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**2008 Ryan White HIV/AIDS Program Meeting  
Opening Plenary  
Health Resources and Services Administration and the  
American Academy of HIV Medicine  
August 25, 2008**

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**STEVEN YOUNG, M.S.P.H.:** Good morning. Welcome to Washington D.C. and the 2008 Ryan White HIV/AIDS Program All Grantee Meeting, *A New Era, A New Act*. And it is an honor for me to moderate this opening plenary.

Personally, I've worked in the program since the beginning and before, and I'm always humbled by the site of this group, the work and tremendous impact we have had. Roughly, 2,500 strong are in this room and it helps bring into perspective our work and reminds us why we do what we do, but only partially so. I know many of you have colleagues, who are working hard back at home, in hundreds of communities, in thousands of agencies serving hundreds of thousands of people. And we trust that you will learn much at this meeting and that you'll bring back that information to your colleagues.

Now the words we just saw on the screen make the point of what this program means to so many. So many services, so much creativity and adaptability, so much working together and yes, even the occasional conflict, let's admit it. We are after all, human.

We'd like to start off this morning with a little audience participation, a big round of applause for the Ryan White Program, ourselves and the work that we do. [Applause] And that is a good way to help people wake up.

So much good, but we have also seen so much loss, and so much change. Early on, this program was about helping people die with dignity and comfort and pride in their homes and in other settings. And that strong undercurrent of the human soul remains within our core even today, though what we strive for is different.

Today we are about life, about doing work the right way, at a high level of quality. And this meeting is constructed so that we can share in our collective experiences. This meeting is about what lies ahead in our ever evolving quest to seek better ways to provide care, hence, the title; *A New Era, A New Act*.

But before we walk off into the future, let's take a moment and remember where we came from. Let's remember those who have left us, their dedication and spirit. Look at the panels around this room; you may know some of the people that are on these panels. Get a glimpse of their legacy and look from within, from within your soul to connect with the dedication and spirit that they have left us. If we could please as we've done in the past, a moment of silence for them. Thank you.

Okay, let's get started with a few important acknowledgements. The first goes to our meeting co-sponsor, the American Academy of HIV Medicine. [Applause] They are an organization of HIV specialists dedicated to promoting

excellence in HIV/AIDS care. Thanks to the Academy for joining with us this year, and they will be hosting our luncheon tomorrow.

I also want to acknowledge the staff of the International AIDS Society, USAID over in the corner, front corner here. [Applause] And they have been working with us on our clinical update, along with co-chairs of the clinical update, Dr. Laura Cheever, Dr. Michael Saag, and Dr. Carmen Zorilla, and you'll be meeting them shortly.

And as you know, once again this conference is a twofer, if you will, two meetings in one, the Grantee Meeting and the Clinical Update going on simultaneously. And finally, thanks to the Kaiser Family Foundation, they are broadcasting this opening plenary as well as the closing plenary as a web casting event.

And I would encourage folks in the back of the room if you want to sit down there are some seats up here. So please feel free to move forward as we begin.

So, the next three and a half days, what will they bring? We have a 180 workshops, organized into seven meeting tracks, and you are going to have to make some tough decisions. I think at a couple of different times we have 19 or 20 workshops going on all at once. So take a careful look at your program book. There are seven institutes on special topics;

Young Men Who Have Sex with Men, the Ryan White Data Report,

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Women of Color, Peers, Motivational Interviewing, Quality and Capacity Development and Global.

We also have 106 Poster Sessions, on Tuesday afternoon from 5:00 to 6:30, there is dedicated time to view those posters and meet the authors. And I really encourage you to do so, because I know folks have worked really hard on those posters. That will be repeated on Wednesday from 1:00 to 3:00. And we have 58 exhibitors in the exhibit hall, and we're really thrilled to see so many agencies and organizations that recognize the professional and compassionate force that this program represents, and they want to be with us.

And we have three plenary sessions, which is down from four from last time because you told us we have too many Plenary sessions so we cut one out, we heard you. And let me review them briefly. This morning's plenary, we're going to look at where we are within HRSA and our accomplishments under the Ryan White HIV/AIDS Program and our connections. We are also going to hear from a panel of experts to give us a clinical update. The remarkable progress continues, but it's complex, and the panel will make it all crystal clear for us.

Tomorrow we are going to hear a dynamic presentation on Excellence in HIV Care by Dr. Donna Sweet of the University of Kansas School of Medicine and the American Academy, and that will be a real nice lead in to our award ceremony that will

follow her remarks as we in the bureau recognize our heroes at the mid-day awards ceremony.

Thursday, please stick around for the last day, we're going to close by talking about the alarming trends regarding HIV in the African American community. And joining us will be Dr. Robert Fullilove of Columbia University, and I guarantee it you do not want to miss his remarks.

We have a team of roving reporters compiling the daily conference newsletter, putting in some extra time, so look for the Ryan White Daily News. In fact, you should have seen the first edition on your chair this morning when you came in for breakfast. It has some late breaking changes in it, so please look at it. And if you happen to meet one of our roving reporters, you might be able to work them a little bit and see if you can get a story in on your program.

Finally, I'd be a bit remised if I didn't tell you how we're going to help keep you going throughout this arduous schedule. We have plenty to of time for breaks and informal networking, which we all enjoy. There is a respite room, 2022 on the second floor, available for those living with HIV who need it, as well as we have medical support available, and also our help desk outside and to the right is available if you need assistance or have any questions.

Dessert, we have dessert today at 1:30 in the Exhibitor Hall, so please join us there. And tonight is our Opening

Networking Forum with music included, starting at 6:30. And as I mentioned tomorrow at 11:30, this is very important actually, the workshops. Tomorrow there is a workshop from 10:00 to 11:30, all of our moderators have been instructed to get you out of your workshop and immediately back here because lunch will be ready for you at 11:30, and we are going to start our program promptly probably at 11:45, so we want a chance for folks to start eating before we start the program. And the following mornings we will have a continental breakfast available for you.

Now, one last thing, evaluation is always last, right? But never an after thought really to those of us and Ryan White, and you let us know what you thought of the meeting in 2006, and we spent a lot of time reviewing your input and making some changes. So if you could please take a few minutes, there is a blue evaluation form in your packet, please take the time to fill that out and give us your thoughts about the meeting. You can turn it in outside at the desk. And remember, with a good evaluation comes a good incentive. Many of you were here in 2006 and you completed an evaluation, you remember that nice little grant supplement we sent you? [Laughter] Well not quite, not quite. Can't go that far, but we have a very nice, very nice Ryan White t-shirt with our meeting logo on it. So you get one of these if you fill out an

evaluation form, so please do so. So with those highlights, let's get into our program.

It is now my please to introduce the Administrator of the Health Resource and Services Administration, Dr. Elizabeth Duke. Dr. Duke is a Career Senior Executive. She was named to lead HRSA in March 2001 and that now makes her the longest serving administrator in the history of the agency.

Before joining HRSA, Dr. Duke was a Deputy Assistant Secretary for a sister agency of ours in HHS, the Administration for Children and Families and there she was in charge of Grants Policy, Financial Management and Human Resources. She has had a lifetime of interesting jobs. Starting her work life as a seventh grader at a newsstand in Philly's 30<sup>th</sup> Street Railroad Station, and I can see her wearing a Philly's cap I believe. Before joining governments some three decades ago, she was a writer for the *Congressional Quarterly* and covered Capitol Hill and federal agencies.

Now at HRSA, she directs a \$7 billion annual budget and programs that provide direct health care services to 20 million people a year. In addition to Ryan White, the portfolio includes the Nation's Health Center Program, which over the last six years as a Presidential initiative has grown to serve 16 million patients annually at over 7,000 sites.

Other HRSA responsibilities include programs to promote maternal and child health, train health care workers and place

them in areas where they're in short supply. HRSA also supports cost saving networks of care among rural health care providers and encourages organ and tissue donation, and I hope you have a card in your wallet.

Dr. Duke has a Bachelor's Degree in Political Science from Rutgers University, her home state of New Jersey and Master's in Political Science and African Studies from Northwestern University. She later earned a Doctorate in Political Science from GW here in Washington, and she still finds time to teach at local colleges.

So, with that brief summary of her background and her work at HRSA, will you join me in warmly welcoming Dr. Betty Duke? [Applause]

**ELIZABETH DUKE, PH.D.:** Good morning. I am delighted to be here. And guess what I just did? I am going to make sure I do my evaluation. [Laughter]

I am so happy to be here, I came in this morning and looked around and saw you all gathered here, and it just really warmed my heart. I am a schoolmarm, I'm use to the fact that my students always sit in the back of the room and leave the front seats empty. But my heart does go out to some of you who are standing, so it does not upset me at all if while I am speaking you feel comfortable coming up and filling in these front seats, because it is easier to be closer to the schoolmarm than to stand, so please come on up.

This was a very meaningful morning for me. I spent my time coming in, and I must admit that the prayer this morning or the moment of silence really hit me right in my gut. I spent my time coming in this morning and sort of culminated that in that moment of silence thinking of one of the dearest friends I have had in my whole life who suffered from this awful disease and has gone on to another world and this world is poorer for his loss.

And so I came here this morning committed to making every effort I can to support this program and provide the care that folks need. And I think that's the most beautiful part of it, is that I know when I walk into this room that I am really walking into the arms of heroes. You are the heroes of this nation because you come to work every single day to do what is right, to take care of those who need help, and I just want you to know how much I personally as well as professionally appreciate what you do. It makes the world a better place and I thank you for that.

You know you're actually being very successful in what you do. I know day in and day out we feel the pressure and the pain of loss, but when you look back to where we started, we've come a long way, baby. We started out in a terrible era, that Steve so well described, and we've now come to a point where people really are living longer and healthier better lives, and it's largely because of you. And you may say, well yes but you

know it's really because of all those wonderful drugs. And yes, we are so grateful for the brilliant, dedicated people who have made the strides forward in the creation of new drugs.

But you know something those drugs would stay in those bottles if it weren't for you. You're the people who really are on the front line to make sure that first rate comprehensive care is available. You're there on the front line doing the outreach and making sure that people who need service are getting the services they knew that they needed.

Another way of looking at it is how many people in this nation can get up in the morning and say, I'm making a difference in the lives of over half a million people? You can say that.

And so when you are having a hard day, take a deep breath, and think of what you're engaged in. You are not alone, and that's one of the things that these meetings help us all to see. We are not alone, we are together and incredibly powerful force and I thank you for that, and I hope you recognize yourselves as genuine heroes every single morning when you get up and go to work.

You know we have a special inspiration in our program, most of our bureaucratic programs are known by horrible acronyms. For example, HRSA itself is a terrible acronym, but a great agency, an agency that makes a difference, and yet it's called HRSA. It doesn't sing and people can't grab hold of it

and love it, and so I do and I hope you love HRSA because HRSA is such an important part of your lives.

But, the important thing is our program, which is one of HRSA's biggest, in fact the biggest program in HRSA, your program has an absolute inspiration in its name, Ryan White. I'm actually old enough, I remember Ryan White. I remember seeing that little guy. He was so incredibly smart, so incredibly a kid. He was so genuinely marvelous, as frankly all kids are.

I remember he sort of took on big important people and really came out of a depth of courage. I can remember when he took on the school principal and the school board and he really demanded and commanded the kind of respect that every human being has a right to. And he did that in the face of ignorance and hate. And I find him and his life absolutely inspiring.

And you know his mother had a lot to do with that. She gave him courage and tenacity and support and love, and she is here with us today. Jeanne White-Gender, would you please stand and allow us to recognize you for your [Applause] help. It is wonderful to be able to recognize Jeanne because through her love and mothering of Ryan, she gave the world a great and noble spirit to inspire us all now, and that is really incredible mothering and incredible human story.

Well, before I tell you a little bit about our challenges and our achievements, I want to recognize a few

people myself. We have an incredible group of people in our HIV/AIDS program. In our bureau we have people who get up in the morning and come into work with an incredible dedication and they do that as a team and they are led by a team of great leaders, Deborah Parham and Laura Cheever, who both know how to lead, to advocate to be team players and to help us help you.

And I was trying to think of something that you would recognize immediately and that is, characteristic of both of them. In this town, it is in very short supply which is, when you want to know what they think they tell you, and I appreciate that. They are superb leaders, and I will tell you that Deborah and I spent a week in Tanzania last year together. We spent a lot of that time looking at the challenges of the world wide epidemic in that country, which is struggling, and our hearts are still a little bit left in Tanzania.

We are challenged by a world wide epidemic as well as a nationwide epidemic, and we bring that heart felt love to you as a part of a world community, and I thank Deborah and Laura for their leadership and their friendship. It matters so much in what we are doing.

Well, what's happened since we last met? Doesn't seem like that long ago, but it was over two years ago. Well the most startling one was three weeks ago, CDC announced that they needed to revise upward the estimate of people infected

annually with HIV, from 40,000 which we had used since I have been in this job, they raised the estimate up to 56,000.

And the first thing I did was when I was briefed on this was to say, oh wow, what an impact that is going to have on our program. Then I realized we had already been faced with that impact all along. But what it did for me was to increase my commitment to do everything we possibly can to prevent new HIV/AIDS infections.

Another thing that has happened in those two years has been the reauthorization of the Act in December of 2006. I remember it vividly it was in the middle of the night. It was in the middle of the night on what would have been my mother's 101<sup>st</sup> birthday had she still been here. So I recognized the importance of the event.

The Ryan White HIV/AIDS Treatment Modernization Act of 2006 provides a lot more flexibility to respond to this changing epidemic. The law directs that we put more of our funds in supporting primary HIV/AIDS care, as well as taking into consideration more emphasis on HIV and the allocation of money.

It also added five new cities to the transition grant areas and they are in Memphis, Baton Rouge, Nashville, Indianapolis and Charlotte. It also recognized the incredible and disproportionate impact of HIV/AIDS on racial and ethnic minorities because it co-defied the minority AIDS Initiative.

And so we are proud and pleased to have the opportunity to implement this new Act.

Now I mentioned particularly the minority AIDS Initiative because we've had recent criticism of the federal government's HIV/AIDS efforts relative to the African American community. I'd like to give you some statistics about HRSA's Ryan White Program in regard to this issue.

Though African Americans are about 13-percent of the American population in general, they account for nearly half of the HIV/AIDS cases in the U.S. In turn we know that nearly half of the 530,000 people that you serve in our Ryan White Program are African Americans. And overall, three-quarters of the people served by the Ryan White Program are minorities. And that's why the National Minority AIDS Education Training Center is located at Howard University right here in Washington D.C. And that's why the Minority AIDS Initiative has been such a prominent part of every reauthorization.

It is clearly a tragedy when any community is so seriously impacted by a disease as devastating as HIV/AIDS. So I can guarantee you we are committed to making every effort to assure that our work follows the changing track of this epidemic as it moves across this nation. Sometime in 2009, we will start again on another chapter in reauthorization of Ryan White, and as always we will make sure that we see a law that

insures that we insure that we serve the people who need our help most.

In the meantime, we are faced you and I are faced with the reality that we are going to be balancing the increasing demands on Ryan White Programs with level or nearly level funding. And compounding or perhaps contributing to this challenge is the fact that many in the American public no longer consider HIV/AIDS epidemic to be a priority, because they have a mistaken impression that the AIDS crisis is over.

We know that's not the case, in spite of your heroic efforts somewhere between 14 and 16,000 Americans die of HIV/AIDS each year. Whatever measure you use this epidemic is not over. But we are doing our part, you and I and all of us together working as a team are working hard to make an impact on this epidemic.

I want to talk a little bit about some of the visits I've had with grantees across this nation. It would be easier to sit in Washington behind my big desk, which I can't even reach across. They should get one of those big guys. I have to stand up to put stuff in my outbox, and I guess that's why I know it's far better to get on those airplanes that are always late, over crowded and all of the new challenges about how much I am going to have to pay for a bottle of water or to take on my little suitcase. By the way, I am getting stronger. I can now heft my suitcase right up there into the carry on bin.

So, why do we put ourselves through that? We put ourselves through it because we know you can't do this job sitting in Washington, you've got to be out there seeing what's happening, seeing what's going right and seeing what's going wrong.

Well let me tell you about some of the things that are going right with some of our grantees and I am going to talk about a visit I made to Hattiesburg, Mississippi. I took a check for \$1.8 million to the Southeast Mississippi Rural Health Initiative. This Center already served a 17 county area, and with the new funds they would be able to serve an additional county and bring in 11,000 more people into care. That money included a Part C Grant to provide primary HIV/AIDS care for a community that desperately needed its help.

Why, why, why you're saying, if they already had 17 counties did we need to reach out to another, and why did we need to bring in these 11,000 new people. I'll tell you why. If you know your geography, Hattiesburg is right up from New Orleans, and Hattiesburg gained think of this, in terms of change, they gained 20,000 additional citizens in one month. And they knew they needed to reach out and care for those people who needed them.

And so, what HRSA did in that instance was take extra money down to Mississippi to help them deal with the challenge, but also the privilege of helping the folks who came there from

a devastated area, but also the folks who lived there over a long period of time. Hattiesburg deserved our nation's help and it was marvelous that HRSA's HIV/AIDS Program could reach in and help. By the way, they also have one of the most beautiful dental clinics I have ever seen in my life.

It is amazing how thrilled I can get just going in and seeing what we've done together. It is a joy, and I love that visit. By the way, the other thing about it was the morning we were there that whole board was there, every community leader was there. Everybody was there to pitch in and help, and it was heart warming.

The Hattiesburg Center is a health center, and about a third of our Ryan White providers are health centers. And so, if you don't know about the health centers in your neighborhood, I'd like to encourage you to go to the HRSA home page on our website and if you follow the prompts, you will be able to find maps of our grantees and perhaps you'll find a partner through that effort.

So go to the HRSA home page, and identify perhaps there is a health center there, it may already be a Ryan White Grantee or it maybe one that would love to partner with you. So please go and check our website for perhaps some help along the way.

I spent World AIDS Day in Portland, Oregon at a County HIV/AIDS Health Center. It is one of the few HIV/AIDS care

providers in this state of Portland, Oregon. And it accepts an incredible number of uninsured individuals. That center does an incredible job. Their patient involvement, their outreach with volunteers, their fabulous staff made a very moving World AIDS Day for me. It wasn't in some fancy, big presentation, it was just a bunch of us crowded into a room to recommit ourselves, and it made me glad to be alive and glad to be of service.

This past spring, I went home. I went home to New Jersey. I always say I am one of those people, I am very proud to be from New Jersey, and I owe everything I am to the state of New Jersey. New Jersey was one of those wonderful states. [Applause] Oh, thank you there is some of you here. New Jersey was a wonderful state to me.

I was a kid who wasn't going to get to go to college, except the wonderful people of the State of New Jersey gave me wonderful scholarships and aid and I try to pay that back to the State of New Jersey everyday. I can't pay it back to the State of New Jersey directly, what I can do is get up, put on my shoes and go to work, and that's what I do.

Well, I went to visit Camden, New Jersey. Camden is a challenged city, but we're there and we're making a difference there. The first place I visited was an area health education center. We call them an AHEC, you see we really are bureaucrats, everything has an acronym.

Now, the AHEC is not a Ryan White Grantee, but while I was there the AHEC staff was conducting their HIV testing in their neighborhood health van. And so I joined them on the van to make the stops along the way. It was such an incredible outreach effort. I am so proud of what that AHEC is doing. Well my next step in Camden was to the Cooper Health System, which is a Part A and Part B provider serving a four county area, including my home county.

After I left Cooper I looked over their handout and noticed that they were hoping to either buy or rent or borrow a van to go do outreach and HIV/AIDS testing. Well, I thought, here is my chance, my chance I am going to be a van matchmaker. [Laughter] I was ready, but as usual they grantees were ahead of me. As it turned out, Cooper had already found a program willing to share its van. It was the local homeless outreach program of Lourdes Medical Center, which is also a HRSA Grantee. Sharing that van with the folks from Lourdes, Cooper can do HIV testing in one of the hardest to reach populations, the indigent homeless.

This kind of innovative outreach, this is characteristic of the grantee's who I proudly work with, The Ryan White Grantees. As you can see there is a common thread that runs through it all. Partnerships and collaborations stretch our dollars and make us more effective. Now, there is

another way to stretch your resources, and I want to tell you about that.

We have a program that can help reduce the costs of medication, and that's the HRSA 340B Pharmaceutical Program that can knock 30-percent off the costs of medication. Many of you are already registered for 340B program involvement. But if you're not, please see one of us during this conference, please get on our website. Please look into it because it can stretch your resources.

Now, while I'm talking about medication, let me tell you about another effort of ours which is our Patient Safety and Clinical Pharmacy Services Collaborative. Boy is that a long name, but does it have a noble purpose. What this is about is we're trying to improve performance with a whole bunch of partner organizations. And our goal is to improve health outcomes, to improve patient safety and to increase clinical pharmacy services.

Now the impetus for this program grew out of a major Institute of Medicine Study a few years ago, which was called To Err Is Human. And what that report told us, that medication errors injure 1.5 million people every year and it told us that for every dollar spent on ambulatory medicine, another dollar has to be spent to take care of the problems caused by medications. So we decided to try to do something about that, and our collaborative really addresses insuring that pharmacy

services provided by our grantees and by our partner organizations are the safest and the best in the nation.

The collaborative has formed 80 teams, made up of health care providers and experts from our allied professional organizations. Ryan White providers are on 11 of those teams, and our goal is that each team will rapidly identify and disseminate the very best practices of the safety net. These are the people whose pharmacy programs have achieved outstanding safety through innovative delivery programs.

We believe that we can optimize medicine management and maximize patient safety by sharing the best of the best with everyone, and that's what our collaborative is about. If you are interested in knowing more about it, grab one of us. Unfortunately, you'll probably get a long discussion because this is vital and it's cross all programs in HRSA and so Ryan White is an integral part of that.

Another integral part of our program in HRSA is our health information technology program. This is very dear to the heart of my boss, Secretary Mike Leavitt, who is a real advocate for improving HIT, Intelliseek [misspelled?] it's a bureaucrat. HIT, Health Information Technology. He believes and I believe that HIT has the potential to revolutionize the delivery of safe, cost effective high quality health care.

A recent Harvard study estimated that HIT could cut serious medication errors by 55-percent. Now you know what

that is? Because all of us in this country suffer from penmanship deficiency, I am one of the worst. Steve Smith, my Senior Advisor can read my handwriting, it took him four years, but he can do it. Now everybody goes to Steve to say, what did she say?

Well, that is fine with somebody like me, but it is not fine when it has to do with improving the care of our patients. HIT can cut through that problem and others. It can allow our practitioners to track the jigsaw of people's health profiles in a way that allows for rapid, careful health care that people have a right to.

I hope you're exploring HIT, if you would like help in doing so, our new office of HIT can help you. They have put a tool kit on our website. You can find it there, you can also find a health IT community that can help you also and we did that with a collaboration of one of our sister agencies, the Agency for Health Care Research and Quality. The design of both of those is for you to be able to get advice, so you don't make the mistakes that people made in the first round. You can learn from these sites. It can make your work better.

And the last thing I am going to tell you about is our core clinical performance measures. We have strived hard and fast to improve the quality of our programs, and we know that the quality measures in our HIV/AIDS program are some of the best in the world.

And so we've developed the same approach going across all other HRSA programs and I want to thank you all who participated in that effort because we couldn't have done it sitting there in Washington by ourselves, so thank you for all of you who helped on that.

I told you a little while ago about my passion for oral health care. And many of you have heard me speak before, have heard me say that the thing that bugs me most is the fact that if you want to define the difference the rich and the poor in America there is just one way to do it. Look in people's mouths. Well in HRSA's Ryan White Program, we have a special story to tell.

We all know that some of the first symptoms of HIV infection are likely to be oral. We also know that when these problems improve, frequently it's in oral examinations that we see those first signs of improvement. So, it's not an accident that dental reimbursement program is part of the reauthorization of Ryan White.

And you know that we have the reimbursement program and we also have a community based dental partnership program, and the goal of that is to increase access to oral health care for HIV positive individuals. It is also the goal of that program to increase the skill of this generation and the next generation of oral health care providers so that they can

provide quality health care services for oral patients who are HIV positive.

Last year we had 12 grantees in 11 states who received funding under this program, and the results are promising. Some 2,500 dental students and post doctoral dental residents received training under this program, and they treated over 4,300 HIV positive patients.

In addition, last year 16 new grantees joined a five year oral health initiative and began testing the best ways to get oral health care to HIV positive patients. And last year we completed, and now we are adding onto the President's Health Center Initiative by adding 1,200 new or expanded health centers sites. And as a result, HRSA providers are now providing seven million patients with oral health care, that's more than double what it was when I first came to this job.

You see we are making some progress, but the road is long and we've only come so far. So, this conference is a really important joint effort for every single one of us. I hope it will be encouraging and enlightening and fun and edifying for every single one of us in the room.

But I also want you to know that we're here for you to teach us, we're here to learn from you. We want to know what works and what doesn't work. We want you to tell us honestly what we need to be doing better. We are here to listen and to learn. We're also here to thank you for your services to this

country. And I just want you to know that Ryan's courage lives on through each and every one of you.

Thank you. Thank you for everything you do everyday and thank you for letting me be here with you this morning. Thank you very, very much. [Applause]

**STEVEN YOUNG, M.S.P.H.:** Thank you Dr. Duke for your words, for your message and for supporting us in this room. It is always good to get an update and an understanding of the larger context as we strive to serve the underserved. And I hope you took note of that quick promotional item for our target center website where you can find lots of resources, web based resources available for you to use.

Our next speaker is Dr. Deborah Parham Hopson. Deborah is our Associate Administrator for the HIV/AIDS Bureau and she has been our leader since 2002. And she has long been a career officer in the United States Public Health Service. She has a significant experience, not only in HIV/AIDS, but in primary care, nursing, public health at a variety of levels. In our Bureau, the Bureau of Primary Health Care, the National Health Service Corp, the White House as a Presidential Management Intern, The Office of the Surgeon General and the Institute of Medicine.

Deborah has roots in North Carolina, having received her Master's and Doctorate Degrees at the University of North Carolina at Chapel Hill. And I understand from her that she

may retire there someday. But we're not going to let that happen anytime soon.

In 2003, Deborah was promoted to the rank of Assistant Surgeon General, a rank well deserved. And recently, Deborah was selected as a Fellow of the American Academy of Nursing. Now being selected as an Academy Fellow is a very important recognition of one's contributions to nursing and health care. Fewer, than 1-percent of nurses nationally achieve this recognition she joins about 1,500 others in influencing education, management, practice and research and health policies for the benefit of all Americans.

Within the HIV/AIDS Bureau, we are proud of her recent accomplishments and its professional recognition, and we believe it serves us well.

So, ladies and gentlemen, it is my pleasure to present the leader of our Ryan White Program, who guides us through, my colleague and my boss, Deborah Parham Hopson. [Applause]

**DEBORAH PARHAM HOPSON, PH.D., R.N.:** Good morning, it is great to see all of you. Thank you Steve for that very warm welcome, and thank you Dr. Duke for those comments.

I want to say to you that throughout Dr. Duke's tenure at HRSA, she has made it a priority to be with us at our Grantee Meeting. She even delayed her vacation this year to be with us, so thank you again for being with us and showing us your very visible support. We appreciate it.

And while we are on the subject of thanks, I also want to say a special word of appreciation for all of my absolutely terrific colleagues at HRSA's HIV/AIDS Bureau. They have worked tirelessly to plan and produce what I know is going to be a fabulous conference. A special thank you to the co-chairs, Helen Rovito and Kelly Weld. I know Kelly was over at table six, if you could please stand. [Applause] I mentioned Helen Rovito, she is unable to be with us due to the passing of her father on yesterday. So, I would ask that you would please keep Helen Rovito and her family in your thoughts and prayers as we go throughout this week.

I also want to extend a special thanks and appreciation to my senior staff who help me on a daily basis to lead the HAB Team, and also to all of the HAB Staff Members that are here. And I want all of the HAB Staff that are here, if you could just please stand and take a bow. [Applause] Thank you very much.

I am very glad, like Dr. Duke to be out from behind my desk today to share with you, and I'm very glad that you're here too. This Grantee Meeting comes around only every two years, and I think that we don't really get a chance to spend enough time together. So I'm really glad to be here today.

I want to use this opportunity to say, that we at HRSA's HIV/AIDS Bureau know that without you there would be no Ryan White HIV/AIDS Program. We honor your compassion and

commitment, we honor your skills and humanity, and we are honored to stand with you to work with you, to do things that none of us could do alone.

The Ryan White HIV/AIDS Programs implementation requires all of us, a variety of people playing a variety of roles, diverse organizations from diverse sectors. Just look out over this room and you will see how diverse we are. We come from government and non-profits, we represent community based organizations and large medical centers, we are every color and gender, we are young and not so young anymore, we are gay and straight, bi-sexual and transgender and together, we share an extraordinary privilege, we implement the Ryan White HIV/AIDS Program.

We are part of an 18 year experiment whose success was far from a forgone conclusion, and yet the results of that experiment have been absolutely astounding. The Ryan White HIV Program reaches over 530,000 people every year. We reach people that others don't. Twenty-seven percent of our patients have no insurance, public or private, 57-percent are living below the federal poverty level.

We are reaching the very populations most likely to suffer health disparities in this country. As Dr. Duke mentioned, about 48-percent of our patients or clients in 2006 were African American, another 21-percent were Hispanic.

Building on our success at home, today many of us are involved

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in work that extends beyond the Ryan White Program and beyond our borders.

Through HRSA's Global HIV/AIDS Program, we are helping people with HIV/AIDS in places like Haiti and Tanzania and Zambia. Where ever work abroad may take you or me, we all know that here, right here at home we still have so much more to do.

We have done a lot, and we have learned much. And I believe that one of the most important and far reaching successes of our work is that it has implications far beyond HIV and AIDS. Each and everyday we are proving that one we can deliver health care to the uninsured.

Two, we can provide the kind of comprehensive services upon which health care depends, and three we can build systems of care that create, rather than block access to care. And when we do so, the outcomes of our work are seen in the smile of someone who has just received dental care for the first time, or in the victory of someone learning that their viral load is undetectable, or in a person speaking out for the first time at a support group, at a coffee shop.

In the time we have together this morning, we could explore more thoroughly our victories and short comings and learn much in the process. We could give hours of attention to what is occurring in the clinical care realm. We might review the latest innovations in service delivery. We could spend just as long talking about the 2006 reauthorization or the 2009

reauthorization that we at HRSA are already preparing for. And we will address some of these issues throughout the conference.

But I think it is important this morning to take a little step back for a moment. I want us to look at what has made us successful. If you think about this question I'm sure many things come to mind. There are values like cultural competency and consumer involvement. It is our commitment to quality and innovation. There is the professional capacity that we bring to our jobs. There is the training and technical assistance that we have access to. These are many ingredients of our success. But for me, there is one thing in particular that binds us all together, and that is the power of connections.

Maybe the first time most of us ever thought about connections was in high school, when an English teacher introduced us to the work of John Dunn. It is Dunn of course, who said, "No man is an island entire to of itself. Every man is a piece of the continent, a part of the Maine". Dunn was talking of course about connections. It is these connections that drive many of us to do the work that we do. And it is these connections in an almost unlimited number that make our program what it is today.

When you got up this morning, you should have received a copy of our Due Progress Report in your bags. Looks like this. It's hot off the press, I hope you'll read it and enjoy

it. I also hope that you can use it to build a relationship with a new funder, or to build a new partnership in your community. One of the people that you'll read about is Dr. Nina Kim. Dr. Kim usually works at Harbor view Medical Center in Seattle. But when we met her she was traveling across the Puget Sound. She was going to deliver HIV/AIDS care to patients in Bremerton on the Kitsap Peninsula.

Dr. Kim and two of her colleagues take turns making the same journey every Friday to see their HIV positive patients. And as they do so, they are quite literally taking health care to people that without them might not have it. Although these doctors make this journey alone, they are not working alone, far from it.

The Puget Sound separates the Kitsap Peninsula from the rest of Washington State. The Peninsula is a stunning place. It is very lush, very green and somewhat remote. In the past, its isolation from urban parts of Washington State translated into a barrier to care, for some people living with HIV and AIDS. A round trip was eight hours or more for many of these people. This burden resulted in missed appointments and unnecessary risks to health and well being. Through the power of connections, this burden doesn't exist anymore.

Many relationships were forged to bring the Bremerton Satellite Clinic to life. These relationships include Harbor view Medical Center, King County and Washington State

Department of Health. They also include the Kitsap County Health District, and of course the Part A and Part B, Ryan White HIV/AIDS Programs. By building connections together to one another and then using them, these diverse organizations have reduced barriers to care.

There is really a lot that I really love about this story. The connections, the creativity, the determination, and even the beautiful boat ride itself. Because of all of this, local people who previously made the long trip to Seattle don't have to do it anymore. And even though the program is still less than one year old, 12 people who weren't receiving care now are.

This story is not just Dr. Kim's story. It is not just the story of the Bremerton Clinic, or the patients that get their care. It is your story and mine, and it is repeated hundreds of times everyday in cities and towns across America.

It is repeated 3,000 miles away from the Kitsap Peninsula in Miami, Florida, where three organizations have combined their resources to take dental services to an underserved community in a mobile van. It is being repeated in Atlanta where the Families Circle Network, a coalition of Part D funded service providers has combined forces to make it easier for women and their families to stay healthy and stay in care.

It is being repeated in Denver, where the Part A Grantee is uniting government, community planners and providers to create a continuum of care that has never been more powerful and has never been more complete. It is being repeated in Jacksonville and Mobile, in Kansas and Minnesota, in rural Alabama and urban Chicago. It is being repeated in your hometown and in mine, in your life and in mine.

And everywhere this story occurs, it is about individuals and organizations uniting forces to get the job done. It is about working together to break down barriers. It is about using the interconnectedness of our organizations and missions to get people the health care that they need.

Our connections run the gamut. Planning councils are connected to study governments. Key points of entry into the medical system are connected with outreach workers. Case managers are connected with consumers. Peer advocates with the newly diagnosed hospital, outpatient clinics with community based organizations. And I could go on and on, our connections are limitless, and so is their power. They have never been more vibrant, and they have never been more important. They are important because our work isn't over.

With hundreds of thousands of people not in care, our work is not over. With nearly 15,000 deaths from AIDS in the U.S. last year, our work certainly is not over. And with new

HIV infections every year now estimated at 56,300, our work is far, far from over.

For so long now we have been working together to reach populations, still so disproportionately affected by HIV/AIDS. Men who have sex with men, African Americans, Hispanics, women, these are the very populations that we serve through the Ryan White HIV/AIDS Programs. They are the populations that you and your organizations have reached. These are the historically underserved populations from whom we work to remove barriers to AIDS care and to primary health care each and everyday, but our work is not over. There is still so much more to do, and we must not waver until that glorious day when skin color, gender, and sexual orientation are no longer predictors of illness, suffering and death. [Applause]

Continuing to break down barriers for the historically underserved is a course, one of the biggest issues that we face in the future. And you know very well there are many other issues to. In that same progress report, where you'll read about Dr. Kim in Washington State, you'll find stories about providers and grantees tackling all sorts of challenges.

You'll find data that will continue to help us measure our successes, and beginning on page 30 of the report, you'll find a discussion of some of the strategic concerns. And those concerns aren't just for the future, they are here and they are now.

For example, the effects of aging on people with HIV/AIDS are already upon us. What are the implications for service delivery? Do older HIV positive people need an infectious disease doctor or a primary care doctor, or both? How can we address their growing need for care and the pressures to reduce appointment times and hold down costs? We must continue our ongoing quest to enroll people with HIV in care.

Listen to this one last statistics. People are coming in to care so late that nearly two out of five patients newly diagnosed with HIV progress to AIDS within one year. How can we use the power of connections to reach their individuals earlier? After enrolling people in care, we need to keep them there. Retaining patients poses another challenge that we are dealing with today. And we need new tools for overcoming it. HRSA and the CDC are funding six sites to identify what retention strategies work.

Many of you here today are also working on this issue in your organizations. Please, please share with us what you are learning. We can't keep people healthy if we can't enroll them and keep them in care.

Just as we're interconnected, so are our challenges. For example, the question of how to get people in care exists alongside a second one. How are we going to take care of them in the context of a looming woman power and manpower shortage?

Or consider the issues of finance. At the government level, America is facing record deficits and global challenges. At the provider level, there is a lack of security about what insurer's will pay for, how much they will pay, and when they will pay it.

There are other organizational challenges too, like our ability to affectively gather and use data, and dealing with the unknown changes that will occur as the current Ryan White Program sunsets into 2009 and another one is enacted.

In conclusion, I'd like to say that the interconnected force of everyone engaged in addressing HIV/AIDS care can never be fully defined. We are inseparable parts of a whole, indivisible in our work.

The Ryan White HIV/AIDS Program must continue to grown and evolve, because we enter a future in need of new miracles and new pathways, and it is up to us to find them. We should not be scared. We go forward standing on the shoulders of people who had the courage to step into the fray before AIDS even had a name.

We go forward armed with the knowledge we have gained over three decades. We go forward having made comprehensive wrap around services more than just an ideal. The power of coming together and working together, of being a unified force is what has made the Ryan White HIV/AIDS Program work in the past, and it is the key to our success in the future.

Although we continue to play different roles, our jobs are ultimately the same. We must stay at the table, ponder the possibilities, and make those possibilities a reality for people living with HIV and AIDS. I thank you for being here.

[Applause]

[Video Played]

**STEVEN YOUNG, M.S.P.H.:** Well thank you Deborah for your comments and thank you to everyone in this room for what we just saw on the screen in the timeline. I don't know about you, but I think we should all feel very proud to be part of this history. It's quite remarkable, and you can see the living history on the bureau website which captures our work over the years.

Now it's time for a bit of science. And we are going to have a panel join me up here on the podium. Some of our nation's leading HIV clinicians who are going to give you insights into where we are with promising developments and critical treatment issues.

And heading up our panel is Dr. Laura Cheever. She is our Deputy Associated Administrator in the Bureau. I will introduce her and then she will introduce our respected colleagues.

Dr. Cheever's leadership in HIV treatment is impressive. She provides technical expertise in the administration of the Ryan White Program and HRSA's Global

HIV/AIDS Program. She's a member of the department's Adult and Adolescent Antiretroviral Treatment Panel, and she's worked tirelessly to expand Hepatitis prevention and substance abuse services within Ryan White Programs, to increase retention and care as well. She is also leading our current activities, one of our strategic priorities related to understanding what it takes to insure an adequate HIV clinical workforce.

Laura was an Assistant Professor of Medicine at Johns Hopkins in Baltimore and she developed a regional HIV program which reached out to county health departments in most of Maryland. She served as Medical Director of a Women's Methadone Program and a Peer Based Adherence Program at Hopkins, and she's worked within Parts, A, B, and the AIDS Education and Training Center Program.

Every Friday morning, Laura is not with us, she is continuing to provide medical care to a group of patients in inner city Baltimore. And on a personal note, it's just great having Laura around to bounce ideas off of and to try to come up with some solutions to some challenges that we face it seems like everyday.

So, let me present to you a truly knowledgeable and caring Clinician, Dr. Laura Cheever and the panel. [Applause]

**DR. LAURA CHEEVER:** Good morning. I am so glad to be here today. We have been planning this meeting for literally two years. It is an exciting time, I always get energized and

at the end of these meetings I always go back to work really doing things truly differently.

I'd encourage any of you in the audience who have good ideas about the ways we should be doing things differently, regarding clinical care or quality in the program, who have innovative models of delivering care or getting something done on the clinical realm, to please seek me out and talk to me. Because really I'm here as all of you are to learn, and I want to take as much as I can back with me to the office.

Today during the remainder of the opening Plenary, we will be discussing four different cases, and through those cases we hope to share with you some of the new insights or changes in HIV/AIDS care that we think significantly impact Ryan White Programming.

To do this today, I have two of the giants. Deborah said that we stand on the shoulder of giants, and I have two of those people with me here today. First let me introduce Dr. Michael Saag. He is a Professor at the University of Alabama in Birmingham and he has really devoted his career to understanding the nexus between HIV Pathogenesis and treatment.

He's published over 150 articles in the field, and is the Director of the Division of Infectious Diseases and the Geographic Medicine Program at the University of Alabama and is Director of the Center for AIDS Research there. He founded the

HIV/AIDS Clinic at the University of Alabama and has really been a tireless advocate for treatment, Dr. Saag. [Applause]

The third person to join on this part of the Plenary today is the third co-chair of the clinical conference this year and that is Dr. Carmen Zorilla. Dr. Zorilla is known for her incredible energy and enthusiasm in getting the work done that needs to be done for HIV/AIDS care, particularly for women. She founded the first longitudinal care program for women in Puerto Rico where she continues to be a Professor of OB/GYN at the University of Puerto Rico.

She was instrumental in developing the University of Puerto Rico as a pilot site for the PACPG076, the trial that initially showed us that AZT could reduce Para natal transmission and she continues to be a principal investigator at the AIDS Clinical Trial Unit at the University of Puerto Rico, Dr. Zorilla. [Applause]

I can't tell you actually how much fun I've had working with both of these people this past year in organizing the Clinical Conference.

So, moving on to our first case, it is a 44 year old woman diagnosed with HIV, when she developed Shingles. At that time her viral load was 80,000 CD4 Count of a 156. In addition to her HIV infection, she has obesity, diabetes, high blood pressure, she's a smoker and who is Hepatitis C. The patient is really terrified she is going to die of AIDS in the next few

months and that's her sort of overriding concern and that she has been unable to really function at home because of this terror. So what would you say Mike?

**MICHAEL SAAG, M.D.:** Well I think things have improved dramatically over the last couple of years, and in fact there is some data that you're seeing on the screen now that basically describe that people who enter care today, especially if their CD4 Counts are higher can live almost a normal life expectancy.

If you look at the data in front of you, you can see that those who are diagnosed between the years of 20 and 44 years of age compared to age match controls, that is people who don't have HIV, you can see that they have about an 85.7-percent chance of having a normal life span, and that's assuming that they get on therapy and get into care earlier.

There is one caveat to this. Could we go to the next slide please? And that is that finding people and getting them into care early is important. As you can sort of see from this graph in the line that is obscured there in black, you can sort of see that those are the people that started with CD4 Counts less than 50. And the red line that they started with a CD4 Count between 50 and 200, the mortality at eight to 10 years at least in our clinic is about 25-percent.

If they are less than 50, it is about 50-percent. But note the upper two lines, if they start with CD4 Counts that

are higher, in the 200 to 350 range, then their mortality is very, very low. And these are older data, so the newer data in fact, a lot better.

**DR. LAURA CHEEVER:** And one of the questions that is often asked, well why do people die of AIDS now that we've got highly active antiretrovirals? And there was an important study retrospective look in England done in the last year. And what they found is exactly what Dr. Saag said, overall in England less than 1-percent of people living with AIDS actually died in 2006. But of those who did die of AIDS, by far the most common reason was late diagnosis, meaning the patient wasn't diagnosed with their HIV infection until they were diagnosed with a fatal illness related to that infection.

Another 30-percent were on antiretrovirals when they died but had an untreatable diagnosis such as a lymphoma that didn't respond to therapy. Poor adherence in patient refusal for treatment continues to be an important reason why patients are dying.

But interestingly the thing that has kept me up for many nights in the 2006, 2007 were patients for which I didn't really have much to offer. They were resistant to every single medication. But in fact those patients that really had multi drug resistant HIV only accounted for a small proportion of people that died.

But I think it is important in the context of talking about deaths from AIDS to remember that when you look at all cause mortality all the different reasons people die with HIV infections today, AIDS is only a small part of the reasons they die.

The Cascade Cohort is a very important cohort study that looks at multiple studies of large with the patients around the world. And when they study 10,000 patients over eight years, which is a huge achievement, they found about 600 deaths. Only about 27-percent of those deaths were directly what we consider AIDS related causes, cardiovascular Disease, liver disease, non AIDS cancers respiratory illness also accounted for important percentages of deaths as well as substance abuse, suicide and violence.

I think it's important to focus a little bit on the non AIDS related cancers. In the past we knew that there were certain cancers that are definitely associated with AIDS that give an AIDS diagnosis. Things like lymphoma and cervical cancer.

But what we've discovered now with these large cohorts studies and the power to really detect differences is that patients with HIV infection are also at risk for other cancers we don't usually think of being AIDS related. Patients with HIV infection are three times more likely than general

population to have lung cancer or leukemia's, as well an increase rate for lots of other types of cancer.

**MICHAEL SAAG, M.D.:** Another thing this slide tells us is that we all have to be internists, don't we. We all have to be able to take care of a myriad of problems so that once we get HIV under control, then our challenge is to take care of folks with diabetes and high blood pressure and hyperlipidemia's and then as we said earlier, as people get older and as we get older we have to take care of the geriatric populations.

**DR. LAURA CHEEVER:** That's true, and yesterday Donna Sweet mentioned as well that because of all these other diseases that we need to worry now, we are spending a lot more of our Ryan White dollars on screening tests. The routine colonoscopies and mammograms that everyone needs, we now are funding for our patients.

**MICHAEL SAAG, M.D.:** So for this patient we actually have good news to tell her if we can get her on therapy.

**DR. LAURA CHEEVER:** Right. She should live a long life but she's got to quit smoking, loose some weight and get her diabetes under control. It's true. [Laughter]

**MICHAEL SAAG, M.D.:** Minor problems, all achievable.

**DR. LAURA CHEEVER:** And the other piece of it to is that in terms of the mortality rates in these illnesses that people with lower CD4 Counts die at a high rate of all these

illnesses. So having a lower CD4 Count is not just bad in terms of AIDS, it's bad in terms of your mortality across the board.

**MICHAEL SAAG, M.D.:** That's right.

**CARMEN ZORILLA, M.D.:** I'm going to read the next case. Is a 47 year old man, was recently diagnosed with HIV at an STD clinic. And he's healthy except that he has high blood pressure, takes no medications; his CD4 Count is 380 cells and viral load 45,000 and copies. So should we treat this man right now or what should we do with him?

**DR. LAURA CHEEVER:** Right, so I guess I'll start. Well I think that's an interesting question. A CD4 Count of 380, do we treat him? The people in the [inaudible] after all say, No we can't afford to, but it's an important question. [Laughter] If you ask the three of us here, would we see this patient or not, you'd get six different answers. I think it's really one of those nexus' of things we don't understand today.

We've had a huge evolution of what the HHS Guidelines tell us to do, and we spent a lot of time training people on the HHS Guidelines because they do change regularly as we learn more about the disease.

Back in 2006, 2007 David Ho was on the cover of *Time Magazine*, he states we're going to cure AIDS, five years of treatment, it's done, everyone should be treated, hit hard, hit early, CD4 Count of less than 500 start treatment. But within

about two years of really using these drugs in clinical practice, we learn that it was just not that easy. Our patients in our practices just didn't do as well as the patients were doing in those clinical trials.

And we knew that most patients really didn't tolerate the medication very well, and resistance was developing, so we pushed it down to treating people with a CD4 Count of less than 350. Well as we found more about the long-term complications, the diabetes and hyperlipidemia that patients were suffering with an increase heart disease rates we were seeing we back off even further.

And a year ago the HHS Treatment Guidelines said if their CD4 Count is less than 200 or they have AIDS they need to be treated. But if their CD4 Count is between 200 and 350, you should consider treatment, but they didn't really push in that direction.

**MICHAEL SAAG, M.D.:** And this was all for the asymptomatic patients.

**DR. LAURA CHEEVER:** All for asymptomatic patients, right. And so last year in December we had a major rewrite of the HHS Treatment Guidelines. Mike Saag was a part of this process as well, and they continued to say that we should definitely treat patients with AIDS or symptomatic patients with low CD4 Counts, but as well patients between CD4 Counts between 200 and 350 should be treated.

We should continue to treat pregnant women which has been an important part of our program, as well as patients with HIV Nephropathy, HIV kidney disease that the treatment is antiretrovirals, as well we've learned in the last couple of years about the cross resistance between some Hepatitis B medications and HIV medicines so that if you need to treat someone for Hepatitis B, you need to be treating your HIV concurrently.

But looking at when is the optimal time to treat asymptomatic patients with CD4 Counts of greater than 350, the guidelines tell us it's not well defined, we know that, and we need to look at patients scenarios and their co morbidities.

So, in terms of weighing when to start, I can tell you that in 2002, even 2004 when I had a patient that came in the clinic I rarely encouraged treatment if their CD4 Count was over 250, and I was really sort of a late treater, and that's because of the balance on this graph here. Treatments were incredibly complicated, they had high pill burdens.

If you remember our patients who take handfuls of pills everyday, they had a lot of side effects. As a result patients developed pill fatigue they just couldn't do it in the long run, they couldn't tolerate these medications and they developed resistance, and once the patient had resistance, we didn't have a lot more to offer them.

So I tended to wait until their T-Cell Counts dropped fairly low. And just to explain this graphically for those of us that weren't practicing in 1996, this was a classic regimen that I used a lot. This was like my favorite regimen it was one of the best ones out there at the time. Patients were taking four pills, three times a day on an empty stomach, and another set of pills three times a day on a full stomach. Patient's lives revolved around taking their medication. And almost everyone on the early Prodrugs Inhibitors had some side effects.

A decade later, we were down to one pill, once a day for HIV treatment. I mean really sort of miraculous how fast we came in this field. And most people tolerate treatment pretty well now.

**MICHAEL SAAG, M.D.:** Yes, so, another way to look at this in my mind is not just pill burden, but tolerability. Nobody wants to take something that makes them feel bad, that's not our objective. We're not trying to punish people who are HIV infected by giving them medicine that makes them sick to their stomach or gives them the gripe or the grip in their stomach or diarrhea.

And what you're looking at on this particular graphic it's colorful in a way, but what you are noticing first off is that with the more modern regimens, up to 80-percent of patients in clinical trials are able to get less than 50 copies

and this is by intent to treat meaning, no matter whether they were on treatment or not, if they'd stop taking therapy they were judged as failures.

So 80-percent, less than 50 copies and if you look really carefully at the color here, in the turquoise, those are the non nucleus side reverse Transcriptase Inhibitors, and you can see that they are doing a little bit better than say a boosted PR regimen in general.

And the reason for that, a lot of people say, was it more potent? No, not really in my opinion, what I really think it is it's all about tolerability. People can tolerate those regimens a little bit better, and I think the emerging trend that we started with earlier about improve mortality in people that have HIV today. I think a lot of it is not only reduce pill burden, but it's also that the newer medicines, including the ones we're going to talk about in a few minutes are really much more tolerable and I think that's what its all about.

One other way to look at this is the length of time that it takes before someone fails their first regimen and goes to their second. This is another way of looking at it. You can think about it durability of the first regimen. In this particular study from the Moore Clinic at Hopkins, you can see that the incidences per 100 patient years, that's just a fancy statistical way of saying, how long does somebody stay on their first regimen. You can see that that is improving over time

that people are able to stay on their first regimen much, much longer. Again, my opinion and I think that of many other people is that's all about tolerability and to some degree convenience.

**DR. LAURA CHEEVER:** True. So, when do we start treatment today? Well I think the balance has really shifted here in the last few years. We understand more about survival and we have improved survival, and we understand that it's not just survival of AIDS related complications, but all those other things patients are dying of. I can tell you I've had two patients die of lung cancer in the last year. I mean it's just big and it's out there.

We have much more convenient dosing, fewer side effects. We have a lower risk of failure because patients can tolerate these medicines as well we know that we have a better T-Cell response and patients are less likely to have adverse drug reactions if we start treatment earlier.

In addition, we have better second and third line therapies. When patients fail their first group of drugs, we have other drugs to offer them.

**MICHAEL SAAG, M.D.:** That's true.

**DR. LAURA CHEEVER:** So, I guess the question for you, would you start therapy earlier now?

**MICHAEL SAAG, M.D.:** Absolutely. And when we were first working on this a lot of folks in addition to David Ho's

group, our group and others were looking at viral dynamics. If you remember those of you who are in the field back then, in 1994 we looked at the replications and found that there were 1 to 10 billion viruses produced a day in an infected patient, 1 to 10 billion viruses, and that's sort of screamed to us, why wait? Why do you let something like that continue to happen? And that's where the treat early, treat hard came from.

But as the side effects came in we sort of the pendulum swung back, but it's clearly moving back in the direction of earlier intervention now. And the IS/USA Guidelines that just came out earlier this month, said that there really shouldn't be necessarily a ceiling above 350, just kind of start considering therapy for everyone.

**DR. LAURA CHEEVER:** Right, so I agree and today I do treat patients with CD4 Counts greater than 350. It's really obviously that partnership between what the patient wants and where they are in their lives. I think the most important thing for this newly diagnosed patient, in terms of his long-term survival, is making sure that he's access care, he's come to care once, that doesn't mean very much. He's got to come to care at least twice, often before patients are really well retained in care. So you've got to get him into care and especially if we don't start therapy to make sure he understands that it's important for him to stay in care.

**MICHAEL SAAG, M.D.:** And they have to be willing to start therapy.

**DR. LAURA CHEEVER:** Right.

**MICHAEL SAAG, M.D.:** It's always the case.

**DR. LAURA CHEEVER:** It's always a partnership.

**MICHAEL SAAG, M.D.:** Right.

**DR. LAURA CHEEVER:** Right.

**MICHAEL SAAG, M.D.:** So, one thing that we are all dealing with is, we talk about when to start this sort of hypothetical 350 or higher, but in our clinic and in a lot of your clinics in the "real world". What we're finding is that people are being diagnosed late, Right?

These are data from our clinic, you can look at that one column and see from '96 to 2004 the median CD4 Count was less than 200 for a lot of these years. Now after I pulled this slide together I turned to our data base colleagues and said, well what's happened since then? And there is some good news there.

Actually the median CD4 Count is now approaching 300 perhaps because of the universal opt out testing. But the bottom line is that still less than 300, and so this whole discussion of when to start 350 or higher for a lot of patients is moot.

**DR. LAURA CHEEVER:** Right, and we do spend a lot of

[inaudible] on HHS Guidelines Panel discussing when to start

therapy and it is fairly irrelevant for most of the people I see.

**MICHAEL SAAG, M.D.:** So, the partnerships that were discussed earlier this morning about getting together with other agencies, we really need to get people into care, we really need to find out whose infected and universal opt out testing is a must. And what I say to a lot of people is that anyone who is sexually active or whose even thought about being sexually active should be tested for HIV, [laughter] It's kind of a good idea. [Applause] So, it is a national problem, it's not just at our clinic.

**DR. LAURA CHEEVER:** The other important thing is this was a slide I first saw it at one of the retrovirus's conferences about two years ago, and I always moan about the poor access to care we have in this country. We've got a fragmented health care system. A lot of people are medically underserved, and I've always thought that explained why people came to care and were diagnosed so late. But in fact when you look internationally at places like Canada, and Western Europe who have nationalized health care system with universal access to care they are doing about as badly or worse than we are.

So, really in fact for HIV, our fragmented health care system is certainly something we need to work with, and that the Ryan White Program really actually helps wrap around. But there are other issues about being HIV infected. The

populations that are impacted and issues around stigma that we're really going to need better understand, because it's not all about just having the perfect health care system.

**MICHAEL SAAG, M.D.:** That's right, and I think the best evidence is actually in Obstetrics where the median CD4 Count of a woman coming into care who's pregnant isn't 150 or 200, it's 400. So that universal opt out really does work and we just have to get people into care.

So, let's go to our third case. This is a 25 year old woman who is speaking of pregnancy, who presented for prenatal care at 18 weeks. And she has two children, five and seven year olds. Her CD4 Count is 430, there we go, and her viral load is 50,000. She's very intermittent about her prenatal care, misses about 50-percent of her scheduled appointments.

So, here you've got a lady who's maybe tough, Carmen what would you do in this situation?

**CARMEN ZORILLA, M.D.:** Well, there is several things we need to consider and of course, there is the medical aspect biomedical aspects of treating her, and of course we will treat her during the pregnancy to prevent transmission, but there is also other social aspects of her care. First accessing her care, second making sure about adherence, making sure testing or screening for violence. We know that violence increases during pregnancy as well.

Children at home affect women's adherence particularly to medications. The good thing is that when women are pregnant we're more adherent and we're more adherent, not only with HIV drugs, but with most of the medical conditions. So we have to use this opportunity to actually make sure that when we start her in therapy that she's adherent for her own sake and for her prevention of transmission.

The other opportunity that we have, that actually we need to rush because she's 18 weeks, so this is almost the borderline for a prenatal testing for generic screening. Some of the curves are up to 20 weeks, so we have to actually grab her by the hand and take her to the lab to do the screening for neural tube defects and other chromosome abnormalities as well.

So, important things for her would be access to care, making sure that she has some social support and then choosing drugs that are appropriate for pregnancy.

**MICHAEL SAAG, M.D.:** Right. And so after you do all those things you would advocate treatment I suspect at this point, is that correct?

**CARMEN ZORILLA, M.D.:** Yes. We just mentioned that when there is social support, there is increased number of visits to the clinic and that correlates with outcomes.

The things about also treating women is that studies have shown that when women are treated following guidelines, they have better outcomes, they have less switching and overall

they are doing better. So we need to make sure that we pay attention to guidelines, particularly when we are treating non pregnant or post partum women. In pregnancy, we can have the next slide, things are different and we need to think about whether drugs cross the placenta or not, and the PK's of the drug. And let me give you an example.

When we treat pregnant women, we want drugs that cross that placenta because we want that fetus to have drugs in his or her system so if there is a small inoculum, there is enough drug to prevent transmission. But we might not necessarily want all drugs to reach the fetus. So we have a balance.

That's why for example, Parodius Inhibitors are large molecules are usually bound to albumin and they barely cross the placenta. So if you treat with Parodius Inhibitors, you are treating the mother, but you're not treating the fetus. You certainly need the non nucleus side analogues that cross the placenta to prevent transmission as well and to have some levels.

So, the other aspects that we need to make sure is that certain drugs are pathogenic and certain drugs are also highly toxic in pregnancy, there's mortality associated to specific drugs, and so we want to avoid those drugs. Newer drugs we don't have enough information. There is a pregnancy registry so that every pregnancy that can be reported we have

information eventually about the aspects of these drugs in terms of terogenicity or side effects.

Women should avoid breast feeding, particularly in our country. There's infant formula that's available and when we are allowing women in labor, the guidelines call for elective Cesarean Section for women who have more than 1,000 copies at their last testing.

So if we're allowing for labor and delivery to ensue the mean number of hours for labor is about 14 to 16 hours. So we're talking about virus replicating, we need to make sure that these women receive the drugs that they were taking during pregnancy because otherwise we're losing this opportunity while they are in labor, there might be viral rebound and all kinds of problems.

**MICHAEL SAAG, M.D.:** What about resistance testing prior to treatment?

**CARMEN ZORILLA, M.D.:** Certainly it's essential that we do resistance testing, and it complicates our therapy, because previously we would say, well there's this and this and this drug that we do have information on PK that we do have information on safety, and we're very comfortable using in pregnancy.

Now we have Genotype and now we have all these complications because there is resistance to this one, resistance to this other one and then the person's virus is

sensitive to combinations that are unheard of in pregnancy. So we need to actually treat with the best we can. If she's sensitive to the drugs that we have more information in pregnancy, which are Nelfinavir, which the problem with Nelfinavir contamination is over, Ritonavir with Zidovudine [misspelled?] and Kaletra, Lopinavir and Ritonavir those are the three drugs that we have enough information about PK and safety.

There's information on the newer drugs, but not as wide. If we can use those that's better, if not we will have to use whatever is best for the patient.

**MICHAEL SAAG, M.D.:** Then we're not using Efavirenz

**CARMEN ZORILLA, M.D.:** We cannot use Efavirenz particularly in the first trimester because of the terogenicity.

**MICHAEL SAAG, M.D.:** Right.

**DR. LAURA CHEEVER:** Okay. For our last case today. It's a 42 year old woman diagnosed with HIV in 1991, has had multiple opportunistic infections, has taken all existing antiretrovirals available, except for Darunavir and the drugs that were approved in the last year or so. She's on Tenofovir and Elvucitabine, Tipranavir boosted with Ritonavir, a CD4 Count of 33, the lowest she's had in the past is six. Her CD4 Count three months ago was 76. So she's definitely going in the wrong direction. Her viral loads 98,000, the highest it's

ever been is 167,000, so she's getting some benefit from this regimen.

**CARMEN ZORILLA, M.D.:** Before you go on, I'm glad that she's not pregnant. [Laughter]

**DR. LAURA CHEEVER:** Okay, so Mike what would you do here?

**MICHAEL SAAG, M.D.:** Well the first thing I get is a resistance test, and what I'll show you that even at from the back of the room you can see that that's not good news. There's an awful lot of gray bars and you don't need much more to tell you, but this woman has multi drug resistant virus.

Three years ago this would have been almost a death sentence, but there has been some new drugs that have been developed that together, not only because they have been designed with new mechanisms of action and activity against resistance virus, but a lot of them are much more better tolerated than some of our prior drugs.

So let's just kind of spend a few minutes talking about this surge of new drugs in the last three years that's really been another breath of fresh air, not just for patients but also for us, the providers because nobody wants to go back to the era when we were watching so many patients die.

So let's think about some of these new drugs. One of them interferes with the mechanism of binding and entry and there's T-20 that interferes with the actual entry of the

virus, the fusion of the virus with the membrane. But there is also now R-5 Inhibitors that's a co-receptor, CCR5 and there is some new drugs out that are blocking that. The one that just licensed is Maraviroc.

Once the virus enters the cell, it comes as a single stranded RNA it then goes the doubled stranded DNA through a process of reverse transcription, going from RNA to DNA. This can be blocked in two ways, and these are the drugs that you already know very well, the nucleus side of reverse transcriptase inhibitors and then the non nucleus side.

But what's new is that when the virus gets through being transcribed it integrates into the host DNA, and this is bad news in terms of cure because you have to get rid of that cell at that point and time, but it's good news in the sense of some new drugs, in particular the Integrase inhibitors, like Raltegravir that was just approved, and has fairly significant potency, and I'll show you about that in a second.

Then the virus goes ahead and matures a new variance being created and as that virus buds from the membrane it has even further maturation through an Aspartyl Protease and that Protease cuts protein from long segments into smaller ones and we have for a long time now the protease inhibitors that work there.

To give you a little bit more detail about the R5 because a lot of you even who are not in practice, but a lot of

you who are administering, these clinics are going to hear about this, there is a CCR5 on the right, and the other co-receptors, CXCR4. The R5 blockers, like Maraviroc only work against virus that's R5-Tropic that uses that receptor.

Some of the viruses, though can use both receptors, they're called dual-tropic and some of them as you can tell are X4-Tropic where these drugs won't work. So to determine this we have to get Tropism Assay, that I'm not going to go through the complicated mechanisms here, but so facet to say that there is now a test available that puts a fragmented or sort of genetically manipulated virus from the patient that they put something called Luciferase.

If you think about lightning bolts, they light up, right? That's the enzyme that is called Luciferase. They put it in here and when those viruses go in and actually infect the cell, they light up and they actually measure the amount of luminescence or lightning that's produced in that cell. That means the virus got in, and this case it's an X4 and inherits an R5, and in two separate assays they can tell you whether the virus is pure R5 or whether is dual mixed.

If it's dual mixed, and all likelihood those are R5 inhibitors won't work. That Tropism Test is new, it is also very expensive, and so that's what's been a problem for a lot of the clinics to order that test.

**DR. LAURA CLEEVER:** Well, it makes resistance testing look cheap.

**MICHAEL SAAG, M.D.:** It does. Exactly, and so what we're hoping is over time that test costs will come down.

Let's review very briefly some of the new data. This is one of the new drugs, Darunavir that is a protease inhibitor and in a lot of studies it's at least equal if not a little bit better than some of the existing prior drugs like, Lopinavir. This is the Maraviroc. This is looking at Maraviroc plus optimize background like in a patient like we saw just now. And you can see in the orange and the blue whether it's given once daily or twice daily. It works a lot better than if you just use optimized background alone.

And here's the Integrase inhibitor, Raltegravir and again, the same study design where you took the best drugs available and then you either added Raltegravir or not, and the group that got Raltegravir in the green line again, you don't have to be a statistician to see that those patients did a lot better. And this is less than 50 copies. Can you imagine that in a patient like we just saw? Less than 50 copies and Dr. Parham Hopson just said, what a joy it is to sort of see patients coming down for the first time with their first less than 50 copy.

Let me just spend a brief minute describing what at least I believe is going on. We think about transmission of

HIV from person to person. The same things happening in the body except not person to person, it's from cell to cell. And let's kind of look carefully at this. In the center as you see a cell that's producing a lot of viruses that happens to unfortunately infect its next door neighbor right about the time that it's dying.

So that it's steady state we know that viral load is proportional to the number of cells in the body that are producing virus, and this creates that vicious cycle. You'll notice that a lot of those stars or a lot of those viruses around that cell that just produced virus, a lot of them don't infect a single cell at all they just fill into the blood stream. And in essence blanks that contribute to that viral load that is from a billion copies a day, but this is what's happening everyday in an untreated patient.

What happens in the situation where we give antiretroviral therapy is we prevent that uninfected cell from becoming infected. That's in essence all what we're doing, we're either giving a nucleus side agent or non nuc or we get preventing entry. And if we have a Protease Inhibitor we don't infect the cell that we're protecting, rather we're affecting maturation of that virus as it streams up and tries to infect, and it's no longer infectious because the Protease hasn't worked.

So, I think it's important for clinicians as well as administrators to understand this is why we say patients have to be taking their drugs everyday 24/7 because you don't want that force field around that uninfected cell to go away. And in fact, if you can sort of look carefully at this diagram now, it looks like a picket fence there doesn't it?

When the protection of that cell is compromised by a resistant virus, say an M84V or a K103-N for those of you who keep up with this, then that virus then infects this cell and every virus that that newly infected cell produces has those mutations carried on and on and on, and that's why it becomes so difficult to treat patients with resistant virus, and that virus is the one that you just saw up here right now.

So, what does it mean to us clinically? It means that we can't just let these new drugs come in and hang out to dry by themselves. If they don't have protection with other active drugs, that new regimen is going fail and this patient in particular will be in really bad shape. These two studies that I'm going to show you right now, on the bottom you'll see the number of active drugs paired with, and in this case Maraviroc.

So on the far left hand side, there is no drugs paired with it. On the far right hand side there is three active drugs. And you can see for yourself that when you have two or three active drugs in a regimen, that's when you have the best chance of getting less than 50 copies, and that's how you can

preserve these options. Take home point the sequential model therapy of the past is a bad idea. All we're going to do is create more resistance like we saw in the patient coming in.

However, if we can use for example, Maraviroc with Raltegravir and Darunavir or perhaps Etravirine whichever drugs are active. At least two, preferably three, then we can not only get the patient less than 50, we prevent the development of resistance and that patient has a really good chance of living a normal life span and becoming one of our geriatric patients which is what we're looking for. And this is just another slide in this case with Raltegravir showing the same thing.

**DR. LAURA CHEEVER:** Right. So I think it's important to note that these drugs in addition to being potent and having new drugs and now we've got six classes of drugs today. We've had a lot of expansion in terms of really different types of treatment for patients, that the new drugs are really tolerable.

**MICHAEL SAAG, M.D.:** Yes, they are much more tolerable.

**DR. LAURA CHEEVER:** In the old days when you failed your first line therapy, you went to some pretty nauseating drugs usually, and that's really not true today.

So the HHS Treatment Guidelines definitely say that even for really advance patients with highly resistant virus, our goal in treatment is to get the viral undetectable.

**MICHEL SAAG, M.D.:** And sometimes with some trainees, and I can't really advocate that all of you do this. But for myself as these new drugs were coming out, I every now and then took one to see what it felt like. And let me tell you, some of them had me in the bathroom for three days. Nobody wants to live through this. [Applause]. So you want to have drugs that are more tolerable, and I think that's why we're seeing such success now.

**DR. LAURA CHEEVER:** Right. So, just to summarize some of the key points we had today.

Patients with HIV really are living longer and potentially can have a normal life span, but really we need to be worried about both AIDS related mortality and non AIDS related mortality. Our patients with HIV are dying at higher rates of all sorts of diseases and we need to be mindful across the board. It really is all about primary care and expert HIV care.

If we start HIV treatment at a higher CD4 Count, we improve results, but frankly that's theoretical in many cases because our patients are diagnosed late. We need to do a better job of getting patients into care earlier.

Our patients have a lot of unmet needs and unless we meet some of their social needs which is sort of a tenant of the Ryan White Program, we're not going to be able to really give them care.

And finally, patients with highly resistant virus today can achieve and maintain an undetectable viral load and that's our goal.

**MICHAEL SAAG, M.D.:** Right.

**DR. LAURA CHEEVER:** And that is our conclusion.

Thanks.

**MICHAEL SAAG, M.D.:** Thanks a lot. [Applause]

**STEVEN YOUNG, M.S.P.H.:** Thanks Laura and Dr. Saag and Dr. Zorilla, that was a great clinical update. A couple of announcements, if you are speaking at the meeting, you need to check into the speaker ready room, which is the McKinley rooms. Just go outside and ask at the desk.

I want to let you know that you can take these Ryan White mugs with you, okay? You need to leave the rest of the place setting there; [laughter] but you can take the mugs. I don't think the hotel will let us back in 2010 if we take anything else.

And let me remind you, please tomorrow, try to get back here, right here, as soon as possible after the last morning workshop. Try to get here a couple minutes after 11:30, lunch will already be on the table and we're going to get started promptly. We have a jam packed plenary session and awards luncheon.

So we're going to send you on your way to your first set of workshops. And thank you Souls of America and have a great meeting. [Applause]

[END RECORDING]