

TREATMENT UPDATE

July - August, 2007

Welcome to the 16th Queensland Positive People (QPP) Treatment Update Newsletter!

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Contact Peter on (07) 3013-5505 or email: pwatts@qpp.org.au

*The information, comments and editing in this newsletter do not necessarily represent the views of those involved in direct primary medical care...
...Always seek the opinion of your doctor.*

Aptivus (tipranavir): A New Protease Inhibitor Now Available on PBS in Australia

On 1st August 2007 *Aptivus* 250mg capsules were listed on the Pharmaceutical Benefits Scheme (PBS) as part of anti-HIV combination treatment with other antiretrovirals.

Aptivus is an important and necessary new edition to HIV treatment armamentum when there has been drug failure or resistance with existing treatments (especially Protease Inhibitors). It is reserved for people who need it later on when these other drugs have failed. Like most other Protease Inhibitors it also needs to be taken with low-dose ritonavir (Norvir) to keep its blood levels boosted up to a certain concentration levels to inhibit HIV effectively. Two (250mg) capsules should be taken twice daily with food (plus two x 100mg ritonavir capsules, also taken twice daily). It must also be kept refrigerated.

There are some drugs it should not be taken with, and precautions are needed if there is coinfection with Hepatitis B or C. Your doctor will monitor and discuss these with you if necessary. Your doctor may also advise you how to manage the most likely side effects reported in the earlier trials (diarrhoea 10.9%; Nausea 6.7%; raised temperature 4.6%; and fatigue 4.0%). There are some serious side effects reported from the initial trials, but these were rare and the link not fully established. Your doctor may also monitor your blood fats, blood sugar and liver function on this drug.

Treatment Officer's Comments:

Because it has taken such a long time for tipranavir to come into the market, some clinical researchers have speculated (although no head to head comparison studies have been done) that other more potent newer PIs (Prezista/darunavir) - and new drug targets such as *Integrase Inhibitors* (raltegravir/MK-0518) - appear to have more efficacy than tipranavir in treatment-experienced patients, along with a better safety and side effect profile. Nonetheless, of the comparison PIs already compared against tipranavir - in the test tube - it remains active against the majority (90%) of virus mutations that reduce the susceptibility to those current PIs: amprenavir (Agenerase), atazanavir (Reyataz), indinavir (Crixivan), lopinavir (Kaletra), ritonavir (Norvir), nelfinavir (Viracept) and saquinavir (Invirase).

Double PI use, sometimes necessary in salvage - or rescue - treatment for people running out of options may also prove more difficult with tipranavir, because it lowers the levels of some other PIs. Subsequently boosting it further with more ritonavir only increases the safety risk of increased side effects.

...It is important for all new drugs to be experienced in wider use before we can say one way or another whether the trial safety and efficacy data is borne out in the longer term, or in the clinical experience. This is why post-marketing surveillance on new treatments is so important, and to report any new side effects or changes to your doctor.

So what do Protease Inhibitors Do?

Protease Inhibitors block the HIV viral enzyme called "protease", and so inhibit the last stage of HIV replication within an infected T cell before it buds into a new virus particle to infect other cells. Protease inhibitors changed the face of HIV treatment when they were first introduced back in 1996, and are attributed to the massive reduction in morbidity and mortality from HIV.

What's the buzz about next generation future HIV Treatments?...Are we on the verge of new drugs which attack the virus in different, and perhaps more potent, ways?...

Prezista (darunavir)

This new PI is now approved in Australia (formerly known under the experimental name "TMC114"). However, it is yet to be listed on the Pharmaceutical Benefits (PBS) for Medicare co-payment PBS subsidy scheme, but this is expected sometime soon.



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Nonetheless, the drug is now available, for people who have reduced current treatment options (due to resistance), or those experiencing other treatment limitations from the current treatments. This new treatment, whilst not a new class of treatment, is an important new - next generation - Protease Inhibitor (PI) to be used when other drugs might not be working as well as they could, and CD4 counts are low. It is also required to be taken with ritonavir in order to keep its levels up high enough in the blood to make it work.

Side effects are considered to be low, but in very rare cases a severe skin rash can develop, as is the case with other existing NNRTIs.

CCR5 Antagonist (maraviroc)

This novel new drug target has just recently been approved in the US, quite aptly under the name "Selzentry" - The drug inhibits HIV virus from entering the cell by the co-receptor molecule on the host T cell surface called "CCR5" (or sometimes just "R5").

This is the first drug a new class called "entry inhibitors", strongly awaited for over a decade since protease inhibitors. This is exciting in itself, but the virus can also evade using the R5 receptor, and use another co-receptor called "X4" instead. Therefore, it is under study (including in Australia) as an additional drug to existing combination treatments, including protease inhibitors, in treatment-experienced people. The early results are promising, showing greater viral load reductions and CD4 count increases compared to existing salvage treatments - amidst drug resistance - with currently approved therapy. Disappointingly however, preliminary data from a study evaluating the drug in people first starting HIV treatment suggests that it is somewhat inferior to standard-of-care when the regimen contains efavirenz (Stocrin). However, moderate CD4 count and side-effect benefits were found to be associated with the drug when compared to efavirenz.

...Meantime, we await advice about possible access approval in Australia from these trials.

Integrase Inhibitors (raltegravir/MK-5018)

This new drug heralds yet another new class of HIV treatments - **Integrase Inhibitors** - which have been long - long- awaited. Raltegravir (MK-0518) is currently under trial in late phase-III human trials in both treatment naive and experienced people (i.e. those first starting treatment, and those longer term on treatment). In people with multi-drug resistance there have been unprecedented reductions in viral load and CD4 count recovery within a rapid time frame compared standard optimised salvage treatments. In treatment naive settings, compared to standard

treatment it is showing comparable results so far. It is currently available under and expanded access program in the US.

Raltegravir is the first of a new class of Integrase Inhibitors (IIs) that most people's viral strain has not been exposed to. It inhibits HIV at a completely different part of HIV replication cycle inside infected CD4 cells (i.e. the integration phase with the host cell nucleus). It is thought that an Integrase inhibitor (which attacks the virus at a completely new target site in HIV's replication cycle) may alter the way HIV responds and reemerges from infected cell reservoirs, challenging the current theories about HIV viral kinetics and dynamic mechanisms which HIV replicates. Subsequently it's easy to get excited about this remarkable (well tolerated) new treatment; especially the potential paradigm shift in the way we may possibly treat HIV in very near future. Although current data is limited regarding resistance (or cross resistance) to these new drugs, it is thought that may also need to be used sequentially like existing classes of HIV treatment. Theoretically - and it's too early to tell - this may reduce or alter the need for Protease Inhibitors. Nonetheless, Integrase inhibitors will still rely upon use in combination with existing treatments, where its additive efficacy is currently most evident.

...And finally...two new - long awaited - NNRTIs

...Currently, the only viable Non-Nukes (NNRTIs) are efavirenz (Stocrin) and nevirapine (Viramune)...However, the following two next generation NNRTIs are strongly in the research pipeline:

The first new NNRTI is called by the experimental name "**TMC278**" (**rilpivarin**). This drug is currently under trial **for people first starting treatment** - comparing it to efavirenz. Efavirenz can affect the central nervous system - giving rise to mood and sleep disturbances. These side-effects of efavirenz can be particularly hard to cope with for some people first starting treatment - even though those side-effects tend to diminish after 6-8 weeks. Although it is only early days, TMC278 may prove to be useful new option.

The second new NNRTI drug is **TMC125** (**etravirine**), and it is intended (like darunavir) for **treatment-experienced people**, where the current limited number of NNRTIs is not enough if they begin to stop working well. Switching from currently available NNRTIs to PIs can tend to bring along greater metabolic side-effects (such as lipodystrophy), so another NNRTI to use may prove useful to overall care and avoidance of some of the PI-associated side effects. TMC125 is currently available under an expanded (early) access program.



More about Selzentry (Maraviroc)

The U.S. Food and Drug Administration (FDA) has granted approval to Pfizer's [Selzentry](#) (maraviroc), an HIV entry inhibitor that targets the CCR5 receptor on CD4 cells. The drug—the first member of a new class of oral HIV drugs in more than a decade—is approved for patients with HIV strains resistant to multiple antiretrovirals and is expected to be available through pharmacies by mid-September.

Selzentry in Development

Researchers have long known that, in order for HIV to infect a T cell, the virus must first bind with a receptor called CD4 on the cell's surface (T cells expressing the CD4 receptor are known as CD4 cells). Researchers also suspected that HIV requires the use of a second receptor on the surface of CD4 cells, but this elusive "coreceptor" remained a mystery for more than a decade of intense research.

It wasn't until 1996 that research groups in New York City, Boston and Bethesda, Maryland, simultaneously discovered what they were looking for: chemokine (C-C motif) receptor 5 (CCR5). In turn, a more complete picture of HIV "fusion and entry" came into view. While HIV first binds with the CD4 receptor, it must then latch on to a coreceptor, either CCR5 or CXCR4, with CCR5 being the most common of the two.

As research into CCR5 continued, a fascinating picture began to form. It turned out that people born with two defective CCR5 receptor genes (dubbed the CCR5 delta-32 mutation)—one from each parent—are highly resistant to HIV (provided that they are exposed to CCR5-tropic HIV, not CXCR4-tropic HIV). There are also people who inherit a defective CCR5 gene from one parent. While they're still able to contract HIV, studies suggest that they're more likely to experience slower disease progression than those without the genetic defect.

With these important data, along with additional research suggesting that CCR5 is not vital to health or survival, pharmaceutical and biotech companies scrambled to develop therapeutic compounds that block the CCR5 receptor. In effect, Pfizer's Selzentry—which made its research debut in 1997 as UK-427,857—is the first approved treatment for HIV that works by targeting a function of normal cells in the body, not the virus itself.

Tests of Efficacy

The FDA approval of Selzentry is based on preliminary results from MOTIVATE-1 and MOTIVATE-2, two Phase III clinical trials pitting Selzentry against placebo. While the studies intend to follow patients for a total of 48 weeks, 24-week results indicated that Selzentry, combined with an

optimized background regimen (OBR), is associated with greater viral load reductions and CD4 count increases compared to placebo among HIV-positive patients with limited treatment options due to drug resistance.

Patients in these studies were highly treatment-experienced; 69.7 percent of those on Selzentry and OBR and 66 percent on OBR alone had two or fewer active drugs in their optimized background regimen.

Selzentry is not yet approved for HIV-positive patients beginning antiretroviral therapy for the first time or for those with limited treatment experience. Preliminary data from a study evaluating the drug in patients new to HIV treatment suggest that it is somewhat inferior to standard-of-care Sustiva (efavirenz). However, moderate CD4 count and side-effect benefits were found to be associated with the drug, compared to Sustiva.

Safety Issues

Patients receiving Selzentry in the studies had a rate of discontinuation due to adverse events (3.8 percent), which was the same as the group receiving OBT plus placebo (3.8 percent). The most common adverse reactions associated with Selzentry therapy in the studies were cough, fever, upper respiratory tract infections, rash, musculoskeletal symptoms, abdominal pain and dizziness.

Although there was no overall increase in serious liver problems in patients treated with Selzentry in the clinical trials completed to date, liver toxicity has been seen in some patients using the drug. Certain allergy-like signs and symptoms—for example, rash, a drop in the number of eosinophils (a type of white blood cells) or elevated IgE antibodies—prior to the development of liver toxicity may occur. If these signs or symptoms occur while taking Selzentry, Pfizer warns, patients should be evaluated immediately.

Of note, more cardiovascular events, including heart attacks, were seen in patients receiving Selzentry as compared to placebo. In turn, the manufacturer and the FDA are recommending that the drug be used with caution in patients at increased risk for cardiovascular events.

Because Selzentry blocks the CCR5 coreceptor located on some immune system cells, Pfizer says that there is a potential increase in the risk of developing infections and cancers.

The Trouble With Tropism

Selzentry will only be effective against CCR5-tropic HIV. It will not be effective against virus targeting CXCR4 (and will have a limited effect against HIV with the ability to target both receptors). Because CXCR4-tropic and dual-tropic HIV are more common in people who have been infected for



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several years—the people who are most likely going to be using Selzentry—a new laboratory test, Monogram Bioscience's Trofile tropism assay, will be necessary before Selzentry is used, to determine if treatment with the drug will be useful.

Even among patients with CCR5-tropic HIV who begin Selzentry treatment, there is the possibility that their virus will switch to the CXCR4 receptor during therapy, meaning that the addition of Selzentry will no longer have any significant benefit. Much like drug-resistance testing, tropism testing can be ordered by a healthcare provider if Selzentry treatment failure is suspected.

What's more, because CXCR4-tropic HIV is usually seen in people who have advanced infection, experts have speculated that the emergence of CXCR4-tropic virus during entry inhibitor therapy would result in more rapid disease progression. In another Phase III study, however, patients who experienced a "switch" to CXCR4-tropic virus while taking Selzentry actually ended up with significantly greater CD4 cell counts. In other words, while therapy with a CCR5 inhibitor may not be virologically effective in patients who experience a switch to CXCR4-tropic HIV, it does not appear to be harmful.

Pfizer says that the drug will be available through U.S. pharmacies by mid-September. Outside of the U.S.—Pfizer is in the process of submitting approval applications to regulatory agencies throughout the world—maraviroc is to be sold under the brand name Celsentri.

The Selzentry dose depends on other medications being used in combination with it. With most [protease inhibitors](#), the Selzentry dose should be 150 mg twice daily. With [nucleoside reverse transcriptase inhibitors](#) (NRTIs), [Aptivus](#) (tipranavir) plus [Norvir](#) (ritonavir), and [Rescriptor](#) (delavirdine), the dose should be 300 mg twice daily. And when used with Sustiva (efavirenz), provided that protease inhibitors are not also being used in the drug regimen, the dose should be 600 mg twice daily.

Source: www.aidsmeds.com. *Pfizer's Selzentry (Maraviroc) Gets FDA Approval in the US.* Article by Tim Horn, Senior Writer & Editor. August 6, 2007

Crystal Meth Linked to Lower CD4s in Positive People

HIV-positive people using crystal methamphetamine have lower [CD4 cell counts](#) than their HIV-positive counterparts who don't use the drug, according to new data reported at the fourth IAC Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2007) in Sydney. The study is among the first to show a possible clinically significant effect of methamphetamine use on the



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health of the immune system in people infected with HIV.

While much has been written about meth use and its association with unsafe sexual activity and HIV transmission, less is known about the effects of the drug on immune function in people already infected with the virus.

Most studies completed to date have been test-tube or rodent experiments. One test-tube study published in 1994 suggested that meth can reduce levels of interleukin-2, a cytokine that promotes immune function in the body and plays a significant role in the immune system's response to HIV infection.

The drug was also shown to decrease the function of CD8 cells, which play a role in the control of HIV replication, particularly during the early stages of infection.

Another study involving retrovirus-infected rats, published in 2002, demonstrated a significant increase in tumour necrosis factor (TNF), an inflammatory cytokine that can negatively affect the immune system's response to HIV and increase viral replication.

While these studies pave the way for further investigation, they do not conclusively answer whether methamphetamine speeds up immune suppression in HIV-infected people.

To explore this further, Jason Barbour, PhD, and his colleagues at the University of California, San Francisco, conducted a pilot study to describe HIV disease parameters associated with the use of the drug.

His group recruited a total of 28 HIV-positive adults, 19 of whom had used meth within 72 hours prior to enrolment (confirmed using a urine drug screen). The remaining nine did not have evidence of recent meth use.

Unfortunately, the study's poster presentation did not specify if the recent users used the drug chronically or heavily, nor was it clear if those who did not test positive for the drug had a history of use.

The average age at enrolment was 40 years and all of the study subjects were men. Two of the recent meth users and one of the methamphetamine-negative participants were on antiretroviral therapy at the time of joining the study.

Regrettably, the authors did not report the average length of time the volunteers had been infected with HIV prior to joining the study, or if there were any differences between the two groups in this regard.

The recent meth users had a lower average CD4 count compared to the methamphetamine-negative participants: 362 vs. 551 cells respectively. This difference was statistically significant, meaning that it wasn't likely due to chance.

The recent meth users also tended to have higher [viral loads](#) (4.38 log vs. 3.86 log), although this difference was not statistically significant.

Using phenotypic [drug resistance testing](#), Dr. Barbour's group noted that HIV from the recent meth users was more sensitive to zidovudine (found in [Retrovir](#), [Combivir](#) and [Trizivir](#)). While the significance of this finding isn't clear, it possibly reflects a shorter duration of prior antiretroviral therapy use among the methamphetamine-positive participants.

Surprisingly, HIV's replication capacity—a measure of the virus's fitness or virulence—was lower in the recent methamphetamine users (83 percent) compared to the methamphetamine-negative volunteers (113 percent).

Three of the methamphetamine-positive patients had dual-tropic virus—a potential indicator of more rapid disease progression—compared to none of the methamphetamine-negative participants.

Running the data through a mathematical model, Dr. Barbour's group found that recent meth use was the strongest predictor of lower CD4 cell counts in the study.

Additional studies, the study authors conclude, are needed to better understand the possible association between meth use, CD4 cell depletion and other markers of health.

Reference:

Barbour J, Philip S, Cohen A, et al. Methamphetamine using HIV-1+ adults have lower CD4+ T cell counts than HIV-1+ adults who do not use methamphetamine [Abstract MOPEB095]. Fourth IAS Conference on HIV Pathogenesis, Treatment and Prevention, Sydney, 2007.

Source:

www.aidmap.com Article by Tim Horn. July 23, 2007

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Alcohol and HIV: Heavy Drinkers Have Lower CD4 Counts

One of the most common `healthy living` questions asked by people after an HIV diagnosis is: `how will alcohol affect my HIV disease?` .

Up until now it's been difficult to answer this question, but [last week US researchers published findings showing that](#), on average, people with HIV not on antiretroviral therapy who drink heavily have

lower CD4 counts than people with HIV who don't drink.

The findings imply that someone who consistently drinks heavily would be quicker to reach the point at which treatment is recommended than someone who is teetotal or drinks only moderately.

However, the study's definition of heavy drinking is actually quite modest by the standards of some communities. Fourteen drinks a week (the equivalent of two small bottles of beer a day) for a man would be considered pretty self-denying in many South African townships, among young people in Russia and among many gay men in London. On the other hand, it would be considered a level of alcohol abuse requiring professional intervention by many in the United States, and would be unaffordable in many parts of rural Africa.

Definitions of problem drinking differ from one community to another, just like the ways that alcohol is consumed and enjoyed, so the findings will be viewed differently by people with HIV around the world.

Above all, it's worth bearing in mind that the difference in CD4 cell count only occurred in untreated people, and was only 50 cells. Those 50 cells only become critical when an individual reaches the level that puts them at risk of opportunistic infections – around 200. Isn't earlier diagnosis the priority, rather than panicking people about alcohol consumption?

Treatment Officer's Comments:

Remember, alcohol lower inhibitions. This is a double-edge sword. It can be a great 'social lubricant' when taken in moderation, and a glass of wine with dinner in the evening is suggested to have health benefits. Conversely, consuming large amounts of alcohol with the feeling that you can't go without it, can affect not only your capacity to function daily, but also your decision making skills and relationships. One decision we all make is about **choosing** to have safe-sex, and excessive alcohol can mess with our real choices and lead to sexual risk taking we might not ordinarily do under other circumstances. People with Hepatitis C who drink more than one alcoholic drink a day may also develop more liver complications than people who do not drink alcohol. Remember alcohol is toxic to your liver and leaches out important vitamins from your body as well.

Below are the **Australian Guidelines** on alcohol consumption:

MEN:

No more than 2 Standard Drinks* in the first hour and 1 per hour after that

No more than 4 Standard Drinks* a day on average, and no more than 6 Standard Drinks on any one occasional day



One or two alcohol-free days a week

WOMEN:

No more than 1 Standard Drink* per hour
No more than 2 Standard Drinks* a day on average, and no more than 4 Standard Drinks on any one occasional day
One or two alcohol-free days a week

* **Note:** A standard drink is a light beer, or a small glass (middy or pot) of full strength beer, or a small glass of wine, or a single measure of spirits.

For further information on the Alcohol Guidelines as recommended by the National Health and Medical Research Council, see [Fact Sheet 1.27 Australian Guidelines for low-risk drinking](#), or visit the [Alcohol Guidelines website](#)

Reference:

- 1) Samet JH et al. *Alcohol consumption and HIV disease progression*. J Acquir Immune Defic Syndr (advance online publication), 2007.
- 2) UK CHIC Study Steering Committee. *HIV diagnosis at CD4 count above 500 cells/mm3 and progression to below 350 cells/mm3 without antiretroviral therapy*. J Acquir Immune Defic Syndr (advance online publication), 2007.

Source: www.aidsmap.com Adapted from article by *The Editor*.

Dental Treatment Access for People with HIV

The federal Government announced a \$377 million initiative in the May budget to improve access to dental care for people with chronic and complex conditions—including HIV.

The new funding will provide up to \$2000 per calendar year per patient for treatment through private dental practitioners. The program will operate under the Government's Enhanced Primary Care (EPC) scheme where the referral to the dentist will first come from a GP.

To get this dental cover patients need to be on a GP Management Plan with team care arrangements (Medicare Items 721 and 723) or an Enhanced Primary Care multidisciplinary care plan. The treating GP needs to use a form called "EPC referral form for dental services" under Medicare to refer the patient to the private dentist. Dentists must be registered with Medicare and all patients must have a dental assessment (MBS item 10975).

The scheme is scheduled to start in November 2007 after some legislative changes go through Parliament. It is unclear if it will be means tested although this seems unlikely as other EPC program items are not. People who have private dental cover can use their \$2000 per calendar year on



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treatments and then utilise their private scheme for further treatments within the calendar year but cannot claim for both treatments at once.

Further information at www.health.gov.au (look for "enhanced primary care" link). Ask your GP about setting up an EPC Plan if you would like to access this scheme in the future.

Source: PosLink. The newsletter of People Living With HIV/AIDS Victoria Inc. Issue 34 July 2007

We all age, but can we age well?
Yeronga Natural Therapies
proudly presents
AGEING WELL

A seminar dedicated to those who are serious about their health

- * Understand how natural medicine and preventive treatments can assist you
- * Watch the practitioners demonstrate their treatments and join in (optional)
- * Learn some basic techniques to keep you fit and healthy as you age
- * Ask questions of the professionals and talk to other like-minded people
- * Tell your family and friends how they too can benefit from preventative treatment

Featuring Guest Speakers: Amie Steel - Naturopathy & Nutritional Medicine
Nina Seto - Acupuncture & Chinese Medicine | Sandra Venables - Homoeopathy
Mary Kelsey - The Feldenkrais Method & Physiotherapy | Jenny Palmer - Craniosacral Therapy | Geeta Harmon - Massage, Shiatsu & Bush Flowers

Yeronga Services Club (RSL), Main Function Room, Cnr Fairfield Rd & Kadumba St.
Saturday 15th September, 2.00pm - 5.45pm
\$15.00 (pre-booked by 5pm 5th Sept.) or \$25/\$22 on the day.
Price includes light refreshments & information pack.
Registration from 1.15pm Question/Answer session until 5.45pm

Numbers are strictly limited! Avoid disappointment & reserve your place today

call or visit the YNT Clinic: 3848 4992, Cnr Devon St & Fairfield Rd, Yeronga

Website of the Month

Calculate Your Heart Disease Risk
Over recent years there has been a significant amount of attention and research

placed on HIV-related, treatment-related, and lifestyle-related cardiovascular (heart) disease risk in PLWHA. Use the calculator the experts use to work out what your risks is over the next 10 years for developing heart disease:

<http://hin.nhlbi.nih.gov/atpiii/calculator.asp>

Note: To use the calculator you first need to convert your results for total cholesterol and HDL cholesterol - **multiply by 39**

The US system in this calculator uses a different unit of measurement.

...If you have further concerns speak to your doctor about the results.



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