Transcript: Beyond Condoms: Medical Approaches For Prevention

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In a videocast interview from the International AIDS Society Conference in Sydney, Regan Hofmann talks with Dr. Nancy Padian from UCSF about PrEP, microbicides, and circumcision, and asks “when can my boyfriend and I stop using condoms.” To see the video, click here.

Regan Hofmann: Hi!

Nancy Padian, MD: Hi! Nice to see you.

RH: Nice to see you. I’m here with Dr. Nancy Padian, who is the director of International Programs at the AIDS Research Institute of UCSF. Thank you for joining us today.

NP: A pleasure.

RH: We’re here in Sydney, in Australia, and we’re going to talk about a few things today. One is I know you do a lot of work with women and behavioral issues. You know, we’ve talked a lot about PrEP and the idea of treating people prior to a potential exposure for HIV. What do you think about…this application has mostly been tested in men, but what is the implication for women and the use of PrEP in terms of changing the paradigm for how infection is spread.

NP: Well, I think there’s an incredible potential and, as I think you know, a lot of the international studies are being done involving women and certainly there’s every reason to believe that it could be as effective for women in preventing acquisition of infection as it could for men. I mean, it’s the same mechanism of action. It’s not female-controlled in that men can use it similarly, but it could definitely be a female-controlled method where women could protect themselves, if it’s efficacious.

RH: Right. When do you think we’ll get data on this?

NP: I have it in my slide; I don’t have it in my head. I think probably in the next couple of years, but all of the studies have target endpoints that would be easy to find out.

RH: Right. Now, as I understand it, in the studies they’re mostly testing men who are HIV positive having serodiscordant relationships with women who are negative and the women taking the antiretrovirals. Will it work in both directions?

NP: Well, I think you have to test it in both directions, but my understanding and again, this is something you’ll probably have to edit out, I think that the designs go in both directions, but I

would have to check.

RH: Okay. Is this like when women had the birth control pill and it sort of changed the way men and women have sex?

NP: Well, people are using that analogy. Now that said, I think that whether it would be efficacious enough to the point where you wouldn't have to use condoms I think is really something that's for the future. I think at this point everyone's seeing all of these prevention methods as enhancing and something that should be used with condoms and not something that's going to replace that. And I think it's really important to know that.

RH: Right, but I think it's a step in the right direction to give a tool to women.

NP: Oh, unequivocally. I mean, this epidemic, and especially in many countries in the developing world, is driven by gender disparities.

RH: Right. And especially as HIV is spread more in marriage.

NP: You're absolutely right and one of the advantages of PrEP is that one could imagine that a woman could take it perhaps without her male partner knowing.

RH: Right. And I know in a lot of countries, I've just been traveling in Asia in particular, the women are not empowered as they are in the West and if they were to ask their partner to wear a condom they could be thrown out of the relationship or out of their home or their village.

NP: Absolutely and that's the whole impetus behind the entire field of research for female controlled methods. And I think what your asking is that sometimes people are just thinking about microbicides, barriers, and they're not thinking about PrEP as part of that, but it actually would fall into that category of methods.

RH: Now, we've known about PrEP or the potential for it to be efficacious for a long time. Why has it taken so long?

NP: Well, these studies are hard to do. I mean, these studies, just having finished one myself, these studies take a long time, there's a lot of moving parts, there are phases of studies—you don't just all of the sudden go to a giant Phase III study. Each study represents almost a field of research from soup to nuts and it takes several years.

RH: And of course the outcome is potential infection, so it's…

NP: There's that as well.

RH: A much more dangerous situation.

NP: Absolutely. So you have to be very cautious about how you do it and it's just not easy.

RH: Now tell me a little bit about microbicides, both for vaginal and for anal use.

NP: Well, actually now I'm glad that you brought that up because one of the things I was going to say about PrEP is that, the other possibility is that some of these antiretrovirals, in sort of the same way that PrEP works which is that you take it in advance, but in this case it would be vaginal application, also of, perhaps some similar antiretrovirals that would be used for protection. So I think that we're about to see—I mean, there's been some disappointing results—but people are

very hopeful that, in a PrEP-like product, that is a antiretroviral with specific viral targets, used as a microbicide would, in fact, have a lot of potential.

RH: Right. About microbicides, when can we expect to see something in the market?

NP: In the market, well, I think everyone is looking towards, sometimes people call them second-generation microbicides, ones that are based on antiretrovirals, it's still going to be…the *large* scale trials, that will involve …I'm guessing. At least five years, I'd say.

RH: Right. Five years.

NP: I could be wrong.

RH: We hope___

NP: It's still years away.

RH: Male circumcision—let's talk a little bit about that. That's been another hot topic. What is your feeling about how effective male—adult male—circumcision is as a prevention method.

NP: Highly effective. I mean, it's the best thing that's come out of these studies so far, but I think, as you know if you've been to any of the sessions, the issue is sort of the cultural and the social context in which it's being promoted and have we adequately…the other thing is "we." That sort of highlights the problem, which is you can't just, because it has efficacy, doesn't mean that you can ensure that people will adopt it and it's up to those people and it has to be a collaborative process. And, you know, Bob Bailey, I don't know if you want to his talk this morning, he did a great job talking about some of those issues. And I think we will see more scale-up, but it's not completely trivial where you get these great results for a study and "boom," you know; you can just scale it up. There are lots of issues involved.

RH: Right. What are some of those issues?

NP: The issues are cultural acceptance of the practice. We also need to do a little bit more work on disinhibition, that is, if you're circumcised are you likely to have higher risk behavior, although Bob Bailey really presented some good data to the contrary. The other thing is, you need to be sure, there's a little period of increased risk right afterwards.

RH: Because of the healing?

NP: Yeah and so you have to sort of abstain and, then again, keep in mind that, as we were talking about with PrEP, I think everyone is sort of advocating circumcision as part of a larger prevention practice, which includes condoms. And we need to come up with ways to ensure that, when it's promoted, it is promoted as part of a larger prevention package and not as a magic bullet in and of itself.

RH: Right, so it's almost a harm reduction technique as well as prevention.

NP: Yeah, sort of. I would say it's a bit more than that. I mean, there's really good efficacy data and so it's not exactly harm reduction, but the idea is that is promoted as part of the larger… It will make that prevention package all the more strong, but not that it should be promoted in and of itself.

RH: Right. And for adult males in other cultures, is that a significant medical procedure for them to go through, to be circumcised?

NP: Again, it's not my area of expertise. I think it can be done safely. They've done three trials now where there've been minimal adverse events and so I think the data are there that it can be done safely, if people are willing to do it.

RH: Now, you have a plenary talk tomorrow morning. What are you going to be talking about?

NP: I am going to be talking about methodological challenges in some of these prevention trials and use my own study, which was looking at the female diaphragm as illustrative of what some of these challenges are.

RH: And can you elaborate a little bit more about…?

NP: I'm going to be talking about that if you have a prevention method that has a modest effect as, you know, circumcision is a big effect, it's like 60 to 70% protective, but if you have something that has a modest effect and it's hard to be able to detect that in our current study designs. We're really promoting condoms, we're doing STD treatment and diagnosis you're wanting to look at the marginal effect of the new intervention on top of that and it's difficult to do. So then you might say, "Then why do you need the new intervention," right? And I do think there's something to be said for that which is we need to a do a better job scaling up what we know works which is male condoms, counseling and testing, STD treatment and diagnosis. I think one of the issues is, as we were talking about female-controlled methods, many women cannot or are not in a position to negotiate male condoms and, for them, these interventions that perhaps, at best, have a modest effect, it's very difficult to be able assess that effect in the context of everything else that goes on in a trial.

RH: Right. We wrote about PrEP in *POZ* and it was interesting because looking at the data and seeing that, just as you described, when they were doing these trials, to be fair to people, they had to give counseling, education, they had to distribute condoms and therefore they got the incidence down so low that it was hard to see, hard to have a control group.

NP: You summarized it.

RH: So, I think it's very important for people to understand that that's sort of a good byproduct that comes out of these trials.

NP: Absolutely. It is a good byproduct.

RH: And do they share that sort data out of these, I mean, it's secondary data, but it proves a point.

NP: No, no, no! I mean, it's not even secondary data. The fact is that if you have reduced incidence in your control arm, there's your data.

RH: Right, exactly. So, as a woman living with HIV in 2007, what are some of the most important things I should be looking forward to in the future in terms of…I mean, if you had to rank them: microbicides, PrEP. Because I'm asked all the time by women, especially in the states, "When can I have PrEP? When can I have a microbicide?" They know people are working on these.

NP: I would say it’s still years away but it will happen. I know that’s sort of a fudge, but I think that that’s the case.

RH: So, as a woman who’s used condoms my whole life with my partner…

NP: Got to still do it.

RH: Still do it. And all the way through, even when these new treatments come out?

NP: I think so, yeah.

RH: Just to be doubly sure. I just wanted to thank you very, very much for joining us and for being on POZ.com and AIDSMeds.com and good luck tomorrow with your plenary.

NP: Thanks, and I wish you all the best, I really do. I think it’s very brave and great that you’re doing this.

RH: Thank a lot.

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http://beta.docker.poz.com/article/prep-microbicides-circumcision-13270-4764