HIVI

HIV Initiative of Garfield Memorial Research Fund/ The Permanente Federation

Expanded Access Programs: The Payer Perspective

Michael Horberg, MD, MAS, FACP
Director, HIV/AIDS Policy, Quality Improvement, Research
Kaiser Permanente and The Permanente Federation

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KP/GHC* HIV DEMOGRAPHICS—OVERVIEW

- We now have over 16,000 active patients in our care.
- We are the second largest provider of HIV care in the United States and largest private provider of HIV care in the US.
- Southern California has the most active patients, but the range is from about 200 patients (Ohio) to nearly 5,500 patients.
- Over 100 Providers in 8 KP regions plus Group Health Cooperative

*--We include Group Health Cooperative in all of our interregional HIV efforts.

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KP GHC demographics—2006 (some results are estimates)

Region	Number Active	% Active of Total Active	% Female*	% Black/ % Latino (% API)*	Total Ever Cared for in Region
Colorado	600	3.7%	9%	Not available	2000
Georgia	1050	6.4%	24%	Not available	1939
GHC	495	3.0%	9%	10%/5% (2%)	800
Hawaii	420	2.6%	12%	<5%/<5%	2500
Mid-Atlantic	1958	11.9%	36%	Not available	4484
Northern California	5398	32.8%	11%	18%/13% (5%)	17300
Ohio	180	1.1%	15%	50%/15%	500
Oregon	890	5.4%	12%	5%/ 7% (approx.)	3000
Southern California	5448	33.1%	11%	16%/26% (3%)	16000
TOTAL	16,439		16%		48,523

*While majority of cases are still GWM, there are rising numbers of black and Latino. % female is steady.

KP/GHC HIV Clinical Results

- >90% are in care within 120 days (most 30 days) of being identified as HIV-infected.
- Over 60% have CD4 counts over 350, BUT majority are still diagnosed meeting AIDS criteria.
- Over 74% of our patients have ever been on HIV medicine (called “HAART”), with over 70% on HAART in the last year.
- While 80% are HIV RNA BLQ, many are very treatment experienced requiring newest ARV in development for successful HAART therapy.
- Our results do not differ by gender or race/ethnicity.

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Expanded Access in KP/GHC

- Most regions participate
- Most regions participate in all of the available EAP offerings
- Try to now promote ourselves as a network for purposes of gaining industry interest
- Considered research care and not clinical care (budgetary considerations)

Expanded Access in KP/GHC[2]

- Since 2002, KP Northern California has participated in 7 EAP trials, screening 210 and enrolling 173.
- Variable reimbursement has led some regions to not offer all EAP.
- Goal for pharmacy and research budgets would be for EAP to be at least budget neutral (rarely is).
- Per research nurses/pharmacists—time for EAP nearly equals time required for phase III trials.

Expanded Access in KP/GHC: Advantages

- KP has many ARV experienced patients and need early access to new drugs.
  - Not all patients qualify for ph. III trials
  - Patients would be likely on inferior regimens
- Early experience with new drugs
- Clinical trial-like experience for some clinicians
- Improves patient satisfaction
- Potentially serves to increase industry interest in KP/GHC for phase IV studies and phase III trials with other drugs in development

Expanded Access in KP/GHC: Advantages(2)

- **Can save money:**
  - **KPNW estimates savings of > $110,000 from darunavir EAP alone.**
  - **KPCO estimated in 2006 saved $180,000 from EAP programs combined.**
  - **GHC estimates ~$110,000 cost avoided in 2006 with EAP**
  - **KPSC:**

TPV EAP

Number of pts enrolled = 43

Total # months of drug supply provided = 172 months

Average # months of drug supply provided per patient = 4 months

Total drug savings= **$153,768**

TMC114 EAP

Number of pts enrolled = 19

Total # months of drug supply provided = 77 months

Average # months of drug supply provided per patient = 4 months

Total drug savings= **$57,750**

Expanded Access in KP/GHC: Disadvantages

- IRB work is no less than for phase III trials
- Establishes immediate "market" for drug in KP/GHC when FDA approved
  - Must budget and make projections for that
- Takes a lot of staff time—nearly as much as for ph. III trials
- Yet, reimbursement is often less than for other trials
  - Thus, we must budget for EAP trials (administrative costs)

HIV Care in KP—Concerns for the Future

- #1 line item in pharmacy budget for larger regions.
- Over 7% are known HIV+/HCV+, but only 13.5% of those have been treated for HCV.
- Each new regimen devised is seemingly more effective, but also more expensive.
- Our HIV-infected patients (and providers!) are aging.

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