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DIANE HAVLIR: Today's plenary, Turning the Tide on Transmission, is a vital one. As you heard today from our plenary is a high priority. We're making great progress, and we need a vaccine. Women are still disproportionately affected by HIV/AIDS, and that needs a dramatic turnaround in terms of our AIDS response.

I'd like to start without further delay and introduce our first speaker. Dr. Bart Haynes is really one of the leaders in American science and immunology. He's director of the Duke Human Vaccine Institute and Center for HIV/AIDS Vaccine Immunology. He will talk to us about HIV vaccines.

BART HAYNES: Thank you, Diane. HIV vaccine development has faced many roadblocks over the past 25 years. The two roadblocks that I chose to talk about today are the two major ones facing us. That is understanding what types of immune responses we need to induce in order for the vaccine to be protective, and secondly, the holy grail, if you will, of HIV vaccine research, that is being able to induce antibodies that will totally prevent transmission and work against the wide variety of HIV species that are infecting people around the world today. These antibodies are called broadly neutralizing antibodies.

What I talked about initially was the RV144 trial, and what we learned from the RV144 trial. If you go back six or

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seven years, HIV vaccine development was still working on an empirical basis. We would try all of those strategies that have worked for past vaccines, and that's the way most vaccines have been made, using empirical trials.

What we have learned is that we are not making enough progress. Seven years ago, the field got together and decided to work in a different way to try to understand the biology of the virus. Now, about 10 years ago, the RV144 trial was started and was announced in 2009 and showed an estimated efficacy of 31-percent decreased risk of transmission using that vaccine versus a placebo.

Over the past two years, a global initiative was spawned to look at those immune responses that were associated with the increased infection risk. I talked about an immune response against the envelope that the field is now working on to try to understand how that might have protected. We don't know if that immune response protected. That's what the field is trying to find out now.

That vaccine trial did not induce broad neutralizing antibodies. We believe that the ultimate success of a global vaccine that will work anywhere in the world is going to be a vaccine that induces antibodies that targets the Achilles' heels, those conserve regions that every active a virus has, and to which antibodies combined. One of the things that's frustrated the fields so much over the past years has been the

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fact that even though we've immunized both humans and animals with the outer coat of the HIV envelope that has these Achilles' heels exposed, the body chooses not to make these kinds of antibodies in a vaccine setting.

Two advances within the past couple of years has been number one, using some very new technology. A number of investigators led by the group at Scripps has found a number of new broad neutralizing antibodies that prove that humans who are chronically infected with HIV can make these antibodies, and therefore, humans can make these antibodies. The question is, when they do happen, what happens such that these are made? How do you convert that into a vaccine strategies? That's by and large what I talked about with regard to broad neutralizing antibodies.

Then I guess in addition, we've learned an awful lot about what happens when the antibodies are not made. That is that the host tends not to make these because many of these antibodies, or all of these antibodies, are highly unusual, and many of them are controlled by what we call tolerance mechanisms, the dampening effect of the human immune system to prevent certain types of antibodies to be made. Exactly why the broad neutralizing antibodies share these traits that make them vulnerable to being modulated or down-regulated or not made by the human immune system is what we're working on now.

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What's different now than in the past seven years is that before we've really had no clues. Now, we have clues and a direction, and we're moving with rational strategies now that we know the face of the enemy and we know what the problem is.

DIANE HAVLIR: Thank you very much, Dr. Haynes. Our second speaker is Chewe Luo, who is Senior Adviser, HIV/AIDS at UNICEF, and the title of her talk was *Turning the Tide on Children and Adolescents*.

CHEWE LUO: Thank you. What I tried to do this morning in addressing this topic is to structure my talk into three main areas that are important in turning the tide on children. I started off by talking about the global effort to eliminate mother-to-child transmission and keeping mothers alive. I then talked a little bit about the importance of making sure that we treat the children that are getting infected early to prevent them from getting AIDS and dying. Finally, I talked about protecting children in the second decade of life. We can do everything we want to do around prevention in early childhood and also treating kids, but if we're going to lose them in adolescence, that's something that we really need to focus on.

Just to highlight some of the things I said around elimination of mother-to-child transmission, I actually started off by saying it's been as far back as 1994 since we actually discovered that giving antiretroviral drugs to pregnant women that are positive can actually reduce transmission. In that

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particular landmark study by Conner and colleagues in the U.S., 67-percent of infections were actually avoided by giving mothers antiretroviral drugs during pregnancy, during labor, and to baby post-labor.

Now, the issue has always been for the developing world that that particular, what we call the PACTG 076, regimen was very difficult for some of us that were working in the developing world to actually adopt. There were a number of things, and I can highlight them here. One, the cost of the regimen of the time was \$1,000 per woman treated. Now, that was way beyond what could be imagined in the developing world.

The second point was that it was awfully complicated starting from 14 weeks, going into labor, and actually changing the regimen to actually administer that regimen by intravenous infusion, and then the post-labor to baby just seemed impossible for a lot of the settings where you're lucky if the woman comes to antenatal clinic once.

What has happened over time, which is very exciting for some of us who've been working in this area, is the partnership that emerged between the scientist, the policymakers and also the people that were supporting in terms of the donor community that was the supporting this particular initiative, that gives us the confidence now that we can eliminate.

The body of evidence has been from as far back as looking at simplicity. Can we actually deliver this

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intervention close to delivery? Can we change how we deliver during labor so that women don't have to come the hospital to actually have the intravenous infusion to get the drug, and can we also look at the whole effort of breastfeeding knowing that in many of these countries, breastfeeding is extremely important for survival of children?

This place that we're in right now in terms of the science is that we have the body of evidence to actually say we can actually reduce this transmission in positive women down to less than 5-percent in all settings including in settings where women are actually breastfeeding. What I tried to highlight in my talk is that despite what we're doing that, despite the fact that the data that has been released at this conference by UNAIDS saying that 57-percent of women in low- and middle-income countries are actually receiving retroviral drugs for prevention of mother-to-child transmission, when we look at the trajectory of where we're going and how much reduction were making year by year to get to the space where we want to say we have eliminated this infection by 2015, we're totally off target. The analysis that we've done is that at most, we're reducing this infection by 10-percent each year. What we have today is 330 children actually acquiring new infections every year if we look at the 2011 statistic.

What I am suggesting, and what I think a lot of people are starting to rally behind, is the fact that in fact, part of

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the problem is we have focused our interventions on prevention. Prevention of infection from mothers to children, and we have not actually looked at how we can we efficiently program or transform our programs to identify those women that need treatment for themselves, and why is that? The data that we have is that in any hospital, any clinic in any part of the world, and you ask them yourself that of the women coming through the door, what percentage of these women who need treatment for their own health. What is clear is that the percentage is quite huge.

The study from Zambia which I highlighted in my talk demonstrated that it was as high as 68-percent of those women coming through the door. Now why is that important? It's important because these are the women that are transmitting the infection. Two, most of the infections that are happening today are from women who need treatment for themselves. Second, if we do nothing about these women, they will die in the next 24 months. Third, if we have to do anything about the huge epidemic that we have, especially in Africa, on orphaning, we need to do better at identifying women that need treatment now.

Now, the new standard that WHO has put out on B Plus for us is a step in the right direction. The one thing it does do is develop a standard for all women that is applicable across the board. We do away from the fact that you have to

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have a CD4 four less than 350; you have to - we're going to have one standard where we say every woman coming through the door, the optimal regimen that they need is treatment.

Now, the issue with that is that we need to make sure that the delivery of this intervention is very efficient. The second point that I made in my presentation is that this is only going to happen if we keep treatment simple and our programs simple to the level that every person in the health care system can relate to this. What I'm suggesting is that part of what we have to do is to integrate these programs in the primary health care facilities, the lowest level of care that a woman is likely to access.

What gives us the confidence that we can do this? The fact that WHO has put up an update the talking about the safety of Efavirenz in pregnancy gives us a step in the right direction in that, for the first time, we can now talk about the one pill once a day of Tenofovir 3tC and Efavirenz, which can then be delivered at the lowest level of care without complexity. These are the sum of the things I talked about, but it doesn't stop there.

The second point that I talked about is the whole issue that we not doing enough on treating children, and the statistics that had been released at this conference that 28-percent of children today in low- and middle-income countries are accessing treatment is unacceptable. One of the things

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that I highlighted in my talk is that we're still grappling with how do we test these children? How do we identify them and link them into care?

Part of the problem is the standard we have today, that DNA PCR for diagnosing infants is not actually achieving the results that we need. The fact that we have to do dried blood spots, put some blood on a filter paper, transport it to some remote lab, and then the remote lab should send those results before we even link children into care. We're losing a lot of children. Our analysis in UNICEF is that by one year of age, even the children that we would have invested in identified as infected, we don't know where they are. They've either died or their lost to follow up.

What is the value on our investment? One of the things that that was actually released here and UNITAID, and I applaud UNITAID, is that UNITAID is going to invest \$140 million on point of care diagnostic technologies. For UNICEF, we're very excited about being a partner with UNITAID because for the first time, we'll start looking at the feasibility of putting these very small machines, costing \$5,000 per machine, into the low-level facilities for us to be able to do two things.

One, we'll be able to do HIV testing in kids, but secondly, we'll also be able to do CD4 for mothers at the point of service. These are the exciting developments at this

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conference they give us confidence that we can achieve elimination.

Finally, I just want to talk to the fact that all this as well and done, but if we can't protect the second decade of life – all the investments in PMTCT, all the investments in treatment – we have to do better in identifying infected adolescents, and we have to do better in making sure that adolescents have access to testing services and high-impact interventions for prevention. Thank you.

DIANE HAVLIR: Thank you, Chewe. Our final of speaker is Linda Scruggs. She's a consultant, a community leader, and her plenary topic was *Making Women Count: A Comprehensive Agenda*.

LINDA SCRUGGS: Good morning, everyone. Please let me start by point of clarity. It was brought to my attention at one point in my talk when I was speaking about providers. I noted providers were bad when they continued to stipendize consumers. I said providers are bad you. The screen wrote bad Jew. I do apologize. Under no intentions or no mistake did I say such a word or give such an intention to the community. I came here unified as a woman. I came here unified as a Christian loving all people, so I did want to make clarity that that was an error on the part of the transcriber. I said bad you.

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My talk this morning was really focused on me being a woman diagnosed and living with a diagnosis of HIV for the past 22 years. As the moderators noted, I am a consultant. I've run national education and training program for the past 10 to 12 years, but I came to the platform this morning talking about the day in November when I was 13 weeks pregnant and my life changed. That life changed because really identifying as a woman who did not but have risk, who was not from the inner city, who had not been a drug user, who had not slept with drug users, who had all her needs met, I took a routine test within the clinic of perinatal care and received a positive diagnosis for HIV.

Somewhere along my life, as a heterosexual woman engaging with heterosexual men, I transmitted to HIV. I came here to talk about the power of stigma, the power of disclosure. I came talking about the difference in the complexities that women living with HIV bring to this arena, everywhere from the young lady I gave a description of named Karen, who lives in Baltimore City, who spent 38 years as an IV drug user in the community and in the system of care that continued to lower her and to stigmatize her for her choices or un-choices or her realities of the life that she lived.

I shared of a woman who lives in Northern Virginia, who's a vice president in a national corporation, but because of the stigma, because of the shame because of us, many of us,

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maybe even in this room and in this place, who've not always championed HIV, she lives within the secrecy of her diagnosis. Her husband died as a complication of AIDS, and they had to tell their family because in middle class white Michigan, HIV was really unacceptable. After all, as far she knew she'd only been with one man and he had supposedly only been with her. They told their friends and family that it was lung cancer, but when he died in 2000, she received her diagnosis the year before.

I came talking about we were, as women, a comprehensive agenda is really addressing the complexities that women bring to the arena. It talks about we are mothers. We're partners. We're spouses. We have jobs. We need skills. There's a lotta things that incorporate women. We come with trauma. HIV did not start at the door the day that I received my diagnosis.

HIV may have started the first time my uncle touched me. It may have started the first time in middle school when someone introduced me to marijuana. Why did I accept it when I knew it wasn't right? I can't tell you where HIV started with me, so it's hard for me to tell you where the comprehensive agenda must begin. I believe that it has to start when we begin to birth our daughters into the world.

I think that we really need to go back and retool our systems that they really do allow for the complexities of a woman who has to catch four buses and then walk three more

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blocks to get to the clinic, or a woman who has to come the night before because it's a three or four hour ride to appropriate health care system that doesn't have the stigma, that doesn't bring condemnation to her. I really didn't come to apologize or to ask for anything. I did come and note that there were few things we were given directions to.

I think we spent two decades asking to make us count. I think we've been spending those – like if we keep asking something, maybe it hasn't been heard, or maybe it wasn't understood, so I'll repeat the directions that I gave. We've talked about – to truly make women count, to really turn the tide on our needs, that we needed to accurately count all women. This is all women inclusive of race, sexuality, sexual orientation, all women in research, data collection, and surveillance.

We're constantly underrepresented in the work supposed to be on our behalf of all persons living with HIV. We talked about the meaningful involvement of women at all levels, the importance to have women not only at the table, but in the power positions to have authority and influence that is meaningful at tables that were not designed for them. That is not a myth to this country or any other country. HIV did not start in the women's backyards.

It started in a gay male response. It was fought and championed by gay men, but as a result, we, too, sit at the

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table now, and we have to prepare for that change and really give women the tools. It's not enough to have the title, we must be able to have the tools to be effective to support our sisters.

We must capture social and economical factors that lead to the increase of vulnerability in worse health outcomes among women. Our social impact does impact women. When a woman receives a diagnosis, she doesn't receive it alone. She receives it with her family, her children, her partners, her community, her church, her synagall [misspelled? 00:21:34]. Everything around her is impacted by her ability to, or not to, be able to access the life care that she needs.

We talked about addressing the inequality and the balance against women in all regions, that we must bring any end to the criminalization and violation of rights of women living with HIV, especially our sisters both behind bars, who continue to use drugs, and who are sex workers. These are human rights. We need to stop marginalizing women and acknowledge that we're talking about all women.

For the U.S., recently the president has formed the interagency workgroup looking at the intersection of HIV and violence against women and girls. We applaud this action, but we really call for support and resources to be able to sustain these committees and these groups and the research. There's no use in having a national AIDS strategy. There's no use and

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having these groups to find the information if we don't have the adequate resources to implement them in our communities.

Another piece that I really wanted to talk about this morning, I didn't get to spend as much time, was the importance of peer-to-peer support, woman-to-woman support within leading organizations as well as talking about accessing and getting women into care, understanding the complexities, what that means and the different dynamics that women bring to any arena and the importance of other women being the role model, other women being hope and vision for her.

What's been successful in my life and in many other the women in this community is we've given women a I. We've given them hope. We've given them someone to look at, someone to say outside of all the ills that I've performed in this world, outside of every drug that I've used, outside of every bad decision I've made, I made a conscious decision on this side of HIV to live and to live again. I made a conscious decision to be a part of, and not a part of what could have been.

We but have to put women in the position that they don't just see us in and platforms like this. We need champions within our community. We need champions within our organization just as the male gay community, they championed. They gave visual. I can list 100 names of men that men have called out. We need to be able to put women in the same position, that it's okay to be in my workplace and wear a

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button that I'm HIV-positive and I live in your community. It should be okay for me to be on the subway, and if someone noticed that I read something about HIV, that doesn't mean that I have HIV.

We have to be in a position that we de-stigmatize the ills and the wrong ideologies and the wrong stigmatization that came up about this disease over 30 years ago. At some point in time, we have to be able to give women the opportunity to be free, to live shackled-free, to live with peace and serenity, and to be whole again. Thank you.

DIANE HAVLIR: Thank you, Linda. The session is now open for questions. I would request that for your questions, you identify your organization and also, please keep the questions as short as possible. Thank you.

LAURAN NEERGARD: Lauran Neergaard [misspelled?] with the Associated Press for Dr. Luo. Do you have any idea of how many of the countries aside from Malawi are moving toward this option B Plus and how they're faring as they do that?

CHEWE LUO: We have been actually following up that trend, and it's actually quite exciting that a number of countries are actually starting to do that. Off the cuff of my head, I can talk to Botswana, Rwanda; South Africa is having conversation; Zambia is having conversation, so it's come around. It looks like countries are actually starting to think through this and having discussions within their countries.

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As I said in my plenary, part of the problem is actually for most countries, is where's the money going to come from? We're also watching the tide in terms of the cost of the regimen that we are recommending, which is the one pill, once a day of Tenofovir 3tC and Efavirenz. Just in the last year, the price of that drug has dropped from \$180 per year per woman treated to actually \$125, and Clinton Foundation is actually following up on that.

Apart from that, we're also starting to talk to the donor community, especially the global fund, PEPFAR, to see whether we can work together to support those countries that want to make that transition. Just because of the prevention benefits and also the treatment benefits that I highlighted in my talk, that if we're going to have more efficient programs, we actually do need to support.

In our modeling work that we've done, it's very clear that the upfront cost may actually be higher, and we estimate for the 22-high burden countries that we're focusing on that we'll need probably \$300 million more than what the current estimate of what we need is, but that seems to balance off in the next two or three years just because of the benefits that we'll see in implementing this regimen.

LAURAN NEERGARD: Thank you.

CHERYL WETZSTEIN: My name is Cheryl Wetzstein with the Washington Times. There has been a real elevation of black

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gay and bisexual men, new data showing that they're really the focus or they really have a major problem. They want to be the focus of the AIDS battle. Now I hear that you're elevating women after two decades. There's got to be some intersection here between these two groups, and I'm wondering if you can address what are the next steps to handle both the elevation of black MSM and women of all colors? Thank you.

LINDA SCRUGGS: You're definitely right. There definitely is; one of the highest new infection rates are among young African-American men who have sex with men. I think there are a number of things being elevated to support that. I think for this morning and this panel, I'm elevating women because that was the focus of the panel.

Is there intersection? I think there is, but I probably would still go with for today, I would like to talk about the major disproportion rate of black women with HIV when we look around across the pinnacle of HIV infections and infections of women over 50, and black women over 50, race of new infection.

Definitely, there is a place in the conversation for young, black MSMs, but I think for today, women really would like to have the platform to talk about we are disproportionately infected, that we need to be able to have the resources, and that really, the focus on us today is okay, and that it takes nothing away from our gay or MSM brothers.

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CHEWE LUO: I couldn't agree with you more. I think we're starting to see this across the globe, including Africa, but the problem for us is people will support programs all over the world. It's just the paucity of data to actually inform what we have to do with AIDS advocacy or programming. One thing I did same a plenary is the need for us to actually come together to make sure that we develop the relevant tools and networks to identify this as a problem, to inform what we do in many of these countries.

One of the problems that I'm sure you're aware of is just also the attitude of our governments towards young MSM or black MSM, especially in Africa. The push for better legislation and support, less stigma, discrimination is something that were already doing, but it's founded on very little information for us really to push hard on this.

The reaction has always been if we hear that a young MSM or an MSM has been arrested in Senagal, for instance, or in Uganda, then we build up the advocacy with government for that not to happen. We don't have enough information on which to program, and a lot of organizations are starting to look at what are the type of networks we need to feed into for us to do this effectively?

LINDA SCRUGGS: If I could add, I would also probably note that as intersection, when we talk about intersection to women and we're talking about men, where the absent community,

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really, the invisible black community is black heterosexual men. I really would love as well when we begin to talk about women, we also note that women, when they're in heterosexual relationship, they're in them with heterosexual men.

That's an invisible category when we talk about research, when we talk about collection of data, when we talk about intersection of women. It's not necessary the MSN population, again, taking nothing from them, but it really is the absence of the heterosexual men that these women are engaging with. I'm just one of probably many women do believe that every black man in this world is not sleeping or have slept with another black man, so women are engaging their relationships with heterosexual men.

VENA: My name is Vena [misspelled?] from VOA Indonesian Service. My question is for Ms. Luo. In many developing countries including my country, Indonesia, there's not enough ARV formula for infants and children. Sometimes, what they do is divide the adult fixed formula, and then give them to children. What's the risk of doing this, and what is UNICEF doing to improve this? Thank you.

CHEWE LUO: We are aware of the practice, and it's something that we do not encourage just because when you do that, you don't even know what dose you're giving to the baby because the specificity of dosing in babies is very important,

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not just from the issue of toxicity, but also resistance developing if you're under-dosing the baby.

What are we doing about it? I'm for one, one person who is very concerned about – the global push for elimination is becoming a disincentive for actually pediatric HIV Care programs. Having said that, there's a lot of effort going into standardization of treatment algorithms for children, that also standardization of what we actually need in the field for children.

The idea that when you look at AZT, for instance, or Zidovudine, you have probably more than seven types of formulation for kids compared to maybe two dosing platforms for adults is a problem. What that does is that you're fragmenting the delivery of these drugs so much that it becomes a disincentive for industry to actually produce these formulation.

What we've been doing as an interagency task team on pediatrics and also mother-to-child transmission is to come up with a standard list of what we need in each country so that those lists actually get into the drug formularies of countries, and by so doing, we hope that we can continue to stimulate pharma to produce those products for children.

I also talked in my plenary about the continued research that we need to actually be able to standardize some of this. Fixed dose combinations for kids are very limited.

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We still need more research on that. Whether liquid platforms are better than sprinkles, we need to look it that. We continue to stimulate that type of research with the research community to make sure that we have the right platforms.

On top of that, we also have the PPP platform, private public partnership platform with industry where we continue to talk about this and to hear them out as well in terms of their investments and what they would like to focus on.

DIANE HAVLIR: Thank you for your questions. This session is now closed, and our speakers will be available afterwards for additional questions. Thank you.

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