

Calculating the Affordability of Antiretrovirals in St Lucia

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ABSTRACT

The cost of antiretrovirals is borne by donors in many low- and middle-income countries, including St Lucia. Although donor involvement has facilitated access to antiretrovirals, donor engagement in HIV/AIDS has changed over the years. This paper assesses the affordability of antiretrovirals at the individual level if donors were no longer available to fund the cost of first and second-line antiretrovirals and a prospective third-line regimen. Various conceptions of affordability are reviewed using different assumptions of what is required to maintain a standard of living that would avoid individuals descending into poverty as a result of antiretroviral purchases. These concepts of affordability are operationalized using data from the Household Budgeting Survey conducted in St Lucia in 2005/2006. While there is a range of results for the affordability of first and second-line antiretrovirals depending on which standard of affordability is used, third-line antiretrovirals are unaffordable to more than 80% of the population across the four standards of affordability used – the national poverty line, 50% of median annual consumption, 10% of annual consumption and a proposed reasonable minimum standard.

Keywords: Antiretrovirals, drug affordability, HIV/AIDS, St Lucia

Cálculo de la Asequibilidad de los Antirretrovirales en Santa Lucía

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RESUMEN

El costo de los antirretrovirales descansa sobre los hombros de los donantes en muchos países de ingresos medios y bajos, incluyendo Santa Lucía. Aunque la involucración de los donantes ha facilitado el acceso a los antirretrovirales, el compromiso de aquellos con respecto al VIH/SIDA ha cambiado con los años. Este trabajo evalúa la asequibilidad de los antirretrovirales a nivel individual, en caso de que no hubiera ya más donantes disponibles para financiar el costo de los antirretrovirales de primera y segunda línea, y un régimen prospectivo de tercera línea. Se examinan varias concepciones en torno a su asequibilidad a partir de diferentes supuestos de lo que se requiere para mantener un determinado nivel de vida, sin que las personas caigan en la pobreza como resultado de la compra de antirretrovirales. Estos conceptos de asequibilidad se operacionalizan usando datos de la Encuesta de Presupuestos de Hogares realizada en Santa Lucía en 2005/2006. Si bien hay una gama de resultados para la asequibilidad de los antirretrovirales de primera y segunda línea, en dependencia de cual estándar de asequibilidad se utilice, los antirretrovirales de tercera línea son inasequibles para más del 80% de la población en los cuatro estándares de accesibilidad utilizados: la línea de pobreza nacional, el 50% del consumo anual promedio, el 10% del consumo anual, y un estándar mínimo razonable propuesto.

Palabras clave: antirretrovirales, asequibilidad de los medicamentos, VIH/SIDA, Santa Lucía

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INTRODUCTION

The cost of antiretrovirals is the most expensive factor in the treatment of HIV/AIDS patients and is mostly covered by donor funding to St Lucia and the other countries in Eastern Caribbean (1, 2). For several years after the first HIV case

was reported in 1984, none of the countries could afford to provide antiretrovirals to HIV/AIDS patients in public programmes (3). As a result, very few patients in the Eastern Caribbean were able to access antiretroviral therapy.

In February 2005, St Lucia and the other countries in the Organization of Eastern Caribbean States (OECS)¹ received the first disbursement from The Global Fund to purchase first and second-line antiretrovirals under a multi-country grant of US\$8 million (4). The Global Fund later provided US\$2.5 million from 2008 to 2012 (5). St Lucia obtains antiretrovirals through a pooled procurement system with the other OECS countries which is more cost-effective than if prices were negotiated by individual countries (6).

In a recent study, the OECS countries were assessed as highly dependent on external financing for antiretroviral therapy (7). This emphasis on donor funding leaves countries vulnerable to changes in the donor environment. Donor contributions to the Global Fund declined for the first time in 2010 after showing steady increases since 2002 (8). The 2008/2009 financial downturn and donor fatigue resulted in donors shifting their attention away from HIV/AIDS (8–10). There is currently no private health insurance offered to HIV/AIDS patients, and by World Bank estimates, individuals in St Lucia covered 98.8% of their out-of-pocket costs between 2008 and 2012 (11). An evaluation of the capacity to pay is one way of assessing the likelihood of the catastrophic impact of antiretroviral purchases.

This study explores the potential ability of individuals to pay for antiretrovirals if donor or government assistance is no longer available. It discusses various approaches to conceptualizing affordability of healthcare and the assumptions underlying these perspectives and addresses what proportion of the population would be unable to afford first, second and third-line antiretrovirals using household budgetary data from St Lucia.

This paper proposes a threshold called “the reasonable minimum approach”. This standard of affordability establishes food, clothing, shelter and transportation as necessary for subsistence, and proposes that in order for antiretrovirals to be affordable, they should not constitute more than 40% of an individual’s remaining budget once these subsistence needs are met.

Literature review

Affordability is one of three factors in the accessibility of healthcare; the other two components being availability and acceptability (12). A treatment or health intervention is available if it is offered and is within reach of the patient without barriers or restrictions (13). The acceptability dimension is satisfied if the patient and the provider share the view about

the efficacy of the treatment, and if care is delivered in conditions amenable to the patient (12, 14). A treatment is not affordable if patients do not have the ability to pay for it either from their own income, credit arrangements or health insurance (15). The three components of access are relevant to the equity and efficiency of health systems (16–18).

In addition to antiretrovirals being available and acceptable to patients in St Lucia, this paper affirms the premise that antiretrovirals are necessary to prolong and enhance the quality of life for patients with HIV and that the ultimate consequence of unaffordable antiretrovirals is death (19, 20). For people who are already socio-economically disadvantaged and have neither savings nor health insurance to cover out-of-pocket expenses, HIV/AIDS triggers a health-poverty trap if their income does not allow them to maintain an adequate standard of living while meeting health-related expenses (21). A disease (such as HIV/AIDS) with premature mortality and high morbidity is likely to have high productivity losses in the working age population which would subsequently have a catastrophic impact because of the resulting inability of the household to maintain the customary standards of living (22). Direct healthcare costs after being diagnosed with HIV/AIDS, including out-of-pocket costs for medication, worsen the financial situation of the already poor, and for others precipitates a downward spiral into poverty initiated by increased allocations of income on healthcare expenditure, sale of household assets or depletion of personal savings (23, 24). Russell defines HIV/AIDS-related impoverishment as “household asset depletion and income loss that cause consumption levels to fall below minimum needs” (25). In the absence of insurance coverage to alleviate the economic burden, government-sponsored treatment softens the economic impact by removing the need for patients’ out-of-pocket costs for pharmaceutical purchases (26). For both high- and low-income individuals, expenditure for antiretrovirals are involuntary, unanticipated and require a lifetime of medication since there is currently no cure.

Affordability is characterized relative to an individual’s ability to pay. By the most stringent definition, a treatment is unaffordable if it exceeds a person’s budget, or if an individual’s entire earnings has to go towards that treatment. However, this definition of affordability is too restrictive. Although the possibility of death conveys the priority of obtaining this treatment, all income cannot be allocated to medication because there are other life-sustaining expenditure that will be incurred (for example food) for a person to be able to survive. Therefore antiretrovirals cannot and should not constitute 100% of the budget. A further consideration of affordability considers what standard of living people aspire to maintain – which is a normative choice with an almost infinite number of possibilities (27). Several ways of defining an adequate standard of living are applied in the empirical section of this paper.

¹The six OECS countries benefiting from The Global Fund grant are Antigua/Barbuda, Dominica, Grenada, St Kitts/Nevis, St Lucia and St Vincent and the Grenadines.

A specific health purchase is affordable if there is enough income after the purchase to meet other socially-determined minimum needs (28). Some health economists use the term “catastrophic”, “impoverishing” or “excessive” to describe medical expenditure that prevent a family (or individual) from maintaining the customary standard of living (22, 29, 30). Three concurrent conditions lead to catastrophic health expenditures: (i) health services that require out-of-pocket payments, (ii) low household capacity to pay and (iii) the absence of pre-payment mechanisms for risk pooling (31).

When introduced in absolute terms, that acceptable standard of living which differentiates the poor from the non-poor can be determined by poverty lines that are either globally recognized or nationally established. Neither of these two standards is without critics. National poverty lines are said to underestimate local poverty for political purposes (32). The World Bank’s poverty line (originally set at US\$1.00 per day) has been critiqued for being too low for middle-income countries and for being based on unrealistic living standards (33). In 2008, there were upward revisions of the global poverty lines to US\$1.25 for extreme poverty, US\$2.00 for developing countries, and a further proposition that \$4.00 per day was more acceptable for Latin America and the Caribbean (34–36). On the basis of a gross national income (GNI) per capita (using the Atlas method²) of US\$6530, St Lucia is classified as a middle income country (36, 37).

The 2005 official poverty line in St Lucia of EC\$5086 (US\$ 1904.87) per annum is obtained using the cost of basic needs, derived from a food-poverty line, which is then adjusted upwards by the non-food component (38). The non-food component is obtained by taking the average non-food consumption of the adult equivalent expenditure of the bottom two quintiles of the population (38, 39). The food-poverty line, also referred to as the indigence line, is the minimum amount of money required to purchase a nutritionally-balanced diet that provide the daily caloric requirements for a household (37). The caloric requirements are computed by creating a recommended food basket which is obtained by the FOODPROG software of the Caribbean Food and Nutrition Institute which also computes prices based on locally available food (37, 40).

Efforts to address the issue of unrepresentative poverty cut-offs have included using the wage of the lowest-paid un-

skilled government worker or the average income of a farmer in farming communities. Although these wage-based standards might be less abstract than the poverty lines established for policy and statistical purposes, salaries of government workers for example might over-estimate the poverty cut-off where civil servants earn more than low-income workers in other industries like tourism or other service industries.

Others have set thresholds of 5, 10, 15 or 20% of income (22, 41, 42). These percentage-based approaches require the application of a standard that has been admitted to be normative even among authors who have used this approach (29). Also, introducing a specific annual income or consumption target which might seem average by national standards can be catastrophic to low-income households (41). To address the disproportionate impact of percentage-based thresholds, others have introduced the concept of discretionary budget – sometimes called capacity to pay – which is what is left once basic food needs are covered. The non-subsistence portion of the budget is what is used to evaluate affordability – using the idea that this discretionary budget is now such that room can be made to pay for the drug. Authors recommending the discretionary budget approach use a much higher threshold (around 40% of capacity to pay), but this is out of a smaller portion of the budget (43).

Finally, a relative (rather than absolute) approach to poverty has been proposed in an effort to further standardize determinations of poverty. Proponents of this measure advocate using 50% of median income or consumption to establish what level of wealth or poverty would be acceptable. Half of the median annual consumption in the survey is EC\$4447.96. Some critics of this median approach say there is no clear basis for taking 50% of income (or consumption) as optimal, since it is based on an assumption that the midpoint of consumption or earning is optimal relative to higher or lower levels (44).

Applications of affordability to healthcare goods and services

Xu *et al* estimated the percentage of households in 59 countries in Europe, North America, Asia and Africa where catastrophic health expenditure was defined as 40% of income remaining after basic [food] subsistence needs were met (45). Subsistence expenditure adjusted for household size was taken as the median food expenditure for the 45th to 55th percentile, recognizing the fact that poorer households spend more of their income on food. The health expenditures were out-of-pocket costs for consultation fees, purchases of medication and hospital bills. A multiple regression across the 59 countries revealed that out-of-pocket payments were the main factor explaining the likelihood of catastrophic expenditures. Other significant variables considered which were not as strongly associated were total health expenditure share of gross domestic product (GDP) and percentage of households below the poverty line.

²GNI per capita is calculated using the Atlas method. “The Atlas conversion factor for any year is the average of a country’s exchange rate (or alternative conversion factor) for that year and its exchange rates for the two preceding years, adjusted for the difference between the rate of inflation in the country, and through 2000, that in the G-5 countries (France, Germany, Japan, the United Kingdom, and the United States). For 2001 onwards, these countries include the Euro Zone, Japan, the United Kingdom, and the United States.” Available at [http:// data.worldbank.org/about/country-classifications/world-bank-atlas-method](http://data.worldbank.org/about/country-classifications/world-bank-atlas-method)

In a study of 30 countries in Africa, the Americas, Eastern Mediterranean, European Union, South East Asia and Western Pacific regions, Gelders *et al* applied survey methodology used by the World Health Organization/Health Action International (WHO/HAI) survey where the daily wage of the lowest paid unskilled government worker in each country is used as the standard of affordability (46). Prices of medication were gathered from pharmacies in the private and public sectors and nongovernmental organizations. The World Health Organization/Health Action International assessed the affordability of medicines as the number of days the lowest paid unskilled government worker would have to work in order to afford to purchase 30 days of treatment for a chronic condition. These conditions included in the survey were bronchial asthma, diabetes mellitus, epilepsy, hypertension and psychiatric disorders.

Using data collected from public hospitals and private pharmacies in Hubei Province, China, Yang *et al* evaluated the availability and affordability of generic and originator versions of 39 essential medicines used to treat the most prevalent diseases based on global and local disease burden (47). The medicines were for cardiovascular diseases, diabetes mellitus, bronchial asthma, respiratory tract infections and mental illness. Availability was determined based on the percentage of medicines in stock. The authors used three standards for evaluating affordability: (i) the median price ratio – a ratio comparing the medicine's local unit procurement and retail prices in the private and public sectors with the international reference price, (ii) the number of days wage required to treat an acute condition for seven days and a chronic condition for 30 days using the income level of (a) the national poverty line and (b) the per capita net income of a farmer living in Hubei province. Gelders *et al* applied the WHO/HAI standard where twice the international reference price for a generic equivalent product and more than one day's wage at either income level was seen as unaffordable (46).

A nationally-representative sample of 14 615 families in the United States of America about health services utilization, expenditures, health status and socio-economic characteristics found that about one of every five had out-of-pocket expenditures of at least five per cent (or more) of their income and almost half of those families incurred out-of-pocket medical care expenditures that were 10 per cent or more of their income (22).

METHOD

Prices of first and second-line antiretrovirals used in St Lucia were obtained from the OECS Pharmaceutical Procurement Services (PPS) in EC dollars. The procurement price included insurance and freight. The required 10% customs duty charge was added to the procurement price. The annual cost of each drug was calculated using the recommended dosages for adults. The most frequently used first and second-line regimes were obtained using data about phy-

sicians' prescribing patterns obtained from the OECS PPS (Figure). Since there are no patients currently on a third-line

First-line regimen: Lamivudine + Nevirapine + Zidovudine	EC\$301.64
Second-line regimen: Tenofovir + Lamivudine + Lopinavir-ritonavir	EC\$1036.80
Third-line regimen : Raltegravir + Darunavir-r + Etravirine	EC\$16275.8

Figure: Annual antiretroviral regimens and prices. *US1\$ = EC\$2.70

regimen, the third-line combination recommended by the WHO was used. For the third-line regimen, prospective procurement prices of raltegravir and duranavir were obtained from OECS PPS and prices for ritonavir and etravirine were obtained from the Global Fund Price and Quality Reporting, and 2012 prices for Jamaica (a Caribbean upper middle-income country included in the Global Fund price reports) were used. It is possible that OECS PPS might negotiate prices different from those for Jamaica. However, the quoted prices from Jamaica for ritonavir and etravirine were used as an approximate estimate for what St Lucia would be charged as an upper middle-income country under differentiated pricing arrangements.

Consumption data are considered reliable proxy for income in the Caribbean where there tends to be under-reporting of income by respondents, and is a more accurate representation of actual living expenses among seasonal workers and individuals including the very poor who rely on gifts to meet daily expenses (39, 41). Expenditure rather than income is a better reflection of resources since it more accurately measures what an individual actually consumes, whereas income might underestimate the resources an individual uses because it fails to capture what is supplied as donations by friends or family. In developing countries with a large informal sector, survey respondents may not want to reveal their true income (48).

Total annual consumption of adult individuals was obtained from St Lucia's household budgetary survey which was conducted from September 2005 to March 2006. The survey is the most recent source of information on national consumption patterns. Consumption figures were adjusted to 2012 values by applying the consumer price index obtained from St Lucia's Statistics Division and the Eastern Caribbean Central Bank. The July 2012 annual cost of first, second and third-line antiretrovirals was subtracted from the annual consumption of individuals in the survey (Figure).

First-line regimes are provided to patients when they are initially diagnosed, which is usually a three-drug combination of antiretrovirals – one from each category of nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors (49). Typically second and third-line regimens are constructed based on the patient's medical history, the selection of drugs available when patients initiated treatment, and the comorbidities or opportunistic infections which are present. If a patient develops resistance to first-line antiretrovirals, they are advanced to second-line antiretrovirals and ultimately to

third-line. Organization of Eastern Caribbean States and World Health Organization treatment guidelines indicate which drugs are recommended for different stages of the disease progression.

This paper applies four conceptual approaches to assess the affordability of the most frequently-prescribed antiretrovirals. Three of these approaches have been discussed in earlier sections (a national poverty-line, a median poverty-line and two percentage-based thresholds). The World Bank's extreme and adjusted poverty lines were not considered because those estimates are below the national poverty line which has been set based on empirical measurements. The lowest paid government worker standard was not used because of reasons stated above. The 10% of annual consumption threshold is used as a comparator in preference to the other levels as it is supported by research showing that almost half of families who spend 10 per cent or more of income on medical care are at or below the poverty level (22).

Prices of each of the first, second and third-line regimens were subtracted from annual consumption of individuals in the dataset. After the prices included in the annual consumption, an indicator variable was assigned to individuals (i) whose total consumption was below the government poverty line after purchase of the first, second, and third-line regimen, (ii) whose total consumption was below 50% of the median consumption after purchase of the first, second, and third-line regimen, (iii) for whom the cost of

clothing, shelter and transportation are considered to be reasonable and minimum requirements necessary for subsistence, antiretrovirals are affordable if they constitute 40% of the budget remaining after expenses for these basic necessities are met. Annual food costs were determined by the government established food poverty (indigence) line discussed above. Median transportation, clothing and housing costs were obtained from consumption reported in the data. Forty per cent is admittedly an arbitrary figure which is meant to represent less than half of non-subsistence expenditure.

RESULTS

By various standards of affordability, first-line antiretrovirals are unaffordable to at least 7% of the population, second-line antiretrovirals are unaffordable to at least 23% of the population, and third-line antiretrovirals are unaffordable to at least 84% of the population (Table). The results from all scenarios suggest that a third-line regimen is unaffordable to almost all St Lucians using all standards of unaffordability. Since the antiretrovirals in the WHO-recommended third-line treatment comprise three drugs which are still under patent, there are no cheaper generic versions available. Under the Trade-Related Aspects of Intellectual Property Rights, cheaper generics cannot be available until the patents expire – which in the case of raltegravir and darunavir will be in 2025 and etravirine in 2019 (50). Patents were extended beyond the usual 20 years after the initial patent applications because of “evergreening” by pharmaceutical companies – a

Table: Percentage impoverished by antiretroviral purchases at various thresholds

	National poverty line*	50% of median annual consumption**	10% of annual consumption	Reasonable minimum
First-line regimen	30% (+ 1.2%)	17.1% (+ 3%)	7.4%	73.4%
Second-line regimen	36.8% (+ 8%)	23.4% (+ 9.3%)	63.8%	77.6%
Third-line regimen	86.9% (+ 58.1%)	84.8% (+ 70.7%)	100%	98.1%

*Percentage of the population below the national poverty line before purchase: 28.8%. **Percentage of the population below 50% of median annual consumption before purchase: 14.1%. Numbers in brackets reflect the percentage change in proportion of the population impoverished after purchase of antiretrovirals.

first, second, and third-line regimens constituted more than 10% of total consumption and (iv) for whom the cost of first, second, and third-line regimens constituted more than 40% of non-subsistence consumption.

The fourth standard of affordability is based on an observation by Ravallion that “[p]overty can be said to exist in a given society when one or more persons do not attain a level of material well-being deemed to constitute a reasonable minimum by the standards of that society” (34). If food,

practice where manufacturers extend the patent by demonstrating (or claiming) that an updated version of the drug is available as a result of scientific innovation by the manufacturer's researchers.

DISCUSSION

In 2004, before the disbursing of the Global Fund grant, St Lucia received a World Bank loan of US\$6.4 million to introduce antiretroviral treatment, support government,

³The New Funding Model will be implemented in late 2013 after finalization of funding for the 2014–2016 cycle. See http://www.theglobalfund.org/Documents/core/newfundingmodel/Core_NewFundingModel_Overview_en/

community and civil society initiatives as well as for health system strengthening and capacity building (51, 52). The Global Fund's proposed new funding model³ and suspension of the annual call for proposals in 2011 because of concerns about the sustainability of funding suggest a change in operational policies (53). Recent Global Fund eligibility criteria require upper middle-income countries to be evaluated based on their respective disease burden and to provide 60% counterpart (cost-sharing) financing for future Global Fund projects (54, 55). These events signal a need for the re-examination of the affordability of antiretrovirals and an assessment of the potential economic impact of antiretroviral purchases at the individual level in the event that donor or government assistance was not unavailable.

Global health initiatives (like the President's Emergency Plan for AIDS Relief (PEPFAR) and The Global Fund) were established to improve the availability of antiretrovirals in developing countries (56, 57). The 2002 Accelerated Access Initiative (AAI) brokered by the WHO allowed pharmaceutical companies to institute differentiated pricing arrangements for low- and middle-income countries in the Caribbean and Africa. The lowering of prices through AAI and the emergence of The Global Fund as a leading resource-mobilization entity for HIV/AIDS and other diseases facilitated the provision of antiretroviral therapy at no cost to patients in the public system.

Affordability is an ambiguous concept since it involves normative decisions at the household or individual level (58). Defining affordability of medicines or any other commodity is a moot issue because it relies on definitions of poverty which are governed by various methodological and ideological definitions (43). The ability to maintain a customary or socially-acceptable standard of living is an important component of the concept of affordability. By establishing median consumption levels of clothing and housing expenses as acceptable, individuals have a relatively satisfactory level of well-being compared with others. Unlike the subsistence method proposed by Murray and colleagues which incorporates only food expenses (41), the reasonable minimum standard incorporates other necessary consumption – namely food, clothing, shelter and transportation. Under the proposed reasonable minimum standard, there is ample room for other discretionary spending since this approach to affordability leaves 60 per cent for other spending after antiretroviral purchases. The inability of patients with HIV/AIDS to obtain health insurance to cover the cost of antiretrovirals might be linked to the pervasive stigma associated with the disease. Policy changes in the insurance industry that allow coverage for HIV-positive patients would alleviate concerns about possibilities for financing antiretroviral care.

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