CHAP Winter 2001-2002 Newsletter

News

Ginette Bernier: In the fall, Ginette Bernier was promoted to the title of Manager, Health Education of Acute Coronary Syndromes at Merck Frosst Canada. As such, she will no longer be the direct Merck liaison for CHAP. A letter of appreciation for all of Ginette's work and support over the past several years was sent on behalf of the network. We wish her the best in her new role.

Sponsorship of the network. Merck Frosst Canada is no longer able to provide full sponsorship for CHAP. A letter to Amar Pabla, Director of Sales & Marketing, Merck Frosst Canada, was sent on behalf of CHAP to thank Merck for their past support.

John-Paul Holtz, Product Manager at Abbott Laboratories has very generously offered to provide sponsorship to the network on an ongoing, annual basis. More details will be provided on this arrangement at the annual meeting in April.

Communications

Distribution of Newsletters

Since our group e-mail list has greatly facilitated electronic communications among us, Pierre has suggested that hard copies of correspondence be sent only in the following situations:
- Distribution of documents that are not in an electronic format (hard copy presentation, flyer, etc)
- On member's request due to difficulty in opening existing attached documents.

In the latter situation, Pierre is willing to send a disk/CD-ROM with the hard copy. Sometimes, electronic transmission of data is the problem rather than the version of the program.

Website

Based on feedback from CHAP members who were not able to easily access the group website on Yahoo, a **New Website for CHAP** has been created. The address is: www.tthhivclinic.com/chap This website can be readily accessed without the need for user names or passwords. The Toronto General Immunodeficiency Clinic has kindly provided the space and webmastering support for this site. Items on the website include: CHAP description, mission statement, goals, membership list, network structure, activities, copies of our newsletters and publications, and summaries of our projects.

The link for the CHAP website can also be found on the TGH Clinic's homepage (www.tthhivclinic.com) under the Useful Links - HIV Pharmacology section.

CHAP Working Group

A **call for candidates** for open spots in the working group took place in October and in early December. This resulted in 3 new members: **Charmaine Turner**, the Pharmacy Manager at the Cool Aid Community Health Centre in Victoria, BC, **Rolf van Heeswijk**, who is the new Director of Pharmacokinetic Research at the Clinical Investigation Unit/Ottawa Health Research Institute, and **Lizanne Beique**, who is the consultant pharmacist at the University of Ottawa Health Services. The group is thrilled that Charmaine, Rolf, and LIzanne will be contributing their skills and expertise, and look forward to working closely with them.

New members

At this time, we would like to officially say hello to new members which have joined CHAP recently (you may already have noticed their contributions to the discussions on the group e-mail list!):

- **Angela Doucette**: pharmacist in PEI. I am currently working at the Provincial Pharmacy in Charlottetown which is the only pharmacy on PEI that dispenses HIV medication.
- **Nancy Sheehan**: HIV pharmacy resident at Toronto General/St. Michael's Hospital for 2001/02. Nancy is originally from Sept-Iles, Quebec, where she earned her undergraduate and master's degree in pharmacy, and also worked for a few years prior to starting the residency program.

Next CHAP meeting - Wed. April 24th, Winnipeg

The annual Canadian HIV/AIDS Research Conference (CAHR) will be held from Thursday, April 25-Sunday April 28th, in Winnipeg, Manitoba. The annual CHAP meeting is scheduled for Wednesday, April 24th at the Delta Winnipeg. This will be an all-day meeting, with our network dinner planned for that evening. An agenda will be distributed next month. CHAP members are responsible for making their own travel and hotel arrangements.

Project Updates

Poster for the International AIDS Conference

An abstract on the development of CHAP has been submitted to the International AIDS Conference:

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.

BACKGROUND: 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.
METHODS: 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.[1] 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.
CONCLUSIONS: 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.
Categories: E32, E30

This abstract is currently undergoing review, and we should receive a reply by April 15, 2002.

Publications/Research

a) Pregnancy survey: 12 completed surveys were returned, and the data have been compiled. Laura is in the process of analyzing and summarizing the final results. These results will be presented at the network meeting.
b) HIV Drug Interactions website paper: Due to ongoing time constraints, this year we will attempt to do a bulk of the website review at the annual CHAP meeting. Time has been set aside in the agenda for this activity, and the meeting room will have internet access for one or more computers. Debbie and Sandy will attempt to put together a protocol and website list prior to the meeting.

Upcoming Conferences

3rd International Workshop on Clinical Pharmacology of HIV Therapy

The 3rd PK Workshop will be held in Washington DC at the Monarch Hotel from Thursday April 11th to Saturday April 13th, 2002. This workshop will again aim at providing a unique opportunity for international interchange on all aspects of clinical pharmacology of HIV therapy by gathering the latest findings in the field.

Registration can be done on-line. The deadline for registration is February 15th, 2001. Upon receipt of registration a preliminary reservation will be made, with confirmation upon receipt of payment. Abstract submission will be possible as of January 1st and the deadline for abstract submission is March 1st, 2002. Abstracts may only be submitted via the online abstract submission form. For further details, please check the website at: www.virology-education.com

XIV International AIDS Conference

This will be held in Barcelona, Spain, July 7–12, 2002. http://www.aids2002.org/IE_Home.asp Some important dates:

- Abstract submission deadline: January 14, 2002 paper form and on a diskette
- Abstract submission deadline: January 21, 2002 online submission
- Early registration fee deadline: February 1, 2002
- Satellite meeting application deadline: February 1, 2002
- Scholarship application deadline: February 1, 2002

Annual Conference on AIDS/HIV Research (CAHR)

This year's Canadian HIV conference will be held April 25-28, 2002 (Thursday to Sunday) in Winnipeg. More information is on the website www.cahr-acrv.ca. Registration may be done on-line at www.fusionmdnetwork.com. As already noted, our annual CHAP meeting will be held on Wednesday April 24th at the Delta Winnipeg, prior to the beginning of CAHR.

Summaries of Past Conferences

International Congress on Antimicrobial Agents and Chemotherapy (ICAAC)

December 16-19 in Chicago.
More information is available on the website: http://www.icaac.org/

9th Conference on Retroviruses and Opportunistic Infections (CROI)

This meeting will be held February 24-28, 2002 in Seattle, WA. As usual, attendance will be limited to 3800 people. Abstracts will soon be available at http://www.retroconference.org/2002/

Drug Updates

New Amprenavir Dosing Approved in the U.S.

On February 5, 2002, FDA approved a new dosing regimen for Agenerase (amprenavir) and Norvir (ritonavir) used in combination. The Dosage and Administration section of the amprenavir package insert was revised to include the following statement:

Concomitant Therapy: If Agenerase and ritonavir are used in combination, the recommended dosage regimens are: Agenerase 1200 mg with ritonavir 200 mg once daily or Agenerase 600 mg with ritonavir 100 mg twice daily.

The following revisions were also made to the Agenerase package insert regarding the use of the Agenerase plus ritonavir.

* The Clinical Pharmacology section was revised to add information about the pharmacokinetics of amprenavir when it is co-administered with ritonavir
* Table 8 (Established and Other Potentially Significant Drug Interactions) was revised to state that when amprenavir and ritonavir are co-administered, the dose of amprenavir should be reduced.
* The Precautions section was revised to provide additional information about possible cholesterol, triglyceride and liver transaminase elevations when amprenavir is co-administered with ritonavir.
* The Precautions section was also revised to provide information about the potential for lipid elevations; guidance on monitoring and managing these clinical chemistry abnormalities was included.
* The Adverse Reactions section was revised to include a table describing common adverse events observed in patients who received amprenavir 600mg + ritonavir 100mg BID (twice daily) and amprenavir 1200mg + ritonavir 200mg QD (once daily).

The label hyperlinked below in PDF format: http://www.fda.gov/cder/foi/label/2002/21007s010lbl.pdf

Efavirenz Tablet

The FDA approved on February 1, 2002, a new formulation of Sustiva (efavirenz), a non nucleoside reverse transcriptase inhibitor for the treatment of HIV infection. Sustiva will now be available as a 600 mg tablet to be taken once daily, in combination with a protease inhibitor and/or nucleoside analogue reverse transcriptase inhibitors (NRTIs). Sustiva, will continue to be available in the 50mg, 100, and 200 mg capsules in addition to the new 600 mg tablet.

In addition, the Sustiva label was revised to include new statements in the DOSAGE AND ADMINISTRATION section. The revised statements are shown within < symbols, below.
"Adults: The recommended dosage of SUSTIVA is 600 mg orally, once daily, in combination with a protease inhibitor and/or nucleoside analogue reverse transcriptase inhibitors (NRTIs). It is recommended that SUSTIVA be taken on an empty stomach, preferably at bedtime. The increased efavirenz concentrations observed following administration of SUSTIVA with food may lead to an increase in frequency of adverse events. Dosing at bedtime may improve the tolerability of nervous system symptoms.<"

In addition the CLINICAL PHARMAOLOGY and PRECAUTIONS sections have been updated to include drug interaction information on Sustiva with the following medications; St. John's wort, lorazepam, methadone, cetirizine and rifabutin. The ADVERSE REACTION section was also revised to update the incidences of adverse events and laboratory abnormalities seen in clinical trials.

The revised label hyperlinked below in PDF form at: http://www.fda.gov/cder/foi/label/2002/21360lbl.pdf

Trizivir®

October 18, 2001: Health Canada's Therapeutic Products Directorate (TPD) has issued a Notice of Compliance for Trizivir. Trizivir is indicated for the treatment of Human Immunodeficiency Virus (HIV) infection in adult patients. Trizivir combines the active ingredients of three existing antiretroviral medications: 3TC (lamivudine 150mg), Retrovir (zidovudine/ AZT 300mg) and Ziagen (abacavir sulfate 300mg). 3TC and Retrovir are already available in a dual combination product called Combivir (lamivudine150mg/zidovudine300mg).
Trizivir is approved for use in adults at a recommended dosage of one tablet twice daily; Trizivir can be taken with or without food.

Didanosine EC

On October 4, 2001, Health Canada approved a new capsule formulation of the anti-HIV drug ddI (didanosine, Videx). The new formulation is called Videx EC and consists of a capsule filled with tiny beads of ddI. These beads are covered with a coating designed to protect them from the damaging effects of stomach acid. Videx EC is available in white capsules containing the following doses of ddI: 400 mg (DIN 02244599), 250 mg (DIN 02244598), 200 mg (DIN 02244597), and 125 mg (DIN 02244596).

This nucleoside analogue is approved for use by HIV positive adults in combination with other anti-HIV drugs. The recommended dose of Videx EC is 400 mg once daily for people who weigh more than 60 kg (roughly 132 pounds), and 250 mg for those who weigh less than 60 kg. The drug should be taken on an empty stomach, 30 minutes before a meal or two hours after a meal.

Previous formulations of ddI were taken together with an antacid (buffer) to protect the drug from stomach acid. Indeed, 95% of a ddI tablet consists of buffer. Because of the large amount of buffer, users of ddI tablets often experienced symptoms such as nausea, bloating, diarrhea and gas when they took the tablets. In a recent study comparing ddI tablets to Videx EC, subjects who switched to the capsules had significantly fewer of these side effects.

Another advantage to Videx EC is that, because it has no buffer, it does not interact with drugs such as indinavir (Crixivan), Cipro and with the "azole" group of antifungal drugs including ketoconazole (Nizoral) or itraconazole (Sporanox).

Earlier concerns that Videx EC may not be as effective as the tablet formulation have proven unfounded and regulatory authorities in the European Union and the United States have also approved Videx EC for once-daily use.

The drug is now available in drugstores.

Tenofovir DF

On Friday, October 26, 2001, The Food and Drug Administration approved Viread (tenofovir DF), for treatment of HIV-1 infection in combination with other antiretroviral agents. The complete indication is as follows:

VIREAD is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. This indication is based on analyses of plasma HIV-1 RNA levels and CD4 cell counts in a controlled study of VIREAD of 24 weeks duration and in a controlled, dose ranging study of VIREAD of 48 weeks duration. Both studies were conducted in treatment experienced adults with evidence of HIV-1 viral replication despite ongoing antiretroviral therapy. Studies in antiretroviral naïve patients are ongoing; consequently, the risk-benefit ratio for this population has yet to be determined.

Additional important information regarding the use of VIREAD for the treatment of HIV infection:
* There are no study results demonstrating the effect of tenofovir on clinical progression of HIV.

* The use of VIREAD should be considered for treating adult patients with HIV strains that are expected to be susceptible to tenofovir as assessed by laboratory testing or treatment history. (See Description of Clinical Studies)

The Package Insert is located on the FDA/CDER website in PDF format:
http://www.fda.gov/cder/foi/label/2001/21356lbl.pdf

FDA Talk Paper http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01111.html or see below:

The Food and Drug Administration has approved Viread (tenofovir disoproxil fumarate), a new antiviral drug indicated for treatment of HIV-1 infection in combination with other antiretroviral medicines. Tenofovir disoproxil fumarate is the first nucleotide analog approved for HIV-1 treatment. Nucleotides are similar to nucleoside analogs, and block HIV replication in the same manner.

The introduction of potent antiviral drugs and the combined use of these drugs has markedly reduced replication of HIV in many patients and has improved survival rates. Yet because HIV mutates rapidly, resistance to one or more of these potent drugs may develop over time, necessitating the development of new drugs to treat these resistant virus strains.

FDA based its approval of tenofovir disoproxil fumarate on two clinical studies involving more than 700 patients who had previously been treated with antiretroviral agents, but showed signs of continued HIV replication despite drug therapy. The two clinical studies were a placebo-controlled 24-week study and a controlled dose-ranging 48-week clinical trial. Patients who received tenofovir disoproxil fumarate showed significant decreases in the quantities of HIV RNA in their blood compared to patients who received a placebo with the standard antiretroviral regimen. Because the approval of tenofovir disoproxil fumarate was based on clinical trials involving patients who were previously treated with antiretrovirals, the risk-benefit ratio for untreated patients has yet to be determined. Furthermore, there are no study results to show long-term inhibition of the clinical progression of HIV by tenofovir.

Tenofovir disoproxil fumarate is available as a 300 mg tablet to be taken orally, with a meal. The use of tenofovir disoproxil fumarate should be considered for treating adult patients with HIV strains that are expected to respond to tenofovir as assessed by laboratory testing or treatment history.

The most frequently reported adverse events among patients in the clinical trials were mild to moderate gastrointestinal problems including diarrhea, nausea, vomiting and flatulence. Lactic acidosis and hepatomegaly with steatosis (severe liver enlargement and excess fat in the liver) have also occurred among patients treated with nucleoside analogues alone, or in combination with antiretrovirals. These are severe and possibly fatal conditions.
Viread is the brand name for tenofovir disoproxil fumarate and is marketed by Gilead Sciences, Inc. of Foster City, CA.

Clinical Pearls

Tenofovir capsules

Alice: Hi everyone, A patient of ours wants to know exactly how large the tenofovir pills are - does anyone know? He has a major swallowing problem (recently had a GJ tube inserted) and size really matters. thanks!

Tony: I just saw them; maybe around the size of a Trizivir, but in an attempt to make them esthetically pleasing, they have this funny, tear drop-ish/almond kind of shape happening. The patient who I showed them to also has difficulty swallowing, but seemed to think he could do tenofovir; a patient of mine with esophageal strictures, however, didn't think she could.

Jeff: Hi Alice.... I just had two tabs returned, so I was able to compare; the Viread tabs are almost as long as Trizivir, but flatter; they're maybe 1/2 as fat. Film-coated, not scored but very easy to break..

Herbal drug interaction resources

Sandy: can anybody recommend a good drug interaction website for antiretrovirals and herbal medications? We have a patient on Combivir and Sustiva that wants to begin herbal medications with Black Walnut Hull, Wormwood, cloves, and ornithine. Any information you guys could provide would be most appreciated.

Jeff: try www.naturaldatabase.com - it's a service from Pharmacist's letter, does require a subscription..... there's also a print version; both are nicely referenced. Good luck!

Lizanne: I also use the natural database of the Pharmacist Letter. It's excellent. There's also a book that was put out last year by CPhA and CMA called Herbs Everyday reference for Health Professionals. It's not as extensive as the database of the pharmacist letter, but it's a good start.

Alice: Yes, I agree. I find the Natural Database to be very good in terms of the amount of information on different products, and also because they often do provide more detailed information on metabolism when available (as opposed to the standard "metabolised by liver" phrase that you often get in Micromedex).

Pierre: the cost for natural database on the web is 92$ per year (the same for the hard copy version). If you take both versions, you have a deal: 132$. Also you can consult U of T website at
http://www.library.utoronto.ca/pharmacy/netres.html#altern
There are 3 sites on alternate medicine. I have not yet looked at them though.

Amprenavir capsules

Kathy: Does anyone know anything about the shortage for Amprenavir 150 mg capsules- we were told it is on backorder-available at an unknown date - only the 50 mg caps & liquid are available?? Anyone know anything further??

Jeff: Glaxo Smithkline has the 150 mg caps on backorder, expected to arrive 2 Nov.

Lactaid for Nelfinavir-associated Diarrhea

Kathy: Apparently the nelfinavir rep told one of our clinic nurses that Lactaid can help with the nelfinavir associated diarrhea. He said that he would even be willing to pay for it for our patients. I did a quick search to see if in fact this is an effective treatment for nelfinavir induced diarrhea and could't find anything. Does anyone else have any info on this???
(I realize that HIV in itself can cause lactose intolerance- but this issue has to due specifically with Lactaid helping nelfinavir induced diarrhea, hmm any data??)

Rachel: I dont know if nelfinavir is really the cause but our first intervention is to ask the patient to reduce milk product and/or take lactaid . It seems to work for a lot of patients.

Marie: I know it has been tried with a few patients in Montreal and it seems to work. Counselling on avoiding milk intake and other food guidance by a dietician for patients on nelfinavir has also improved the patient's status in some cases. In a small trial here 8 out of 12 patients have seen an improvement with that type of counselling. I will look if I can dig out the data.

Lizanne: I'm not aware any data with Lactaid helping for Nelfinavir-induced diarrhea. I suspect the rep got confused with a general approach that some centres use to help patients who develop diarrhea while on nelfinavir. When diarrhea occurs, we try to get the patient to temporarily cut down on certain types of foods such as fatty foods, and get them to limit their intake of milk products for a week or so. We would use lactaid only if the patient does have lactose intolerance. Maybe what the rep had in mind is that you don't need to ask patients to decrease their milk product intake if you give them Lactaid? That's the only thing I can see...

HIV Teaching Tools for Children

Alfred: Does anyone out there have any powerpoint or graphics that illustrate HIV/AIDS geared towards children???

Dominic: We have quite a number of pediatric patients in our clinic and we use a variety of resources and team members to teach parents/caregivers and children about their HIV diagnosis. Our clinic Nurse (Marilyn Allen) is the person most involved with patient education and she would be happy to chat to you about some of the literature she has on file. Our clinic number is 604-875-2212. You might want to check out www.kidsconnect.org for a great site done by the Francis Xavier Bagnoud group in New Jersey. The information is basic and presented in a kid friendly way.

We also have a number of easy-to-read patients handouts (viral loads/starting meds/immune cells/drug resistance etc) that were developed by the Vancouver Native Health Society and BC PWA Society which we've used for some of our older children.

Fusion Inhibitors (e.g., Pentafuside, T20)

Kathy: Has anyone enrolled anyone yet in your clinics ? ie Do any of your patients have access to this?

Jeff: We're not using it in Calgary yet, but I'm anticipating we'll be getting into it in the next couple of months. BC CfE may be ahead, since Julio Montanner was doing some studies with the fusion inhibitors.

Alice: We've been participating in the T20 (pentafuside) study for a couple of months: patients failing therapy are randomized to start a new ARV regimen +/- T20. Some good initial viral load responses, but in many patients, viral load is now starting to rebound.

Linda: Most of our patients have reached week 24...all were salvage patients who had failed on everything. Unfortunately, T20 was the only new addition to their regimens. Approximately 50% of these patients have achieved undetectable viral loads. For patients who did not respond, it was quite evident early on in therapy....usually viral rebound would occur around weeks 4-8 or 12. Site reactions were seen in all patients, but was not a reason for discontinuation from the study.

Colette: We have about 10 patients at the clinic, and they start in march 2001.

Management of protease inhibitor related hot flashes

Nancy Sheehan: I was wondering if someone had any suggestions / past experiences with the management of severe hot flashes/night sweats related to protease inhibitors.

I am seeing a patient who has just started Fortovase 1000 mg BID, Ritonavir 100 mg BID, Abacavir 300 mg BID and Stavudine 30 mg BID. She is also receiving B12 injections once a month and Depo-Provera 150 mg every 2 months for endometriosis. I suspect that there might be an interaction with the Depo-Provera that explains the severe night sweats / hot flashes and/or that saquinavir is contributing (<2% prevalence). Very little information is available on protease inhibitor related hot flashes (ie: onset, duration, management). She says that these symptoms are severe enough to prevent her from sleeping more than a few hours a night. Do any of you have any suggestions?

Marie: There has been insomnia reported with depo-provera. With provera in pill form it is dose related. Why is the patient on a dose of 150mg every 2 months rather than every 3 months when used for contraception. The purpose of endometriosis treatment is to maintain anovulatory state. From my own personal experience treatment of endometriosis is often accompanied by many hormonal side effects. is

there a link between the addition of the PI and the symptoms to think it is related to PI rather than depo-provera. You forgot to mention how old is the patient?

As you may already know. If you looked at the liverpool drug interaction chart at www.hiv-druginteractions.org. Progesterone/progestogen are listed as possibly interacting with all PI except Saquinavir. Having checked myself before with Upjohn they do not have any information regarding the metabolic pathway of depo-provera, It is possible it is simply an additive interaction as far as side effects of two drugs or a cumulative effect overtime of depo-provera. I would still ask the patient or gynaecologist if a lower dose of depo-provera could be tried .

I know that female patients complain a lot about effect on their menstrual cycle of all antiretrovirals. (or HIV?) May be this is something we should be looking into as a group.

As far as relief of symptoms, if it is hormonal only changes made to her hormonal treatment would relieve her. If someone else knows of any other treatment let me know! Even though it is not a definite answer I hope this can help you!

New references

Handbook of HIV Drug Therapy

At long last, the 2002 version of the Handbook of HIV Drug Therapy by Michelle & Alice will soon be available. This latest version is over 300 pages! The handbook is currently in press. Copies will be distributed to CHAP members at the annual network meeting.

Updated Drug Interaction Tables

Updated drug interaction tables have been posted on the Toronto General Hospital Immunodeficiency Clinic's website at: www.tthhhivclinic.com. A new table on management of antiretroviral side effects is now also available, and many of the medication fact sheets have been updated.

New Treatment Guidelines

*****Updated Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, February 4, 2002*****

The February 4, 2002 Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents include several substantial changes from the previous guidelines:

* New information on initiating therapy in patients with asymptomatic HIV infection begins on page 7.
* An expanded section on adverse reactions to HAART begins on page 16. A new table, Adverse Drug Reactions and Related 'Black Box Warnings' in Product Labeling for Antiretroviral Agents supplements this section; see Table 16 on page 49.
* A new section on prevention counseling for patients with HIV infection has been added; see page 29.

*****Updated Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States, February 4, 2002*****

The February 4, 2002 updated Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States includes two major revisions from the previous guidelines:

* New information on combination antiretroviral therapy and pregnancy outcome begins on page 5.
* The section on Antiretroviral Drug Resistance and Resistance Testing in Pregnancy has been revised; see page 19.

****Updated Guidelines for the Use of Antiretroviral Agents in Pediatric HIV**

Infection, December 14, 2001**
The December 14, 2001, update of the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection is now available. Developed by the Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children, the document addresses the pediatric-specific issues associated with antiretroviral treatment and provides guidelines to health-care providers caring for infected infants, children, and adolescents.

The guideline document was updated to include a more detailed discussion of major classes of antiretroviral drugs and individual drugs for treatment of pediatric HIV infection. This new information can be found in the Pediatric Antiretroviral Drug Information hyperlink section.

*****UPDATED Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States*****
*****UPDATED Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy*****
The Update Perinatal HIV Guidelines along with the Updated Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy document were updated on December 5, 2001.

The updated documents include information on the use of Tenofovir DF relevant to pregnancy. Specifically, the updates include Table 2 of the Perinatal Guidelines and pages 87, and 89-90 of the Safety and Toxicity document.

Both documents can be viewed or downloaded at http://www.hivatis.org/trtgdlns.html#Perinatal

****2001 USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus, November 28, 2001****
The 2001 USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus are now available. Originally published in 1995, the guidelines provide information for preventing opportunistic infections (OIs) in persons infected with human immunodeficiency virus (HIV).

A list of the major changes in the guidelines since 1999 can be found on page 7 of the document. Some of these changes are:

*The importance of screening all HIV-infected individuals for hepatitis C virus (HCV) is emphasized.
*Additional information about transmission of human herpesvirus 8 infection (HHV-8) is provided.
*New information on drug interactions is provided, especially with regard to rifamycins and antiretroviral drugs.
*Revised recommendations for immunization of HIV exposed/infected adults and children are provided.

The guidelines can be viewed or downloaded at http://www.hivatis.org/trtgdlns.html#Opportunistic.

****Revised Recommendations for HIV Screening of Pregnant Women - November 9, 2001****
The Revised Recommendations for HIV Screening of Pregnant Women is now available. It will replace the U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Testing for Pregnant Women, 1995. Major revisions to the 1995 recommendations include:
-Emphasizing HIV testing as a routine part of prenatal care. Strengthening the recommendation that all pregnant women be tested for HIV.
-Recommending simplification of the testing process and making the consent process more flexible.
-Recommending that providers explore and address reasons for refusal of testing.
-Emphasizing HIV testing and treatment at the time of delivery for women who have neither received prenatal testing nor antiretroviral drugs, if HIV-positive.
The Guidelines can be accessed at http://www.hivatis.org/atisnew.html.

AIDS and the Role of the Pharmacist

Conference update on the 61st International Congress of the International Pharmaceutical Federation (FIP), September 1-6, 2001, Singapore
http://www.medscape.com/Medscape/pharmacists/journal/2001/v02.n06/mph1205.berg/mph1205.berg-01.html

The Effect of Garlic Supplements on the Pharmacokinetics of Saquinavir

Stephen C. Piscitelli,1,a Aaron H. Burstein,1 Nada Welden,2 Keith D. Gallicano,3 and Judith Falloon2
Clinical Infectious Diseases 2002;34:234-238
http://www.journals.uchicago.edu/CID/journal/issues/v34n2/010586/brief/010586.abstract.html

Herbal therapies are widely used, but there are few data on their interactions with conventional medications. This study evaluated the effect of garlic supplements on the pharmacokinetics of saquinavir. Ten healthy volunteers received 10 doses of saquinavir (Fortovase) at a dosage of 1200 mg 3 times daily with meals for 4 days on study days 1–4, 22–25, and 36–39, and they received a total of 41 doses of garlic caplets taken 2 times daily on study days 5–25. Blood samples were obtained on study days 4, 25, and 39 for determination of saquinavir plasma pharmacokinetic parameters. In the presence of garlic, the mean saquinavir area under the curve (AUC) during the 8-h dosing interval decreased by 51%, trough levels at 8 h after dosing decreased by 49%, and the mean maximum concentrations (Cmax) decreased by 54%. After the 10-day washout period, the AUC, trough, and Cmax values returned to 60%–70% of their values at baseline. Patients should use caution when combining garlic supplements with saquinavir when it is used as a sole protease inhibitor.