Report to Congress on Costs of Treatment in the President's Emergency Plan for AIDS Relief (PEPFAR)

July 2010

Summary

The chart below shows the estimated mean cost of treatment, per patient-year, to PEPFAR. These estimates are based on a sampling of PEPFAR-supported treatment sites across 12 countries and seek to capture all elements of support for treatment at the site level and above.

CATEGORY	MEAN COST TO PEPFAR
Treatment, all patients	$436
Treatment , pediatric patients	$489
Treatment, adult patients	$431
Second-line patients	$942
First-line patients	$402
Patients in lower-income countries	$467
Patients in higher-income countries	$366

The mean cost is determined per patient-year. When this calculation includes partner country and other donor contributions, the total mean cost to all parties is $812.

Antiretroviral drug (ARV) purchases account for approximately 39% of the annual cost of treatment, with costs above the site level accounting for an additional 20%. Non-ARV recurrent costs represent 36% of total costs, and non-ARV investment (health systems) costs represent approximately 5%.

Background

The rapid expansion of access to antiretroviral therapy (ART) under PEPFAR has been one of the program's most significant achievements, reaching nearly 2.5 million people by the end of Fiscal Year (FY) 2009. With PEPFAR as the cornerstone of the Obama Administration's Global Health Initiative, the Administration has announced a goal for PEPFAR's second phase of direct support for more than 4 million people.

It is essential to understand the costs of treatment programs in order to ensure that programs are making the most of available funds and saving as many lives as possible. The truly unprecedented size and scope of PEPFAR's treatment programs – often operating in severely resource-constrained settings – has made it very challenging to capture these costs.

Perhaps the easiest element of ART costs to capture is the cost of ARVs. Over time, thanks in large part to the efforts of PEPFAR's Supply Chain Management System, PEPFAR programs have been able to obtain dramatic savings through increasing reliance on pooled procurement of low-cost, generic ARVs (see http://www.pepfar.gov/documents/organization/105842.pdf). More information on this topic will be available in an article to be published the week of July 18, 2010 in the Journal of the American Medical Association, co-authored by Ambassador Eric Goosby, former Ambassador Mark Dybul, and others.

Methodology

Over several years, PEPFAR has evaluated the costs of providing comprehensive HIV treatment, which comprises all the elements of ART and associated supportive care, through a series of centrally supported and country-initiated studies of treatment costs.

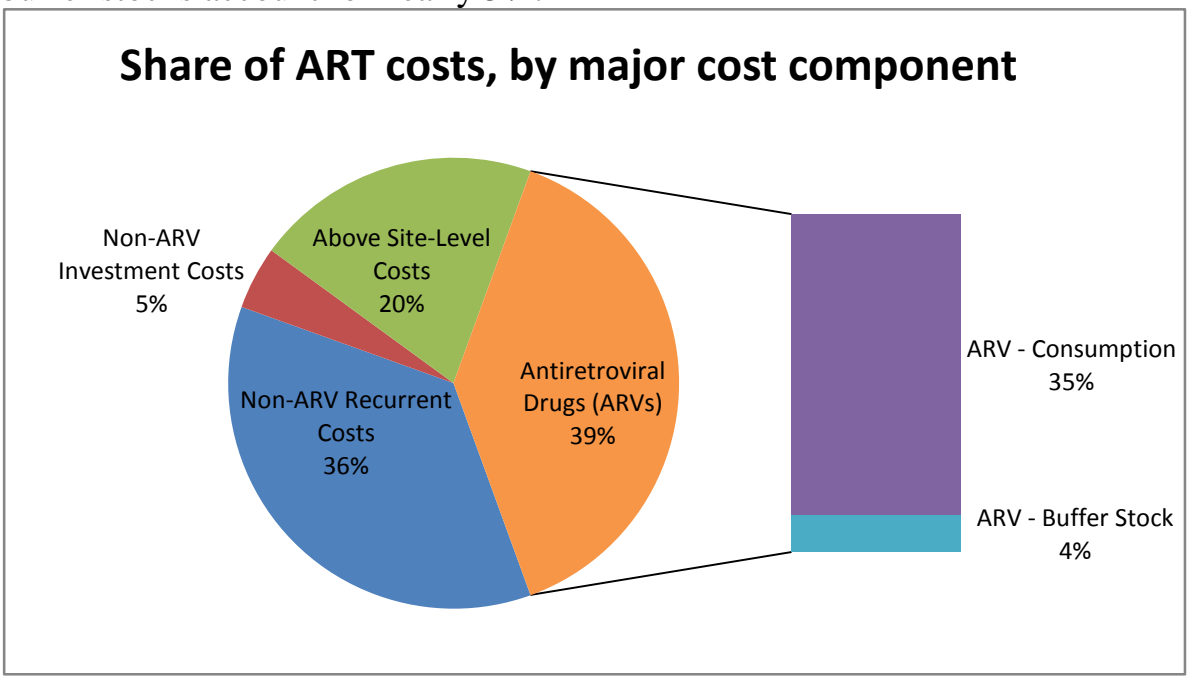
The first of these efforts, the PEPFAR ART Costing Project, was initiated in FY 2006 as a centrally funded evaluation study of PEPFAR-supported treatment programs in five countries. This effort has been expanded over time, incorporating data from 64 sites across seven countries. A manuscript providing additional detail on facility-level costs from the PEPFAR ART Costing Project has been submitted for peer-reviewed publication. To augment these studies, country-initiated studies of additional sites have contributed to PEPFAR's growing understanding of treatment costs. In total, the estimates of ART costs provided in this report reflect data from 14 studies across 12 countries, conducted between 2006 and 2009. The costing effort is ongoing; studies continue in new settings and updated data are being gathered in some settings previously studied. While these studies represent a wide range of countries and service environments, they still represent a limited sampling of PEPFAR-supported treatment activities. In fiscal year (FY) 2011, PEPFAR will begin to pilot routine expenditure analysis activities as a method to update cost estimates more rapidly. These analyses will begin to yield cross-program area cost data on a more regular basis, and over time will reduce the need for the type of time-consuming, labor-intensive special data calls to the field and reviews relied upon for this study.

Elements of support for treatment

The total mean per-patient cost of treatment reported here represents the full cost of providing ART and supportive services in FY 2010, and includes all resources required to provide comprehensive treatment at and above the site level. These include:

- Antiretroviral drugs (ARVs)
- Non-ARV recurrent costs such as:
  - clinical staff salaries and benefits
  - laboratory and clinical supplies
  - non-ARV drugs for opportunistic infections
  - building utilities
  - travel
  - contracted services
- Investment (health system strengthening) costs such as:
  - building renovation and construction
  - laboratory and clinical equipment
  - in-service training of ART providers
  - ARV buffer stock (inventory) to support a reliable supply chain

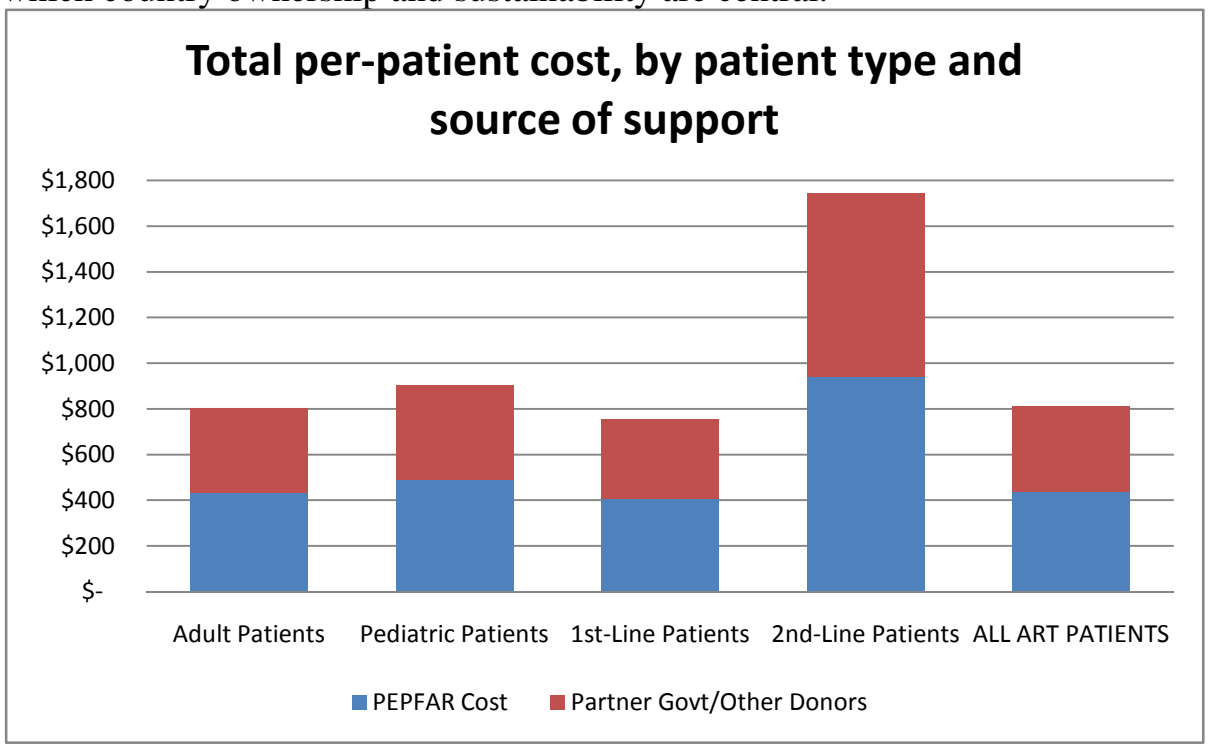
With respect to these cost components, purchases of ARVs to support patients on treatment represent 39% of the annual cost of treatment. Investment in ARV buffer stocks represents a significant share of total ARV costs and is necessary to avoid drug stock-outs that would lead to poor patient outcomes, especially during periods of rapid program scale-up such as PEPFAR's initial phase in-country. Non-ARV recurrent costs represent 36% of total ART costs, costs above the site level represent 20% of costs, and non-ARV investment (health systems) costs other than buffer stocks account for nearly 5%.



Cost estimates

The estimated mean total cost per patient-year of treatment in the programs, including financial and in-kind contributions from all sources (including partner governments and other bilateral and multilateral donors), is $812. Excluding the contributions of partner governments and other donors, **the estimated PEPFAR cost per patient-year of treatment is $436.**

The estimated mean cost includes central support costs that occur above the level of service provision, including the resources required for national management of the program. This is an area of heightened emphasis in PEPFAR's second phase, in which country ownership and sustainability are central.



Available data, and data-sharing agreements with partner governments and organizations, do not permit some breakouts of costs (e.g. urban and rural providers, or providers by country) at this time, though some additional breakouts may be possible in future years. However, other key cost breakouts are currently possible.

- The mean cost per patient-year of ART for **pediatric** patients is estimated at $902; **the PEPFAR share of these costs is estimated at $489**.
- For an **adult** ART patient, the mean is estimated at $803, and **the PEPFAR portion at $431**.

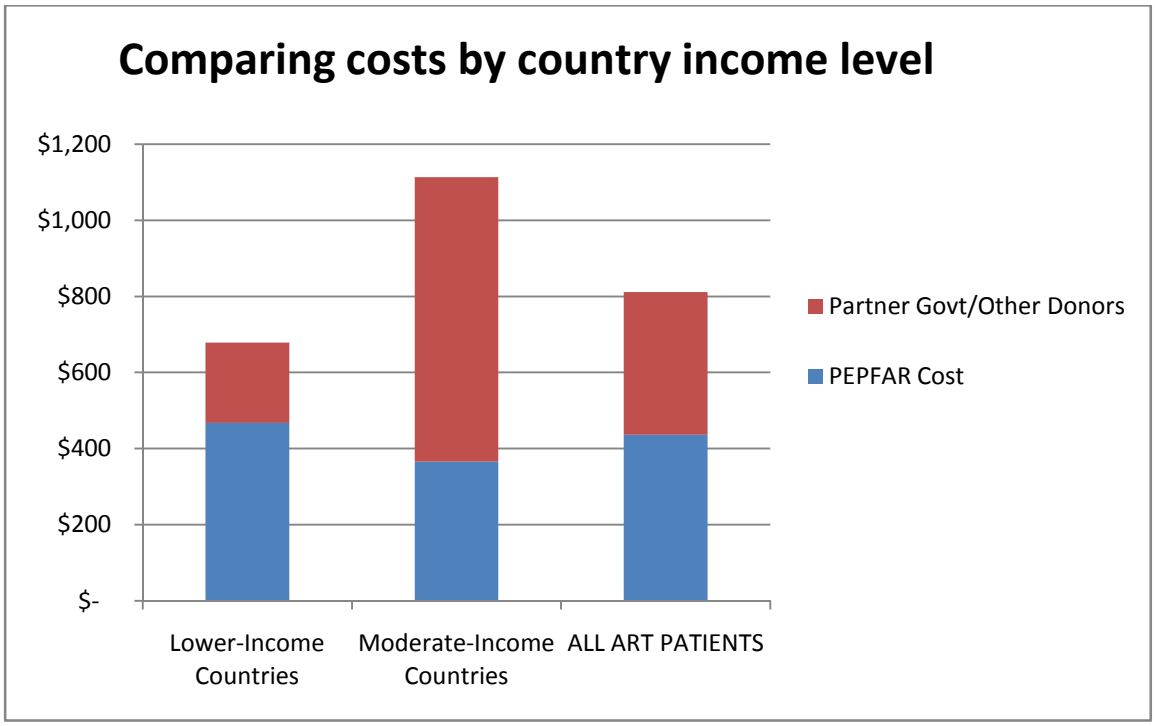
A similar pattern is exhibited for patients receiving second-line ARVs, which typically include more branded formulations. These drugs are usually more expensive than first-line ARVs, although costs of second-line therapy are beginning to decline with the introduction of two FDA-tentatively-approved generic formulations of second-line drugs (lopinavir/ritonavir fixed-dose combination), and new drug combinations that are expected to enter the market in FY 2011.

- The current total cost per-patient year for **second-line patients** is estimated at $1,745; **the PEPFAR share of costs is an estimated $942**.
- This may be compared with an estimated $754 total annual cost for **first-line patients**, and a **PEPFAR cost of $402**.

The estimated cost per patient-year of treatment varies widely across individual patient settings, and reflects differences in program maturity and scale, as well as country settings.

- In **lower-income countries**,[1] the mean cost per patient-year of treatment when taking into account all sources of support is $679. **The PEPFAR cost for these patients is $467.**
- In **moderate-income countries**, the estimated mean cost from all sources of support is $1,114 per patient-year of treatment. The **estimated PEPFAR cost is $366**, reflecting the higher contribution to the treatment program by partner country governments in these settings.

[1] For these studies, economies are classified according to 2009 Gross National Income (GNI) per capita, calculated using the World Bank Atlas method. 'Lower-income' includes what the World Bank classifies as 'low income,' with per capita GNI of $995 or less, and 'lower middle income,' with per capita GNI of $996 - $3,945 ((the former category includes inputs from Ethiopia, Uganda, Mozambique, Tanzania, Zambia and Rwanda; the latter includes data from Nigeria, Cote d'Ivoire, and Vietnam). For these studies, 'moderate-income' includes countries the World Bank classifies as 'upper middle income,' with per capita GNI of $3,946 - $12,195 (including data from Botswana, Namibia, and South Africa). Estimates for global mean costs and the USG share reflect weighting by the number of patients directly supported by PEPFAR that fall into each national income category.



Comparison with study of costs in non-PEPFAR programs

Because PEPFAR provides such a large share of global support for treatment, the availability of recent cost studies that do not include any PEPFAR partners is limited. A 2006 study conducted by RAND focused on non-PEPFAR supported treatment sites in two countries.

- The 2006 study examined 4 sites in Uganda and 1 in South Africa.
- Including costs at the site level and above, the estimates of per-patient costs in the 2006 study were $360-$449 in Uganda, and $959 in South Africa.
- Of those totals, the costs at the program site level only ranged from $287-386 per patient-year of treatment in Uganda to $892 per patient per year in the South African site.

It is difficult to assess the comparability of the RAND study estimates with the findings of the studies that form the basis for PEPFAR's cost estimates. At the most basic level, the data in the PEPFAR studies range from 2006 through 2009, while the RAND study contains only 2006 data. Furthermore, because the overall service packages at the sites sampled in the RAND study appear to be more limited than those at the sites reviewed in the PEPFAR studies (which include fuller laboratory and clinical monitoring practices, and non-ART supportive services), the estimates may not represent costs for equivalent services. For example, PEPFAR cost estimates include both the cost of ARV drug purchase to support

recurrent patient consumption of drugs, as well as investment in the necessary ARV buffer stock purchases required to assure reliable drug supply. Finally, in the 2006 RAND study, capital costs were annualized and discounted over an investment's useful life, while PEPFAR estimates take a planner's perspective and assess the full cost of investments at the time the expenditure is made.