Summer/Fall 2012

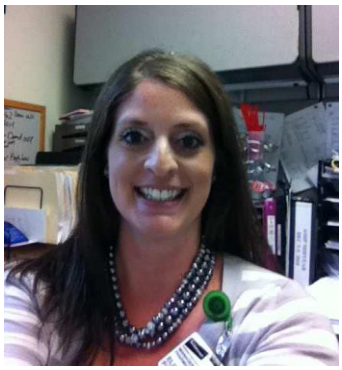
Bulletin

of the New York City Society of Health System Pharmacists

INSIDE THIS ISSUE:

President's Message

Elizabeth Palillo, Pharm.D.



Over the past year, under the leadership of Kwaku Marfo, Pharm.D, our chapter has truly done amazing things.

Our monthly CE meeting attendance has continued to rise to an average of over 85 attendees each month and I could not be prouder. It is a great feeling to see all of you each and every month.

This year's AIDS walk team surpassed our fundraising goal of $2,000 with the support of many of you here tonight.

Our website has also grown out of its start up phase and has truly become a valuable resource to our members- thank you Wilson and Ray for all of the time you put into the website to make it so successful.

It is with this exciting momentum that I am honored to serve as your next president. I know with the support of our board members that we will continue to succeed as a chapter.

Some of my ideas for the next year include the development of a CE speakers directory of our members. This will help us showcase our own chapter experts while helping out the other chapters who may need a CE speaker.

I am also interested in planning a Quad Chapter Softball game. Those of you who attended the Annual Assembly know how much fun we had at the Industry vs Pharmacists softball game. A little competition is always a good thing.

I also want to continue with new student programming ideas. The first of which would be an interview workshop. In this challenging economy it is crucial that our students can really nail their interviews and outshine other candidates.

I know the year ahead will be challenging but with your support and enthusiasm I am more than ready to step up to the plate. So please don't be a stranger. Come say hello to me at our meetings so we can work together to find a way for all members to be involved.

Thank you all for your continued support of our chapter and I look forward to the memories we will make together over the next year.

Upcoming Events

Save the Dates!!!

NYSCHP Mid-Year Clinical Meeting
Date: Tuesday, September 11, 2012
Location: LaGuardia Mariott, East Elmhurst, NY

NYC Industry Relations CE Meeting
Date: Thursday, September 27, 2012
Location: The NY Academy of Medicine,
1216 5th Avenue NY, NY

NY Cares Day
Date: Saturday, October 13, 2012
Location: TBD
How to sign up: http://www.newyorkcaresday.org
Team name is NYC Pharmacy (NYCSHP) Fee for registration is $20
For more information contact Fran Jordan at fjordan@nyp.org

CE Meeting: "Impact of Hyponatremia: Role of the Pharmacist in Improving Care"
Date: Thursday, November 15th, 2012
Location: NYU Hospital for Joint Diseases, 301 East 17th Street NY, NY

President-Elect's Greeting
-Mary Choy, Pharm.D.

Greetings!

As I start my term of planning all the educational programming monthly meetings for 2013, I am excited to bring forth innovative ideas coupled with new culinary experiences. I believe leadership starts with our members. I first met a board member at a meeting while I was a student and since then, I have been actively involved as a board member for > 5 years. It is now my goal to connect new and existing members with board members so we can begin the dialogue of leadership in pharmacy practice and continue to advance the profession. I look forward to seeing everyone at the meetings and beginning this conversation.

Professionally yours,
Mary Choy, Pharm.D.
President-elect, NYCSHP 2012-2013

So Truvada was approved for PrEP: Now what???

Alina Lyubarskaya, Pharm.D, PGY-1 Pharmacy Resident, Beth Israel Medical Center

In July 2012, the U.S. Food and Drug Administration approved the combination medication tenofovir disoproxil fumarate plus emtricitabine (Truvada) for use as Pre-exposure Prophylaxis (PrEP) for sexually active adults at risk for HIV infection. With the increasing prevalence of HIV, additional measures of prevention are being explored. Recently, the New England Journal of Medicine published two original research articles which evaluated the efficacy of PrEP in heterosexual males and females (Partners PrEP Study) and in African women (FEM-PrEP) and reported conflicting results.

Study 1: Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women (Partners PrEP Study)

This was a double-blind, randomized, placebo controlled clinical trial. From July 2008 through November 2010 researchers enrolled heterosexual couples in which one partner was infected with the HIV-1 virus while the other was not from nine sites in Kenya and Uganda. The seronegative partners had normal renal functions, were not infected with hepatitis B, and were not pregnant. The infected partner was not taking antiretrovirals at the time. The seronegative partners were enrolled into one of three arms: once-daily tenofovir (TDF), tenofovir/emtricitabine (TDF-FTC) or placebo. TDF was given at 300mg daily and FTC was given at a dose of 200mg. All participants received comprehensive HIV-1 prevention services, including testing, counseling, condoms, screening and treatment for sexually transmitted diseases and vaccination from hepatitis B was also offered. Participants had monthly follow up visits.

The primary end point was seropositivity in partners who were previously seronegative. The primary analysis was modified-intention-to-treat analysis. The study data was independently reviewed every 6 months. The study enrolled 4758 participants and followed 4747. For majority of discordant couples, the seronegative partner was male and the average CD4 count was 495 cells/mm^3 for the seropositive partner. A total of 82 HIV-1 infections occurred in seronegative participants during the study, 17 in the TDF group, 13 in the TDF-FTC group and 52 in the placebo group. This indicated a relative risk reduction of 67% in the incidence of HIV-1 with TDF (95% CI: 44-81; $p<0.001$) and 75% with TDF-FTC (95% CI: 55-87; $p<0.001$). Protective effects of either intervention alone showed no statistically significant difference between TDF or TDF-FTC and placebo

Study 2: Preexposure Prophylaxis for HIV Infection among African Women (FEM-PrEP Study Group)

This was a double-blind, placebo-controlled trial. From June 11, 2009 to April 15, 2011 women from Kenya were recruited at four study centers funded by a grant from the Agency for International Development and by the Bill and Melinda Gates Foundation. To be eligible, women in good health who were between the ages of 18 and 35 years had to test negative for HIV antibody, be at increased risk for HIV infection, not be pregnant or breastfeed, be willing to use an effective nonbarrier contraceptive method, and pass a written, informed consent quiz. Women were considered to be at high risk for HIV infection if they had one or more vaginal sex acts in the previous 2 weeks or more than one sex partner in the previous month. Women were excluded if they tested positive for hepatits B virus surface antigen or had evidence of abnormal renal or hepatic function. Participants attended clinic at 4 week intervals for up to 60 weeks. At each visit, participants received a month's supply of medication, underwent rapid HIV antibody testing, pregnancy testing and received counseling on risk reduction, study-drug adherence and contraceptive use.

(Continued on next page…)

So Truvada was approved for PrEP: Now what??? *(cont)*

The primary objective was to assess the effectiveness and safety of TDF-FTC in preventing HIV infection. The primary effectiveness endpoint was incident infection with HIV type 1 or type 2. Other endpoints included adverse events. The study was designed to test the hypothesis that once-daily TDF-FTC is more than 30% effective in preventing HIV infection. The primary effectiveness analysis was based on a confidence interval for the hazard ratio for infection in the TDF-FTC group compared to placebo using a proportional-hazards regression model. The study enrolled 2120 patients for randomization and 1741 who were included in the primary endpoint analysis. A total of 68 HIV infections, 33 in the TDF-FTC group and 35 in the placebo group, resulting in an estimated hazards-ratio in the TDF-TFC group of 0.94 (95% confidence interval 0.59 to 1.52; P=0.81). The study was stopped early because of lack of efficacy.

Discussion

The studies presented raise different opinions in the healthcare community. Despite Truvada's recent approval for preexposure prophylaxis for HIV-1 infection, at least one study showed a complete lack of efficacy as compared to placebo. This can be due to several factors.

First off, the Partners PrEP Study Team attempted to control which type of HIV infection they would study by including couples with one partner being HIV-1 seropositive and the other negative, while the FEM-PreP Study Group studied women who were not in stable relationships. The FEM-PreP Study Group's primary effectiveness endpoint included both HIV-1 and HIV-2 infections, though HIV-2 infection is more resistant to treatment and now perhaps more resistant to preexposure prophylaxis. The study group attributed their lack of efficacy to minimal adherence to medication regimens. Furthermore, if such low adherence prevailed for the entire cohort, the study was substantially underpowered to detect a statistically significant difference between TDF-FTC and placebo.

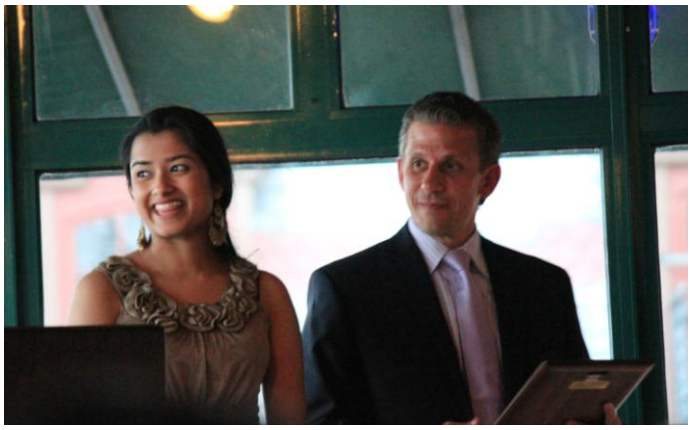
The common theme between both studies however, is the fact that Truvada alone will not prevent any HIV infection unless it includes frequent and in-depth counseling of patients regarding reduction of risk, pregnancy, other sexually-transmitted diseases and the importance of adherence to the medication regimen.

Although it is still unclear why these results differ so much it is important to consider these factors when recommended PrEP:

1. Patient population studied
2. The likely routes of HIV transmission
3. The inclusion of established discordant couples in the Partners PrEP study whose sexual behaviors may differ from others
4. Medication adherence

Lastly, if recommending PrEP it is important that it be accompanied by counseling on the continued use of condoms and on adherence to therapy, in order to avoid the lack of effectiveness that was observed in the FEM-Prep study.

Photo Gallery



Annual Installation Dinner at Bridgewater's

June 2012

Photo Gallery

CALL FOR POSTER PRESENTATIONS

Have you always wanted to do a poster presentation, but never got a chance?

Now you can have your poster presented at our Monthly CE Meeting.

Please submit your poster to nyschp@gmail.com

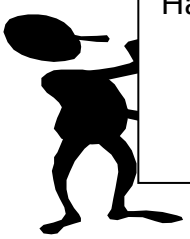
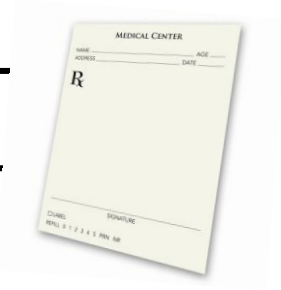


Photo Gallery

“Pass the Gavel” Board Meeting

August 2012

Curbside Consult



Ulcerative Colitis: Redux

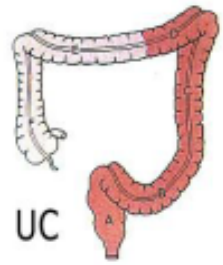
James Hwang, PharmD candidate 2013, Kimberly Chan, PharmD candidate 2013,
Tran H. Tran, PharmD, BCPS, Assistant Clinical Professor, St. Johns University

Ulcerative colitis is a mucosal inflammatory chronic disease which is continuous and diffuse around the colon and rectum (more common site). Symptoms include bloody diarrhea due to ulcers, rectal urgency and tenesmus. It can be categorized as mild, moderate, or severe.

Mild disease is having less than 4 stools daily, with or without blood, no systemic signs of toxicity and a normal erythrocyte sedimentation rate[1]. **Moderate disease** is having more than 4 stools daily with minimum signs of toxicity[1]. **Severe disease** is more than 6 bloody stools daily and evidence of toxicity with fever, tachycardia, anemia, or elevated erythrocyte sedimentation rate[1].

The cause of ulcerative colitis is still uncertain but the current hypothesis states that excessive immune response to normal microflora is due to dysregulation of mucosal immunity[2]. Smokers are less likely to develop ulcerative colitis, although risk increases for former smokers[2].

Goals of treatment for ulcerative colitis include induction and maintenance of remission of symptoms in order to minimize cancer risk, use of long-term corticosteroids, and improve quality of life[1]. The treatment guideline is outlined in the table below in the corresponding order of first line to last line treatment options



INDUCTION THERAPY

	Distal Colitis	Extensive Colitis
Mild-Mod	**1) Mesalamine (topical)** > CS (rectal) **2) Aminosalicylates (topical + PO)** > Aminosalicylates (topical or PO) **3) CS (PO)**	**1) Aminosalicylates** (PO) **2) Aminosalicylates** (topical + PO) **3) CS (PO)**
Severe – Refractory	**1) CS (PO over IV)*** **2) AZA/6-MP ± CS (IV/PO)*** **3) Infliximab**	**1) CS (PO/IV)*** + **Aminosalicylates** (PO + topical) **2) AZA/6-MP ± CS (IV/PO)*** **3) Infliximab** or **CSA (IV)**

MAINTENANCE THERAPY[t]

	Distal Colitis	Extensive Colitis
Mild-Mod	**1) Aminosalicylates (topical + PO)** > Aminosalicylates (topical/PO) *Topical CS has not been proven effective in maintaining remission in distal colitis **2) Aminosalicylates (PO)** **3) Infliximab** or **AZA** or **6-MP**	**1) Aminosalicylates (PO)** **2) AZA/6-MP** **3) Infliximab**
Severe – Refractory	**Infliximab** or **AZA** or **6-MP**	**1) Infliximab** **2) AZA/6-MP + CSA (PO)**

CS: corticosteroids; **CSA:** cyclosporine; **AZA:** Azathioprine; **6-MP:** Mercaptopurine;
Note: Thiopurines (AZA and 6-MP) are considered for their steroid sparing-effect for those who fail to respond or cannot be weaned off steroids. Cyclosporine is a short term bridging therapy to thiopurines.
*IV is used only if hospitalization is required
[t]CS not used chronically because no evidence of its efficacy in maintenance therapy

1) Kornbluth, Asher, and David B. Sachar. "Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee." *The American Journal of Gastroenterology* 2010; 105 (3): 501-23.
2) Langan, Robert, Patricia Gotsch, Michael Krafczyk, and David Skillinge. "Ulcerative Colitis: Diagnosis and Treatment." *American Academy of Family Physicians* 2007 Nov 1;76(9):1323-1330.

Azithromycin-Associated Cardiotoxicity

Karina Tselencuk, Pharm.D, PGY-1 Pharmacy Resident, Beth Israel Medical Center

A*zithromycin* is a macrolide antibiotic previously believed to be free of any cardiotoxic effects. FDA approved indications include bacterial exacerbations of chronic pulmonary disease, bacterial sinusitis, community-acquired pneumonia, pharyngitis/tonsillitis, uncomplicated skin and skin structure infections, genital ulcer disease, urethritis and cervicitis.

Reportedly, 55.3 million prescriptions for azithromycin were written in the year 2011 according to IMS Health. Several cases of torsades de pointes were reported during the post-marketing surveillance phase. At least seven published reports provided evidence to suggest that azithromycin may have proarrhythmic effects in patients with normal baseline QT intervals.

Erythromycin and clarithromycin were the two macrolide antibiotics known to be associated with an increased risk of ventricular arrhythmias and increased risk of sudden cardiac death. A new study now finds that azithromycin may also raise the risk of death related to cardiac causes.

Researchers compared the risks of cardiovascular death in individuals treated with azithromycin, amoxicillin, ciprofloxacin, levofloxacin and those with no antibiotic treatment.

Compared with individuals who took no antibiotics, those who took azithromycin had an increased risk of cardiovascular death (hazard ratio 2.88; 95% CI, 1.79-4.63; P< 0.001). Additionally, compared to the amoxicillin group, azithromycin was associated with a higher risk of cardiovascular mortality (hazard ratio 2.49; 95% CI, 1.38-4.50; P = 0.002). Among patients in the highest decile of the cardiovascular risk score, there were an estimated 245 additional cardiovascular deaths per one million courses of treatment with azithromycin compared to amoxicillin. The risk of cardiovascular death was significantly greater with azithromycin versus ciprofloxacin, but no significant increased risk was identified when compared to levofloxacin.

The authors of the study stated that the potential harm is even greater among patients who already had an increased risk of cardiovascular adverse events. Individuals at high risk include those with heart failure, diabetes, a history of a myocardial infarction, and those who have undergone bypass surgery or have had stents implanted.

There are a few drawbacks to consider with this study prior to ruling out treatment for all individuals. The study was observational, which can often times be misleading. It is uncertain whether the results that were discovered are directly related to the treatment or may be due to undetectable differences among treatment groups. Although, the researchers tried to account for the possible differences among treatment groups, one cannot rule out that some deaths may be potentially explained by differences in illness severity.

In practice, azithromycin is often indicated for respiratory infections such as pneumonia and chronic obstructive pulmonary disease (COPD) exacerbations, whereas amoxicillin is used for urinary tract infections.

Azithromycin may have been prescribed for a sicker population with a greater risk for cardiovascular death at baseline. Therefore, it is uncertain how many of the deaths reported were directly drug related as opposed to the illness itself.

The results of this study do not apply to individuals treated with azithromycin for sexually transmitted diseases. Since the study population did not include a single dose regimen as recommended for chlamydia or with dual therapy for gonorrhea, it may not necessarily apply to patients being treated for these infections.

As health care professionals we should be mindful of the potential for QT interval prolongation when reviewing treatment with a macrolide antibiotic. At this time it may be appropriate for clinicians to consider a different antibiotic for patients with known QT interval prolongation, patients with uncorrected hypokalemia, or those taking drugs that may prolong the QT interval.

NYCSHP Board Members

NYCSHP Board Members		Email Contact Information
President	Elizabeth Palillo	epalillo@chpnet.org
President-Elect	Mary Choy	mary.choy@touro.edu
Past-President	Kwaku Marfo	kmarfo@montefiore.org
Secretary	Michele B. Kaufman	michekauf@yahoo.com
Treasurer	Yi Guo	yiguo@montefiore.org
Directors-at-Large		
	Amisha Arya	amisha.arya@nyumc.org
	Wilson Tam	mrwilsontam@gmail.com
	Kanika Ballani	kanika.ballani@nyumc.org
Bulletin Editors		
	Haniyyah (Honey) Ahmad	hahmad@montefiore.org
	Basirat Shoberu	bshoberu@montefiore.org
Committee Chairs		
Constitution and By-Laws	Leila Tibi	tibi@gnyha.org
	Erika Zak	ezak89@gmail.com
	Esther Huang	chuang@chpnet.org
Special Projects	Yolanda Rodriguez	yrodrigu@chpnet.org
	Kenny Ng	kennxp@gmail.com
	Joe Pinto	pintoj@nyackhospital.org
Public Relations	Suzanna Gim	suzanna.gim@liu.edu
	Antony Pham	antony.pham@liu.org
	Joe Pinto	pintoj@nyackhospital.org
	Leila Tibi	tibi@gnyha.org
	Frances Cheng	fcheng@chpnet.org
	Wilson Tam	mrwilsontam@gmail.com
Installation Program	Janna Roitman	jroitman@chpnet.org
	Erica Nunes	enunes@chpnet.org
	Amisha Arya	amisha.arya@nyumc.org
Membership	Barbara Romeo, Lena Ngai, Amisha Arya, Elizabeth Ha, Alana Farrell, Vickie Powell, Fran Jordan, Shalini Dosi	bromeo@chpnet.org, lngai@chpnet.org, amisha.arya@nyumc.org, eha@chpnet.org, afarrell@chpnet.org, vip9006@nyp.org, fjordan@nyp.org, shd9041@nyp.org
Industrial Relations	Kwaku Marfo, Elizabeth Palillo, Joe Pinto, Fran Jordan, Kanika Ballani, Erica Zak, Mittal Sutaria, Diana Esaian, Aniwaa Owusu Obeng, Amisha Arya	kmarfo@montefiore.org, epalillo@chpnet.org, pintoj@nyackhospital.org, fjordan@nyp.org, kanika.ballani@nyumc.org, ezak89@gmail.com, mittal.sutaria@nyumc.org, diana.esaian@nyumc.org aniwaa.oben@alumni.acphs.edu, amisha.arya@nyumc.org
Clinical Pharmacy	Andras Farkas, Joe Pinto, Anna Vichiendilokkul, Mittal Sutaria, Jerry Altshuler, Tamara Iskhakova, Diana Esaian, Shalini Dosi, Lana Borno, Antony Pham, Kanika Ballani, Jason Babby, Rachel Sussman, Aniwaa Owusu Obeng, Amisha Arya	farkasa@nyackhospital.org, pintoj@nyackhospital.org, aungkanavt@gmail.com, mittal.sutaria@nyumc.org, jerry.altshuler@nyumc.org, tamara.iskhakova@nyumc.org, diana.esaian@nyumc.org, shd9041@nyp.org, lana.borno@liu.edu, antony.pham@liu.edu, kanika.ballani@nyumc.org, jason.babby@mountsinai.org, sussmans89@gmail.com, aniwaa.oben@alumni.acphs.org, amisha.arya@nyumc.org
Student Relations	Lana Borno (LIU)	lana.borno@liu.edu
	Keith Veltri, Mary Choy (Touro)	kveltri@montefiore.org, mary.choy@touro.edu
	Tran Tran, Ebtesam Ahmed (SJU)	trant1@stjohns.edu, ahmede1@stjohns.edu
Legislative	Esther Huang	chuang@chpnet.org
	Kyeong Yoo	kyoo@chpnet.org
Supportive Personnel	Ruth “Cookie” Jean	ruj9001@hyp.org
Grant Writing	Anna Vichiendilokkul	aungkanavt@gmail.com
	Leandra Miko	leandra.miko@mountsinai.org
New York State Council of Health-System Pharmacist Liaisons		
	Mark Sinnett	msinnet@montefiore.org
	Fran Jordan	fjordan@nyp.org
	Ted Friedman	ted.friedman@msnyuhealth.org