

Hudson Institute

Global Health Initiatives: Pre- and Post-2015

*Center for Science
in Public Policy*

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Pre- and Post-2015**

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Center for Science in Public Policy**



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Introduction

The Center for Science in Public Policy (CSPP) has researched and written about global health issues for over 15 years. This research has included both communicable and non-communicable diseases, pandemics and epidemics, healthcare financing, global health institutions, drug safety, quality and efficacy, and the philanthropic contributions of NGOs, foundations, corporations, religious organizations, universities, and volunteers in overseas health programs.

This report takes an in-depth look at global health initiatives pre and post 2015. With the Millennium Development Goals (MDGs) ending in 2015 and new Sustainable Development Goals (SDGs) coming soon, it is timely to take a look at these programs to see what worked and what did not over the last 35 years, what goals were met and why, and what lessons were learned that we can take forward into the post 2015 period.

To do this we have selected four major global health initiatives developed within the last 25 years for in-depth review. In assessing these programs, we will make reference to various other well-known initiatives, both successful and not, in order to pull out lessons learned for future international health programs. This research looks at reports, studies, and evaluations on the purpose, outcomes, partners, costs, implementation, and lessons learned for purposes of providing a reference point to inform the forthcoming deliberations on SDGs and Universal Health Care (UHC).

What were the health outcomes of global initiatives, and at what cost? What organizational structures worked best to fight the pandemics and other diseases? What are the optimal roles of different global health players? Will the current global health SDGs meet the needs of the world's population over the next 20 years? These and other questions are relevant to people throughout the world, along with global policy-makers, and researchers. With big decisions about sustainable development goals, targets and their implementation being made now come big responsibilities to look at the track record of programs, gauge best practices, and build on a successful foundation to truly help the world's poorest people.

Background

There have been many global health initiatives implemented by the international health community over the last 35 years. From the dramatic agenda at Alma Ata in 1978, *Health for All by the Year 2000*, to the Abuja Declaration of 2001 where African countries pledged to contribute at least 15% of their annual budgets to healthcare, to WHO's '3 by 5' HIV/AIDS program to cover 3 million people by the year 2005, to the more recent *Lancet* Commission efforts funded by bilateral government donors and the Gates Foundation, and written by well-known health and development experts, including Lawrence Summers, Richard Feacham, and Julio Frank.

Based largely on a 1993 World Bank *World Development Report*, the *Lancet* Commission report, *Global Health 2035: A World Converging Within a Generation*,

maps out an ambitious agenda for “achieving dramatic gains in global health by 2035 through a grand convergence around infections and reproductive, maternal, newborn, and child health (RMNCH) disorders, major reductions in the incidence and consequences of NCDs and injuries, and the promise of Universal Health Coverage.”

Universal Health Coverage, a key tenet in the comprehensive global health agenda of *Global Health 2035*, is being launched just as MDGs are being replaced by SDGs in another ambitious United Nations-led initiative to reduce world poverty. In fact, UHC falls under SDG #3, target 3.8 among a total of 17 goals and 169 targets. Many of these goals and targets are being created to take care of unmet goals of the MDGs as well as unmet targets in other financial and health agendas between 2000 and 2015.

Introduction to the Case Studies

Four global health initiatives were selected as case studies: 1) WHO/UNAIDS Treating 3 Million by 2005 program; 2) The African Union’s Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases; 3) The World Bank’s Investing in Health projects; and, 4) *The Lancet* Commission’s report and recommendation for Universal Health Coverage. The first three took place within the last 25 years. The fourth is a relatively new initiative whose roots began in the World Bank over 20 years ago, but whose recommendations were made only several years ago and now appear in the UN Sustainable Development Goals (SDGs).

The first three were selected to represent different types and organization of global health initiatives that have already occurred, and for which we have information about outcomes, costs, implementation, roles of different players, and lessons learned. The fourth was selected because it offers an overall global framework for achieving broad health goals over the next 20 years. It is reviewed here to see whether and how this new initiative has taken into account lessons learned and best practices from past global health programs.

These and other global health initiatives over the last 35 years occurred against a backdrop of great suffering, pandemics, and innovation. Funding for global health surged, and new players and partnerships came onto the scene. Public-private partnerships emerged as a new model of cooperation for complex health challenges. Multiple partners from both government and private sectors stepped up to the plate to bring their comparative advantages to bear on the diseases ravaging the developing world.

The outpouring of public concern was seen in donations and volunteerism throughout the world as private philanthropy grew by the billions of dollars. In fact, the private financial flows from developed to developing countries starting in the early 1990s - philanthropy, remittances, and private investment – now far exceed government Official Development Assistance (ODA). Of all financial flows from developed to developing countries, 80 percent are private and only 20 percent are government, the opposite of 40 years ago.

Innovation and creativity prevailed during this time period as well. The global health community was able to abruptly change from an ill-conceived strategy of using only prevention techniques against HIV/AIDS to treatment therapies for the disease. Phenomenal pharmaceutical research resulted in a new antiretroviral drug therapy (ART) for HIV/AIDS. There was great creativity in treating both new and old diseases as they reemerged after decades of being controlled. Companies provided production licenses and technical assistance in manufacturing to developing countries. Patents on ARV drugs went unchallenged so that Indian and other companies could make lower cost generic substitutes. New research centers for neglected tropical diseases were also built in the developing world to provide subsidized and often free drugs to poor people.

Throughout it all, outreach and communications technology was changing the way the world worked, raising our awareness of the plight of poor people and making it easier for individuals to get involved through online giving and organized volunteer opportunities. The internet allowed the public and health practitioners to stay in touch with the latest therapies, and connect with peers around the world.

At the same time, the developing world was undergoing a major demographic shift in aging and began experiencing the chronic diseases that accompany older populations. Cancers, cardiovascular disease, diabetes, and accidents were now the largest causes of disease and death, all of which require more expensive treatment than preventative measures that have occupied WHO and other global health programs. There was a realization that past programs, focusing largely on infectious diseases and maternal child health, would not meet the needs of the large and growing adult populations, whose good health and productivity are essential to economic growth and the eradication of poverty.

Various approaches were discussed or tried over the last 25 years, from primary health care to health care financing, to universal coverage, and to single global disease programs. Billions of dollars were spent on these approaches. What we learned was that money cannot buy it all. Director General of the WHO, Dr. Margaret Chan, said in 2008, “As we have seen, powerful interventions and the money to purchase them will not buy better health outcomes in the absence of efficient systems for delivery.”¹ We saw the proof of this with the outbreak and response to the recent tragic Ebola crisis in Africa. Despite all the global health aid over the last quarter of a century, the efficient systems for delivery were not in place to combat Ebola effectively. Largely due to this aid, health budgets as a percent of GDP in both Liberia and Sierra Leone exceeded 15%, ranking even above that of the United States. Clearly, high government health spending as percentages of GDP do not assure viable health systems.

These anomalies point to the importance of political will, good governance, and transparency in the developing world. Without these elements, all the technology, affordable drugs, and ideas under Universal Health Coverage cannot bring about the goals of sustainable development. These key factors should be included in the SDGs, along with the lessons learned from the Case Studies below.

Case Study 1. Treating 3 Million by 2005: Making it Happen

I. Purpose of the Program. The program, Treating 3 Million by 2005: Making it Happen, more simply known as “3 by 5,” was officially launched in Geneva on December 1, 2003 by the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). The plan was to treat 3 million people living with HIV/AIDS in low and middle income countries by the end of 2005. The strategy was intended to mobilize the international community to address a global inequity in access to antiretroviral therapy as a human right.²

When “3 by 5” was launched, WHO estimated that 6 million people needed Anti-Retroviral Treatment (ART) in developing countries, but less than 8% were receiving it, with the biggest treatment gap in Africa. When United Nations partners declared this situation a global health emergency, they added to a growing worldwide political movement advocating the right to treatment, rather than just prevention, as had been the case. The purpose of the “3 by 5” program was to be pursued through five strategic objectives combining treatment and prevention for HIV/AIDS:

- Global leadership, strong partnership and advocacy;
- Urgent and sustained country support;
- Simplified, standardized tools for delivering ART;
- Effective, reliable supplies of medicines and diagnostics; and,
- Rapid reapplication of new knowledge and successes³

In September 2000, just before the “3 by 5” program began, member states of the UN unanimously endorsed the Millennium Declaration. One of the provisions resolved “...to encourage the pharmaceutical industry to make essential drugs more widely available and affordable.”⁴ Later that same month, the UN established the Millennium Development Goals (MDGs). There were eight goals, with Goal #6 being specific to HIV/AIDS by setting the target of “...to have halted and begun to reverse the spread of this disease by 2015.”⁵ Dr. Lee Jong-wook, Director General of WHO, authored an article in *The Lancet* prior to the launch of “3 by 5,” commenting: “If we cannot reach ‘3 by 5’, there is no reason to believe we will achieve the Millennium Development Goals.”⁶

II. Partners in the WHO “3 by 5” Program. The WHO realized the importance of working with many partners to achieve the “3 by 5” goals, and a special unit was established within the HIV Department at WHO headquarters to promote these partnerships. Prior to the program’s launch, the WHO held meetings with the United States’ President’s Plan for Emergency AIDS Relief (PEPFAR); the Global Fund to fight HIV/AIDS, TB, and Malaria; and the United Nation’s Accelerated Access Initiative (UN/AAI). Despite these meetings with key players in HIV/AIDS treatment and prevention, by the beginning of 2004, the WHO had only established 14 partnerships. In May of 2004, it identified more than 180 potential partnerships after its first and only global partnership meeting. Despite its intentions, the 2006 evaluation concluded: “WHO never came anything close to establishing a global partnership network to achieve the ‘3 by 5’ target.”⁷

In general, WHO found it challenging to develop and influence new types of partnerships within countries, outside of its traditional relationship with Ministries of Health. Efforts to learn from the implementation experiences of the PEPFAR program did not happen, and meetings between its executive leadership and the World Bank in 2004 and 2005 did not produce any follow-on collaborative activities either. The most active partner was the Canadian International Development Agency (CIDA), although its grant of \$100 million Canadian dollars in 2004 was for monitoring and evaluation activities, not operational implementation of “3 by 5.”⁸

WHO’s sole clients in member states, rather, were Ministries of Health. It was through them that partnerships at the country level were established, but this was problematic from the start. In a 2000 World Health Report, WHO forecast the problem: “Ministries of Health in low and middle-income countries have a reputation for being among the most bureaucratic and least efficiently managed institutions in the public sector, [they are] fragmented by many vertical programs which were often run as virtual fiefdoms, dependent on uncertain international donor funding.”⁹

III. Costs and Implementation. WHO estimated that the funding needed to achieve the “3 by 5” goal was at least \$5.5 billion, which was expected to come from multiple sources, including the budgets of low and middle-income countries, multilateral and bilateral funders, as well as private foundations and other organizations in the private sector. In late 2003, the funding target for WHO’s HIV/AIDS activities in the 2004-2005 biennium was initially established at \$400 million. The WHO Executive Board then revised the planned budget to \$218 million. As of November 2005, total resources allocated by WHO came to \$192 million, less than half its original request.

The official start date of “3 by 5” was December 1, 2003, World AIDS Day, even though at the time the WHO lacked formal organizational approval and an approved budget. WHO did not secure formal approval until May of 2004 when it was unanimously endorsed at the 57th World Health Assembly. The 2006 evaluation referenced the slow speed of implementation, commenting: “Significant delays occurred in implementing the planned program of work due to the initial lack of secured funding and subsequent slow grant disbursement.”¹⁰

The other factor that impeded implementation was WHO’s reliance on an effective and reliable supply of medicines at affordable prices, with anti-retrovirals (ARVs) that ensured patients’ adherence to the therapy. When WHO announced the plan in December 2003, it specified that a fixed dose combination ARV from two different manufacturers had been placed into its prequalification program. This consisted of three drugs, nevirapine+stavudine+lamivudine in a single tablet formulation. Both were manufactured in India by pharmaceutical companies Cipla and Ranbaxy. These fixed dose combination therapies were considered by WHO to be the backbone of its program.

But in May 2004, just five months into “3 by 5,” WHO encountered a major barrier to rapid distribution of ARVs. The WHO lacked adequate proof of its drugs’ bio-equivalency. To achieve bio-equivalency, a drug must be tested to show the same

therapeutic effect as the patented drug. Without bio-equivalency it cannot be labeled a generic drug—it is only a copy drug. The WHO began a process of de-listing 5 ARVs in its prequalification program, one of them being the fixed dose combination product. Other ARVs were de-listed during the summer and fall, reaching a total of 36 by October. In a September public announcement, WHO provided the rationale for de-listing five HIV/AIDS medications, which was due to a lack of proof of bio-equivalency.¹¹

This global notice by WHO revealed that all of the de-listed ARVs were copy drugs rather than true generics, and that there were no known regulatory standards on bio-equivalency for them. Secondly, there was no reference (innovator) product for the fixed dose combination ARV, a regulatory requirement for certifying a drug as a true generic. The WHO simply stated that these drugs “were of acceptable quality,” and at the same time, issued a disclaimer on the drugs saying the WHO “makes no representations or warranties, either expressed or implied, as to their accuracy, completeness, or fitness for a particular purpose.”¹²

The following four factors combined to prevent WHO from meeting its goals in “3 by 5:” 1) A delayed formal approval from the World Health Assembly; 2) Its organizational requirement to work through weak Ministries of Health; 3) A reduced operating budget from its own Executive Board; and, 4) The loss of one major supplier of inexpensive ARVs and those manufacturers who produced the fixed dose combination products. Taken together, and weighed against the strong headwinds WHO faced from ongoing, more rigorous and well-funded HIV/AIDS programs such as PEPFAR and the Global Fund, the organization had set itself upon an Everest too steep to climb.

IV. Commentary and Criticisms of “3 by 5.” A major criticism in WHO’s March 2006 formal evaluation of “3 by 5” stated that “WHO is not itself an implementing agency,” yet when setting goals in December 2003, it stepped out of its role as a membership organization by designing a plan with all the critical elements for its execution, i.e. acquisition of active pharmaceutical ingredients, regulatory approvals, global procurement, staffing at local levels, supply chain systems to store and move products, and end use administration to patients. These roles resided in entities other than WHO, some of which were dependent upon weak operational capacities of Ministries of Health. While there was consensus that WHO was the multilateral agency mandated to lead the global health sector response to HIV, there was also the perception that the organization had yet to fulfill its role to meet this level of expectation. The 2006 evaluation did attempt to cite some positive results of the efforts:

- The “3 by 5” initiative substantially contributed to promoting the right to health for people living with HIV/AIDS;
- Target setting for scaling up treatment access was considered to be an effective mechanism for driving both international and national responses;
- “3 by 5” established important implications for the health gains that can be achieved by pursuing the goal of universal access;
- “3 by 5” established ART as an essential public health intervention; and,
- Future targets, like the MDGs, needed to be realistic and country-owned.¹³

In another report on the “3 by 5” program by WHO/UNAIDS, two additional benefits were cited:

- The declaration by WHO and UNAIDS of a global health emergency on treatment access helped to mobilize countries, communities, and individuals to address the overwhelming and urgent need to provide antiretroviral therapy; and,
- Although the goal was not met, lessons learned in scaling up access to treatment have fundamentally altered the public health landscape and will continue to influence the choice of strategic approaches and actions as the world now moves towards the goal of universal access by 2010.¹⁴

V. The Roles of Governments and Pharmaceutical Companies. In a direct response to the WHO’s de-listing of ARV products, the U. S. Food and Drug Administration (FDA) offered in May 2004 to accept any file on an ARV product, from any country, wishing to have its product classified as a true generic. The FDA also offered to move any file to the head of the line and to waive all fees. However, since all of the ARVs files from India would contain products covered by existing patents, the FDA had to offer the patent holders an opportunity to present a legal challenge. As contributors to the fight against HIV/AIDS, the U.S. pharmaceutical companies did not challenge any patents.

Even with this substantial regulatory assistance from the FDA and the agreement of pharmaceutical companies not to challenge, it was not until 2007, after the end of “3 by 5,” that WHO was able to classify the fixed-dose combination drug, Triomune, a combination of nevirapine, stavudine, and lamivudine, as a generic product in its prequalification program. The FDA subsequently approved over 100 ARVs as generics, so many that Doctors without Borders declared India “pharmacy to the developing world,” because its producers dominated the ARV market, accounting for more than 80% of global sales.¹⁵

In October 2009, the U. S. Department of Health and Human Services announced the FDA’s 100th approval of ARVs as true generics on WHO’s prequalification program. This allowed PEPFAR to purchase generic drugs from India using foreign aid funds, and opened the way for all USAID contractors to do the same. This action allowed PEPFAR to spend \$150 million more each year on increasing patients’ access to care” rather than on higher-priced innovator products.

With regard to the main goal of “3 by 5,” to treat 3 million people by the year 2005, the WHO never achieved it nor did it clearly acknowledge this. The only specific groups that WHO identified as providing ARV coverage and treatment were in the following programs:

PEPFAR	471,000 persons treated
The Global Fund to Fight HIV/AIDS	384,000 persons treated
The UN/AAI Program	716,000 persons treated
Total	1,571,000 persons treated ¹⁶

The WHO itself did not specifically claim that “3 by 5” had contributed to these numbers. Thus, we can conclude that they were an accurate representation of what other global programs accomplished. WHO does mention increases in ARV coverage by saying “in Latin America, the number of people receiving treatment has increased gradually to 315,000, up from 210,000 at the end of 2003.” It does not, however, identify any group responsible for that increase, indicating that they could be recipients in any of the three groups listed above.

In the global AIDS community, there has been extensive discussion on how programs like “3 by 5” contributed to lowering prices of ARVs. Yet, WHO’s official evaluation states: “A study commissioned as part of this evaluation reported that there is no evidence that “3 by 5” has reduced the prices of ARVs significantly in Africa.”¹⁷

The research based pharmaceutical industries provided all of the ARVs used by PEPFAR, the UN/AAI Program, and at least one third of the Global Fund’s program (since PEPFAR funded its budget at that level, requiring procurements only from FDA-approved sources). For patients in the other two thirds of the 384,000 recipients of the Global Fund’s activities, they were given access to its “Option C” policy for procurements. This allowed the Fund to purchase products that had not been submitted or reviewed by a regulatory agency even when there was an approved, prequalified alternative and their purchase even at prices higher than approved products if that serves a political purpose.”¹⁸

The grand total that can be attributed to pharmaceutical companies is 1.315 million AIDS patients during the time period of WHO’s “3 by 5” program, or 84% of the total that was documented in the WHO/UNAIDS Report.¹⁹ This number does not even include most of the ARV patients in Bristol-Myers Squibb’s Secure the Future Program (initiated in 1999) in 10 Southern African countries, which treated over 8,000 people, nor the African Comprehensive HIV/AIDS Partnership (ACHAP) that was supported by Merck & Co., Inc./The Merck Foundation and the Gates Foundation that treated patients in Botswana, initiated in 2000. PEPFAR admitted to double-counting when it included 56,000 ARV patients from ACHAP into its total of 471,000. PEPFAR used the Botswana ACHAP as a model of how to build an HIV/AIDS program. Its then director, Dr. Mark Dybul, commented on how important the ACHAP information was to starting the PEPFAR program.

The WHO had predicated its “3 by 5” plan upon a steady supply of inexpensive ARVs from India that had been prequalified. Of the 1.571 million patients that actually received ARV therapy, however, 84% of them were recipients of drugs produced by the research based pharmaceutical industry. The transformation in ARV drug approvals by the FDA took place after “3 by 5” was over. The substantial progress made toward the goal of covering 3 million by 2005 was, in actuality, due to the pharmaceutical industry’s collaboration on pricing policies with the FDA, along with the programs of PEPFAR, the UN/AAI Program, and the Global Fund. These activities by other organizations advanced WHO’s “3 by 5” goals by complying with Goal #6 of the MDGs. Industry independently met the “3 by 5” objectives which were to eliminate “the global inequity

to antiretroviral therapy ... with an effective, reliable supply of medicines.” The MDGs were the main impetus for these actions, rather than the “3 by 5” program.

VI. Lessons Learned for Application to SDGs and Universal Health Coverage. The execution of “3 by 5” by a membership organization rather than an implementing agency points to the difficulties of a “top down,” unsustainable approach that can foster dependency on foreign aid. WHO had to work with six different WHO regional directors, all of whom were elected to their positions by their member states as opposed to being appointed by the Director-General. The directors are, individually and collectively, beholden to their members as a first priority of business. This was in contrast to well-funded programs like PEPFAR and the Global Fund, which implemented their activities closely with health care provider groups at the local level. In doing so, they avoided entanglement in the slow-moving bureaucracies of government agencies, including Ministries of Health.²⁰

If the U.S. government, the Global Fund, UN/AAI, and the pharmaceutical companies had waited for WHO approvals to act, they would have had to secure permission from the appropriate regional directors. Those directors, in turn, would have had to contact ministers of health, further delaying the program.

WHO works best as a joint member with other public and private organizations, in overall awareness building and governance, not in implementation of programs. A case in point is when the WHO became a founding member of the UN/AAI program, along with five pharmaceutical companies. In the WHO and UNAIDS’ 2006 evaluation, the UN/AAI program accounted for the highest number of HIV/AIDS patients receiving ARV therapy during the “3 by 5” time period.²¹

Case Study 2. The Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases

I. Purpose of the Program. In April 2001, African Union countries meeting in Abuja, Nigeria, pledged to increase government funding for health to at least 15% of their annual budgets. They also urged donor countries to scale up support. What emerged from this meeting became known as the Abuja Declaration. The driver of the declaration was the African Union, established one month after the Abuja Declaration on May 26, and formally launched on July 9, 2002, in South Africa. Every state in Africa, except Morocco, was a member of the Union.²² Its goal was to ensure that containing and reversing the spread of HIV/AIDS, TB, and other infectious diseases would be a top priority in the first quarter of the 21st Century, as stated in Article 15 of the Abuja Declaration. The declaration laid out ambitious goals, many of which were dependent upon donor support to reach 15% of their annual budgets for health:

- Urged countries to fulfill the 0.7% GNP target for ODA;
- Called for the creation of a Global AIDS Fund, financed by the donor community at the \$5-10 billion level, and made accessible to affected countries to assist with the implementation of action plans;
- Urged continuing discussions to cancel Africa's external debt within the framework of the 1999 Sirte Declaration;
- Supported the development of effective, affordable, accessible HIV vaccines;
- Called for necessary resources for the improvement of the comprehensive multi-sectoral response while allocating [funds] to the National Commissions/Councils for the fight against HIV/AIDS, TB and other Infectious Diseases;
- Encouraged further development of traditional medicines and traditional health practitioners.²³

Along with these goals, the Abuja Declaration placed special emphasis on malaria. This was called the Abuja Declaration on Roll Back Malaria in Africa. The initiative consisted of:

- Halving malaria mortality by 2010;
- Ensuring prompt access to affordable and appropriate treatment for 60% of those suffering from malaria by 2005;
- Ensuring that by 2005, 60% of pregnant women and children under age 5 benefit from the most suitable combination of personal and community protective measures, such as insecticide treated mosquito nets and other materials to prevent infection and suffering;
- Promoting community participation and joint ownership;
- Reducing or waiving taxes and tariffs for mosquito nets and materials, insecticides, anti-malarial drugs and other recommended goods and services that are needed for malaria control strategies.²⁴

The Abuja Declaration is an interesting example of the limitations of setting numerical targets. This was best explained in a 2013 article by Sophie Witter, et al in *Oxford Journals*, which concluded: "It is not clear how 15% was chosen, and it is hard to justify the figure itself. Health expenditure levels should reflect local health needs, utilization and costs, and so there is no one optimal amount for countries to spend on health care."²⁵

II. Partners in the Abuja Declaration. The Abuja Declaration listed numerous partners, including an array of UN agencies, such as FAO, UNAIDS, UNDP, UNESCO, UNFPA, UNICEF, the UN International Drug Control Program, UNIFEM, and WHO. The African Development Bank, the ILO, the U.S. Institute of Medicine, and the ECA also became partners.

Most of these partners were involved in the UN's Millennium Declaration of 2000 and its subsequent MDGs, of which Goal #6 was specifically directed "to combat HIV/AIDS, malaria and other diseases." This then became the main goal of the Abuja Declaration.

The African Union had several regional banks as associate members, including the African Central Bank, the African Investment Bank, and the African Monetary Fund. Together, these financial institutions should have been instrumental in assisting the Abuja Declaration to convince African Ministers of Finance to mobilize 15% of their government budgets for health.

III. Costs and Implementation. There were no direct costs associated with the Abuja Declaration, as the African Union did not have an implementing agency. The African Union and its partners sought to galvanize support from both domestic and international sources through a call for moral leadership against the infectious diseases that were ravaging their countries. Despite the good intentions, in a March 2011 report by WHO, only one African country, Liberia, had reached the target of 15% of its budget in health. Overall, 26 had increased the proportion of government expenditures allocated to health, but not to 15%, and 11 had reduced government health expenditures since 2001. In the other 9, there was no obvious trend either up or down.²⁶

In the same year, WHO released data on countries' public and private health expenditures as a percentage of GDP, which is another way of determining government commitment to its health budget along with other private health expenditures. Liberia ranked first at 19.5%, Sierra Leone was second at 18.5%, and the United States was third at 17.9%.²⁷ Since these countries with the highest health expenditures were also among the poorest in Africa, it is likely that the resources were derived from external sources. In Liberia, for example, "the United States provided 22% of its health budget in 2009. The U.S. financial commitment was even larger when one takes into account additional contributions to initiatives like the Global Fund and the GAVI Alliance which had large programs in Liberia."²⁸

With regard to program implementation, The Abuja Declaration may well have contributed to the formation of the Global Fund to Fight HIV/AIDS, TB and Malaria as the establishment of a Global AIDS Fund was one of its goals in 2001. Its call for a cancellation of Africa's external debt led to the Paris Club agreement to write off \$18 billion of Nigeria's debt, among other African countries in 2005, as an incentive to get them to increase spending on education and health.

However, as demonstrated by the recent Ebola epidemic, increased government spending on health does not always lead to better health infrastructure or outcomes. Weak public health systems, woefully inadequate healthcare facilities, improper sanitation measures, and a lack of healthcare workers all contributed to the rapid spread of the deadly disease in both countries.²⁹ Liberia struggled to provide even basic healthcare to their citizens, despite the fact that it met the Abuja Declaration's call for 15% health expenditures of annual budgets. Adding to these problems, the WHO was also criticized for its lack of leadership and slow response to the epidemic. The inadequate and uncoordinated response to the Ebola crisis at both the country and global levels has reignited the discussion on reforming global institutions.^{30,31}

IV. Commentary and Critiques of the Abuja Declaration. The Abuja Declaration made an initial point of measuring its goal of 15% using only governmental

expenditures on health. When Africa began to shed its colonial linkages in 1961, there was virtually no private health sector in any of its countries. This changed rapidly in the following decades. As people increasingly began to rely on non-governmental services, donor support also increased. Many African countries now spend the majority of their national health resources on private care. For instance, in 2003, in Nigeria, Africa's largest country, private expenditures on health as a percentage of total national expenditures on health were 74.5%; 56.6% in Rwanda; 64.8% in Malawi; 61.3% in Kenya; and 61.4% in South Africa. In Malawi, churches alone "are responsible for 40% of all healthcare provision."³²

Ministries of Finance most probably noted this reversal of resource flows and acted accordingly: by limiting public finance of health care. This is borne out by a statement from UNAIDS and the African Union, which found that "Private expenditures on health and governmental expenditures on health have grown since 2001, with private expenditures growing more than governmental expenditures."³³ Private expenditures represent an income stream to national treasuries from taxes, duties and tariffs on imported medicines and equipment, while public expenditures are an expense.

The Abuja Declaration's drive towards 15% of governments' budgets was eclipsed by the launch of the Global Fund to Fight HIV/ AIDS, TB, and Malaria in 2002, PEPFAR in 2003, and the UN/AAI initiative. These programs covered the same disease categories as the Abuja Declaration, and because they were so well-funded from external sources at billions of dollars per year, they acted as disincentives for governments to dedicate 15% of their budgets to health.

Abuja was also preceded in 1999 by Bristol-Myers Squibb's Secure the Future Program, operating in ten Southern African Countries, and in the same year, the Merck & Co., Inc.-Gates Program in Botswana, both of which covered the same diseases. These substantive sources of external funding for health in African countries may well have served to dissuade governments from adhering to the Abuja Declaration as well. Still, the Abuja Declaration was Africans setting their own health priorities and Africa speaking to the developed world in the full expectation that it would listen.

V. Roles of Governments and Pharmaceutical Companies. In July of 2003, the African Union held a session in Mozambique during which it affirmed the Declaration's aims. It promoted "partnerships with pharmaceutical companies to increase local and regional capacity for production and distribution of affordable generic drug products for the management of HIV/AIDS, TB and Malaria."³⁴

The African Union had observer status at the World Trade Organization (WTO) in 2003 when the WTO ratified the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS). TRIPS drew its moral legitimacy from the Millennium Declaration of 2000 that committed the international community to alleviating global disparities in access to medicines in cooperation with pharmaceutical companies.³⁵ The agreement was designed "to find an expeditious solution to the problem of the difficulties of WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector."³⁶ Perhaps as a direct result of TRIPS and the African Union's 2003 session in

Mozambique, six pharmaceutical companies issued voluntary licenses to developing countries for the production of ARVs in 2005. The companies were: Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Merck & Co., Inc., and Eli Lilly.³⁷

Merck & Co., Inc. alone granted five royalty-free licenses for its ARV 'efavirenz' to South African generic manufacturers. All but one donated a percentage of their net sales to the Msizi (Cares) Trust, a charitable trust established to further the fight against HIV and AIDS in South Africa. Merck & Co., Inc. also extended royalty-free licenses to pharmaceutical firms in India.

Various pharmaceutical companies actively promoted and funded institutional capacity building efforts, such as the Infectious Disease Institute in Uganda, now run by Makerere University; the AIDS Reference Laboratory in Botswana, operated by Harvard University; and Africa's first Pediatric AIDS Hospital and Outpatient Clinics in Botswana.

Merck & Co., Inc. also established four new immunization centers in Uganda, Zambia, Kenya and Mali, transferring its technology on cold chain security at a cost of \$4.4 million. In 2004, GlaxoSmithKline issued a voluntary license to a South African generic company, Thembalami Pharmaceuticals to produce generic versions of two of GSK's antiretroviral drugs. Thembalami was allowed to produce generic versions of lamivudine and zidovudine, as well as a pill that combines the two drugs³⁸. Eli Lilly not only granted voluntary licenses to developing countries, but provided technical assistance, production monitoring activities, and assistance on WHO drug approvals for TB drugs to be produced in South Africa. Eli Lilly also helped South Africa to build the plant and bring it into production, both for domestic sales and international exports.

The example of how the African Union interacted with and encouraged a productive partnership with the pharmaceutical industry and other health care companies stands in contrast to the WHO leadership and some of its members. In her address on the Ebola crisis to the WHO's Regional Committee for Africa in November 2014, Director General, Dr. Margaret Chan, said: "...Because Ebola has historically been confined to poor African nations, the R&D incentive is virtually non-existent. A profit-driven industry does not invest in products for markets that cannot pay."³⁹ However, an objective review of the history of pharmaceutical industry involvement in global pandemics and other diseases illustrates that the pharmaceutical industry has invested over \$1.2 billion on research and development of neglected tropical diseases and other therapies between 2000 and 2011. From these neglected tropical diseases to TB, HIV/AIDS, Hepatitis, and vaccine research, the industry has been active in drug research for markets that cannot pay. Moreover some of these medicines are then provided free of charge or subsidized to people in developing countries.

This counterproductive attitude has now found its way into the World Health Assembly, WHO's annual meeting occurring in Geneva starting May 18, 2015. In a 36 page draft "Overarching Framework of Engagement with Non-State Actors," the WHO singles out businesses as being one of "the most important institutional conflicts of interest," with

WHO's interests.⁴⁰ A resolution is on the table to put non-state actors in this subordinate and even contentious light. Rather than embrace the NGOs, foundations, community foundations, academic research centers, volunteers, and corporate donations, the WHO refers to this as a problem. "The health landscape has become more complex in many respects," says the overarching framework. "Among other things, there has been an increase in the number of players in global health governance." So, missionaries providing almost half of many African countries' health care services, the pharmaceutical companies providing \$94 billion in donations, research, and cash grants over a 10 year period, and the foundations and NGOs whose local level work saves lives are simply "complex," and not embraced as a good thing for the world.

The WHO must embrace the growth of civil society and the diversity, choice, and prosperity that democracies and economic growth create in order to optimize its relevance to global health and development.

VI. Lessons Learned for Application to the SDGs and Universal Health Care.

In its time, Abuja did serve to marshal critical moral support at the country level behind efforts to combat HIV/AIDS and other infectious diseases. The Abuja Declaration morphed into several other African initiatives, extending its life span. One example is the 2010 Kampala Declaration which "extends the Abuja call for universal access to 2015, and commits to accelerated efforts to improve the health of women and children."⁴¹

This Abuja model of ownership greatly enhanced the ability of African countries to assume control of these diseases. To the credit of the Abuja Declaration's leadership, the governments never attempted to use this initiative to implement their own program activities. Instead, they encouraged donors to work with various provider groups at the country level as the means to reduce HIV/AIDS, TB and other infectious diseases. They threw their considerable institutional weight behind a universal call to create a fund to fight these diseases. And through their umbrella organization, the African Union, they created a framework for pharmaceutical companies to build partnerships for the local production of therapeutic drug products.

In spite of the Abuja Declaration's inability to meet the fiscal goals of countries in the African Union, they continued to pursue healthcare goals. At the African Union Special Summit on HIV, TB and malaria in Abuja, July 2013, it took cognizance of the need for an African Center for Disease Control and Prevention to conduct research on priority health problems in Africa. The request was reaffirmed at the 22nd Ordinary Session of the African Union held in Ethiopia in January 2014, which stressed the urgency for its establishment.

In this sense, then, the Abuja Declaration, with active participation by the African Union, may have managed to achieve a goal far more important than having each country dedicate 15% of its national budget to health. The African Union began a process wherein African countries became involved in and worked together to solve their own health care problems.

Setting realistic targets is another lesson learned from the Abuja Declaration. The UNAIDS and African Union 2013 *report, Abuja + 12: Shaping the Future of Health in Africa*, reported that only six countries had reached the goal of allocating 15% of public expenditures to health. Similarly, the founders of the “Smart Development Goals” movement warned against too many unrealistic targets: “Governments should forego the instant gratification of promising everything to everyone, and instead focus on choosing smart development goals.”⁴²

Finally, measuring targets has its own limitations. A former health economist with UNFPA, Howard Friedman, contends that most of the MDG improvements came from events preceding the MDGs. With the exception of debt relief, other indicators did not result in a statistically significant acceleration in change after 2000.⁴³

Case Study 3. The World Bank’s Investing in Health

I. Background. The World Bank adopted a formal health policy in 1974 after several years of informal activity in the sector. “The Health Sector Policy Paper” published by the Bank in March 1980 laid out the plan. It limited health operations to components of projects in other sectors, reflecting concerns at the time about the feasibility of low-cost health care systems, the lack of political will, and uncertainty about the Bank’s proper role in the sector and about how its activities should relate to those of the WHO.⁴⁴

Health policy was also beginning to receive more attention at the international level, which led to the WHO sponsoring the 1978 Conference on Health for All by the Year 2000 in Alma Ata. This gathering formalized the consensus that developing countries should improve health status by providing low-cost primary healthcare services. The World Bank responded to this interest.”⁴⁵

In 1980, the Bank initiated lending in the health sector, and by 1993, it had become a robust funding agency for global health projects, both on a loan and grant basis. It sent major financial streams directly into health sectors of the developing world. This case study will assess the Bank’s role starting in 1993 when it placed an institutional stamp of approval on the financing of health care in the developing world, to its first evaluation of outcomes in 1997, and then onward to 2009 when it conducted another evaluation to assess the corrective measures it had set in place in response to project deficiencies from the 1997 evaluations.

The principal author of the Bank’s *World Development Report 1993: Investing in Health* was its Chief Economist (later Harvard University President) Lawrence Summers. The significance of his role is seen through the Bank’s subsequent health investments, and most importantly his co-authorship of *The Lancet Commission’s* 2013 report promoting the concept of Universal Health Coverage (UHC).⁴⁶

II. Purpose of the Program. Given the primacy of the World Bank within the international development community, its promotion of the private health sector in 1993 was a clarion call to global health leaders that it had become an active partner in this sector. *The World Bank Development Report 1993: Investing in Health* determined:

- While global health spending was \$1.7 billion in 1990, governments accounted for \$1 billion of it, or nearly 60%;
- Of this amount in Africa and Asia, governments accounted for only 50%;
- There should be a greater reliance on the private sector to deliver clinical services to help improve efficiency;
- The private sector already served a larger and more diverse clientele in developing countries, and often delivered services of higher quality without long lines and inadequate supplies frequently found in government facilities;
- Private doctors and pharmacies face unnecessary legal and administrative barriers and these need to be removed;
- The for-profit private health sector should move away from fee-for-service to pre-paid coverage;
- The formation of health maintenance organizations (HMOs) was encouraged;
- Reforms in pharmaceutical usage offer the greatest gains in efficiency, i.e. governments that introduced competition in drug procurement achieved savings of 40 to 60%;
- Many countries rely on user fees to supplement strained public budgets, and they should be levied at government health facilities;
- There should be more effective utilization of nongovernmental resources, including nonprofit groups, private physicians, pharmacies, and other health practitioners.

III. Costs, Implementation, Commentary, and Critiques. In 1997, the Bank began a comprehensive evaluation to determine the outcomes from health financing programs that it started in 1993. Costs were calculated by each program financed. Program design costs of World Bank personnel were also included since they have to be repaid by the recipient country. These can be considerable, as health design activities consume several years before the Bank gives its approval. Time is a major consideration when Ministries of Health change posts frequently, requiring the Bank to restart negotiations with a new minister, extending the time frame considerably. In one example, the Bank had to deal with five different Ministers of Health in Turkey before it reached final negotiations on a health loan.

Once implementation commences, World Bank member states then consider the loan/grant health finance program as their sovereign property and act accordingly. This significantly reduces the World Bank's oversight and monitoring role. Three findings from the 1997 internal evaluation of 107 Bank health projects reveal the difficulties of global health lending:

- The Bank does not adequately assess borrower capacity to implement planned project activities;
- Notably lacking in most Bank analyses is an adequate assessment on demand for health services;
- Little is known about what the Bank has “bought” with its investments.

The 1997 evaluation also found the following problems in monitoring and evaluation:

- Although a third of projects supported pilot interventions, or intended to evaluate the impact of a specific activity or program, few proposed evaluation designs;
- Pilot projects or components without an evaluation design described in appraisal documents were never evaluated;
- Among the consequences of poor monitoring and evaluation, and the absence of baseline data, were irrelevant objectives and inappropriate project designs;
- Unrealistic targets, either too high or too low, led to an inability to assess the actual effectiveness, thus, limiting opportunities for learning from these shortcomings.⁴⁷

Another World Bank report found limited impact on health outcomes, among the 107 health projects examined:

- Insufficient flexibility in design and implementation constrained achievement of objectives in about one-third of completed Bank projects;
- Several project completion reports found that no significant changes [were made] in design or implementation arrangements even in the face of highly critical supervision reports or mid-term evaluations;
- Conversely, a number of projects recorded substantial improvements following major restructuring, often resulting from negative evaluations;
- Several pilot projects purporting to demonstrate the efficacy of a reform or new delivery system collected no evaluation data and therefore could not demonstrate whether the approach was effective.⁴⁸

Following the 1997 evaluation of World Bank health projects, corrective measures were undertaken to ensure that the lessons learned were being implemented in new projects. The major critiques from the 2009 evaluation can be summed up in this manner:

- The Bank has made little progress in improving the health of the poor in spite of a \$10 billion increase in spending since 1997;
- Annual funding rose from \$6.7 billion in 1997 to \$16 billion in 2006, but progress has been poor;
- Performance in Africa was particularly weak, with only 27% of projects considered satisfactory;
- Lack of monitoring and evaluation has led to irrelevant objectives, inappropriate project design, unrealistic targets, and an inability to measure the effectiveness of interventions;

- While the Bank's raison d'être is to end poverty, that was the specific objective of only 6% of projects and a secondary objective of another 7%.⁴⁹

Despite these criticisms, evaluations found that two-thirds of global projects fell at least into the category of "satisfactory." The 1997 and 2009 internal evaluations of World Bank projects did not bear out expectations that simply putting money into a sector would lead to improved health outcomes. A lack of resources was not identified as a problem by evaluators. The evaluations did show, however, that projects designed at a central level were very difficult to implement at the local level, especially when objective measurements of outcomes were absent.

The 2009 internal evaluation was co-authored by the private financing arm of the World Bank, the International Finance Corporation (IFC). It found that the majority of the pharmaceutical projects financed by IFC had resulted in significant declines in the price of generic drugs, thus enhancing affordability. Four of the six evaluated projects in pharmaceuticals involved the production of generic drugs. The introduction of generic drugs in Mexico resulted in a 30% decline in prices, and in Brazil, generic products cost, on average, 40% less than brand-name products.⁵⁰

Many of the Bank financed health projects involved the procurement of pharmaceutical products during their lifetime. In many cases, as the loan/grant period was nearing its end and significant funds were unspent, countries would request that the World Bank in Washington permit expenditures for drugs that were not FDA or EMEA approved. This resulted in the procurement of copy drugs from India that were WHO approved but had only GMP certifications—a manufacturing standard rather than a product standard. Once permission was granted, funds could be rapidly expended for products that were much more inexpensive than brand-name products.⁵¹ World Bank regional directors became concerned about the procurement of drugs that had not been tested for safety and efficacy. In fact, in March 2005, the Bank held a seminar called "Counterfeit and Substandard Drugs: Good Intentions, Bad Results."

IV. Lessons learned for SDGs and Universal Health Coverage. Like the WHO, the World Bank is a membership organization that must work under the health officials of its member countries. As such, it cannot control or have full implementation responsibilities in health projects. The top-down project design process requires a high level of government investment, and without local involvement and ownership, can foster greater dependence on international aid.

The top-down design process in healthcare, particularly in Africa, did not work well. A majority of Africa's health services are in the private sector in smaller and more dispersed facilities. More flexible and locally developed systems and solutions lead to more successful projects in this—and in most—circumstances. The bottom line is that no one size fits all, as *The Economist* warned about the new SDGs.⁵²

The Bank evaluations showed that setting unrealistic targets proved to be a suboptimal way of proceeding. In addition, while the Bank initially was skeptical about member states' low investment in health and lack of political will to improve this sector, they

nevertheless jumped into large health investments, of which the majority were at best only satisfactory, and at worst, deficient. Good governance, transparency, and political will are essential components to successful global initiatives, and should be taken into account, especially in the SDGs.

Case Study 4. Universal Health Coverage

I. Purpose of the Program. Universal Health Coverage (UHC), also referred to as Universal Health Care, refers to health care systems which provide health care and financial protection for all its citizens. It is organized around providing a specific package of benefits to all members of society, with the end goal of providing financial risk protection, improved access to health services, and improved health outcomes. It is not a one-size-fits-all concept and does not imply coverage for all people for all things. Still, it recognizes a ‘healthy public policy’ as the overarching framework. Under this, public health, primary health care and community services are the cross-cutting interventions from prevention to long-term care and end-stage conditions.⁵³

The WHO definition of Universal Health Coverage is, “Ensuring that all people can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.”⁵⁴ By 2035, the investments in UHC would bring preventable diseases, MCH, major reductions in NCDs, and injuries down to low levels. Ten million deaths across low income countries could be averted.⁵⁵

The origins of UHC can be traced to the World Health Report of 2000 entitled *Health System Financing: the Path to Universal Coverage*. In December of 2013, the UN passed a resolution, taking note of the WHO 2000 Report, and reaffirming the concept of Universal Health Coverage. During the May 2013 World Health Assembly, World Bank president, Jim Yong Kim, made a presentation to delegates saying: “We must be the generation that delivers Universal Health Coverage.” Warning that UHC could become a toothless slogan, he went on to say: “Anyone who has provided health care to poor people knows that even tiny out-of-pocket charges can drastically reduce their use of needed services. This is both unjust and unnecessary.”⁵⁶

In July 2015, all of the policy impetus for UHC will find receptivity in Addis Ababa during the Third Financing for Development Conference, where *The Lancet* Commission’s report will be at the core of policy formation for health interventions through 2035. Following these proceedings, its recommendations will influence the final drafting of the UN’s Sustainable Development Goals (SDGs) in September 2015.

II. Partners in Universal Health Coverage. The World Bank, WHO, and *The Lancet* are the principal groups that have joined their considerable institutional credentials to actively support UHC. Following this, NGOs such as Oxfam and Doctors without Borders took up the cause. *The Lancet* conducted several major launches

around the world to promote UHC, one through the African Development Bank Group in Tunis, another with USAID in Washington D.C., and another with the Mailman School of Public Health at Columbia University. This is a substantial array of partners promoting UHC.

III. Costs and Implementation. In December 2013, *The Lancet* Commission published *Global Health 2035: A World Converging Within a Generation*, which is rapidly becoming the intellectual torch lighting the way to UHC implementation.⁵⁷ Chairman of *The Lancet* Commission, and co-author of the report, Lawrence Summers, linked the concept of UHC to “progressive universalism.”

Summers further elaborated on this idea in *The Lancet*: “The Commission endorses two progressive pathways towards UHC that are pro-poor from the outset. ... The first type of progressive universalism involves initial rapid movement toward publicly financed coverage of the entire population for a defined set of interventions. These would tackle infectious disease, maternal, and child mortality, to achieve convergence; and would also include essential packages of interventions to curb NCDs and injuries. These interventions disproportionately benefit the poor and would require no financial contribution from them. A second type provides a larger package of interventions that might require patients to pay premiums or copayments but exempts the poor from these payments. This approach can be financed through a greater variety of financing mechanisms than the first type, including general taxation revenue, payroll taxes, mandatory premiums, and copayments- but the poor are exempt from contributing.”⁵⁸

The price tag first laid out in *The Lancet* Commission report and mentioned in an Op-Ed by Lawrence Summers calculates: “System strengthening in low and middle-income countries would be about \$30 billion per annum for the next two decades.”⁵⁹ This estimate pales to the estimate cited in *The Economist* in March 2015 of \$2–3 trillion a year for just a 15 year period.⁶⁰ UHC is to be implemented through the following four modalities:⁶¹

- An appropriate taxation on extractive industries, particularly of tobacco, and of multinational industries;
- Reducing or eliminating energy subsidies on air-polluting fuels;
- Non-concessional loans from the World Bank and the regional development banks; and,
- As national incomes grow, public finance would supersede private sources [and] some of the Non-Communicable Disease interventions would generate substantial net revenues.

Global health activists have translated UHC into a platform that considers: “Access to quality care for everyone regardless of ability to pay. They believe governments must move away from relying on employment-based contributory insurance models. Instead, health care must become a right of citizenship, financed in large part through general government revenues.”⁶²

A component of the Bank's new vision for UHC was expressed by World Bank President Kim, addressing the World Health Assembly, when he criticized user fees. This was 20 years after the World Bank report "Investing in Health" recommended user fees as a financing mechanism. If Ministers of Finance follow the Bank's new advice to eliminate user fees, they will have to find alternative means to increase public financing, and patient choice will be further diminished.

In his address to the 2013 World Health Assembly, World Bank President Kim outlined five specific ways in which the Bank would support countries to realize UHC:⁶³

1. Enhance analytic work and support for strengthening health systems;
2. Help countries to reach MDGs #4 and #5 on maternal and child mortality;
3. Develop a monitoring framework for UHC coverage in collaboration with WHO;
4. Intensify work on the science of delivery; and,
5. Step up efforts to improve health through action in other sectors that impact health.

The process for accessing this support would involve member states of the World Bank requesting technical assistance and loan financing.

IV. Commentary and Critiques of UHC. If anything, the World Bank's outcome evaluations of its health projects in its 1997 and 2009 evaluations reveal a programmatic reluctance on the part of its loan/grant officers and recipients either to monitor implementation activities or to follow a lessons learned approach from any evaluations conducted by the Bank.

Second, most of WHO and World Bank health interventions are targeted more towards a country's public health sector emphasizing maternal child health, infectious diseases, and primary care. Every UN member state is experiencing increased life expectancies, and non-communicable diseases (NCDs) now constitute the majority of the disease burden. The World Bank reported over 20 years ago: "The adult population is the productive sector of society. Any impairment of its capacity through disease or disability will inevitably lead to a decline in national productivity and a slowdown in overall national development. This, in turn, will adversely affect the health of persons of all ages within the population."⁶⁴ Formulating a robust response to these chronic diseases, such as cancer, cardiovascular disease, and diabetes, should therefore also involve Ministries of Higher Education, which control the medical schools and clinical staffing at tertiary medical centers. Thus far, neither the World Bank or NGOs are reaching out to these ministries for assistance on UHC, and unless they do a better job at dealing with the full range of morbidity and mortality, they will lose relevance to the health problems of the next 20 years.

Third, just as Ministers of Finance were excluded from deliberations on the Abuja Declaration on HIV/AIDS and malaria, they do not appear to be involved in *The Lancet* Commission's activities. Yet, UHC is heavily dependent on these same ministers for raising taxes on their extractive industries and multinational corporations. Raising a

total of \$30 billion per year, including from developing countries, means that we cannot expect Ministers of Finance to be active partners on the landing if they are not included in the takeoff.

Finally *The Lancet* Commission report has a list of 268 references. Yet, neither the 1997 or 2009 published evaluations of World Bank global health initiatives can be found among these citations. These earlier evaluations laid out the deficiencies and lessons learned from World Bank health projects, including setting unrealistic health goals and budgetary targets. Yet, the commission is presenting a \$600 billion budget estimate without evidence that lessons learned are being applied to UHC.

Summary of Case Studies' Lessons Learned

Lessons learned have been discussed in the above Case Studies. To summarize, they include:

- Confirm governments' political will in global health initiatives, and include good governance and government transparency in the SDGs;
- Partner with local institutions to avoid top-down planning and to achieve local ownership – whether government or civil society - in global health initiatives;
- Learn from the successes and mistakes of past global health programs, and conduct continuous measurement of outcomes versus end point evaluations, so that adjustments in program design and implementation can be made;
- Avoid setting unachievable or exaggerated numerical targets in global health initiatives, but rather, measure incrementally from each country's baseline to assure realistic goals and realistic means of reaching them;
- Assure that measures of new SDG indicators are not reflecting prior changes, by measuring acceleration in change after 2015.
- When estimating resources for global health initiatives, take into account the new landscape of economic growth, development, and foreign aid recognizing that private financial flows are dominant, and governments' role has changed to one of a convener and facilitator of resources.
- Embrace creative approaches through new public-private partnerships, drug development and approvals, and new technologies for health care delivery; and,
- Avoid biased and counterproductive criticism of all non-state actors and recognize their generous contributions to global health; and,
- Recognize the full spectrum of diseases that are affecting the productivity of adults in developing countries and promote a more balanced portfolio to deal with their health problems.

Roles of Global Health Partners

Based on many of the lessons learned in our Case Studies and other global health initiatives, it was clear that the successful projects had clearly defined and appropriate roles for different partners. These roles were natural to partners' participation, reflective of each one's comparative advantage in global healthcare services. It is useful to underscore these roles as the global health community looks forward to meeting the daunting health challenges over the next 25 years:

- **Bilateral and Multilateral Government Agencies** have important roles to play in global health initiatives. These include raising awareness of global health problems; serving as conveners and facilitators resources for global disease programs by bringing the healthcare providers, donors, and other talent together to help them solve problems they have identified; supporting the necessary infrastructure investments for health, improving the legal /regulatory environment for private capital investments in health and for other major financial flows such as philanthropy and remittances to grow; mobilizing sufficient domestic resources to enable developing countries to sustain their global health programs generously supported by public and private donors; and, in the true spirit of enlightened leadership and governance, work in a collaborative, trusting, and unbiased relationship with all non-state actors in global health.

The African Union, through the Abuja Declaration, encouraged non-state actors to help on HIV/AIDS. Its African government members also helped facilitate their operations. The Union made positive suggestions for a future Global Fund for HIV/AIDS, TB, and Malaria which resulted in a productive disease treatment program for Africa.

As was seen in the Case Studies, government membership organizations should avoid roles in project implementation. WHO's failure in meeting its HIV/AIDS goal of treating 3 million people by 2005, its failure to meet its Alma Ata primary health care goal of "Health for All by the Year 2000," and the poor record of World Bank health projects as documented by its two internal evaluations, are examples of membership organizations destined to encounter implementation barriers because they do not have the capacities for or control over direct project operations. The UN/AAI program is an example of a more successful WHO endeavor that worked jointly with governments, pharmaceutical companies, and other UN agencies to treat a large number of HIV/AIDS patients.

- **Foundations, Academia, and NGOs** have important research and implementation roles in global health initiatives, including support for research that evaluates and identifies new technologies and strategies; the implementation of healthcare programs on the ground; participation in public-private partnerships with governments, pharmaceutical and other healthcare companies, and indigenous NGOs. There are many examples of successful programs of

foundations and NGOs whose clear research and implementation roles made it possible for all partners to contribute appropriately and coordinate their actions.

Some of these include the collaboration of several NGOs with Merck & Co., Inc. to eliminate onchocerciasis in Africa, the Edna McConnell Clark Foundation that joined WHO to support studies on trachoma epidemiology and control, and numerous other organizations including Helen Keller International, DeWorm the World, Uganda's Makerere University, Baylor College of Medicine, Save the Children, the Bill and Melinda Gates Foundation, Imperial College London, and Liverpool School of Tropical Medicine, just to name a few among many others.

- **Pharmaceutical and Other Healthcare Companies** most important roles are to provide therapies of high quality, safety, and efficacy to global health initiatives in a reliable manner. The lack of quality control of anti-retroviral drugs in the WHO prequalification program resulted in the WHO having to de-list numerous drugs that could not be shown to be true generics due to lack of bio-equivalency. World Bank regional directors were concerned about quality in the Bank's procurement of anti-retroviral and other drugs as well. This is a more appropriate role for pharmaceutical companies, whether ethical or generic, along with developed drug regulatory authorities. Global health programs need to maintain the highest standards of efficacy to assure successful patient outcomes and to avoid development of drug resistant strains of HIV/AIDS from substandard drugs.

Another important role of healthcare companies is to encourage and support research institutes that are developing cures for global health diseases. In just over a 10 year period, U.S. pharmaceutical companies contributed \$ 1.2 billion to overseas research institutes including the Infectious Disease Institute at Makerere University, the AIDS Reference Laboratory in Botswana, the Bangalore Infectious Disease Institute, and Institute for Tropical Diseases in Singapore, among others.⁶⁵

Pharmaceutical companies are also valuable partners in global health initiatives through their product donations and technical support for monitoring administration of drugs, side effects, and outcomes. Between 2000 and 2011, pharmaceutical companies contributed some \$94 billion in total contributions, including product donations, cash grants, and support to research institutes.⁶⁶ This saved governments hundreds of millions of dollars in product costs.

Conclusion

In conclusion, this report has tried to take a broad look at global health initiatives over the last 30 years. Through in-depth Case Studies of four major initiatives by different organizations, we have analyzed the outcomes, costs, implementation issues, roles of different partners, and lessons learned from three of these programs. For the fourth program, we have provided valuable lessons learned for the future.

We hope that the results and conclusions can be helpful to organizations who design and implement health programs, to healthcare providers on the front lines of providing health care to poor people around world, to policy-makers who must decide where and how to make resource allocations for global health, and, most importantly, to the people who lack access to quality health care services in countries everywhere.

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- ²⁰ Jim Yong Kim and Arthur Ammann, "[Is the '3 by 5' Initiative the Best Approach to Tackling the HIV Pandemic?](#)," *PLOS Medicine*, 30 November 2004.
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