Medical Care and Access to HIV Treatment

Research Team:
Raquel Corona
Laura Iannacone
Jennifer Pierson
Samantha White

“People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off.”

-Kofi Annan, Secretary-General of the United Nations

The Big Picture
Currently, most major pharmaceutical research, development, manufacturing, and distribution are centered in the more industrialized nations of the world. Since the research is funded and carried out largely in industrialized nations, drugs are exclusively designed to meet the needs of citizens in these countries in regard to dosage, routines, and the specific HIV strains treated. Further, medical research neglects the specific needs of children worldwide in regard to development and manufacture of effective medication. A dangerous hierarchy exists worldwide with regard to access to treatment. Men most often receive treatment before women and adults before children, which contribute to the great number of people without access and disruption of social structures. Further, middle income countries are often left out of lower cost deals and donor-funded initiatives which improve treatment access. Pharmaceutical companies generally only offer special pricing, extensions on full patent compliance, and generic brands of medications to low income rather than middle income countries.

History
In 2000 the cost of triple cocktail therapy cost between US $10,000-12,000.i As a result of multiple factors: public pressure from national leaders, NGO leaders, AIDS activists, people living with HIV, their families, etc. and the introduction of generic competition, by 2003 the price of generic fixed dose combinations (FDC) fell between $140 and $300.ii The year 2001 is often credited as a turning point in the global movement for universal access to treatment. A basic tenet of this movement upholds access as a fundamental human right. This is illustrated by recent developments in international trade negotiation and passage of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Doha Declaration. In November 2001, the World Trade Organization’s annual meeting of member countries signed the TRIPS agreement into international trade law. The agreement defended patent rights against the importation, sale and distribution of generic products in most all cases, but included a necessary loophole in the case of national emergencies. It allows a country to lift patent restrictions and manufacture and distribute generic drugs domestically if they officially declare a national health emergency. This is called compulsory licensing. One important limitation for most countries was the requirement that countries who issue a compulsory license produce and distribute ARVs solely for domestic use. For low income countries without the capabilities of manufacturing generics
In general: Statistics

30 million people have died of HIV/AIDS in two decades and at present 40 million people are infected worldwide. In poor countries, 6 million people with HIV/AIDS need immediate ART, but less than 8% receive treatment. The worst hit area is sub-Saharan Africa, where 28.5 million people are infected. HIV/AIDS has destroyed communities, health care systems and put a shadow upon the future of entire countries.

As of December 2003 only 400,000 (7%) of individuals living with HIV/AIDS have access to treatment. Although global spending on combating HIV/AIDS has increased 15 times since 1996, from US$300 million to almost US$5 billion in 2003, it is not enough. The most recent estimates calculate that US$20 billion will be needed in low and middle income countries by 2007 (UNAIDS). The cost of treatment for HIV/AIDS contributes to its inaccessibility for most people infected by the virus. In 2000, HAART (Highly Active Antiretroviral Therapy) for one patient for a year cost US$10,000 to US$12,000. In 2002, some combinations, mostly generic, dropped to US$300 per year. In 2003 negotiations between the Clinton Foundation and generic drug manufacturers decreased costs in some countries to US$140 per year.

However many nations making great strides in providing needed medical treatment to those living with HIV/AIDS. Several countries in Latin America and the Caribbean now offer universal coverage for antiretroviral treatment, including Argentina, Barbados, Chile, Costa Rica, Cuba, Mexico, and Uruguay (UNAIDS). Many African countries plan to set up their own production facilities to manufacture drugs.

Among most recent efforts to supply medical care and treatment to those infected with the HIV/AIDS is the 3 by 5 initiative. The 3 by 5 initiative is the goal set by WHO and UNAIDS, in September 2003, to get 3 million of the 6 million HIV positive people in poorer countries on life-saving HIV/AIDS medicines by the end of 2005. The ultimate goal of the 3 by 5 initiative is universal access to HIV/AIDS treatment. With a little over a month left in the year 2005, the Director of WHO, Dr. Jim Yong Kim, publicly apologized on November 28 for not reaching the target. “In sub-Saharan Africa, the region worst affected by HIV/AIDS, about half a million people were receiving treatment by the middle of 2005. Although it was a three-fold increase in the last year, it was still only about 15 percent of those who need it” (CNN). Dr. Jim Yong Kim highlights dreadful statistics and worldwide failure.

The number of individuals affected by HIV/AIDS and whether or not they receive treatment expose inequitable power relations in the world. In high-income countries, those living with HIV/AIDS and in need of treatment generally receive ARV therapy. Citizens of these countries have many more opportunities to get a hold of ARVs. Specifically, the United States and several nations in the European Union dominate global access to treatment for HIV/AIDS. With the wide availability of antiretroviral treatment in high-income countries, high-risk behavior is on the rise, leading to an increase in new HIV infections. For example, in North America there were 950,000 people living with HIV in 2001 compared with one million in 2003. In Europe, there were 540,000 people living with HIV in 2001 and 580,000 in 2003. (UNAIDS July 2004).

The HIV/AIDS pandemic disproportionately affects women and correspondingly, women face greater difficulties in accessing treatment than men. Women make up 50% of those living with HIV/AIDS around the world and 57% individuals infected by HIV/AIDS living in sub-Saharan Africa. Women are not only more vulnerable biologically and socially to the virus, but they are also less likely to receive treatment than men.
Inequalities in Access

Beyond the extensive need for HIV medications around the world, there are gender and age inequalities which further serve as a barrier in accessing treatment. For example, in some cultures and households, providing treatment for infected men precedes treatment for infected women. Furthermore, families with a limited budget often perceive treatment for women as less of a priority. Oftentimes, health care centers are far away or offer inflexible hours. This makes it very difficult for women, in some cultures, to receive the medical attention they need. Largely due to extensive daily household duties and responsibilities women find traveling to clinics within working hours difficult or impossible. Further, when women are able to access treatment, many receive the same dosages as men, despite their smaller body sizes and face severe risks in under or over dosage. Under dosage results in increased vulnerability to infection and over dosage is extremely toxic. As the primary caregivers for children and households worldwide women must be a priority in ARV distribution. They are the backbone of a myriad of societies.

There is a severe lack of awareness and interest in pediatric AIDS treatment. Médecins Sans Frontières estimates that around 50% of children with HIV/AIDS die before they turn two. This is far too high in the face of moderate global progress in HIV/AIDS treatment. The first barrier to care for children living with HIV is diagnosis. Tests that are currently in wide use are unreliable for children under 18 months because results are unclear as to whether the mother’s or child’s antibodies are found.iii Most problematic are inadequate pediatric formulations of ARVs. Drugs marketed for children exist in difficult to measure and awful tasting syrups that ineffective in most resource poor settings because they require refrigeration or clean water. The alternative option is crushing adult pills into proper dosages but this poses severe risks of under-dosage and over-dosage. Under-dosage increases vulnerability to infection and over-dosage is extremely toxic. Even the best options for children are largely unavailable for the majority of children living with HIV/AIDS. Generic versions of pediatric formulations do not exist and brand name drugs that do exist are way over-priced and often not registered or marketed in developing countries. In addition, regardless of ARV price and availability, age of consent laws in some areas restrict access to treatment for younger girls and boys. The only way the world will save the millions of infected children worldwide is to create incentive for multinational and generic drug companies to develop pediatric ARV formulations in tablets of varying sizes according to weight and age dosages, swallow or chewable, or non refrigerated syrups.

Health Care Workers

There is a dire need for additional well-trained health care workers around the world. The introduction of efficient and qualified health care workers in many medical systems would ensure quality and quantity in the distribution of AIDS treatment. These health care workers must be trained in the holistic aspect of AIDS treatment, which provides counseling, guidance on dosage, nutrition, and how to properly take ARVs. However, even when qualified personnel are available, many countries face a “brain drain” issue. Many doctors and nurses are attracted to higher wages offered in more industrialized nations in comparison with the wages in lower income nations. UNAIDS estimates that 56% of trained medical personnel in low income countries leave their country for more developed nations and only 11% flow the opposite direction. In addition, many health care workers are also dying as a result of AIDS, being infected in the workplace or elsewhere, restricting access to quality treatment. The best quality care has arisen in low income countries where community-based care models have been developed and proven to be the best possible method for people living with HIV/AIDS.

Success Stories Around the World

Many countries in the world, including Namibia, have had trouble distributing appropriate drugs that prolong the lives of people with HIV/AIDS. Countries experience problems ranging from unclear communications strategies, lack of appropriate and efficient transportation methods, high cost and demanding clinical requirements. However, among the many struggling countries, there have been a few that represent a
Glimmer of hope. Namely, both Brazil and Thailand serve as excellent role models as to how to increase the distribution of antiretroviral (ARV) drugs to people in need.

In order to make progress in any country, the first imperative step is to ensure ARV distribution ranks high on the national agenda. This means that in whatever way possible, people must let the government know that the lack of distribution is a problem and propose ways to have it solved. Whether it is writing letters to government officials or grassroots programs taking a stand in spreading education, something must be done.

The following serves as a list of possible solutions to propose to appropriate government officials. These methods and suggestions have proven successful in other countries and should be used as models for the future.

• In 1996, a presidential decree mandated free, universal access to ARVs through Brazil’s public health system.
• A project in Haiti promotes adherence through, among other things, use of “accompagnateurs,” who visit patients daily to ensure they are taking their medications. The “accompagnateurs” receive extensive training on TB and HIV, including medications and their side effects, confidentiality, referral systems, and strategies for promoting adherence.
• Simplified, standard regimens of fixed-dose therapies have proven easier to manage for the patients.
• Thailand expanded its universal health care scheme to provide immediate access to first- and second-line ARV drugs for around 80,000 people with HIV/AIDS.
• Simplified clinical monitoring in addition to drug intake is essential.
• Maximum use of available human resources including non-professionals, families, and community members increase successful ARV distribution.
• In Botswana, the Masa program provides free ARVs and counseling at Gaborone, Francistown, Serowe and Maun, targeting four priority groups of HIV-positive people with CD4 counts of less than 200: pregnant women, children older than six months, TB patients and all adult patients with AIDS-defining illnesses.
• In Brazil, the prices of antiretroviral drugs have been decreasing over the last few years. This is because the Ministry of Health has helped to establish national laboratories along with effective negotiation of prices with pharmaceutical companies.
• Zambia benefited from asking for help. Brazil has offered to support Zambia in the development of technology in the production and administering ARVs.
• The integration of ARV therapy and tuberculosis programs has aided in reaching out to more people who wouldn’t have received treatment.
• Training more professionals who are able to diagnose and distribute the drugs is imperative to continue the increasing success.
• Better systems for tracking and monitoring people receiving treatment must be created to ensure not only that people are receiving their drugs, but also that they are remembering to take them at the right times and in the right quantities.
• In addition to providing drugs, people must still focus on prevention methods. Just because the drugs are available doesn’t mean that people should assume that it is acceptable to have unprotected sex.
• Further, it has been found that expansion of treatment distribution actually enhances prevention efforts. ARV access provides hope because an HIV positive result is not an immediate death sentence. Thus more individuals will get tested and receive counseling. The following graph illustrates the simultaneous increase of ARV treatment and HIV testing.
What are the contributions of NGO’s throughout the world?

In General:

According to popcouncil.org, NGO outreach workers have facilitated in the provision of physical and mental support and health care education. These workers have additionally referred and accompanied clients to health care facilities. NGO’s serve to reinforce the abilities of HIV-positive volunteers in order to carry out outreach activities and provide both technological and economic support for recently established groups of people living with HIV/AIDS.

Tremendous efforts have been made by several NGO’s and non-profit organizations in order to make access to HIV treatment more readily available to those who in need.

The Clinton Foundation

The Clinton Foundation has made critical breakthroughs in encouraging generic drug manufacturers from India and South Africa to lower the prices of their HIV/AIDS medications. By the end of 2003, the foundation negotiated a landmark deal with five drug suppliers, Aspen Pharmacare Holdings Ltd., Cipla Ltd., Hetero Drugs Ltd., Ranbaxy Laboratories Ltd., and Matrix Laboratories Ltd., to provide antiretroviral medications for as low as US$ 140 per person per year, which works out to less than US$ 0.50 per day.

In mid-2004, the Clinton Foundation announced an agreement with Bayer Diagnostics, Beckman Coulter, Inc., BD (Becton, Dickinson and Company), bioMérieux and Roche Diagnostics to lower the cost of two important diagnostic tests, the CD4 and viral load, by eighty percent of current market value. The reduced price also provides equipment, training for lab technicians, service and maintenance, as well as reagents and consumables. These tests are widely used in developed countries, but are not commonly available in resource-limited countries due to their high expense. Obtaining a CD4 count and viral load can improve the quality of care and treatment by allowing healthcare workers to monitor the progression of the disease and the effectiveness of antiretroviral treatment.

Médecins Sans Frontières (Doctors Without Borders)

Médecins Sans Frontières (MSF) calls on pharmaceutical companies to make easy-to-use children’s versions of all their AIDS medicines in order to help prolong and improve the lives of children with HIV/AIDS. There is also a strong need for simple and affordable AIDS tests for babies in underserved communities. MSF is a non-profit organization that currently provides antiretroviral therapy (ART) to over 57,000 people living with HIV/AIDS in 29 countries. Children make up 6% (3,500) of all patients enrolled in MSF ART programs. The attached map illustrates the areas where MSF has treatment facilities and programs.
The Importance of Universal Access to Treatment

It is evident that resources and energies must be spent on access to HIV treatment. Long term, access to treatment will mitigate the powerful impacts of AIDS on national economies. HIV/AIDS affects the working age population in many countries, which is dramatically decreasing the number of workers in all professions, teaching, factory work, agriculture, government, healthcare, etc. Antiretroviral therapy serves to prolong an HIV+ individual’s life and keeps them in a healthy state for a longer period of time. In effect, people are healthier, strong enough to work and carry less of a burden from extensive replacement and training within professions.

Treatment also results in healthcare savings and improves prevention knowledge. Consistently taking ARV medications decreases an individual’s viral load and thus postpones full blown AIDS and opportunistic infection. As a result, individuals infected with HIV/AIDS less frequently require hospitalization. Since most treatment programs require counseling services to accompany the administration of drugs, more individuals are receiving quality prevention education. This education increases their knowledge on re-infection, condom use, and the possible risks of passing HIV to others. The possibility of receiving treatment offers people choices as well as a hope for the future. Thus, people are more likely to get tested for HIV.

Expanding ARV treatment strengthens prevention efforts. It does so by “increasing demand for voluntary counseling and testing; reducing stigma and promoting greater openness on HIV/AIDS; and helping to keep families intact and economically stable, thus slowing the growth of at-risk populations such as orphans and sex workers”

(Jong-wook, WHO).

Although there is still no cure for the disease, the best way to combat HIV/AIDS is prevention coupled by the best quality treatment and care for those living with the virus.

Recent Threats to Universal Access

One of the most recent threats to universal access globally are U.S. brokered free trade agreements. The U.S. has completed a number of agreements and is conducting a number of ongoing negotiations with a diverse set of countries and regions. CAFTA (Central America Free Trade Agreement), though very controversial, was passed within the past year and currently the US and SACU (Southern African Customs Union) are working to reach an agreement. Though FTA can have numerous benefits in terms of opening markets and increasing economic growth and development, agreements can also significantly impair public health. In
all FTA negotiations, a U.S. priority is strengthening intellectual property rights. These measures have been frequently referred to as TRIPs plus because they increase intellectual property right protections and punitive measures beyond international consensus, outlined in the WTO’s TRIPs agreement. The effect is strong barriers to procurement, manufacture, and distribution of affordable and reliable HIV/AIDS treatment, as well as other essential medications. A number of provisions are discussed and perhaps agreed upon, including extension of patent periods, inhibition of parallel importation of essential medicines, data exclusivity, and barriers restricting freedoms and conditions of countries issuing compulsory licenses. Data exclusivity is a measure included in CAFTA and will effectively hamper generic production because it outlaws the use of clinical test data to prove generic drug efficacy. The use of pharmaceutical data by generic manufacturers has been an important cost effective measure to speed up the entrance of generic medication on the market. CAFTA is attributed in part to the recent increases in drug cost throughout Central America. Similar concerns are raised in the US-SACU negotiations as well as a measure that would provide the opportunity for pharmaceutical companies to directly place law suits with member countries for violations of intellectual property provisions. Many people are very critical of FTA because they perceive it as an opportunity for the U.S. to advance its interests and undermine multinational World Trade Organization agreements by entering trade negotiations characterized by power imbalances in the United States’ favor.

Summary

This paper highlights the current conditions around the world concerning medical care and access to HIV treatment. Although treatment is available, it is unequally accessible to those in low income situations, women, and children. Needless to say, there are many countries, of both low and high income standings, that have had extreme success in distributing appropriate medical treatment. These countries can be used as role models in working toward a future filled with sufficient medical care for all those in need. Additionally, non-governmental and non-for-profit organizations are making considerable strides in their efforts to provide affordable care for everyone living with HIV/AIDS. These organizations are mobilizing big name companies and distribution agencies to provide medications at little or no cost to the patient. The most important thing that must be ensured throughout the world is that treatment is universal and free. There is no reason for anybody to be deprived of treatment when it is in existence.

"Lack of access to antiretroviral treatment is a global health emergency… To deliver antiretroviral treatment to the millions who need it, we must change the way we think and change the way we act."

LEE Jong-wook, Director General, World Health Organization
This price refers to the brand name antiretroviral combinations that existed as the only option available at the time.

FDCs combine all three drugs of the triple cocktail therapy in to one pill, resulting in 2 pills/day.

Current tests available in resource limited settings use “serological methods” and the more accurate tests for children are “virological confirmation tests,” which are expensive and unavailable.


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