The CAC was pleasantly surprised and a little worried

that there was such a great turnout at this holiday party. We thought there would not be enough food for everyone. However, when everyone was done going through the buffet line everyone was fed .The CAC was relived there was enough food and very happy that everyone had such a great time.

The CAC was glad to see familiar faces as well as meeting new attendees. The CAC wants to thank you for coming and making this year's Holiday Party the best so far, and offer an invitation to attend future events sponsored by the CAC. If you attended the

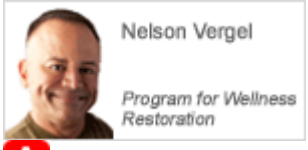
event tell your clinic friends that they missed and excellent event and Santa!

See you at the next CAC Event….

Question and Answer

Q Getting Weak of Just Can't Gain Strength- How to Reverse Frailty

I am a 53 year old male. I have been positive for over 10 years. I have never had any infections. My CD4 is in the 500's, which is good for me, and my viral load is undetectable. I have started taking Testim as well. I try to get plenty of rest and eat healthy. So, why am I unable to make any gains in strength at the gym. I do my best, but I seem to go nowhere. I can't go up in reps or weight, and sometimes I feel like I'm sliding backwards. It is incredibly frustrating, and I'm kind of ashamed at how weak I am for my size (6 ft, 4 in, 200 lbs). I know it could partially be my age, but could it also be due to muscle atrophy or some form of weakening from being positive for over 10 years? Any tips or ideas on what to do?



A Response from Mr. Vergel

There is some data on increased frailty in aging HIV+ people. A study found that our level of frailty is similar to the one of HIV - people 15 years older than us.

This is I would do to reverse some of the frailty, if possible:

1- Make sure you are sleeping well and at least 7 hours a day. If you snore a lot, you may have sleep apnea. Talk to your doctor about a sleep study if so.

2- Go back to your doctor and ask for a thyroid function test and to recheck your free and total testosterone. Total testosterone should be above 500 nanograms per dl to 1000 ng/dl. If testosterone has not gone up to that range, you need to increase the gel's dose or concentration. If your thyroid is low, you may need to take thyroid medication.

3- Make sure you avoid nucleoside analogs like AZT, DDI and D4T since they have been associated with muscle weakness and mitochondrial dysfunction.

4- Eat a light snack like peanut butter on a banana or multigrain toast 20 minutes before exercising to make sure that you have given your muscles enough glycogen for the work out.

5- I am a true believer in carnitine as a muscle catabolism (destruction) preventer. 2000 mg per day is a good dose. Coenzyme Q10 is essential if you are taking statins for cholesterol to avoid muscle problems. Statins lower coenzyme Q10, which is responsible for heart muscle strength and proper mitochondrial function in your organs and muscles. Call the folks from the New York Buyers Club for recommendations on brands, etc. Their contact info is on their web site : New York Buyers Club

6- I drink two cups of green tea also 1 hour or so before working out. As long as your blood pressure does not sky rocket after you take it and work out, green tea can give you energy and there is some pilot data that showed that it may be help fat burning.

7- Use machines at the gym until you feel you are getting stronger. I love cable machines since I have back surgery.

8- Make sure that your bones are strong. The new bone guidelines recommend bone density scans in any HIV+ person above 50. Also, get your vitamin D blood levels checked in winter and summer. Most people have to take at least 2000 units a day of Vitamin D to bring levels up to suggested ranges for bone health.

9- Oxandrolone or nandrolone along with testosterone replacement could improve frailty in those that do resistance exercise. So you may want to talk to your doctor about the use of those anabolics. Oxandrolone is available by prescription as Oxandrin and nandrolone, also by prescription, can be compounded in pharmacies like collegepharmacy.com, apsmeds.com and gotocompoundingshop.com.

10- Remember to eat enough lean protein: fish, chicken, eggs, yogurt, cheese, grains, nuts, tuna, cottage cheese, whey protein shakes (I like Isopure since it is very light), and all color fruits and vegetables.

I think this information should help. Please let me know what works. I hardly hear from people that get my advise about what did and did not work for them. It would be great to have that input so that we can help from your experiences.

HAPPY 2014 NEW YEAR

Don't Forget to Pick up YOUR Participation Cards

"Undetectable": Safe or Not?

Continued From Page 2

by LGBT and HIV groups and more importantly, the umbrella organizations of surgery and dentistry.

Are there any further implications for undetectable people living with HIV?

Well, let's put this in context. There's still no definitive proof that being undetectable, on treatment and immune-healthy means no risk of transmission. In world terms, this is also a small step to benefit a relatively small number of people in the UK but it suggests that health authorities are beginning to think differently about the issue.

If health workers are deemed to be no risk to their patients, with all the possibilities of cross infection via blood and bodily fluids, then by definition, non-health workers with the same HIV profile must also be of no risk to their partners. Or is that an assumption too far and wishful thinking? Am I missing something? You can't imagine that the top health experts in the UK are taking a risk here, based on a mistaken premise; so when will the rest of the world, including HIV organizations and the media, put two and two together and come up with four, instead of five, six, or seven!

Once again, it can't be stressed enough; you can't escape the fact that there's no official, scientific proof. The studies so far have been grasped at by many as being suggestive of proof but they are few and far between and hardly large scale and none have been directed at gay men having gay sex.

So it seems reasonable to surmise; what do the health authorities in the UK know that the rest of us don't?

Should HIV Serodiscordant Couples Always Take Preventive Measures? Experts Debates

Continued From Page 3

found seven cases of transmission in the delayed therapy group, but only one in the early treatment group -- and that single case occurred prior to the patient achieving virologic suppression. Not that HPTN 052 was the only study to see such findings; Sax noted several additional studies published between 2008 and 2011 -- elucidated in a PLoS

One article earlier this year -- showing a nonexistent transmission rate among patients with an undetectable viral load.

"Protection for these individuals is no longer needed," Sax concluded. "Are we actually going to be taking no risks in our life? ... Unprotected sexual intercourse is a viable option -- I'm not saying recommend that they stop using protection, but it's up to them -- for serodiscordant couples in long-term, monogamous relationships."

Where do you stand on the issue? The audience present at this debate -- a collection of infectious disease clinicians and researchers -- overwhelmingly sided with Gulick's assertion (by a margin of 63% to 37% among those who voted via remote controls located near many seats) that serodiscordant couples should perpetually take preventive measures to curb the risk of HIV transmission. But surely that won't be the final word on this challenging, complicated question.

IF YOU ARE INTERESTED IN RECEIVING OPEN DOOR'S MONTHLY NEWSLETTER VIA E-MAIL OR HAVE ANY TOPICS THAT YOU WOULD LIKE TO SEE IN THE NEWSLETTER.

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JANUARY EVENTS

01 - HAPPY NEW YEAR
Clinics Closed
03 - HIV/AIDS Activity Education Group 4p-6p (A)
06 - Substance Use Group 11a-12p (A)
06 - Smoking Cessation Group 1p-2p (A)
07 - Positive MH Group 4p-5:30p (A)
08 - Positive MH Group 4p-6p (E)
10 - HIV/AIDS Activity Education Group 4p-6p (A)
13 - Substance Use Group 11a-12p (A)
13 - Smoking Cessation Group 1p-2p (A)
13 - Game Night 4p - 6p (W)
14 - Positive MH Group 4p-5:30p (A)
15 - Positive MH Group 4p-6p (E)
15 - Positive MH Group 4p-6p (E)
16 - CAC Meeting Group 5:30p-7p (G)
17 - HIV/AIDS Activity Education Group 4p-6p (A)
20 - Newsletter Articles Due
20 - Substance Use Group 11a-12p (A)
20 - Smoking Cessation Group 1p-2 p (A)
20 - HIV/AIDS Activity Education Group 4p-6p (A)
21 - Positive MH Group 4p-5:30p (A)
22 - Positive MH Group 4p-6p (E)
24 - HIV/AIDS Activity Education Group 4p-6p (A)
27 - Newsletter to Clinics
27 - Substance Use Group 11a-12p (A)
27 - Smoking Cessation Group 1p-2p (A)
27 - Game Night 4p-5p (W)
28 - Positive MH Group 4p-5:30p (A)
29 - Positive MH Group 4p-6p (E)

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