The Pitt Men's Study

News and Notes **Summer 2011**

Post and Pre-Exposure Prophylaxis: How Effective Are They?

by Bill Buchanan

prophylactic, adj., Serving to defend against or prevent something, esp. disease. – n., A prophylactic measure, drug, or device.

prophylaxis, n., Protective treatment for or prevention of disease.

I remember a more genteel and demure time when people, if they had to refer to condoms (and they tried not to), called them prophylactics. We use prophylaxis all the time, whether it's that annual flu shot, buckling up in the car, looking both ways before crossing the street, or using a condom when having sex (whether to prevent pregnancy or avoid a sexually transmitted disease).

When a possible exposure to HIV occurs, one can take highly-active antiretroviral therapy (HAART or drug cocktails) in an effort to try to stop the establishment of an infection. This method of prophylaxis has been used in the medical community as a way to prevent HIV infections, and it has proven to be fairly effective following accidental work-related exposures such as needlesticks. We call this Post-Exposure Prohylaxis or PEP.

Important caveats with PEP are that medications must be started as soon as possible after the exposure and that PEP is not 100% effective. People usually stay on PEP for a month, and can experience the side effects (not to mention the expense) associated with these potent medications. PEP's not perfect, but it does cut the number of infections from work-related, accidental exposures and is an accepted medical practice.

What is not entirely clear is how effective PEP is in preventing infection after a sexual exposure.

Our recommendation is to use condoms correctly and consistently, and should an accidental sexual exposure occur, get into care immediately either by calling your doctor or going to an emergency room where you can be evaluated. PEP should never be seen as a substitute for safer sex practices – it is at best a back-up for when safer sex practices fail.

Another strategy, PrEP (or Pre-Exposure Prophylaxis), made the news a few months back when the results of an interesting but controversial study were released. Men who have sex with men and transgendered women were given the anti-HIV oral drug Truvada to take daily in the hope that by having the drug in their systems it would reduce their risk of infection if safer sex failed. The trial reported a reduction in HIV infections of 44% in the main analysis, but in sub-analyses it was reported

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PrEP and PEP

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that adherence to the drug critically affected the degree of protection.

That sounds better than nothing until you realize that condoms are 95% effective when used correctly and consistently. If you look at those numbers a different way: approximately 60% of those who took the drug got infected anyway. Additional drawbacks to oral PrEP in the US are:

- The expense (almost $40 a day and probably not covered by insurance).
- Finding a doctor willing to prescribe it.
- Having to take a very potent medication daily (and dealing with the possible side effects).
- Its potential ineffectiveness if one is exposed to drug-resistant strains of HIV.
- PrEP has no effect on the transmission of other sexually transmitted diseases like a condom does.
- Worth repeating – its effectiveness is far less than that of condoms (which are cheap and readily available).

Our recommendation is that people not use oral PrEP. Until an effective HIV vaccine is found, condoms and other risk reduction methods are the best bet to avoid HIV infection. The staff of the Pitt Men's Study is more than willing to discuss safer sex, risk reduction, PEP and PrEP with you at your next visit (or call us at 412-624-2008 or 1-800-987-1963), and free condoms and lube are available at our clinic.

If this were that more genteel and demure time, I would pour you a cup of Earl Grey in a cup of Lenox china and chat. But there's no time for all that civility. Condoms: 95% effective. PrEP: approximately 60% *in*effective. Do the math.

World AIDS Day Service 2011 - We Need Your Photos!

We are looking for photos for a special commemoration video which will be displayed this December at the 24th annual World AIDS Day service.

Help us commemorate the 30th anniversary of the identification of AIDS and to celebrate all of those who have stood up to help heal our community and our world by volunteering for research, providing services to people, and advocating on our behalf. If you are such a person, or know one, send us your photo or the photos of others you know.

We'll be providing you with more information on World AIDS Day 2011 as the date approaches, so stay tuned!

You can email your photos to Ray Yeo: **rgy2@pitt.edu**

Or mail them to: **Ray Yeo, 3520 Fifth Avenue, Suite 450, Pittsburgh PA 15213**

Rectal Microbicide Update

Pittsburgh Advances the Rectal Microbicide Development Agenda

Microbicides are substances intended to prevent or reduce the sexual transmission of HIV when applied topically inside the vagina or rectum. Much of the current microbicide research is taking place in Pittsburgh, directed by the Microbicide Trials Network (MTN).

The MTN recently conducted a trial of topical, vaginally-formulated tenofovir 1% gel that was applied rectally in HIV-1 seronegative adults. In one experiment rectal biopsy tissue was removed from the participant after they had used the gel, and the biopsy was exposed to HIV in the laboratory. These biopsies were found to be highly protected from HIV infection.

The results, based on rectal tissue biopsies sampled from HIV-negative men and women who used the product daily for one week, provide the first-ever evidence that tenofovir gel could help reduce the risk of HIV from anal sex, even though the vaginal gel formulation may not be optimal for rectal use.

Tenofovir gel was not especially well-liked by a majority of men and women in the study, yet most reported they would be likely to use the gel if it became available in the future as a method for preventing HIV. Although the study found use of the gel generally safe, side effects were problematic to a few study participants. In hopes of making tenofovir gel more acceptable for rectal use, researchers have since modified the gel and are now testing it in another study.

“We are very encouraged about these findings that indicate applying tenofovir gel topically to the rectum could be a promising approach to HIV prevention,” said Peter Anton, M.D., professor of medicine and director of the Center for Prevention Research at the University of California, Los Angeles (UCLA), who led the study with Ian McGowan, M.D., Ph.D., co-principal investigator of the Microbicide Trials Network (MTN) and professor of medicine at the University of Pittsburgh.

“These are early results, but help set the stage for current and future trials of rectal microbicides and the development of a rectal-specific formulation of tenofovir gel,” added Dr. McGowan, who is leading the second study of the new gel formulation.

Another study, MTN-007, now underway in Pittsburgh, Boston, and Birmingham is using a formulation of tenofovir gel with less glycerin, a common additive found in many gel-like products, in the hope that this will make it better tolerated when used in the rectum. Laboratory tests of the reformulated gel suggest it is just as effective as the original formulation but less irritating to the epithelium – the layer of cells that serves as a protective barrier inside the rectum.

The study began in October 2010 and has completed enrollment of 60 men and women at three sites – University of Pittsburgh, University of Alabama at Birmingham and Fenway Health in Boston. In addition to Drs. Anton and McGowan, other authors of RMP-02/MTN-006 are Ross Cranston, M.D., University of Pittsburgh; Alex Carballo-Dieguez, Ph.D., Columbia University; Angela Kashuba, PharmD, University of North Carolina; Elena Khanukhova, UCLA; Julie Elliott, UCLA; Laura Janocko, Ph.D., MTN and Magee-Womens Research Institute; William Cumberland, Ph.D., UCLA; and Christine Mauck, M.D., M.P.H., CONRAD.

You Have a Website.

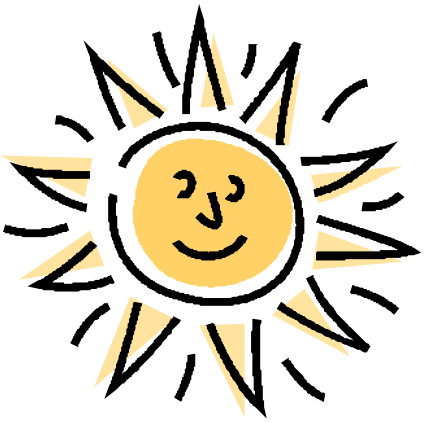
Did you know that the Pitt Men’s Study has a website? And because we wouldn’t exist without our clients, it’s really *your* website.

We update it regularly with news, health information and research development that’s important to you and your well being.

So check it out:

pittmensstudy.com

Summer Food Safety



Planning on picnicking this summer? There's more to look out for than just ants!

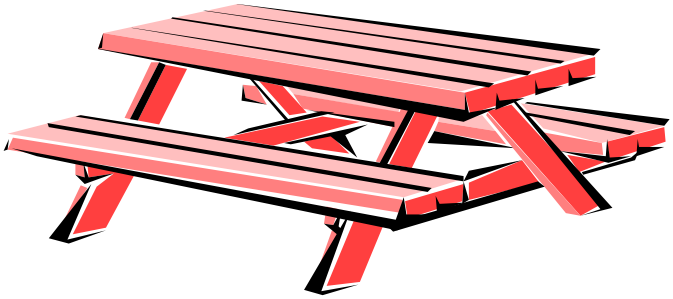
While enjoying the warm weather, picnics, and barbecues, be sure to protect yourself from getting sick. Food poisoning is caused by eating foods contaminated with harmful bacteria and usually causes diarrhea, abdominal cramping, nausea, and vomiting. Summer outdoor eating may increase your chances of eating foods that can make you ill. In order to decrease your risk of food poisoning, follow these simple recommendations:

DO'S

· Always wash hands before eating – use warm soapy water and vigorously rub hands together for at least 30-45 seconds.
· Be sure to rinse all fruits and vegetables to remove pesticides and bacteria – Even fruit and vegetables that don't look dirty may contain bacteria.
· Always cook red meat to 165 degrees – While cooking hamburgers on the grill be sure to check the color of the inside before serving. Keep cooking until it's no longer pink.
· Always cook poultry to 180 degrees – It's always a good idea to use a meat thermometer to be certain safe temperatures are reached.
· Remember to keep dairy products and foods made with dairy products refrigerated – Dairy products should not be left out during a picnic. Remove from the fridge right before they're needed and promptly return them when finished.

DON'TS

· Never eat raw meat or fish – This includes popular dishes such as sushi, raw oysters, or steak tartare.
· Don't thaw meat at room temperature – Instead, thaw in the refrigerator ensuring that the drippings won't come in contact with other foods.
· Never use any item past the expiration date – Before buying any perishable items check the expiration date and make sure you plan to use them before the date. Also, periodically inventory items in the refrigerator to make sure nothing has expired.
· Don't eat cheese that has mold on it – When buying cheese of any kind read the label and make sure it has been pasteurized.
· Never eat fruits with soft spots that show signs of mold – When buying fruit, choose pieces that are not quite ripe so that if they aren't eaten for a few days they don't spoil.
· Never use raw eggs in mayonnaise or ice cream – Always substitute frozen egg products that have been pasteurized in recipes that call for raw eggs. When eating food prepared by someone else ask if raw eggs were used in the preparation.
· Never eat soft-boiled or sunny-side-up eggs – Runny eggs are undercooked and can cause food poisoning.



As always, eat well-balanced meals that include food from all food groups, and limit your intake of alcohol. Remember, foods contaminated with harmful bacteria don't always look or smell spoiled.
When in doubt, throw it out!