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Analysis of Anti-Retroviral Procurement for HIV-Affected Countries from Fiscal Years 2012 to 2014

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ABSTRACT

Analysis of Anti-Retroviral Procurement for HIV-Affected Countries from Fiscal Years 2012 to 2014

Dejené Marshall

8/16/2016

BACKGROUND:

In 2015, the World Health Organization expanded eligibility for anti-retroviral therapy (ART) to all individuals affected with HIV, regardless of CD4 count. Although, anti-retroviral drugs (ARVs) are essential to HIV/AIDS treatment and therapy, ARVs may also pose a financial burden on low-income countries affected by a high prevalence of HIV. Programs funded by global donor organizations such as the President's Emergency Plan for AIDS Relief (PEPFAR) may provide assistance to these HIV-affected populations through the procurement of ARVs. The objective of this analysis was to determine total ARV expenditures for SCMS participating countries from fiscal years 2012 to 2014 and to discuss the implications of generic ARV procurement under the WHO and UNAIDS guidelines.

METHODS:

The SCMS Delivery History Dataset was used to determine the number of purchase orders for generic and brand name ARVs, as well as calculate the expenditures for overall, brand name and generic ARVs for 2012-2014.

RESULTS:

From 2012 to 2013, the procurement of overall and generic ARVs increased, however, from 2013 to 2014, there was a decrease in generic and overall ARV procurement. The number of brand name ARV transactions increased during this three year period from 78 in FY 2012, 144 in FY 2013, and 164 in FY 2014 respectively. The anti-retroviral drug Keletra was the most frequently purchased ARV in FY 2012 and FY 2014. In FY 2013, the most frequently purchased ARV was Aluvia.

DISCUSSION:

It is recommended that the international public health community continues to develop more cost-effective methods of procuring ARVs to resource-limited, HIV-affected populations. Although there are barriers to obtaining generic formulations for anti-retrovirals, there are possible consequences of low uptake of generic ARV procurement. If a country is unable to efficiently secure enough ARVs for HIV-affected individuals, it is more unlikely that HIV/AIDS will be eliminated in that location within the next several years, according to the UNAIDS and WHO recommendations.

**ANALYSIS OF GENERIC ANTI-RETROVIRAL PROCUREMENT FOR PEPFAR-SUPPORTED
COUNTRIES**

by

Dejené Marshall

B.A. SOCIOLOGY, GEORGIA STATE UNIVERSITY

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of the
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APPROVAL PAGE

**ANALYSIS OF GENERIC ANTI-RETROVIRAL PROCUREMENT FOR PEPFAR-SUPPORTED
COUNTRIES**

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AUTHOR'S STATEMENT PAGE

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Dejené Marshall

TABLE OF CONTENTS

Chapter I. INTRODUCTION	1
1.1. Background	1
1.2. Purpose	3
1.3. Research Questions.....	3
Chapter II. REVIEW OF THE LITERATURE	4
Chapter III. METHODS.....	5
Chapter IV. RESULTS.....	6
Chapter V. DISCUSSION	11
Chapter VI. CONCLUSION	13
Chapter VII. LIMITATIONS.....	14
REFERENCES	15

Chapter I

INTRODUCTION

1.1 Background

In 2015, although 36.7 million people were living with HIV/AIDS globally, only 17 million of those infected with the virus were able to access and undergo anti-retroviral therapy (ART) (UNAIDS, 2016). Two-thirds of those infected resided in Sub-Saharan Africa (PEPFAR, 2016). UNAIDS suggests that approximately 26.2 billion US dollars will be needed for the HIV/AIDS response in 2020 and approximately 23.9 billion US dollars in 2030 (2016).

Several international organizations have implemented programs and initiatives to address the HIV epidemic. One of the major unifying goals between these organizations are the 90-90-90 targets developed in 2014 by Joint United Nations Programme on HIV/AIDS, known as UNAIDS. The 90-90-90 targets include the following: 90% of HIV-positive individuals will know their status, 90% of HIV-positive individuals will have sufficient ART and 90% of those on ART will have viral suppression (UNAIDS, 2014). UNAIDS suggests that meeting the 90-90-90 targets by 2020 will result in the end of the AIDS epidemic by 2030, while acknowledging this is an ambitious goal (UNAIDS, 2014).

One year later in 2015, the World Health Organization (WHO) published guidelines that recommended universal ART for adults, adolescents and children who are HIV positive regardless their CD4 count (WHO, 2015). This guideline dramatically increased the number of individuals who may need ART and inspired countries throughout the world to revisit their national guidelines to meet these new WHO recommendations.

The President's Emergency Plan for AIDS Relief, known as PEPFAR, is the U.S. government initiative to globally combat the HIV/AIDS epidemic (PEPFAR n.d.). In 2008, PEPFAR was expanded under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, which authorized 48 billion US dollars towards this multi-year HIV/AIDS strategy (PEPFAR, n.d.). Since the launch of PEPFAR until Fiscal Year (FY) 2013, there has been over 52 billion US dollars committed to various international HIV/AIDS, tuberculosis and malaria programs across 54 countries (PEPFAR, n.d.). PEPFAR 3.0 has allocated approximately 5.2 million US dollars to bi-lateral HIV/AIDS programs so far in 2016 alone (PEPFAR, 2016). Since PEPFAR funds are appropriated through Congress, there are accountability measures that must be taken to ensure the proper allocation of funding.

The Office of the US Global AIDS Coordinator, also known as OGAC, manages the entire PEPFAR program and PEPFAR funding. Additionally, OGAC approves all PEPFAR activities and funding that is allocated to a country or region. In order for a country to receive assistance, their government must work with OGAC to develop a Partnership Framework. Partnership Frameworks detail a 5-year plan between the specific HIV-affected country, the United States Government, and other partners to eliminate HIV/AIDS through coordinated financial contributions and service delivery. Then, the host country must develop a Country Operational Plan, which vastly details the use of all sources of U.S. appropriated funds for each fiscal year, along with several other quarterly and annual reports from each PEPFAR site. OGAC reports this information back to Congress on a quarterly basis.

The Supply Chain Management System, also known as the SCMS, was established in 2005 under PEPFAR and United States Agency for International Development (USAID) to procure HIV/AIDS supplies to partnering countries (SCMS, n.d.). Since then, over 2.6 billion US dollars' worth of essential commodities have been delivered, particularly for anti-retroviral drugs (ARVs), which dramatically increased accessibility to many HIV-affected countries (SCMS, n.d.). Currently, SCMS provides 70 percent of all ARVs that are funded by PEPFAR (SCMS, n.d.).

1.2. Purpose

WHO and UNAIDS' ambitious goals to eliminate HIV/AIDS reinforce the importance of anti-retroviral treatment (ART) for HIV-affected individuals across the globe. Reaching these objectives requires an increase in delivery of anti-retrovirals (ARVs) to a larger concentration of people. Consequentially, an increase of international ARV funding and procurement to resource-limited settings requires a closer look at the global supply chain system to ensure that the expenses are appropriately spent and the outcomes are maximized. The purpose of this analysis is to review international ARV expenditures and discuss the implications of generic ARV scale-up for countries highly affected by HIV/AIDS. The data collected will be useful to guide future policy decisions.

1.3. Research Questions

1. What are the total ARV expenditures (overall, generic and brand name) for a sample of HIV-affected countries from fiscal years 2012 to 2014?
2. What are the implications of generic ARV procurement under the recent WHO and UNAIDS recommendations?

Chapter II

REVIEW OF THE LITERATURE

In response to the WHO/UNAIDS recommendations, there will be a two-fold increase in ARVs supplied worldwide to ensure that all 25 million HIV-affected individuals are on treatment (Jamieson & Kellerman, 2016). An estimated 45.8 billion US dollars in facility-level resources are also needed to scale up ART from 2015 to 2020 (Dutta, Barker and Kallerakal, 2015). Based on these and other recent findings, it is important to review previous studies for more cost-effective methods to scale-up ART worldwide. It has been proposed that ARV prices must be reduced in order to ensure universal access to ART (Vasan et al., 2006). Additionally, international drug tendering processes should be negotiated between the partnering country government and the supplier before the implementation phase to avoid delays and unnecessarily purchasing expensive ARVs (Steyn et al., 2009). For example, South Africa escalated ART delivery in January 2005 but due to an inconsistent flow of ARVs and incomplete drug tendering negotiations, many HIV-affected individuals died waiting on the first supply (Steyn et al., 2009).

A study from the Office of the US Global AIDS Coordinator found that by 2008, 90% of the 22 million PEPFAR-sponsored ARV packs procured were generic (Holmes et al., 2010). Generic ARVs are more cost-effective than brand name ARVs, especially when they are procured through a global donor organization such as the Clinton HIV/AIDS Initiative (CHAI) or the Global Fund (Waning et al., 2009). Additionally, through these international organizations, the quality of the ARVs must meet the standards of the WHO Prequalification Programme and the United States Federal Drug Administration (FDA) (Waning et al., 2009). This aims to ensure that quality is not compromised by the price of the ARV.

Chapter III

METHODS

The SCMS Delivery History Dataset contains transactional information from the distribution of HIV/AIDS supplies to PEPFAR-supported countries. USAID collects, manages, and publishes the SCMS procurement data on an almost quarterly basis. The SCMS Delivery History Dataset used in this analysis was published on the PEPFAR Data Dashboard website in the first quarter of the 2016 fiscal year. This dataset was used to calculate the expenditures for overall, brand name and generic ARVS for 2012-2014 and all costs are recorded in US dollars. There were 33 total data fields included in the SCMS Delivery History Dataset, however, only the following eight data fields were used for this analysis: destination country, date of delivery to client, product group, item description, line item value, pack price, unit price, and first line designation. It is worth noting that both adult and pediatric formulations were considered, but the only product group measured was ARV. The raw data collected were associated by calendar year, but for this analysis, the delivery dates were grouped by fiscal year. Only the line item value and collective unit prices were included in the dataset and in some cases, the line item contained more than four drugs at a time. Therefore for this analysis, the aggregate totals were calculated in Microsoft Excel. Lastly, there were 21 PEPFAR-supported countries that provided expenditure information for the SCMS for 2012, and 19 countries in both 2013 and 2014. The dataset was cleaned by removing entries that contained duplicates, blanks, null and zeros. Microsoft Excel was used to generate PivotTables and charts. Since the data were collected from a procurement system and not individuals, Institutional Review Board approval was not a requirement.

Chapter IV

RESULTS

Table 1: Total Generic ARV Expenditures from High Burden Countries in FY 2012

Country	ARV Expenditures
Angola	\$6,806.40
Burundi	\$167,493.51
Cameroon	\$6,297,229.33
Congo, DRC	\$454,474.97
Côte d'Ivoire	\$10,284,116.10
Dominican Republic	\$50,787.80
Guyana	\$159,026.12
Haiti	\$5,912,640.20
Malawi	\$5,745,000.00
Mozambique	\$17,103,688.22
Nigeria	\$41,698,164.61
Rwanda	\$6,435,373.72
South Africa	\$1,029,267.29
South Sudan	\$217,128.46
Tanzania	\$17,449,741.06
Uganda	\$23,288,284.69
Vietnam	\$8,055,755.10
Zambia	\$24,057,471.54
Zimbabwe	\$18,162,235.57
Total	\$186,574,684.69

Table 2: Total Generic ARV Expenditures from High Burden Countries in FY 2013

Country	ARV Expenditures
Burundi	\$236,728.03
Cameroon	\$5,451,156.16
Congo, DRC	\$1,036,139.04
Côte d'Ivoire	\$11,784,474.95
Dominican Republic	\$622,758.46
Ethiopia	\$14,975.66
Ghana	\$2,865,796.85
Guyana	\$194,319.26
Haiti	\$2,481,226.20
Mozambique	\$45,068,284.16
Namibia	\$1,091,981.73
Nigeria	\$38,506,387.29
Rwanda	\$10,709,618.45
South Africa	\$983,092.93
South Sudan	\$117,420.34
Tanzania	\$27,355,756.54
Uganda	\$14,006,450.26
Vietnam	\$6,180,101.20
Zambia	\$31,945,622.57
Zimbabwe	\$25,961,770.18
Total	\$226,614,060.26

Table 3: Total Generic ARV Expenditures from PEPFAR-Supported Countries in FY 2014

Country	ARV Expenditures
Botswana	\$1,109,720.71
Burkina Faso	\$280.00
Burundi	\$355,857.97
Cameroon	\$459,717.30
Congo, DRC	\$1,602,386.02
Côte d'Ivoire	\$12,512,816.03
Ghana	\$2,348,550.74
Guyana	\$105,519.58
Haiti	\$12,766,271.17
Mozambique	\$40,208,699.02
Namibia	\$2,531,325.26
Nigeria	\$54,552,209.40
Rwanda	\$9,780,723.70
Senegal	\$200.00
South Africa	\$502,464.76
South Sudan	\$811,416.93
Swaziland	\$649,350.00
Tanzania	\$1,322,314.13
Togo	\$153,781.24
Uganda	\$12,497,819.86
Vietnam	\$7,537,796.65
Zambia	\$27,087,851.26
Zimbabwe	\$22,477,140.19
Total	\$211,374,211.92

Based on the SCMS Delivery History Dataset, PEPFAR-supported countries spent \$186,574,684.69 on generic ARV drugs in FY 2012, \$226,614,060.26 in FY 2013, and \$211,374,211.92 in FY 2014 as shown in Tables 1, 2 and 3. Nigeria spent \$41,698,164.61 in FY 2012 and \$54,552,209.40 in FY 2014 on generic ARVs, more than any other country program observed, respectively. Similarly, Mozambique spent the most funds on generics (\$45,068,284.16) than the other observed countries in FY 2013.

Table 4: Total Name Brand ARV Expenditures from High Burden Countries in FY 2012

Country	ARV Expenditures
Angola	\$14,793.60
Congo, DRC	\$3,698.40
Côte d'Ivoire	\$580,923.60
Guyana	\$2,493.62
Haiti	\$29,260.64
Mozambique	\$1,150.80
Rwanda	\$12,328.00
South Africa	\$273,711.92
Tanzania	\$22,806.80
Uganda	\$444,287.29
Vietnam	\$1,270,870.78
Zambia	\$69,653.20
Zimbabwe	\$496,276.32
Total	\$3,222,254.97

Table 5: Total Name Brand ARV Expenditures from High Burden Countries in FY 2013

Country	ARV Expenditures
Congo, DRC	\$10,293.88
Côte d'Ivoire	\$2,058,297.18
Dominican Republic	\$148,250.80
Guyana	\$66,329.92
Haiti	\$71,271.50
Mozambique	\$1,066,103.80
Nigeria	\$2,314,167.56
Rwanda	\$286,559.88
South Africa	\$190,873.93
Tanzania	\$1,482,592.34
Uganda	\$1,394,936.06
Vietnam	\$2,598,901.00
Zambia	\$1,680,488.80
Zimbabwe	\$77,341.50
Total	\$13,446,408.15

Table 6: Total Name Brand ARV Expenditures from High Burden Countries in FY 2014

Country	ARV Expenditures
Burkina Faso	\$171.25
Burundi	\$6,048.00
Cameroon	\$6,660.00
Côte d'Ivoire	\$53,780.90
Guyana	\$23,107.44
Haiti	\$554,634.70
Mozambique	\$1,552,459.00
Nigeria	\$3,245,867.70
Rwanda	\$88,470.88
Senegal	\$1,864.00
South Africa	\$75,568.80
Uganda	\$1,237,351.95
Vietnam	\$2,851,679.00
Zambia	\$279,290.84
Zimbabwe	\$995,732.56
Total	\$10,972,687.02

From FY 2012 to FY 2014, these SCMS partners spent \$3,222,254.97, \$13,446,408.15, \$10,972,687.02 on name-brand ARVs respectively for a total of \$27,641,350.14 over three years. In FY 2012 and FY 2013, Vietnam spent more funds on name brand ARVs than the other countries observed (\$1,270,870.78 and \$2,598,901, respectively). Nigeria had the highest expenditures for FY 2014 with \$3,245,867.70.

Table 7: Total Name Brand Purchase Orders from PEPFAR-Supported Countries in FY 2012

Brand Name of ARV	Number of Purchase Orders
Aluvia	11
Epivir	4
Intelence	3
Isentress	4
Kaletra	28
Norvir	13
Prezista	4
Videx	4
Zerit	3
Ziagen	4
Total	78

There were 78 name brand ARV transactions in FY 2012. The most frequently purchased name brand medication was Kaletra with a total of 28 purchases.

Table 8: Total Name Brand Purchase Orders from PEPFAR-Supported Countries in FY 2013

Brand Name of ARV	Number of Purchase Orders
Aluvia	49
Crixivan	1
Epivir	5
Intelence	5
Invirase	1
Isentress	6
Kaletra	37
Norvir	17
Prezista	8
Reyataz	7
Videx	4
Viread	1
Zerit	1
Ziagen	2
Total	144

In FY 2013, there were 144 name brand ARV transactions. The most frequently purchased name brand medication was Aluvia with a total of 49 purchases.

Table 9: Total Name Brand Purchase Orders from PEPFAR-Supported Countries in FY 2014

Brand Name of ARV	Number of Purchase Orders
Aluvia	29
Epivir	1
Intelence	17
Invirase	7
Isentress	26
Kaletra	32
Norvir	22
Prezista	19
Reyataz	10
Stocrin/Sustiva	1
Total	164

There were 164 name brand ARV transactions in FY 2014. The most frequently purchased name brand medication was Kaletra with a total of 32 purchases.

Chapter V

DISCUSSION

There are a few implications to the WHO's recent recommendations to increase ART to all HIV-affected individuals and the UNAIDS 90-90-90 goals. To meet these targets established by UNAIDS and WHO, it is necessary to increase the volume of ARVs to the affected countries and populations. The increase in ARVs would require a closer look at how countries spend their allocated funds on ARV procurement to supply the target populations adequately and efficiently.

From 2012 to 2013, the procurement of overall and generic ARVs increased, however, from 2013 to 2014, there was a decrease in generic and overall ARV procurement. The number of brand name ARV transactions increased during this three year period from 78 in FY 2012, 144 in FY 2013, and 164 in FY 2014 respectively. The anti-retroviral drug Keletra was the most frequently purchased ARV in FY 2012 and FY 2014. In FY 2013, the most frequently purchased ARV was Aluvia.

One obstacle in obtaining generic ARVs is slow registration processes in a few PEPFAR-funded countries (PEPFAR, 2009). Drugs that are distributed through the supply chain must be registered with the FDA through PEPFAR. Once they are FDA approved or even tentatively approved, drugs are then listed on the WHO website and/or submitted for the WHO Prequalification Programme (FDA, 2015). WHO Prequalification Programme ensure the quality of drugs and supplies for high burden diseases. This entire process can take months or years to complete. If there is an extensive delay, countries are forced to use the innovator drug, the product that was initially developed and typically sold at a higher price, instead of the generic that is under the registration process.

Another obstacle is the ARV tender process. Country governments often discuss the transactional processes and prices with the drug manufacturers far in advance to the implementation of services. In most cases, countries may agree to multi-year contracts with ARV drug manufacturers which reduce the flexibility in lowering ARV prices in the future (Holmes et al., 2010).

Producing ARVs locally, instead of importing, may also be considered. One study presented a case where two countries, Mozambique and Zimbabwe, implemented their own pharmaceutical manufacturing sectors (Russo & Banda, 2015). Another study from Tanzania found that locally produced drugs were found both in rural and urban areas, while imported medicine was mostly found in urban areas (Mujinja et al., 2014). This suggests that having local production may increase the availability of drugs in rural areas. However, it is worth noting that these initiatives faced obstacles, such as human resources deficiencies and unfavorable business environments (Russo & Banda, 2015). The current challenge for these companies is ensuring the costs of production remain low in order to compete with international manufacturers.

Although there are barriers to obtaining generic formulations for anti-retrovirals, there is a dire consequence of low uptake of ARVs. If a high burden country is unable to sustain or secure enough ARVs for HIV-affected individuals, it is unlikely that HIV/AIDS will be eliminated in that location within the next several years, according to the WHO recommendations.

Chapter VI

CONCLUSION

It is also recommended that the international public health community continues to explore solutions to overcome obstacles that prevent countries from securing generic ARVs. Policy officials may consider revising the ARV registration process to decrease the time between the initial drug submission, drug approval and drug distribution to the country. High burden country governments may consider establishing shorter contracts and negotiating the ARV tender processes annually, instead of every few years in order to make adjustments to cheaper ARVs as needed. Countries may also invest in producing their ARVs locally. In the implementation phase, this may require the support of non-profit or international organizations to develop an efficient production system, but this effort may have the potential to increase the number of ARVs in rural and urban regions over time. As the quantity of treatment supplies increases, it will be necessary for international partners to consider the burden on the countries and regions who may not have the capacity for this unprecedented scale-up (Jamieson & Kellerman, 2016). It will also be necessary to adjust the storage space, tracking methods and human resources to meet these needs over time.

Integrating planning methods between the global supply chain managers, partnering organizations and policy makers will be critical in achieving such ambitious goals, such as the UNAIDS 90-90-90 targets and WHO recommendations. As researchers, health staff and policy officials continue to work together to reduce the prevalence of HIV, eventually the global community will be able to overcome this epidemic.

Chapter VII

LIMITATIONS

Only SCMS data were considered, therefore the findings of this study cannot be generalized and may only be applied to countries who receive support from SCMS and PEPFAR. Also, the cost of shipping and international taxes were not considered in the total expenditure calculation. Other costs associated with HIV treatment and supplies were not applied to the final calculations. Lastly, the SCMS Delivery History Dataset lists the ARV delivery date but does not label the fiscal year in which the funds originated. Therefore, it is worth noting that the SCMS ARV expenditures indicated by fiscal year are estimates.

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