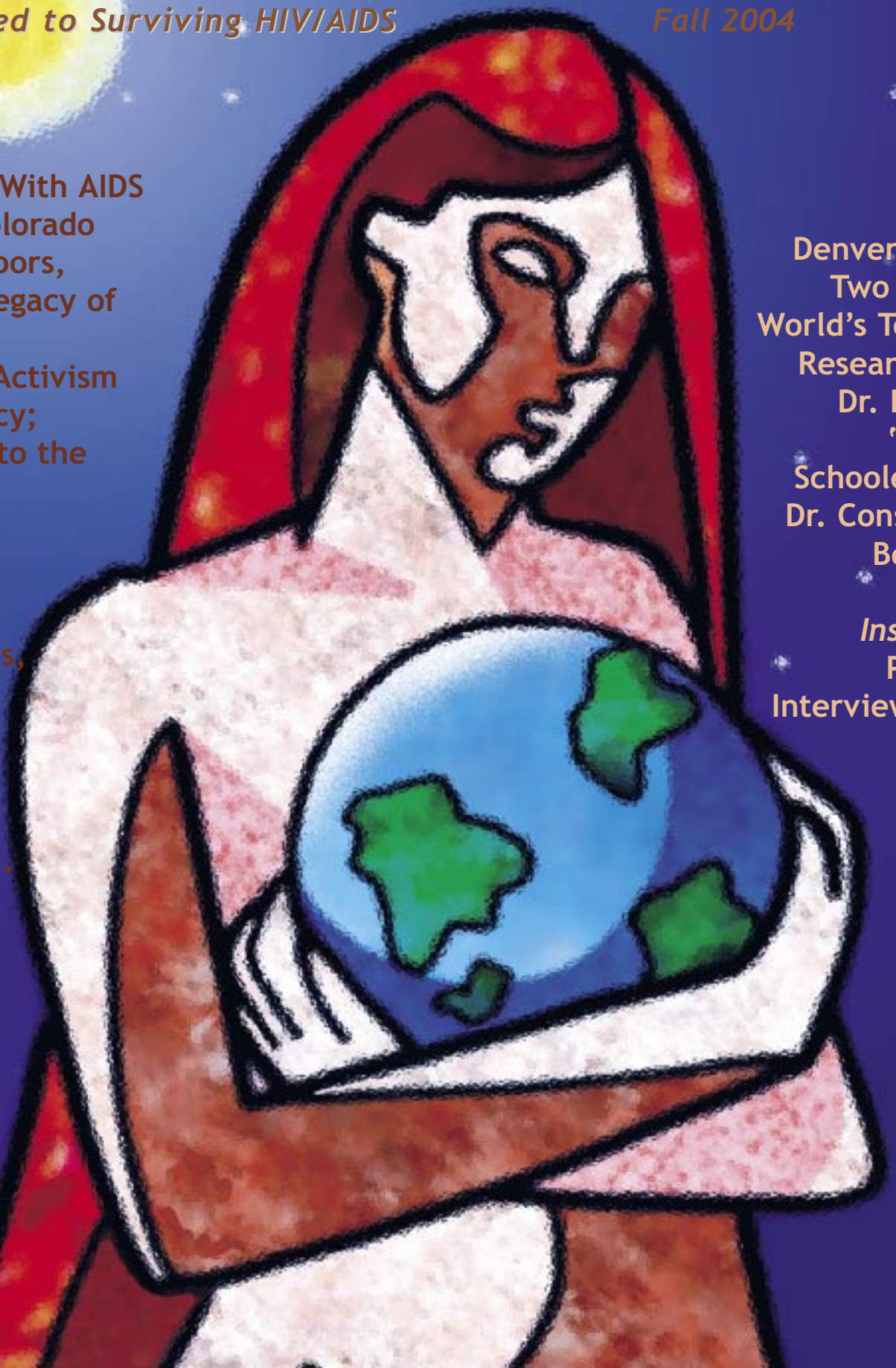
Resolute!

Dedicated to Surviving HIV/AIDS

Fall 2004



The People With AIDS Coalition Colorado Closes its Doors, Leaving a Legacy of Community Education, Activism and Advocacy; Giving Way to the Future.

What's Up? New Combos, New Meds, New Info on Viral Suppression.

Denver Loses Two of the World's Top HIV Researchers: Dr. Robert "Chip" Schooley and Dr. Constance Benson.

Inside: A Parting Interview with Chip

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What We Did For Love: The Closing of the PWA Coalition Colorado

By Al McKittrick

The PWA Coalition Colorado officially closed its doors on August 15th, 2004. Over the seventeen years of its existence, PWACC changed the lives of thousands of people living with HIV and AIDS through its education programs, its publications, its advocacy programs, its medication access programs and its fierce commitment to defending the rights of PLWH that had been so dearly fought for in the 1980's and early nineties.

The Coalition began in 1987 in humble settings; under the stairs at the old CAP offices with one desk and a phone. Earl Thomas, a Denver PWA, had just returned from one of his regular visits to D.C., where he was participating in the NIH AZT clinical trial. While there, he visited an organization called the National Association of People With AIDS (NAPWA). Inspired by their message of empowerment, Earl agreed to open a PWA Coalition in Denver. He returned home and enlisted the help of a Latino AIDS Activist, Steve Montano. Together with a lot of their friends and a Beer Bust at the Lumber Company that netted $65, they began to work.

The PWACC gang in the summer of 2001, Top Row: Paul Miller, Mary Blanton, Tony Garcia-Pelaez, Shirley Nichols, Shannon Behning. Middle Row: Rodolfo Martinez-Puentes, Lola Taylor, Amanda Rosas. Bottom Row: Al McKittrick, Earl Thomas, Shelley Cohen McKittrick.

The message was simple. "You are not a victim and you don't have to die." On the surface, the message seemed a bit naïve. Since the beginning of the epidemic, the American public and government had ignored the holocaust that had permeated the gay community. One can tend to feel like a victim when your pleas for help fall on deaf ears. Secondly, the medical establishment had no treatment to offer at an AIDS diagnosis besides, "I'm sorry." People were getting sick and disappearing at alarming rates. So the mental and emotional blow of an AIDS diagnosis didn't do much for the survival rate. The Coalition "was about changing that perception, I don't mind telling you" Earl told Resolute! in a 1999 interview.

PWACC also served as the Denver chapter of ACT UP in its initial years, and with a combination of activism and advocacy the Coalition was at the forefront of many battles in Denver to further the cause. Most ingenious of these was the protest and negotiation over Mayor Pena's proposal to cut services to the Infectious Disease Clinic at Denver Hospital to help balance the city budget. While orchestrating protests at Pena's home in North Denver and at the hospital, other organization members met with city officials to amicably resolve the situation.

As with most organizations, PWACC was not without inner conflict. An upheaval between individuals in the organization caused its dissolution as a non profit corporation in 1992. However a few months later, CHAP, Inc.(The Denver Buyer's Club) registered the dba of PWA Coalition Colorado with the Secretary of State.

In 1993, PWACC published the first issues of Resolute! Dedicated to Surviving. And then a man named Jeff Davis came back to town. Jeff was a Denver native who had moved in the eighties to Hollywood, where he was later diagnosed with AIDS. Under Jeff's leadership, the Coalition and Resolute! became recognized as models of empowerment. No one before or since has had the negotiation skills and the people skills to accomplish so much in such a short period of time. Jeff was instrumental in the Coalition's participation on the Governor's Council on AIDS, The Mayors Council on HIV Resources, the saving of ADAP funding at the State Legislature, the President's Panel on AIDS, and the promotion of Resolute! to a regionally recognized status as a resource for PLWH. His column about his lone missing T-cell, "Where's Ezmerelda?" was a source of laughter and delight in an all too gloomy community. Jeff died in September of 1996. Reader Warning: Caution! Author will down shift to first person in the next sentence.

I came to work at PWACC on September 6, 1996. Board President Chad Kenney met me on the steps and told me Jeff Davis had died that morning. My 27 year-old wife, Dee Dee, had died from AIDS just nine weeks earlier. It was the darkest of days just before the dawn. Time seemed incredibly precious.

Once again the Coalition went through a period of mourning and transition. *Resolute!* was kept going by Jeff's best friend and assistant-editor, Sarah Brighton and Chad

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Losing PWACC
We Remember, We Grieve, and Ultimately, We Move On and We Survive
By Jerry W. Adams

What happens when an organization dies? What impact does it have on those it served? How does it affect their lives, their worlds? What kind of loss is felt? Do we try to remember and look back at what was once there? Do we grieve and mourn? Of course we do. As we do with all death, all loss.

In the Spring of 1994, I began participating in a support group at the Colorado AIDS Project (in the old building on 16th & Sherman.) After my first few meetings, a young man with bright hair, bright eyes and a bright set of beads dangling at his neck asked me if I would be interested in volunteer work for an organization called the People With AIDS Coalition. [That bright eyed, bejeweled man was Jeff Davis, the Editor of Resolute! and community leader who died in 1996.] I had mentioned that I was an English teacher and he asked if I would be interested in helping to proofread their newsletter, Resolute! I agreed. I had been officially diagnosed with AIDS a few months earlier and I desperately needed to focus my attention on some positive aspect of living with this disease. I soon found myself proofreading each issue from beginning to end a total of three times. Many things must be read more than once to be fully understood and appreciated. After the third reading each month of editorials, news briefs, medical updates, resources, bulletins, references, profiles and columns, I quickly realized two things: One, here was a warehouse of information and two, a vast amount of knowledge and experience. Knowledge and experience of women and men who were working, struggling and fighting for those living with AIDS and those affected and impacted by it.

Like many in the early 90's, I didn't think my chance of surviving this pandemic was great. I thought I was at the end of my life. Before acquiescing, I decided, firmly, to be a part of what was going on around me.I wasn't sure exactly what I could do. But I could try. And I could learn.

And what an education. What did we do at the Coalition? We helped people with their drug regimens-both prescriptions and over the counter. We sold vitamins and - nutritional supplements at or below cost, through the Denver Buyer's Club. And we provided prescription medications for those who had no funds, no income and no health insurance. We listened to the needs and concerns of the AIDS community. We tried to provide current, up-to-date information on the many different facets of this disease. We served on committees and advisory panels; attended meetings, conferences and seminars. We told the government how we felt - our concerns, our fears, our apprehensions about an uncertain future. And we fought for Ryan White funding for all AIDS service organizations. In the two years of my work with the Coalition, I participated as a volunteer, a proofreader, and eventually a contributing writer for Resolute! I also had the privilege of serving on the Ryan White Council and on the Editorial Advisory Board for Resolute!

Ultimately, on a higher level, what was the PWA Coalition? It was the voice of a community struggling to survive a nightmare. It was the bastion and the beacon of the AIDS community throughout the Rocky Mountain area. It was a haven for new information, new ideas; for change in an often unchanging and uncompromising world. It was a platform from which our voices could be heard - in the Mayor's office, the Governor's office, in Congress, in the Senate and in the courts. And ultimately we would be heard in Washington (under a different administration in different times).

A few years have passed since I have been actively involved in the AIDS community. Things have changed-treatment has improved, new drugs and new therapies have changed this disease from a death sentence to a chronic, manageable illness. So what are we to do? Sit back? Relax? No! - we must continue to educate, to inspire and to fight. Yes, we grieve. Yes, we mourn. But eventually we move on. We must. We have no choice.

In his defense in the Supreme Court for the Amistad Africans, John Quincy Adams referred frequently to the past - to the heroes who forged the difficult path, who fought, and many times, won the difficult battles of injustice and inequality. With the memory of their strength, their courage, their wisdom, we are able to go on. We are able to face the future with new goals and new battles ahead.

What do we do when we lose a support system? What fears and concerns are we plagued with? Will our voice continue to be heard? Will it be answered? How do we go on?

With the strength, the undaunted courage and the wisdom of those who went before us. We survive and we move forward, always forward. We look to a new future and new challenges, new goals. We go on. We must. We have no choice.

Jerry Adams is a long-term survivor of HIV who has recently reconnected with us here at Resolute! You can expect to hear more from him in the future!

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Kenney. The Denver Buyer's Club was cut back to four hours a week. Somewhere in early 1997, I realized that a lot of guys who had been very sick were walking through our door looking much healthier. It seemed like the promise of HAART therapy was maybe going to come to fruition. Over the next two years, the Coalition continued to publish Resolute! and operate the Denver Buyer's Club and began to offer treatment information to PWA's who would stop by.1999 was a watershed year for the organization. I became the Executive Director. A new Board of Directors was elected and met for the first time in three years. Shelley Cohen McKittrick came to work in January of that year; the Coalition became the home of Shannon Behning's Women's Lighthouse Project. Tony Garcia-Peláez from CAP and Rodolfo Martinez from Servicios de la Raza also joined the Staff. Shelley and Tony launched the Peer Advocacy Project with Congressional Black Caucus Funds that summer. It became a nationally recognized program for advocacy and self-empowerment. Advocates of every background were walking folks who were newly diagnosed into the system and helping PWAs who'd felt shut out, back into the continuum of care. The advocates were well trained and life experienced and were able to collectively make a difference in the lives of other PLWH in our community. Another inner upheaval took place in the Fall of 1999 and the Coalition set course to become a multi cultural, multi ethnic, bilingual organization of advocacy and education.

The next three years were some of PWACC's best. Earl Thomas, came out of seclusion and came back to help out at the organization that he had co-founded. Resolute! under Shelley Cohen McKittrick and Resuelto! under Tony Garcia-Peláez, became nationally and internationally recognized resources for not only PLWH but for providers as well. The Peer Advocacy program helped hundreds of people of color access treatment and was recognized by HRSA as one of the best programs to come out of the Minority AIDS Initiative. We were able to provide hundreds of PLWH with life saving medications through our drug exchange program. The Denver Buyer's Club provided great nutritional support, at affordable prices, to many PLWH. The seed of advocacy was planted throughout the community by the H.E.A.R.T. Institute and its training courses. We were riding high.

We approached 2002 with optimism and unfortunately a feeling of invincibility. We expanded our staff to 12 and projected a $500,000 budget. By mid 2002, we realized that traditional funding sources were drying up. Beyond the recession and the floor dropping out of foundation giving after 9/11, we took serious funding reductions from Ryan White funds. No other agency but PWACC had over a 66%

VOICES CARRY

By Barry Jay Glass

Within the world of Quantum Physics, matter can exist in more than one place at the same time. One universe parallels many others. In a world of Quantum Physics, we may be living our lives backward. I long to live in such a world, where Fred and Rik and David and too many other Davids stand side to side by my side, physically manifest.

This is no history lesson although those of you who never lived in *The Early Years* would do well to learn who birthed you. Some of our heros are still around, most are not. But that doesn't mean they have disappeared.

Paul Monette said, "Grief is a sword, or it is nothing." Edmund White said, "Everytime a person dies, a library burns." Whether it be AIDS or the Sudan, silence still equals death.

Our lives are a series of choices. Every day, we make decisions that shape who we are. We are always becoming who we will be Those who died too early often spent the last days of their lives fighting for you. You can show your graditute now by fighting for them.

reduction in funding from Title I in just two years. The next year PHRMA rules for Industry grants changed and this caused losses in funding that we hoped could make up for cuts from our friends at the HIV Resources planning Council. We started downsizing in the fall of 2002 in the hopes of salvaging the organization. Two years later, we lost those hopes. As Executive Director I was responsible for the financial well being of the organization. I would admit to financial mismanagement, though it wasn't the type that got me a Lexus. Many times we would buy another week in a motel for a client because they had run out of emergency housing resources and they would be on the street if we did not intervene. Or instead of paying one of our bills, we would pay for a medication, crucial to the life of a client without resources for even a co-pay. We were loyal to our employees and clients to a fault and they returned that loyalty. In hard times, the prioritizing of funds in this manner is not prudent. We made the right choices for humans but suffered the business consequences.

Although PWACC has gone, the principals and mission are being carried on by new entities and new people. Peer advocacy programs have begun at other organizations over the last couple of years. The Women's Lighthouse Project has been its own for two years now and has expanded its outreach to include women who are incarcerated. Rachel Hansgen at the Colorado AIDS Project has taken over the monthly community education forums and I am delighted that Shelley is continuing *Resolute!* and The H.E.A.R.T. Institute as a separate 501©3 non-profit. Proyecto Nosotros will be continuing the drug donation program. Check the Resource Guide for their number.

For seventeen years, the mission of the PWA Coalition Colorado remained the same; To Empower People Living With HIV and AIDS through education and advocacy. For seventeen years, the PWA Coalition remained an organization that was of, by and for people living with HIV. We always spoke the truth as we saw it and we never compromised our commitment to serve our community. All who participated should be proud of what was accomplished.

None of the above would have been possible without the tireless dedication of hundreds of volunteers, staff and Board members, many living with the dis-ease themselves. They gave of their time, their money, their love and too often, their lives, to leave a legacy of hope, pride and empowerment for all of us who survive. It remains a sacrifice to be honored.

"Won't forget,
Can't regret,
What we did for love"
-Chorus Line-

I Raise My Glass

By Paul Loper, Ph.D.

Hello. I have accepted Shelley Cohen McKittrick's invitation to join the board of Resolute! (Full disclosure: she and I are first cousins.) I want to write a "little something," to introduce myself to you. Tomorrow being my birthday, I am prompted to sit down and begin writing.

I have a thing for milestones, for ritualizing passages, dates that have meaning for me (and also those that have meaning for others). I have usually treated my making of special events that mark important cycles or transitions as extensions of my postmodern performance art, which since forever predominantly uses my own life as source material. For example, I did a one-man-show for my 40th birthday 6 years ago, which incorporated processing my having been HIV+ at that time for 14 years, not having died 3 years prior when I got my AIDS diagnosis and became really ill, and "rejoining" life to the extent I had enrolled in a doctoral program and moved to San Francisco the year before.

So, doing some math, we see that 14 + 6 = 20, and sure enough, I had been pondering what I wanted to do this year to mark the fact that I have been living with HIV for 20 years.

I kept thinking in the One-Man-Show category, but didn't quite see it. For whatever reason, that wasn't calling me enough. I had done a lot of wonderful performance work of late with a group called Out/Rage-"gay men of various ethnicities and nationalities using artistic inquiry and theatrical dialog to explore issues of race and racism in the gay male community," according to our press releases-so maybe my "meaningful performing" need was currently satisfied. But what, then, should I do?

My sister lives here in San Francisco, and generously hosted my graduation party in May this year (yes, I have completed my doctoral program, and am officially Doctor Paul Loper, although-no Dr. Laura, me!-full disclosure: it's a Ph.D., not a medical doctorate). One of my gifts that day was a very nice (and very BIG) bottle of white wine. My sister suggested I leave it refrigerated chez elle, invite a friend over, she'd make a scrumptious dinner, and we could have this fancy wine together. I thought that was a lovely idea.

It wound up taking two months for this soirée to finally happen, but in July we did it. I invited Weihaur, a friend from Out/Rage. At my sister's that evening, I took a closer look at this special bottle of wine that was the motive for the dinner. Well, what do you know? It was vintage 1984!

And it struck me that I was actually infected in July of '84 -- 20 years ago to the month!

As this sank in, I realized how significant it was for me to be having this 20-year-old wine, at a special dinner event with family-my sister and I have known each other all her life-and with a new friend, who I had met 8 months prior via a "meaningful performance" group, using embodied, aesthetic modes to wrestle with important social issues, and to create a transformative presence in the gay community. Weihaur does outreach work for the gay Asian-Pacific Islander community around issues of HIV, among other physical, emotional, and social health issues. Out/Rage had been partially funded by HIV organizations and grantors who have increasingly expanded their scope to support larger, more complex dimensions of wellness than the narrow "don't fuck without a condom" model.

It also struck me as pertinent that this wine was a gift to celebrate my completing a doctorate. Not something everyone does (full disclosure: yeah, you bet I'm proud of it!). And, I'll add, I was the only person in my program who was living with HIV. It wasn't an "HIV doctorate," but rather a program that seeks to enfold and yet "unpack" many intersecting facets of our inner and outer dynamics, from identity constructs around statuses like "disabled," "gay," and so on, to the processes of power, legitimization, and currency that frame and fuel our culture.

After we sat down at the table, opened the bottle, and poured the first round, I asked if they would be willing to indulge me a request. They were. I asked us to each say where we were 20 years ago, back when the wine was put in that bottle-what we were doing and how our lives were unfolding then, and how we link that time to our lives today.

It wound up being my perfect ritualizing event, my milestone marking. In a way, it was perfect because I did NOT make a whole big production-it was a serendipitous coming together of real and varied aspects of my life today-including the powerful role HIV plays in it.

So Happy Birthday to me! And Happy Birthday to each of you, however old you are, and whatever enfolding and unpacking your stories are doing in relation to physical health, and to emotional, social, conceptual, spiritual, economic, and political living, loving, and learning!

Dr. Loper once resided in Denver, CO and was a regular contributor to Resolute! He wrote a column titled "La Vie Boheme."

Notes From The Intersection - Chapter 1

By Lucas Walker

I had a little anniversary yesterday. I have worked for two years now in HIV service provision, and in hindsight, loved every minute of it. Well, ninety percent, which isn't a poor figure. I know by some standards that two years is practically fresh out of the gate, but I think anyone who works in a high-stress, fast-paced field would understand how these last two years have felt much more… involved.

I know it can be trite to use anniversaries as a chance to look back. But still, in our goal-oriented culture, you are more likely to be introspective at those periods when you suddenly realize the earth has been moving, and you've been traveling the same trajectory. We humans dearly love progress, and one of the sure methods for defining progress is revisiting one's journey. So, trite or not, I started thinking about all the things that have brought me here, to this office, in this town, with these coworkers and friends - and what keeps me here? This is not the kind of question that anybody necessarily wants to ask. I don't mean it to be intimidating. It can be a good question, the kind that provokes you to take stock. Consequently, I decided to clarify all the reasons that I choose to stay here.

Somewhere in the middle of this random composition was my job. There is no other place I would rather be. I remember the first thought I had when I began my time at this little AIDS service organization. I thought, "I'll never have to volunteer again. My vocation will be my community service." Well. There's nothing like the defeat of expectation. I stumbled on a truth after I started here, and one that I'm sure I would have heard if I had listened to the right sources. Giving of oneself and one's time increases the desire to give more of oneself. It is a delicate line to walk. I needn't say more than that I love my work - a privilege that too few can claim. I get to take a part in the efforts of agencies like ours to improve the lives of people in the HIV positive community. I view this as a gift, and it is certainly part of what keeps me rooted and connected to my life.

I added to my list for most of the day. Having realized how blessed I am to work in a place with supportive coworkers and a passionate mission, having realized that there were a host of details about my little city that made it dear to my heart, and even more, that such gifts do not always come to the young and transient, I circled around to the original question. What keeps me here - and what keeps me going?

I must look beyond my self for the restorative power necessary to make it through the years; perhaps most of us do. Spirituality, pastimes, partners, home and garden, the quiet center of solitude. They sound familiar because they are acknowledged avenues for finding something larger, perhaps separate, from oneself. Nobody could deny that tedious or painful times come to us all - usually for longer than we would like. The dreaded 'burnout' we speak of is merely this - depleting oneself, and finding no way to be restored. In that respect, burnout is far from being the bane of social service alone; it is merely the name that a specific vocation has found to describe the malaise of the weary.

Having said that, where can we turn for a reprieve? For a new reason to stay where we are, doing what we do? My personal list revealed that my friends and coworkers, books, music, solitude, and art all play a role in bringing me back to myself. This would undoubtedly be a very different list for someone else. The point is to find what you love - and always to look for a better, deeper way to grasp it. More importantly, it is essential to keep oneself open to new possibilities. Take a look at any of the numerous studies that verify the direct line between quality of life and increased health; there's reason enough to explore and deepen your interests. This exploration is an examination of who you are, and answering that can clarify just exactly what keeps you here - wherever that may be for you.

I'm always encouraging my clients to embrace something new; how can I do the same? What keeps me here? I want to study these questions, which is bound to take time - maybe a lifetime. Questions that lie in the interrelation between you, your chosen family, your pursuits, decisions, loves, fears…so many crossing paths. Part of what makes life so amazing is what happens when the different aspects of who we are combine, overlap, even repel, like a highway interchange. My current theory is that answers to why we remain faithful to life and its demands can lie in those spaces - the spaces between, where all the things that make up you and your existence intersect. In what I hope will be a regular column, I want to encourage others, and myself, to look into all the ways that art and music, travel, relationships, and more can help you to grow and be renewed.

Those of us living and coping with HIV know that life offers us a thousand and one intersections. Perhaps we can find more strength to keep going by taking the time to investigate the intersections of life - and maybe, find more reasons to stay here. Start your own list of what keeps you here. Let me know how it goes.

Lucas Walker is a domestic violence / sexual assault victim's advocate, freelance writer, and the Volunteer Resources & Program Assistant at the Northern Colorado AIDS Project. He may be reached at luke@ncaids.org.

State of Grace

By Al McKittrick

Most of us who are infected or affected by HIV and AIDS remember the day that HIV bulldozed into our lives. A visit to a doctor or clinic; a friend who died unexpectedly or those phone calls from friends or lovers with some really bad news. From that moment on your life is forever changed and was never the same again. My moment was getting the phone call. On the evening of April 9,1993 I was still on tour in Salt Lake City when my young girlfriend, Dee Dee, called me at my motel room. She had received the results of her HIV test that day and had not only tested HIV positive but with only 75 T-cells, was already at an AIDS diagnosis. Not good news for a woman of 24 in 1993. I received my test results about 5 weeks later. ***Positive***. In June, I returned to Denver and Dee Dee joined me here. We were introduced to the community and its amazing infrastructure by an actor friend of mine named Greg Britten who also was a PWA. He took us to Denver Health ID Clinic and on to CAP. Everyone was compassionate and empathetic. Infected, affected and providers made up this incredible community of people where there was limited time for bullshit and everyone gave 100% for the continued good of others who were afflicted. The helpfulness that was extended to all, by people who were sometimes very sick themselves, created a heightened sense of awareness that had more than a few cosmic and spiritual overtones. It had a certain state of grace.

When Dee Dee passed away at the end of June in 1996, there was an incredible display of visual effects in her room until the mortuary took her away. The air glittered, and small oval shaped rainbows appeared in the room about every minute. All of us who were there felt like we were in the presence of grace.

After Dee Dee died, my friend Daryl and I drove straight through from Denver to Dallas for her funeral. It was an incredible drive through New Mexico and western Texas where tornadoes spread out on the panhandle horizon to warn that the journey could be perilous. But still riding the emotions of what we had seen at Dee Dee's death, we felt like no harm could come to us. Two months later, on the first day I went to work for the PWA Coalition, Jeff Davis died and I ended up going with the Board President to see Jeff's family. It seemed a continuance of purposeful predestination guided by powers not understood, but coincidence seemed like a less and less viable concept in the world of AIDS.

In the grieving process, one often has casual conversations with the deceased. I think it helps in the journey of accepting their physical absence. Because of this communication between the worlds, it took me many months before I wasn't living on both plains.

Almost a year later, I met Shelley at an AIDS, Medicine and Miracles Conference in Denver. We had known each other for a while professionally but not until that afternoon did we allow our hearts to be open enough for an incredible energy to flow between us that took over our lives. We believed that the AIDS angels in our lives had brought us together. It seemed like this dual existence of living in constant blessing was never going to end. We married 16 months later in a community ceremony that overflowed with love, hope and good wishes for everyone. Although we included hopes for children in our vows, I certainly didn't believe that would come to fruition. I was more certain of that when less than a year later, Shelley suffered an ectopic pregnancy on our third try of using donor insemination. We talked of trying again or adoption, but months turned into years and our work at the Coalition became all consuming. We lost touch with friends, we took on our client's lives as our own and that became a self fulfilling prophecy. Our lives were our clients' and our organization.

I called tech support to draw upon my spiritual connections and discovered that due to neglect the lines had been down for years.

And yet, we kept putting one foot in front of the other to find a child. Faced with the incredible costs of international and private adoption, we began to look at foster adoption. In the spring of 2003 we started the process with Boulder County; went through our indoctrination, our weekend trainings, our Red Cross certification and endless paperwork. Early that summer, they rejected us. I lost hope. At the time when I needed some of that "grace" and some of those "blessings," I didn't seem to have any on reserve. Four years of giving hope to my clients had left me with no hope at all. I called tech support to draw upon my spiritual connections and discovered that due to neglect the lines had been down for years. I began to think of the events of the last decade to have been nothing more than coincidence. It was a dark time.

Two months later, on a Saturday in late July, our friend Shirley called with news of a young woman who was 6 ½ months pregnant and looking for a family for her baby. We met the young mother two days later and hit it off. On October 6, 2003 at Porter Hospital, I held the birth mom and Shelley cut the cord and our daughter came into our lives. We named her *Grace.* Grace Monet McKittrick. We took her home the next day.

Over the next two months, we were challenged, as all new parents are with the tasks of having a newborn. I felt assured that my experience as a caregiver would make parenting a piece of cake. Buzz! Wrong! But thank you for playing. Trying to balance clients, parenting and keeping an organization afloat seemed impossible and it was. I was frustrated and exhausted and basically toasted. Here was the ultimate blessing in my life, handed to me in a precious bundle and I was not being able to celebrate her presence as much as I wanted to. I remembered a minister I had heard in Indiana while I was on tour. It was around Thanksgiving of 1992 and she reminded us that many blessings were given to us daily, but we failed to recognize them. "So, quit it, just quit it" she had said to us. I also recalled all the friends I lost to this disease who hoped that someday people living with HIV could go on with their lives and not live daily in fear of when they would be the next to die. I was a beneficiary of that legacy and I wasn't fulfilling its promise. I had to make a choice, and I chose my family; my daughter, my wife and myself.

Grace has just turned one and I have been able to spend the past year watching this amazing young being grow from a helpless infant to a walking, running, talking and curious-about-the-whole-world toddler. She says Daddy and comes to hug me, pats me on the back and kisses my cheek. And then she lays back on the rug and stares up at me with those beautiful brown eyes and I'm just eating it up. With that gift comes the child's complete belief that you will always be there for them. I hope to be. I choose to take the legacy left to me to live long and prosper. ***All I need is a little Grace in my life.***

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What's Up? New Combos, New Meds, New Info on Viral Suppression

By Shelley Cohen McKittrick

Two New Combo Nukes, Both One Pill, Once a Day

Over the past few years we have gotten FDA approval for one QD (once-daily) drug after another: efavirenz, ddI EC, tenofovir, 3TC, atazanavir, abacavir, FTC and fosamprenavir (Abbott Labs has submitted data for QD approval of Kaletra). We have had many QD drugs, but not as many QD regimens. That is changing. Now we have the FDA approval of two nucleoside analogue back bone regimens in one pill, taken once daily. Combine one of these nifty new pills with a QD boosted PI or with efavirenz and you've got a kick-ass first line regimen all taken once-a-day at the same time! So let's look at these two new kids on the block and see what you have to choose from. Keep in mind that these two new options come from two different companies. Many times physicians (and treatment writers) have biases toward one company's drugs or another. Sometimes this is because of ongoing relationships, other times because of access to education. We will attempt to present the data and the arguments for and against each combo pill.

From GlaxoSmithKline we have Epzicom®: abacavir/3TC in one pill once a day. Just so that no one is confused, abacavir is also known as Ziagen® and 3TC is also known as lamivudine or Epivir®. And abacavir and 3TC are both part of the combo pill Trizivir® (along with AZT). So this new combo pill contains two drugs that have been around quite a while. Abacavir was approved in December, 1998 and 3TC was approved in November, 1995. This is one of the main arguing points for Epzicom® over the other new combo pill - many years of experience with both agents. The main argument against Epzicom® is the possibility of abacavir hypersensitivity reaction (HSR), which is explained below. Although there are no studies with the new fixed dose pills, there are a couple of studies that the FDA used to approve Epzicom® that looked at ABC/3TC in combination with efavirenz (EFV).

Table 1
CNA30021 48 Week Data:

Study Arms	ABC/3TC + EFV QD	ABC/3TC + EFV BID
% VL <50	64%	65%
Adverse Events	13%	11%

Table 2
CNA30024 48 Week Data:

Study Arms	ABC/3TC/EFV	AZT/3TC/EFV
% VL <50	69%	69%
Change in CD4	+209	+155
% HSR	9%	<1%

Based on these two studies, and GSK's ability to show that the two drugs were stable in the new co-formulation the FDA granted approval of Epzicom® on August 2, 2004.

Abacavir Hypersensitivity Reaction (HSR):

The incidence of HSR ranges from 5% to 9%. Recent clinical trials have seen an increase in incidence which is likely due to 2 factors: an increased awareness and diagnosis of HSR; and the fact that the more recent ABC trials were in combination with efavirenz (Sustiva®) which can also cause a rash and lead to over-diagnosis of HSR (especially in combo with a common side effect when starting any combo, like nausea or fatigue). These explanations are not meant to lessen the seriousness of HSR, but to put it into context of real-world experience.

If you have ever had a possible hypersensitivity reaction (HSR) to abacavir, Ziagen® or Trizivir® you MUST NOT TAKE EPZICOM®!!!

Hypersensitivity Reaction to abacavir is a multi organ clinical syndrome usually characterized by a sign or symptom in **2 or more** of the following groups:

- fever
- rash
- gastrointestinal (including nausea, vomiting, diarrhea, or abdominal pain)
- constitutional (including generalized malaise, fatigue, or achiness)
- respiratory (including dyspnea, cough, or pharyngitis).

Most (but not all) HSR happens in the first 6 weeks of therapy. If you are taking an abacavir-containing regimen and experience 2 or more of the symptoms listed above, CALL YOUR HEALTH CARE PROVIDER IMMEDIATELY. Rash alone does not constitute a diagnosis of HSR. Once you stop taking abacavir due to possible HSR YOU CAN NEVER TAKE ABACAVIR AGAIN. It is in restarting abacavir that the HSR can be life-threatening.

From Gilead Sciences we have Truvada®: tenofovir/FTC in one pill once a day. Again, to avoid confusion, tenofovir is also known as Viread® and FTC is also known as emtracitabine or Emtriva®. These are both newer antiretroviral agents. Tenofovir was FDA approved in October, 2001 and FTC was just approved last year I July 2003. Truvada® gained FDA approval on the same day as Epzicom®, August 2, 2004. What do we know about these two agents?

Study 903 in table 3 above shows that over 3 years, tenofovir/3TC vs. d4T/3TC + efavirenz performed equally well virologically, but that there are striking differences in toxicities and side effects between the two regimens. In Study 934 (table 4) at only 24 weeks mind you, comparing tenofovir/FTC (the Truvada components) vs. AZT/3TC + efavirenz (the gold standard for quite a few years), the TDF/FTC arm significantly outperformed the AZT/3TC (Combivir) arm in both virologic and adverse events measurements. The take away point in both of these studies is that tenofovir (Viread®)-based regimens appear to be equally effective in suppressing HIV, and significantly less toxic than older standard of care regimens.

That being said, there is a tenofovir safety caveat. People with renal insufficiency (kidney function/disease issues) -- which is measured by a things like creatinine clearance, and other significant kidney dysfunction - need to use caution when considering including tenofovir in their antiretroviral regimen. If your creatinine clearance rate is less than 50ml/minute, or you have other kidney problems, tenofovir must be dose-reduced. The dose reduction strategy is to take 300 mg tenofovir 3 times per week. Data on this issue was presented at ICAAC 2004 through the Recover Study. In this study 5 out of 1,193 individuals developed acute renal failure after starting tenofovir. This equaled 0.4% of participants. Four out of five of these folks recovered after stopping TDF. One individual with diabetes and baseline renal insufficiency died 2 days later.

Table 3
Study 903, 144 wk (3-year) data, ITT missing = failure analysis

Study Arms	TDF/3TC/EFV (n=299)	D4T/3TC/EFV (n=301)
VL %<50	73%	69%
Change in Triglycerides	+1	+134
% Neuropathy	3%	10%
% Lipodystrophy	3%	19%

Table 4
Study 934, Planned 24 wk (6 month) Interim ITT missing = failure analysis

Study Arms (n=509, 1:1 ratio)	TDF/FTC/EFV	AZT/3TC/EFV
VL <400	87%	78%
VL <50	73%	65%
Mean CD4 Increase	+129	+111
Total Adverse Events (AEs)	9%	15%
AEs that lead to discontinuation	3%	8%

How Fast Is That Viral Load Dropping? It Appears to Matter!

In a Medscape (www.medscape.com) journal review John Bartlett, MD of Johns Hopkins highlighted the results of a new study by Smith, Stasewski, Sabin, et al. The study showed that treatment naïve participants whose viral load dropped below 1,000 by week 4 of the study, had a greater chance of having a VL <50 at 24 weeks. In other words, if your viral load drops quickly to a very low level in the 1st month of therapy, your chance of suppressing your virus on that combo, over the long run, is much greater. What's really interesting is that it didn't seem to matter how high the participants' viral loads were to begin with. If individuals' viral loads did not drop quickly, they had a harder time maintaining viral suppression to 24 weeks.

These types of results have been seen in other trials over the years, yet we still see a degree of "patience" when it comes to how fast new treatments work. Many times we hear, "well, don't worry that your viral load isn't undetectable yet, it can take up to six months." This study and others show that it had better be low level viremia (<1,000) that you're looking to see come down even further. The usefulness of these studies is in how they change clinical practice. Maybe there's something wrong with the combo. Maybe you're missing doses. Maybe there was underlying resistance…

The Study was published in the Journal of Acquired Immune Deficiency Syndrom, 2004;37:1155-1159

Continued on page 22

A Parting Interview with Chip

Denver Loses Two of the World's Top HIV Researchers: Dr. Robert "Chip" Schooley and Dr. Constance Benson.

Recently I spoke with Chip Schooley about his and Connie Benson's impending move, his time in Denver, the history and the future of the HIV epidemic.

Q: *When did you come to Denver?*

A: I came to Denver in 1990 from Harvard Medical School where I was an Associate Professor of Medicine.

What was the current state of affairs in Denver as far as research and clinical services?

There was a well functioning group down at Denver Health. They were doing primarily clinical trials and epidemiology. There wasn't any significant laboratory-based HIV research -- there was no AIDS Clinical Trials Group here.

Was there an HIV clinic at University Hospital?

There was one person, Ken Baum, who had just joined the faculty and went to see patients on Friday afternoons; otherwise they had to be seen in the ER.

So you started the ACTG site as well as the clinic, is that right? When did that get up and running?

We were able to do an initial study or two through the Boston program, and then we wrote an NIH grant that was awarded in 1992. Steve Johnson came to Denver in 1994 to head up the Infectious Disease Group Practice.

I understand that you and Dr. Connie Benson are leaving us to go to the University of California at San Diego (UCSD)?

That's right.

What will each of your roles be there?

I will be the Head of the Infectious Disease Division and Connie will direct the UCSD AIDS Clinical Trials Unit.

What do you hope to be able to do there that you can't do here?

I think that the research infrastructure here is fraying to the point that it is going to be increasingly difficult to support multidisciplinary types of research. We've lost a lot of faculty in other divisions and disciplines that we work with. In contrast, the University of California at San Diego has been growing relatively rapidly. So the ability to do multidisciplinary research is much easier there than it is here.

What do you think the future of the ACTU in Colorado looks like.

I think it looks quite solid. The ACTU itself has been functioning very well. We have close ties with the community we serve. Clinical investigation can go on as long as the hospital continues to function and deals with the fact that clinical research is important.

So you think funding will stay in place here?

We hope so, yes.

Do you have any idea who may be coming in to replace either one of you?

Tom Campbell is going to take over the Colorado ACTU. A search committee has been formed to recruit a new Chief of Infectious Diseases. The bad news is they also have to find Chiefs of cardiology, oncology, gastroenterology, pulmonary medicine, clinical immunology, pathology, pediatrics and bone marrow transplantation and electrophysiology. Right now, with the melt down at the University, there are a lot of challenges in keeping it staffed. There's been a major exodus over the past 18 months.

[After our interview was over Dr. Schooley made the point that Colorado is one of the very few States that elects their Regents instead of appointing them. This has led to a situation in which the governing body of the University may have only limited expertise in medical research and health care. In many other systems, those governing medical schools and health sciences centers are appointed because of their specific expertise in the area.]

What do you think CU's most important contribution to the HIV research?

We've been the group that has been leading the overall NIH AIDS clinical research program - coordinating it for the rest of the country from here. The leadership has been here in Colorado for the last decade - myself for the first 7 years and Dr. Benson for the last 3 years. That's been something that we've been very happy to be able to do. In terms of antiretroviral therapy, we've been involved in pivotal clinical trials that have gotten us from the days of monotherapy to the current state of the art in which combination therapy is the norm. There have been some important studies in pharmacology and immune-based therapy studies that have been led from here. Those are the major areas in which we have distinguished ourselves.

I will miss Chip very much. He is a true visionary and we were lucky enough to have him here for 15 years. I wish him the best and I know that he will perform very well in San Diego even though W is in the central office. He was very kind to all his faculty members in that he shared his spotlight. It will be difficult to find anyone else with his vision and stature.

John G. Gerber, MD
Professor of Medicine and Pharmacology
Divisions of Clinical Pharmacology and Infectious Diseases, UCHSC

Are there any individuals, people with HIV, who have left and impression on you, that you still carry with you -- or are there any memories that you would like to share?

One of the things that happened in the last ten years and the best thing about being a physician is that this has become a chronic disease. In the early 80's we'd get to know patients in the late stages of the illness and 6 months later you'd be helping them and their families to deal with their impending deaths. Over the last 10 years, I've seen people go back to work, have children, do things they've always wanted to do, and they've become friends. From my standpoint that's been the most gratifying thing that's happened to me in the last 15 years -- the ability to be involved in a disease in which the research has transformed what we can offer patients to a life expectancy that is not all that different from the rest of us. It has been really wonderful to see and it has given me a chance to get to know people as human beings in a much more long-term and intimate way than could ever be done before these advances in therapy came along.

That being said, do you promise to come back and talk to the community when we invite you?

Oh, absolutely.

What are your fondest memories here?

Well, I think the patients are the fondest memories. I'm going to miss all of them. Some of them come in from out of town already and are going to be coming to San Diego to see me. Others I'll keep up with by phone and by email. The people in the infectious disease department are some of the closest friends I've ever had in my life and they are family to me. I'm going to miss them terribly. The people in the division and the patients are my fondest memories.

What do you believe that the most important discoveries and advances in HIV research have been, breaking it down by decades - the first 10 years the last 10 years and the next 10 years?

The first 10 years starting in 1981 when the disease emerged and the end of the decade in 1990 the most important 2 things were discovering the cause of the disease - HIV, and the first demonstration with AZT that if you could inhibit the virus, even a little bit, that you benefited people clinically, if only for a short while.

Between 1990 and 2000 we developed multiple additional drugs and learned about combination chemotherapy, which was based on a much deeper understanding of how the virus replicated in people. We understood in that decade that it required multiple drugs to get around the virus's error rate, which leads to high level of resistance. With this discovery the disease became one with which people could live for years.

Since 2000 I think we've learned how to use the drugs better with side effects for people. And we are about to see new classes of drugs that prevent the virus from integrating into the host DNA and prevent the virus from getting into the cell. So I think this will be a very exciting decade as well.

Do you think that entry inhibitors are the most exciting thing on the horizon?

I think integrase inhibitors are actually more exciting, but I think they both require active investigation.

What is it about integrase inhibitors?

Viral entry uses glycoproteins that are on the virus surface and directly exposed to the human immune response. This has led to a very plastic viral surface in proteins that exhibit tremendous variability. Thus, entry inhibitors may run into major challenges with rapid resistance development and

significant differences from virus to virus in terms of susceptibility to these inhibitors. In the case of integrase, the enzyme is very conserved and doesn't seem to be able to change very much and still be able to maintain its infectivity. Thus drug resistance may be more difficult with this target. So I think it's a very exciting potential target.

I know there's been quite a bit of difficulty in the development of integrase inhibitors. Are those difficulties starting to be overcome?

Yes, there several companies that have compounds that are looking very good.

I had a question about CROI [The Conference on Retroviruses and Opportunistic Infections]. You and Melissa Sordyl founded the conference, correct?

That's right.

What were your initial goals for CROI and have they changed?

To try to have a place where people could come and talk about HIV from the bench to the bedside. To make the kinds of advances you can't have if you only have the clinicians talk to clinicians and the basic scientists to the basic scientists. It's the place where a lot of the "Ah hahs" have happened. People understanding, for example, the replication rate at the basic science level, then clinicians saying, well good grief, the obvious solution to drug resistance is to use the drugs together. Those are the kinds of things that the Retrovirus meeting seeks to do.

Recently, I was giving a talk out of town and the doc who spoke after me made a point of saying that resistance testing wasn't yet very useful in clinical settings...

I disagree strongly. Not knowing what the virus is like, and treating a patient blindly, is kind of like driving around Denver with paint on your windshield. It makes no sense to give patients drugs that aren't active against their viruses, with all of their side effects. And when you think one drug is active and it's not, the other two rapidly develop resistance. So that's the problem. Anybody that says resistance isn't important probably should be in another field.

What are your opinions on what is happening with the transmission of resistant virus, acute infection, and superinfection?

Like with any infectious disease that we have dealt with in the past, when treatments become available, more people in the community carry resistant organisms. HIV is no exception. It makes it more complicated than it used to be because we can't assume that just because a patient hasn't been treated, doesn't mean his virus hasn't. I think it's now good medicine when you see someone for the first time, to test their virus for sensitivity to antiviral drugs before you start treating them.

Do you think that's true even if people are chronically infected?

The problem these days is knowing how long people have been infected. It could be three years or it could be ten years. We know that as recently as three years ago there were a significant number of people getting resistant virus with their acute infection. I think you've got very little to lose by being reassured that you're starting out with sensitive virus as best you can. You have to also realize, of course, that you may miss it because the virus reverts to wild type, although we think now that when people are initially infected with resistant virus that it tends to stick around longer than virus that has selected for resistance by drug therapy. When you are infected with a resistant virus, you tend to not have as much of a mixture of resistant and sensitive viruses that are competing with each other so the resistant virus tends to stick around more. We used to think that if you didn't test somebody right away, you missed it. Susan Little has presented some very interesting data that shows that resistant virus may hang around for several years, maybe longer, in terms of being able to pick it up in the plasma. So unless there's a reason not to - and there are very few other than figuring out a way to pay for it - in my view, everybody should have their virus tested for resistance before they start therapy.

Don't you believe though, that over the long-term, resistance testing reduces the cost of health care?

I think it reduces the cost of care, both directly, because you end up not burning through a bunch of drugs in a patient that would otherwise work, [and instead use] drugs that were active against their virus; but it also reduces the cost of the disease to the community because it results in less resistant virus circulating.

What about treating acute infection?

I don't think we know yet whether that's the right thing to do, that's why it still remains a research question. But with today's drugs, there's very little evidence that you harm people and you might help them - we don't know that yet. That's the kind of situation that can only be resolved by well-designed research studies.

Since arriving in Colorado in 1990, Chip Schooley has worked tirelessly to establish the University of Colorado as a premier AIDS research program with an international reputation. He has been a steadfast advocate for HIV infected Coloradoans. Dr. Chip Schooley and Dr. Connie Benson are two of the most prestigious and respected HIV/AIDS researchers in the world. Their departure from UCHSC is a terrible loss to our faculty, our patients, and the Colorado community. The University of Colorado needs to address the issues that have prompted Drs. Schooley, Benson, and many other distinguished faculty to leave UCHSC in recent years.

Thomas Campbell, M.D.
Associate Professor of Medicine
Division of Infectious Disease, UCHSC

And what are your thoughts about superinfection?

There are increasing data that show that it is something that happens not infrequently. We didn't have a way of looking for it very effectively in the past, because our techniques of picking up virus mixtures weren't as good as they are now. The first places it was picked up were in places where there is a lot of exposure, such as in commercial sex workers. Certainly there are also people in our community that get exposed frequently, and the incidence of superinfection is probably higher than we used to think it was. And the greatest risk for people is that you pick up a virus that your immune system can handle less well or you pick up a virus that's resistant to the drugs that you had been taking in the past - so there are real down sides to picking up other people's viruses.

Can you give us your opinion on when to start therapy?

There is not a single time when everyone should start, which is one of the problems with the guidelines. There are people who want to simplify things to the point where it is no longer medicine -- just accounting. There are a lot of factors that weigh into [the decision]. Obviously, one of the most important ones is whether the patient is ready to start therapy and will take the drugs the way you need to in order to not have the virus develop resistance. In people who have high risk of cardiovascular disease you may wish to hold off for a little while; in people who have been stable for a long time, you may hold off on for a little while; these are the kinds of patient variations that we take into account in other areas of medicine and HIV is no exception. You have to think about the person in front of you because the guidelines are for the average patient and none of us are average; we're all individuals.

Taking that all into consideration though, is there an area of immunological status that you are more comfortable with?

I hate to see anyone go below [a CD4 count] of 250 and I prefer to start people around 350. But there are a lot of people who we see that come in who are presenting with their first [opportunistic] infection, who didn't know they were infected and they have 10 CD4 cells. The good news is that most of them do pretty well. Nonetheless, I wouldn't recommend that as an approach to therapy.

What do you think the biggest challenge facing the HIV community - all of us - research and care…in the US is, and then secondly globally?

I think in the US the biggest challenge is to continue to make certain that care is readily available to anyone who needs it and wants it. I worry about the insidious attacks on resources that are needed for both the drugs and the care structure that is required to deliver the drugs in an intelligent way. I think that the reason that we've had the success that we have over the last 10 years has been the Ryan White coverage and the decision on the part of this society that AIDS is not going to be a disease that we ignore. I think if we do begin to ignore it what we'll find is that the infection rate will begin to increase because people have no reason to be tested and it will cost us a lot more in the long run to not treat HIV than it will to treat it - if you're just doing a cold-hearted economic analysis. I think it's not only morally right to make certain that care is readily available but it is economically a very smart decision.

It is also an obvious point that we must make certain that we can deliver care abroad the same way that we have been able to here. There are no short cuts and there is no easy way to do it, but if you look at a country like Zimbabwe where a third of the adults are infected, you don't have to be George Bush to figure out that your teachers and nurses and physicians and factory workers and parents and everybody in that 18 to 45 age group is at risk and if they disappear the whole society collapses. And that it is much more difficult to try and pick up the pieces from ignoring AIDS than from dealing with it up front. I really hope that we, as a global community, figure out that providing care is the right thing to do everywhere that it is needed. There's a very interesting study in Taiwan that shows that when they made the decision, about 4 years ago, to give antiretroviral therapy to anyone who needed and wanted it, the new infection rate dropped by 50%. And that's something that will happen everywhere when we make this a priority because people will realize that there's a reason to find out whether they are infected. When a disease is treatable it is less stigmatizing. When it is less stigmatizing, people stop hiding it. We already know from bitter experience that there is no better partner for HIV than secrecy. There are all kinds of reasons to figure out how to deal with this epidemic the right way on a global basis.

Are you hopeful?

Absolutely; I'm always hopeful. If I weren't hopeful I wouldn't have jumped into this disease like I did in 1981. The hope that we've had, has been rewarded with success; I believe it will continue. It's why we all come to work in the morning - so things will be better next year than this.

Chip, thank you for your time this evening and for everything you've done for our community here in Colorado and for people living with HIV throughout the world.

- Shelley Cohen McKittrick

Chip's vision made the University of Colorado one of the premier research units in the country. He assembled an awesome team of researchers with a wide variety of expertise- virology, immunology, pharmacology, and endocrinology. He built a program that is strong and we will be able to carry on his legacy. Our ability to remain a top research center will be a testament to the strength of the program he built. We will all miss his wit and his warmth. I hope San Diego will appreciate him as much as we do.

Graham Ray, Rn, MSN
ACTU Study Coordinator, UCHSC

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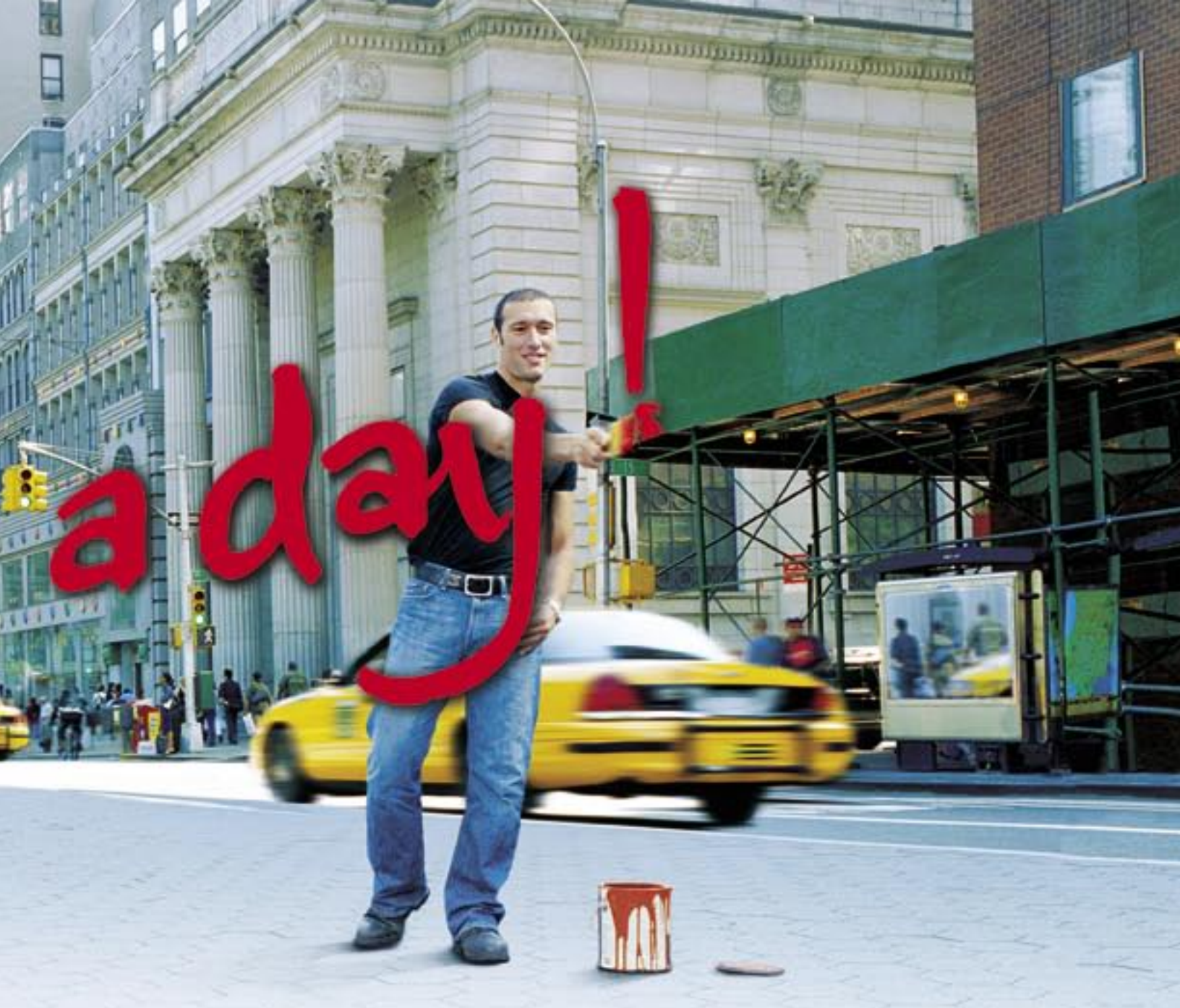
IMPORTANT SAFETY INFORMATION:

- **Lactic acidosis** (a buildup of acid in the blood) can be a medical emergency and may need to be treated in the hospital. **Call your healthcare provider right away if** you have nausea, vomiting, unusual muscle pain, and/or weakness.



- **Serious liver problems** (hepatotoxicity), with liver enlargement (hepatomegaly) and fat in the liver (steatosis), may occur. **Call your healthcare provider right away if** you have light colored stools, dark colored urine, and/or if your skin or the whites of your eyes turn yellow.
- **Flare-ups of hepatitis B virus (HBV) infection:** If you have HIV and HBV, your liver disease may suddenly get worse if you stop taking TRUVADA. Do not stop taking TRUVADA unless directed by your healthcare provider.
- **Kidney problems:** If you have had kidney problems or take other medicines that can cause kidney problems, your medical professional should do regular blood tests to check your kidneys.
- **Bone changes:** It is not known whether long-term use of TRUVADA causes damage to your bones. If you have had bone problems in the past, talk to your healthcare provider before taking TRUVADA.

Changes in body fat have been seen in some people taking anti-HIV medicines. The most common side effects of TRUVADA when taken with other anti-HIV medicines are dizziness, diarrhea, nausea, vomiting, headache, rash, and gas. Skin discoloration (spots and freckles) may also occur.

Discuss all medicines you take with your healthcare provider and be aware:

- **TRUVADA should not be used with Combivir®, Emtriva, Epivir, Epivir-HBV®, Epzicom™, Trizivir®, or Viread**.
- Your healthcare provider may need to follow you more closely or adjust your therapy if you are taking Videx®, Videx EC®, Reyataz® or Kaletra® with TRUVADA.

There is additional information about TRUVADA on the next page.

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GILEAD

Patient Information

TRUVADA™ (tru-VAH-dah) Tablets

Generic name: emtricitabine and tenofovir disoproxil fumarate
(em tri SIT uh bean and te NOE fo veer dye soe PROX il FYOU-mar-ate)

Read the Patient Information that comes with TRUVADA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. You should stay under a healthcare provider's care when taking TRUVADA. **Do not change or stop your medicine without first talking with your healthcare provider.** Talk to your healthcare provider or pharmacist if you have any questions about TRUVADA.

What is the most important information I should know about TRUVADA?

- **Some people who have taken medicine like TRUVADA (nucleoside analogs) have developed a serious condition called lactic acidosis** (build up of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your healthcare provider right away if you get the following signs or symptoms of lactic acidosis.**
  - You feel very weak or tired.
  - You have unusual (not normal) muscle pain.
  - You have trouble breathing.
  - You have stomach pain with nausea and vomiting.
  - You feel cold, especially in your arms and legs.
  - You feel dizzy or lightheaded.
  - You have a fast or irregular heartbeat.
- **Some people who have taken medicines like TRUVADA have developed serious liver problems called hepatotoxicity**, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). **Call your healthcare provider right away if you get the following signs or symptoms of liver problems.**
  - Your skin or the white part of your eyes turns yellow (jaundice).
  - Your urine turns dark.
  - Your bowel movements (stools) turn light in color.
  - You don't feel like eating food for several days or longer.
  - You feel sick to your stomach (nausea).
  - You have lower stomach area (abdominal) pain.
- **You may be more likely to get lactic acidosis or liver problems** if you are female, very overweight (obese), or have been taking nucleoside analog medicines, like TRUVADA, for a long time.
- **TRUVADA is not for the treatment of Hepatitis B Virus infection.** Patients infected with both Hepatitis B Virus and human immunodeficiency virus (HIV) who take TRUVADA need close medical follow-up for several months after stopping treatment with TRUVADA. Follow-up includes medical exams and blood tests to check for Hepatitis B Virus that could be getting worse. **Patients with Hepatitis B Virus infection, who take TRUVADA and then stop it, may get "flare-ups" of their hepatitis. A "flare-up" is when the disease suddenly returns in a worse way than before.**

What is TRUVADA?

TRUVADA is a type of medicine called an HIV (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitor (NRTI). TRUVADA contains 2 medicines, EMTRIVA® (emtricitabine) and VIREAD® (tenofovir disoproxil fumarate, or tenofovir DF) combined in one pill. TRUVADA is always used with other anti-HIV medicines to treat people with HIV infection. TRUVADA is for adults age 18 and older. TRUVADA has not been studied in children under age 18 or adults over age 65.

HIV infection destroys CD4 (T) cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

TRUVADA helps block HIV reverse transcriptase, a chemical in your body (enzyme) that is needed for HIV to multiply. TRUVADA lowers the amount of HIV in the blood (viral load). TRUVADA may also help to increase the number of T cells (CD4 cells). Lowering the amount of HIV in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

TRUVADA does not cure HIV infection or AIDS. The long-term effects of TRUVADA are not known at this time. People taking TRUVADA may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium complex* (MAC) infection. **It is very important that you see your healthcare provider regularly while taking TRUVADA.**

TRUVADA does not lower your chance of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood. For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom or other barrier to lower the chance of sexual contact with semen, vaginal secretions, or blood. Never use or share dirty needles.

Who should not take TRUVADA?

Do not take TRUVADA if you are allergic to TRUVADA or any of its ingredients. The active ingredients of TRUVADA are emtricitabine and tenofovir DF. See the end of this leaflet for a complete list of ingredients.

What should I tell my healthcare provider before taking TRUVADA?

Tell your healthcare provider if you:

- **are pregnant or planning to become pregnant.** We do not know if TRUVADA can harm your unborn child. You and your healthcare provider will need to decide if TRUVADA is right for you. If you use TRUVADA while you are pregnant, talk to your healthcare provider about how you can be on the TRUVADA Antiviral Pregnancy Registry.
- **are breast-feeding.** You should not breast feed if you are HIV-positive because of the chance of passing the HIV virus to your baby. Also, it is not known if TRUVADA can pass into your breast milk and if it can harm your baby. If you are a woman who has or will have a baby, talk with your healthcare provider about the best way to feed your baby.
- **have kidney problems or are undergoing kidney dialysis treatment.**
- **have bone problems.**
- **have liver problems including HBV infection.**

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take:

- COMBIVIR®, EMTRIVA, EPIVIR®, EPIVIR-HBV®, EPZICOM™, TRIZIVIR®, or VIREAD. **TRUVADA should not be used with those medicines.**
- Drugs that contain didanosine (VIDEX®, VIDEX EC®). Tenofovir DF (a component of TRUVADA) may increase the amount of VIDEX in your blood. **You may need to be followed more carefully if you are taking TRUVADA and VIDEX together.**
- REYATAZ® (atazanavir sulfate) or KALETRA® (lopinavir/ritonavir). These medicines may increase the amount of tenofovir DF (a component of TRUVADA) in your blood, which could result in more side effects. You may need to be followed more carefully if you are taking TRUVADA and REYATAZ or KALETRA together.

Keep a complete list of all the medicines that you take. Make a new list when medicines are added or stopped. Give copies of this list to all of your healthcare providers and pharmacist **every** time you visit your healthcare provider or fill a prescription.

How should I take TRUVADA?

- Take TRUVADA exactly as your healthcare provider prescribed it. Follow the directions from your healthcare provider, exactly as written on the label.
- The usual dose of TRUVADA is 1 tablet once a day. TRUVADA is always used with other anti-HIV medicines. If you have kidney problems, you may need to take TRUVADA less often.
- TRUVADA may be taken with or without a meal. Food does not affect how TRUVADA works. Take TRUVADA at the same time each day.
- If you forget to take TRUVADA, take it as soon as you remember that day. **Do not** take more than 1 dose of TRUVADA in a day. **Do not** take 2 doses at the same time. Call your healthcare provider or pharmacist if you are not sure what to do. **It is important that you do not miss any doses of TRUVADA or your anti-HIV medicines.**
- When your TRUVADA supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to TRUVADA and become harder to treat.
- Do not change your dose or stop taking TRUVADA without first talking with your healthcare provider. Stay under a healthcare provider's care when taking TRUVADA.
- If you take too much TRUVADA, call your local poison control center or emergency room right away.

What should I avoid while taking TRUVADA?

- **Do not breast-feed.** See "What should I tell my healthcare provider before taking TRUVADA?"
- **Avoid doing things that can spread HIV infection** since TRUVADA doesn't stop you from passing the HIV infection to others.
  - **Do not share needles or other injection equipment.**
  - **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
  - **Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.
- COMBIVIR, EMTRIVA, EPIVIR, EPIVIR-HBV, EPZICOM, TRIZIVIR, or VIREAD. **TRUVADA should not be used with these medicines.**

What are the possible side effects of TRUVADA?

TRUVADA may cause the following serious side effects (see "What is the most important information I should know about TRUVADA?"):

- **Lactic acidosis** (buildup of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your doctor right away if you get signs of lactic acidosis.** (See "What is the most important information I should know about TRUVADA?")
- **Serious liver problems (hepatotoxicity)**, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your healthcare provider right away if you get any signs of liver problems. (See "What is the most important information I should know about TRUVADA?)
- **"Flare-ups" of Hepatitis B Virus infection**, in which the disease suddenly returns in a worse way than before, can occur if you stop taking TRUVADA. Your healthcare provider will monitor your condition for several months after stopping TRUVADA if you have both HIV and HBV infection. TRUVADA is not for the treatment of Hepatitis B Virus infection.
- **Kidney problems.** If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare provider should do regular blood tests to check your kidneys.
- **Changes in bone mineral density (thinning bones).** It is not known whether long-term use of TRUVADA will cause damage to your bones. If you have had bone problems in the past, your healthcare provider may need to do tests to check your bone mineral density or may prescribe medicines to help your bone mineral density.

Truvada™

200 mg emtricitabine · tenofovir disoproxil fumarate 300 mg

Other side effects with TRUVADA when used with other anti-HIV medicines include:

- Changes in body fat have been seen in some patients taking TRUVADA and other anti-HIV medicines. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long-term health effects of these conditions are not known at this time.

The most common side effects of EMTRIVA or VIREAD when used with other anti-HIV medicines are: dizziness, diarrhea, nausea, vomiting, headache, rash, and gas. Skin discoloration (small spots or freckles) may also happen with TRUVADA.

These are not all the side effects of TRUVADA. This list of side effects with TRUVADA is **not complete** at this time because TRUVADA is still being studied. If you have questions about side effects, ask your healthcare provider. Report any new or continuing symptoms to your healthcare provider right away. Your healthcare provider may be able to help you manage these side effects.

How do I store TRUVADA?

- **Keep TRUVADA and all other medicines out of reach of children.**
- Store at room temperature up to 25°C (77°F).
- Keep TRUVADA in its original container and keep the container tightly closed.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away make sure that children will not find them.

General information about TRUVADA:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use TRUVADA for a condition for which it was not prescribed. Do not give TRUVADA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about TRUVADA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about TRUVADA that is written for health professionals. For more information, you may also call 1-800-GILEAD-5 or access the TRUVADA website at www. TRUVADA.com.

Do not use TRUVADA if seal over bottle opening is broken or missing.

What are the ingredients of TRUVADA?

Active Ingredients: emtricitabine and tenofovir DF

Inactive Ingredients: Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and pregelatinized starch (gluten free). The tablets are coated with Opadry II Light Blue Y-30-10671-A containing FD&C Blue #2 aluminum lake, hypromellose, lactose monohydrate, titanium dioxide and triacetin.

Rx Only

August 2004

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GILEAD

Stigma of AIDS is Helping to Spread Epidemic

By Vincent J. Lynch, Ph.D.

Acquired Immune Deficiency Syndrome. I first heard those words more than 20 years ago. But it wasn't until six years later, while I listened to a man dying of AIDS tell the story of what he was going through, that the reality of what it meant really hit me. By that time more than 100,000 Americans had contracted HIV, and over 60,000 had died of AIDS. The disease had become real for me and for my colleagues in virtually every corner of the country.

So much about HIV/AIDS and the epidemic has changed since then. Yet one thing has not changed nearly enough - HIV is now, as it was in 1989, the most stigmatized disease in American society.

In 1989, the stigma attached to HIV, while undeserved, was at least a little more understandable. We knew very little about the disease then. Fears of being infected from kissing, holding hands or sharing a cup with someone with HIV were still common.

Doctors and patients were scrambling to stir up scientific research programs that in many ways had been slow to respond. Despite a rapidly expanding caseload, there was very little reliable medical or scientific information about the virus, how it was transmitted, or what could be done to treat it.

In fact, effective HIV treatments were virtually non-existent at that time. The few medicines that were being used were no match for the virus, which quickly became resistant. The treatment regimens often involved so many pills and such severe side effects that many people felt that taking their medicines every day was as difficult as the disease itself.

Too often, being HIV positive meant having to cope on your own. It wasn't uncommon for doctors and other healthcare workers to refuse to see patients who they knew were HIV positive. Social workers around the country responded at that time, and services for many people began, gradually, to improve.

The situation today is very different. We know how HIV is transmitted, and we know how to prevent infection. Scientists have learned how HIV attacks the body's immune system, what its weaknesses are and how to exploit them. They've even mapped out the virus's genetic structure.

HIV treatments have also improved dramatically in recent years. With the introduction of powerful new drugs in the mid-1990s, HIV/AIDS death rates began to drop for the first time since the start of the epidemic. More recently, treatments that require fewer pills and cause fewer side effects have begun to help people with HIV/AIDS lead longer, healthier lives. Thanks to these advances in care, HIV is on its way to becoming a chronic medical condition.

Support services for people with HIV have also improved. In practically every city across the country you will find community organizations and groups dedicated to helping ensure that HIV positive individuals get the care and support they need and deserve.

Yet, despite all this progress, the terrible stigma associated with HIV and AIDS still has not lifted. Isolation, fear and shame continue to cloud this diagnosis for many.

What's worse is that the stigma surrounding HIV actually helps to perpetuate the epidemic. Half of the one million Americans estimated to be infected with HIV don't even know they have the virus. The cause is not ignorance as much as it is fear. Each year, tens of thousands of people who have contracted HIV do not get tested out of fear that an HIV positive diagnosis will mean a life of isolation and discrimination.

Misinformation accelerates the spread of HIV in communities across the country, particularly among minority and poorer populations that already suffer more than their share of prejudice and discrimination. Despite progress in other areas, HIV infection rates among African Americans, Hispanics and women have increased dramatically in recent years.

We can't afford to let another 20 years go by before we separate the myths surrounding HIV and AIDS from the reality. It's time we started seeing the disease for what it is: a serious communicable disease that is both avoidable and treatable. We need more open and frank education and more community leadership to address this epidemic. We must also target resources to address the changing demographics of the disease, so that information and education programs can be tailored to the audiences that need them most.

Finally, people living with HIV/AIDS must have access to the medical care and prevention and treatment information they need. Research advances have meant that more and more people with HIV are living full, normal lives. It's time that the human progress in how we handle HIV/AIDS in our community begins to match the advances being made in the research lab.

Vincent J. Lynch, Ph.D., is Director of Continuing Education at Boston College Graduate School of Social Work, and founder and organizer of the Annual National Conference on Social Work and HIV/AIDS.

Continued from page 13

Good News for Long-term Survivors Needing New Drugs!

Boosted Tipranavir Looks Good for Highly Drug-Resistant Virus

Boehringer Ingelheim has applied for FDA and European approval of their new protease inhibitor tipranavir. When boosted with ritonavir, it performed nearly twice as well as the comparator arm, in a study with highly drug resistant individuals. 620 participants were randomized to either 500mg tipranavir with 200 mg ritonavir or to the comparator arm that could include T-20 and could be lopinavir, saquinavir/r, amprenavir/r, or indinavir/r.

"A study like this gives us practical information regarding the way to use a new HIV agent," said Denver's own Steven Johnson, MD, director of the Infectious Disease Group Practice at the University of Colorado Health Sciences Center. "It may be a niche drug for highly exposed patients, but it does provide some evidence that this drug may be effective where other protease inhibitors are not." (Medscape, 2004)

In an ongoing attempt to rectify the absurdity of a 400% increase in their drug's price, an Abbott Labs community representative recently informed us at *Resolute!* that Abbott has agreed to provide the ritonavir necessary for tipranavir patients free of charge, regardless of income or insurance coverage. We do not have an official written announcement from the company on this matter.

RESIST 1 Study at 24 wks ITT analysis

Study Arm	Tipranavir/r	Comparator Arms (other boosted PIs)
Viologic response *(> 1 log drop)*	41.5%	22.3%
VL <400	35%	16.5%
VL <50	25.1%	10%

Sculptra (formerly known as New-Fill) Wins FDA Approval for HIV-Related Facial Wasting

For many PWAs, facial wasting has become a barrier to maintaining self-esteem, medical privacy and sometimes employment. Trying to reverse advanced facial lipoatrophy through changing drug therapy seems at best to be a decades-long task. So the approval of a product that is safe and available in the US has been long awaited. Unfortunately, FDA approval does not mean insurance coverage. So availability does not equal access. Right upfront -- Sculptra treatment will run you between $5,000 and $10,000! There is hope of a patient assistance program in the future.

Sculptra is a "bio-compatible" injectable poly-L-lactic acid that has been used in various medical applications for years. It has been used in cosmetic procedures in Europe for the past 20 years. The product causes the skin to thicken and fill-out. How well it works varies from individual to individual. The training and expertise of the health care professionals doing the procedure is of utmost importance. There are very few trained physicians performing the procedure in the US. You will, most likely, have to travel. For a really thorough discussion of Sculptra, with personal stories and insightful and accurate information, see the latest issue of Positively Aware. If you can't find a hard copy, go to www.tpan.org.

Charles Clifton, 1959-2004.

Test Positive Aware Network, Publishers of Positively Aware, Loses a Rare and Extraordinary Leader.

Resolute! bids farewell to a colleague and friend

On far too rare occasions in our lifetime we get to cross paths with extraordinary souls who touch us with their spirit, bring a sense of peace and possibility to our community and make everyone feel valued and welcome. Charles Clifton was such a soul. I knew him all too briefly. I was very much looking forward to knowing him better. We happened to be born just days apart and joked that perhaps we were really twins (what a lovely thought). He was a thoughtful, open and incredibly smart community leader.

His death is a loss to all of us in the AIDS community across the country and world; for it is far too infrequently that we are graced with the presence of individuals who truly bring people together, rather than pull them apart. Our thoughts, prayers and condolences go out to his family, those at TPAN, and the Chicago community who knew him best.

Vaya Con Dios, Charles.

Love, Shelley

Charles pictured here with Grace McKittrick, Shelley and Al McKittrick's daughter, in San Diego at the GSK Spring Summit this past May.

RESEARCH STUDY!

We need HIV-Positive volunteers to participate in a research study to look at different ways to confirm test results from a new rapid (30 min.) HIV test.

Participation Would Involve:

- receiving infomration on the study
- signing a consent form
- having blood drawn for lab tests
- one visit only - to collect blood and oral fluid

RAPID HIV TEST

Participants will not be provided test results.
Payment is available for qualified participants.
Participants must be 18-55 years of age.
Please call for more information

303-436-7266
303-436- 8226
303-436-8229

"Avance con Salud"

Denver Area Youth Services is providing the **"Avance con Salud"** (advance with health) project, funded by the Ryan White CARE Act Minority AIDS Initiative. This program is designed to serve Latino HIV positive individuals who are experiencing problems with alcohol and other drugs. The Avance program is based on the harm-reduction model which works with individuals to gradually reduce their consumption of chemicals in order to eliminate the effects of substances and to improve the overall health and functioning of the individual and their family. The goal of the "Avance con Salud" is to promote safer health behavior among HIV positive Latinos and to increase linkages to other providers who are serving the HIV positive population.

Services are FREE and include: 6 week group and support therapy, biweekly individual and family sessions, in-home family sessions, assistance with methadone reimbursement, random urinalysis testing, 8 week aftercare groups, family bonding activities, bus passes, and referrals to services available within the Denver area. Services are provided in English and Spanish.

Interested parties should contact Roseann Prieto at 303-302-3275 (English) or Kathi Bui at 303-302-3269 (Spanish).

We are located at 1240 W. Bayaud, Denver, CO 80223

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1st Study of Black Same-Sex Couples

The Bay Area's 2,114 black same-sex couples represent 2.5 percent of all black same-sex couples in the U.S., according to a first of its kind study released Oct. 5 by the National Gay and Lesbian Task Force. The study, Black Same Sex Households in the United States, was compiled using census data and is the largest set of data available on same-sex couples. It examined eight categories, including age, education, income and military service. In announcing the findings, the Task Force and the National Black Justice Coalition said the study was full of surprising trends. For example, black lesbian couples are raising children at almost the same rate as black married couples, and black same-sex couples raise children at twice the rate of white same-sex couples. "For all these reasons, black same-sex couples have more to gain from the legal protections of marriage, and more to lose if states pass amendments banning marriage and other forms of partner recognition," the report concludes. The full study and details on Bay Area figures can be found online at www.thetaskforce.org.

San Francisco Chronicle 10/07/04

Bush League
Prevention Education for Texas

On November 5, the Texas Board of Education approved four high school health textbooks that promote sexual abstinence. Only one of the four textbooks includes a mention of condoms. By state law, sex ed curriculums must include information about contraception. Board members said the textbooks meet standards because contraceptive information is included in separate supplements or in the teacher's edition.

Not surprisingly, for several years, Texas has been among the top five states for teen pregnancies, according to CDC figures. Surveys indicate, a wide majority of parents support a strong abstinence message to teens in sex education. When he was governor of Texas, George W. Bush pushed for an abstinence-based sexual education curriculum.

Additionally the board asked for a change in the definition of marriage because one member said new language was needed to replace what she felt were code words promoting a homosexual agenda. The board approved the definition, "Marriage is a life-long union between a husband and a wife."

Reuters 11/05/04

Briefly HIV News Update

PEP for All

A recent cost analysis of post exposure prophylaxis (PEP) for social exposure concluded that PEP following (social) exposures could be a cost-effective complement to existing HIV-prevention efforts in most cities across the United States. The cost analysis results were published in AIDS. The cost was based on serving 20,000 people per year for a cost of $22 million. PEP includes treating individuals with antiretrovirals immediately after a possible high-risk exposure to HIV. It should be started within 72 hours of the exposure. Currently PEP is only available to health care workers and other occupational exposures who receive needle sticks on the job. The study was conducted by Steven D. Pinkerton; Jeffrey N. Martin; Michelle E. Roland; Mitchell H. Katz; Thomas J. Coates; James O. Kahn.

AIDS 18(15):2065-2073.

Risk of Syphilis Through Oral Sex

The CDC sent out notice that a new report by the Chicago Department of Public Health shows that about 14 percent of primary and secondary syphilis cases reported there between 2000 and 2002 were transmitted through oral sex. Roughly 20 percent of MSM with syphilis in Chicago indicated only oral sex exposure. Of the MSM exposed to syphilis through oral sex, 54 percent were already HIV-positive, 32 percent were unaware of their status, and 14 percent were HIV-negative.

While the risk of transmitting HIV through oral sex is much lower than through anal or vaginal sex, oral sex is a high-risk activity for syphilis. Many people falsely believe that unprotected oral sex is a safe behavior and fail to use condoms or dental dams. Authors stress the importance of alerting people to the risk of syphilis transmission through oral sex, the role of syphilis in facilitating HIV transmission, and its possible role in HIV disease progression.

CDC - MMWR 10/22/04

Editor's Note: Recent studies have shown as high as 7% of HIV + MSM had no other risk than oral sex. Resolute! reminds all readers that low risk is not no risk and that latex barriers and lots of lube in all forms of sex are still your best bet for not giving or receiving HIV and other STDs.

Comic Recruits Superhero with HIV

A superhero with HIV has joined the long-running Green Arrow comic, the first major comic book series to deal with HIV. Mia is a teenage runaway who discovers she contracted HIV during time spent as a homeless prostitute. The DC Comics character adopts the name Speedy and becomes a crime-fighter. "Mia is coming to terms with it in the way most young people are," said writer Judd Winick. "Young people, for good or for bad, are still pretty fearless."

The latest issue shows Mia becoming the lead character's sidekick after discovering she is HIV positive. "It's not as a death wish, but she can't fool around anymore," said Winick. "This isn't about an abbreviated life span. It is about life having focus." Winick said he wanted to approach HIV from the point of view of other young people. "She seems to be unafraid of death, she's mostly feeling like no-one is ever going to love her." As Speedy, she will later join the Teen Titans comic book series alongside Batman's sidekick Robin, Cyborg and Raven.

BBC 10/14/04

Indian Firm Withdraws All Its HIV Drugs from WHO's Approved List

The Indian drug firm Ranbaxy Laboratories withdrew all seven of its generic antiretroviral drugs from the World Health Organization's (WHO) list of pre-qualified drugs. Ranbaxy de-listed the drugs after it found "discrepancies in the documentation" necessary to prove its generic AIDS drugs were bioequivalent to the original patented versions. A Ranbaxy spokesperson had no immediate comment. The de-listed Ranbaxy drugs include indinavir, 3TC, nevirapine, d4T and AZT tablets, and two combinations of 3TC and d4T. Meanwhile, Ranbaxy has proposed dates to submit new bioequivalence studies to support the drugs, WHO said. The first study is expected to be completed by December.

The current de-listing follows WHO's removal earlier this year of generic drugs that failed to prove bioequivalent to the patented medicines. That de-listing affected three pre-qualified antiretroviral drugs made by Ranbaxy and two made by the Indian firm Cipla. In response, WHO warned all manufacturers of pre-qualified HIV/AIDS drugs to verify their data submissions and check labs that conduct bioequivalence tests.

AP 11/09/04

Basketball Greats Yao Ming and Magic Johnson Team Up to Raise Awareness On HIV/AIDS In China

The Chinese AIDS Initiative and the NBA jointly released a series of television ads promoting HIV/AIDS awareness in China, in conjunction with the first-ever NBA games to be played in that country in October. The ads, the first of their kind to be broadcast on the Chinese mainland, featured Houston Rockets' NBA All-Star Yao Ming and Basketball Hall of Famer Earvin "Magic" Johnson. Yao Ming is a hero both in his native China and in the U.S. Magic Johnson, a former L.A. Lakers superstar, disclosed his own HIV-positive status in 1991 and has worked to raise AIDS awareness on a worldwide basis ever since. The PSAs are designed to help educate Chinese citizens about HIV/AIDS prevention and dispel common misconceptions about how the disease is transmitted. In the four English and Chinese language ads, Yao and Magic play basketball together, embrace and share a meal…each an important visual confirmation that HIV/AIDS is not transmitted casually. Viewers are then told about a Chinese-language AIDS information website. "China is taking action to address HIV/AIDS, but the epidemic there is still growing rapidly," noted Dr. David Ho. "Today, there is a small window of opportunity to change the course of this epidemic in the world's most populous nation. Education, especially for young people, is key to slowing this epidemic in China." UN AIDS estimates that 10-20 million Chinese will be infected with HIV by the year 2010 unless immediate action is taken to prevent the disease's spread.

Aaron Diamond AIDS Research Center 10/13/04

World Briefs

GlaxoSmithKline Allows Kenyan Firm to Make Generic AIDS Drugs

In late October in Nairobi, pharmaceutical giant GlaxoSmithKline (GSK) signed an agreement with Cosmos Limited that allows the Kenyan firm to make generics containing AZT and 3TC and then market the drugs in East Africa, including in Kenya, Rwanda and Burundi. Cosmos will begin manufacturing the drugs "in the next couple of weeks," said Prakash Patel, the firm's managing director. Patel said the drugs' costs would depend on the level of production. "We are pleased that another local health-care company will play a significant role in addressing the HIV/AIDS crisis," said Andrew Bullock, GSK's general manager for East Africa.

Agence France Presse 09/22/04

Uganda Suspends Sales of Antiretroviral Drugs at Pharmacies Over Reports of Counterfeit Drug Sales

Uganda's Director General of Health Services, Francis Omaswa, directed the country's National Drug Authority to suspend antiretroviral drugs sales on the open market following reports that some doctors had been selling counterfeit drugs to patients. Peter Mugyenyi, director of the country's Joint Clinical Research Centre, said that some people have been selling the counterfeit drugs in containers resembling those used to sell authentic antiretrovirals. Mr. Omaswa said that the two pharmacies that had been licensed to sell the drugs would be ordered to stop doing so until guidelines on the drugs were issued

Xinhua News Agency 8/10/04

PEPFAR Money Should Go to Local Agencies, Multilateral Organizations

Most of the funding for the President's Emergency Plan for AIDS Relief "actually ends up in U.S. hands of U.S.-based nongovernmental organizations and pharmaceutical companies, rather than going to Africans or their institutions," wrote Stephen Gloyd, director of the International Health Program at the University of Washington School of Public Health and Community Medicine, in a Seattle Post-Intelligence opinion piece. Because much of PEPFAR money goes through U.S. NGOs (non-governmental organizations) and drug companies, it is "likely that less than 25% of PEPFAR aid value actually goes to recipient-country people or institutions," Gloyd says, adding that African governments will be "lucky to see a total of $3 billion to $4 billion of the $15 billion the Bush administration pledged to spend on PEPFAR over five years. Worse still, African governments during the past two decades have been paying rich countries $15 billion per year in debt repayments -- money that could cover all AIDS treatment costs, improve crumbling health services and provide much-needed basic services in the poor countries. The sum effect is that poor countries of Africa are subsidizing the rich countries while the rich country governments are putting aid money into their home-country organizations in the name of poor Africans. Therefore, rich countries should forgive African countries' debts to liberate a huge sum of money to train health workers, pay salaries, buy medicines and improve health infrastructure," Gloyd says. Rich countries should also "provide external support through institutions that can provide money to local agencies in Africa." He added that institutions such as the Global Fund to Fight AIDS, Tuberculosis and Malaria can "channel such money much more efficiently than PEPFAR. The time to act is now."

Seattle Post-Intelligencer, 7/30/04

The sum effect is that poor countries of Africa are subsidizing the rich countries while the rich country governments are putting aid money into their home-country organizations in the name of poor Africans.

International AIDS Society-USA and Department of Health and Human Services Guidelines for Initial Antiretroviral Treatment in a Snapshot - What To Start With?

Recommended or Preferred Regimens/Components

IAS-USA – Updated July, 2004

NRTI	NNRTI	PI
TDF + FTC or 3TC AZT + FTC or 3TC ddI + FTC	EFV or NVP*	LPV/r SQV/r ATV/r IDV/r

DHHS – Updated October, 2004

Combos		
(3TC or FTC)+ (AZT or TDF) + EFV	or	LPV/r + (3TC or FTC) + (AZT)

**In selected pts.*

Alternative Components

IAS-USA

Nuke Combos	+	PIs
ABC + 3TC, or ddI + TDF, or ddI + 3TC, or AZT + ABC, or d4T + 3TC, or		Fos-APV/r , or ATV, or NFV

DHHS

Non-Nuke Combos
EFV +(3TC or FTC) + (ddI or ABC or d4T) NVP + (3TC or FTC) + (AZT or d4T or ddI or ABC)

Nukes	+	PIs
(3TC or FTC) +(AZT or d4T or ABC)		Fos-APV, or Fos-APV/r, or ATV, or LPV/r, or IDV/r, or NFV, or SQV/r

Special Circumstances Only

Triple Nukes
AZT + 3TC + ABC*

** No longer recommended for initial therapy except when use of NNRTIs or PIs precluded*

The Department of Health and Human Services (DHHS) Guideline can be found at: http://aidsinfo.nih.gov/guidelines/

The IAS-USA Treatment Guidelines are, unfortunately only available on line with a fee. For more information you can go to to: http://www.iasusa.org.

Glossary of Treatment and Research Abbreviations and Terms

Antiretroviral Meds

Nucleoside Reverse Transcriptase Inhibitors, Nucleoside Analogues, NRTIs, Nukes
AZT, ZDV = zidovudine, Retrovir®
ddI =didanosine, Videx®
ddC = zalcitabine, HIVID®
d4T = stavudine, Zerit®
3TC = lamivudine, Epivir®
ABC = abacavir, Ziagen®
FTC = emtricitabine, Emtriva®

Nucleotide Reverse Transcriptase Inhibitor, Nukes
TDF = tenofovir, Viread®

Combination Nukes
AZT + 3TC, CBV = Combivir®
AZT + 3TC + ABC, TZV= Trizivir®
ABC + 3TC = Epzicom®
TDF + FTC = Truvada®

Non-Nucleoside Reverse Transcriptase Inhibitors, NNRTIs, Non-Nukes
NVP = nevirapine, Viramune®
DLV= delavirdine, Rescriptor®
EFV = efavirenz, Sustiva®

Protease Inhibitors, PIs
ATV = atazanavir, Reyataz®
SQV (HGC), saquinavir hard gel capsule, Invirase®
SQV (SGC) = saquinavir soft gel cap, Fortovase®
IDV = indinavir, Crixivan®
RTV = ritonavir, Norvir®
NFV = nelfinavir, Viracept®
APV = amprenavir, Agenerase®
APV = fosamprenavir, Lexiva®
LPV/r, KLT = lopinavir/ritonavir, Kaletra®

Fusion Inhibitors
T-20 = enfuvirtide, Fuzeon®

Terminology

Anecdotal = individual stories that accumulate into a body of "knowing" with no clinical science behind it.
Antiretroviral = drugs that fight retroviruses. HIV is a retrovirus.
Double-Blinded, placebo controlled = clinical trial design in which neither the researchers nor the study participants know which arm of the trial they are randomized to, or which drugs they are taking. This is the most scientifically rigorous and reliable model of evaluating whatever the study is looking to find.
Efficacy = the effectiveness of a particular drug or regimen. "How well it works."
Open Label = clinical trial design in which both the researchers and study participants know what arm of a trial individuals are randomized to.
Retrovirus = a class of enveloped viruses (including HIV and hepatitis C) start out as RNA and use the reverse transcriptase enzyme to translate their RNA into DNA.
Undetectable = desirable results of a viral load test. It means that the virus could not be detected using the assay that particular lab uses at the level that labs can count to. In other words <20 or <50 or < 400... This is a moving target. As the science and laboratory capabilities improve, undetectable is a lower and lower number. See BLQ below.

Abreviations

AE = Adverse Event
BLQ = below the level of quantification. Essentially means undetectable, but if you study the definition of undetectable, you will see that this is a more accurate way of defining a viral load result.
n = number of people participating in a study, or a given arm of the study
pts = patients
tx = treatment

QD = Once a day/ every 24 hours
BID = Twice a day/ every 12 hours
TID = Three times a day/ every 8 hours
QID = Four times a day/ every 6 hours
prn = as needed

ITT = intent-to-treat, missing = failure. Counts as "failures" any study participant who stopped meds, changed meds, or left the trial. This is the most rigorous evaluation of a clinical trial.
OT = only those still on their original regimen at the end of trial

TC = Total Cholesterol
LDL -c = low density cholesterol (the bad stuff)
HDL-c = High Density cholesterol (the good stuff)

Pharmaceutical Companies

Abbott Laboratories, *RTV, KLT (LPV/r)*
Agouron Pharmaceuticals, *NFV*
Boehringer Ingelheim Pharmaceuticals, BI, *NVP*
Bristol Myers Squibb, BMS Virology, *ddI, d4T, EFV, ATV*
Gilead Sciences, *TDF, FTC, Truvada®*
GlaxoSmithKline, GSK, *AZT, 3TC, ABC, APV, CBV, TZV, Epzicom®*
Merck & Co, *IDV, EFV (Outside US)*
Roche, *SQV (HGC, SGC), ddC, T-20*

Clinical Trials

CPCRA
Community Programs for Clinical Research on AIDS

Strategies for the Management of Anti-Retroviral Therapy (SMART)
The SMART study is a randomized trial comparing long-term effects of two strategies for use of antiretroviral therapy (ART): ***Drug Conservation (DC) Strategy:*** Episodic use of ART with the aim of conserving ART options. ART use is guided by CD4+ counts irrespective of viral load levels. ***Virologic Suppression (VS) Strategy:*** Continuous use of ART to maximally suppress viral load immediately following randomization and throughout follow-up, irrespective of CD4+ counts. Criteria: Greater than 350 CD4, not currently pregnant.

Long Term Monitoring(060)
A prospective study of long-term clinical virologic and immunologic outcomes of HIV+ individuals. Open to Treatment Naive individuals only.
Parking, transportation and child care available.

To enroll or for more information
Call Julia Weise....303.436.7195

Pediatric ACTU
(AIDS Clinical Trials Unit)

ACTG 219C: Pediatric Late Outcomes Protocol

PACTG P1006: The Effects of Highly Active Antiretroviral Therapy (HAART) on the Recovery of Immune Function in HIV-Infected Children

PACTG P1015: Intensification of HIV-specific CD4 and CD8 Activity by cycling Highly Active Antiretroviral Therapy (HAART) in Pediatric/Adolescent patients with < 50 HIV RNA copies/ml

PACTG 1020-A: Phase I/II Open Label Pharmacokinetic and Safety Study of a Novel Protease Inhibitor (BMS 232632) in Combination Regimens in ART Naive and Experienced HIV-Infected Infants, Children, and Adolescents

PACTG P1021: An Open-Label Study to Evaluate the Safety, Tolerance, Anti-Viral-Activity and Pharmacokinetics of Emtricitabine in Combination with Efavirenz and Didanosine in Once Daily Regimen in HIV Infected Antiretroviral Therapy Naïve or Very Limited Antiretroviral Exposed Pediatric Subjects

PACTG P1025: Perinatal Core Protocol

PACTG P1026S, Version 2.0: Pharmacokinetic Properties of Antiretroviral Drugs during Pregnancy

PACTG P1045, Version 1.0: Prevalence of Morphologic and Metabolic Abnormalities in Vertically HIV-Infected and Uninfected Children and Youth

PACTG P1030, Version 1.0: A Phase I/II Study of Lopinavir/Ritonavir in HIV-1 Infected Infants < 6 Months of Age

PACTG 1042s: Cognitive, Behavioral, and Psychosocial Correlates of Medication Adherence in Children and Adolescents with HIV-1 Infection

PACTG 1030: A Phase I/II Study of Lopinavir/Ritonavir in HIV-1 Infected Infants <6 Months of Age

PACTG 1034: A Comparative Trial of Protease-Containing and Protease-Sparing HAART Regimens in HIV-Infected Adolescents with an Evaluation of Therapeutic Drug Monitoring

PACTG 394: A Phase I Study of the Safety Tolerance, and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-1 Infected Pregnant Women and Their Infants

PACTG 1057: A Phase I/II Randomized Trial of the Safety and Immunogenicity of Cold Adapted Influenza Vaccine (Flumist™) in HIV-Infected Children and Adolescents

Issues Affecting Adherence in HIV Positive Adolescents

Serum Bile Acid Levels in Pregnant Women With and Without HIV Infection

For more information or to enroll call
Carol Salbendblatt...303.861.6751

University of Colorado Adult AIDS Clinical Trials Unit

Studies Open to Enrollment

Acute/Recent Infection

CORE01 - "Acute Infection and Early Disease Research Program (AIEDRP) CORE01 DATABASE PROTOCOL".

Treatment Naive Patients

ACTG A5073: "A Randomized Phase II Open Label Study to Compare Twice Daily Potent Antiretroviral Therapy With Once Daily Potent Antiretroviral Therapy and to Compare Self-Administered Therapy and Therapy Administered Under Direct Observation".

ACTG A5173: "A Pilot Study to measure the Clearance of Replication-Competent HIV-1 in Resting Memory CD4+ Cells in HIV Infected Subjects Who Receive T-20 + Oral Combination Antiretroviral Therapy"

ACTG A5175: A Phase IV, Prospective, Randomized, Open-Label Evaluation of the Efficacy of Once-Daily Protease Inhibitor and Once-Daily Non-Nucleoside Reverse Transcriptase Inhibitor-Containing Combinations for Initial Treatment of HIV-1-Infected Individuals from Resource-Limited Settings (PEARLS) Trial.

Treatment Experienced Patients

ACTG A5126: A Phase II Study of the Predictive Value of Pharmacokinetic-Adjusted Phenotypic Susceptibility (C12h/IC50) on Antiretroviral Response to Ritonavir-Enhanced Protease Inhibitors in Subjects with Failure of Previous Protease Inhibitor-Based Regimens.

ACTG A5146: A Randomized Controlled Trial Evaluating the Impact of Therapeutic Drug Monitoring (TDM) on Virologic Response to a Salvage Regimen in Subjects with a Normalized Inhibitory Quotient (NIQ) Less Than or Equal to One to One or More Protease Inhibitors.

Tibotec TMC114: A Phase II Randomized, Controlled, Partially Blinded, 48-Week Trial to Investigate Dose-Response of TMC114/RTV in 3-Class-Experienced, Multi PI-Experienced HIV-1 Infected Subjects.

Tibotec TMC125: A Randomized, Controlled, Partially Blinded Phase IIb Dose-Finding Trial of TMC125, in HIV-1 Infected Subjects with Documented Genotypic Evidence of Resistance to Currently Available NNRTIs and with at least Three Primary PI Mutations.

Vaccine Studies

ACTG A5197: A Phase II Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Antiretroviral Effect of Immunization with the MRK Ad5 HIV-1 GAG Vaccine in HIV-1 Infected Individuals who Interrupt Antiretroviral Drug Therapy.

Opportunistic Infections/ Miscellaneous

ACTG A5090 (cognitive impairment): A Phase II, Placebo-Controlled, Double-Blind Study of the Selegiline Transdermal System (STS) in the Treatment of HIV Associated Cognitive Impairment.

ACTG A5163 (Bone Density): A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Once-Weekly Alendronate in HIV-Infected Subjects with Decreased Bond Mineral Density Receiving Calcium and Vitamin D.

ACTG A5164 (Acute OIs): A Phase IV Study of Antiretroviral Therapy for HIV-Infected Adults Presenting with Acute Opportunistic Infections: Immediate versus Delayed Initiation

ACTG A5178 (HCV/HIV coinfection): Criteria: Patients must be HIV/HCV Coinfected. Patients may be treatment naive or previously treated for HCV. Patients will receive peg interferon and ribavirin in step one.

ACTG A5186 (Fish Oil and Fenofibrate on Triglycerides): A Phase II Trial of the Effect of Combination Therapy with Fish Oil Supplement and Fenofibrate on Triglyceride (TG) Levels in Subjects on Highly Active Antiretroviral Therapy (HAART) Who Are Not Responding to Either Fish Oil or Fenofibrate Alone.

COMIRB 01-844: Concentration-Controlled Antiretroviral Therapy in Patients Experiencing Persistent Viremia.

For additional information contact:
Graham Ray, RN, MSN (303) 372-5535
Bev Putnam, RN, ANP (303) 372-5537
Cathi Basler, RN, ANP (303) 372-5539
Jim Scott, RN (303) 372-5543

WebSite INFO:
http://www.uchsc.edu/sm/caactu/

HIV/AIDS Services

Denver Area

Public Health Clinics

Children's Hospital HIV Program (CHIP)
303.764.8233
1056 E 19th Ave., B055,
Denver, CO 80218.
Ryan White funded pediatric, youth and family HIV specialty care. Medicaid/Medicare and private insurance accepted.

Children's Hospital Pharmacy
Ph: 303.436.7335

Denver Health & Hospitals ID/AIDS Clinic
Open Until 7:00 PM on Wednesdays!
Ph: 303.436.7240 Fax: 303.436.7244
605 Bannock St., Denver, CO 80204
Ryan White funded specialty HIV care for those who live in the City and County of Denver and have no insurance. Medicaid and Medicare also accepted.

Denver Health ID Pharmacy
Ph: 303.436.7335 Fax: 303.436.7663
605 Bannock

Early Intervention HIV Clinics
Ph: 303.436.4727
Fax:303.436.4779
Pager (303) 891-9360
Cell Line (303) 880-5747
Traveling HIV Clinic, please call most convenient location. Ryan White funded HIV medical care for uninsured people living in the City and City of Denver. Also accept Medicaid and Medicare.

University Hospital Infectious Disease Group Practice
Ph: 303..315.1540
Fax: 303.315.1469
4200 E. 9th Ave., Denver, CO 80262
Ryan White funded HIV specialty care for those who live outside the City and County of Denver and have no insurance. Also accepts most insurance, Medicaid and Medicare without residency requirement.

University ID Pharmacy
303.315.1455 Fax: 303.315.1463
4200 E 9th Ave.

Veterans Hospital
303.393.2837
1055 Claremont, Denver, CO 80204
Infectious Disease Clinic for Vets with VA medical benefits.

Private Clinics

Apex Family Medicine
Ph: 303.321.0222
Fax: 303.321.6683
210 University Blvd., Ste. #440,
Denver CO 80206

Colorado Infectious Disease Consultants
Ph: 303.777.0781
Fax: 303.777.0786
950 E. Harvard Ave., Ste. #690
Denver, CO 80210

Denver Infectious Disease Consultants
Ph: 303.393.8050 Fax: 303.320.1953
4545 E. 9th Ave., Ste. #120
Specialty HIV care. Accept most insurance, Medicaid and Medicare.

Infectious Disease Consultants, P.C.
Ph: 303.831.4774 Fax: 303.830.7750
1601 E. 19th Ave., Ste. #3650
Denver, CO 80218

Kaiser Permanente Infectious Disease Clinic
Ph: 303.861.3133
Fax: 303.831.3772
2045 Franklin St., 4th Floor

South Denver Infectious Disease Specialists
303.788.5900
499 E. Hampden Ave., Ste. #220, Englewood, CO 80110 Accepts most insurance, Medicaid and Medicare.

Western Infectious Disease Consultants
Ph: 303.425.9245 Fax: 303.425.1378
7760 W. 38th Ave. Ste 290, Wheat Ridge, CO 80033 Accept most insurance, Medicaid and Medicare.

Dental Clinics

Howard Dental Center
Ph: 303.863.0772. Fax: 303.832.7823
1420 Ogden St., Denver, CO 80218

HIV Specific Pharmacies

State ADAP Pharmacy
The Apothecary
303.499.2879/ 1.866.499.2879
Fax: 303.499.5308, 350 Broadway, Suite 50, Boulder, CO 80305

Clear Spring Pharmacy
Call 303.333.2010
201 University Boulevard
Denver, CO 80206

Colorado Pharmacy
Ph: 303.863.7644 Fax: 303.863.7656
701 E. Colfax, Denver, CO 80203

Case Management Agencies

The Adoption Exchange Families Connecting for Kids
Ph: 303.755.4756
Fax: 303.755.1339
Provides assistance with permanency planning and case management for families living with HIV.

Colorado AIDS Project
Ph: 303.837.1501
Fax: 303.837-0388
701 E. Colfax, Denver, CO 80203
www.coloradoaidsproject.org

Empowerment/ Women's AIDS Project
Ph: 303.320.1989 Fax: 303.320.3987
1600 York St., #201, Denver, CO 80206
Case management for women living with HIV/AIDS.

POCCAA, People of Color Consortium Against AIDS
Ph: 303.321.7965
Fax: 303.321.6841
1652 Franklin St., Denver, CO 80218

Servicios De La Raza, Inc.
303.458.5851
4055 Tejon, Denver, CO 80211

HIV Testing and Counseling

Colorado AIDS Project
303.837.1501, 701 E. Colfax Ave. Denver, CO 80218.
Free Anonymous and Confidential Orasure HIV testing and counseling. Call for current testing hours.

Denver Metro Health Clinic
303.436.7221
605 Bannock, Denver, CO
Anonymous and Confidential HIV testing as well as a full STD clinic.

Early Intervention Outreach Testing
303.851.4098
Free Anonymous and Confidential Orasure testing and counseling.

Empowerment, Women's AIDS Project
303.320.1989
Free Anonymous and Confidential Orasure testing, 3rd Tues of each month from 5 -6:30 pm. 1600 York St., #201, Denver, CO 80206

The GLBT Center
303.733.7743
Free Anonymous and Confidential Orasure testing and counseling. 1st and 2nd Wed. of each month from 6-8 pm. 1050 Broadway, Denver, CO 80203

It Takes A Village/ Brother Jeff's Health Initiative
Call 720.297.9349 or 303.367.4747
Two Offices: 1532 Galena St Suite 225, Aurora, CO 80010 or 608 26th St., Denver, CO 80205, 303.293.8879

Jefferson County Department of Health and Environment
Arvada: 303-275-7501
Conifer: 303-239-7078
Lakewood: 303-239-7078
HIV anonymous and confidential testing, STD testing and treatment, Hepatitis information.

Mental Health Services

Living and Learning with HIV
Mental Health Corporation of Denver 303-504-6501 4141 E. Dickenson Place, Denver, CO 80222. Callers can ask for anyone on the LLH team.

CAP
303.837.1501

Denver Health
303.436.7240

University Hospital
303.315.1540

Proyecto Nosotros
303.367.0929
Fully Bilingual advocacy,outreach, prevention case management and psychotherapy services. Call Lucy, Rodolfo or Antonio.

Sisters of Color United for Education Comadres Project
303.863.1446 ext 104
1290 King St., Denver, CO 80204
Mental Health and Client Advocacy services available.
Call Bernadette Berzoza.

Substance Abuse Treatment

"ARTS" Special Services Clinic
303.355.1014
Substance abuse counseling and primary medical care. 2121 E. 18th Ave., Denver, CO 80206

Avance con Salud
303.302.3275
Bilingual Harm Reduction Substance Use Services. Call Roseann (English)or Kathi (Spanish).
1240 W. Bayaud, Denver, CO 80223

Project Safe
303.315.0950, 1.800.429.9240
HIV prevention services and treatment entry facilitation for HIV+ drug users.

Education and Advocacy

The HepC Connection
303.860.0800 1-800-522HEPC
1177 Grant Street, Ste 200, Denver, CO 80203. http://hepc-connection.org
A unique support system established to assist Hep C-challenged individuals and their families.

The HEART Institute
303.913.7644
Certification courses in HIV Treatment Education. Courses are open to HIV service providers, volunteers, PLWH/A and others interested in understanding HIV disease and its treatment.

It Takes A Village/Brother Jeff's Community Health Initiative
Call 720.297.9349 or 303.367.4747
Two Offices: 1532 Galena St Suite 225, Aurora, CO 80010 or 608 26th St., Denver, CO 80205,
303.293.8879
Peer-based Prevention Case Management, HIV Testing and Counseling and Peer Advocacy and Education by and for the African American community through the Just Us Project, Phenomenal Women and other programs.

Living Through the Age of AIDS
303.837.1501
Ongoing educational workshop series offered monthly at various times and locations.
Call Rachel

Proyecto Nosotros
303.367.0929
Fully Bilingual advocacy,outreach, prevention case management and psychotherapy services. Call Lucy, Rodolfo or Antonio.

Servicios De La Raza
Bilingual Client Advocacy Services
Call Maria Lopez 303.458.5851

Sisters of Color United for Education
Comadres Project
303.863.1446 ext 104
1290 King St., Denver, CO 80204
Mental Health and Client Advocacy services available.
Call Bernadette Berzoza.

The Women's Lighthouse Project
Ph: 720.331.0408
1290 Williams St. 3rd Floor, Denver, CO 80218.
email: womenslighthouse@aol.com
Education, advocacy and support. Child care, a meal and transportation are always provided.
Call Shannon Behning.

Food Banks/ Home-Delivered Meals

CAP Food Bank
303.837.1501. 701 E. Colfax Ave.

VOA Meals on Wheels
303.294.0111

POCCAA Food Bank
303.321.7965
1652 Franklin, Denver, CO 80218

Project Angel Heart
303.830.0202
Home-delivered meals for people living with HIV/AIDS and other life-limiting conditions. 4190 Garfield St., Unit 5, Denver, CO 80216

Home Health/Home-Based Services/ Hospice

Hospice of Metro Denver
303.321.2828

Jewish Family Services
303.759.4890
Homemaker services free to all People Living with HIV/AIDS in need.

RAIN Colorado
Regional AIDS Interfaith Network
303.355.5665
1290 Williams St., Denver, CO 80218

Visiting Nurses Association
303.698.6405
Home health care for People Living with HIV/AIDS. Call Art Burke.

Housing

Colorado Coalition For The Homeless
2111 Champa Street
Denver, CO 80205
(303) 293-2217

Continental Divide Management Corporation
303.393.7368

Denver Housing Authority
303.534.0821

The Hope Program
303.832.3354
Drop-in Center/Services for the homeless.

Horizon House
Housing for People Living with HIV/AIDS
303.980.9604

Our House II
303.742.4729
Assisted living for People Living with HIV/AIDS who qualify for HCBS services.

Legal Services

ACLU Colorado
303.777.5482
400 Corona St.; www.aclu-co.org
American Civil Liberties Union.

CLIP
303.282.5602 / 1.877.372.CLIP
www.clipcolorado.net.
Contact Michael Brewer.

The Legal Center
303.722.0300/ 800.288.1376
Legal help for HIV/AIDS discrimination. Call Barry or Eric.

Metro Volunteer Lawyers
303.837.1313
Nonprofit organization providing free legal services for people with low income.

Child Care/Family Services

Families Connecting for Kids
The Adoption Exchange
303.755.4756, ext. 253, Call MaryBeth.
Services for People Living with HIV/AIDS and are caring for a child.

VOA Rainbow House
303.355.9582
Day care for HIV infected and affected children.

Holistic Health

The Yoga Group
303.575.1673
Free restorative yoga classes for People Living with HIV/AIDS, three times each week in Denver. No yoga experience necessary. For information on classes, phone us or visit www.yogagroup.org.

Support Groups

***** A New Support Group for HIV+ Young Women!!!**
Meets the 2nd Wednesday of every month. If you are between 13 and 24 years old and are living with HIV you are welcome to attend! Call Jen at 303.837.2796 for more information.

Catholic Support Group-HIV/AIDS Ministry.
303.715.3287.
Meets the first Monday of each month at 6:30pm at St. Dominic's Parish Hall, 29th and Grove st.

"Challengers, " Social Support
303.860.1819
Looking for something fun to do in a healthy alcohol-free environment? Join your peers at a new Friday evening social gathering, with game playing and just plain fun. Come join: Fridays at 7pm at MCC Church of the Rockies. 960 Clarkson.

El Grupo
Bilingual Support and Education Group. Meets alternate Fridays. Call Rodolfo at 303.367.0929 for more information.

Grupo Palanca
303.458.5851
Bilingual/bicultural support for gay and bisexual Latino men living with or affected by HIV/AIDS. Call Lorenzo Ramirez. Meets alternate Fridays at 7:00pm.

HIV/HCV Coinfected Support Group
303.340.4870
About us and by us. Meets at PWACC Group Room. 1290 Williams St. Call Catherine for time and day.

HIV+ Women's Group
303.320.1989
Woman-to-woman support. Meets Tuesdays at 1:30pm. Food, transportation and child care available. Call Crystal.

Jewish Support Group
303.756.5862
Co-sponsored by the AIDS/HIV Interfaith network. Call Carolyn.

PFLAG AIDS Family Support Group
303.333.0286
We meet on the second Monday of every month from 7:30 to 9:00 p.m., at Denver Health Medical Center, in the main building on the second floor. People living with HIV/AIDS, their families, partners, and friends are all welcome.

Positive Impact Group
303.436.5972
Meets every other Tuesday from 1:30-3:30pm. Offers food, support, fun events, guest speakers and help with medication adherence. 605 Bannock St., 5th Floor Conference Room #307. Call Debbie Scott-Young

Positive Support
303.837.1501
For any HIV+ person with alcohol or drug issues. Meets Wednesdays 5 - 6:30pm. 701 E. Colfax Ave. Call Pam Semmler.

RISE
303.832.4188
624 Lafayette. St. Call Marty Flahive

Straight and Positive
Call 303.837.1501 for current place and time.

Two-Spirit Society
303.939.9021
Meets alternate Sundays. Call David Young.

Young and Positive
303.837.7358 ext. 2
A support group for young people living with HIV. 1st and 3rd Wednesday of every month at 4:00 pm. Call Myles Mendoza or talk to your case manager.

Native American Services

Denver Indian Health
303.781.4050

Two-Spirit Society
303.444.9009
Prevention and Intervention Services. Call David Young.

Asian-American Services

Asian-Pacific Development Center
Denver: 303.355.0710
Aurora: 303.365.2959
Multiple support services and AIDS education in Asian-pacific ethnic languages.

Gay and Lesbian Services

ATL Foundation
303-424-1207
P.O. Box 740985, Arvada, CO 80006-0985 The ATL Foundation provides assistance to lesbians in need as a result of ill-health. If you or anyone you know is in need, call or write to us.

The GLBT Center
303.733.PRIDE (7743)
234 Broadway, Denver, CO 80203

EAGR - The Emergency Assistance & Referral Program
303.860.1779
Emergency financial assistance and referrals to other community resources.

Rainbow Alley
303.831.0442
Emergency Pager 303.461.1650
Drop-in center for Gay/Lesbian/Bisexual/Transgender/Queer youth. HIV education and support group.

Social Services

Adams County Social Services
303.287.8831

Arapahoe County
303.365.5770

Denver Human Services
720.944.3666

Douglas County Human Services
303.688.4825

Jefferson County Human Services
303.271.1388

Public Health and Safety/ Community Planning/ Public Policy

Colorado Department of Public Health and Environment
303.692.2700
Partner notification, prevention case management, Ryan White Title II Consortia, HIV/AIDS prevention and epidemiology.

Colorado Department of Health Care Policy and Financing
303.866.3058
State of Colorado Medicaid Program Coordination. Serving all residents of Colorado.

Coloradans Working Together (CWT)
303.692.2736 Hotline: 303.692.2717
HIV prevention community planning group. People directly affected by HIV encouraged to participate.

Jefferson County Department of Health and Environment
One-on-One HIV Prevention Services Please call Amy Robillard at 303-239-7123, or e-mail at arobilla@co.jefferson.co.us.
HIV prevention services and support for those infected with HIV and those concerned about infection.
HIV anonymous and confidential testing, STD testing and treatment, Hepatitis information.
Arvada: 303-275-7501
Conifer: 303-239-7078
Lakewood: 303-239-7078

Mayor's Office of HIV Resources
720.865.5600
Dept. Environmental Health
201 W. Colfax Ave suite 1009
Denver, CO 80202

PLWH Action Network
303.722.3083
Educating the legislature on ADAP and other issues surrounding those living with HIV/AIDS. Call Daniel.

Ryan White CARE Act
HIV Resources Planning Council
720.855.8641 Call Lisa Lawrence
4130 S Tejon St.

Social Security Administration
800.772.1213

Tri-County Health Department
303.363.3071

Boulder County

Boulder County AIDS Project (BCAP)
Ph: 303.444.6121 Fax: 303.444.0260
2118 14th St., Boulder, CO 80302

Monday Night men's Discussion Group
Monday night from 7-8:30 at BCAP Office
For more information contact the group facilitator, Alan Robarge at 303.247.0157 or call Boulder Pride at 303.499.5777

Experience and Exploration of Healing
303.444.6121
A healing circle. Meets alternate Wed. at 7:00pm at First United Methodist Church.
HIV Testing/Anonymous
303.413.7500

Terrie House
The Works: AIDS Prevention/Risk Reduction
303.413.7522
Free and anonymous needle exchange.
3305 Broadway, Boulder, CO 80304

Beacon Clinic
303.938.3167
1136 Alpine, Suite 205
Boulder, CO 80304

Northern Colorado
Northern Colorado AIDS Project
Ft. Collins
970.484.4469/ 800.464.4611
400 Remington Ave., Suite 100
Ft. Collins, CO 80524

Ft. Morgan
970.867.0300
909 E. Railroad Ave., Ft. Morgan, CO 80701

Positive Persons Group
Ft. Collins
970.484.4469
Call for Current Information

Southern Colorado

Southern Colorado AIDS Project
Colorado Springs
719.578.9092
1301 S. 8th St., Ste. #200, Colorado Springs, CO 80906. Email: info@s-cap.org. Web site: www.s-cap.org.

Pueblo
719.561.2616
2410 N Grand, Pueblo, CO 81003

Mom's Groups
Colorado Springs
719.578.9092
Call Phyllis McNaughton.

Pueblo
719.561.2616 Call Phyllis King.

Western Colorado

Four Corners Living with HIV/AIDS
Durango
970.247.5702
For anyone living with or affected by HIV/AIDS. Meets second and fourth Tuesday of every month. Call D.B.

Western Colorado AIDS Project (West CAP)
1.800.765.8594
115 N. 5th St., Ste 210 Grand Junction, CO 81501. Email: Westcap@GJ.net
www. GJ.net/~wcap/Main.html

Resolute!
IS UP ON THE WEB!

Hosted by one of the most respected HIV/AIDS Websites in the Country -- TheBody.com

To access Resolute on the web go to
www.thebody.com
Click on Treatment, then Treatment Periodicals, then Resolute!

National and International HIV/AIDS Resources

AIDS Action
1906 Sunderland Place, NW
Washington, DC 20036
Call..... 202-530-8030
Website.....aidsaction.org

AIDS Educational Global Information System
Website.....aegis.com

AIDS in Prison Project
Call.....718.378.7022
Accepts collect calls from incarcerated.

AIDS Meds.com
HIV+ owned and operated great website with cool tools and information.
.....www.aidsmeds.com

AIDS Medicine & Miracles
1290 Williams St, Denver, CO 80218
Call.....303.860.8104
Toll Free.....800.875.8770
Fax.....303.860.8105

AIDS Project Los Angeles
Online Publications
Positive Living, Impacto!, Optimist
www.apla.org/apla/ed/publications.html

AIDS Treatment News
1233 Locust St., 5th Fl. ,
Philadelphia, PA 19107.
Call.....800.873.2812
Website.....http://www.aidsnews.org

amfAR
American Foundation for AIDS Research
Website.....amfar.org

AVERT
Check this site out! It has great stats, maps and pictures.....www.avert.org

Being Alive
621 San Vicente Blvd.
West Hollywood, CA 90069
Call.....310.289.2551
Fax.....310.289.9866
Web site.....beingalivela.org
Website en Español:
www.beingalivela.org/spawelcome.html

BETA:
San Francisco AIDS Foundation.
Call.....415.487.8060
Website.....sfaf.org/beta.html
Email.....beta@sfaf.org

The Body
AIDS and HIV Information Resource
Website.....thebody.com

Centers for Disease Control (CDC)
Website.....cdcnpin.org

CMV Hotline
Call.....800.838.9990

Conference on Retroviruses and Opportunistic Infections (CROI)
.....www.retroconference.org

Critical Path AIDS Project
Hosts over 80 AIDS Websites
Website.....critpath.org

The Cutting Edge, TCE Consults
Nutritional Information on HIV/AIDS
Website: .....tceconsult.org

Denver Public Health
Website:.....aidscentral.com

Gay Men's Health Crisis
AIDS Hotline.....212/807-6655
Toll free.....1-800-AIDS NYC
TTY 212/645-7470
Website.....gmhc.org

HIV/AIDS Treatment Info Service
Call.....800.448.0440
Website.....www.hivatis.org

HIV Resistance Web
Website.....hivresistanceweb.com

IAPAC: International Association for Physicians in AIDS Care
"Battling complacency, advancing commitment"
Website.....iapac.org

International AIDS Society.....www.ias.org

International Community of Women Living with HIV/AIDS
.....www.icw.org

Medscape
Online Medical Journal with excellent HIV/AIDS Information
Website.....medscape.com

National AIDS Hotline
Call.....800.342.2437

NATAP: National AIDS Treatment Advocacy Project
Website.....natap.org

NAPWA:National Association for People With AIDS
1413 K Street, NW, 7th Floor, Washington, DC 20005
Call..... 202.898.0414
Fax..... 202.898.0435
Website.....napwa.org

New Mexico AIDS InfoNet
Website.....aidsinfonet.org

NMAC: National Minority AIDS Council
1931 13th Street, N.W., Washington, DC 20009
Call.....202.483.6622
Website.....nmac.org
National Pediatric AIDS Network
Call.....800.646.1001
Website.....npan.org

Positively Aware
Test Positive Network
1258 W. Belmont Ave., Chicago, IL 60657
Website.....tpan.com

POZ Magazine
349 West 12th Street, New York, NY 10014
Call..... 212-242-2163
Website..... .poz.com

Project Inform
Treatment and Advocacy information
205 13th St., Ste. 2001
San Francisco, CA 94103
Hotline.....800.822.7422
Phone.....415.558.8669
Accepts collect calls from incarcerated
International Callers.....415.558.9051
Website.....projectinform.org

Project Return to Work
Creating good work at home jobs and benefits for disabled Americans.
PO Box 19381, Boulder, CO 80308
Call.....303.415.9187
Fax.....303.564.0534
Email.....webmaster@return2work.org
Website..... .http://www.r2w.org/

RITA!
Research Initiative/*Treatment Action!*
Website.....centerforaids.org/rita/

San Francisco AIDS Nightline
Call.....415.434.AIDS

Teen HIV Hotline
Call.....800.440.TEEN

UN AIDS.....www.unaids.org

University of California San Francisco AIDS Program
Website.....hivinsite.ucsf.edu

Women Alive
Call.....800.554.4876
Website...../www.women-alive.org

World Health Organization 3 by 5 Inititative
.....http://www.who.int/3by5/en/

NORVIR®

(ritonavir capsules) Soft Gelatin
(ritonavir oral solution)

ALERT: Find out about medicines that should NOT be taken with NORVIR. Please also read the section "MEDICINES YOU SHOULD NOT TAKE WITH NORVIR."

Patient Information
NORVIR®
(Nor-veer)

Generic Name: ritonavir
(rit-ON-uh-veer)

Please read this leaflet carefully before you start taking NORVIR. Also, read it each time you get your NORVIR prescription refilled, just in case something has changed. Remember that this information does not take the place of careful discussions with your doctor when you start this medication and at check ups.

You should remain under a doctor's care when taking NORVIR and you should not change or stop treatment without first talking with your doctor.

You should tell your doctor about any medicine you are taking or planning to take because taking NORVIR with some medications can result in serious or life-threatening problems.

Talk to your doctor if you have any questions about NORVIR. Your doctor or pharmacist can also give you more information about NORVIR.

What is NORVIR and how does it work?

NORVIR is in a class of medicines called the HIV protease (PRO-tee-ase) inhibitors. NORVIR is used in combination with other anti-HIV medicines to treat people with human immunodeficiency virus (HIV) infection. NORVIR is for adults and for children age 2 years and older.

HIV infection leads to the destruction of CD_4 (T) cells, which are important to the immune system. After a large number of CD_4 (T) cells have been destroyed, acquired immune deficiency syndrome (AIDS) develops.

NORVIR blocks HIV protease, a chemical which is needed for HIV to multiply. NORVIR reduces the amount of HIV in your blood and increases the number of CD_4 (T) cells. Patients who took NORVIR in clinical studies had significant reductions in both death and AIDS defining diseases; however NORVIR may not have these effects in all patients.

Does NORVIR cure HIV or AIDS?

NORVIR does not cure HIV infection or AIDS. The long-term effects of NORVIR are not known at this time. People taking NORVIR may still get opportunistic infections or other conditions that happen with HIV infection. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium* complex (MAC) infections.

Does NORVIR reduce the risk of passing HIV to others?

NORVIR does not reduce the risk of passing HIV to others through sexual contact or blood contamination. Continue to practice safe sex and do not use or share dirty needles.

How should I take NORVIR?

- You should stay under a doctor's care when taking NORVIR. Do not change your treatment or stop treatment without first talking with your doctor.
- It is very important that you take NORVIR every day exactly as your doctor prescribed it.
- The usual dose for adults is six 100 mg capsules or 7.5 mL of the oral solution twice a day (morning and night), in combination with other anti-HIV medicines.
- The dosing of NORVIR may be different for you than for other patients. Follow the directions from your doctor, exactly as written on the label.
- Children from 2 to 16 years of age can also take NORVIR. The child's doctor will decide the right dose based on the child's height and weight.
- Take NORVIR with food if possible.
- NORVIR Oral Solution is peppermint/caramel flavored. You can take it alone, or improve the taste by mixing it with 8 ounces of chocolate milk, Ensure®, or Advera®. NORVIR Oral Solution should be taken within 1 hour if mixed with these items. Ask your doctor, nurse or pharmacist about other ways to improve the taste of NORVIR Oral Solution.
- Do not change or stop taking NORVIR without first talking with your health care provider.
- When your NORVIR supply starts to run low, get more from your doctor or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to NORVIR and become harder to treat.
- Be sure to set up a schedule and follow it carefully.
- Only take medicine that has been prescribed specifically for you. Do not give NORVIR to others or take medicine prescribed for someone else.

What should I do if I miss a dose of NORVIR?

It is important that you do not miss any doses. If you miss a dose of NORVIR, take it as soon as possible and then take your next scheduled dose at its regular time. If it is almost time for your next dose, wait and take the next dose at the regular time. Do not double the next dose.

What happens if I take too much NORVIR?

If you think that you took more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately.

As with all prescription medicines, NORVIR should be kept out of the reach of young children. NORVIR liquid contains a large amount of alcohol. If a toddler or young child accidentally drinks more than the recommended dose of NORVIR, it could make him/her sick from too much alcohol. Contact your local poison control center or emergency room immediately if this happens.

Who should not take NORVIR?

Together with your doctor, you need to decide whether NORVIR is right for you.

- Do not take NORVIR if you are taking certain medicines. These could cause serious side effects that could cause death. Before you take NORVIR, you must tell your doctor about all the medicines you are taking or are planning to take. These include other prescription and nonprescription medicines and herbal supplements.

For more information about medicines you should not take with NORVIR, please read the section "MEDICINES YOU SHOULD NOT TAKE WITH NORVIR."

- Do not take NORVIR if you have had a serious allergic reaction to NORVIR or any of its ingredients.

Can I take NORVIR with other medications?*

NORVIR may interact with other medicines, including those you take without a prescription. You must tell your doctor about all the medicines you are taking or are planning to take.

MEDICINES YOU SHOULD NOT TAKE WITH NORVIR.

- *Do not take the following medicines with NORVIR because they can cause serious or life-threatening problems such as irregular heartbeat, breathing difficulties or excessive sleepiness could occur:*

  Cordarone® (amiodarone)
  Ergotamine, ergonovine, methylergonovine, and dihydroergotamine such as Cafergot®, Migranal®, D.H.E 45®, and others
  Halcion® (triazolam)
  Hismanal® (astemizole)
  Orap® (pimozide)
  Propulsid® (cisapride)
  Quinidine, also known as Quinaglute®, Cardioquin®, Quinidex®, and others
  Rythmol® (propafenone)
  Seldane® (terfenadine)
  Tambocor® (flecainide)
  Vascor® (bepridil)
  Versed® (midazolam)

- Do not take NORVIR with St. John's wort (hypericum perforatum), an herbal product sold as a dietary supplement or products containing St. John's wort. Talk with your doctor if you are taking or are planning to take St. John's wort. Taking St. John's wort may decrease NORVIR levels and lead to increased viral load and possible resistance to NORVIR or cross-resistance to other antiretroviral medicines.
- Do not take NORVIR with the cholesterol-lowering medicines Mevacor® (lovastatin) or Zocor® (simvastatin) because of possible serious reactions. There is also an increased risk of drug interactions between NORVIR and Lipitor® (atorvastatin); talk to your doctor before you take any of these cholesterol-reducing medicines with NORVIR.

Medicines that may require dosage adjustments:

It is possible that your doctor may need to increase or decrease the dose of other medicines when you are also taking NORVIR. Remember to tell your doctor all medicines you are taking or plan to take.

- The following medicines require dose reduction if taken with NORVIR:

  If you are taking Viagra® (sildenafil), your doctor may lower your dose of Viagra.

Before you take Viagra with NORVIR, talk to your doctor about possible drug interactions and side effects. If you take Viagra and NORVIR together, you may be at risk of side effects of Viagra such as low blood pressure, visual changes, and penile erection lasting more than 4 hours. If an erection lasts longer than 4 hours, you should get medical help immediately to avoid permanent damage to your penis. Your doctor can explain these symptoms to you.

- If you are taking Oral contraceptives ("the pill") to prevent pregnancy, your doctor should increase the dose or you should use a different type of contraception since NORVIR may reduce the effectiveness of oral contraceptives.
- If you are taking Mycobutin® (rifabutin), your doctor will lower the dose of Mycobutin.
- **Other Special Considerations:**

  NORVIR oral solution contains alcohol. Talk with your doctor if you are taking or planning to take metronidazole or disulfiram. Severe nausea and vomiting can occur.

- **If you are taking both didanosine (Videx) and NORVIR:** Didanosine and NORVIR should be separated by at least 2.5 hours.
- Rifampin, also known as Rimactane®, Rifadin®, Rifater®, or Rifamate®, may reduce blood levels of NORVIR. Be sure to tell your doctor if you are taking rifampin.

What are the possible side effects of NORVIR?

- This list of side effects is **not** complete. If you have questions about side effects, ask your doctor, nurse, or pharmacist. You should report any new or continuing symptoms to your doctor right away. Your doctor may be able to help you manage these side effects.
- The most commonly reported side effects are: feeling weak/tired, nausea, vomiting, diarrhea, loss of appetite, abdominal pain, changes in taste, tingling feeling or numbness in hands or feet or around the lips, headache, and dizziness.
- Blood tests in patients taking NORVIR may show possible liver problems. People with liver disease such as Hepatitis B and Hepatitis C who take NORVIR may have worsening liver disease. Liver problems including rare cases of death have occurred in patients taking NORVIR. It is unclear if NORVIR caused these liver problems because some patients had other illnesses or were taking other medicines.
- Some patients taking NORVIR can develop serious problems with their pancreas (pancreatitis) which may cause death. Tell your doctor if you have nausea, vomiting, or abdominal pain. These may be signs of pancreatitis.
- Some patients have large increases in triglycerides and cholesterol. The long-term chance of getting complications such as heart attacks or stroke due to increases in triglycerides and cholesterol caused by protease inhibitors is not known at this time.
- Diabetes and high blood sugar (hyperglycemia) have occurred in patients taking protease inhibitors. Some patients had diabetes before starting protease inhibitors, others did not. Some patients need changes in their diabetes medication. Others needed new diabetes medication.
- Changes in body fat have been seen in some patients taking antiretroviral therapy. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast and around the trunk. Loss of fat from the legs, arms and face may also happen. The cause and long term health effects of these conditions are not known at this time.
- Some patients with hemophilia have increased bleeding with protease inhibitors.
- Allergic reactions ranging from mild to severe have occurred in patients taking NORVIR.

There have been other side effects noted in patients receiving NORVIR; however, these side effects may have been due to other medicines that patients were taking or to the illness itself. Some of these side effects can be serious. If you have questions about side effects, ask your doctor, nurse, or pharmacist. You should report any new or persistent symptoms to your doctor immediately.

What should I tell my doctor before taking NORVIR?

- *If you are pregnant or planning to become pregnant:* The effects of NORVIR on pregnant women or their unborn babies are not known.
- *If you are breast-feeding:* Do not breast-feed if you are taking NORVIR. You should not breast-feed if you have HIV. If you are a woman who has or will have a baby, talk with your doctor about the best way to feed your baby. You should be aware that if your baby does not already have HIV, there is a chance that HIV can be transmitted through breast-feeding.
- *If you have liver problems:* If you have liver problems or are infected with Hepatitis B or Hepatitis C, you should tell your doctor before taking NORVIR.
- *If you have diabetes:* Some people taking protease inhibitors develop new or more serious diabetes or high blood sugar. Be sure to tell your doctor if you have diabetes or an increase in thirst and/or frequent urination.
- *If you have hemophilia:* Some people with hemophilia have had increased bleeding. It is not known whether the protease inhibitors caused these problems. Be sure to tell your doctor if you have hemophilia types A and B.

How do I store NORVIR?

- Keep NORVIR and all other medicines out of the reach of children.
- Store NORVIR Oral Solution at room temperature. Do not refrigerate NORVIR Oral Solution. Avoid exposing NORVIR Oral Solution to excessive heat or cold.
- Refrigeration of NORVIR soft gelatin capsules by the patient is recommended, but not required if used within 30 days and stored below 77°F (25°C). Avoid exposing NORVIR soft gelatin capsules to excessive heat or cold.
- Store NORVIR soft gelatin capsules and NORVIR Oral Solution in the original container.
- Shake NORVIR Oral Solution well before each use.
- Use NORVIR Oral Solution by the expiration date on the bottle.

Do not keep medicine that is out of date or that you no longer need. Be sure that if you throw any medicine away, it is out of the reach of children.

General advice about prescription medicines:

Talk to your doctor or other health care provider if you have any questions about this medicine or your condition. Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. If you have any concerns about this medicine, ask your doctor. Your doctor or pharmacist can give you information about this medicine that was written for health care professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people.

* The brands listed are trademarks of their respective owners and are not trademarks of Abbott Laboratories. The makers of these brands are not affiliated with and do not endorse Abbott Laboratories or its products.

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04A-017-A985-1 **MASTER**

ABBOTT LABORATORIES
NORTH CHICAGO, IL 60064, U.S.A.

04A-017-B766-2
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Expanded Access to Norvir®

Abbott Laboratories has expanded the scope of its Patient Assistance Program (PAP). Now, patients without prescription drug coverage or public assistance may be eligible to obtain Norvir® at no cost, regardless of income level.

To apply or obtain more information, contact us using any of the following methods:

- On the Web: **abbott.com**
- Phone: 1-800-222-6885 (select option #2)
- Fax: 1-847-937-9826

norvir®
(ritonavir) Soft Gelatin Capsules 100 mg

Please see adjacent page for Patient Information.

Abbott Laboratories
Abbott Park, IL 60064

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