POSITIVE VOICES - December 2011

Your Newsletter by Positive People for Positive People

"Reclaiming emotional wellness" - The challenges of HIV and mental health.

By David Fawcett PhD. from : positively aware.com Nov. 2011

Deep in the shadows of the aids epidemic there are powerful forces that dramatically impact the quality of life for many living with HIV. Depression, anxiety, post-traumatic stress, and other mental health disorders can confuse, discourage, and stigmatize a significant portion of HIV-positive people.

Mental health impacts the full spectrum of HIV. It can determine who is at risk for acquiring the virus (people with a history of trauma or depressive disorders are more likely to become infected) and, after seroconversion, it affects quality of life, medication adherence, levels of social support, and even the progression of the illness. Consider the following three cases:

Steve had been living with HIV for 20 years and experienced the demise not only of his good health but nearly everything that defined him. His career as an attorney abruptly unraveled which, in turn, eroded his financial independence. His marriage dissolved because his wife couldn't adjust to the demands of caretaking when he was extremely ill. He was forced onto disability, which left him bitter and judgmental about himself and others living with HIV. But the most significant loss of all was his sense of hope. He felt doomed to suffer medical complications and social indignities until he finally succumbed to the virus. His medication adherence became sporadic and on most days, despite being medically stable, he verbalized despair and no desire to keep living.

Angela was stunned when the counselor at the testing site told her she was HIV-positive. Although just 30 years old, she had survived several traumatic incidents in her life, including sexual abuse and witnessing violence in her home while growing up. She had always been able to tap into some internal strength to keep moving forward, but her positive HIV test result completely swept away her emotional foundation. For reasons unclear even to her, she felt herself becoming numb at the testing center and had stayed that way for nearly two months. She was having trouble sleeping, couldn't concentrate, was crying every day, and memories of all the prior trauma she thought had been resolved began flooding into her daily life. She felt overwhelmed and emotionally paralyzed.

Brian and his partner Paul had been in a relationship for six months. Early in their life as a couple they had gotten tested together for HIV and both were negative. They decided to remain monogamous and began having unprotected sex with each other. After six months, they went for an HIV test and were horrified to learn that Paul's test came back positive. Despite his own negative result, Brian began to notice strange aches and pains and was certain his lymph nodes were swollen. He felt compassion for Paul, but he secretly wondered if he could remain in the relationship. Brian found himself becoming obsessed with his own health, his partner's wellbeing, and their future. He began to experience shortness of breath, difficulty going out in public, and on many days, panic that left him housebound. The stronger these feelings became, the more he retreated from Paul and the world in general.

Understanding mental health

The ability to maintain emotional and behavioral health is the result of many complex factors ranging from biology to culture. Genetics determine the potential for certain emotional disorders onto which we add life experiences that shape our personalities and create unique profiles of emotional resilience. Elements of culture, such as spiritual beliefs and ideas about death, further impact our capacity for handling emotions, as do recreational or prescribed drugs that can numb feelings, affect thoughts and dreams, and propel our moods up or down.

A mental health diagnosis, for someone living with HIV, can add another layer to existing shame and stigma, which remains a potent force 30 years into the AIDS epidemic. Homosexuality or condemnation by one's spiritual community adds even more stigma, undermining the self-concept of vulnerable individuals to the point of collapse.

Mental health disorders impact everything from quality of life to physical health, and healing involves building emotional resilience to the greatest extent possible. Although this requires commitment, support, and often medication and/or psychotherapy, most people who make the journey discover renewed compassion not only for themselves but for others as well.

Adjusting to a new diagnosis of HIV/AIDS

Learning that you are HIV-positive is a life-changing moment. Anyone who has had this experience remembers the exact circumstances and their emotional and physical reactions trying to comprehend and assimilate this news. A lifetime of prior events guides our subconscious response at that moment of emotional shock. Reactions can include tears, inappropriate laughter, a flattening of affect (feelings or emotions expressed by physical gestures and body language), relief ("I knew this was coming"), or total numbing of feelings. At first, some people may be unable to comprehend the news ("that's impossible"), while others, such as Angela mentioned above, may experience a reawakening of prior trauma. Anyone in this position is vulnerable and requires emotional support. Rash decisions should be discouraged and assistance should be offered to enable any emerging feelings to be identified and expressed.

Assimilating this shock is a process of acceptance that varies with each individual. Feelings such as sadness, anger, or fear are completely normal, even if delayed. This is identified by the Diagnostic and Statistical Manual IV-TR (the standard set of guidelines published by the American Psychiatric Association) as an "Adjustment Disorder." There is no way to predict who might develop such a reaction, which is diagnosed through a variety of symptoms such as depressed mood, physical complaints, and agitation. Such adjustment reactions typically do not last longer than six months, although in the case of a chronic illness such as HIV/AIDS, the duration may vary. Supportive psychotherapy, including expression of feelings and assisting in the identification and creation of a support system, is usually sufficient to resolve an adjustment disorder and early intervention can prevent the development of more significant anxiety and depressive problems.

Common mental health issues associated with HIV

A variety of mental health problems can be experienced by people living with HIV/AIDS. The following section describes the more typical diagnostic categories and their associated interventions.

Neurologic complications of HIV-

While antiretroviral therapies have greatly reduced their prevalence, more than half of HIV-positive patients do experience some form of neurologic dysfunction ranging from mild to very severe.¹ The most typical of these disorders is MCMD (minor cognitive motor disorder), characterized by mild impairment which may totally escape detection. MCMD does not necessarily progress to dementia. A more serious form is HAD (HIV-associated dementia), which includes cognitive dysfunction (problems with concentration, memory, and attention), declining motor performance (strength, dexterity, coordination), and behavioral changes. Both MCMD and HAD are diagnoses of exclusion, meaning other potential causes such as substance abuse or medication must be ruled out. Recent studies indicate that the risk of dementia related to cerebral atrophy may be associated with the CD4 nadir (the lowest point) rather than current CD4 levels.² While there are no specific treatments, antiretroviral therapy along with other interventions, such as structured routines, memory aids, and good nutrition, may greatly reduce symptoms.³ Other HIV-related neurologic disorders include encephalitis, meningitis, neuropathy, and the very rare but lethal PML (progressive multifocal leukoencephalopathy).

Mood disorders-

Mood disorders, or conditions that affect an individual's mood, include those that result in depressive symptoms (major depressive disorder and dysthymia) and those with intermittent mania which can be frequently accompanied by a depressive phase (bipolar disorder). Depressive disorders are one of the most common mental health concerns among HIV patients. While they can appear or become more severe following an HIV diagnosis, symptoms can increase at any time due to medical complications, loss of a loved one, or other psychosocial stressors. Certain subgroups of individuals living with HIV are at greater risk for mood disorders. Major depressive disorder, for example, occurs more frequently in substance abusers,⁴ older patients,⁵ and females with a history of abuse (as in the case of Angela noted above).⁶

Major depressive disorder (MDD) creates a pervasive low mood which inhibits the ability to experience pleasure. It has a prevalence as high as 36% among individuals living with HIV.⁷ People experiencing depression may be preoccupied with thoughts or feelings of worthlessness, regret, hopelessness, and despair. A second, milder type of depression called dysthymia, in which symptoms are chronic but less severe than with major depressive disorder, is also prevalent.

Depressive disorders are frequently difficult to diagnose because their broad cluster of symptoms (increased or decreased sleep and/or appetite, low mood, low energy, etc.) can also occur as a result of HIV itself, various opportunistic infections, or co-morbidities such as hepatitis C. If undiagnosed, major depressive disorder can lead either to an increased risk of HIV transmission, or among those already positive, a lack of adherence to HIV medication regimens or relapse of substance abuse.

Suicide is a serious risk for someone experiencing ongoing MDD and any suic idal thoughts and/or plan must be immediately addressed. In one recent study, 26% of people with HIV reported suicidal thoughts at some time in their life, and 13% reported a suicide attempt. Those who attempted suicide were more likely to also have a problem with substance abuse.⁸ These statistics underscore the need to address concurrent mental health and addiction problems in people living with HIV.

There are no laboratory tests for depression, but there are several widely-used screening tools that are used to identify those at risk for the disorder. Once diagnosed, a number of medications are effective at treating depression. The most common are called SSRIs (selective serotonin re-uptake inhibitors) that are generally well-tolerated by HIV-positive people, but which can take two to four weeks before patients begin to feel relief from their depressive symptoms. While they are helpful for depression, they can cause a reduction of sexual desire and delayed ejaculation. Besides SSRIs, there are several other classes of antidepressant medication that are also effective.

Some HIV drugs, such as Norvir (ritonavir), can interact with certain SSRIs and create blood levels which are too high. When monitored, however, both SSRIs and an older class of antidepressants called tricyclics are safe when combined with HIV medications. Herbal remedies for depression represent another significant drug interaction risk with HIV medications. For example, St. John's Wort should not be used as it can cause a drop in blood levels of the antiviral. Patients should always discuss all their medications, including herbs, with their physician.

Psychotherapy is an effective treatment for depression. In fact, research suggests that the most powerful intervention is a combination of pharmacological and psychotherapeutic approaches.⁹ A psychotherapist works with patients to teach them specific skills to modify thoughts and behaviors, as well as other types of interpersonal therapy which can focus on issues of loss and grief, acceptance, and identity. Group modalities, as well, are a powerful way to break the isolation typical of HIV and provide a forum in which patients can both give and receive support.

Anxiety disorders-

Anxiety disorders are common among those living with HIV. One recent study found that as many as 45% of HIV-positive individuals also had an anxiety disorder.¹⁰ Surprisingly, these rates were highest among those on antiretroviral medications with an undetectable viral load. Anxiety disorders significantly impact an individual's quality of life and have an adverse effect on adherence to medications and other treatment interventions. There is also evidence that chronic anxiety affects hormonal balance in such a way that immune function is impeded.¹¹

Symptoms of anxiety range from those that are barely noticeable to paralyzing panic attacks, making them difficult at times to diagnose. Many symptoms are physiological, such as a racing pulse, chest pain, sweating, and hyperventilation. Brian, mentioned above, experienced disabling symptoms of panic based on his fear of having become infected by his partner Paul. Anxiety disorders frequently occur with other mood disorders. For example, as many as half of individuals who experience panic disorder also experience MDD.¹² Women experience anxiety disorders, particularly panic disorder, more frequently than men.¹³

Post-traumatic stress disorder (PTSD) can result from witnessing or experiencing an event beyond what would be considered normal and which involves the threat of death or actual injury. As noted earlier, a history of abuse can increase the risk of PTSD among persons living with HIV. Symptoms, such as those described for Angela, include frightening physiological reactions, nightmares, and other symptoms of emotional shock. PTSD can result in social withdrawal and a sense of a foreshortened future.

Treatment for anxiety disorders often includes pharmacological interventions. Specific SSRIs (noted above for treatment of depression) are effective for certain anxiety disorders, including obsessive-compulsive disorder (OCD). Other medications are approved to treat anxiety, including buspirone and some beta blockers. Benzodiazepines can be effective at resolving acute symptoms of anxiety but, because of their addictive potential, should only be used in the short-term and with great caution in anyone with a history of substance abuse. Benzodiazepine withdrawal is dangerous and should always occur under the direction of a physician.

Psychotherapy is also an effective means of treating anxiety disorders. Cognitive behavioral therapy can greatly reduce symptoms of anxiety by focusing on thought patterns and the "here and now." Therapy can also teach various stress management techniques that significantly improve one's ability to engage in social and medical activities. Specialized treatment techniques such as hypnotherapy and EMDR (eye movement desensitization and reprocessing), among others, are effective for treating PTSD.

In addition to medication and therapy, anyone experiencing symptoms of anxiety should refrain from ingesting caffeine. Symptoms can also be controlled through increased exercise and relaxation procedures such as deep breathing and meditation.

Substance abuse-

The use of recreational drugs along with the abuse of prescription medication, particularly benzodiazepines and opiates, is intimately bound to HIV and mental health. Addiction increases both the risk of acquiring HIV and greatly complicates the medical and psychological management of living with the virus. The desire to numb feelings or escape into fantasy, despite potential life-threatening complications, is seductive for many with HIV. The grief of cumulative losses, shame, fear, and other overwhelming feelings can easily propel someone to the short-term relief of a mood-altering substance.

While a comprehensive discussion of substance abuse is beyond the scope of this article, it is important to note how HIV, mental health, and substance abuse converge into syndemics, or simultaneous epidemics, each impacting the other. One striking example is the methamphetamine epidemic among gay men. Meth is an amphetamine that works on the pleasure center of the brain, releasing a torrent of dopamine that quickly washes away any feelings of inhibition and even depression. It also triggers intense sexual thoughts that can result in high-risk sexual marathons.

While meth is a risk factor for becoming HIV-positive, it creates havoc among those who have already seroconverted. I work with many gay men in their 40s and 50s who have lived with the virus for years. Many have begun to feel less energetic, less attractive, less sexual, and socially isolated. Meth washes away these concerns, creating an artificial sense of confidence and empowerment. A significant number of meth users soon become drawn into a vortex of increased drug use and severe social, medical, and sometimes legal consequences. Many stop taking their antiretroviral medications, which can create drug resistance. The depletion of dopamine can result in severe depression and feelings of hopelessness which can persist well into recovery because the brain requires months to "rewire" neural pathways damaged by the drug.

There are many resources available to anyone seeking assistance for substance abuse. Medications can reduce cravings for certain types of drugs. Support groups, whether twelve-step or alternative, such as SMART

Recovery, have saved thousands of lives. Counseling can assist with underlying issues as well as the development of relapse prevention plans. Recognizing substance abuse and taking steps to reduce its harm can have a tremendous impact on HIV-related mental health concerns.

Building emotional resilience

HIV presents formidable barriers to achieving and maintaining emotional well-being. Despite these challenges, there are steps that anyone living with HIV can take to promote their own mental health and quality of life. Here are a few that can build emotional resilience:

Collaborate with your healthcare providers—

Carefully monitor your emotional state and share any concerns with your physician or other providers. Certain disorders require pharmacological intervention. If your depressed, manic, or anxious moods seem beyond your control, you might benefit from medication that could give you a stable foundation on which to implement the other suggestions in this section.

Identify and express feelings-

Living with HIV produces a number of negative emotions which must be identified and released. Whether at the initial diagnosis, when making the decision to begin meds, or during a medical setback, an emotional process ensues which can include a swirl of anger, denial, and sadness. Because holding on to these feelings aggravates both physical and mental conditions, it is important to find ways to release them through verbal expression, physical exercise, creative endeavors, or any other means possible.

Maintain social support—

HIV, in many cases, creates increased isolation and loneliness. Physical mobility, feeling ill, shame, and depression can all contribute to a withdrawal from society. It is critical to fight the urge to isolate and to reestablish connections with others. Social contact promotes healing at a number of levels and benefits not only the individual but everyone they come in contact with.

<u>Live consciously</u>—

Each of us needs emotional nourishment to heal. Many people derive strength from their spiritual life. Others find that nature, or work in the garden, or playing with their pet can ground them and re-establish emotional balance. Maintaining an awareness of our inner thoughts and feelings assists us in overcoming stigma, shame, and other negative emotions, and in expanding our connection with others and our role in a larger healing community.

Practice daily self care—

Daily healthy routines are not only beneficial in and of themselves, but they subtly affirm our inner sense of value and worth. A healthy diet, adequate sleep, minimal use of mood altering substances, and physical exercise all contribute enormously to mental health. Remaining focused on the present and not letting our thoughts drift too frequently into the past or the future can greatly reduce stress. If negative emotions take hold, a simple act, such as creating a list of things for which we are grateful, can often bring us back into balance. Any actions that reinforce personal empowerment are beneficial for our health and our emotions.

Living with HIV creates challenges to mental health that cannot be underestimated, yet the power to create positive feelings, healthy relationships, and an inner sense of peace lies within each of us. When we maintain our emotional balance, HIV can remain just one piece of the rich emotional mosaic of our lives.

David Fawcett is a psychotherapist and clinical hypnotherapist in private practice in Fort Lauderdale, Florida. He is active in the gay men's health movement, writes regularly for TheBody.com, and is a national trainer for the National Association of Social Workers' "HIV Spectrum Project." (*<u>I felt it important to include the entire article.</u>)

Free EDUCATIONAL Lunch/Dinner :

<u>**New Date** December 12th</u>: STAP and Gilead will be hosting a free educational lunch at NOON at Grande's located on Upper Front Street in Binghamton. The topic of this presentation will be "NBLCKA: Many Women, One Voice." Please call Martha at 238-8350 to reserve your seat.

There will be a guest speaker on the topic "NBLCKA: Many Women, One Voice:" A program that features women from across the country and from all walks of life speaking openly and candidly, sharing their personal stories, experiences and broad knowledge. The program aims at inspiring women to take care of themselves, to protect one another and to make a difference in their communities. A valuable message will be shared relevant to ALL women and ALL others that have women they know and love....Please call Martha to reserve a seat: 238-8350. STAP clients are welcome to bring <u>one</u> guest.

Friends Support Groups

Broome County: Every Tuesday at 3 pm - 4:30 pm at Trinity Memorial Church located at 44 Main St. in Binghamton... come join us for Binghamton's HIV/AIDS Support Group **(open to clients only).

Chemung County: Men Living with HIV Support Group; 2nd Monday of each month; 6-7:30pm; Ivy Clinic, 600 Ivy St., Suite 206, Elmira. For more information people can contact me via phone or email. Lynn Bassler, LMSW Treatment Adherence Counselor, Ivy Clinic, 737-8188.

Tompkins County: The IVY Clinic is pleased to let all HIV+ men in the Ithaca and surrounding area know there is a support group that is held the third Tuesday of every month at the Ithaca STAP office. Time for the group is 6-7:30 pm and topics vary from month to month. If you are interested in attending please e-mail Shannon Sprague at <u>ssprague@aomc.org</u> for further information.

Tompkins County: A NEW support group open to <u>ALL</u> HIV+ clients of STAP is starting in Ithaca. The first group meeting will be on December 1st from 1:00-2:00PM at the Ithaca office, and the 1st Thursday of the every month thereafter. Please call Autumn Cook, STAP Medical Advocate at 607-426-9445 for more information.

ON GOING MEETINGS AND COMMUNITY SERVICES Join/ Attend: Consumer Advisory Committee [CAC] Meetings

The STAP <u>Consumer Advisory Committee</u> is a committee facilitated by and made up of consumers (STAP clients) who welcome other consumers and their significant others, caretakers and family members to join them on the second Tuesday of each month. This collaborative effort provides a confidential space for clients to make recommendations regarding STAP client services and other programs in a non-judgmental environment. The meetings are held following the Friends Dinner @ 5:45 at Trinity Memorial Church (on the corner of Main & Oak Streets) in downtown Binghamton. Call 1-800-333-0892 for directions or more details. If you cannot attend these meetings, mail your opinions or suggestions to STAP, 122 Baldwin Street, Johnson City, 13790, Attention CAC. CAC is encouraging consumers in other counties to organize monthly meetings in their area.

* December 13th is our next meeting and Gayle will be joining us to update us on "what is going on at STAP" and new changes to State & Federal programs that will effect us and them.

* I also ask: with all the people who receive this newsletter only a few times a year (less than 5) will someone take the time to write an article / story / question for the medical advocates that would be informative to all. This newsletter is for us / from us. No one is required to include their name - share your story or your concerns or fears, someone else maybe feeling the same thing. LETS SPEAK UP.

Dragon Slayers

Hepatitis C and Co-Infection Support Group. Meetings at 6:00 - 7:00PM on alternate Tuesdays at Trinity M, 44 Main Street, Oak Street Entrance in Binghamton. For information, call (607)798-1706.

Friends Dinner

Friends meet every Tuesday evening for a time of fellowship and good food. Join us at Trinity Memorial Church (on the corner of Main & Oak Streets) in downtown Binghamton. Doors open at 5PM and dinner is served @ 5:30. No charge, just come with a smile and a friendly attitude - ready to meet and greet friends and have a hearty meal. Parking is available on Oak Street behind the Church Annex. Use the Oak Street entrance for the cafeteria. Free bus passes are available for STAP clients! Call your case manager for details. Bus passes available for transportation to/from the Friends Dinner only. For more information call Bill at 607-296-4416.

Ask The Medical Advocates

Wixie #206-0331 (Boome, Chenango, Delaware and Otsego), or Autumn #280-8322 (Chemung, Tompkins, Tioga and Cortland)

We are also pleased to welcome *Stacy Nickerson* back to the Medical Advocacy team effective November 1st. She will be supervising the Medical Advocacy program as well as our Elmira case management team. Stacy has been in the role of Medical Advocate twice in the past 8 years. She is a Register Nurse and also has several years of experience with case management and mental health services. Stacy will spend her time in both the Elmira and Johnson City offices working with both staff and clients. Please welcome Stacy back to the Medical Advocacy team!

** Do YOU know what C.H.O.I.C.E.S. is? **

CHOICES is a self-paced educational series designed specifically for YOU to learn and understand HIV and your body. Whether you take one quick course or decide to go through the entire program and take charge of <u>YOUR</u> HIV, ask a Medical Advocate about CHOICES today...

This program can help you by:

- Answering general questions or concerns regarding HIV
- Help you better manage side effects of your HIV medications
- Alleviate concerns about interactions between your HIV meds and other meds that you take
- Help you better understand the results of your blood work or other lab tests
- Learn how to reduce HIV exposure risks for your negative partners

But the information is only good if you use it!

<u>Every 3rd Tuesday</u> of the month at 5 pm - just before the Friends Dinner come join us for our monthly CHOICES module. (open to all) We have found that we get more out of the program when we learn the modules as a group. Informative questions and discussions are raised.

* Next Program will be Dec. 20th at 5PM located at Trinity Memorial Church, 44 Main Street in Binghamton. A meal with "Friends Who Care" will be provided too!

BECOME INFORMED, someday your life may depend on it.

Blogging Anyone???

Anyone interested in blogging messages is welcome to join in at <u>thecubebinghamton.tumblr.com</u> or contact <u>Noah@thecubebinghamton.org</u> for more information.

LGBT Information Site

www.asaging.org/larc

The American Society on Aging has created a Lesbian, Gay, Bisexual, and Transgender (LGBT) Aging Resources Clearinghouse that holds information related to and resources for people aged 50 and older. The site's searchable resources span several categories: education and training; health and mental health; housing and support services; populations and communities; and public policy, advocacy, and legal issues. Also available are annotated listings for service providers, community and professional organizations, information sites, reports and articles, and links for ordering DVDs, books, and other useful products.

Free Cell Phones

There is a government sponsored program available that can provide you with a free cell phone. Eligibility is based on your participation in one of several State or government programs like PUBLIC HOUSING, FOOD STAMPS, MEDICAID and more. There is also a limit to the amount of income you receive each month. This program is called LifeLine Assistance and you can find out about it through safelink.com or calling 1-800-378-1684. If you need help with the application process, please call your STAP case manager for assistance.

Free Anonymous Rapid HIV Testing

Walk-in *Anonymous* testing is available in our STAP Johnson City office every Monday from 1:00-4:30PM and Thursdays from 1:00-3:00PM. *Confidential* testing is available in our STAP Johnson City office Thursdays from 9:00AM - 12:00PM. STAP's office is located at 122 Baldwin Street Johnson City, NY 13790. Walk-in *Anonymous* Testing is also available at STAP's Ithaca office located at 501 S. Meadow Street, Ithaca, NY 14850 on Tuesdays from 9:00AM-11:30AM, and *Confidential* testing can be scheduled Thursdays, 9:00AM-11:30AM. For more information and other testing opportunities available throughout the month, please call (607)798-1706.

Complete One-Pill, Once-Daily Prezista-Based HIV Regimen Enters Development

Tibotec Therapeutics—the research and development division of Janssen Pharmaceuticals—has entered yet another agreement with Gilead Sciences to develop a fixed-dose combination (FDC) tablet. Now, according to a November 15 <u>press release</u>, the companies will develop a complete FDC regimen containing Janssen's protease inhibitor Prezista (darunavir) and Gilead Sciences' Emtriva (emtricitabine), boosting agent cobicistat and tenofovir prodrug GS 7340.

Plans for the newest Tibotec-Gilead FDC development strategy follow a <u>similar announcement</u> in June indicating plans to produce a single tablet combining Prezista with cobicistat.

During the past decade, a number of different HIV drugs have been combined into single pills, both to reduce the total number of pills that people with HIV take and to extend the rights of companies to exclusively sell their drugs. The most successful of these combinations, Atripla—which contains Bristol-Myers Squibb's Sustiva (efavirenz) and Gilead's Truvada (tenofovir plus emtricitabine)—was the first to combine drugs from two different companies.

To date, no protease inhibitors (PIs) have been co-formulated with other necessary agents to allow for complete one-pill, once-daily regimens.

The complete FDC being developed by Tibotec and Gilead will contain two approved drugs—Prezista and Emtriva—with two still-experimental agents: cobicistat and GS 7340.

Cobicistat is currently in Phase III studies and is being explored as an alternative to Norvir (ritonavir) to boost blood levels of other PIs.

GS 7340 is a "prodrug" of tenofovir (sold as Viread)—its mechanism of action is the same, but it requires a dose that is 10 times lower than Viread and provides greater effectiveness. Though Gilead <u>announced in 2004</u> that it had no interest in further developing the drug, arguing that it "does not believe that GS 7340 has a profile that differentiates it to an extent that supports its continued development," the company now plans to conduct a Phase II study to explore its efficacy, in preparation for its combined formulation with Prezista, cobicistat and Emtriva.

"We are pleased to once again be partnering with Tibotec to advance and simplify HIV treatment for patients," said Norbert Bischofberger, PhD, Gilead's chief scientific officer, in the company's announcement. "This is the first time we are developing a protease inhibitor-containing single-tablet regimen, and we're able to do that based on the small milligram size of GS 7340, which is less than one tenth of the amount of the 300 mg of tenofovir disoproxil fumarate contained in Viread and Truvada."

Gilead will be responsible for the formulation, manufacturing, registration and, subject to regulatory approval, distribution and commercialization of the single-tablet regimen worldwide. Tibotec will have the right to co-detail the single-tablet regimen in certain major markets.

WHAT IS COMPLERA ?

Complera is a tablet that contains three antiretroviral drugs (ARVs) used to fight HIV: <u>rilpivirine</u> (<u>Edurant</u>), <u>emtricitabine (Emtriva</u>), and <u>tenofovir (Viread</u>). Complera is manufactured by Gilead and Tibotec. In Europe it is called Eviplera. It is the second tablet that includes a complete antiretroviral regimen.

The drugs in Complera are a non-nucleoside reverse transcriptase inhibitor (rilpivirine) and two nucleoside analog reverse transcriptase inhibitors, or nukes (emtricitabine and tenofovir). These drugs block the reverse transcriptase enzyme. This enzyme changes HIV's genetic material (RNA) into the form of DNA. This has to occur before HIV's genetic code gets inserted into an infected cell's own genetic codes.

WHO SHOULD TAKE COMPLERA ?

Complera was approved in 2011 as an antiretroviral treatment for adults with HIV infection who have not already taken antiviral drugs. It works best in people whose viral load is below 100,000.

There are no absolute rules about when to start antiretroviral therapy (ART). You and your health care provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your attitude about taking ART.

If you take Complera, you can reduce your viral load to extremely low levels, and increase your CD4 cell counts. This should mean staying healthier longer.

Complera provides three drugs in one pill. It can be more convenient to use Complera than some other combinations of drugs. This could mean fewer missed doses and better control of HIV. Complera can be an effective regimen of ARVs in one pill.

WHO SHOULD NOT TAKE COMPLERA ?

Complera should not be used by people who have already used any other anti-HIV medications. Also, it is not recommended for patients less than 18 years of age. Complera has not been studied in people age 65 and over.

Complera is a fixed-dose combination. Dosages of the individual components cannot be adjusted. Patients who have moderate or severe kidney disease, or severe liver disease, should not use Complera.

WHAT ABOUT DRUG RESISTANCE ?

Many new copies of HIV are mutations. They are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called "developing resistance" to the drug.

Sometimes, if your virus develops resistance to one drug, it will also have resistance to other ARVs. This is called "cross-resistance."

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS COMPLERA TAKEN ?

Complera is taken by mouth as a tablet. The normal adult dose is one tablet, once a day. Each tablet includes 25 milligrams (mg) of rilpivirine, 200 mg of emtricitabine, and 300 mg of tenofovir.

Complera should be taken with a meal. If you miss your dose, you can take Complera up to 12 hours late. Otherwise, take your next dose at the regular time.

WHAT ARE THE SIDE EFFECTS ?

When you start any ART, you may have temporary side effects such as headaches, high blood pressure, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Complera are the same as with the drugs it contains: rilpivirine,

emtricitabine, and tenofovir. They include depression, headache, diarrhea, nausea, vomiting, anxiety, rash, dizziness, insomnia, and loss of appetite.

If you have had hepatitis B or C, your liver function tests may increase significantly. These should be monitored carefully. Some people taking Complera who have previously taken emtricitabine or tenofovir have had their hepatitis B worsen significantly.

HOW DOES COMPLERA REACT WITH OTHER DRUGS ?

Complera can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. Make sure that your health care provider knows about ALL drugs and supplements you are taking.

Drugs to avoid include some antacids. Drugs to watch out for include other ARVs, drugs to treat tuberculosis for erectile dysfunction (such as Viagra), for heart rhythm (antiarrhythmics), and for migraine headaches. Interactions are also possible with several antihistamines (allergy medications), sedatives, drugs to lower cholesterol, and anti-fungal drugs.

The herb St. John's Wort lowers the blood levels of some non-nucleoside reverse transcriptase inhibitors. Do not take it with Complera.

A NOTE FROM THE EDITOR:

Holiday Client Dinner:

A special "THANKS" goes out to STAP and all the volunteers who devoted their time and effort to make this years Holiday Dinner another success. From what I understand this years turn out was one of the largest and from those who did attend we all know the place was full. As for the food: You out did yourself this year - everybody I talked to loved it. It is so nice that "Our Community" can get together for such a nice event and find a way to stay in touch around this time of year.