

Horizontal and Vertical Delivery of Health Services: What Are The Trade Offs?

By

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1. Background

Horizontal and Vertical Programs:

Health services (curative and preventive) can be provided using two modes of delivery: horizontal and vertical. By horizontal delivery, services are delivered through public financed health systems and are commonly referred as comprehensive primary care (WHO 1978). Vertical delivery of health services implies a selective targeting of specific interventions not fully integrated in health systems (Banerji 1984; Rifkin and Walt 1986). Horizontal programs are the oldest of the two modes of delivery – they were derived from Primary Health Care (PHC), originated as part of the WHO/UNICEF declaration in Alma Ata in 1978 (WHO 1978).

In the 80s, the concepts behind the design of PHC systems in most countries focused on the health crisis that a country faced at a particular time. With emergence of communicable diseases such as drug-resistant Tuberculosis (TB), Ebola, drug-resistant Malaria, HIV/AIDS, challenges facing most health systems in developing countries have been paramount. Selectivity and prioritization of interventions, particularly in resource-limited settings are important issues for consideration for health planners. As most of the diseases are global public goods, selectivity is done at the country and global levels – with the latter increasingly packaged in international initiatives with specific goals – such as “Health for All by 2000”, and “Millennium Development Goals”.

Country-specific health crises were prioritized in PHC systems, but cost and efficiency in delivering health services drove the nature of the PHC design (WHO 1978). Efficiency and effectiveness of delivering health services are important contributors to the attainment of international health goals at all levels. In most settings, this implies the ability

to identify and to reach poor people. In addition, this requires a multi-sectoral approach in delivering health services. At the launch of the World Health Organization initiative of 'Health for All by 2000', the strategy to attain the set goals was a comprehensive primary health care based on a horizontal mode of delivery of basic services (WHO 1978). A few years of implementation of the initiative proved to be too difficult to attain the set goals (Banerji, 1984). Failure to control malaria in India during the early 80s is one example. This recognition led to a change in the strategy of delivery of services from horizontal to vertical programs.

The past few years have seen increased advocacy for vertical programs for a number of reasons. For donors and political establishments, vertical programs are attractive because they show quick results and they are easier to manage than horizontal programs. However, most policy makers in developing countries see vertical programs diverting human and financial resources from already resource-constrained health systems (Schreuder and Kostermans, 2001). One example can be found in vertical programs undertaken as part of "National Immunization Days NIDs" which are supplemental to horizontal programs that include routine vaccination services. A study of immunization services in Southern Africa which focused on poliomyelitis eradication programs, showed that polio programs divert resources and attention from comprehensive Primary Health Care (PHC) Services. On the other hand, the study showed that NIDs are cost-effective and show good results – with respect to immunization coverage. Some argue that NIDs do promote PHC services but evidence supporting this argument is very weak. Questions remain on the long-term sustainability of vertical programs in terms of outcomes and resources.

Various factors influence the choice of mode of delivery of health services. For example, public officials in developing countries would consider factors such as geographical demands of health services, poverty numbers and distribution, limited resources (human and financial) and sometimes long term sustainability of programs and political dynamics in a country in making a decision on the mode of delivery of services. The incentives driving donors and Non-Governmental Organizations to provide services are quite different. Factors influencing the decisions made by donors on financing of programs include: the need for quick results to attract political support from their constituents for additional funding in the future or strategic importance of the recipients at that particular moment. In making such choices, as a public official or as a donor, there are trade offs. The question becomes what are the trade-offs in selecting horizontal or vertical programs.

This paper will look at case studies and from them summarize the trade offs between the horizontal and vertical delivery of services. Review of the literature is the basis of the content of this paper. The four case studies are:

- (i) Direct Observed Treatment Strategy (DOTS) for Tuberculosis (TB)
- (ii) Immunization programs – routine and National Immunization Days (NIDs)/Polio eradication programs
- (iii) Onchocerciasis Control Program (OCP)
- (iv) African Programme for Onchocerciasis (APOC).

Although not a focus of the review, the paper will briefly look at the evolution of the mode of delivery in the Onchocerciasis program – from vertical (OCP) to horizontal (APOC) delivery of services. Experiences from the case studies can help us understand what lessons can be learned and applied to the delivery of Anti-Retroviral Therapy (ART) in resource-limited settings.

2. Strategies

Section I - Vertical Programs:

a) Direct Observed Treatment Strategy (DOTS)

In 1991, the World Health Assembly launched a strategy to control TB called Direct Observed Treatment Strategy (DOTS) (WHO 2001). The adoption of DOTS as the primary strategy to control TB followed a comprehensive reassessment of TB control efforts across the world. Years of global neglect of TB and increased HIV/AIDS prevalence led to poorly managed TB control programs and an increase in the incidence of TB. WHO estimates about 8.4 million people develop active TB every year and deaths from TB average 2 million people globally (WHO 2002b). Ninety five percent of global TB cases and 99% of deaths from TB are in developing countries. Data from India indicate every year more than 300 000 children leave school to attend to their TB-infected parents and more than 100 00 (NOTE: Is this really 10,000 or is it 100,000?) are socially isolated because of TB (WHO 2000). The attainment of Millennium Development Goals in most developing countries will depend on the ability of governments to control diseases such as TB. How effective has DOTS - as a strategy - been in controlling TB?

Success of DOTS at the country level is judged on five elements – (i) political commitment (ii) accurate case detection based on *sputum* microscopy of people with prolonged cough (iii) standardized short course chemotherapy under directly observed treatment (iv) regular anti-TB drug supply and (v) an effective recording and reporting system. DOTS as a strategy forms the basis of the third element above. The element of DOTS which involves “direct” observation in service delivery has been used in other programs such as BRAC (formerly known as Bangladesh Rural Advancement Committee) family planning projects in Bangladesh. Door-to-door delivery of contraception and training

offered by women trained by BRAC has increased contraceptive consumption in Bangladesh by 50% in the last decade (BRAC 2002). Although no one doubts the success of the approach behind DOTS, questions remain on sustainability (Note: Sustainability in what sense? You might consider using “the relative importance” in place of “sustainability”) of such programs – in particular, in areas with limited resources and are HIV/AIDS prevalent. A major challenge is to adequately address the lack of capacity to scale up DOTS activities in areas where the magnitude and scale of the challenge is enormous. Twenty three percent of all smear-positive cases detected in 1999 tested positive using DOTS tests – representing a significant improvement compared to 1995 when the proportion was 11%. Significant scaling up is still required to meet the challenge. A study by WHO has identified the major constraint to the success of DOTS to be weak political commitment (WHO 1998). Other constraints are: limited financial and human resources, deficiencies in organizational structures, problems in drug supply and lack of public awareness of the benefits of the program.

However, DOTS as a strategy or program is easier to manage than integrated programs and when managed properly results can be impressive. A well-managed DOTS program can reduce the number of TB infections per patient by about 73% (Borgdorff 2002).

b) National Immunization Days (NIDs)/Polio

Polio eradication goals set by the global community in 1988 began immunization campaigns that are now referred as National Immunization Days (NIDs). According to WHO, NIDs have been undertaken in every polio-endemic country – with an estimated 470 million children immunized every year (Hull and Aylward 2000). Establishment of NIDs followed the success of Pan-American Health Organization (PAHO) and Rotary

International campaigns to vaccinate every child against polio by the 1990s. The rising of global immunization and initial success of campaigns in the Americas led to a WHO-sponsored goal in 1998 to eradicate polio by the end of 2000. Today, NIDs are a common phenomenon in most polio-endemic countries.

Exploring the factors behind the rapid expansion of NIDs can provide insights into the characteristics of a successful/effective program. In most developing countries, NIDs, or more accurately national polio eradication programs, are independent, freestanding programs, heavily financed by donors and other agencies. The initial idea behind polio programs was for NIDs to complement routine immunizations in providing immunization services to children under 5 years of age. WHO requires all children to receive a minimum of three doses of oral polio vaccine in the first year of life (Hull and Aylward 2000). A fourth dose is recommended for children living in polio-endemic countries. Most health systems do not provide the fourth dose due to limited resources. Although 100% coverage is necessary to eradicate polio, three doses of OPV (a vaccine used for polio immunization) are estimated to provide only 70-80% coverage (John 1982; Patriarca 1991). For this reason, NIDs aimed at increasing immunization coverage were launched.

NIDs are massive campaigns in developing countries - aimed at delivering OPV to all children under the age of five. The campaigns are intensive, well publicized, and mostly financed by donors, multilateral agencies and other development agencies. By all accounts, NIDs seem to be effective in reaching the target group. As effective as these programs are they are very demanding on resources of public services. Volunteers for NIDs, most of whom are public employees, receive significant compensation, increasing the costs of the campaigns and taking resources away from other services. Budgets and expenditures of national polio programs tend to be higher than other immunization services and because of

financial incentives granted to volunteers – most poorly paid public health providers are attracted to NIDs. Some scholars have argued that same benefits or even greater can be achieved for less money – if delivered through horizontal programs like PHC services (Banerji 1984; Rifkin and Walt 1986). Analysis of costs and benefits must be at the forefront of any program design. However, some costs and benefits which are not easily quantifiable can be crucial to a program’s effectiveness and must be incorporated into program strategy. Lessons from NIDs that can be applied to other programs are the power of communication, political commitment and partnerships in service delivery. Media campaigns, sponsored by donors, governments, NGOs and private sector are examples of effective communication strategies behind NIDs. It is not uncommon to have public figures – from celebrities to royal figures – providing polio vaccines to children on NIDs.

However, the cost of undertaking NIDs in all polio-endemic countries is very high. As of February 2000, the estimated total cost of the global polio eradication initiative through the year 2005 was \$1 billion – of which \$400 million remains to be raised. In addition, political commitment to NIDs at the country level is fading. Because of success stories of polio eradication in other countries or parts of the countries, policymakers assume that polio has been eradicated - and in some instances transfer funds to other priorities (Hull, and Aylward 2000). Data from WHO indicate that between 2000 and 2001, the number of polio cases was halved to 2870. Major challenges remain to achieve the goals set by WHO (Hull, and Aylward 2000). High costs of the program, fading political commitment to sustain outcomes achieved to date, inability to immunize children living in conflict-affected countries and increased movement of people across geographical boundaries are some of the issues that remain to be addressed.

c) Onchocerciasis Control Program

The Onchocerciasis Control Program (OCP) was created in 1974 with two primary objectives – (i) to eliminate Onchocerciasis as a public health problem and obstacle to socioeconomic development in eleven countries ¹ and (ii) to build local capacity to maintain the achievements of the program after its completion in 2002. The principle tool in OCP has been vector control. Biologically safe larvicide spread along riverbeds kills the fly larvae, the intermediate host of the illness-producing parasite called *Onchocerca volvulus*. The parasite infects humans through the bite of an intermediate host, the blackfly. At the end of the program in December, 2002 – after 30 years of OCP existence - the program has prevented 600 000 cases of blindness and 18 million people have grown up free of the disease (WHO 2002f). The program even led to additional benefits: WHO estimates that OCP has freed 25 million hectares of fertile land for cultivation – allowing thousands of farmers to reclaim the land for agricultural activities (WHO 2002f).

Aerial spraying of larvicide – the main thrust of OCP strategy – required significant capital investments and highly trained personnel. Vector control activities, including epidemiological and statistical evaluation, were planned centrally from the program headquarters in Ouagadougou, Burkina Faso. From its beginning, OCP was managed as a classical vertical program – with administrative and operational activities centrally located and with minimum integration with health systems in recipient countries. A World Bank Study has shown that OCP is a cost-effective program – with an estimated Economic Rate of Return (ERR) of 20% (Kim and Benton 1995) - yet long-term sustainability of the benefits obtained from OCP is unknown. The criteria used to evaluate the economic efficiency of the project in Kim and Benton study included net present value (NPV) and the

economic rate of return (ERR). The analysis considered the costs, labor-related benefits, and land-related benefits of OCP. Following preliminary studies on sustainability of OCP, the strategy of OCP evolved to a more integrated one that included the distribution of a drug called Mectizan®. The evolution occurred in 1998 following an announcement by Merck and Co., Inc. to donate the drug free of charge to recipient countries. NGOs played an important role in establishing the first large-scale efforts to distribute Mectizan® in parts of Africa and Latin America (Etya'ale 1998, Cross 1998, Blanks et al 1998). Financial support from a large pool of donors, multilateral agencies and NGOs allowed establishments of large-scale drug distribution systems which were managed in partnership with Ministries of Health in the 11 countries. OCP, as a vertical program, has many unique features that distinguish it from other programs. It started as a centralized program, then scaled up to cover 11 countries and later evolved into a program that actively involved governments, the private sector and NGOs. One could argue that OCP is a good example of “experimentation” and “scaling up”. Experiences and lessons from implementation of OCP led to the creation of the African Program for Onchocerciasis Program (APOC). The success of OCP in eliminating onchocerciasis in 30 years might have been because the operation was efficiently managed and run from the center in Ouagadougou. The success of OCP is good news for donors but now that external funding has ceased OCP is a challenge for policymakers who have to sustain the achievements of the program over the last 3 decades.

¹ Benin, Burkina Faso, Cote d'Ivoire, Ghana, Guinea, Guinea-Bissau, Mali, Níger, Senegal, Sierra Leone, Togo

Section II - Horizontal Programs

a) Routine Immunization

Routine immunization refers to the Expanded Program on Immunization (EPI), implemented at the country level, to ensure that all children under the age of one receive a basic immunization regimen as required by WHO. The EPI initiative started in the 1970s to establish an effective and sustainable immunization program in every country (Hull and Aylward 2000). Immunizations covered in EPI include BCG (*bacillus calmetguerin*), DPT3 (diphtheria, pertussis, tetanus), OPV3 (oral poliovirus vaccine) and measles. In most countries, EPI services are fully integrated into health systems and are financed by the public sector. By 1990s, WHO estimated that 80% of the infants born each year received BCG, DPT3, measles and TB vaccinations – a significant achievement in 20 years of EPI's existence (Hull and Aylward 2000). However, EPI – as an integrated ‘horizontal program’ has its own challenges. Problems such as high costs of providing EPI services, deficiencies in health systems and a lack of basic infrastructure get in the way of EPI coverage.

Where health systems are working effectively and efficiently, such as in developed countries – immunization coverage under EPI is impressive and well regulated. Problems with coverage elsewhere are associated with non-functioning health systems and poor infrastructure to support the delivery of vaccines to remote areas. Furthermore, polio eradication campaigns – offered through NIDs – put additional demands on limited-resource settings commonly found in developing countries. Data from WHO show that although routine immunization programs (in Bangladesh, Cote d'Ivoire and Morocco) continued at normal levels of funding after the introduction of NIDs, the logistical requirements associated with NIDs put extraordinary demands on personnel and funds allocated to EPI (WHO 2002d). Empirical evidence of direct effects of intensive polio

eradication campaigns on routine immunization is weak but there are reports showing that routine immunization services often stop during NIDs as resources and health personnel are transferred to well publicized and intensive campaigns (Macedo and Melgaard 2000). Studies in Tanzania, Nepal and six countries in the Americas have shown that NIDs divert public focus, donors' attention and resources from routine immunization programs. (Pan American Health Organization 1995; Mogedal and Stenson 1999). NID campaigns distorted established national policies and priorities for health development set by policymakers in the countries studied. The problem is similar to the fungibility of funds issues faced by aid agencies. Health ministries may perceive NIDs as substitutes for routine immunization and decrease allocations of resources accordingly. Because 'frontline' service providers are rarely appreciated by communities they serve, in some countries like Nigeria, NIDs are attractive to health personnel because of the perceived social exposure that comes with the NIDs campaigns.

Forming incentive structures, both social and financial, for the delivery of immunization services in developing countries is a big challenge to policymakers and service providers. Clearly, organizational structure and program management including incentives to service providers, have an influence on quality of service delivery. The scale of the challenge increases in countries where different donors – each with its own organizational structure, demands and incentives - are involved in service delivery. Recent debates on the need for harmonization of donor procedures is a good start to address this problem. However, donors and policymakers must show results to their respective constituents and financial incentives – given through vertical programs like NIDs - are often seen as means to obtain quick results. Therefore, incentives influence both inputs and outputs – affecting decisions about what mode of delivery to use and affecting quality and efficiency of service delivery.

At the end of the line of service delivery is a client who in most developing countries does not have options in immunization services because most private providers focus on curative rather than preventive health services like immunization.

b) African Programme for Onchocerciasis Control (APOC)

The African Programme for Onchocerciasis Control (APOC), launched in 1995, was built on the success of OCP program and was empowered by Merck's donation of the drug, Mectizan®. APOC covers fourteen ² infested countries in Africa. Similar to OCP, the objective of APOC is to eliminate onchocerciasis as a public health problem and a constraint to socio-economic development in the fourteen countries. What sets APOC apart from OCP is the strategy of the program – APOC aims to establish integrated and sustainable Mectizan® distribution systems in concerned countries. Lessons and experience from the OCP program influenced the choice of APOC strategy – the key being an integrated system helps long-term sustainability of program outcomes and benefits. Bilateral and multilateral donors established a trust fund managed by the World Bank to finance APOC projects for a maximum period of 5 years. After 5 years participating governments are expected to have the capacity and resources necessary to sustain the projects.

Preliminary studies to support APOC strategy identified five elements important to the success of APOC:

- Empowerment and participation of endemic communities – in the context of Primary Health Care (PHC)
- A unique global partnership between affected communities, public and private sectors

- Research of innovative tools to adopt the strategy to local circumstances
- Commitment of Merck & Co., Inc. – to donate Mectizan® as long as needed
- Lessons and experience from OCP

The biggest achievement of the program is the treatment coverage attained using the Community-directed treatment (ComDT) strategy, which in most countries has been integrated into health system and infrastructures. WHO data show that the number of people treated every year has risen from 8 million in 1996 to more than 20 million in 2000 (Seketeli 2002). The reasons behind APOC's success in such a short period has recently been the subject of discussions among experts working on community-driven initiatives.

Unlike OCP or EPI, the foundations of APOC were built on well-established NGO drug distribution networks in developing countries. The first large-scale networks to distribute Mectizan® in Africa and Latin America were started by NGOs (Drameh et al 2002). APOC was in a healthy financial state at its launch – with donor commitments of about \$20 million per year (Kim and Benton 1996). In addition, the strong partnership – at the global and country levels – played a major role in the implementation of APOC projects. One requirement of implementing APOC projects at the country level is a partnership between the Ministry of Health and NGOs. As part of the agreement to receive funding from APOC Trust Fund, authorities in participating countries are required to waive all levies associated with importing of Mectizan®. Moreover, cross-country learning is encouraged through monitoring and evaluation activities that encourage policymakers from one country to monitor projects in other countries. WHO acts as an implementation agency by working closely with other partners at the country level through their country offices to ensure

² Cameroon, Central African Republic (CAR), Chad, Congo, Democratic Republic of Congo, Ethiopia,

project activities are undertaken as planned. Equally important is the role played by WHO local offices in ensuring that APOC activities are integrated into national health strategies and plans from very early on in the process.

Along with the success, APOC faces challenges frequently associated with integrated programs. Because of competing demands on national budgets and increased prevalence of diseases such as HIV/AIDS, political commitment towards APOC is fading. APOC has to deal with constraints associated with incentives for health volunteers who distribute the drug without compensation. A number of donor-financed health programs in Africa provide a fee to their front-line health providers – making it harder to convince APOC volunteers to continue to distribute Mectizan® without any compensation. A few commentaries suggest that the incentive issue was purposely left out of the discussions at the beginning of the program due to fear that donors' support of the program would have decreased (Seketeli, 2002). Results from WHO surveys have shown that the incentive issue is a major constraint to APOC activities (Amazigo et al 2002). The sustainability of APOC projects after five years when external funding ceases is also in question.

The strategy behind APOC as a means to deliver services (distribution of Mectizan®) is rational in many ways: (i) it is an integrated strategy based on empowerment and participation of citizens (ii) it is built on a strong partnership between public and private sectors (iii) it includes the active involvement of NGOs and (iv) it works through a global financing mechanism – APOC Trust Fund. Yet questions remain on political commitment, incentives, future financing of projects at the country level, and long term sustainability of activities that depend on significant external financing during the implementation phase.

Would a ministry with competing demands and priorities and limited resources continue to support onchocerciasis after the donors' financing cease even with no obvious morbidity and mortality?

In the five years that APOC has been in operation, issues of conflict, governance and organizational structures of the state have gained prominence. How can horizontal and vertical programs deliver services to poor people in federated states like Nigeria or in conflict areas like Southern Sudan? There are no simple answers to these questions. What is clear is that no matter what mode of service delivery is selected, whether in politically stable countries or in conflict-affected countries— or combinations of both – there are trade offs to be made. Recognizing the trade offs and considering them when planning for service deliveries can help selectivity and prioritization of service, in particular, where resources are limited and the challenges are enormous.

3. Trade Offs: What Are They?

Selection between horizontal and vertical modes of service delivery, as has been discussed in the four case studies, is driven by various factors. To reach beneficiaries of basic services such as immunization, an integrated and comprehensive delivery mechanism – commonly seen in horizontal programs – seems to be the most effective choice. The same is true for ART services that in most cases would have to reach thousands of people affected by HIV/AIDS. Experiences from APOC and routine immunization programs suggest that where there is a sound infrastructure and functional health systems, horizontal programs can work well. However, most developing countries have weak health systems, poor infrastructures and limited resources. In the long-term, horizontal programs are cost-effective and when services are fully integrated into health systems, programs can be sustained by the public sector. More importantly, horizontal programs, financed by the

public sector, deliver preventive services to poor people who cannot afford to go to private providers. For policy makers, horizontal programs are attractive because of their long-term sustainability. The fact that horizontal programs are financed by government revenues and are part of a broader health plan, they are fully integrated into the public sector.

However, in resource-limited settings, where a significant portion of government expenditures on health come from external assistance, horizontal programs have their flaws. Because the programs are integrated into existing health systems, they are very difficult to manage and can be easily misused by a selected few. The challenge of providing routine immunization services in large and federated countries like Nigeria is one example. Donors supporting service delivery in developing countries need to show quick results to maintain support for foreign assistance within their constituencies. Unlike horizontal programs, vertical programs are also easier to manage. They can be kept away from the bureaucracy (and in some instances political interference) that comes with implementing programs in government structures.

Vertical programs are expensive to run and divert resources and attention from regular basic services. Many country-level studies of NID campaigns, for example, have drawn this conclusion. As mentioned previously, horizontal programs work well in a context of sound infrastructure and functional health systems and work poorly otherwise. This may seem to suggest that vertical programs are preferable in most developing countries, yet some may argue that the opposite is true. Vertical programs may in fact provide a short-term solution, allowing countries to postpone desperately needed health care system reforms. Vertical programs can be used as an experiment and over time integrated into existing health infrastructures. Evolution of onchocerciasis programs is a good example of experimentation and scaling up.

In summary, there are trade-offs to be made in both horizontal and vertical programs. The trade-offs can be managed and it is important that they be taken into consideration from the beginning - when setting the objectives of a particular program/initiative. The setting of objectives depends on the seriousness of a problem and whether one is a donor, policymaker, or service provider. Considerations of trade-offs for donors differ from that of policy makers. Poorly paid service providers have different incentives in selecting vertical or horizontal programs from policy makers. At the end of the line is a client who in most cases does not have many choices in service delivery, but has the power to influence policy through social mobilization. The push by Brazilian citizens to obtain “free ARV drugs” is a powerful example of social mobilization.

4. Implications for Delivery of Anti-Retrovirals (ARV)

a) Anti-Retrovirals Drugs

The most urgent public health problem the world is facing today is HIV/AIDS. Forty-two million people in the world are living with HIV/AIDS – 95% of them in developing countries (WHO 2002e). The epidemic in the countries most severely affected, such as Sub Saharan African countries, is damaging key sectors – from education to social cohesion - and is slowing down economic development. Luckily, people living with HIV/AIDS today have reason to feel more hope than they would have a decade ago. The introduction of highly active antiretrovirals (ARVs) in 1996 provided HIV/AIDS patients with opportunities for quality of life improvements by stopping or inhibiting the replication of retrovirus such as HIV (WHO 2002c). Although ARVs cannot cure HIV/AIDS infections, they can reduce HIV-related morbidity and mortality as well as prolong lives and improve the quality of life of people living with HIV/AIDS. Today there are at least 10 approved ARVs on the market, administered as a single dose or in combination. WHO data

show that in 2002 an estimated 6 million people in developing countries needed Antiretroviral therapy (ART) – but only 230 000 have access to ARVs and half of them live in Brazil (WHO 2002e).: Targets set by WHO aim at increasing access to ARVs to 3 million people by 2005. Availability of drugs on the market is one issue, but a more important issue is the capacity of developing countries to deliver ARVs to millions of people who are in need of the drugs. Experiences from programs described earlier point to central challenges that need to be addressed in the delivery of ARVs. What is complex about ART is the difficulty of administering ARV drugs that have to be used in a lifetime and the requirement of close monitoring of patients' completion of doses and possible side effects of the drugs – in resource-limited settings.

Recently published WHO guidelines on ARV treatment provide policymakers in developing countries with a framework to expand access to ARVs using the best available scientific evidence in the field (WHO 2002e). The guidelines seek to scale up antiretroviral therapy (ART) in areas where the drugs are needed the most. The WHO recommendations cover administration of ARV, monitoring of ART, and side effects associated with ARV. It is important to note that most of HIV/AIDS affected areas are poverty-stricken with very little capacity, weak health systems and poor health infrastructure.

WHO recommends that the initial administration of ARV to infected adolescents and adults occur when there is evidence of clinical AIDS. In areas where health services are poor and diagnostic laboratories are ill equipped or non-existent even though many have AIDS, cases are diagnosed very late in the infectious cycle. Late clinical diagnosis is usually associated with opportunistic infections like TB and pneumonia at advanced stages of the infection. Another recommendation from WHO involves close monitoring of the “CD4” or lymphocyte cell counts that are key determinants of infection. The lower the CD4 count

the more advanced the disease. For example, most HIV patients develop clinical signs of AIDS when CD4 count is below 200 per cubic meter of blood (WHO 2002e). As useful as a CD4 cell counts, the reality is that most health facilities in developing countries do not have the equipment or the trained staff to perform these tests. And the limited trained personnel and equipment available tend to be in health facilities in urban areas. As populations increasingly move out of rural to urban areas, the scale of the challenge to deliver ARV services to infected populations residing in urban areas is bound to increase significantly.

Close monitoring of therapy is another challenge. Procedures recommended by WHO are quite demanding and in most cases require highly trained professionals. When comparing the duration of ART compared to the duration of one-time off malaria treatment or a couple of immunizations that children require, the feasibility of large- scale ART services is daunting. A more serious problem is the association of incomplete doses with emergence of HIV drug-resistance. The emergence of resistance to anti-malarial medicine has shown how difficult it is to administer a full course of drugs in areas with poor health infrastructures and limited personnel. Unlike ARV drugs, which have to be used for a number of years, anti-malarial medicines such as chloroquine which is used for curative purposes, are administered over a seven- day period. Equally important to the effectiveness of ART is well-balanced nutrition. Unfortunately, nutritional choices are limited in poverty-stricken areas.

b) Experience from Developing Countries

Experience with delivery of ARV drugs in developing countries is, in most cases, on a small scale with mixed results. In Haiti, one of the poorest countries in the world with a GNP of around \$400 and a 70% unemployment rate, HIV treatment programmes are reported to be successful (Farmer et al 2001). Using the infrastructure initially put in place

for TB control, ARV drugs were administered under “direct observation” to 60 patients in the western part of the country. What is not clear from this study is the capacity of local health personnel to deliver ART services without significant external support and on a large-scale basis. For example, social support such as children’s school fees, were used as incentives for parents to seek treatment at the clinic that is easily accessible by patients. Even though the authors of the study are convinced that such an initiative can be scaled up in other areas, they fail to provide specific suggestions as to how the expansion can be done on a large-scale and without substantial external support. On the other hand, the “directly observed treatment” offers a real opportunity to minimize the emergence of drug-resistance commonly associated with incomplete therapy. However, it is important to recognize that TB treatment is different from HIV treatment – the former lasts only 6-8 months whereas ART is an ongoing treatment.

In Brazil, a country known to have the largest and most successful ART programme, the challenges facing the national AIDS programme are political, financial and logistical. In 1996, the Ministry of Health in Brazil guaranteed every citizen living with HIV/AIDS to have free and universal access to ART (Brazil Ministry of Health 2001, Passarelli 2001). In November 1996, the President Fernando Cardoso signed a law establishing free distribution of ARV drugs to people living with HIV/AIDS. Much of the success of the ART programme in Brazil is owed to mobilization of the society, in particular, representatives of people living with HIV/AIDS and religious organizations. The launch of the “free ARV drugs” policy in 1996 rose the reporting of AIDS cases in Brazil by 40% - suggesting that there was a significant underreporting of HIV/AIDS cases before 1996 (Galvao 2002).

While local manufacturers produce most ARV drugs, the majority of newer and expensive drugs are imported from abroad. Financing imported drugs remains a major challenge to ART services in Brazil and more recently has been a major cause of disputes on process and patents between the Brazilian government and international pharmaceutical companies (Galvao 2002). More than any other problem, the high cost of importing ARV drugs, is a threat to the feasibility and sustainability of the Brazilian HIV/AIDS programme. In 1999, 53% of ARVs, and 81% of expenditures on them, were from international pharmaceutical companies. What sets Brazil apart from other developing countries is the capacity for local production of ARV drugs. In 2001, 63% of ARVs and 43% of expenditures were produced by local firms compared to 47% of ARVs, locally produced in 1999. By the end of 2001, Brazil was producing seven of the 13 ARVs used to treat HIV/AIDS patients in Brazil (Brazil Ministry of Health 2002).

Yet, most of developing countries affected with HIV/AIDS do not have the local drug production capacity that Brazil has – nor can they afford to pay for ART services for their citizens. Unique to the Brazilian story is the willingness of the country to challenge the international patenting laws. In 2001, the Brazilian government announced that it intended to break Roche's (one of the major international pharmaceutical companies) patent to produce *neftravir* locally. The argument of Brazil was that the government was spending 28% of the annual budget on this drug alone. A month later, Roche agreed to reduce the price of the drug and plans to break the patent were cancelled (Galvao 2002).

In a federated country the size of Brazil, logistics and strategic considerations of delivering ART services are considerable problems. At the launch of the program, the main logistical challenge was to develop a strategy that would both distribute and monitor ARVs through the public health system. Elements of the strategy included: (i) defining locations at

which HIV/AIDS patients could receive ARV, (ii) creating a monitoring system to track the distribution of drugs and (iii) establishing a network of laboratories for clinical diagnosis. Today, there are 424 sites around Brazil – providing ART services and computerized systems to track the distribution of drugs. A good investment has gone into establishing good networks of public-financed laboratories for clinical tests. Data generated from these laboratories are computerized and sent via the Internet to the center (the National AIDS Programme). These networks, including computerized databases of patients' records and drugs, have played a major role in overcoming logistical challenges. To have such a well-connected system of networks, a country needs sound and functional infrastructure. Although the Brazilian model could be hard to scale up in other parts of the world, the Brazilian experience has many lessons to offer to other countries.

c) Summary

Evidently, there are important challenges in delivering ARV drugs in developing countries. High cost of drugs, the need for sound infrastructure, and the need for highly trained personnel are some of the issues that need to be addressed for ART services to work effectively in developing countries. Studies in Senegal and Uganda had similar observations to those of Haiti and Brazil (Laurent et al 2002; Weidle et al 2002). The United Nations through the “Accelerating Access Initiative” is collaborating with a number of international pharmaceutical companies to reduce the cost of ARVs in developing country markets (WHO 2002a). Generic manufacturers in countries like Brazil and India offer significant price reductions in developing countries. Yet, at close to US \$1 per day for a first line ART regimen, the cost of ARV drugs is too high for most developing countries, given their current health expenditures (WHO 2002a). Whereas the challenge of financing ARV drugs can be fixed, weak infrastructure and limited human resources in administering ARVs are

bigger challenges facing most developing countries. The story of Brazil has lessons on how to address logistical challenges in a middle-income country. Scaling up of ART services would require an integrated “horizontal” mode of service delivery. However, most health systems in affected countries do not have the resources or the infrastructure to support ART. A key lesson from Brazil is the power of social mobilization – including representation of affected communities in government – to influence policy. Other lessons include the involvement of NGOs and increased public awareness of AIDS, similar to the story of decreased HIV/AIDS prevalence in Uganda.

d) Lessons from Immunization, DOTS and Onchocerciasis Programs: Implications for delivery of ART services.

The scale of the challenge posed by HIV prevalence numbers in developing countries is vast. Yet, the available ARV drugs to prolong lives of those affected have specific regimens for different groups (children, pregnant women, patients with TB etc.) and the drugs require close and regular monitoring systems. With available ARV drugs there are issues to be addressed - the high cost of drugs, complexities of administering the drugs and poor infrastructure to support ART services. The discussion around vertical and horizontal might be too premature for ART services because the science behind ART therapy is still evolving – but lessons from immunization, onchocerciasis and TB programs offer insights on possible implications for the delivery of ART services.

First, the nature and scale of the challenge of HIV/AIDS suggest that comprehensive health coverage is essential. To reach the people living with HIV/AIDS, an integrated mode of delivery seems to be the most sensible method. Such a program would allow scaling-up of ART and allow participation of beneficiaries in service delivery.

However, given the complexities that come with administration of ARV drugs, highly trained personnel and well-equipped facilities are required. Experience from immunization and malaria programs suggest that an integrate ‘horizontal’ system may not be as effective as a vertical program – in particular serious side effects have to be monitored, as is the case for ART. The failure of malaria programs in developing countries and emergence of anti-malarial resistance is largely due to failure of close monitoring of patients – to ensure appropriate completion of drug regimen. The idea of “direct observation” in TB control programs (DOTS) was to correct this problem.

For ART services to work effectively in developing countries, under the current WHO recommendations, a combination of horizontal and vertical programs is essential. National programs in Brazil and Uganda adopted the combination approach but focused mostly on urban areas. In both Brazil and Uganda, political commitment, social mobilization, involvement of NGOs, communication and citizens’ participation in influencing policies were key in the reported success. Similar elements of success are found in polio eradication campaigns and APOC.

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