

The Financial Impact of the 2009 DHHS Guidelines for the use of Antiretrovirals in a Community Based Program

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Change in DHHS Guidelines

- In December 2009, the Department of Health and Human Services (DHHS) updated the guidelines for the use of antiretrovirals (ARVs) in adults and adolescents.
- These recommendations include providing ARV treatment to patients with higher CD4 counts than was previously suggested.

Rationale for Beginning Therapy Sooner

- Decreasing the long term inflammatory effects of HIV on individual patients
- Decreasing the “pool” of virus in the community and thus, theoretically reducing new infection rates.

NA-ACCORD

- All cause mortality was significantly higher in patients who deferred treatment until their CD4 count was ≤ 500 cells/mm³ compared to those who began highly active antiretroviral therapy (HAART) with CD4 counts above 500.
- Combined with other studies the data was compelling enough to cause the DHHS panel to change the guidelines to advise beginning therapy in patients with CD4 counts between 350 and 500.

NEJM April 2009

Even Earlier Treatment

- Some experts support the “Test and Treat” model which proposes starting all willing patients on ARV treatment at time diagnosis.
- The model is now being implemented in San Francisco Health Department.

NY Times 4/2/10

Objective

- To determine the proportion of patients that will be potentially impacted by the changes in DHHS guidelines
 - Seen at the Peabody Health Center
 - Within the Dallas EMA
- To estimate the addition cost of medications

Method

- A retrospective analysis of the patients with documented CD4 values seen at the Peabody Health Center (PHC) between March 1, 2009 and February 28, 2010 based on data from the Lab Tracker™ database.
- A survey of other clinical practices in the Dallas EMA to determine the percentage of patients in their practices that would be impacted by the new guidelines

Method

- Used straight-line projection from the Dallas EMA Ryan White Needs Assessment to estimate the number of patients in care that would be impacted by the guideline changes and project the cost
- Evaluated the cost of drug for those not on ARV and if 100%, 75%, or 50% were to start therapy

Medication Cost

- The average cost for a typical antiretroviral regimen (i.e. Reyataz/r plus Truvada; or Atripla) was calculated as an estimate of medication cost as a wholesale amount or at a 340B rate.
- The average monthly cost at the 340B rate is \$1147 per month.

Results

Peabody Health Center



Peabody Health Center (PHC)

- Between 3/1/09 and 2/28/10 a total of 928 unique patients received medical care
- A total of 562 had CD4 counts below 500 on their last visit
- 371 (66%) of this population were on ARV medications, while 191 (34%) were not
 - Of those not on ARV 94 (10.1%) of the total population had CD4 counts between 350 and 500

PHC Demographics

- 928 PLWHA in medical care at PHC in 2009
 - 750 (80.8%) male; 178 (19.2%) female
 - 466 (50.2%) Black
 - 300 (32.3%) White
 - 162 (17.5%) Hispanic



Guideline Impact within PHC

100% on Care *		75% on Care		50% on Care	
Monthly	Annual	Monthly	Annual	Monthly	Annual
\$107,780 †	\$1,293,365	\$80,835	\$970,024	\$53,890	\$646,682

* Total of 94 new patients recommended to be on ARV

† Based on a month average cost of \$1,147

Results

Survey of other clinical practices in the Dallas EMA



Survey

- A telephone survey of 4 clinical practices that care for >200 HIV patients was done between May 17-21, 2010.
- Each provided the total number of patients seen in calendar year 2009 stratified by last CD4 cell count available, across 4 ranges:

<200	200-350	351-500	>500
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Survey

- Each also provided the number of patients with CD4 counts between 350 and 500 that were NOT on ARV at the end of 2009.
 - This was divided by the total number of patients in care to get the percentage of patients that would meet the new DHHS Guidelines
 - The range across the practices was 5.6% to 12.1%

Results

Dallas EMA Projections



RW Planning Council

- In February 2008 the Ryan White Planning Council of the Dallas Area reported the results of the 2007 Comprehensive HIV Need Assessment.
 - In 2006 there were 14,709 known PLWHA in the Dallas EMA
 - Using straight-line trend projections on data between 2002 and 2006, it was estimated that by 2010 the number of PLWHA in the EMA would reach 21,074

EMA Demographics

- 21,074 Total projected PLWHA in 2010
 - 17,013 (80.7%) male; 4,061 (19.3%) female
 - 8286 (39.3%) Black
 - 8839 (41.9%) White
 - 3639 (17.3%) Hispanic

Dallas EMA Projections

- Using the Ryan Planning Council projection of 21,074 we estimated the number of patients that would meet the DHHS Guidelines based on the ranges across the clinical practices surveyed.
 - 5.6% (1,180)
 - 12.1% (2,550)

Range of Projected Additional ARV Cost in the Dallas EMA for 2010

Range	# New on ARV*	100% on Care †		75% on Care		50% on Care	
		Monthly	Annual	Monthly	Annual	Monthly	Annual
5.6%	1,180	\$1,353,460	\$16,241,520	\$1,015,095	\$12,181,140	\$676,730	\$8,120,760
12.1%	2,550	\$2,924,850	\$35,098,200	\$2,193,638	\$26,323,650	\$1,462,425	\$17,549,100

* New patients recommended to be on ARV per 2009 DHHS Guidelines

† Based on a month average cost of \$1,147

Discussion



Association of HAART Coverage and New Infections

- Recent cohort data and mathematical models showed a “strong population level association between \uparrow HAART coverage, \downarrow VL, and \downarrow # of new HIV diagnoses/year”.
- For every 100 additional pts of HAART:
 - # new HIV cases decreased by a factor of 0.97
- Per 1 log₁₀ decrease in VL
 - # new HIV cases decreased by a factor of 0.86

Montaner et al. 2010. DOI:10.1016/S0140-6736(10)60936-1

Cost Effectiveness of HIV Interventions

Intervention	Drug	Cost-Effectiveness Ratio (\$/QALY) ^a	Reference
PCP/toxoplasmosis prophylaxis	TMP-SMX	\$2600	Freedberg et al, JAMA, 1998
Antiretroviral Therapy	Zidovudine / lamivudine / Efavirenz	\$13,000	Freedberg et al, N Engl J Med, 2001
Genotypic resistance test, at treatment failure	NA	\$17,900	Weinstein et al, Ann Intern Med, 2001
Genotypic resistance test, treatment-naïve	NA	\$20,200	Sax et al, Clin Infect Dis, 2005
Inpatient HIV screening	NA	\$15,100	Walensky et al, Am J Med, 2005
MAC Prophylaxis	Azithromycin	\$44,500	Freedberg et al, JAMA, 1998

Walensky RP. Cost Effectiveness of HIV Interventions: From Cohort Studies and Clinical Trials to Policy. Topics in HIV Medicine IAS/USA: 17 (4) 2009

Cost Effectiveness of HIV and Other Screening Interventions

Intervention	Drug	Cost-Effectiveness Ratio (\$/QALY) ^a	Reference
HIV Screening every 5 years in patients at high risk	NA	\$42,200	Paltiel et al, N Engl J Med, 2005
Breast cancer screening: Annual mammogram, 50-69 years old	NA	\$57,500	Salzmann et al, Ann Intern Med, 1997
Colon cancer screening: FOBT + sigmoidoscopy every 5 years, 50-86 years old	NA	\$53,600	Frazier et al, JAMA, 2000
Type 2 diabetes: one time FPG, >25 years old	NA	\$63,000	CDC, JAMA, 1998

Walensky RP. Cost Effectiveness of HIV Interventions: From Cohort Studies and Clinical Trials to Policy. Topics in HIV Medicine IAS/USA: 17 (4) 2009

Annual Cost of ARV Therapy

- On an annual basis ARV therapy cost approximately \$14,400 per patient per year
- Estimates range from \$16,241,520 to \$35,098,200 across the Dallas EMA;
 - Even with 50% up take in acceptance of the recommendations the cost would still be between \$8.1 and \$17.5M
- PHC is projected to contribute between \$1.3M and \$646K alone in 2010

Annual Cost of ARV Therapy

- The new DHHS Guidelines will add substantial additional cost to provide ARV therapy to patients.
- Estimates suggest that every additional 100 pts placed on HAART will ↑ cost ~1.44M per year
 - This does not account for ↑ in non-ARV medications, labs or office visits

Unanswered Questions

- Will there be sufficient funding to cover the added medication cost?
 - Medicaid
 - Ryan White
 - Private

Unanswered Questions

- Given the demographics of the population of newly diagnosed individuals will Ryan White funds increase at a rate quick enough to absorb these expanded medication costs?

CDC 2010. Communities in Crisis: Is There a Generalized HIV Epidemic in Impoverished Urban Areas of the United States.

Unanswered Questions

- What will have to be compromised in order to acquire enough funds to compensate for this increase in medication?
 - Implications for social services
 - Impact on access to care for new clients

Unanswered Questions

- Will increased medication cost lead to reallocation funds from one source of Ryan White to another?
 - Social services to medical care and treatment

Unanswered Questions

- Will clinical trials play a more prominent role in clinical practices?
 - as an option to increase revenue
 - alleviate pt out of pocket to fund ARVs.

Conclusion

- This reality forces us to re-evaluate how funds are allocated, what this means for our program structure, and how we care for current patients and our expanding patient base as new clients seek care.