

Expanded Access Programs: A Lifeline for HIV+ Patients

By Alice Welch, MPH, RPh



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Last year, when Dr. John Weiser and I decided to participate in three Expanded Access Programs for new HIV medications, I had no idea how much work I was signing myself up for, or how many lives I was about to touch.

Expanded Access Programs (EAPs) allow treatment of desperately ill patients with drugs that are still in the testing stage and can be critical for people like "George," a patient of mine at the Institute for Family Health who has lived with HIV for 20 years. George is healthy and has always adhered to his medication regimens. Unfortunately, he has extensive drug resistance and his viral load has never been undetectable—a key indication of successful treatment.

George is not alone. As a result of their high levels of drug resistance, patients who cannot be successfully treated with currently available medications are extremely immune compromised, and are at high risk of developing life threatening illnesses. Access to newer HIV medications may provide a life-saving opportunity for these patients, who may otherwise have limited—or no—treatment options.

But new treatments can be a long time coming. Typically, the time between when a new drug is submitted for FDA approval and when it actually hits the pharmacy shelves can be a year or more. EAPs are used by pharmaceutical manufacturers to bridge this gap, by permitting patients enrolled in clinical studies to receive treatment before new medicines receive final FDA approval.

The start-up process for the three programs we chose ranged from relatively easy to extremely difficult.

The Institute's senior program associate, Diane Hauser, helped us to successfully navigate the regulatory process. We were able to start TMC-125 (a Tibotek study) and MK-0518 (Merck) quickly, but initiating the Maraviroc (Pfizer study) took about 5 months and involved mountains of regulatory paperwork!

By January 2007 we were screening patients for TMC-125 and MK-0518, and in July we finally began screenings for Maraviroc. Some study participants were already Institute patients, while others were referred to us by HIV specialists throughout the city. Each patient came with a unique history. By November we had enrolled 25 patients who began receiving medication for HIV who might otherwise not have had access to such effective medications.

One month after receiving his new medication, George's viral load became undetectable. His CD4 count (an indicator of immune function) increased 4% in five months. These are truly incredible results, and would have been impossible at this time without the EAP.

The Institute's successful participation in HIV-related EAP programs, which typically are available only through academic medical centers, is a notable achievement for us and for our patients. Through EAPs, we are able to provide the most advanced care available to patients who might not otherwise have access to these therapies.

Note: MK-0518 and Maraviroc have received FDA approval and are currently available by prescription; TMC-125 will be available in about one month.

Alice Welch is the Institute's pharmacy services coordinator and clinical study coordinator. Contact her for more information at awelch@institute2000.org; Dr. John Weiser is clinical director, Manhattan COMPASS Program (Ryan White).

EHRs: A Tool for Improving Quality of Care for Underserved Populations

By Michelle Pichardo, MPH



Anne Beal, MD, MPH

The potential for electronic health records (EHRs) to improve health care quality is becoming widely recognized. However, implementing an EHR system alone does not improve care. Health care organizations must adopt strategies for harnessing an EHR's capabilities to effectively execute quality improvement efforts and to promote patient-centered care.

Recently, Anne Beal, MD, MPH, assistant vice president for the Program on Quality of Care for Underserved Populations at The Commonwealth Fund in New York City, shared her insights into the advancement of EHRs and quality improvement. "EHRs are a tool for quality improvement, not the panacea," she said.

Dr. Beal is currently engaged in research exploring health information technology (HIT) and the role it plays in creating a medical home. She is interested in identifying components of HIT, such as clinical decision supports and reminders, that improve health outcomes. She is also interested in how HIT can enhance the relationship between health care delivery organizations, physicians, and patients.

Promoting innovations in quality improvement (QI) that reduce health care disparities among low income and racial/ethnic minority patients is another priority. Dr. Beal has followed the Institute's progress in promoting HIT and incorporating evidence-based QI initiatives into our ambulatory-based EHR. She is currently working with the Institute on a project supported by The Commonwealth Fund to use the EHR as a tool for improving diabetes care, an area of great disparity in health outcomes. The Institute has identified components of care in its practices that are associated with reductions in hemoglobin A1c (blood sugar) levels among diabetic patients. In the next phase of the project, we will implement interventions based on these findings at pilot sites, to test their replicability.

Dr. Beal believes that the Institute has demonstrated that an EHR can have an impact on the relationship between providers and their patients. She would like to

see this relationship expand so that providers use the EHR to manage their entire patient panels, and practices to manage their populations of patients.

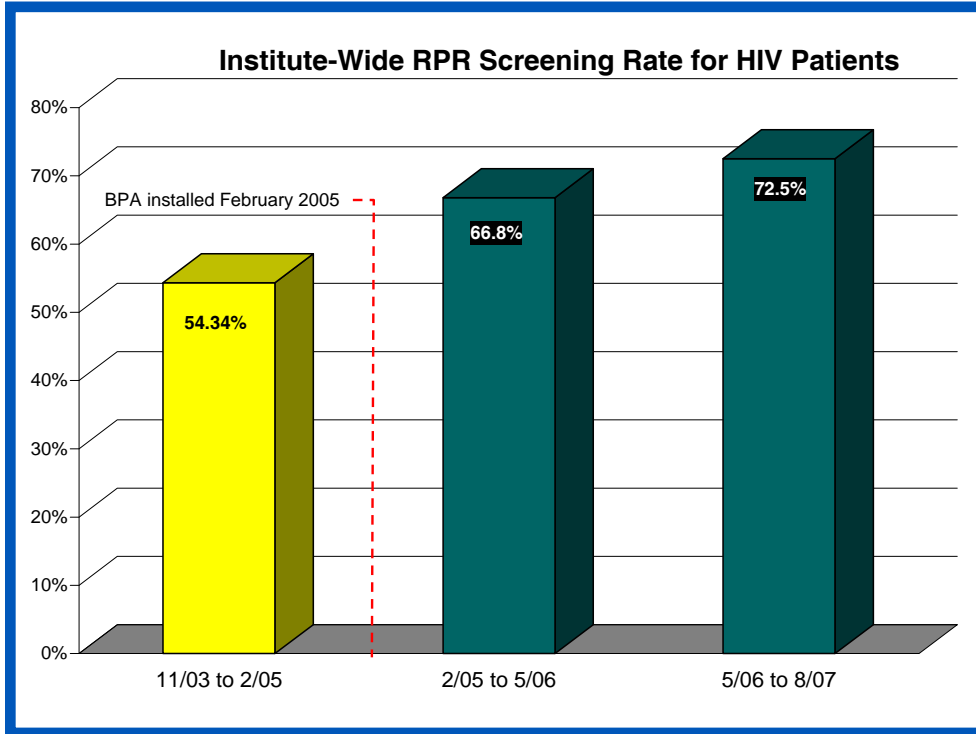
In fact, the Institute's QI office uses the EHR on a continuous basis to conduct population-based QI activities in areas such as diabetes, asthma, hypertension control, HIV care, and patient utilization and access to care. Institute providers will soon have an EHR tool, known as Reporting Workbench, at their fingertips to examine the care they are providing across their entire patient panels, as well as patient health measures and outcomes.

Dr. Beal noted that this type of analysis can provide powerful information to health care providers. She believes that the future of QI and EHRs will focus on two major challenges currently facing medically underserved communities: chronic disease management and adoption of healthy lifestyles. An example of the Institute's work in this area is our collaboration with the New York City Department of Health and Mental Hygiene to incorporate key components of the City's Take Care New York initiative into our EHR. The Institute has implemented a series of EHR-based clinical decision supports and other electronic tools to promote disease management and healthy behaviors in ten priority health areas established by the City.

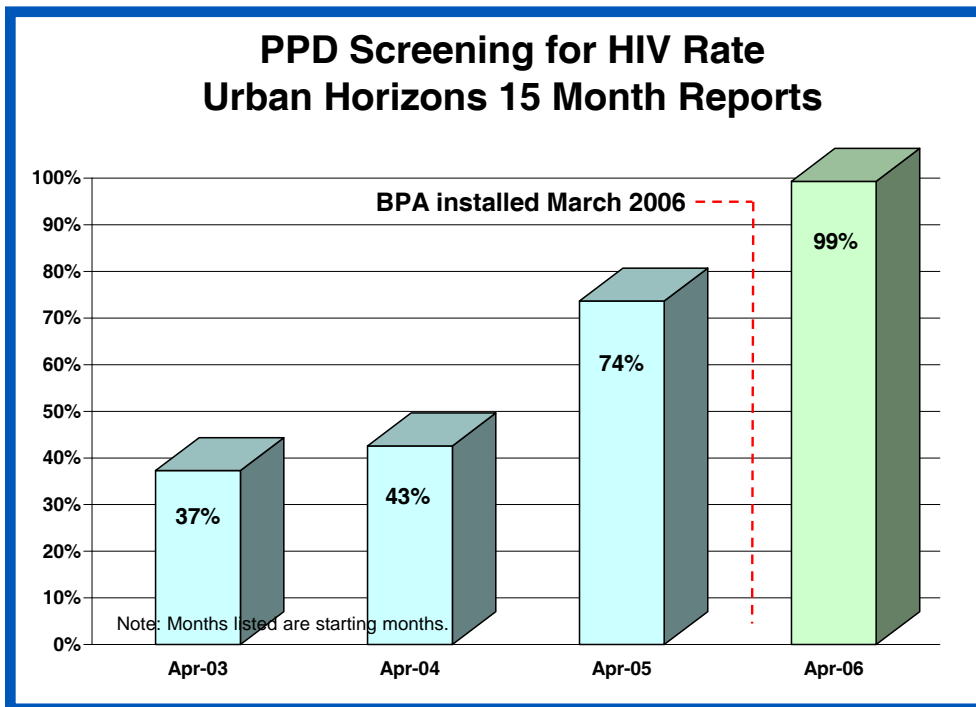
Dr. Beal also believes that health care providers will need to engage patients in their own care through the use of HIT. This is a message that Institute leadership has taken to heart: the Institute will soon introduce MyChart, a patient portal available through Epic Systems, our EHR vendor. MyChart enables patients to access portions of their medical record via the Internet. The Institute will couple patient EHR with web-based health education and self-management tools.

As EHR adoption continues across the country, Dr. Beal urges health care providers to use these systems as a tool for population-based health care, to ensure that patients get the care they need when they need it, and to automatically alert providers to disease prevention opportunities and serious health conditions. The Institute supports this agenda and is working to realize the potential of EHRs in improving health. ■

The Institute for Family Health has Applied Electronic Best Practice Alerts to Special Target Populations



In response to the rise in syphilis rates a few years ago, the NYSDOH AIDS Institute strongly recommended mandatory annual RPR (rapid plasma reagin) screening for all HIV positive patients. The Institute initiated an RPR Best Practice Alert in February 2005. There has been a 13% jump seen in the next cycle after BPA's were put in and another 6% from 5/06 to 8/07.



A Best Practice Alert for PPD (tuberculosis) screening in HIV patients was also installed in the 4th quarter 2005 after it was noted on chart review that there were deficiencies in this measure. The Bronx COMPASS (HIV care) team at Urban Horizons Family Health Center had the biggest success among Institute sites with this measure. The screening rate from April 2006 to July 2007 was 99%. This represents an increase of 56% from what was achieved there between April 2004 and July 2005.

Trauma-Focused Cognitive-Behavioral Therapy

A Closer Look at Short-Term Evidence-Based Treatment Modalities

By Jennifer Stone, LMSW

The Institute for Family Health's Psychosocial Department is committed to using research-based methods to provide optimum care in treating our patients. Interest in trauma-focused cognitive-behavioral therapy at our mental health centers lies in the high incidence of reported trauma among children.

To address this problem, staff members from the Westchester Avenue and River Avenue health centers attended a four-day summer conference on trauma-focused cognitive-behavioral therapy (TF-CBT) sponsored by the American Professional Society on the Abuse of Children. They then attended a three-day training sponsored by the Office of Mental Health (OMH) in New York City. The OMH training continued for one year with biweekly conference supervision calls. Each clinician being trained by the Office of Mental Health will complete three case presentations throughout the year using TF-CBT.

Research on TF-CBT uses participants five to eighteen years of age with a known, reported trauma. Beginning assessment measures include:

- Clinical Global Assessment Scale
- Post-Traumatic Stress Disorder Reaction Index
- Revised Children's Anxiety and Depression Scales
- Strengths and Difficulties Questionnaire, which is a brief behavioral screening questionnaire.

When a client's score on the PTSD-RI indicates the presence of mild to severe symptoms of posttraumatic stress disorder, the clinician, client, and parent begin ten modules of treatment:

1. Psycho-education on trauma and risk reduction.
2. Stress management with controlled breathing.
3. Stress management with relaxation training.
4. Stress management with thought stopping to aid children in managing intrusive thoughts associated with trauma.
5. Affect expression and modulation, wherein a child learns feeling identification and appropriate expression of emotions.
6. Cognitive coping, which aids children in understanding the association between thoughts, feelings, and behavior.

Trauma-Focused Cognitive-Behavioral Therapy, called TF-CBT, is a promising type of documented treatment for children to late adolescents diagnosed with post-traumatic stress disorder (PTSD). The growing popularity of TF-CBT lies in the efficacy of treatment (Cohen, Deblinger, Mannarino, & Steer, 2004). Studies comparing TF-CBT to other typical treatment models, including non-directive methods such as child-centered, supportive therapy, and non-directive play therapy, indicate that clients treated using the TF-CBT model report greater PTSD symptom relief in fewer sessions. Follow-up studies (two years following treatment) show that improvements persist over time. Further research shows that 80 percent of children treated using TF-CBT show reduction of symptoms in 12 to 16 sessions (using 60 to 90 minute weekly sessions).

<http://www.childwelfare.gov/pubs/trauma/trauma.pdf>.

7. Creating a trauma narrative to address avoidance, which is common after a trauma.
8. Cognitive processing to correct accurate and inaccurate thoughts about a traumatic event by challenging cognitions.
9. Behavior management training.
10. Parent-child sessions.

Assessment measures described above are completed again at the midpoint and ending sessions to identify gains from the use of TF-CBT methodology.

Studies demonstrate the effectiveness of TF-CBT in treating this population (see box, above). Indeed, TF-CBT appears to be a promising strategy to help us reach our goal of adapting best practice methods in treating our patients.

Congratulations to our staff members who participated in one or both TF-CBT training programs: **Jennifer Stone, LMSW; Carolyn Stiman, LCSW; Amanda Vogel, LMSW; Laura Leone, LMSW; Victor Franco, and Delores Blackwell, LCSW.**



Practices

Amsterdam Center
East 13th St. Family Practice
Family Practice Center of Ellenville
Family Practice Center of Hyde Park
Family Practice Center of Kingston
Family Practice Center of New Paltz
Family Practice Center of Port Ewen
Mt. Hope Family Practice
Parkchester Family Practice
Phillips Family Practice
River Center for Counseling
Sidney Hillman Family Practice
Specialty Care Center of Kingston
Urban Horizons Family Health Center
Walton Family Health Center
Washington Irving High School Health Center
Westchester Avenue Center

Programs

Area Health Education Centers (AHECs)
Beth Israel Residency in Urban Family Practice
Bronx Health REACH /NY CEED
Care for the Homeless
Community Health Workers and Healthy Families of Dutchess County
COMPASS Programs
Faculty Development Program in Urban Primary Care
Healthy Start Program of Ulster County
Mid-Hudson Family Practice Residency Program
Walton & New York City Free Clinics

CONGRATULATIONS TO OUR TOP PROVIDER PERFORMERS!

Osteoporsis Screening

Congratulationto the providers below who had the highest screening rates over the past three years for female patients 65 years and older. [Rate calculated was by ordering provider].

Dr. Ruth Lesnewski

Dr. Joseph Lurio

Dr. Ginger Gillespie

Dr. Elizabeth Molina-Ortiz

Dr. Jocelyne Sanon

Dr. Robert Schiller

Dr. Andreas Cohrssen

CQI Notes is a publication of the Institute for Family Health.

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