i everyone.

I was just looking through the communications to see if we have any on delavirdine (found some - this only reinforces my obsession for keeping e-mail! but I was glad I did save them). I have never used this drug before.

We have someone potentially entering the tipranavir study and I must admit I'm not sure of the ins and outs of this yet as the study nurses are usually better informed and I've been on vacation for a bit so I have to look into it today. I was asked about this regimen to look for potential DIs etc:

tenofovir, DDI, delavirdine, ritonavir/indinavir.

- I am aware of the tenofovir + DDI interactions although we are still using full dose here + large spacing interval after discussing it with the team....
- spacing DDI + delavirdine
- my main question which might be very stupid is: isn't ritonavir redundant considering indinavir Cmin, AUC and Cmax will be increased by using 1200 mg IND/600 mg DLV bid? Am I missing something that they are aware of and I am not?

ANdrea

Hi Deborah.

I wonder if another option could be that instead of increasing doses of phenytoin and then having to adjust Kaletra, and so on, if the neurologist could consider using another AED in addition to the phenytoin. Perhaps the addition of the second agent could minimize the risk of a seizure if the PHT level is not therapeutic? Not sure if that's a reasonable strategy at all.

deborah

## Hi folks:

I have a theoretical question for you. Suppose you had a female patient

who presented during pregnancy, not on ARV. She has detectable VL, so  ${\tt ARV}$ 

is indicated. You know she has a history of intermittent AZT use and poor

adherence, so she is likely AZT-resistant. My question is what type of ARV

regimen would you recommend for this patient? If resistance testing confirmed AZT resistance, would you still include it in her ARV regimen?

These are some of the issues being raised in an interdisciplinary HIV care

case for our pharmacy, medicine and nursing students, so I am interested in  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

your viewpoints. Thanks for your thoughts on this! Debbie

### Hey Michelle

In Canada, only the 100 mg tabs are available I believe; there is a  $200 \ \text{mg}$ 

tab in the US (maybe SAP?).

We use 600 mg bid, since nothing else is tid.

Have never used it with ritonavir for the sake of boosting the delavirdine

per se, but has ended up in regimens where ritonavir was included with no

real deleterious effects (in my experience).

The 190X thing - worth a shot; I have never seen clinical data (perhaps

others have?) on the efficacy of delavirdine when patients have substitutions at 190, but the in vitro data does suggest either a sparing of

delavirdine or increased sensitivity as you mentioned; as well, there is no

evidence (yet) that this mutation is frequently accompanied by other  ${\tt NNRTI}$ 

mutations (unlike some other mutations that "spare" individual NNRTIs), so

it may be worth a try.

## On 27 Mar 2003, at 16:25, Foisy, Michelle wrote:

```
> Hello all,
```

> I have few questions about delavirdine (which I have not used in 4

> years now.... so I am a tad outdated!) NOt the hot drug in our clinic

> as you can see. 1) Is there a newer tab strength than the 100mg's? 2)

> Prelim. data suggest using 600mg BID instead of 400TID- what have you

> been using? 3) Are any of you using DLV 600mg BID + RTV 100mg BID for

> extra DLV boosting? (would you use the RTV routinely if using DLV

> BID)? 4) How dependable are the GART results when there is only a

> G190A mutation, indicating NVP/EFV resistance and DLV sensitive (and  $^{\mathrm{T}}$ 

> have even read that the presence of the G190A confers DLV

> hypersensitivity).

>

Thought this might be of interest to others.

We got a virtual phenotype back from BC for a patient that has essentially been on d4T/3TC/NVP for the last year (had a short trial with AZT/3TC/EFV but developed anemia and a rash). The genotype showed a K103"T" mutation and was interpreted by Virco as resistance is

"likely" to nevirapine and delavirdine and "possible" resistance to efavirenz. Other RT mutations included 184V, 211K and 219E.

We couldn't find much info other than that it appeared in isolated from patients treated with delavirdine and nevirapine and appeared in some only exposed only to nukes. We wondered if the threonine substitution altered the site significantly to cause resistance to the class like the

asparganine substitution and wondered if Sustiva still could be used (if

not for the rash)?

Wondering if others had any experience?

Deborah**FYI** 

## From Michelle

http://www.amedeo.com/

We started a 9 year old on efavirenz, Kaletra and zidovudine. After ONE

dose of efavirenz, he started acting up at school (yelling out inappropriately, disturbing his classmates and fighting.) He is itchy

(one week later) but no fever, no rash. We are closely monitoring the situation. His mother is to call us immediately if she sees a rash. So my

question is a pharmacology question. Would you see a behavioural side-effect after just one dose? Any one have experience to share? Thanks Natalie i everyone.

Has anyone heard of glycerin lubricants as being responsible for causing infections? I have had this question from someone at the coalition who was told this by a lubricant rep.

### Andrea

Hi everyone,

One of our ID docs wanted me to check with all of you as to whether any of your needle exchange programs or other community programs routinely use naloxone or have it available for overdose situations. Apparently it is used quite frequently in community programs in the US, however for some reason it is much cheaper there than it is here. Our needle exchange program would like to have it more readily available at injection houses or on the "needle exchange van" for these overdose situations but it is very expensive. Any thoughts?

### Christine

Christine Hughes, PharmD
Clinical Assistant Professor
Faculty of Pharmacy & Pharmaceutical Sciences
University of Alberta
Clinical Pharmacist, HIV, UAH site

Hi guys,

as discussed briefly at the meeting, find attached the survey.

CTAC is a national not-for-profit organization dealing specifically with HIV/AIDS treatment advocacy issues. The organization was formed out of a growing need for community advocacy on a broad spectrum of treatment-related issues that impact the health and quality of life of people living with HIV/AIDS. CTAC advocates to ensure the research and development of safe and effective HIV/AIDS treatments, a cure for HIV/AIDS, and equitable, affordable and timely access to all HIV treatments.

I was asked to disseminate the survey to our group to improve accessibility to the survey. For those of you who would like pre-stamped return enveloppe, contact Mr DesGranges below by email or phone (1-866-253-7277). There is also the possibility to fax it back (no charge line).

Hi everybody,

I would like to inform you of a new addition into our listserve. Marie-France Goyer is a pharmacist working at Hôpital Ste-Justine in Montréal. Her expertise in Pediatric will be for sure beneficial to our group. Her e-mail address is <a href="mailto:marie-france">marie-france</a> <a href="mailto:goyer@ssss.gouv.qc.ca">goyer@ssss.gouv.qc.ca</a>.

So welcome Marie-France. Our chat group keeps growing. Fantastic! **Development of a National HIV/AIDS Pharmacists Network In Canada**Tseng A, Foisy M, Hughes C, Courchesne M, on behalf of the Canadian HIV/AIDS Pharmacists Network.

<u>BACKGROUND</u>: In Canada, HIV pharmacy specialists comprise a small proportion of pharmacists spread across a vast geographical region. With the increasing complexity of HIV pharmacotherapy, it is essential for pharmacists to collaborate. The objective is to describe the development of a national network of pharmacists specialized in HIV practice and research.

<u>METHODS:</u> The national network was developed by pharmacists at two urban hospital HIV clinics, with industry support through an unrestricted educational grant. Pharmacists involved in HIV practice or research across Canada were invited to join. A mission statement and goals were developed, and a chair and secretary were elected.

RESULTS: The Canadian HIV/AIDS Pharmacists Network (CHAP) was formed in January 1997, and comprised 13 pharmacists from various HIV practices across Canada. The mission was to connect pharmacists in order to optimize patient outcomes and promote the profession through communications, education, research, and clinical practice. CHAP's activities include: clinical information sharing via group e-mail; annual meetings in conjunction with a national HIV conference; regular production of a newsletter; multi-site research projects; creation of a group website; and publication of a Canadian position paper on the role of the pharmacist in HIV care. Membership is free. In the fall of 2001, CHAP was expanded to include a working group and general members. Working group members also act as provincial delegates, and take an active role in

communicating and involving their provincial colleagues in CHAP activities. Currently CHAP has 33 members.

<u>CONCLUSIONS</u>: CHAP has successfully linked HIV pharmacists across Canada, resulting in improved communication, clinical sharing, education and collaborative research. The role of the HIV pharmacist in Canada has been strengthened and further defined as a critical member of the health care team.

## Ref. (1) Can J Hosp Pharm 2000;53:92-103.

## www.tthhivclinic.com/chap/

Word count: 291 (incl. reference); character count: 1986 (with spaces)

Categories: E32, E30

Hi Debbie:

I checked with our  ${\mbox{Ob}}/{\mbox{Gyn}}$  (Deborah Money) and she mentioned that the Italian

group has the most experience with this procedure. She's not aware of any

centres in Canada offering this service. I happened to notice that the London Health Sciences Centre has listed "sperm washing" on their bio

on the second link, but their website does not mention anything about it.

Our clinic has yet to establish guidelines on fertilty/infertility.  $\operatorname{Hi}_{\bullet}$ 

Does anyone know if any companies are currently sponsoring beepers or timers

to remind pts to take meds? I think Merck program is D/C. We have the black

beepers called  $\ensuremath{\mathsf{MedTimer}}$  which are better than the green ones, but are out

now.

Any info would be useful.

Also, do you know who makes the MedTimer or how they can be ordered? Hi Michelle... we're currently looking into some new beeper options. We got replacement batteries for ALRs, but still have had some reliability problems. I've just found a source for new batteries for the MEDTimers, so we'll use our current supply up probably before switching. The phone # on the back of the MEDTimers is (250)769-5475 (somewhere in BC?) but I don't know how we got our current stock of them (it pre-dates my time at the clinic). Jinell has charmed individual drug reps into making a contribution to cover the cost of some compliance aids... and you are at least as charming as she is!

Jeff Hi,

We have been reviewing our Blood Borne Pathogens policies and it was

mentioned at the last meeting that for  ${\tt HIV}$  prophylaxsis for needle sticks

that the initiation of antiretroviral therapy could be delayed by upto 12

hours. We had originally had in our policies to initiate therapy within 2

hours. Is anyone out there aware of a change to this protocol? Thanks, Andrea

Andrea Kent BScPharm PharmD Clinical Coordinator Aberdeen Hospital Pharmacy 835 East River Rd New Glasgow NS B2H 3S6 Hi Sandy,

I think that confusion arises because therapy has been shown to be more effective in the animal model if initiated sooner rather than later (ie within 1--2 hours of the exposure). However the extent to which this can be

translated in the human model is not clear. The idea of initiating therapy

later on (ie after 36 hours) is that it may favourably alter subsequent disease (ie later onset of advanced disease.) Therefore, the cut-off time

for treatment is not an absolute in higher risk exposures and the CDC even

recommends treatment for longer time periods (eg. 1 week post exposure) when

the exposure represents an increased risk of transmission.

Linda Akagi BC CFE in HIV/AIDS Coordinator Outreach Pharmacy Program 1081 Burrard Street Vancouver, B.C. V6Z 1Y6

I am wondering if you have seen more data on the use of once daily ABC. One

of the speakers at CAHR who gave the talk on QD drugs mentioned this. I thought that it was no longer under study, given the kinetics that don't

quite make it for QD dosing. Michelle

## Hi everyone,

The CHAP website is located on the TGH clinic website at: http://www.tthhivclinic.com/chap/index.html

The newsletters are under the Publications link. Pierre's most current newsletter isn't up yet (should be up in a few weeks), so here is the word document in the meantime.

## Hi everyone,

One of our ID docs wanted me to check with all of you as to whether any of your needle exchange programs or other community programs routinely use naloxone or have it available for overdose situations. Apparently it is used quite frequently in community programs in the US, however for some reason it is much cheaper there than it is here. Our needle exchange program would like to have it more readily available at injection houses or on the "needle exchange van" for these overdose situations but it is very expensive. Any thoughts?

### Christine

Christine Hughes, PharmD
Clinical Assistant Professor
Faculty of Pharmacy & Pharmaceutical Sciences
University of Alberta
Clinical Pharmacist, HIV, UAH site

## Hi Christine,

I'm not aware that any of our needle exchange programs in Vancouver routinely have/use naloxone for overdose situations.

## Linda.

Hi Christine

We keep naloxone on hand in the crash cart here at Cool Aid Community Health Centre for the doctors and nurses to use. Our nurses are former Victoria Street nurses as well. They tell me that the street nurses do also have access to naloxone, and a policy in place for the use of it. I'm sorry, I don't know if they carry it with them or if it is just on hand at the needle exchange for them to use. If you would like more information about their policy, you could try contacting the Victoria Health Unit at 250-388-2220. I believe the street nursing supervisor's name is Audrey. I hope that helps. Charmaine

Hi Christine, sorry for the late response...I checked with the nurse coordinator of our Safeworks program. They had made a decision to not keep naloxone in the van - lack of ability to monitor and carefully check people. They leave that for anambulance to take care of (so O2 could also be administered if needed. The van also doesn't have room or insurance to transfer clients to hospital. To quote Virginia,

- "1. I would never want clients to not call an ambulance because they were waiting for us to show up. It can take us up to 1/2 hour to respond as we drive the whole city. A clients could die while waiting for us rather than the ambulance.
- 2. We have a current policy that we don't go into drug houses. We see all clients in the van for staff safety. We may know the guy who calls, but what about the guy shooting up in the bathroom? There would be safety concerns. I believe that EMS dispatch a police car also in a case like this for paramedic safety."

The Safeworks site actually operates within a 24-hour walk-in urgent care medical clinic (it's a department of our health region, designed to take some of

the pressure off the hospital ERs) downtown (same building where we are, in fact), and they have naloxone as part of their emergency drugs.

Jeff

# Benchmarking Data- Outpatient HIV Clinical Pharmacy Services in Select Canadian Institutions

| Location/Regio | Type of  | # HIV Patients | # HIV Patients | Pharmacy FTE | Average t  |
|----------------|----------|----------------|----------------|--------------|------------|
| n Served       | Practice |                | seen by        |              | per patien |
|                |          |                | pharmacist     |              |            |

| British Columbia   |   |  |   |   |   |
|--|---|--|---|---|---|
| Vancouver and province of B.C. St. Paul's Hospital Centre for Excellence | Clinical and dispensing functions combined for the province of B.C.                                   | ~ 2700 patients in the province of B.C 5 offsite pharmacies that are compensated on a per prescription basis.  | 700-800 patients at St. Paul's Hospital, with the remaining patients in the rest of the province of B.C.  | 1.0 FTE Program Administrator 6.0 FTE clinical + dispensing pharmacists 1.0 FTE dispensing pharmacist 1.0 FTE HIV pharmacy residency position 6.0 FTE | 45 minutes<br>or complex<br>patients<br>30 minutes<br>prescription<br>15 minutes<br>refills |
| Victoria Cool Aid Centre Inner City Health Clinic                        | Clinical and dispensing functions for mixed population (HIV, Hepatitis C, addictions, mental health). | Of the 1500 clinic patients, 100 are HIV positive ~50% on ARVs  In Victoria, there are about 200 patients on ARVs; the rest are served at the hospital or at a couple of methadone pharmacies. | 40-50 patients who are on ARVs and some of the patients not yet on ART for counseling, other meds, etc.  Pharmacist also helps coordinate and monitor the patients at the methadone pharmacies. | 1.0 FTE   | Varies with patient. Bills 10 m for each vi   |

| Location/Regio<br>n Served   | Type of Practice   | # HIV Patients       | # HIV Patients<br>seen by<br>pharmacist  | Pharmacy FTE                           | Average t<br>per patien                 |
|--|--|----------------------|--|--|---|
| Alberta  |  |                      |  |  | •                                       |
| Calgary<br>Southern Alberta<br>Region  | Clinical and dispensing functions (ARVs and HIV study drugs only).   | 700<br>65% on ARVs   | All patients on<br>ARVs and others<br>on a consult<br>basis                                      | 1.6 FTE (split among 3 pharmacists)    | 10                                      |
| Edmonton Northern Alberta Region 3 sites: - University of Alberta Hospital - The Royal Alexandra Hospital - The STD Clinic | Clinical, non-dispensing. There are three HIV clinics at separate sites. Two of the sites have part-time clinical pharmacists. | 886<br>~ 55% on ARVs | Most new patients starting on ARVs. Follow-ups are variable due to significant time constraints. | 0.65 FTE (split between 2 pharmacists) | 1-2 hours (<br>15- 30 min<br>(follow-up |
| Manitoba   |  |                      |  |  |   |
| Winnipeg and province of Manitoba 3 sites: - St. Boniface General Hospital - Health Sciences Centre - Village Clinic       | No formal pharmacy services at any of the city sites.  ARV dispensing occurs on the retail sector.                             | ~ 450 in province    | None   | None                                   | None                                    |
| Ontario  |  |                      |  |  |   |
| Ottawa The Ottawa Hospital Serves the area from Cornwall to Pembroke and Outaouais.  | Clinical with a smaller research component   | 900                  | 100%   | 1.0 FTE                                | 20 min                                  |

| Location/Regio<br>n Served   | Type of<br>Practice                                   | # HIV Patients                               | # HIV Patients<br>seen by<br>pharmacist                                    | Pharmacy FTE                        | Average ti<br>per patien              |
|--|---|--|--|-------------------------------------|---------------------------------------|
| Toronto The Toronto Hospital- University Health Network  | Clinical with a smaller research/teachin g component  | ~ 1200                                       | Data not provided.   | 1.0 FTE                             | Data not provided.                    |
| Toronto St. Michael's Hospital- Health Centre at 410   | Clinical<br>ambulatory<br>primary care                | > 1000                                       | 50 per month   | 1.0 FTE                             | 1-2 hours (<br>30 min (fo<br>up)      |
| Toronto St. Michael's Hospital   | Clinical hospital and ambulatory tertiary care        | 800  | All new patients<br>and follow-ups<br>as necessary                         | ~ 1.0 FTE                           | 20-30 min                             |
| Quebec  Montreal One program split among 3 sites: - Hotel Dieu Hospital - St. Luc's Hospital - Notre Dame Hospital | Mainly clinical with a small portion of distribution. | 1500 over the 3 sites                        | ~ 250 per month  | 2.1 FTE                             | 30 min (ne<br>10-15 min<br>(follow-up |
| Montreal Montreal Chest Institute  | Clinical  | 750  | Data not provided.   | 0.6 FTE                             | Data not provided.                    |
| Maritimes and Newfo  | undland   | <u>.                                    </u> |  | <u> </u>                            | 1                                     |
| St. Johns, NFLD<br>Serves NFLD<br>and Labrador   | Clinical<br>Affiliated with<br>Memorial<br>University | <100   | 100%<br>Pharmacist sees<br>all patients at<br>tertiary care HIV<br>clinic. | 0.2 FTE for HIV portion of position | 15-60 min<br>depending<br>issues      |
| Halifax, N.S.<br>Queen Elizabeth<br>II Hospital  | Clinical HIV and inpatient Infectious Diseases        | ~300   | 100%   | 0.4 FTE for HIV portion of position | 15-90 min<br>depending<br>issues      |

ARVs= antiretrovirals; FTE= full-time equivalents

Prepared by: Michelle Foisy, Pharm.D. & Christine Hughes, Pharm.D., Capital Health, Edmonton, Alberta.

Data was obtained by a national survey conducted in collaboration with the Canadian HIV/AIDS Pharmacy Network, December 2002.

Hi Nancy,

Looks promising for sure with very minor changes. I know Referee D commented both times that Table 1 is the most important and should be as

brief and clear as possible. However, he wasn't really clear this time if

he was satisfied with our rebuttal/changes or if he had any specific changes

in mind. As for the rest of the appendices, I do not recall any of the other reviewers suggesting to cut them so I think perhaps we should just

include in the rebuttal that we have made the tables/appendices as clear and concise as possible.

Thanks again!

Christine

Hi all.

I know this issue has been brought up in the past but I thought this site could potentially help for travel questions and meds. There is a list of embassies and I called the one for a country that one of our patients was going to in order to get the info on what they should do about their medications or would there be problems with taking meds there. I found it helpful.

http://www.ottawakiosk.com/embass.html

Andrea

Title: Evaluation of HIV Drug Interaction Websites: A

Cross-Sectional

Review

Category: Research Report - Infectious Diseases

Dear Nancy:

We are pleased to provisionally accept your manuscript for publication in

The Annals of Pharmacotherapy. This conditional acceptance is based on

alterations being made in conformance with the enclosed recommendations.

Include a response indicating the changes you have made and a rebuttal addressing the specific points with which you disagree.

We would like to receive your final draft within four weeks of your receipt

of this letter. If this presents a problem for you, let us know. We will

need two copies of your paper.

Please send one diskette which contains the text of your manuscript, making

sure that it has the most recent corrections and is identical to the paper

copy. You should name your file 'D039 RR'. Contact our office if you need

further information about submitting this diskette. To expedite the processing of your manuscript you may email your revised paper and eliminate

the need for the diskette and paper copies.

Your interest in The Annals of Pharmacotherapy is appreciated.

Sincerely,

Harvey Whitney
Publisher and Editor

HI Nathalie,

We have been trying icepacks with a few of our patients and we have the impression that it is helping a bit. They apply icepacks before and after

the injection, for approx 5 minutes. The problem isn't so much the pain at

the time of injection but rather the very sensitive and sometimes painful

nodules that form. They become approximately 1 to 2 inches in diameter,  $\hspace{0.1in}$ 

are inflammed, red and very sensitive or painful to the touch. Unfortunately, they last approx 2 - 3 weeks despite the application of cold. One of my patients claims the nodules aren't as bad on the legs than

on the abdomen.

Hope this helps

Hi everyone,

Does anyone out there have any recommendations/guidelines for the discontinuation of Sustiva plus 2 NRTIs in the setting of a supervised treatment interruption? ie do you continue the NRTIs for about a week after

discontinuing the Sustiva or do you stop all drugs together? Also, are you

assessing all or any of your patients for a supervised treatment interruption?

Thanks,

Linda Akagi

Linda,

At our clinic we do most treatment interruptions as a study (protocol  $\mathtt{CTN}$ 

 $164\mbox{"STI"}$  and CTN  $167\mbox{ "OPTIMA"}), otherwise also on an individual basis. For$ 

patients on Sustiva or Viramune, we will stop this medication three days prior to

the complete stop of all antiretrovirals. Monitoring is our "usual" care of blood

work done every three months to coordinate with physician appointments of this

frequency. We monitor for rate of drop in CD4 count to determine when to cease

the interruption for patients not on the study protocol. As pharmacists, we do

not monitor these pxts closely, as we have researchers and nurses doing this.

Hope this helps....

#### Jinell

Hi everyone, we might have covered this in the past, but perhaps you could refresh my memory: in any of the provincesor regions, is NIHB being charged for antiretrovirals for aboriginal patients, or are they being covered under other provincial programs?

Jeff

Hi Jeff,

In BC the NIHB is not being charged for ARVs. We cover all BC residents for  $\,$ 

ARVs, aboriginals or not.

Linda.

Hi everyone,

As I wrap things up this last week of work (yay!), I wanted to introduce

Dylana Arsenault-Thompkins and Nelson Dasilva, who will be covering my maternity leave at Toronto General. Dylana hasn't officially started at our

hospital yet, so I don't have a work e-mail for her, but Nelson's is: nelson.dasilva@uhn.on.ca.

I'd like to thank them both for covering for me while I'm off.  $\ensuremath{\mathsf{Alice}}$ 

Hi Marie,

I received this e-mail message, and thought I would pass it along to you.

It sounds like this person came across our CHAP webpage/listserve on Yahoo

(although I'm not sure how, since we had created it to be unlisted for general yahoo members).

Do you want to touch base with him and if you think it would be a good idea

to add him to the listserve, let me know and I can do that.

Thanks! Alice

----Original Message----

From: Donald Ekekhomen [mailto:doneke@yahoo.com]

Sent: Thursday, June 05, 2003 2:55 PM

To: chap\_chair@yahoo.ca Subject: participation

I am a community pharmacist and a volunteer with NGO clinics in my locality. I have for long been searching for a group of pharmacist involved in the treatment/management of PLWAs.

Do send me other dretails of your organisation as i am deeply interested in sharing knowledge with you and hopefully be better trained for the responsibilities here as there is not much around here .

Thanks

Ekekhomen O. Donald

Plusieurs d'entre vous sont probablement au courant que nous organisons la conf,rence ACRV pour 2004. La pr,sente est pour vous informer que cette conf,rence se d,roulera ... l'H"tel Centre Sheraton ... Montr,al du 13

au 16 mai, 2004. Nous esp, rons vous voir tous ... cet , všnement.

Meilleurs v ux.

Mark Wainberg

Yet more textbooks on-line.....

http://hivmedicine.com/textbook/download.htm

http://aidsinfo.nih.gov/guidelines/default\_db2.asp?id=50 (look under "Other materials" to download)

From Michelle

Hi everyone.

After the tenofovir trial had closed in our hospital we have not gone through ethics again with the protocol changes. After the trial had first shut down, the plan was to "wait until it comes to market" as we thought this wouldn't take long. Even if we did go through ethics

again I think the majority of our patients would not meet the T cell cut off as their numbers are too high.

I am just trying to get a sense of what the issues are re: why it is taking so long and my understanding is that cost was the biggest issue. Does anyone know how much is costs in the States?

Is there any other way to get this drug?

Thanks for your help and I hope I haven't already asked this!! Andrea

For patients not meeting the T-cell or VL criteria, you may write a letter for exemption explaining why your patient needs TDF. Usually they

will grant it.

Tom

We have been able to obtain it for those that do not meet the criteria with

a separate letter of explanation and some pressure (i.e  $\mbox{\ensuremath{\text{F}/U}}$  phone calls ) to

the company.

As for the marketing.....

I spoke to the Gilead contact in Canada (based out of Montreal) - I will get

his phone number when I am at work...

He said that we can anticipate a wait of 9-12 months or more until all marketing, pricing and regulatory issues are sorted out. Also, Gilead is

trying to set-up a 'company' in Canada, thus creating some delays as well.

Michelle

Members of the CAHR Conference <Mark.wainberg@mcgill.ca>

cc:

Subject: CAHR 2004

Hi.

Further to my e-mail of last week announcing the dates of the CAHR meeting in Montreal May 13-16, 2004, this is to ask you to please visit our conference website at www.symposiumSIDA.ca for new information as it

becomes available.

At this time, rooms in Montreal can be reserved at Le Centre Sheraton hotel, our conference headquarters at the rate of \$ 195 per night. Please be sure to specify that you are a CAHR attendee when making your reservation. The toll free number in U.S. and Canada is 1-800-325-3535. You will soon be able to link the hotel from our

conference website www.symposiumSIDA.ca.
Best wishes.

Mark Wainberg

Hi,

The name of the independent consultant I had spoken to is  ${\tt Marco}$  Petrella in

Montreal, however it looks like Gilead has a confirmed Canadian contact now

who will be moving to Vancouver in mid-July- she is still in the US company.

Her name is Alex Israel (? spelling) at 650-522-5276

Michelle

Michelle Foisy,

I everyone,

Just wanted to know which dose of saquinavir / ritonavir you were giving

with efavirenz in your centers. I have reviewed some of the literature and

have simply found data suggesting to use 400 mg / 400 mg BID. As EFV decreases SQV AUC by 62%, does anyone believe using SQV 1000 mg / rtv 100

mg BID would not be sufficient with efavirenz?

Thanks for the info,

Nancy Sheehan

Hi Nancy,

With SQV/RTV 400/400 mg EFZ will not have much of an effect on SQV PK. We

have PK data on 3 patients (study still ongoing) on SQV/r 1000/100 mg with/without EFZ and found a significant decrease in SQV Cmin (>50%), but

Cmin remained above 350  $\rm ng/mL$  for these subjects. Some studies suggest that

200 mg of RTV is required to counterbalance the inducing effects of  ${\tt NNRTIS.}$ 

Kind regards,
Rolf

> ----Original Message----

> From: Nancy Sheehan [SMTP:nancy.sheehan@muhc.mcgill.ca]

> Sent: Monday, June 16, 2003 11:33 AM

```
> To: chap acpv@yahoogroups.com
> Subject: [chap acpv] Saquinavir / efavirenz interaction
>
> HI everyone,
> Just wanted to know which dose of saquinavir / ritonavir you were
> with efavirenz in your centers. I have reviewed some of the
literature
> and
> have simply found data suggesting to use 400 mg / 400 mg BID. As EFV
> decreases SQV AUC by 62%, does anyone believe using SQV 1000 mg / rtv
100
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> Thanks for the info,
> Nancy Sheehan
>
Hi Nancy,
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With SQV/RTV 400/400 mg EFZ will not have much of an effect on SQV PK. We

have PK data on 3 patients (study still ongoing) on SQV/r 1000/100 mg with/without EFZ and found a significant decrease in SQV Cmin (>50%), but

Cmin remained above 350  $\mathrm{ng/mL}$  for these subjects. Some studies suggest that

200 mg of RTV is required to counterbalance the inducing effects of  $\ensuremath{\mathsf{NNRTIS}}$  .

Kind regards,
Rolf

Hi everyone.

We have a patient who has been getting foscarnet from our medical day unit for herpes simplex II confirmed resistant to acyclovir (via TKinase). He was taken off the foscarnet in attempts to see how he would do in the past and had one or more SEVERE outbreak(s) so the decision was to keep him on this giving it three times a week. He recently had a pseudamonas bactermia which is believed to be a result of his central line. They now want to remove the central line and therefore his foscarnet goes. In the list of therapeutic alternatives, cidofovir was tossed around. The only catch is his SCr is fluctuating in the 170-200 range (clearance around 35 mL/min). The manufacturer "contraindicates" its use at 55mL/min.

I have several questions....

- do any of you have enough experience to know if the creatinine clearance cut off is more for the induction dose (5 mg/kg)?
- i have no idea what dose to give for this off label indication (i.e. prophylaxis of Acyclovir resistant HSV) and haven't found info on this..
- will special access program release this drug as technically he probably shouldn't start the drug due to CrCl and it is for an off label

indication...?

- has anyone encountered this before... am I missing any alternatives?

Any thoughts you have would be great ... Thank you.

Andrea, Andrea,

We've used cidofovir for this indication, but not for a very long time. I'm

pretty sure that you won't be able to get it approved with a SCr that high

and I'd be reluctant to even try it. Also, it's verrry expensive (approx  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left$ 

\$700 US/dose.)

This may be a dumb question, but is this a HIV positive patient? If so, is

he on antiretrovirals? If not, the better option might be to put him on  ${\tt ARVs}$ 

or maximize his therapy if he's on ARVs to improve his immune function.

Linda.

### Hi Andrea

This is a bit of a long shot, but you might want to talk to somebody at Gilead about the potential for using adefovir 10mg per day for your patient;

adefovir has pretty good in vitro activity against HSV (including TK deficient) and was associated with very little nephrotoxicity at this dose

in patients with chronic hep B. I don't know of any clinical info for this

indication, but the company may have data on file. I also don't know if

they will release it for this purpose, since its only available in Canada

via SAP (I think) for chronic hep B, but I guess there's no harm in asking

(or begging).

Tony

Hi Linda.

Yes he is on ARV. As I recall his numbers are good ....but I will check that again. I am trying to recall what his regimen was and I can remember combivir as I dose reduced his ARV to single products due to his increased SCr. I don't remember if he was PI or NNRTI. Thanks for that suggestion.

I am also apprehensive about even entertaining the cidofovir given how unstable his kidney function is and am not currently pursuing it for that reason. If they do improve, it could be an option. The cost is tremendous! I found out today that we have had one patient on it in the more recent past and they couldn't figure out who paid for it (ie. which cost centre it came out of). Andrea

# Hello everyone

# Alice's baby girl, Sophie Lukashenkova. Sophie was born on June 29 at 5:08 a.m. and weighed 7 lbs 2 oz.

I cannot find any guidelines to direct nelfinavir plus fluvoxamine or another SSRI used to treat OCD. HIVInsite reports that ritonavir (more potent 3A4 inhibitor than nelfinavir) and fluoxetine (a weaker 3A4 inhibitor

than fluvoxamine) can be co-administered without dosage adjustment. The

patient requires OCD treatment ASAP. Any suggestions (the company could not

add further information)? Thanks Natalie

already know.

Here is the site:

http://www.tthhivclinic.com/pdf/psych-int.pdf

## Michelle

### Hi Natalie.

This is probably too late in coming (just got back from vacation) and if you've already looked at the drug interactions table I'm likely not contributing anything but I thought I'd throw a thought in. I asked a psych colleague re:OCD treatment and was informed any SSRI could be used therefore looking at one with less potential for DIs would be the best alternative and then judge response by clinical findings re:OCD symptoms.

### Hi Deborah,

I would not use AZT as part of her antiretroviral regimen if there was documented resistance, with the exception of IV AZT during labor and po to the baby. Depending on her antiretroviral history and genotype, I would probably recommend d4T/3TC and either nevirapine or nelfinavir. We would then recommend to hold d4T during labor while the mom is receiving AZT to avoid antagonism.

### Christine

#### Hi Debbie:

I would like to second Christine's recommendations. We've had a few mothers that we've had to manage with d4t until delivery, then added the usual AZT IV intrapartum and oral AZT to babe. David Burdge et al from our clinic have recently published an update to the Canadian consensus guidelines for the management of HIV+ pregnant women in CMAJ. There are three pdfs attached, the consensus guidelines, a summary and clinical practice scenarios.

### Dom

Thanks, Christine and Dom for for your comments and feedback on this. The

issue of whether or not to use AZT in the face of suspected/known resistance seems to be fairly controversial still. I suspect this is clouded by the fact that the guidelines to date have not addressed this issue directly. My thoughts were along similar lines to both of you, that

it should not be a backbone to the regimen for mom, but should definitely

be given, possibly with nevirapine, during L&D and to baby. As it happens

in our case, Mom's VL is only 7500 without ARV so I'm sure this is stimulating the debate further, as some believe she doesn't even need ARV

until last tri....

### Hi folks:

Just want to get your input on how you are managing your patients who

to take phenytoin (ie. other AED's ineffective and/or neurologist does not

think are appropriate for sz type). When a NRTI only regimen is not possible, I've typically been recommending Kaletra 4 caps bid as the PI of

choice. However, we are finding that we are having a hard time keeping

phenytoin therapeutic with this combo. This 2-way interaction was described at Retro this year (pdf poster:

http://www.retroconference.org/Archive/Posters/Retro10/535.pdf).

But what alternatives are you all using with phenytoin in your ARV combinations? Also, is increasing the phenytoin dose "safe" to do with this combo in the absence of TDM for Kaletra -- ie, will increasing the dose of phenytoin increase the amt of enzyme induction (I would think yes,

but I defer to the PK experts)? Any advice or experience is welcome!!

Thanks, Deb

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Hi Debbie,

fax: (709) 777-7044

Hope you are well. This is a indeed a difficult situation: increasing  $\ensuremath{\mathsf{PHT}}$ 

may further decrease LPV, and increaseing LPV/r may further decrease PHT as  $\,$ 

higher doses may increase the enzyme induction. The only way to ensure adequate exposure to both drugs is to do TDM. I would be happy to measure

the LPV levels (trough).

Kind regards, Rolf