

**Universal access to antiretroviral therapy in Thailand:  
an analysis of the policy process**

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by

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## **ABSTRACT**

Antiretroviral therapy (ART) is effective in reducing HIV morbidity and mortality as well as improving patients' quality of life. However, because of several hurdles, resource-poor countries have provided treatment to only a few people in need. Thailand is unusual in having opted to offer universal coverage for therapy. This thesis aims to understand the process by which ART reached the Thai Government agenda, and to explore the lessons learned from the design and implementation of the publicly-organised treatment programme.

This study suggests that Thailand's ART programme was influenced by the networks and learning of several actors which evolved over time. During a period of policy continuity between 1992 and 2000, the policy process developed within a relatively closed subsystem dominated by health officials in the Disease Control Department and HIV experts. The cost of antiretrovirals was the major factor restraining treatment coverage. The dramatic shift in ART service towards universal access took place in 2001, as a consequence of drug price reduction and political transformation that allowed participation of new Health Minister, health financing reformists, and an alliance of non-governmental organisations (NGOs). Apparently, local and external treatment experiences inspired these actors to pursue similar paths in Thailand. The rapid policy formulation process was facilitated by common interests, shared experience, previously established collaboration, as well as awareness of interdependency among members of the Ministry of Public Health's Technical and Administration Panels. Learning about the intricacy in ART administration, especially from existing programmes and research studies in the country, played a crucial role in devising treatment expansion plans. The individual expertise of clinical specialists, researchers, health officials, NGOs and PLWHA helped to accelerate lesson drawing from policy feedback, anticipating future obstacles and selecting appropriate policy options.

At the sub-national level, the process by which the universal ART policy was translated into action involved another set of actors, comprising hospital administrators, health professionals, officials in the Health Ministry's Regional and Provincial Offices, local NGOs and PLWHA groups. A key feature of policy in this phase was that the front-line workforce struggled to carry out the tasks prescribed by national policy makers. The discrepancy between the programme's expectation and actual therapy delivered in two study provinces was significant,

resulting from insufficient number of experienced health personnel, increased workload as an effect of parallel reforms in the health and public administration systems, and stigma attached to HIV. To counter these impediments, treatment execution networks of government staff and civic groups were instigated. Collective learning among service providers, supporters and clients had an important role in ART scaling up. Different coping strategies were implemented in study hospitals, aiming to balance the contradictory goals of achieving the allocated targets while maintaining treatment quality.

This thesis demonstrates that to understand policy development in such a complex circumstance governments cannot unilaterally deal with particular problems. Employing a policy network concept to address the partnership between state and non-state actors is not only useful but essential as the policy environment has expanded beyond merely state actions, to depend, to some extent, on non-state actors. Moreover, the integration of policy learning model into policy analysis framework can provide insights into the increasingly dynamic interactions between actors, context and processes of public policy in focus.

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## LIST OF ABBREVIATIONS

AIDS	acquired immune-deficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral drug
ATSI	Bureau of AIDS, Tuberculosis and Sexually Transmitted Infections
CSO	civil society organisation
CSW	commercial sex worker
DOTS	directly observed therapy, short course
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GP	general practitioner
GPO	Government Pharmaceutical Organisation
HAART	highly active antiretroviral therapy
HIV	human immunodeficiency virus
HSRI	Health Systems Research Institute
IDU	injecting drug user
OI	opportunistic infection
MOPH	Ministry of Public Health
MSF	Medicins Sans Frontiere
NAC	National AIDS Committee
NGO	non-governmental organisation
NNRTI	non-nucleoside reverse transcriptase inhibitor
NRTI	nucleoside reverse transcriptase inhibitor
PCP	<i>Pneumocystis carinii</i> pneumonia
PDA	Population and Community Development Association
PHO	Provincial Health Office
PI	protease inhibitors
PLWHA	people living with HIV/AIDS
STD	sexually-transmitted disease
TAC	Treatment Action Campaign
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UC	Universal Health Coverage Scheme
UN	United Nations

<b>UNAIDS</b>	<b>Joint United Nations Programme on AIDS</b>
<b>UNDP</b>	<b>United Nations Development Programme</b>
<b>UNGASS</b>	<b>United Nations General Assembly Special Session</b>
<b>UK</b>	<b>United Kingdom</b>
<b>US</b>	<b>United States</b>
<b>WHO</b>	<b>World Health Organization</b>
<b>WTO</b>	<b>World Trade Organization</b>

*'While we must move ahead boldly, making use of the best current knowledge, there is much to be learned in the process. Systematic learning while doing will be critical to the ultimate success of these historic initiatives to scale up antiretroviral therapy. Such learning must be accomplished through rigorous monitoring and evaluation of the diversity of programmes employed from country to country and in countless villages, towns, and cities. Targeted evaluations and a rigorous programme of operational and applied clinical and behavioural research to answer specific questions must be thoughtfully designed, well coordinated, and funded from the beginning with ample dedicated resources.'*

Curran and Debas (2001:xi)

*'To gain support and maintain co-operation, collaboration and even solidarity, the key leaders had to learn and to implement new ways of doing things. Ultimately, advocacy was a very valuable learning process. Among other things, actors learned perseverance, patience, flexibility and adaptability to change in dynamic conditions. They also learned to work with others in an effective manner.'*

Vichit-Vadakan and Anukansai (2004:89)

## **CHAPTER 1: INTRODUCTION**

The devastation caused by human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) is recognised as a global crisis. Over the two decades of its emergence, the disease has afflicted a large number of people. In addition to the infected individuals and family members, many components of society are affected by the epidemic. While HIV/AIDS is so far incurable, several approaches to disease prevention, treatment, and care exist and are being implemented at different levels. Among the medical interventions, antiretroviral therapy (ART) is the most effective in increasing survival time and improving the quality of life of infected persons.

This thesis aims to understand better the introduction of antiretroviral medication in Thailand. In 2001, the Thai government opted for a policy to provide universal coverage for treatment, an unusual move for a middle-income country, with almost one million people living with HIV/AIDS (PLWHA). Although the country had succeeded in curbing the disease from the early 1990s, treating all infected persons became the next challenge for the government and health system. Given the high cost of the drugs, this thesis seeks to get answers to the questions: how and why Thailand decided to roll out nationwide therapy. It also explores the features of the national ART initiative during the first three years of scaling up.

To provide a background to the issue, this chapter describes the global HIV epidemic and its implications. Critical elements, caveats and potential externalities of ART as well as the integration of therapy into health systems are also discussed. In addition, it reviews the resources needed, advocacy and debates in relation to treatment scaling up in poor countries.

### **1.1 The Global HIV epidemic: the disease, epidemiology and impact**

HIV is the causative agent of AIDS. The virus transcribes its genetic materials in infected host cells, after which the newly-replicated viral particles are released in the blood (Rubbert and Ostrowski 2003). The infection develops slowly with long intervals between the initial phase and the onset of serious clinical manifestations, varying from 1 to more than 15 years in adults but only 2 years in children. When the infection reaches the full-blown stage, the immune system does not function and patients are vulnerable to several opportunistic

infections (OIs), malignancies and neurological disorders, which define AIDS status clinically (Bartlett and Gallant 2003). Many of these complications are life threatening and require hospitalisation and expensive medicines.

Transmission of HIV occurs by contact with contaminated secretions, blood and other biological fluids from infected persons. Sexual relationships, sharing needles and syringes, and blood transfusions spread the virus in adult populations (CDC 2003). The virus can also pass from mothers to newborns during gestation, delivery and breastfeeding. Health workers may be infected from needle pricks tainted with infected blood or secretions or coming into contact with these fluids through open wounds or mucous membrane. Transmission can be prevented through various means, for example condom use, blood product screening, exercising universal precautions in health facilities, and antiretroviral (ARV) prophylaxis and breast milk substitution in infected mothers and the neonates (Phoolcharoen and Detels 2002). HIV vaccine trials are being conducted in many countries, but are not expected to be useful for many years (Peiperl and Buchbinder 2005).

### ***The global HIV epidemiology***

The first report of HIV-related illness was published in 1981 in the United States (US) (CDC 1981). The epidemic in most regions started during the late 1970s to early 1980s, except in North Africa, Middle East, South and South East Asia, and East Asia and the Pacific where the extensive distribution of the virus commenced in the late 1980s (UNAIDS 1996). The global figures indicate that about 40.3 million people were living with HIV in 2005, while 25 million had died of the disease since it was first identified (UNAIDS 2005). Cases and deaths continue to rise: increasing in 2005 by 4.9 million, with 3.1 million deaths. HIV affects different regions unevenly, with 95% of the infection occurring in developing countries. Sub-Saharan Africa is the most heavily affected, with two thirds of the world's HIV cases. The epidemic is expanding in Eastern Europe, Central Asia, and South and South-East Asia where previously little HIV was observed (UNAIDS 2004a). In high-income countries such as France, Sweden, and United Kingdom (UK), prevalence has grown steadily as a consequence of new infections (UNAIDS 2003a). Wide coverage for ART which substantially prolongs patients' life is another reason for the increase in the numbers of PLWHA in these settings.

Despite geographical variation, two features are common to all countries: first, infections are overwhelmingly among young adults, with individuals of 25 to 49 years of age the major group affected (UNAIDS 2004a). By 2003, this group made up 94% of the total world population with HIV/AIDS. Second, the most vulnerable to HIV infection are the marginalised and underprivileged (Bloom et al. 2004). Owing to several barriers, these groups have poor access to public services including disease prevention and health care programmes.

### *Implications of the epidemic*

HIV is well recognised for its negative effects on economies and development efforts. At household level, in addition to the morbidity and mortality of the infected persons, there is a loss of economic security, rising expenditure on health care, depleted household earnings, savings and holding assets (United Nations 2003). The epidemic has major implications for children and the elderly in HIV-affected families (Barnett and Whiteside 2002). Many school-age orphans cannot continue their education. Some children are forced to take on a premature role, for example providing care to the sick and the younger brothers or sisters, leading the family, and starting their work life very early (Egero, Hammarskjold, and Munck 2001). Ironically, the elderly who have given care to their infected children while they live with the illness, may also be responsible for orphaned grandchildren (Knodel and VanLandingham 2002). In the most extreme cases, HIV infection in an adult breadwinner can result in the migration and dissolution of the household.

Since the majority of PLWHA are in their most productive years of life, in countries with high HIV prevalence the epidemic also affects the national economy. An estimated 26 million workforce participants worldwide lived with the disease in 2004 (ILO 2004). HIV-related absenteeism, debilitation and deaths have notable direct and indirect effects on the costs and productivity of manufacturing industry (Greener 2002b). The destructive impact on public service sectors such as the education, health and social welfare and its consequences on the services provided has also been noted (United Nations 2004; World Bank 2002).

HIV also afflicts a country's economic development. As suggested by the Commission on Macroeconomics and Health (2001), apart from the damage to particular agencies and businesses, production loss and cost escalation may lower confidence among investors, subsequently resulting in less investment and possibly, economic recession. In addition, the

increase in demands for foreign currency spending on imported healthcare goods including ARVs and other anti-HIV drugs may deter economic growth and even increase the poverty level (Dixon, McDonald, and Roberts 2002). Some reports have suggested that in some African countries, the effects of HIV may delay the capacity to recover their macroeconomies for many decades (United Nations 2004).

The most effective way to avoid the effects of HIV is to act before the epidemic starts (UNAIDS 2002a). For many countries, however, large numbers of people have already been infected before a policy response has been made. In such cases, the most reasonable strategy is to provide care in addition to prevention in order to reduce morbidity and delay premature death. Comprehensive care for PLWHA, as recommended by international organisations, involves a wide range of services, including voluntary counselling and testing for the infection, prevention of further viral transmissions, prevention and treatment of OIs and HIV-related cancers, ART, and palliative care (WHO 2004d). Although antimicrobials can reduce the risk of major opportunistic diseases such as tuberculosis and *Pneumocystis carinii* pneumonia, the drugs are notably less effective than ART in prolonging survival of HIV-positive persons (Lee et al. 2001).

## **1.2 Antiretroviral therapy**

It was in the late 1980s when the first antiretroviral (ARV) was approved in the US. Thereafter, substantial benefits of ART have been documented and its clinical consequences have shifted the general attitudes towards HIV from a rapidly life-threatening infection to a manageable chronic disease (Siegel and Lekas 2002). At the same time, the use of ARVs has drawbacks as the drugs may cause serious adverse effects (Volberding 2003). There are also serious concerns about resistance to ARVs (Lange 2002). This section reviews different facets of medications including important precautions and caveats in therapy administration.

### **1.2.1 Critical issues in ART: biomedical aspects and associated factors**

Antiretroviral drugs act by controlling HIV replications or intervening in the viral fusion to host cells (Pomerantz and Horn 2003). The first ARV – zidovudine was approved for HIV in 1987. By July 2004, the US Food and Drug Administration had authorised the use of 19 ARVs and related fixed-dose combinations as shown in table 1.1 (US FDA 2004). The drugs

can be classified by their pharmacological actions into 4 classes, namely nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), and fusion inhibitors.

Table 1.1: Antiretrovirals approved by the US Food and Drug Administration, as of July 2004

Categories <sup>1</sup>	Generic name	Approval date
1. Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs)	Delavirdine (DLV)	4 April 1997
	Efavirenz (EFV)	17 September 1998
	Nevirapine (NVP)	21 June 1996
2. Nucleoside Reverse Transcriptase Inhibitors (NRTIs)	Abacavir (ABC)	17 December 1998
	Abacavir + lamivudine + zidovudine	14 November 2000
	Didanosine (ddI)	9 October 1991
	Didanosine EC (ddI EC)	31 October 2000
	Emtricitabine (FTC)	2 July 2003
	Lamivudine (3TC)	17 November 1995
	Lamivudine + zidovudine	27 September 1997
	Stavudine (d4T)	24 June 1994
	Tenofovir DF (TDF)	26 October 2001
	Zalcitabine (ddC)	19 June 1992
Zidovudine (AZT or ZDV)	19 March 1987	
3. Protease Inhibitors (PIs)	Amprenavir (APV)	15 April 1999
	Atazanavir (ATV)	20 June 2003
	Fosamprenavir (FPV)	20 October 2003
	Indinavir (IDV)	13 March 1996
	Lopinavir + ritonavir (LPV/r)	15 September 2000
	Nelfinavir (NFV)	14 March 1997
	Ritonavir (RTV)	1 March 1996
	Saquinavir (SCV)	6 December 1995
4. Fusion Inhibitors	Enfuviride (T-20)	13 March 2003

Source: US Food and Drug Administration (2004)

<sup>1</sup> NNRTIs bind to and disable reverse transcriptase, a protein that HIV needs to make more copies of itself. NRTIs are faulty versions of building blocks that HIV needs to make more copies of itself. When HIV uses an NRTI instead of a normal building block, reproduction of the virus is stalled. PIs disable protease, a protein that HIV needs to make more copies of itself. Fusion inhibitors work by blocking HIV entry into cells.

ART is a highly toxic and complex medication. Initially, zidovudine, didanosine and zalcitabine were prescribed singly as monotherapy or as dual drug combinations, but by 1996, it was found that a more effective treatment was to combine three or more ARVs – the so called highly active antiretroviral therapy (HAART) – became common. The use of multi-drug protocols has increased the difficulties not only in individual case management but also programmatic administration. Critical issues in ART as discussed below are major challenges for large-scale treatment delivery, especially in resource-poor settings.

### ***Treatment regimens, therapeutic outcomes and adverse reactions***

Since the mid-1990s, the efficacy of ART has improved progressively; however, it cannot eradicate the virus. Studies suggest that combinations of ARVs from different classes help to delay drug resistance and sustain viral suppression. Currently, recommended treatment protocols – known as HAART – include three drugs, 2 NRTIs and a NNRTI or PI, which can hinder the disease progression and restore immunological functions for significant periods (Enanoria et al. 2004; Smith et al. 2003). With these actions, treatment has contributed to a substantial decline in mortality, reduction in hospitalisations due to OIs, and lowered the need for palliative care (Detels et al. 2001; Lee et al. 2001). In addition, therapy has changed the public perception of HIV/AIDS from a *highly fatal acute* illness to a chronic disease. As argued by Kobayashi (1997:161, quoted in Siegel and Lekas, 2002:569), the medication availability ‘*was said to have reinserted the word ‘hope’ into the discussion about AIDS for the first time in a decade of treatment trials*’. However, the effectiveness of ART varies, due to multiple factors – insufficient adherence, prior use of particular ARVs, and the clinical condition of patients at the time of treatment (Mocroft and Lundgren 2004).

ARVs have different adverse drug reactions which result in both therapeutic and public health implications. Some unwanted effects are uncommon but serious and life-threatening, while others are moderate or mild but may lead to inadequate adherence and treatment interruptions (Volberding 2003). PLWHA who are aware of the serious side effects may hesitate to commence therapy (Phillips et al. 2003). Serious adverse reactions are mostly generated by the toxicities of ARVs on metabolism, for example lactic acidosis and its consequences such as hepatic dysfunctions, lipodystrophy, insulin resistance, and cardiovascular diseases (Montessori et al. 2004). Morphological abnormalities due to the redistribution of fat from face, limbs and buttocks; and accumulation in the abdomen and breast are among patients’

concerns. ARVs commonly recommended in first-line regimens, such as didanosine, nevirapine, efavirenz, and stavudine, may induce significant changes in hepatic histology and enzyme levels. Most of these undesirable effects are predictable and indicate the need for close monitoring of patients' signs and symptoms. Dosage adjustment or change in regimens can be expected in most patients (Volberding 2003). In this light, regular laboratory assays to monitor CD4+ cell counts<sup>2</sup>, viral load<sup>3</sup>, and drug resistance is necessary during the follow up period (Chaisson et al. 1998).

### *Drug resistance*

Treatment efficacy is time-limited since HIV resistance to ARVs can develop as a consequence of incomplete viral replication and mutation under selection pressure (Rubbert and Ostrowski 2003). Various factors encourage resistance, for example inappropriate regimens, treatment interruption and inadequate adherence to medications (Lange et al. 2004). Sub-therapeutic levels of one or more drugs owing to poor absorption, metabolic disorder, or drug-drug or drug-food interactions may trigger resistance in some cases (Kuritzkes 2004). Incomplete viral suppression which leads to resistance has been reported in patients with low CD4+ cell counts and high viral load at the time of therapy initiation (Saag 2003).

When resistance has emerged as indicated by persisting viraemia during the course of treatment, changing the drugs to non-resistant agents of similar or new classes is recommended (Darbyshire 2000). However, such measures may not be effective if the resistance is associated with patients' poor adherence. To avoid resistance and select suitable drugs, a good infrastructure for therapeutic outcome monitoring and testing of resistant strains is essential (Kuritzkes 2004). Though ARV resistance assessment is recommended as an integral part of therapy in developed countries, high costs and lack of skilled personnel are the major obstacles in routinely assessing drug resistance in poor settings (Geretti and Easterbrook 2001; Hirsch 2002).

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<sup>2</sup> CD4 or CD4+ T lymphocytes are a type of white blood cells that coordinate the immune system's functions. When infected with HIV, CD4 are destroyed by the virus. The assessment of serum CD4 concentration is essential for monitoring of the course of HIV infection and the response to therapy.

<sup>3</sup> Viral load is the amount of HIV in blood circulation. Similar to CD4 count, viral load test is a necessary part of HIV and treatment monitoring as the amount of virus in the blood is correlated with disease severity

### ***Medication adherence***

Patients' adherence to ART at rates of over 95% is required to maintain adequate viral suppression (Paterson et al. 2000). As with many chronic diseases, poor adherence to therapy is widespread in both developed and developing countries (Chesney, Morin, and Sherr 2000). Starting treatment at the early-stages of infection, when the patients remain asymptomatic may result in poor adherence, especially where the drugs can induce toxicities or disturbing side effects (Moatti and Spire 2000). Even in those with advanced infection, perfect adherence to life-time medication is difficult to achieve. Patients' concerns that taking the medicines regularly will disclose their HIV status is another barrier to adherence (Roberts and Mann 2000).

Adhering to ART is so complex that it requires integrated behavioural and biomedical efforts (Ickovics and Meade 2002). Adherence promotion strategies comprise wide ranging interventions, focusing on patient, treatment regimens, health care providers, and institutional elements (Simoni et al. 2003). For instance, providers are recommended to spend sufficient time with patients and also introduce measures, such as use of support groups or peer educators to monitor ongoing adherence; to intensify management during periods of suboptimal adherence; and to identify a family member, friend, or partner who will help and encourage the patient to adhere to therapy (Dybul et al. 2002). As Simoni and colleagues (2003) point out, adherence-enhancing measures need providers' leading advocacy as well as patients' and caregivers' cooperation. The effectiveness and feasibility of these strategies are context-specific, and the success usually declines over time (Howard et al. 2002).

ART experiences elsewhere suggest the need for healthcare providers to have sufficient knowledge and experience, as well as sufficient infrastructures to deliver safe and efficient treatment. However, many aspects of ART remain unclear, especially when it is introduced in the developing world (Neaton 2005). This is because studies to inform medication guidelines, systems arrangement and implementation have been mainly conducted in industrialised countries where the HIV context differs from resource-constraint settings. Neaton (2005) argues that in poor health systems, HIV-related morbidity and mortality rates are extremely high, so that the adoption of simplified drug protocols and low-cost laboratory tests is necessary, but some of these 'practical' interventions have not been sufficiently assessed for their benefits or adverse effects in well-designed trials.

## 1.2.2 Public health spill-over of ART

In addition to the effectiveness of ART and associated medical benefits to infected individuals, the introduction of treatment in the health systems has broader positive and negative effects. Many of these spill-over effects remain controversial and require further examination.

### *Positive externalities*

ART may have significant preventive implications for the reduction of sexual transmission because it reduces infectiousness by decreasing viral loads in plasma and seminal fluid (Kashuba et al. 1999; Quinn et al. 2000; Royce et al. 1997). Since the levels of HIV in body fluids is a contributing factor of transmission, it is expected that any interventions able to decrease the viral load can have a role in HIV prevention for all transmission routes (Blower, Schwartz, and Mills 2003). Modelling analyses indicate that ART, when used at a high rate, can reduce annual AIDS deaths and prevent a number of new infections at population level. It has been argued that, however, despite a decrease in the rate of transmission owing to treatment, the incidence rate may not fall because unsafe sexual behaviour of population has more profound effects on the reduction of HIV incidence than does ART (Blower, Schwartz, and Mills 2003; Gray et al. 2003).

Another positive effect of ART is that the awareness of such benefits may encourage PLWHA to seek institutional care from proper settings (Volberding 2003). For those with unknown sero-status who feel hesitant about obtaining HIV counselling and testing because of the absence of effective treatment, ART implementation may motivate them to seek the services which in turn may contribute to safer sex behaviour (Moatti et al. 2003a; Vermund and Wilson 2002). Further, the availability of therapy is likely to have psychosocial benefits for infected persons since it may alleviate feelings of stigma and isolation (Piot and Coll-Seck 2001; WHO/UNAIDS 2004). Some assert that when treated individuals perceive their lives are valued, they will increase adherence to prevention practices (Lancet Infectious Disease 2003). However, the relationship between ART access, people's perceptions, and their care seeking behaviour is complicated. For instance, a study in South Africa indicated that the availability of therapy encouraged uptake of HIV testing among only a small fraction of subjects (Day et al. 2003). The authors suggested that the fear of uncovering HIV status and

stigma might have counterbalanced the perceived benefits of therapy. In the same vein, Brannstrom et al (2005) demonstrate that although ART has been widely accessed in Sweden since 1996, the proportion of PLWHA unaware of their HIV status before AIDS develops – the so-called *late testers* – increased significantly, from 22% in 1996 to 58% in 2002.

The literature also discusses the positive effects of ART delivery on overall health system improvement which benefits non-HIV related conditions in resource-poor settings (Attawell and Mundy 2003). Though the epidemic has overridden the national healthcare system, the World Health Organisation (WHO) (2004e) maintains that scaling-up treatment will upgrade laboratories, human resources, and research capacity. Some stress that, however, such externalities can be developed only when additional resources are adequate and well-organised (Attawell and Mundy 2003; Holmes 2004).

### *Negative externalities*

It is inevitable that widespread use of ARVs will increase the chance of viral mutations and also promote distribution of resistant HIV strains (Blower and Volberding 2002). Following Blower and Volberding, treatment should be introduced concomitantly with strategies to encourage rational prescribing practices and patients' behaviours in order to avoid resistance, and then to promptly manage drug resistance at the time of its emergence.

ART may also undermine HIV prevention efforts. As Siegel and Lekas (2002) point out, living longer with the disease may increase the likelihood of viral transmissions. Moreover, the perception that the disease is treatable can induce the adoption of risky practices. When patients become healthy and live longer, they may be less likely to maintain safe sex practices, and some may want to have children. Studies of sex behaviour among male homosexuals and intravenous drug users in developed countries suggest the rise of risky practices since ART became widely available (Kalichman and Rompa 2003; Katz et al. 2002; Tun et al. 2003). However, unchanged sex behaviour among PLWHA on therapy has also been reported in other settings (Moatti et al. 2003b; Stephenson et al. 2003).

### 1.3 Integrating ART in health systems: resources needed and barriers

Integrating ART in health systems requires considerable care to ensure service quality and programme efficiency (WHO 2000). This includes training health workers in treatment administration; adequate drug supply; reliable laboratory facilities, and access to related services such as counselling, HIV diagnosis, and management of opportunistic diseases (WHO/UNAIDS 1998). See table 1.2. As therapy is just one component of a comprehensive HIV care package, referral arrangements as well as collaboration between health providers, patients and their families and communities are crucial. Moreover, clear, accurate and appropriate guidance on programme administration and linkages between national agencies, local authorities and implementing units have to be well operated (Harries et al. 2001).

Table 1.2: Minimum requirements for introducing ART to the health system

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- Access to voluntary and confidential counselling and diagnostic testing.
  - Reliable, long-term drug supply
  - Laboratory facilities to monitor clinical outcomes and adverse drug reactions.
  - Management of opportunistic infections.
  - Appropriate training for clinicians and paramedics.
  - Support of a social network to help patients adhere to the regimen.
  - Strengthening of health and social services in a continuum of care.
- 

Source: adapted from WHO/UNAIDS (1998)

Common problems faced by health delivery systems in poor countries include inadequate facilities and workforce to deliver even basic services such as immunisation; maternal and child care and nutrition (Lee 2003; Victora et al. 2004). Given that ART is clinically and socially complicated, rolling out therapy in these settings is even more difficult (Mugenyi 2004; Ruxin et al. 2005). Furthermore, the demands for HIV prevention, treatment and care strain the already limited health resources, especially staff, medicines and hospital beds (Mukherjee et al. 2003; Nielsen and Melgaard 2004).

In addition to the increased workloads, the epidemic exacerbates workforce shortages as many health workers have been infected and died of the disease (Chen and Hanvoravongchai 2005). Difficult working conditions, stress and fear of viral contamination result in discouragement, burn out, and absenteeism. In sub-Saharan Africa, growing outward

migration of doctors and nurses both within the region and to Europe and the Middle East has also affected the workforce (Eastwood et al. 2005). In South Africa, for instance, an estimated 29,000 health worker positions are vacant, while an additional 12,000 posts are required in order to achieve the national ART target of 1.5 million in 2009 (Kober and Van Damme 2004). As Marchal and colleagues (2005) argue, however, the staff crisis in the South is not confined to deficiencies in numbers but also to performance and accountability. The literature suggests that knowledge, experience, and attitudes of health personnel are crucial in ensuring high quality treatment (Hsiung et al. 2001; Kitahata et al. 1996; Souville et al. 2003). Training of respective workers can meet some needs – but many other changes inside and outside the health systems are also necessary (Hongoro and Mcpake 2004).

### **1.3.1 Costly drugs and treatment monitoring**

Among the barriers to ART, the high prices of ARVs and laboratory reagents and machines, as well as associated costs of nationwide implementation have been cited as dominant (Bertozzi et al. 2004; Razum and Okoye 2001; Sendi and Gafni 2003). When triple-drug protocols became standard treatment in the late 1990s, first-line regimens cost between US\$10,000 and US\$12,000 per patient per year. By 2001, prices of the drugs had fallen to US\$350 (UNAIDS 2002b). A decrease of over 50% in drug costs was reported in Latin America and the Caribbean between 2001 and 2002 (Bautista et al. 2003). However, most of new drugs used in advanced protocols, necessary for patients with drug-resistant HIV infections are sold at very high prices (Steinbrook 2003).

Costs of ARVs vary across settings and time, depending on many factors such as price regulations, negotiations, patent laws, and generic competition (Hogg et al. 1998; Reich and Bery 2005). In Brazil, owing to the competency of domestic drug laboratories and negotiations between the Health Ministry and transnational companies, ARV prices dropped markedly once the national treatment programme started in 1996 (Teixeira, Vitoria, and Barcarolo 2003). The price reduction was partly due to the Government's ability to produce generic versions irrespective of patent status (Ortells 2003). By contrast, the decrease in drug costs in some countries, for example Cameroon, Kenya and Uganda began much later, and was due to generic importation; global initiatives including those fostered partnerships between international organisations, governments and drug manufacturers; as well as pressure from non-governmental organisations (NGOs) such as Medicins Sans Frontiere (MSF) and

AIDS Coalition to Unleash Power (ACT-UP) (Martinez-Jones and Anyama 2002; National AIDS Control Committee Cameroon 2004). A few African countries – Congo, South Africa and Tanzania for example – obtained ARVs from generic production, enabled by technology transfer from Brazil and Thailand (Chirac 2002; Steinbrook 2004b).

However, although relatively low-priced drugs are now more available, ART remains costly due to expensive laboratory tests (Diomande et al. 2003; Stephenson 2002). Standard CD4+ and viral load assessment test cost over US\$1,000 per patient per year in the industrialised world, and may be higher in developing countries since most reagents and machines are patented (Kumarasamy et al. 2002). Owing to the high costs of monitoring, simplification of methods or exclusion of some assessment from routine practices is recommended (Grubb, Perriens, and Schwartlander 2003).

### **1.3.2 Improving access to ART: estimated costs and feasibility**

The financial burden of HIV treatment on governments, private sector and households changes over time and differs from setting to setting. Costs of HIV programmes are affected by several elements, for example the number of clients, unit prices of drugs and other supplies, logistic and management features of particular services (Hutubessy, Bendib, and Evans 2001). Spending on ART is the major part of the overall resource needs for HIV response (Gutierrez et al. 2004). Owing to expensive ARVs, in many countries with high HIV prevalence and low national income, the costs of nationwide treatment cannot be met by existing domestic resources.

In Latin America and the Caribbean the estimated costs of ART and related laboratory testing account for 51% of US\$937 million required for the comprehensive HIV service package in 2005 (Opuni et al. 2002). In contrast, expenditure on therapy represented only 17% of the requirements of US\$3 billion to finance HIV programmes in Asia-Pacific countries in the same period (ADB/UNAIDS 2005). The variation in the proportions of resource allocation for ART reflects the difference in HIV policy of countries in the two regions: i.e. in Latin America and the Caribbean policy is to provide wide access to therapy, while in Asia other services are emphasised.

At the global level, to achieve the goal of an initiative organised by WHO to get 3 million PLWHA on ART by 2005, the estimated funding requirements range between US\$5.1 billion and US\$5.9 billion, which cover ARVs, treatment monitoring, counselling, HIV testing, management of complications, palliative care, and support activities (Gutierrez et al. 2004). Such projections are based on the best use of the existing health system resources; advocacy to lower the costs of ARVs and diagnostics; and cooperation of PLWHA and communities. However, the resources needed for the scale up of treatment includes expenditure on routine services, and also workforce and infrastructure development. Introducing ART in settings with structural inadequacies and weak management means that the health system has to be upgraded and large investments are therefore indispensable (Kumaranayake 2002b; Schwartlander et al. 2001).

Although the resources required for HIV prevention and care are immense, surpassing financing capacity of governments and people in many settings, it has been argued that scaling up ART is affordable and feasible if resources are properly mobilised and well allocated (ADB/UNAIDS 2005; Bertozzi et al. 2004). In this respect, the strategies proposed comprise not only mobilising funds from high-income countries and other sources such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), but also using every effort<sup>4</sup> to bring down the costs of ARVs and treatment monitoring. Importantly, it is emphasised that treatment cannot be sustained unless HIV prevention measures are introduced effectively. This is because the growing number of infected cases implies resources for therapy in the future which continue to rise.

#### **1.4 Treatment advocacy**

Improving ART coverage in the developing world during the past decade has been attributed to multisectoral efforts to mobilise resources, overcome impediments, and encourage political commitment (UNAIDS 2002b). HIV activism which has long promoted the rights to care and medical services among PLWHA has played, and continues to play an important role in ART access at the global and country levels (Ammann and Nogueira 2005; von Schoen Angerer et al. 2001). For example, in Honduras, treatment organisations of HIV-infected people and AIDS activists, strongly supported by the general public, influenced the Health Ministry to

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<sup>4</sup> For example, use of generic products; differential pricing; price negotiation; voluntary license agreements; compulsory licensing; bulk purchasing; and donations (Reich and Bery, 2005).

establish an ART programme in 2002 (Ortells 2003). Likewise, the creation of an AIDS drug fund – FONSIDA – in Mexico, and the adoption of a national policy to ensure medication access in South Africa in 2003, was the result of pressure from local and international NGOs (Abdool Karim 2004; del Rio and Sepulveda 2002; Willan 2004).

Apart from organising policy campaigns, coalitions of NGOs, academic, and professional associations have taken part in providing technical, financial and other support to therapy delivery (Paiva et al. 2002). An example can be drawn from MSF prevention and treatment programmes which cover over 13,000 PLWHA in 25 countries (MSF 2004b). Furthermore, civil society networks have been actively involved in making cheap ARVs and laboratory reagents available by accelerating product approval, negotiating with research-based and generic drug companies, and promoting the use of compulsory licensing and parallel importation to mitigate the impact of patents on drug prices and accessibility (Reich and Bery 2005; von Schoen Angerer et al. 2001).

The activities of international agencies have also been vital (Piot and Coll-Seck 2001; UNAIDS 2002b). The first international attempt to improve access to ARVs and drugs for opportunistic diseases – so called the HIV Drug Access Initiative (DAI) was founded by the Joint United Nations Programme on AIDS (UNAIDS) in 1997 (Saba 1998). The Initiative encouraged collaboration among key stakeholders to address treatment barriers. Five research-based drug companies were involved in the discussions regarding price reductions. However, the project was limited to 4 countries: Chile, Cote d'Ivoire, Uganda and Vietnam (UNAIDS 2000). The effort to expand HIV treatment was maintained through a collaboration – known as the Accelerating Access Initiative (AAI) launched in 2001 – between the United Nations (UN) agencies and pharmaceutical industry (UNAIDS 2001a). The same year the UN Secretary General called for intensifying public-private partnerships to increase access to HIV treatment. Through the initiative, drug price reductions and donations made ART feasible in pilot-scale programmes in 26 poor countries.

The UN also took on a stronger advocacy role in early 2000s, encouraging its members to address the epidemic and its consequences. For example, in 2000, reversing the spread of major infectious diseases including HIV was included as a component of the Millennium Development Goals (United Nations 2002). Following the United Nations General Assembly Special Session (UNGASS) Declaration of Commitment to tackle HIV/AIDS (United Nations

2001), all countries agreed to scale up response to HIV epidemic including treatment extension. Funding for ART was also increased through several multilateral and bilateral initiatives (WHO 2002a).

In January 2002, the GFATM was established to mobilise funds for HIV programmes in the South. This financial mechanism attracted, managed and disbursed additional resources through a partnership between industrialised and less developed countries, WHO, UNAIDS, private sector, and civil society (GFATM 2003). As of January 2005, US\$754 million had been disbursed for HIV which enabled 130,000 people to receive ART and more than 1 million to access voluntary HIV testing (GFATM 2005b). Apart from the GFATM, other sources of treatment funding include the World Bank's Multi-country AIDS Programme (MAP), the US President's Emergency Programme for AIDS Relief (PEPFAR), and philanthropic organisations such as Bill & Melinda Gates, and Clinton Foundations (WHO 2002a). Donor countries, for example Canada, France, Germany, the Netherlands, Norway, the UK and the US, also increased their contribution to HIV initiatives in resource-poor nations through the GFATM and bilateral mechanisms (UNAIDS 2004a). All international commitments to HIV/AIDS resources in 2005 amounted to US\$5.1 billion (GFATM 2005a). Another step to extend ART was taken in September 2003, as the WHO in collaboration with the GFATM and UNAIDS announced a programme known as '3 by 5' to provide ARV treatment to 3 million people in the developing world by 2005 (Lee 2003). The campaign aimed not only to ensure quality ART access, but also to promote disease surveillance and integrated treatment-prevention activities, all of which were expected to have spill-over effects for strengthening health systems as a whole (WHO 2004e). Although the 3 by 5 Initiative is acknowledged for improving therapy access, its ambitious target is unlikely to be achieved (The Lancet 2005).

### **1.5 Debates on ART provision in developing countries**

Previous sections illustrate the major financial and organisational impediments to scaling up ART in resource-poor settings, as well as the concerted efforts to overcome such obstacles and facilitate treatment extension over the first half of 2000s. However, the quest for increasing access to therapy has not been consensual. The next section looks at some of the debates around expanding ART.

### 1.5.1 When to instigate treatment programmes?

As low-cost medicines and funding for ART have become increasingly available, attention shifted from the problems of affordability to the readiness of health systems to instigate treatment and expand coverage (Beattie 2003; Kasper et al. 2003). Some have argued that to avoid ‘ART anarchy’, i.e. poor compliance with therapy protocol on both demand and supply sides, drug resistance development, and disinhibition among treated patients – well-prepared healthcare providers and sustainable financing are necessary (Harries et al. 2001; Stevens, Kayne, and Corrah 2004). For example WHO, prior to the 3 by 5 Initiative, emphasised the readiness of health systems as the prerequisite of ART delivery: *‘Due to the high cost of antiretroviral drugs, the complexity of the regimens and the need for careful monitoring, specific services and facilities must be in place before considering the introduction of ART into any setting.’* (WHO 2000:16).

On the other hand, some have argued that therapy should be rolled out immediately since delays hamper the opportunities to save lives, stabilise productivity, and revitalise the economy (Binswanger 2003; Piot and Coll-Seck 2001). Arguments include the proposition that treatment delivery will have positive spill-over effects for health systems as a whole (Buve, Kalibala, and McIntyre 2003; Piot and Coll-Seck 2001). When WHO launched its 3 by 5 Initiative, it supported the latter view, in spite of earlier statements about the need for the health system to be secure. For example, Lee (2003:2086) argued that the attempt to improve ART coverage in the South would facilitate the development of workforce and infrastructure. In addition, in order to achieve the 3 by 5 goals the organisation advocates simplified, adapted therapeutic regimens and monitoring techniques which suit implementation environment in resource-poor settings (WHO 2002c). Others have warned, however, that such interventions may lead to a trade-off between sub-standard practices and quality (Schechter 2003).

### 1.5.2 Valuing costs and outcomes of ART

Economic assessments of health interventions provide useful information for resource allocation (Hutubessy, Bendib, and Evans 2001). Many arguments against scaling-up ART in the developing world are based on its poor value for money. Although ARV prices have dropped dramatically, medication remains prohibitive and less cost-effective than most HIV prevention measures (Creese et al. 2002; Marseille, Hofmann, and Khan 2002). It is therefore

suggested that scarce resources should be allocated to prevention rather than treatment. Respecting cost-minimisation, Brazil's ART programmes demonstrate that substantial resources could be saved from therapy-attributed reduction in OIs (Marins et al. 2003). However, the economic impact of treatment is setting-specific, noticeably depending on how well the programmes are organised (Hutubessy, Bendib, and Evans 2001). Where poor adherence and drug resistance are prevalent, the benefits of ART tend to be trivial compared to costs.

The proponents of therapy extension respond to such arguments in different ways. Some criticise existing economic studies as biased, since positive externalities of medication have been excluded from the models (Boelaert et al. 2002; Yazdanpanah 2004). Others maintain that despite the immense costs of ART, the costs of not providing therapy are enormous because leaving people sick and dying in the prime of their productive life will result in severe psycho-social and economic devastation (van Dam and Hutchinson 2002). The Commission on Macroeconomics and Health (2001) argued that HIV treatment is vital for economic stabilisation and restoring economic development in highly-afflicted areas.

The context of implementing ART in the developing world is subject to rapid changes in ARV prices and uncertainty in its outcomes, which makes economic analysis of HIV programmes difficult, unavoidably limited, and controversial in its role of informing policy (Hutubessy, Bendib, and Evans 2001; Kumaranayake 2002a; Mills and Shillcutt 2004). ART advocating organisations including the WHO, UNAIDS and GFATM have found themselves more comfortable making policies on the grounds that economic assessment and utilitarian-based concepts are important, but insufficient for those involved in policy and priority-setting processes (Boelaert et al. 2002). Thus, current mainstream policies tend to propose simultaneous investment in ART and HIV prevention (Lee 2003; United Nations 2001).

### **1.5.3 Roles of ideologies in ART**

ART advocates use different ideologies in the campaigns for increasing treatment coverage around the world, often covering notions of human rights, equity and ethics (Annas 2003; Heywood 2002; Schneider 2002).

Many argue that *'health is a human right'*, and all parties have obligations to promote health for all people irrespective of their illness conditions (Patterson and London 2002). Some make the point that because of limited access to effective treatment and care, HIV infection equals a death sentence thus global apathy and inaction should be regarded as a crime against humanity (Hogg et al. 2002). The right to obtain proper HIV medications has been adopted as part of many international frameworks. As stated in the International Guidelines on HIV and Human Rights, for instance, *'access to HIV/AIDS-related treatment is fundamental to realizing the right to health.'* (UNAIDS 2003b:13). Following Patterson and London (2002), there is an increasing body of international agreements, treaties and law drawn on a human right basis which benefits treatment access. Examples are the Declaration of Commitment issued by the United Nations General Assembly Special Session on HIV/AIDS, the Doha Declaration, and the Inter-Parliamentary Union's Handbook for Legislators on HIV/AIDS, Law and Human Rights (UNAIDS and IPU 1999; United Nations 2001; World Trade Organization 2001).

Paradoxically, the values of ethics have been used for and against ART in the South. Ethically-oriented concepts are introduced to oppose policy decisions developed on economic grounds. Boelaert and colleagues (2002) argue, for example, the rationale for treatment in industrialised societies is not based on its cost-effectiveness but the contribution to health and quality of life of PLWHA. The authors (2002:1002) also maintain: *'Sound and democratic decision making is not only grounded on technical evidence, but also on ethical principles, respect for and fair representation of the interests of patients, their families and communities'*. According to many activists, despite unsatisfactory cost-effectiveness ratios, access to a health intervention should be strongly encouraged if it is life-saving (von Schoen Angerer et al. 2001).

However, ethics-guided discourses, based on the clash between individual rights to life-saving services and the public interest, have also *opposed* large-scale medication in resource-poor settings (Sills 1994). Some suggest to withhold therapy to patients who are potentially poor adherers, for example homeless and transient persons, drug addicts, and the mentally ill (Eckenwiler 1999). These assertions are supported by the fact that inadequate adherence may lead to drug resistance. This not only wastes resources but may also release unmanageable drug resistant viral strains to a wider population. Others contend that restraining access to ART is unethical as it may force these people to seek sub-standard and un-supervised use of

medicines from the black market (Buve, Kalibala, and McIntyre 2003; Friedman, Wainberg, and Drucker 1998).

With respect to a fundamental professional ethic of ‘doing no harm’<sup>5</sup>, it has been argued that healthcare providers are obliged to deliver HIV treatment and to ensure best practice including facilitating adequate adherence and offering prevention interventions (Friedman, Wainberg, and Drucker 1998; Popp and Fisher 2002). As Von Schoen Angerer (2001) emphasises, failing to provide the most feasible, available treatment to patients is also an act against physicians’ ethics. This argument goes on to propose that, it is the mutual obligation of all social institutions including families and infected individuals, to foster adherence through all feasible measures, rather than resist expansion of ART coverage.

The above contentions are contradicted by others. Pronyk and colleagues (2001) simply raise the question ‘*Is antiretroviral treatment a solution or merely a further complication for countries in sub-Saharan Africa and elsewhere?*’. The ‘doing no harm’ norm, when applied to the case of ART in incompetent health systems, may harm the public, and so implementing therapy should be avoided. Instead, policy should be to prescribe OI prophylaxis which is less complicated, more affordable, and to some extent effective in prolonging patients’ lives.

Finally, there are concerns about equity. Inequitable access to ART between the North and the South, as well as in-region and in-country inequities suggest the need to increase treatment coverage, especially in poor settings. Practically, however, the expansion of ART which cannot meet the demands in all countries has led to inequities. The limited success of international plans such as the Accelerating Access Initiative in lowering drug prices in some areas offers an illustration:

*‘Prices for antiretroviral medications in Honduras dropped 85%, down to about US\$1,300 yearly. Yet in bordering Nicaragua, ..., the price for ART remains above US\$5,000 yearly for most cocktails. This phenomenon occurs because UNAIDS implemented its Accelerating Access programme in Honduras, successfully, and multi-national companies reduced their prices dramatically.’* (Stern 2002)

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<sup>5</sup> Hippocratic Oath: “...I will do so to help the sick, keeping myself free from all intentional wrongdoing and harm, ...” (<http://www.www1.umn.edu/phrm/oaths/oath1.html>; accessed 29 October 2004)

From an extreme view, some note that ART programmes should not be launched unless equitable access for all clinically-eligible PLWHA is guaranteed (Binswanger 2003; von Schoen Angerer et al. 2001). The literature also illustrates the assertions that providing medication in less developed societies can undermine existing inequitable levels of access to health care (IDRC 2004). For instance, financing ART may drain resources needed for primary care services which usually benefit a wider range of people (Holmes 2004; von Schoen Angerer et al. 2001). Under pressure from international advocacy that supports responses to a particular disease the government may re-prioritise national health problems accordingly, distracting attention, resources, and management efforts away from other needs.

## **1.6 Summary**

This chapter provides background information on HIV and ART. Despite substantial prevention efforts, between 1980 and 2000 the virus spread progressively throughout different parts of the world, affecting developing countries in particular. From the mid-1990s the use of antiretroviral drugs as combination regimens proved effective in reducing viral load and restoring immune functions. Experiences in the North illustrate significant benefits of therapy as well as several caveats. Integrating ART into a health system requires sufficient resources to assure service quality. For most settings in the South, the immense costs of ARVs and treatment monitoring and lack of experienced health workers are great impediments in delivering this life-saving medication. Over the past few years, advocacy for treatment expansion has been substantial, through the movement of civil society organisations and several initiatives at the global level. However, scaling-up ART programmes in poor countries has not occurred with consensus, and there continues to be considerable debate within discourses on ARVs and AIDS.

## CHAPTER 2: ART IN RESOURCE-POOR SETTINGS

Chapter 1 discusses the barriers to antiretroviral therapy (ART) of people in the developing world, and the global movement to deal with such obstacles. This chapter reviews treatment programme implementation in poor countries, focusing on how treatment is integrated into the health delivery system. It sets the context of this study, by reviewing Thailand's health delivery system, human immunodeficiency virus (HIV) problems and government policy responses including the evolution of the national treatment programme.

### 2.1 ART in resource-limited countries: diffusion and coverage

When zidovudine monotherapy was initially introduced, the high price of the drug restricted access among most patients even in industrialised societies (Peck and Bezold 1996). Information on the coverage of zidovudine medication in resource-poor settings in the same period is scant. Evidence suggests that it was not until the early 1990s that treatment was provided outside the developed world as Brazil and Thailand began small-scale zidovudine programmes in 1991 and 1992, respectively (Chequer et al. 2002).

In 1996, Brazil became the first developing country to offer universal and free access to antiretrovirals (ARVs) (Galvao 2002). The number of treatment clients in Brazil steadily increased to 106,000 in 2002, representing over half of people living with HIV/AIDS (PLWHA) on medication in the developing world (Chequer et al. 2002). The improved survival rates and cost savings due to the reduction in opportunistic infections as well as related hospital admissions were dramatic (Levi and Vitoria 2002; Marins et al. 2003). Owing to such success, the Brazilian ART programme has been acknowledged as a model for settings in the South (UNAIDS 2002b). Following Brazil, small-scale medication was initiated in several countries between the late 1990s and early 2002 (del Rio and Sepulveda 2002; Desclaux et al. 2003; Katzenstein, Laga, and Moatti 2003; Laurent et al. 2002; Okubagzi and Singh 2002). Promising therapeutic outcomes comparable to the North were observed in pilot and community-based programmes in Ethiopia, Haiti, Mexico, Senegal, South Africa and Uganda (MSF 2004b; Walton et al. 2004; Weidle et al. 2002; WHO 2003a).

However, access to HIV treatment and care including ART in poor settings is limited. In 2001, global ART coverage reached only 2% of an estimated 5.4 million population in need (WHO

2002b). Although therapy has expanded steadily – the number of people receiving ARVs in low- and middle-income countries increased from 440,000 to 970,000 in 2004/2005 (WHO/UNAIDS 2005b) – the service remained inadequate covering only 15% of people needing therapy in 2005.

ART expansion varied across regions and countries. Latin America and the Caribbean made the most significant progress as by 2002 some countries such as Argentina, Brazil, Chile, and Cuba had achieved almost universal coverage (Chequer et al. 2002; WHO 2002b). By June 2005, the World Health Organisation (WHO) and Joint United Nations Programme on AIDS (UNAIDS) (2005b) estimated that in the whole region, 290,000 or 62% of clinically eligible PLWHA were receiving treatment. In the same period the lowest ARV coverage of 5% was reported in North Africa and the Middle East, of an estimated 80,000 population in need. By contrast, the highest HIV prevalent area is sub-Saharan Africa, even on that continent the number of people on medication grew considerably from 310,000 to 500,000 in 2004/2005. However, almost 90% of people needing treatment could not access ARVs.

In summary, although ARV combinations have been in use for therapeutic purposes since the mid-1990s, treatment extension in the developing world has developed only slowly. As a result, only small fractions of PLWHA have access to life-saving medication.

## **2.2 ART programme configurations in an era of scaling-up**

From 2000, substantial progress has been made in ART extension in resource-poor countries. The emphasis of stakeholders has shifted from how to obtain adequate funding for drugs and related services to how to deliver therapy effectively (Gilks 2001; Marchal, De Brouwere, and Kegels 2005). The literature illustrates the variation in patterns of ART programme arrangement, participating organisations and individuals, and financing components.

### **2.2.1 Models of ART delivery in the public sector**

In the North, ART is mostly offered through specialised centres for HIV treatment and care (Bogaards and Goudsmit 2003). In areas with low density populations such as Australia, treatment is primarily provided by general practitioners in community care units, as part of comprehensive referral systems. In contrast, the models of medication delivery in resource-

poor settings are diverse (Stewart, Padarath, and Bamford 2004). ART may be managed as a vertical scheme; may be integrated into existing programmes such as those for HIV/AIDS, other sexually-transmitted infections and tuberculosis; or may be delivered through normal health delivery services including hospitals and primary health centres (Jaffar et al. 2005).

Although in many settings ART has been recognised as a component of prevention and care for PLWHA, therapy is prescribed and followed-up in limited certified sites, while general care is often provided through broader health services. This is the case in Botswana, Cameroon, India and Indonesia (Day 2005; de Korte, Mazonde, and Darkoh 2004; National AIDS Control Committee Cameroon 2004). Kenya is perceived to have a well-coordinated system of care, with certified facilities determined on the basis of geographical coverage and HIV burden (Mundy 2003). These ART-delivery sites also offer other HIV services, and act as referral centres for patients from several entry points, for example tuberculosis clinics, prevention of vertical HIV transmission centres, and voluntary counselling and testing units. In the countries with prevalent HIV infections among injecting drug users (IDUs) such as Indonesia, Malaysia and Vietnam, therapy is also integrated into drug dependence treatment programmes (Ali, Rahmad, and Yaakob 2005; WHO/UNAIDS 2005a).

Since ART coverage has improved, the needs for long-term hospitalisation have fallen markedly (Sabin 2002). Some settings make use of existing home-based care programmes to reduce the burden on the health delivery system. In Cambodia and Uganda, caring for PLWHA in their home with support from health workers is seen to enhance the effectiveness of counselling and education for patients and their families (DeJong 2003; Sano 2005). It is maintained that, furthermore, home care model benefits patients in remote areas where travelling and accommodation costs are expensive.

### **2.2.2 Range of partners involved in treatment scaling up**

Substantial numbers of ART programmes in the developing world have evolved from pilot-scale initiatives organised by multiple partners, ranging from government agencies, private corporations, non-governmental organisations (NGOs), international organisations and donors. The public-private-civil society partnership notion remains vital in the treatment scaling-up

period, and is usually incorporated in national HIV/AIDS plans of many countries (Stewart, Padarath, and Bamford 2004).

The private sector is included in many national frameworks to improve treatment access. But the nature of such involvement is extremely diverse. Some private hospitals have been certified by the government to deliver ART as part of extended treatment plans in Cameroon (National AIDS Control Committee Cameroon 2004). On the other hand, the South African Government has no policy to oversee treatment and care for HIV in private facilities, though attempts have been made to ensure standard service quality in both public and private sectors (South African Ministry of Health 2003). Transnational and local corporations in Botswana, Cote D'Ivoire, India, Rwanda, and South Africa play a role in ART provision to their employees and dependants (Global Business Coalition on HIV/AIDS 2003; UNAIDS 2004a). In many African, Asian, Latin American and the Caribbean settings, ARVs are also offered through private clinics and pharmacies (Brugha 2003; Macharia et al. 2003; Wheeler et al. 2001).

Pilot projects in Haiti, Uganda and elsewhere demonstrate the effectiveness of community approaches in HIV prevention and care (DeJong 2003; Farmer et al. 2001; Wendo 2005). Among the key activities prior to rolling out large-scale ART, is targeting and mobilising communities to raise awareness about the benefits and vital elements of treatment, as well as their potential role in supporting treatment administration (WHO 2002c). The involvement and solidarity of lay people and community-based organisations in partnership with other NGOs has been rising, especially in Africa, as witnessed in the creation of the Partnership for Access to Antiretrovirals in 2002 (WHO/UNAIDS 2005a). In some settings, these organisations import ARVs and deliver medication to people in need, and also take part in organising campaigns for access to treatment at the national level.

PLWHA – those formed into *'self help'* groups – have also had a role in hospitals and communities: offering mental support, reducing stigma, promoting adherence and facilitating uptake of therapy, as well as counselling and testing among people with unknown HIV status (DeJong 2003). A global initiative – the so called Collaborative Fund for HIV Treatment Preparedness – was launched in 2003, aiming to provide support for different preparedness activities through small grants to NGOs and PLWHA groups in Africa, Latin America, the Caribbean, Asia and Eastern Europe (WHO/UNAIDS 2005b).

### 2.2.3 Financing ART

An important feature of ART provision is how treatment is financed. Government budget and health benefit plans are responsible for the major HIV expenditure in many middle-income settings, for example Panama (73%), Mexico (87%), and Chile (99%) (UNAIDS 2004b). In other countries where medication is inadequately offered through public programmes, some PLWHA access treatment is funded through NGOs and private business (Global Business Coalition on HIV/AIDS 2003; UNAIDS 2004a). Whether treatment comes from the public or private sector, the main burden of care for PLWHA in many societies falls on households – many of which cannot afford treatment.

In the scaling-up era, '*new money*' from several international funds and philanthropic organisations has poured into poor countries. From 2002, multilateral and bilateral donors have also had an increasing role in therapy extension (Mukherjee et al. 2003). Rwanda is an obvious illustration. In 2000, total HIV expenditure was US\$5.6 million, 41% of which came from afflicted households (Partners for Health Reform plus 2005). In 2002, overall costs for HIV response amounted to US\$9.9 million, and the share of out-of-pocket payments dropped to 16%, while external and public resources accounted for 75% and 9%, respectively. Funds committed for scaling up ART in the South during 2004 to 2005 came from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), World Bank, the US President's Emergency Programme for AIDS Relief (PEPFAR), Clinton Foundation, and governments of Belgium, Italy, Luxembourg, the United Kingdom and the United States (WHO 2005c). The role of international initiatives in this period was significant, especially in highly endemic areas such as many southern and eastern African settings where the financial support for HIV prevention and treatment from outside accounted for over half the countries' total health budgets (Bennett, Boerma, and Brugha 2006).

The analysis of resource flow and funding recipients within particular countries illustrates the configurations of ART delivery. In Mexico, for instance, treatment costs are subsidised through 5 social security institutions, while the uninsured access the service through the government's National Fund for Persons Living with HIV/AIDS (Bautista et al. 2003). In contrast, in South Africa the government budget for ART implementation is allocated directly from the National Treasury to provincial governments, down to public hospitals and district health centres (South African Ministry of Health 2003). Fragmented financing patterns can be

observed where there are several donors, as each funding agency focuses on different activities, for example drug procurement, treatment delivery, community- and home-based care, prevention, and development of infrastructure (WHO 2005a; WHO 2005c).

### **2.3 Implementing ART in the developing world: the on-going challenges**

A growing body of literature on the introduction of ART in low- and middle-income countries suggests that the success in organising pilot projects is not easily replicated when treatment is brought to a large scale. While clinical effectiveness, acceptable adherence rates and low resistance are experienced in many parts of the developing world, unsatisfactory outcomes and threats of negative consequences in broad respects have also been reported in some settings (de Korte, Mazonde, and Darkoh 2004; Kasper et al. 2003; Marins et al. 2003). The ART initiative in China offers a good illustration. The Chinese government launched free medication programme in poor areas in April 2003, and experienced many difficulties including a drop out rate of almost 20% in the first seven months (Pan 2003).

At the global level, despite the unprecedented increase in resources for HIV over the past few years, the gap between the amount pledged by donors and requirements remains immense. As ART provision in most developing countries is reliant on external funds, this raises a difficult question about service sustainability (GFATM 2005a; WHO/UNAIDS 2005b). The uncertainties of treatment programme financing and long-term support from international initiatives are well recognised. For instance, a WHO senior official pointed out, *'We're going to reach a crisis in terms of supply very very soon ... of antiretrovirals throughout the developing world because the scale-up is happening very very quickly.'* (Jim Yong Kim interview in Zarocostas 2005:1104). Poor coordination between funding agencies and individual projects; conflicting interests of donors; and donor-driven agendas have been reported in recipient nations (National AIDS Control Committee Cameroon 2004; State Council AIDS Working Committee Office-China 2004; Taegtmeier and Chebet 2002), all of which threatens the efficiency of ART implementation.

As suggested elsewhere, impediments in delivering quality ART are also attributed to inadequate staff, infrastructure and drug and reagent supply. In Malawi, for example, staff shortage is so severe that *'in the event of loss of the only clinical officer at a treatment site, many patients and families could be negatively affected leading to cessation of therapy ...'*

(Muula 2004:418). Resource and management constraints, poor geographical distribution of ARVs and other medical services for PLWHA are reported (Day 2005; de Korte, Mazonde, and Darkoh 2004). For instance, although the sites to offer medication have been extended, essential laboratory tests are available only in urban areas or large cities (Muula 2004). During the scaling-up era, governments request technical assistance in many areas such as training, management, planning, monitoring and evaluation from the WHO and other United Nations specialised agencies (WHO/UNAIDS 2005a; WHO/UNAIDS 2005b), requests which are not always met. Slow progress in recruitment and capacity building of health personnel and community workers has been highlighted concomitantly with the problems of internal and external brain drain in sub-Saharan African settings (WHO 2005b; WHO 2005d). Evaluations also report high levels of stigma which act as a barrier to treatment access and adherence among people in need (WHO 2005b; WHO 2005d). Variation and inconsistency in regimens prescribed are prevalent, even though national guidelines have been established (Bautista et al. 2003).

Although ARV prices have fallen considerably, treatment remains unaffordable for large numbers of PLWHA, particularly where there is a lack of support from government or social insurance. The high costs of ART and complementary services are said to be the major factor impeding treatment access and adequate adherence in Malawi, Mexico, and Nigeria (Bautista et al. 2003; Partners for Health Reform plus 2004; van Oosterhout et al. 2005). Shortage of ARVs, drugs for opportunistic infections (OIs) and other supplies owing to over-enrolment of clients, delays in budget release and poor performance in procurement are also evident in these settings.

In some countries, mismanagement in the drug system has resulted in the leakage of donated ARVs to unauthorised health facilities and black markets, as well as re-exportation of the drugs to industrialised countries (Desclaux et al. 2003; Siringi 2004). Within official treatment delivery networks, studies in African settings illustrate the use of substandard and counterfeit drugs that reflect unreliable selection, procurement, logistics as well as ineffective drug regulation (Ahmad 2004; Pau et al. 2005; Penzak et al. 2004). In addition, as the cold chain system does not always work well in areas where ART programmes are implemented, high temperature and humidity are common factors accelerating drug decomposition (Pau et al. 2005).

There are also significant challenges to individual case management resulting from clinical conditions of PLWHA, as many access institutional care and start treatment at advanced stages, with low CD4+ levels and OIs (Bautista et al. 2003; de Korte, Mazonde, and Darkoh 2004). Standard practice guidelines suggest that such complications should be treated before ART initiation; however, therapy is infeasible in some countries because of the lack of appropriate medicines (Muula 2004). Moreover, HIV patients in many areas are commonly infected with tropical or sub-tropical diseases, for example amoebiasis, leishmaniasis, malaria, strongyloidiasis, and trypanosomiasis (Grant and DeCock 2001; Harms and Feldmeier 2002), comorbidities which increase the complexity of ART and costs of treatment provision. Specific expertise and extra resources are needed to address such problems.

As the goal to deliver universal coverage for HIV treatment and care is difficult to achieve, governments face other challenges in allocating scarce resources across interventions, groups of population, and geographical areas. While the literature on the effect of ART introduction for resource diversion from other public programmes is limited, inequity in access to ARV medication has been observed in many countries (Bautista et al. 2003; Day 2005; Msellati et al. 2003; Partners for Health Reform plus 2004). The poor, uninsured, IDUs, men having sex with men, and remote or isolated populations often have less opportunity to receive therapy than others, as a consequence of existing vulnerability; stigma and fear attached to HIV/AIDS; inadequate information; and poor commitment of government. In HIV-prevalent settings with scarce resources, rationing ART in accordance with the criteria other than clinical eligibility is almost always inevitable, and debates around issues of ethics and equity continue (Bennett and Chanfreau 2005; Daniels 2005).

## **2.4 Introduction to Thailand's health system**

Thailand's health system is pluralistic, involving various organisations in public, private and civil society sectors. The Ministry of Public Health (MOPH) is the national health authority responsible for implementing and coordinating programmes on health promotion, disease prevention and medical service delivery (Ministry of Public Health 2005). In addition to the Health Ministry, some disease control activities including HIV prevention and treatment are jointly carried out through the collaboration of many public agencies, private business and CSOs.

Many MOPH departments have regional offices in the 12 health regions. These offices include, for example, the Regional Disease Control Offices, Regional Centres for Health Promotion, Regional Centres for Cancer Treatment, and Regional Medical Laboratory Centres (Ministry of Public Health 2002b). These agencies are in charge of vertical programme implementation. Some, for example the Regional Centres for Cancer Treatment and Regional Medical Laboratory Centres, have sufficient resources to carry out all of the activities in charge. For others including the Regional Disease Control Offices and Regional Centres for Health Promotion, some of their responsibilities are to execute the programmes which target wide population, such as immunisation, health promotion and family planning. These programme activities are integrated into provincial health delivery system, carried out by health workers in hospitals and other health care settings. In such cases, the Regional Centres/Offices take a coordinating role, and provide technical and management support to Provincial Health Offices (PHOs), hospitals and local administrations.

The MOPH also delegates some functions and authority to PHOs in 75 provinces. Primarily, the PHOs are responsible for provincial planning, budget allocation, disease surveillance and reporting, consumer protection of food and health products, medical premise registration, and monitoring health professional practices. They also supervise and coordinate all MOPH health delivery facilities in the province. For the national programmes those require health workers to be implementers: the PHOs act as collaborators between Regional Offices and implementation units. Special arrangement is introduced in the capital city of Bangkok, where health programme development and implementation are responsible by local government – the Bangkok Metropolitan Administration.

#### **2.4.1 Health service facilities**

Thailand has a relatively well-established health delivery system in terms of specialisation and geographical coverage of health care facilities. By the early 1990s, the health service network in the public sector had expanded to cover all urban and rural areas, i.e. in sub-districts and villages. Disease prevention interventions and medical services are mainly organised and delivered by MOPH facilities (table 2.1).

Table 2.1: Number of health facilities by type and administrative level, 2003

	Bangkok Metropolis	Regional	Provincial	District	Sub- district	Villages
Medical schools	5	4		-	-	-
Specialized hospitals <sup>(a)</sup>	19	40	-	-	-	-
General hospitals						
Public (MOPH)	5	25	70	-	-	-
Public (others) <sup>(b)</sup>	24	-	57	-	-	-
Private	100	-	246	-	-	-
District hospitals	5	-	-	725	-	-
Health centres	61	-	-	214 <sup>(c)</sup>	9,765	-
Primary health care centres	-	-	-	-	-	66,223
Private clinics	3,100	-	11,853	-	-	-
Pharmacies	3,393	-	4,832	-	-	-
Drug stores <sup>(d)</sup>	565	-	4,088	-	-	-

Source: data from Ministry of Public Health (2005).

Note: <sup>(a)</sup> For example, psychiatric hospitals, cancer prevention and control centres, communicable disease hospitals and drug dependence treatment centres; <sup>(b)</sup> organised by non-MOPH agencies such as Ministries of Interior and Defence, Bangkok Metropolitan Administration, and state enterprises; <sup>(c)</sup> municipal health centres; <sup>(d)</sup> managed by non-pharmacist professionals such as nurses and midwives

In 2003, primary health care centres, run by community health volunteers, existed in over 66,000 villages. These settings provided basic treatment for minor illnesses, and also offered essential information on healthy practices for health promotion and disease prevention (Ministry of Public Health 2005). At sub-district level, 9,765 MOPH health centres are first-line health care units at which services are delivered by midwives and technical nurses. The other 214 health centres are located in urban areas, organised by local administrations including municipalities and the Bangkok Metropolitan Administration. At these facilities, services are provided by medical doctors and other health professionals. In 2003, there were hospitals with at least one general practitioner established in 725 out of 795 districts (91% coverage). Secondary and tertiary care, emphasising curative treatment, is delivered by specialists in specialised centres and general hospitals at provincial, regional or metropolitan levels, largely by the MOPH (Ministry of Public Health 2005).

The private sector also has a role in health care delivery, especially through clinics, pharmacies and drug stores which offer primary services for minor illnesses. In 2003, there were some 15,000 private clinics, 8,200 pharmacies and 4,600 drug stores, mostly located in Bangkok, provincial capitals and districts (Ministry of Public Health 2005). In addition, people could seek institutional care from 346 private hospitals, most of which were concentrated in the capital city and urban areas of some provinces. The share of hospital beds in the private sector was 20% of the total 133,245 beds available in 2003 (Bureau of Policy and Strategy 2004c).

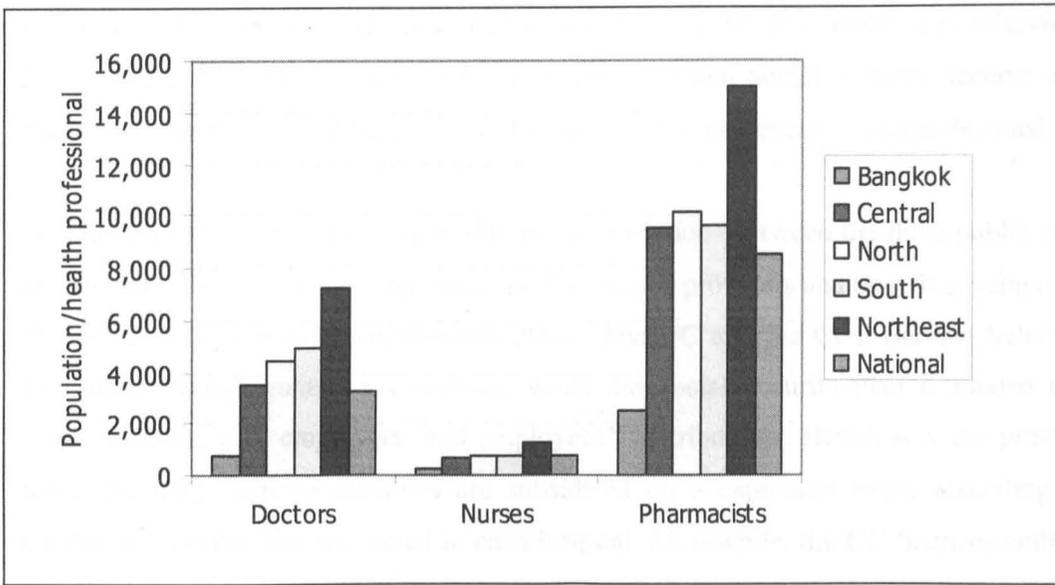
#### **2.4.2 Workforce in the health delivery system**

Thailand has sufficient capacity to produce health personnel of different professions and specialisation. Seventy institutes are responsible for health workforce education and skill development (Ministry of Public Health 2005). The number of health professionals and paramedics has increased over time. In 2002, there were 18,987 medical doctors, 84,683 professional nurses and 7,350 pharmacists, working in the health service sector (Bureau of Policy and Strategy 2002). Twenty-one percent of doctors, 12% of nurses and 11% of pharmacists practiced in private facilities. The country's ratios of population to doctor, nurse and pharmacist were 3,295, 739 and 7,350, respectively. Compared with many HIV-prevalent countries such as Ghana, Uganda and Zimbabwe, where the ratios are one doctor to 11,100, 21,300 and 17,500 people, respectively (WHO 2004c), Thailand is better off. However, inequitable distribution of human resources in health across geographical areas is an important problem in the Thai health system. Figure 2.1 suggests that doctors, nurses and pharmacists are mostly clustered in Bangkok and the Central Region, while the Northeast Region has the highest population to health workers ratio. The disparity of workforce distribution can also be observed at the provincial and district level.

#### **2.4.3 Health system financing**

In 2001, Thailand's health expenditure amounted to 170 billion baht at constant price (2,732 baht per capita), which was 3.2% of Gross Domestic Product (Tangcharoensathien, Vasvid, and Patcharanaumol 2004). The government budget, allocated to the Health Ministry, other public agencies, and health benefit plans, was the major source of health finance, accounting

Figure 2.1: Distribution of doctors, professional nurses and pharmacists by region, 2002



Source: data from Ministry of Public Health (2005).

for 54% of the total, while private funds, mainly came from household spending on medical services and personal care, were responsible for 46%. The share of foreign money was only 0.1% of the national health expenditure.

Before 2001, there were four categories of publicly-subsidised health benefit programmes: Medical Welfare Scheme for low-income groups; Civil Servant Medical Benefit Scheme for government officials, state enterprise workers and dependants; Social Security Scheme for private-sector employees; and Voluntary Health Card Scheme (Tangcharoensathien, Srithamrongsawat, and Pitayarangsarit 2002). These plans varied for their benefit packages, payment mechanisms, costs of care, efficiency and equity across groups of beneficiary with regard to the level of government subsidy as well as quality of services provided. The four schemes covered around 60% of 63 million population, while private health insurance coverage was 10%, and the rest 30% were uninsured.

Considerable changes in health care financing were introduced in 2001, when the government instigated the Universal Health Coverage (UC) Scheme. Three main objectives of the reforms were to provide universal access to health care including disease prevention, health promotion and medical services; to improve health system efficiency; and to standardise the benefit package across different government-organised health benefit programmes (Jongudomsuk

2004). In 2003, the UC was the largest health benefit plan, as it covered the low income and the previously uninsured, which accounted for 75% of the Thai population (Vasvid et al. 2004). Meanwhile, the coverage of Civil Servant Plan and Social Security Scheme was 9% and 10%, respectively, and the fraction of those who had no benefit coverage declined to 5%.

Despite the success in improving health access, variations between the three public schemes in terms of sources of finance, payment mechanisms to providers and benefit coverage remain (Tangcharoensathien and Jongudomsuk 2004). The UC and the Civil Servant Schemes are subsidised through general tax revenue, while the Social Security Plan is funded through public revenue, plus employers' and employees' contributions. Health services provided to Social Security Scheme members are subsidised on a capitation basis, according to the number of beneficiaries registered in each hospital. Meanwhile, the UC finances ambulatory care, health promotion and preventive care on a capitation basis, and has adopted Diagnosis Related Groups as a tool to subsidise in-patient services. In contrast, fee-for-service subsidy is employed in the case of government officials and dependants.

#### **2.4.4 Health system and policy research**

Apart from health facilities, equipment, medical supplies and manpower, Thailand's health system regards knowledge, scientific evidence and different sorts of information as crucial resources (Ministry of Public Health 2005). As research, knowledge management and evidence-based policy decisions are key strategies of the five-year National Health Development Plan (National Economic and Social Development Board 2002), many related activities such as programme monitoring and evaluation, research studies, information system development and dissemination of information derived from research findings, are integral parts of strategic and operational plans of all MOPH departments.

The effort to create a conducive environment for knowledge generation and utilisation in policy making began in late 1970s, when the National Epidemiology Board was instigated as a technical advisory body in the Health Ministry (Wasi 2004). Over the past three decades, this group of clinicians, public health experts and reformists has evolved and established many autonomous agencies, which play a crucial role in producing evidence to inform policies and also strengthening health system research capacity. These include: for example, the National Health Foundation (established 1990), Health Systems Research Institute (1992),

and Thai Health Promotion Foundation (2001). See table 2.2. Owing to the shared visions and strong attempts of several persons involved in these agencies, there has been significant development in the country's health policy and system research including the expansion of research networks through the collaboration between researchers in health with academics and professionals of different disciplines, as well as civil society organisations (CSOs) and communities.

Table 2.2: Objectives and strategies of selected health research promotion agencies

	Objectives	Strategies
The National Health Foundation (NGO)	To encourage knowledge generation and utilisation as an integral part of health system development	<ul style="list-style-type: none"> <li>▪ to create research networks to support a wide range of biomedical, health system and policy studies</li> <li>▪ to disseminate research findings to the public or target populations</li> </ul>
The Health Systems Research Institute (autonomous, government agency)	To promote and support research studies to inform health policy formulation and implementation	<ul style="list-style-type: none"> <li>▪ to foster research and knowledge management to support health system reforms</li> <li>▪ to strengthen research networks for rational public health policies</li> <li>▪ to promote learning from research findings through the local participation of health providers and communities</li> <li>▪ to organise political and social movement to advocate health system reforms</li> </ul>
The Thai Health Promotion Foundation (autonomous, government agency)	To advocate changes in behaviour and environment in order to reduce ailments and premature deaths as well as to improve quality of life	<ul style="list-style-type: none"> <li>▪ to campaign, support and provide funding to Thai organisations involved in health promotion</li> <li>▪ to create awareness of hazardous behaviour and to create belief in health promotion amongst people</li> <li>▪ to conduct studies and research, or encourage the conduct of the study and research, training or organisation of meetings with regard to health promotion</li> <li>▪ to develop the ability of a community in fostering health promotion by the community or other organisations</li> </ul>

Source: Wasi, 2004 ; Health Systems Research Institute, 2005; Siwaraksa, 2004 ; Thai Health Promotion Foundation Act, 2001

### **2.4.5 Pharmaceutical industry and the Government Pharmaceutical Organisation**

The local pharmaceutical industry plays an important role in Thailand as it is the major source of drugs used in the health delivery system. The relatively low prices of generic products make most essential medicines accessible to the Thai people. In 2002 the value of generic drugs produced by 178 local laboratories in the private sector accounted for 55% of the total value of drugs distributed in the market (40,000 million baht, current prices) (Ministry of Public Health 2005). However, the Thai pharmaceutical industry has limited capacity. First, the industry is preparation-based, as it relies on raw materials imported from foreign countries: few of the chemicals, active ingredients and pharmaceutical necessities, can be synthesised locally. Second, most local manufacturers cannot produce drugs which require high technologies such as control-released products, biological and biotechnology-derived preparations (Commission on Thai Drug System Study 2002). Although academic institutes have succeeded in preparing some of these drugs in laboratories, there are many obstacles to scaling-up the production in industrial sites (Umprayn and Reungrungsi 2000). Given that most new chemical entities are patented and the production processes of new drug preparations increasingly require complex technologies, it is predicted that the share of locally-produced pharmaceutical products in Thailand will decrease over time.

The Government Pharmaceutical Organisation (GPO) is a state enterprise under the MOPH. It is responsible for the production and supply of drugs including vaccines, and diagnostic reagents for the public sector (Government Pharmaceutical Organization 2004b). It aims to reduce government spending on imported drugs and reserve essential drugs for national emergencies. According to the Government Procurement Regulation, all government agencies and state enterprises including national programmes, hospitals and other health facilities have to purchase drugs, if they are listed on the essential drug lists, from the GPO as their first priority (Commission on Thai Drug System Study 2002). Essential drugs can be bought from private companies only when they are not produced by the government laboratory, or if those manufactured by private firms are sold at a price lower than median price set by the MOPH. This government laboratory manufactures over 400 products, emphasising the drugs on the National Essential Drug List (Kraisintu 2001). The sales volume of the GPO products is approximately 4,000 million baht a year.

The GPO's Institute for Research and Development was established in 1992, with the mandate to conduct research to develop suitable formula and quality assurance methods of pharmaceutical products for industrial-scale production (Government Pharmaceutical Organization 2004c). Since its conception, the Research and Development Institute has worked on the formulation of many ARVs and drugs for OIs (Kraisintu 2001). By 2004, the GPO had produced 22 ARV products in different strengths, dosage forms and combinations, containing 5 ARV entities: zidovudine, didanosine, stavudine, lamivudine and nevirapine (Government Pharmaceutical Organization 2004a). Compared with the original products, prices of GPO's drugs were significantly lower (table 2.3). The launch of cheaper generic versions has resulted in a price reduction of some originals. However, until 2001, the GPO had only produced a small number of ARVs and certainly not sufficient to meet the needs of PLWHA.

Table 2.3: Comparison of ARV cost per day, original products and GPO's products (baht)

	2000	2001		2002		2003		2004	
		Original	GPO's	Original	GPO's	Original	GPO's	Original	GPO's
d4T+3TC	382	382	106	382	27	382	27	382	27
AZT+3TC	387	387	126	387	48	387	44	387	44
AZT+d4T	278	278	86	278	20	278	20	278	20
d4T+ddI	292	292	78	292	55	292	55	292	55
NVP	324	83	50	54	30	55	30	55	30
EFV	300	107	107	107	107	111	111	111	111

Source: MSF-Belgium, Thailand (prepared by Sarawat and Siriwong, June 2004)

Note: d4T, stavudine; 3TC, lamivudine; AZT, zidovudine; ddI, didanosine; NVP, nevirapine; EFV, efavirenz.

## 2.5 HIV and ART in the Thai context

The HIV epidemic in Thailand reached the generalised<sup>6</sup> stage in the early 1990s. Although public programmes for disease prevention and impact mitigation including small-scale ARV-

<sup>6</sup> Generalised epidemic refers to an HIV epidemic in a country in which 5% or more of women attending urban antenatal clinics are infected; infection rates among individuals in groups with high-risk behaviour are also likely to exceed 5% in countries with a generalised epidemic (World Bank, 1998. *Confronting AIDS: Public Priorities in a Global Epidemic*. Geneva: World Bank.)

based therapy had been established since the problem became apparent, it was not until late-2001 that the nationwide ART initiative began. This section explores the country's response to the HIV epidemic, as well as the evolution of the national treatment programme.

### 2.5.1 Features of the epidemic

The first HIV case in Thailand was diagnosed in a university hospital in 1984 (Phanuphak et al. 1985). In the beginning, the disease was concentrated in homosexual men and IDUs (Kunanusont 2000). In the early 1990s, heterosexual relationships became a major mode of viral transmissions, driving the infections into the general population. According to the national registry, by the end of 2003 HIV/AIDS cases reported from healthcare settings had accumulated to 317,000, of whom 73,000 had died. Ninety percent were 15 to 49 years of age (Deewong and Chitnumsub 2003). The highest number of 28,000 cases and 8,000 deaths was reported in the single year of 1998. Thereafter, there was decline in both morbidity and mortality<sup>7</sup>.

Findings of sentinel sero-surveillance also illustrate the falling trend of the epidemic (Plipat et al. 2003). Between 1989 and 1995, prevalence escalated, and was followed by a decline in all high-risk groups (figure 2.2), except the IDUs (Bureau of Epidemiology 2004b). The prevalence among brothel-based sex workers, for instance, rose from 4% in 1989 to 33% in 1994, and then steadily dropped to 11% in 2003. On the other hand, disease rates among IDUs<sup>8</sup> reached 50.8% in 1999, and fluctuated between 44.9% and 50.0% during 2000 to 2003. Meanwhile, the estimated number of IDUs in the country was between 100,000 and 250,000 (Kaplan 2005).

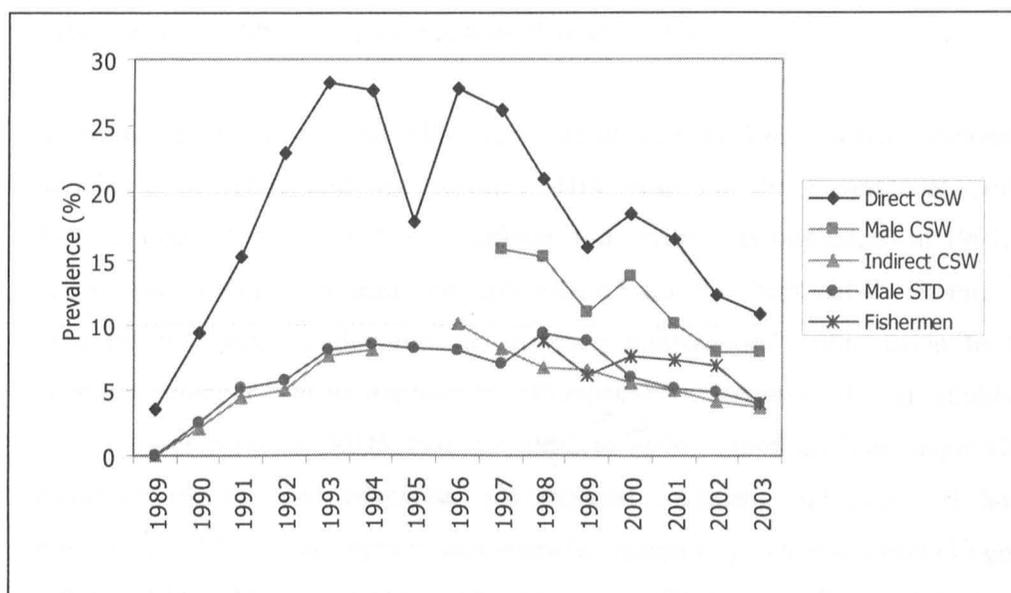
Following a study commissioned by the national planning agency – the National Economics and Social Development Board, the accumulated HIV cases and deaths in 2001 were 700,000 and 358,000, respectively (Thai Working Group on HIV/AIDS Projections 2001). The projections also suggest that, based on the profiles of people's behaviour and national HIV

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<sup>7</sup> The figures from the disease registry more or less represent the number of PLWHA who could access institutionalised health services; however, the case reports were disproportionately submitted by hospitals under the Health Ministry. Underreporting is commonly associated with this type of monitoring system and has been witnessed in many settings (Division of Epidemiology 2002).

<sup>8</sup> HIV testing in injecting drug addicts was carried out in those sought care from public drug addiction treatment clinics.

Figure 2.2: HIV prevalence in high-risk populations, 1989 to 2003



Source: Bureau of Epidemiology

Note: CSW, commercial sex worker; direct CSW, brothel-based sex workers; indirect CSW, sex workers who are based in non-brothel establishments, for example restaurants, night clubs and massage premises; male STD, male attendants of clinics for sexually-transmitted diseases.

policies in 2000<sup>9</sup>, the number of new HIV and AIDS cases and overall PLWHA tend to decline until 2020. This means that if ART access has been promoted, the number of HIV-infected persons at a particular time will be larger than estimated in the baseline scenario owing to the extended survival.

## 2.5.2 National responses to HIV epidemic

After the first AIDS case was reported, the Thai government reacted slowly because HIV was believed to be a problem of limited groups of male homosexuals, especially those in contact with foreigners, thus was not a threat to the whole population (Tarantola et al. 1994). Although later evidence indicated the coming endemic, public information and other means of HIV education was suppressed due to the concerns about adverse effects on foreign investment and tourism, major sources of the country's income (Ungphakorn and Sittithitai 1994; Viravaidya 2001). During this phase, the HIV policies developed and implemented by

<sup>9</sup> ART in the national programme was provided to only 2,000 PLWHA; and the prevention of mother-to-child HIV transmission was in its initial phase.

the Health Ministry were mostly 'health-focused', emphasising risk group education, disease surveillance, and blood screening (Thongcharoen 1991).

Informed by the first-round HIV sero-surveillance in 1989, which demonstrated high prevalence in IDUs and sex workers, HIV rose on the government policy agenda (Phoolcharoen et al. 1999). A new national framework was introduced in 1991, integrating disease prevention, treatment and alleviation into the National Economic and Social Development Plan, which aimed at fostering multisectoral participation to address the emerging epidemic and its implications (Porapakham, Pramarnpol, and Athibhodhi 1995). The five-year National AIDS Plan for 1992 to 1996 comprised four major elements: (1) public information and education, (2) medical treatment and care, (3) human rights protection, and (4) social support, and research, monitoring and evaluation (Ungphakorn and Sitthitrai 1994). Many prevention programmes implemented in this period changed sexual behaviours and contained new infections (Nelson et al. 1999; UNAIDS 2001b). They substantially altered the course of the epidemic. In this period, in addition to the public sector, NGOs and business coalitions had an increasing role in HIV policy making and implementation.

During the first half of the 1990s, HIV treatment mainly comprised OI drugs, though they were perceived to be inefficient since medication was expensive and could prolong life for only a short period (Sawanpanyalert 1997). Owing to scarce resources, HIV inevitably competed with other health problems for budget, personnel and supply allocation in health facilities. As the number of patients escalated, the impact on the health systems became clearer. The strategies employed to reduce the burden were to facilitate the collaboration between healthcare settings, communities and NGOs through the establishment of day care services and self-help groups. Such collaboration has been claimed to have provided the foundation for introducing a holistic care package in the subsequent period (Thanprasertsuk 1997; Tsunekawa et al. 2004).

In the late 1990s, HIV policy direction shifted again: the 1997-2001 National AIDS Plan was formulated to harmonize with the current National Economic and Social Development Goals, i.e. sharing the concepts of 'people-centred' development (Karnpisit 2000). Empowering people as members of families and communities was the main strategy. The plan called for

operationalisation through community-based civil society movements, while all sectors were expected to take active roles (Phoolcharoen et al. 1998).

During this phase, the MOPH's AIDS Division launched two national-scale initiatives: the Comprehensive Care Continuum for PLWHA in 1997 and the Prevention of Perinatal HIV Transmission in 2000. The former aimed to offer timely, holistic medical services and psychosocial support to infected persons and their families (AIDS Division 2000). The programme's activities were carried out in healthcare settings and communities (Simmons and Uthis 2002). For the vertical transmission prevention, the programme was developed on the evidence and experience from clinical trials and pilot projects conducted in Thailand between 1996 and 2000 (Kanshana et al. 2000; Thaineua et al. 1998). After the process of counselling and testing, short-course zidovudine regimen and breast milk substitution formula were offered to all pregnant women who voluntarily joined the initiative. The Health Ministry claimed that due to high uptake this intervention could halve new-born infections (UNDP-Thailand 2004).

The holistic approach principle was maintained to the National AIDS Plan for 2002 to 2006: fostering people-centred strategies and participation of all sectors (Karnpisit 2000; National AIDS Committee 2002). Three main targets to be achieved included (1) reduction of HIV prevalence among the 15-49 year-old population to less than 1%; (2) providing access to appropriate care and services to least 80% of PLWHA and affected persons; and (3) HIV prevention and alleviation activities to be initiated and implemented by local administrations and communities. Apart from encouraging afflicted people, families and communities to be self-reliant in disease prevention and care delivery, this plan aimed to modify the health delivery system for PLWHA in order to guarantee full and fair healthcare and social welfare for the afflicted population.

### **2.5.3 Overview of civil society organisations in HIV field**

Alongside the development of HIV control programmes, civil society organisations took an important part in the policy processes. At national level, NGO leaders started their role in the campaign for prompt government response to the disease in mid-1980s (Ungphakorn and Sitthitrai 1994). Despite this, NGOs were first integrated into the national HIV control framework when there was a change in the administration in 1991, and Mechai Viravaidya –

Chairman of a renowned NGO for family planning, the Population and Community Development Association (PDA) – was appointed to be the Minister to the Prime Minister's Office. The long-standing relationship between PDA and public agencies allowed NGO participation in the country-level policy making (Seckinelgin 2002; UNDP-Thailand 2004). Representatives of people's organisations formally joined government policy decisions from 1991, as they were appointed to be the National AIDS Committee members.

Civic participation in HIV prevention and care at peripheral level began in 1984, at least 50 NGOs were working in the field in that year (Denduang and Charusomboon 1993 quoted in UNDP-Thailand 2004). Apart from the PDA, well-established NGOs such as the Thai Red Cross Society and the Parenthood Association of Thailand were among the first civic groups launching HIV prevention and education interventions (World Bank Thailand Office 2000). The number of associations and foundations registered as not-for-profit HIV-related organisations markedly increased in 1992 and onwards (Rujjanavet and Chinchotikasem 1995). In 2004, more than 650 NGOs including community-based organisations were working in the area of HIV/AIDS, mainly located in Bangkok and disease-prevalent provinces in the north of the country (Ministry of Public Health 2005). When HIV burden to health care providers became visible in certain areas, groups of persons afflicted by the infection were instigated, mostly with support from health facilities or NGOs (UNDP-Thailand 2004). By 2005, over 700 PLWHA groups had been established (ATSI 2005).

HIV NGOs carried out several activities, ranging from education, prevention, care, support and advocacy: for example, providing care for PLWHA, offering social and financial support to afflicted families, organising education programmes on HIV prevention, reducing stigma and discrimination attached to the disease in workplaces and communities, and campaigning to improve AIDS rights (UNDP-Thailand 2004). In many instances, NGOs collaborated closely with government agencies and patient groups to carry out their tasks (Panichpak 2002). PLWHA in '*self-help*' groups also contributed to prevention and care delivery, psychosocial support and other impact mitigation programmes, especially in communities. Since 1992, CSOs involved in HIV services could apply for budgetary support from the MOPH (ATSI 2005). However, government budget could meet only a small fraction of the amount demanded. In 2004, for instance, 24% of the requested 290 million baht was allocated (Ministry of Public Health 2005).

#### 2.5.4 Evolution of the national ART programme

The ARV medication programme in Thailand can be traced back to 1992, when a small-scale initiative was established by the Health Ministry to provide zidovudine monotherapy to low-income patients (Kunanusont, Phoolcharoen, and Bodaramik 1999). The drugs used in this initiative were subsidised by the government, procured centrally by the MOPH's Disease Control Department, and then supplied to participating hospitals, which were small in number, and mostly located in Bangkok. Treatment coverage was insignificant, compared to the size of the epidemic. The number of clients was only 350 in the first year though it increased to 3,600 by 1995 (Tangcharoensathien and Teokul 2002). Despite an increase in treatment, the proportion of those covered declined as the epidemic extended dramatically (Punpanich, Ungchusak, and Detels 2004).

In 1995, the Health Ministry terminated its ART service because an economic evaluation suggested that the programme was inefficient and considerably less cost-effective than vertical transmission prevention (Kunanusont, Phoolcharoen, and Bodaramik 1999; Prescott and Thai Antiretrovirals Study Team 1998). The economic evaluation study also suggested that many factors contributed to the undesirable costs and outcomes: for example expensive drugs, low-efficacy regimens, and poor compliance with treatment protocols on both supply and demand sides. From 1996 the MOPH's ARV budget was relocated to support a newly-established clinical trial project – the so-called Clinical Research Network – which aimed to strengthen health care providers' capacity to deliver ARV medication as a component of comprehensive care for PLWHA (Thanprasertsuk, Lertpiriyasuwat, and Chasombat 2004). Introduced as an operational research project, this initiative assessed the effectiveness of different dual-ARV protocols. By 1999, 58 MOPH hospitals, teaching institutes, and NGOs had joined the network. The number of treatment recipients as research subjects was maintained at 2,000 per year from the Network initiation till 2001 (Tangcharoensathien and Teokul 2002). However, during this period some PLWHA accessed antiretroviral medications through other research initiatives as well as through services organised by NGOs and through private providers (Phanuphak 2004; Punpanich, Ungchusak, and Detels 2004).

Based on experience and information gained from the Clinical Research Network, the MOPH's policy to provide service-based ART was reformulated as part of the Access to Care Initiative in 2000 (Siraprapasiri 2002). The Access to Care Initiative aimed to develop a

comprehensive HIV treatment delivery system, and to improve medication access among infected persons (Ministry of Public Health 2001b). Highly active antiretroviral therapy (HAART) was first introduced in MOPH hospitals in this period. To address the obstacles found in the past, three main strategies included: (1) ARV price negotiation undertaken by the Disease Control Department; (2) selection of participating hospitals on the grounds of their competency in health service delivery, financial status, pharmacy administration, voluntary counselling, HIV testing, referral network, as well as community support; and (3) standardization and development of clinical guidelines (Ministry of Public Health 2001b).

All regional, provincial and district hospitals in 8 upper northern provinces were invited to join the programme on a voluntary basis (Satasit, Kuaykiatikul, and On-Nom 2002). By the end of 2001, the Access to Care facilities had extended to include 109 hospitals and 16 laboratories, most of which were located in the northern region. In its first year, the Initiative targeted 1,200 adults and 500 children, who were enrolled by a local panel comprising government officials, NGO staff, representatives of communities and PLWHA in accordance with centrally-set criteria. Apart from new enrollees, it was the Health Ministry policy to continue to support ARVs to study subjects in the clinical research network, after it had been replaced by Access to Care Initiative.

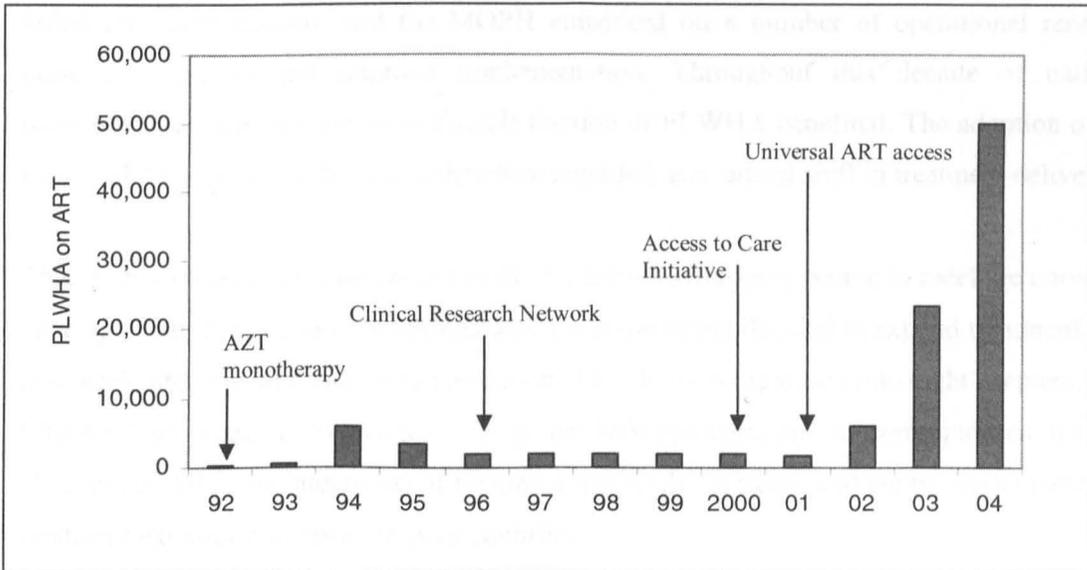
The first-year programme evaluation of the Access to Care Initiative suggested several problems in the preparation and implementation. Only 1,400 clients were enrolled, and as of January 2002, over 30% were lost to follow up (Satasit, Kuaykiatikul, and On-Nom 2002). Poor adherence to therapy was also prevalent. The obstacles in delivering treatment included inadequate experience and knowledge of doctors, counsellors and other health personnel, ARV and laboratory reagent shortages, a lack of laboratories in some areas, and the short life-span of some drugs which resulted in complicated inventory and storage management. A study conducted in 6 northern provinces in the same period demonstrated similar difficulties reported by clinicians, nurses and pharmacists in the execution of the Initiative (Punpanich et al. 2002).

In November 2001, the new government pledged to gradually expand ART coverage to achieve universal coverage (The Nation 2001). According to the new Health Minister, medication would be included in the benefit package of the newly established UC Plan (Matichon 2002). This represented a change from initially limited support for treatment for

PLWHA to a pledge to make ART universally available. After the adoption of the new treatment policy, access to ARV service in public programme increased dramatically. In September 2004, the number of patients on therapy was 50,750, 83% of projected AIDS cases in the country (data from Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections). However, it was not until late 2005 that ART was integrated into the UC scheme, and financed through the National Health Security Office. During 2001 to 2005, the national treatment initiative continued to be subsidised by the Health Ministry's budget.

Figure 2.3 summarises the development of the publicly-organised ART programme from its instigation in 1992 until 2004, when therapy was scaled up to meet universal access goal.

Figure 2.3: ART programme development, 1992-2004



Source: Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections

## 2.6 Summary

The first section of this chapter suggests that in the era of treatment scaling-up, ARV medication in resource-constrained countries has expanded rapidly owing to support from international agencies, donors and CSOs. However, in most HIV-afflicted areas service coverage remains limited. In some settings where therapy has expanded, many challenges emerge, and are likely to hinder treatment quality and programme efficiency. In addition, there are major differences in ART coverage across regions as well as divergence in treatment

programmes the developing world. These situations reflect the roles of several factors that shape policy decisions and implementation.

Thailand is a country with a relatively high HIV prevalence. The swift government response to the epidemic, especially in prevention efforts, led to a decline in new infections from the mid-1990s. National HIV strategies evolved rapidly between 1991 and 2000, addressing the growing demand for medical services in the public sector, by establishing collaboration between healthcare providers, private corporations, communities and NGOs, and promoting holistic prevention and therapeutic approaches through a variety of initiatives.

Despite the progress in healthcare arrangement for PLWHA, Thailand struggled to introduce ART, starting with publicly-subsidised treatment for some from 1992. However, the service failed for many reasons, and the MOPH embarked on a number of operational research projects to assess and improve implementation. Throughout this decade of national programme implementation, only a small fraction of PLWHA benefited. The adoption of the universal ART policy in 2001 was therefore regarded as a radical shift in treatment delivery.

This study explores the scale up of Thailand's antiretroviral programme to meet the universal coverage goal. It describes the reasons why the government decided to expand treatment, and how such intention was translated into action. This thesis is organised into eight chapters:

Chapter 1 provides the overview of the global HIV epidemic and its consequences, the key elements of ART, the integration of treatment into health systems, and controversial issues on treatment expansion in resource-poor countries.

Chapter 2 reviews documents on the introduction of ART in the developing world, including medication coverage in different regions, treatment programme configuration, and problems experienced in programme scaling-up. This chapter also introduces Thailand's health systems and the past development of its HIV problems, policy response and ART provision.

Chapter 3 reviews literature on models and approaches in public policy analysis, focusing on the use of two concepts: policy networks and policy learning, to understand actors' involvement in the processes of agenda setting, policy formulation and implementation. This chapter also sets the framework, objectives and the methods used in this study.

Chapter 4 examines agenda setting and policy adoption processes, including the shifts in policy networks and the perceptions of network members of the large-scale ART programme, transformation of political context, and changes in the administration which led to health care financing reform and ARV price reductions.

Chapter 5 addresses policy formulation by analysing the structure and interests of the Health Ministry's advisory panels responsible for devising the national ART programme configuration, including the process of drawing lessons from past experiences of the panel members as well as treatment implemented in other countries.

Chapter 6 sets the context of case study provinces: Phichit and Rayong. It reviews HIV epidemiology, health system resources, relationships between health providers and CSOs, HIV treatment and care before ART expansion, and the decisions to participate in the national treatment programme of the six study hospitals.

Chapter 7 examines the process of implementation of universal ART policy in study hospitals, including arrangements of staff for service delivery, targets and achievement, constraints and coping strategies. It explores the collaboration between hospitals and networks with CSOs sought by health workers as well as the providers' learning motivated by the desires to meet the hospitals' targets and assure treatment quality.

Chapter 8 discusses the thesis findings against the conceptual framework and existing literature on ART introduction in resource-poor settings. It also highlights lessons learned from the Thai experience on treatment expansion. Conclusions are drawn on the contribution of policy analysis approaches to understand ART policy development in the Thai context, and the potential utilisation of such understanding to inform policy in other developing countries.

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## CHAPTER 3: CONCEPTUAL FRAMEWORK AND METHODS

Chapter 2 illustrates that although human immunodeficiency virus (HIV) is a vital public health problem in many societies in the South, there are variations in national antiretroviral therapy (ART) policy. In most areas ARV medication is available for only limited numbers, and extensive treatment coverage is relatively rare. Given the real difficulties in rolling out ART initiatives in poor countries, understanding why some governments have commenced universal coverage for this service, and how they developed the programmes and strategies to overcome impediments is important and will have lessons for other countries. Thailand has been selected as a case study to explore policy development and implementation of ART. As seen in chapter 2, the national HIV control policy long emphasised prevention elements, but in late 2001 there was a dramatic shift as the government decided to increase treatment coverage from a small-scale programme to meet universal needs.

This chapter reviews theoretical literature and related empirical studies in public policy. An analytical framework is generated to provide an approach for analysing the policy process. Based on this conceptual framework, specific objectives for the study have been developed, which focus on the different roles of actors and their influence on three policy stages: agenda setting, formulation and implementation. The context within which these interactions take place is also explored. Then, two notions of policy networks and policy learning are discussed for their utility in explaining policy in particular phases. Finally, methods employed in this thesis and research limitations are illustrated.

### 3.1 Study of public policy: general conceptual framework

The term ‘public policy’ has been presented with several definitions, ranging from simple to complex formulations (Parsons 1995). However, they all centre around some key aspects: public policies are originated through the decisions of governmental agencies including legislative institutes to retain the status quo or to introduce changes in a policy domain<sup>10</sup>

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<sup>10</sup> Policy domain refers to fields of public activities, for example health, education, agriculture and transportation (John 1998). Such a notion denies the existence of singular political system structures, and suggests a variety of political processes in each area. Particular policy domains differ in several aspects, for example the influence and cooperation of actors; resources and instruments available to policy makers; practice of decision making; balance of power; and likelihood of policy success.

(Howlett and Ramesh 2003). Leichter (1979:38) suggests that public policy analysis has its central role in addressing the question *'Why do governments do what they do?'*

In general aspect, policy sciences aim to get insight into policy making and executing processes (Lasswell 1951:14-15 quoted in Parsons 1995:19). Theories and models developed in particular disciplines contribute to empirical studies of policy in different ways. For example, economics approaches emphasise the rationality, efficiency and equity of public programmes, while sociological frameworks mainly focus on social problems, social structure and power in society, organisations and institutions (Parsons 1995). By contrast, psychology's cognitive theories seek to explain how problems are recognised, how policy alternatives are searched, and how policy decisions are made. However, scholars maintain that in many instances, a policy is so complex that it requires a multidisciplinary framework in the analysis. Among others, Wildavsky (1979:15 quoted in Parsons 1995:29) points out *'Policy analysis is an applied subfield whose contents cannot be determined by disciplinary boundaries but by whatever appears appropriate to the circumstances of the time and nature of the problem.'*

Concerns of policy analysts vary. Some pay attention only to government activities, bureaucracy and outcomes of public interventions, while others look at the roles of different stakeholders and explore why they pursue certain solutions (Parsons 1995). To address the increasing complexity in developing countries' health systems, Walt and Gilson (1994) suggest that apart from exploring the policy content<sup>11</sup>, three interrelated elements need to be taken into account, namely the actors engaged in the policy; the processes as the paths to policy choices and consequences; and the context in which the policy evolves. This 'policy triangle' framework *'can be applied in any country, to any policy, and at any policy level.'* (Buse, Mays, and Walt 2005:2).

### **Actors**

The policy triangle approach considers actors as individuals, or people who form temporary groups such as groups of parents who campaign for nutritious school lunch, or members of permanent organisations, for example political parties, government departments, private

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<sup>11</sup> Policy content is defined as substance of a particular policy which details its constituent parts (Buse, Mays, and Walt 2005:4)

companies, and civil society organisations (CSOs) (Walt and Gilson 1994). Actors as individuals hold different roles and positions such as politicians, civil servants, academics, and professionals. Meanwhile, individual and group actors can also be differentiated by sectors they belong to: public, private for-profit and private non-profit or civil society. In addition, actors may seek to influence policies at certain levels so that they are classified as domestic, national, regional and international. Buse and colleagues (2005) argue that on the one hand, individuals cannot be separated from the organisations or groups they affiliate as they share some interests and destinations. On the other hand, however, any organisation is not homogenous, but consisting of many individuals who may have different ideas and positions towards particular policies. For instance, the Ministry of Health is a key actor in health protection, and at the same time, it is made up of several departments and large numbers of officials, professionals and paramedics.

In the health sector, CSOs such as philanthropic foundations, professional associations, faith-based organisations, and communities are groups of actors those play an increasingly important role in different policy stages (WHO 2001). Civil society refers to the institutional form of voluntarily collective action, distinctive from governmental agencies and private corporations<sup>12</sup> (Centre for Civil Society 2004). Since it exists alongside the state and the market, civil society is often defined as the '*third sector*'. CSOs' action may support or oppose particular policies of the regimes (Post and Rosenblum 2002). The civil society notion is ideologically-oriented, based on a range of ideals about politics, organisation and citizenship (Van Rooy 1998 quoted in Lewis 2001:3). For example, civil society in the United States is developed on the values of voluntarism, liberty, community spirit, and efforts to keep the government accountable and effective (Lewis 2001). Seckinelgin (2002) stresses that civil society movements represent the '*politics of people*' – the underlying ideal of many community organisations in Western countries. However, CSOs in the South may developed on different ideals that affected their involvement in public policies in particular ways.

The roles, position, interests and power of policy participants are important. Actors with different attitudes towards goals and means, may have unequal levels of power (Harrison

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<sup>12</sup> In this sense, the terms non-governmental organisation (NGO) and CSO can be used interchangeably. However, in some instances, NGO is viewed as the CSO with particular features. For example, the United Nations Development Programme defines NGOs as the CSOs which are involved in the contractual delivery of development goods or services (UNDP 2006).

2001). Along the policy process, actors interact with each other, and often those with more power play a leading role in shaping policies to enhance their interests (John 2002). Power and influence of actors are associated with policy resources they command (Howlett and Ramesh 2003). In some developing countries, policy decisions are made within a closed circle of few technocrats and professionals (Grindle and Thomas 1991). Power in policy making of the influential civil servants is based on different elements, for example their authority provided by laws and regulations, their knowledge and skills in special areas, and their ability in access to a wide range of information (Hill 1992:1-11 quoted in Howlett and Ramesh 2003:69). However, the distribution of power in a society depends on policy issues and context (Buse, Mays, and Walt 2005). As Walt (1994) suggests, the extent of actor participation in health may differ according to whether an issue is considered low-politics or high-politics<sup>13</sup>. Moreover, since an organisation is not seamless, power of different departments may be unequal. For instance, Buse et al (2005) argue that in government system of low-income countries, the Ministry of Health usually has less power than many others such as the Ministries of Finance, Defence, Foreign Affairs and Industry.

### *Context*

Public policies also depend on the context within which they develop. They are affected by their environment, and vice versa – some may cause changes in context. Williams and colleagues (2004), for instance, argue that national malaria control policies that suggest the use of particular antimicrobials, especially in the settings with poor treatment administration, may result in widespread resistance of *Plasmodium* parasites. Leichter (1979) classifies policy context into four categories. First, situational factors are transient or impermanent conditions such as wars, technological changes, economic recession, and natural disasters. Second, structural factors, relatively more permanent conditions, including political, economic, social, and demographic structure. Third, cultural factors are political and general social values of groups in the society, such as religion. Finally, environmental (or exogenous) factors are events, structures and values existing outside the domestic political system such as

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<sup>13</sup> Low politics issues are defined as ordinary issues those neither involve core values nor affect important groups in the political system. The policies to address low politics problems are seen as micro, sectoral policies, of which the processes tend to be open for broad participation. On the other hand, high politics issues are connected with macro-level ideals or values. Changes in the policies of high politics often develop in relatively close processes, and involve small groups of actors (Walt 1994).

international collaboration, agreements or pressure. Contextual factors differently motivate and enable actors to recognise problems and also to support or oppose particular solutions (Considine 2005).

### *Processes*

Policy in a broader sense does not focus on only the decisions to carry out particular actions, but looks at the complex, repetitive processes that create the outputs and produce changes from such decisions (Gordon, Lewis, and Young 1977; Harrison 2001). Developed as a heuristic device, the stagist approach has been introduced to disaggregate such messy processes into a series of phases. Among others, Hogwood and Gunn (1984) propose a framework of discrete stages, beginning with agenda-setting and option analysis, going on to policy formulation; implementation; monitoring; and evaluation. Although such simplification helps to facilitate studying public policies, it has been argued that the approach may be misleading as it cannot reflect what actually operates in the political systems (Parsons 1995). Policy processes are not sequential, but comprise feedback loops between different stages: government agendas are continually set and reset, and policies may be reformulated while they have got implemented (Hill 1997).

### **3.2 Conceptual framework for studying antiretroviral policy in Thailand**

The policy triangle framework suggests that to understand the development of Thailand's antiretroviral policy, the issues to be examined in this thesis include the interactions between actors, processes of agenda setting, policy formulation and execution and the context in which those processes took place. However, over the past decade significant changes in policy making have been observed: shifting dominant roles and power from traditional institutions such as governments and political parties to groups of multi-sectoral actors with different interests, resulting in the increased dynamics, uncertainty and interdependence (Hajer and Wagenaar 2003). This shift suggests that the relatively static policy triangle needs exploration. To enhance the explanatory power of the policy analysis framework, the notions of policy network and policy learning are introduced to the conceptual framework of this study. By this, it is expected to allow close exploration into the roles of actor coalitions and the extent to which their policy learning played a part in policy development.

### 3.2.1 Policy networks: framing the interplay between key actors

*'Networks are an organisational form with extraordinary capacities for innovation, managing risk, building trust, facilitating joint action and gathering information.... When networks include the active participation and involvement of decision makers they have the potential to influence policy.'* Stone (2001:13)

Although governments are officially responsible for policy making and execution, in reality public policies are shaped by clusters of representatives from politicians, bureaucrats and organised interests (Marsh 1998a). The policy network approach has been developed to understand the relationships between these actors, especially when decision making in public sector becomes so complex and fragmented that it cannot be explained by the older institution and state theories (Smith 1993). This approach argues that in a policy arena, state and non-state actors are interdependent. This is because they have incentives to create networks whereby the former can achieve specific policy goals with assistance from the latter, while the interest groups can take part in policy making to pursue their benefits (Rhodes 1988). Bressers and O'Toole (1998:215) assert that the increasing attention to policy network concept *'has been fuelled in part by recognition of the complex array of actors involved in policy choices as well as the inability of contemporary government to move unilaterally without incorporating the constraints, preferences, and resources of other social actors.'* Others such as Hajer and Wagenaar (2003) argue that to address globalisation and increasingly fragmented sources of political power in the network society, both government and non-government sides recognise the needs for shared perspectives on problem definitions and collective policy making as new modes of problem solving.

Policy networks differ in terms of number of participants, types of interests, cohesion, resources and power (Marsh and Rhodes 1992). Resources can be finance, knowledge, expertise, technologies, or capacity to mobilise support from members and outside. Through their networks, participants are enabled to create collaboration, exchange information, share resources, and construct common knowledge (Stone 2001). The extent to which particular networks can influence policy processes and meet their ultimate goals relies upon the capacity to manage and maintain such collaborative practices (Hajer and Wagenaar 2003). Policy networks can be classified into two hypothetical categories: policy communities and issue networks (Marsh and Rhodes 1992).

A policy community refers to a tightly-integrated group with a limited number of members who share fundamental values and goals. The community is stabilised by persistent balance of power among members though one or two interests may dominate. A policy community usually involves only one government department, and if two or more agencies participate, only one of them has to be accepted by others to play a leading role (Smith 1993). Smith further argues that as well as the dominant department, on many occasions individual politicians may be involved, and that the policy community may comprise only one or two interest groups. In highly-technical areas such as those relating to some scientific or health issues, the roles of experts and professionals inside government or academic institutes are crucial. For example, in late 1990s clinicians and researchers were dominating actors in changing national malaria policies in many developing countries (Williams, Durrheim, and Shretta 2004). The networks of experts and professionals with recognised expertise in particular areas, who have a common set of beliefs, norms and policy projects, and attempt to use their technical competence to influence public policies are referred to as 'epistemic communities' or 'knowledge communities' (Haas 1992).

By contrast, an issue network comprises large numbers of members with broad values and interests (Marsh and Rhodes 1992). As Smith (1997:81) points out, *'membership in an issue network is extremely large. There are likely to be several government departments, agencies or subcommittees. The range of interest groups could be in the hundreds....'* In the case of smoking policy in the United Kingdom, for instance, the opponents of the tobacco industry which formed part of an issue network between the 1960s and 1990s included the British Medical Association, Action on Smoking and Health, and Department of Health including its departmental agencies such as the Health Education Council (Read 1992). These organisations created links with several government officials and medical doctors to encourage anti-smoking policies.

Marsh and Rhodes (1992) maintain that issue networks have limited access to the policy process, and that they rarely exist at the inner circle of policy-making and therefore have an insignificant role in the policy process. However, on exceptional occasions members of issue network can influence policy though they are not consulted by the government, but act peripherally. For example, in the early 2000s a South African NGO-academic alliance led by the Treatment Action Campaign challenged the government to improve access to antiretrovirals (ARVs) (Schneider 2002). In 2002, the civic organisations won a court case

they filed against the administration: the Constitutional Court ruled that the National HIV Control Programme must offer nevirapine to all HIV-positive mothers in order to prevent vertical transmission (Willan 2004). Some observe that, however, despite the absence of political involvement, networks may affect policy decisions as their values and desires generate particular opinions and public debates (Stone 2001).

Marsh and Rhodes (1992) stress, however, that no network conforms exactly to this categorisation, and that the policy community and issue networks are better perceived as the two ends of the policy subsystem continuum. For them the term policy network is used generically. In addition, the typology is not exhaustive as there may be two tiers within a policy network: a core and a periphery, and the difference between the members with and without resources is distinctive (Marsh and Rhodes 1992). Empirical studies show that even in well-integrated policy communities, different levels of participation and influence in policy decisions can be identified (Read 1992), and that economic and government interests usually dominate policy networks (Marsh 1998b).

A policy network develops and changes in its beliefs, rules and strategies over time (Richardson 2000; Sabatier 1988). In some instances, the tight-knit communities become more open and less integrated, and *vice versa* (Smith 1991). As Marsh and Rhodes (1992) put it, transformation of policy networks is prompted by the internal and external environment, such as economic and social change, new knowledge and technology, and public opinion. For example, when HIV-related problems became overwhelming and governments' response was considered inadequate, many countries including Thailand experienced increasing participation of CSOs in national policy processes (Sills 1994; Ungphakorn and Sitthitrai 1994). Network members do not respond to contextual factors directly, but choose whether or not to respond and how to respond in accordance with their understanding of the issues and circumstances (Marsh 1998b). The literature suggests that, for instance, technical changes may be mediated by economics and professional interests (Marsh and Rhodes 1992).

In a policy domain, two or more networks may exist and interact with each other (Marsh and Rhodes 1992). These policy networks may operate at different levels: global, national and sub-national (Richardson 2000; Shiffman, Stanton, and Salazar 2004). Competition and negotiations between networks and among members of the same network who command different ideas can be expected, with those with more resources and power dominating the

processes, either by retaining the *status quo* or fostering radical shift (Marsh and Rhodes 1992). Substantial evidence demonstrates the important roles of policy networks in agenda setting, policy formulation and implementation. An illustration is the partnership between international agencies, the drug industry, national governments and NGOs those contribute to research & development, donation and distribution of essential drugs and vaccines in many poor countries, for example the Stop TB Initiatives, the Global Alliance for Vaccines and Immunization, the Gates Foundation/Merck Botswana Comprehensive HIV/AIDS Partnership, and programmes involving donations of albendazole, Malarone® (atovaquone and proguanil combination) and Mectizan® (Ivermectine) (Widdus 2001).

However, although a series of case studies illustrates the existence of policy networks, and their effects on policy processes and outcomes in many policy domains, it is emphasised that solely analysing the policy network cannot provide insight into policy decisions and their consequences (Marsh and Rhodes 1992). This is because networks are merely one of the elements responsible for any policy innovation. Marsh and Rhodes (1992) point out that to understand better the policy processes, changes in the networks' environment and its influence on networks' features should be taken into account. In order to develop a more dynamic model to portray the association between policy networks and outcomes, Marsh (1998b) proposes the inclusion of the concept of policy learning among actors, as a factor influencing network interaction. As Marsh (1998b) suggests, skills of network members to interact with each other and with actors outside the network are not only inherent, but also acquired from their learned experiences.

### **3.2.2 Policy learning: acquiring knowledge for policy decisions and action**

Learning refers to cognitive processes of attaining skills and knowledge which can be retained and used as necessary (Smith 2005). It is also applied to the course of interpreting, understanding and making sense of abstract elements such as values, goals and perspectives. Bernard and Armstrong (1998:46) note:

*'Most broadly understood, learning is the process by which people make sense of their social and physical environments in progressively more intricate ways, derive meaning, develop guiding principles, and become better able to predict the consequences of their own and others' actions.'*

Many scholars have tried to establish the explanations of policy change based on the notion of policy learning. Following Hall (1988:6, quoted in Bennett and Howlett 1992:276), policy learning refers to ‘*a deliberate attempt to adjust the goals or techniques of policy in the light of the consequences of past policy and new information so as to better attain the ultimate objects of governance.*’ In the public policy literature, different terms such as lesson drawing, policy learning, policy-oriented learning, policy transfer and social learning are used with overlapping definitions (Bennett and Howlett 1992; Dolowitz and Marsh 1996; Stone 2001). Although these terms share the concept that policy decisions are made on the basis of knowledge of past experiences and knowledge-based speculations of policy outcomes, they are not interchangeable (Bennett and Howlett 1992). Rose (1991), for instance, defines lesson drawing as a particular type of policy learning in which policy makers draw lessons on experiences in other settings. By contrast, Dolowitz and Marsh (1996) maintain that policy transfer has broader definitions than lesson drawing as the latter refers to the policy transfer which occurs on the *voluntary* basis, while the term policy transfer covers both voluntary and coercive actions. A study of Ogden and colleagues (2003) suggests that, for example, directly observed therapy, short course (DOTS) – a strategy for tuberculosis treatment developed by the World Health Organisation (WHO) – was perceived as coercively transferred to low- and middle-income countries in the early 1990s. As the authors point out, DOTS transfer in some settings was viewed as intimidation since the treatment was pushed through influential international donors and sometimes against the wishes of national actors. Despite the variation in definitions, assuming Hall’s (1993) and May’s (1992) assertions, this thesis defines policy learning as a form of learning which involves the use of experience, new information and other feedback that leads to either policy continuation or policy change.

Policy learning may develop consciously and unconsciously, through different mechanisms: experience, observation, or systematic study such as evaluation and experimentation (May 1992; Rose 1993). It can take place at any policy stage, among individuals, groups of actors, policy networks and organisations in policy subsystems. According to Bennett and Howlett (1992), the learned objects as emphasised by different scholars may be policy interventions, processes, goals and ideologies, each of which results in particular effects: if not the *status quo*, changes in organisations, programmes, and paradigms.

Policy networks, policy learning and therefore policy outcomes are affected by contextual elements within and outside policy subsystems (Sabatier 1988). For instance, the transfer of

safe motherhood policy from global agencies to Honduras, followed by successful implementation during the 1990s was facilitated by collaborative advocacy of domestic health officials, donors, and representatives from international organisations such as the World Bank, WHO, United Nations Population Fund (UNFPA) and United States Agency for International Development (USAID) (Shiffman, Stanton, and Salazar 2004). Apart from depicting the influence of the health system context, the Honduran safe motherhood initiative reflected the involvement of multiple partners as members of a policy network.

Following Peterson (1997), policy learning can be classified into two types: substantive and situational. Substantive learning comprises the results of practice, experimentation, analysis, observation, and adjustment in policy, argued on the basis of facts and objectivity. As shown by Williams et al (2004), for example, the replacement of chloroquine by sulfadoxine-pyrimethamine combination for malaria treatment in many African settings in the late 1990s was driven by the evidence on parasitic resistance to the former regimen and the effectiveness of the latter. On the other hand, situational learning is the process by which lessons mostly derived from perceptions of norms, purported cultural differences, and measures of public attitudes through focus groups and surveys are subjectively interpreted. For instance, the introduction of policies on needle exchange and condom programmes is hindered in some societies owing to conflicts in social norms and religious beliefs (Rocheftort and Cobb 1994a). Peterson's (1997) model also illustrates that different sets of actors are involved in, and different outcomes are developed from policy learning of particular type. However, as the author asserts, there is no clear border between the two types of learning, and in practical policy processes substantive and situational learning operate concomitantly. Sabatier (1988) argues that alterations in the political and economic context can affect the core beliefs of actors in policy networks, which subsequently results in a shift in policy learning from substantive to more situational.

Policy learning is presented through social construction, interpretation and understanding of problematic conditions, potential solutions and context (May 1992). It is noted that policy makers may adjust their perspectives on and logical explanations of the problems they address and the preferred policy options on the grounds of their experience, study, and professional training (Grindle and Thomas 1991). In this light, as Klein (1997) points out, learning among those involved in the policy process is not a neutral intellectual exercise, but influenced by selective perception and arguments about the interpretation of evidence. Since

different actors have different perspectives and concerns, variation in patterns of policy learning and outcomes can be expected when particular interests have a leading role in a policy subsystem (Klein 1997; Peterson 1997). For example, bureaucrats tend to focus more on policy feasibility than do their academic counterparts. Therefore, learning among civil servants is process-related and likely to result in incremental organisational change rather than paradigm shift (Bennett and Howlett 1992).

### 3.2.3 Agenda setting

In studying policy, the process by which problematic conditions and concerns come to receive governments' attention, i.e. rise on the government agenda, and thus have the potential for policy alteration is represented by the term *agenda setting* (Nelson 1978). As Marsh and Rhodes (1992) suggest, policy change and continuity are determined by the structure and action of policy networks. Baumgartner and Jones (1993) have proposed a *punctuated equilibrium* model which argues that the shifts in policy networks are a vital factor leading to policy innovations. They suggest a policy domain comprises long periods of stability with policy continuity and intermittent phases of instability with dramatic policy changes. Both dramatic changes and stability in the system are influenced by two interacting elements: policy venues and policy image.

*'Policy venues are the institutional locations where authoritative decisions are made concerning a given issue.'* (Baumgartner and Jones 1993:32). Such institutions can include government agencies, private organisations, local authorities, consumer groups, the family, including policy communities (Baumgartner and Jones 1993). It is maintained that which institution will make the decisions about particular issues depends on how the issue is understood and discussed, in other words: *'how it comes to be associated with one set of images'* (Baumgartner and Jones 1993:32). A condition may be recognised as a public policy problem if it has an image that indicates a demand for the government's intervention (Baumgartner and Jones 1993). The authors point out that such a perspective resembles what other scholars call 'problem definition'. In addition, Baumgartner and Jones (1991:1047) note that policy image and policy venue are closely related: *'as venues change, images may change as well; as the image of a policy changes, venue changes become more likely.'* For instance, when HIV in Thailand was considered as a communicable disease in late 1980s, national HIV policy making involved only government officials in the Health Ministry. In

contrast, from 1992, after the epidemic was recognised as associated with several socioeconomic factors, the policy decisions in HIV area have been influenced by multi-sectoral actors as members of the National AIDS Committee (Porapakham, Pramarnpol, and Athibhodhi 1995).

During stable periods, the same group of privileged elites dominate as members of policy communities and gain political and economic benefits (Baumgartner and Jones 1993). System stability is maintained through shared understandings, preferences and values towards particular issues, while the differences and opposition are excluded from policy making. As Marsh and Smith (2000:6) argue, '*... tight policy networks persist, in large part, because they are characterised by a large degree of consensus, not necessarily on specific policy but rather on policy agenda, boundaries of acceptable policy.*' Actors who have expertise in particular areas attempt to convince others that the issues are so technically complex that the *outsiders* are unable to make appropriate decisions (Baumgartner and Jones 1993). Moreover, they may use their knowledge to articulate the definitions of the problems and policy options to support policy monopolies and continuity.

Apart from the tightly-integrated arrangements of policy communities that discourage dramatic reforms, patterns of policy learning among participants play a role. May (1992) points out that it is the dominant interest's specialisation and unwillingness to challenge core beliefs of the network that constrains policy learning. Similarly, as Sabatier (1988) argues, policy coalitions usually resist information that confronts their fundamental beliefs thus the policy learning during this period is instrumental and merely results in incremental changes. An illustration can be drawn from the global tuberculosis treatment strategy between 1970s and early 1980s, where experts in the field preferred 18-month regimens to the newly researched 6-month protocols since the latter was believed as unsafe and might result in multi-drug resistance development (Ogden, Walt, and Lush 2003).

In the instability phase, the existing privileged members of the network are challenged as new ideas disseminate throughout policy subsystems, allowing a wider range of actors with have different interests, values and expertise to permeate the policy-making arena (Baumgartner and Jones 1993). This may be because politicians, government officials and members of interest groups who hitherto paid little or no attention to specific issues, are encouraged to participate in decisions by a new understanding about the nature of the problems and

solutions (Baumgartner and Jones 1993). *'When they are portrayed as technical problems rather than as social questions, experts can dominate the decision-making process. When ethical, social or political implications of such policies assume centre stage, a much broader range of participation can suddenly become involved.'* (Baumgartner and Jones 1991:1047). For example, when HIV in Thailand was considered as a 'health issue' in the early phase of the epidemic, those who played a central role in devising national HIV strategies included clinicians and specialists in the Health Ministry and universities. From the early 1990s when growing evidence suggested HIV distribution and its consequences were socially-oriented, the range of policy participants expanded to involve private business, NGOs and communities (UNDP-Thailand 2004). The transfer of key participants in policy decisions does not always develop without conflicts between those who support different interpretations of policy issues. Contests between the proponents and opponents of a policy innovation are dynamic and may occur in either stability or instability phases, but are more likely in the latter (Baumgartner and Jones 1993).

Although the subsystems are tightly restricted with technical expertise and other resources, these advantages may be disturbed in certain situations that enhance redefinitions of the policy issues (Baumgartner and Jones 1993). This is what Richardson (2000:1017) observes: *'New ideas and knowledge have a virus-like quality and have the ability to disrupt existing policy systems, power relationships and policies.'* Monopolies may be broken down because of the changes in the policy networks' features such as shifts in individual network members, cohesion and reallocation of resources and power. For instance, a study in Victoria, Australia between 1991 and 1993 suggested that the main issues on the governmental agenda shifted from health care-oriented topics including prevention and health promotion to those on rational funding, economic reforms and cost escalation. It was observed that in parallel, there was increasing influence in the policy network from people with an economics background, while the role of medically-trained academics and civil servants declined (Lewis and Considine 1999). Change in the regime and turnover of key personnel in the policy community such as chairpersons of government commissions and leading politicians in the Congress can encourage the rise and fall of certain agenda items (Kingdon 1984).

Agenda setting may be influenced by surrounding circumstances of the policy subsystems, for example economic stability, political conditions and international and pressures (Grindle and Thomas 1991). The international context may play an important role in the agenda setting of

health policies in developing countries (Shiffman 2003; Williams, Durrheim, and Shretta 2004). Dramatic changes in the government's agenda may also be associated with rapid dissemination of new issues triggered by focusing events<sup>14</sup>, campaigns of organised interests, publications of the issues in the media, and surges of public opinion (Baumgartner and Jones 1993; Kingdon 1984). Evidence elsewhere suggests that, for instance, the WHO's 3 by 5 Initiative and financial support from the Global Fund to Fight AIDS, Tuberculosis and Malaria drew considerable attention of resource-poor countries' governments to ART programme commencement (Steinbrook 2004a).

In a given environment, the chance for an issue to be perceived as a problem and matching solutions to be considered by policy community members may be enhanced by the efforts of particular individuals or groups of participants – *policy entrepreneurs*, who actively promote their proposals to the government for attention and action (Kingdon 1984). Several strategies have been employed by policy advocates to convince the administration and general public to consider particular social conditions as problems, for example by framing debates, crafting arguments, building coalitions, and brokering their ideas and proposals to political supporters and the public (Mintrom 1997).

Actors who desire to influence policy may define and redefine problematic conditions and policy options in rhetorical ways (Rocheftort and Cobb 1994b). For instance, a group of policy advocates in the United States successfully changed the government's child-abuse policy by labelling it as 'battered child syndrome' to legitimise the involvement of medical professionals (Nelson 1978). The effort of ART advocates to articulate delayed treatment provision as a death sentence to PLWHA or a crime against humanity (chapter 1) offers another illustration. *'By dramatising or downplaying the problem and by declaring what is at stake, these descriptions help to push an issue onto the front burners of policymaking or result in officials' stubborn inaction and neglect.'* (Rocheftort and Cobb 1994b:3). In the same

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<sup>14</sup> A focusing event is 'an event that is sudden; relatively uncommon; can be reasonably defined as harmful or revealing the possibility of potentially greater future harms; has harms that are concentrated in a particular geographical area or community of interest; and that is known to the most informed members of the policy community and the public virtually simultaneously' (Birkland 1998). Following Kingdon (1984), focusing events are not confined to negative occurrences such as crisis and disaster but also include personal experience or powerful symbol. In some cases, obvious events not harmful by themselves, highlight the issues to which the government pay attention, for example international conference organized by highly accepted organizations, may be considered as focusing events (Shiffman 2003).

vein, Baumgartner and Jones (1993) have maintained that the distribution of particular policy ideas within the policy communities may trigger substantial changes in policy image, and raise new issues on the government agenda.

Focusing on the policy choices, along with the recognition and conceptualisation of problematic conditions, a shift in agenda items requires corresponding policy options to be identified (Baumgartner and Jones 1993; Kingdon 1984). From several competing proposals for a given problem only a few will be seriously considered (Kingdon 1984). As Kingdon further points out, the interventions are most likely to reach governmental agendas if they meet the criteria of technical feasibility; conformity with social values; and the anticipation of future impediments including financial constraints, public acceptability, and political receptivity. However, the technicalities and anticipated impediments in implementing particular policies are subject to actors' interpretations (Rochefort and Cobb 1994a). In addition, Grindle and Thomas (1991:73-74) have illustrated the influences of system circumstances of crisis or non-crisis for decision making: '*Certain kinds of policy issues – a devaluation, say – tend to get on decision makers' agendas only when crisis conditions exists. Other kinds of policy – to decentralise, for example – emerge almost uniquely under politics-as-usual circumstances.*'

#### **3.2.4 Policy formulation**

When a problematic issue reaches the government agenda, the next policy stage involves the decision to find solutions to the problem. The course of action to explore, assess and accept or reject a given policy option is defined as *policy formulation* (Howlett and Ramesh 2003). Particular public policies may come from the proposals posited in the agenda-setting process, or may be developed later in government offices. As policy formulation involves instrumental and evaluative activities, the concepts of policy learning and issue definition may provide understanding to how programmes are designed.

According to Rose (1991), in most situations policy makers tend not to invest their time and resources in seeking fresh knowledge, i.e. commissioning research to inform policies, but to search for lessons from their own organisations including past experiences, neighbouring agencies and also foreign countries. Learning among policy formulators may involve learning from implementers. As Stone (1999:53) points out, '*Policies sometimes develop on particular*

*local practices – either through pilot schemes, including drug trials, or the innovations of street level bureaucrats...’*. To address the problems which are confined to a few settings of similar characteristics, such as those that share socioeconomic features or face a unique problem, alternative policy models are limited (Dolowitz and Marsh 1996). Lessons may also be drawn across policy domains as illustrated in the case of the United Kingdom’s National Health Service reforms where the government partly learned from its own market-based model established in the education sector (Greener 2002a). Furthermore, as argued by Dolowitz and Marsh (2000), an organisation may be forced implicitly or explicitly by others to adopt particular policies. Such pressure may be significant in highly aid-dependant countries that may be obliged to follow the directions issued by international agencies and donors (Grindle and Thomas 1991).

When the information on potential policy prototypes has been gathered, policy makers need to consider whether or not, and how to introduce such lessons in their settings. Policy learning may involve not only copying but also different degrees of adaptation therefore the policy innovations may be different from its template (Bennett 1991; Rose 1991). This is because the adoption of a policy is contingent on several conditions, especially the internal factors of the policy importer setting, such as the effects of policy legacies, political context and socioeconomic status (Rose 1990). Similar to the agenda setting stage, policy options may be assessed for their technical feasibility, affordability and social acceptability (Cobb, Ross, and Ross 1976), and as a result, undergo some transformation. As observed by Grindle and Thomas (1991), as policy formulation usually involves government officials, their concerns, including bureaucratic implications, for example individuals’ career objectives, competitive positions and budgets between governmental units, as well as administrative capacity, compliance and responsiveness may affect how far policies are adapted.

Since the actors involved in this policy stage are required to search, examine and justify the appropriateness of competing policy options, they have to have a minimal level of knowledge and skills on problems and solutions in the subject domain (Howlett and Ramesh 2003). In addition, given that the policy formulation process is complex, iterative and often long lasting, the participants have to be motivated by enduring interests. Policy networks may be important for policy in this stage. According to Stone (2001:13), ‘... *the interaction of official decision makers (politicians and bureaucrats) with relevant stakeholders and experts, helps*

*to reinforce the credibility and legitimacy of network participants in the formulation and implementation of policy.'*

The role of policy learning among network members in the policy formulation stage has been depicted in Sabatier and Jenkins-Smith's (1993) advocacy coalition framework. The authors argue that continual learning operates throughout policy formulation and implementation stages. Apart from common interests, knowledge and values shared by members of particular coalitions as suggested in such a framework, the influences of available resources and external elements in their learning and related policy change are emphasised.

While advocacy coalitions include a range of state and non-state actors, Rose (1991) has observed that policy makers, especially politicians, often rely upon advice from expert or professional networks – so called 'epistemic communities'. Learning within such networks is prompted by scientific knowledge, which is usually, but not always consensual, systematic and professionally constituted (Stone 2001). In addition to academics and specialists, other actors such as elected officials, bureaucrats and organised interests can lead the policy networks (Marsh and Rhodes 1992). However, as Howlett and Ramesh (2003) suggest, those who are appointed by the authorities, such as scientists or government experts in some policy domains, gain advantage over others in policy formulation.

Owing to the variation in the types of learning, dominant actors shape policy outcomes differently (Peterson 1997). Policy learning among specialists is classified as substantive, based on integrated information and knowledge derived from scientific procedures. If experts take a leading role in policy design, policy change focuses on developing policy instruments for the implementation phase. On the other hand, if politicians are in the lead, they may opt to design policies which are not only feasible to implement, but also attractive among voters. Therefore, policy learning among politicians is more situationally oriented, and can result in reforms. Interest groups with widely ranging goals and positions may emphasise scientific-based learning rather than pursuing reputation among their clients, and *vice versa*, depending on type of interests.

### 3.2.5 Policy implementation

*'An understanding of how and why public policy is put into effect can be conceptualised under the heading of implementation'* Schofield and Sausman (2004:235). As the literature suggests, action is a key moment in the policy process as it significantly affects policy outcomes (Hudson and Lowe 2004). This is because policy content may be adjusted, elaborated or even rejected during implementation (Hill and Hupe 2002). The analysis of policy in this phase aims to understand the process and factors influencing the discrepancies between policy intention and action. Substantial literature in this field discusses two distinctive 'top down' and 'bottom-up' models (Parsons 1995).

The top-down approach sees implementation as the process whereby policy makers at the top of an administrative hierarchy, such as the government and parliament, expect bottom-level bureaucrats to carry out the policy as formulated (Hill and Hupe 2002). Following Walt (1994), such a concept stems from the perception that the implementation stage involves administrative or managerial activities, and is completely separated from the politically-oriented policy formulation. Some studies employing top-down approaches focus on the gaps between policy intention and actual policy implementation. They often aim to provide information on 'best practice' conditions to programme administrators to enhance the complete control over the process and therefore its outcomes (Hudson and Lowe 2004). For instance, Hogwood and Gunn (1984) propose a model comprising ten preconditions required for achieving perfect implementation. This includes, for example, the absence of constraints from external circumstances; adequate time and resources; effective coordination between participating units; and complete understanding of, and agreement upon the objectives to be achieved. However, such a model is ideal since it is almost always impossible to achieve all the listed preconditions, which suggests that implementation will always be flawed (Walt 1994).

By contrast, the bottom-up alternative seeks to explain the process and actors involved in translating policy into action (Hill and Hupe 2002). This approach perceives the implementation stage as part of a policy-making continuum: the policy is remade and fine tuned by those expected to be implementers (Barrett 2004). As Walt (1994:155) maintains, *'the bottom-up view is that implementers often play an important part in policy implementation, not merely as managers of policy percolated downwards, but as active*

*participants in an extremely complex process that informs policy upwards too.* Many have pointed out that implementation is an interactive process, characterised by negotiation and conflict among participating networks, and therefore as political as the policy formulation stage (Grindle and Thomas 1991).

Assuming a bottom-up perspective, Lipsky's (1980) work on public servants' behaviours suggests that *street-level bureaucracy* is where implemented policy is diverted from its prescription. His study illustrates the discretionary freedom in service delivery and distortion of such practices from policy intention. Developed by public officials, these informal practices aim to address implementation constraints and complexity, excess demands, conflicting and ambiguous policy objectives, uncertainties about new jobs, and occupational stress (Lipsky 1980). Eventually, such coping mechanisms become routine and then established practices in the organisations. Lipsky further argues that programme managers and superior officials have found some difficulties in controlling the street-level bureaucrats' behaviours and fostering policy compliance.

The roles of knowledge, skills and understanding among public servants on policy innovations, such as their meaning in relation to service delivery and appropriate ways of executing them, is important since they affect the services offered to clients (Hardiker and Barker 1999; Rees et al. 2004). Hill (2003) has suggested it is essential to explore further how implementers understand policy in order to do it. Implementation involves endless learning of implementers as they are obliged to search for the strategies to meet new policy goals and programme instruments including new technologies (Browne and Wildavsky 1984). As Hill (2003) emphasises, inadequate knowledge and misunderstanding of implementing units may lead to policy failure. Getting better insight into policy implementation, especially in complex contexts, is therefore to conceptualise it as an ongoing learning process (Behets, Miller, and Cohen 2001).

With the attempt to integrate the two major approaches in implementation – the top-down and bottom-up, Sabatier (1986) has embedded policy learning in the model for policy study (Lane 1987). Sabatier's advocacy coalition framework highlights the role of evaluation feedback of policy while it is being implemented as an input to the policy learning process. According to Hudson and Lowe (2004), however, such learning develops among elite policy makers and affects policy formation rather than implementation.

*The model of learned implementation* (Schofield 2004) suggests that the practices of front-line officials are influenced by policy learning as a function of bureaucrats' motivation, competency, acquired knowledge, and latitudes of discretion. In implementing a policy, bureaucrats require technical and procedural knowledge and motivation. Learning about new knowledge, capacity building, and subsequently trying out technical operational solutions continue over time. In this sense, learning among street-level officials aims not only to gain the knowledge on how to get new policy into action but also to acquire the capacity to deal with the undesirable effects of the initiatives, i.e. to develop effective coping strategies. Schofield (2004) also maintains that the learned objects involved in this policy stage can be classified into *technical* and *procedural*. The latter type of knowledge helps to examine, refine and adapt the knowledge in the former category. The cognitive process that produces procedural knowledge – the so called *generative learning* – also results in increasing competence and capabilities of service providers to develop solutions to implementation obstacles. The invented policy execution strategies become routinised as it is recorded into job tasks as well as individual workers' and organisational memories. According to the learned implementation model, the learning process of front-line bureaucrats is facilitated by organisational capacity, resources and expertise, and constrained by problem complexity, inadequate resources and insufficient information. Although such learning is motivated by the possibility to exercise discretion, Schofield (2004) stresses that it does not develop liberally, but is bound by bureaucratic regulations, the bureaucrats' sense of organisational accountability and professional responsibility.

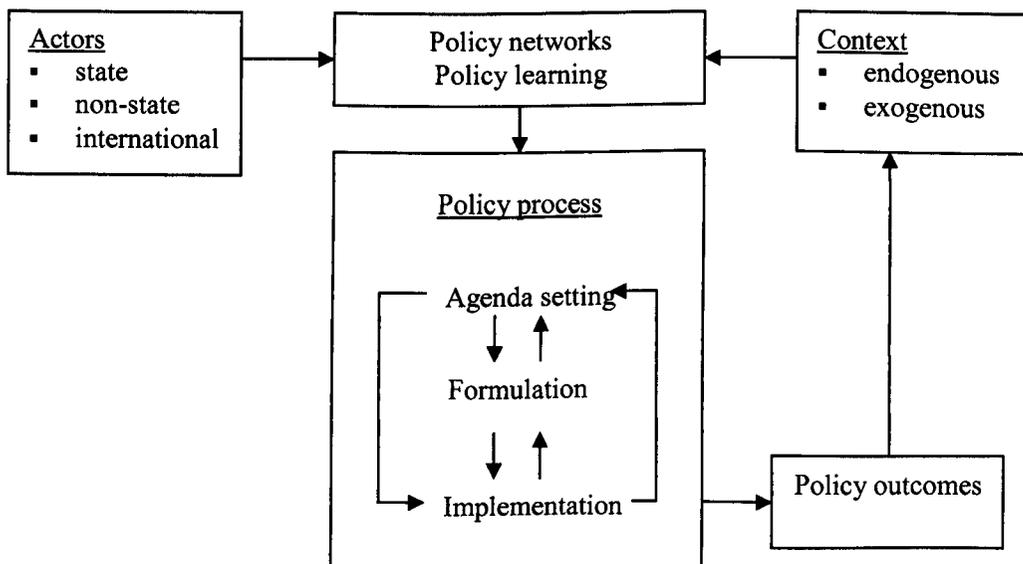
Although Lipsky's street-level bureaucracy concept and Schofield's model of learned implementation focus their attention on the implementing agents, empirical evidence in health sector shows that translating a policy into practice involves several actors outside implementing units, for example politicians, representatives from a range of multi-level government agencies, business corporations, and CSOs including professional organisations (Beyer 1998; Kajula et al. 2004). Rhodes (1996) points out that policy subsystems within which the discussion, negotiation and bargaining operate among these participants exist in this policy stage. Barrett (2004:253) argues: *'the political process by which policy is mediated, negotiated and modified during its formulation continues in the behaviour of those involved in its implementation acting to protect or pursue their own values and interests.'*

According to Marsh (1998b), the obstruction in implementing a policy may be originated by implementation actors who have not been involved in policy making, i.e. policy networks that shape policies are not the same as implementation networks those get the policies into action. Implementation gaps may stem from the differences in the interpretation and understanding of problems, policy goals and prescribed instruments between central-level policy makers and peripheral actors (Hill 2003). An example can be drawn on HIV policy in the Russian Federation: in addition to the political and socioeconomic context, varying interpretations of criminal codes and federal orders relating to HIV/AIDS, as well as the behaviours and attitudes of health administrators and staff influenced priority setting, policy pursued and activities carried out in particular regions (Atun et al. 2005).

### 3.3 Analytical framework for the thesis

The previous section reviews theoretical literature on the development of three stages of policy cycle: agenda setting, policy formulation and implementation, and suggests that the concepts of policy networks and policy learning, in combination can help to explain the processes by which a policy is shaped and translated into practice. Assuming these notions, a conceptual framework for the analysis of Thailand's antiretroviral policy is constructed as shown in figure 3.1.

Figure 3.1: Framework for analysing Thailand's antiretroviral policy



The diagram captures the interaction between three factors central to public policy: the actors, context and process. The actors and context shape the agenda setting, policy formulation and implementation through the networking and learning of participants. Throughout the three policy stages, networks of politicians, government officials, private corporations, CSOs and international agencies in a policy domain evolve and intersect. Elements of change occur: (1) in the features of policy networks such as the members, resources, interests, ideologies, cohesion and positions in relation to particular issues as well as other network clusters, and (2) in the process by which these networks acquire knowledge about problems, solutions, and related environment. A result of the overall processes – the policy outcomes, may affect the contextual factors that lead to further policy making and implementation.

Note that although the above description largely presents policy processes as consisting of sequential, discrete stages, as portrayed in the diagram, the analysis of Thailand's ART policy takes into account the complex features of actual public policy which involves back and forth movements of particular issues through different overlapping phases. Moreover, it has been kept in mind that there may be interactions between the networking and learning among key actors across policy stages.

### **3.4 Objectives of this thesis**

Based on the literature on ART policy in developing countries and the conceptual framework described in the previous section, the objectives of this thesis are developed as follows:

- (1) To describe the shift in the Thai government agenda towards universal ART access, and succeeding adoption of such policy.
- (2) To explain the process to design the national treatment programme in order to achieve the universal coverage goal.
- (3) To explore the process by which ART was integrated into the health delivery system and subsequently provided to the targeted population
- (4) To identify the key actors and analyse their involvement in each stage of the policy processes.
- (5) To assess the context that influenced policy development and implementation.
- (6) To explore the extent to which learning was an important part of the policy process.
- (7) To identify whether policy processes were affected more by the actions of individual actors or by networks of actors coming together to promote particular policies.

### **3.5 Methods**

This study focuses on national ART programme development since the policy to provide universal treatment access was adopted in 2001 until December 2004. The field work of this thesis was carried out in Thailand between October 2003 and December 2004. To explain the national-level policy processes, i.e. agenda setting and policy formulation, data were collected from the Ministry of Public Health (MOPH) and other governmental agencies; academic institutes; private companies; PLWHA groups and NGO offices located in Bangkok and Nonthaburi. To gather information on ART programme implementation, the field work was primarily conducted at Health Ministry hospitals and Provincial Health Offices in two case-study provinces: Phichit and Rayong. Provincial interviews and documentary reviews also covered agencies involved in the translation of treatment policy into practice, i.e. Regional Disease Control Offices and CSOs, established in the areas nearby.

#### **3.5.1 Justification of case study approach and selection of study provinces**

Case studies are a research strategy used in many fields of social sciences where there are demands for thorough understandings of contemporary, complex phenomena, such as in policy and politics areas (Yin 1994). As Yin (1994:3) further notes, such an approach helps to illustrate *'holistic and meaningful characteristics of real events'*. In policy analysis, case studies are valuable to understand the processes of policy change and the factors associating with policy success and failure (Keen and Packwood 1999:51). Following Stake (2002), case studies can be used to test hypotheses, and their exploratory and explanatory power on intricate events as well as contextual conditions is also vital.

As case studies seek to address the 'why' and 'how' questions, they mainly rely on qualitative methods such as interviews and documentary analysis, which are sometimes criticised for their lack of objectivity, precision and generalisability (Hammersley and Gomm 2002). However, several strategies have been introduced to reduce subjectivity and improve precision of qualitative approaches (see section 3.5.4). Research employing case-study design may contain one case or a small series of cases (Yin 1994). While multiple-case studies need extensive resources and time, in comparison to applying the single-case, the advantage is that they offer more compelling explanation, and therefore more robust conclusions (Herriott and Firestone 1983). To understand the processes of policy changes and outcomes, a study of a

particular policy in many settings with different situations would be useful as it can reflect the policy development and influence of several factors those do not exist in every setting. Nevertheless, although research findings drawn from a single case cannot be generalised to a population, some scholars argue that generalisability is not an essential goal for qualitative research (Cronbach 1982 quoted in Schofield 2002:75). Even single case studies are intrinsically interesting and do not mean that findings in one situation cannot help to form hypothesis on what will occur in other situations (Schofield 2002). Analysis of similarities and differences between settings makes it possible to judge the extent to which the findings can be transferred from one situation to another (Kennedy 1979 quoted in Schofield 2002:76). Owing to resource and time limitation, this thesis includes only two provinces in the analysis of ART programme implementation.

The two provinces were selected according to 3 criteria. First, both provinces had relatively high HIV prevalence. Phichit and Rayong were among the top five provinces in term of HIV prevalent rates among pregnant women at antenatal clinics in 2003 (Bureau of Epidemiology 2004a). Second, both provinces had little experience of ART delivery before treatment scaling up: only one out of nine MOPH hospitals in Phichit, and two out of six MOPH hospitals in Rayong delivered ARV medication before 2001 (data from ATSI database). Third, one province had stronger NGO and PLWHA groups than its counterpart. Given that CSOs were recognised by policy makers as important partners who would support ART delivery in particular areas during the scale up era, significant questions arise over the circumstances in and processes by which the providers and civic networks interacted to influence the expansion of the services. Rayong was the province with many well-established NGO-PLWHA networks since the early HIV epidemic. In contrast, a smaller number of AIDS NGOs in Phichit had been recently instigated, and had a small role, compared to those in Rayong, in collaborating with health care providers and providing support to patient groups.

### **3.5.2 Data collection**

To meet the objectives of this thesis, qualitative approaches, including in-depth interviews and documentary analysis were utilised. According to Denzin and Lincoln (1998), qualitative inquiries seek answers to questions on how social experience is created and given meaning. The objectives are to explain behaviours; social relationships, processes and situations; and the meanings people give to their activities and the activities of others (Blaikie 2000). As

qualitative research aims to interpret social interactions, behaviours and events in terms of the meanings constructed by people, it is usually referred to as *social constructive* or *interpretative* research (Patton 2002). Patton also notes that constructivists focus their attention on understanding specific cases in particular circumstances rather than on generalisations to others in different contexts. A key feature of qualitative investigation is that it adopts a multi-method approach in one study (Pope and Mays 1999). In the same way, although this thesis largely involved in-depth interviews and documentary review, other approaches such as direct observation of actors' behaviours, informal communication with knowledgeable persons and lay people, field notes and a personal diary were also used to garner primary data as well as to verify information from other sources.

### *Semi-structured interviews*

The interviews were conducted as face-to-face conversations on specific topics between the investigator and key informants – people knowledgeable about the issues in focus. This method has been used in cases where the studied subjects cannot be directly observed, for example to obtain intentions, opinions, perceptions, attitudes and past experiences or behaviours (Patton 2002). The semi-structured interview employing a set of open-ended, core questions as an interview template, is a useful technique in seeking explanations to specific issues (May 1997). Interviewers have to be open-minded, introducing divergent questions at times, and also take into account any new concepts and frameworks proposed by the interviewees (Britten 1999).

In this thesis, generic interview guides were developed and then adapted for particular groups of key informants with potentially different patterns of policy involvement, for example policy makers, treatment advocates, patient group leaders and service providers of various disciplines (see generic interview guides in Appendix 1). The interviews were carried out in Thai and taped by the investigator, and then transcribed by experienced research assistants. In some cases, key informants were re-interviewed via telephone. Only quotes used in the thesis were transcribed into English. At the beginning, a number of potential interviewees were purposively selected by the investigator on the basis of related public policy documents and literature on the scale up of ART in developing countries. The list of key informants interviewed was eventually extended to cover persons mentioned by other respondents or

emerging from other sources of information during fieldwork. In this study, 80 persons listed in Appendix 2, were interviewed.

### ***Documentary analysis***

Documents are products of structured and informed social practices deriving from the decisions which people make as individuals and members of groups or organisations (May 1997). Documentary sources contribute to the information on past social phenomena and individual behaviours which operated in particular political, economic and socio-cultural contexts (Prior 2003). Documentary analysis provides the evidence explaining why and how particular policies were made and carried out (Buse, Mays, and Walt 2005). Information from documents can be utilised either straightforwardly or interpretively, to produce primary research findings or for verification purpose (Mason 1996; Patton 2002).

The documents mainly explored in social research are written texts collated and recorded by organizations and individuals for particular purposes (Mason 1996). There are several sources of information, written and unwritten, to be explored in analysing health policy, for example journals, reports, documents, statistical databases and the media including the Internet (Buse, Mays, and Walt 2005). Useful evidence can also be retrieved from unpublished documents including letters, email messages, 'internal' materials, as well as grey literature. Documents of all sorts are social products therefore they should be selected and analysed with caution, taking into account not only their content but also other features such as the production and functions (Prior 2003).

In this thesis, a wide range of documents, in Thai and English, were perused. They principally comprised government documents and statistics from central departments, sub-national agencies and study hospitals; they included reports, conference proceedings, work plans and pamphlets produced by NGOs and PLWHA networks at national level and in study provinces. Moreover, articles and other forms of research reports published in domestic and international journals were reviewed for the background information on HIV epidemiology, related policies and ART programmes in the developing world including Thailand. A substantial part of documents analysed in this study were produced by international organisations in particular WHO, UNAIDS, and HIV-related civil society alliances. In

addition, a number of news and commentary articles from national newspapers were included in the review. See the outline of documents reviewed in this study in Appendix 3.

This thesis is a tribute to the learning environment of the Thai health system. At the time of study, there were several research reports on public ART service and health care financing reforms, produced not only by health officials in central departments and academics, but also by front-line professionals and NGOs. Apart from the findings of these studies from which helpful information was excerpted, the investigator synthesised a considerable fraction of this thesis from other researchers' insights and experiences.

### *Other means for gathering information*

Much of this study was carried out while the investigator was an employee of the International Health Policy Programme – a research body of the Ministry of Public Health – which has been involved in the development of policies in the health system including the reforms of health care financing and economic evaluation of health programmes and interventions. Before starting the PhD study in September 2002 and during the fieldwork between October 2003 and December 2004, the investigator participated in conferences, meetings and discussions on many HIV/AIDS and health financing reform topics, among others, for example national HIV policies, ART scaling-up processes and implications for health delivery facilities. For instance, the investigator represented the International Health Policy Programme on the MOPH's Administration Panel, which was responsible for devising management strategies for the National ART Programme while therapy was expanded in 2002. Experience gained from attending the meetings of this Panel contributed to better understanding of the roles and networks of actors in policy formulation.

As the International Health Policy Programme had developed close connections with Health Ministry departments, the National Health Security Office, Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections, and many of the MOPH's sub-national agencies including hospitals, this facilitated the investigator in her contacts with health officials, specialists, health workers as well as researchers in the field. A good deal of information was accessed through personal communications. In particular, exchanging experience with other HIV researchers provided insights into many important facets of treatment expansion in the Thai context. For example, the investigator learned about psycho-social factors hindering

ART seeking and ARV administration from a group of social scientists from Chulalongkorn University. Moreover, such relationships helped to understand the features of knowledge generation and utilisation as well as networking patterns between stakeholders in HIV area.

As an employee of an autonomous research institute contributing to knowledge generation in the health sector, the investigator experienced good cooperation from key informants and their organisations. However, working with the International Health Policy Programme may also have been a source of possible biases. Since this research institute had been involved in economic evaluation of many health interventions and provided policy recommendations based on the efficiency of resource utilisation, the investigator believed strongly that ART should not be included in the universal health coverage plan, until the treatment programme was assessed for its financial consequences in relation to public health outcomes. However, throughout the course of this thesis, the investigator tried to be objective, and employed several methods to reduce bias (see section 3.5.4). Accessing information from various sources, especially from people who promoted and disagreed with treatment expansion, helped to balance the analysis, and to enhance the thesis quality.

### **3.5.3 Data analysis**

In this study, quantitative data on epidemiology, resource availability, programme enrollees and services delivered were utilised to reveal some contextual elements and outputs of the policy. For the documentary review, the *content analysis* approach illustrated by May (1997) and Ericson (1991) quoted in May 1997:173) was employed. The investigator read, conceptualised and interpreted the text according to specific themes, picking out pieces of information relevant for understanding treatment policy processes in particular stages. Afterwards, such information was assembled and shaped to narrate the policy development and implementation, linked with the thesis' conceptual framework. Throughout the process, the documents were examined for not only their content but also the contexts in which they were produced and functioned.

Regarding interview data, the *framework approach* was introduced in the analysis. As Pope and colleagues (1999) maintain, this method has been developed for studies for which the

objectives are set in advance and guided by a conceptual framework. This approach is deductive, differing from the inductive process used in grounded theory where analytical concepts emerge from the data. In this thesis, transcripts of individual interviews was explored for key concepts as informed by the conceptual framework. These thematic keywords were highlighted and rearranged under relevant headings and sub-headings. Finally, the information under particular headings was reviewed and interpreted, by considering the actors and their involvement in the policy processes; searching for patterns of relationship with each other; and seeking explanations for these elements within the data.

#### **3.5.4 Quality control of research**

A significant body of literature illustrates a wide variety of criteria and positions to judge the quality of qualitative inquiries, some of which fit a constructivist perspective while others are located within a positivist paradigm (Spencer et al. 2003). Lincoln and Guba (1985 quoted in Spencer et al 2003:40) reject scientific criteria usually applied to appraise the validity, generalisability, reliability and objectivity of quantitative studies, and instead propose a set of naturalistic criteria defined as credibility, transferability, dependability and confirmability for interpretivist research. In contrast, other scholars such as Morse et al (2002) stress that the usual concepts used to assess reliability and validity can be applied to qualitative investigation. The differences in these criteria and underlying assumptions affect the approaches employed to ensure the rigour of research to a certain extent. Despite the variation, these quality-assurance methods share basic principles: reducing the biases and accounting for the predispositions of researchers as well as data sources, i.e. interviewees and documents (Morse et al. 2002; Patton 2002).

This thesis adopted the approach to improve the validity and reliability of investigation as suggested by Mays and Pope (1999). This included triangulation of data across sources; considering the characteristics of key informants and documents which might influence the information provided; clear illustration of methods of data collection and analysis; attention to deviant or negative cases; and incorporating a wide range of different perspectives. In addition, this thesis was embedded with verification mechanisms. As Morse and colleagues (2002) suggest, verification strategies should be introduced throughout the course of qualitative study, and include systematic and constant monitoring of the fit of data and conceptual work of analysis and interpretation. This can help researchers to determine when

and how to modify research process in order to ensure quality. Wherever possible, the investigator tried to use triangulation and verification methods to assure the quality of this thesis.

### **3.5.5 Consent procedures and ethical clearances**

Key informants participated in this study on a voluntary basis. The investigator sent them an invitation letter with the information on the aims, objectives, methods and expected benefits of this research, as well as the outline of interview questions in advance. Those who agreed to take part were informed about their rights to refuse to answer any particular questions or to leave the study at any time. Every interviewee was asked to sign a consent form before the interview started.

This thesis received ethics approval from Thailand's Ministry of Public Health on 13<sup>th</sup> January 2004 and the London School and Tropical Medicine's Ethics Committee on 3<sup>rd</sup> February 2004.

### **3.5.6 Research limitations**

One of the limitations of this thesis was the case study approach introduced in the analysis of programme implementation. As only two provinces were studied, and they cannot represent all provinces of the country, findings about the policy process at this stage cannot easily be generalised or transferred to other provinces. Even in the same province, it could be seen that the policy responses of hospitals and professional practices varied across districts. Although the case study approach is an appropriate method for the examination of complicated policy events and their circumstances, the results of this thesis should be interpreted and used with caution. Transferring the lessons learned from these two provinces requires understanding the differences and similarities in the context of study settings and others. However, some of the findings may be useful to inform ART implementation in provinces where most elements of the health delivery system are similar to the study provinces. Even in the areas with different environment, this thesis may contribute to some aspects of treatment introduction.

The aim of this thesis was to get insight into the changes in the national ART policy which mainly involved service provision in Health Ministry hospitals. Therefore, another weakness

is that the picture of treatment delivery in non-MOPH public facilities and the private sector is missing. Evidence from the Government Pharmaceutical Organisation suggests that in 2003 approximately 70% of its first-line ARVs was distributed through the MOPH-organised national programme, which meant that other public providers as well as private clinics and hospitals had a significant role in ART provision. ARV recipients outside Health Ministry hospitals included Social Security Scheme members, Civil Servant Medical beneficiaries, and self-financed patients.

Another important problem in conducting this research was the difficulty in finding comprehensive, systematic data. Some of the existing databases of Thai research reports as well as part of provincial and district statistics were incomplete, and not updated. As a consequence, some explanations about ART programme development and its context in this thesis relied on key informants. This was crucial for some particular issues the interviewees tended to conceal such as their failure, mismanagement, poor practices, and embarrassing experiences. Moreover, clients and beneficiaries of public programmes might hesitate to criticise their service providers.

In spite of these limitations, this study can provide a synthesis of available information, useful insights into the policy making process, and lessons for other provinces as well as other developing countries.

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## **CHAPTER 4: UNIVERSAL ACCESS TO ART: AGENDA SETTING AND POLICY ADOPTION**

Thailand launched its first antiretroviral treatment (ART) programme with limited coverage in 1992, and adopted the policy to offer medication to all eligible people living with HIV/AIDS (PLWHA) in late 2001. Despite a substantial decline in new human immunodeficiency virus (HIV) cases, at the time of the policy shift almost one million of the population were living with the disease. The literature reviewed in chapter 2 suggests that even for a middle-income country, introducing such a costly, complicated intervention on a massive scale was unusual, and raises many questions on the government's decisions and action. This chapter explores the agenda setting phase that drove the universal treatment issue on to the Thai government agenda.

### **4.1 The national ART programme before 2001: incremental policy changes**

Although adjustments were intermittently introduced to the national ART programme's targets, strategies and drug regimens between 1992 and 2001, treatment coverage never increased over a few thousand beneficiaries, representing only 3% to 9% of PLWHA (Tangcharoensathien and Teokul 2002). Changes in the programme features during the first ten years of its implementation can be regarded as incremental. This section reviews the roles, positions and interactions of policy participants, as well as the ways they defined ART in this policy continuity phase before 2001.

#### **4.1.1 Interactions between policy makers and civil society**

During this incremental period, HIV strategies and plans were dominated by government officials in the Ministry of Public Health (MOPH), especially the Disease Control Department as evidenced from documents and interviews. Despite the fact that the country's HIV policy development and planning were the responsibility of the National AIDS Committee (NAC) (established in 1991), which comprised representatives from several public agencies, private corporations, individual experts, non-governmental organisations (NGOs) and PLWHA networks, an evaluation of the national HIV control programmes suggests that the role of the Disease Control Department was critical in steering the policy direction (Chalamwong et al. 1997). This partly resulted from frequent turnovers of the administration and associated time

spent on bureaucratic processes to appoint a NAC. Chalamwong and colleagues (1997) suggest that during 1991 to 1997 period, the gap between NAC meetings was typically 5 months to 1 year. Even when the Committee existed, the Prime Minister as the chairperson called for few meetings (Khoaw Sod 1993). As a result, some urgent policy decisions were left to government officials in the MOPH as their positions were relatively permanent. Also, Teokul (1998:5) asserts that the Health Ministry's technocrats and professionals had a comparative advantage, in comparison to NAC members from the private sector and NGOs, in learning about new knowledge and technologies in this area so that the MOPH became '*the country's front-line agency in HIV/AIDS control campaigns*'. This was because health officials and specialists had relevant training background and had access to updated information more easily than others.

Although NGOs and PLWHA played a crucial role in encouraging the governmental response to the early epidemic, and their representatives were appointed to be NAC members, their involvement in HIV mainly focused on implementing prevention and care programmes (Phoolcharoen et al. 1998; Porapakkham, Pramarnpol, and Athibhodhi 1995). However, this does not mean that the civil society movement at the national level absolutely declined. Documents and interviews suggest that NGOs and also individual activists occasionally made proposals to the Health Ministry to revise, enact and enforce laws to curb the illegal distribution, advertisements and clinical trials of vitamins, traditional medicines, herbs, vaccines and many other products claimed to cure HIV, as well as to regulate the quality and marketing of HIV screening test kits (Eaow-sriwong 1991; Intrajitr 1994; Ungphakorn 1991). Meanwhile, some NGOs and patient groups appealed for fewer drug control measures and medicine practice regulations in order to provide more choices in treatment and care for PLWHA since there was no cure for the disease and the approved anti-HIV products and services were financially prohibitive (Asavaroengchai 1994; Dahlan 1994; Tangjai 1994).

In particular with the adoption of ART and other medical services, it was the bureaucrats and experts as members of ministerial task forces who made the decisions on the interventions to be included, and the strategies to have them delivered in the national programmes, while the NAC provided a broad policy framework (interview N10). For instance, the shift in ART provision from service-based to research-based treatment in 1995 (chapter 2) was decided by health officials and specialists (Kunanusont, Phoolcharoen, and Bodaramik 1999).

Treatment advocacy of the NGO alliance started in the early 1990s, and the first campaigns were launched in 1991, with NGOs urging the government to reduce import taxes of zidovudine, as well as to consider the implications of patent regulation for drug prices (Commission on NGO Coordination for Primary Health Care 1991; Matichon 1991). However, civic participation in national ART policy only became significant in the late 1990s when they began campaigns for improving access to generic antiretrovirals (ARVs) and drugs for opportunistic infections (OIs) (Wilson et al. 1999). As noted by Wisartsakul (2004), this happened after 53 PLWHA groups throughout the country formed into the Thai Network of People Living with HIV/AIDS in 1995. The author also points out that the PLWHA network collaborated with the pre-existing National AIDS NGO Network, and jointly participated in several campaigns. In the didanosine case<sup>15</sup>, for example, the coalition employed multiple strategies: urged the Health Ministry to issue compulsory licensing<sup>16</sup> to allow local drug industry to produce a generic version; encouraged the Government Pharmaceutical Organisation (GPO)'s research and development of ARV products; communicated with the United States (US) Presidency not to retaliate with trade sanctions when generic drugs were locally produced; and filed a petition to the Intellectual Property Court to revoke the disputed patent held by Bristol-Myers Squibb (Ford et al. 2004; Wisartsakul 2004).

Apart from the local HIV NGOs and PLWHA, movements for treatment expansion were supported by several other actors: health professionals, intellectual property lawyers, scientists of the government laboratory, school of pharmacy lecturers, and consumer protection organisations, as well as international NGOs such as *Medicins Sans Frontiere* (MSF) (interview N13, N15 and N19). As the literature and key informants suggest, these groups and individuals brought with them different resources, for example strategic advice and expertise in filing court cases of the lawyers; information and knowledge of the academics; proficiency in clinical trials and practices of the medical specialists; capability in producing cheaper medicines commanded by the scientists; and information on foreign

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<sup>15</sup> Didanosine (ddI) was an antiretroviral, patented in Thailand, with a specified a dose range, since 1992 (Ford et al 2004). In 1998, Bristol-Myers Squibb - ddI manufacturer - applied for patent extension to all doses. NGOs organised Didanosine Working Group in 1999 and campaigned against such amendment since it was considered to hinder treatment access among PLWHA. The Working Group also encouraged generic production of ddI by mean of compulsory licensing.

<sup>16</sup> Stated under Article 31 of the TRIPs Agreement, country governments may issue compulsory license - a mechanism to limit patent or intellectual property rights in order to protect public health of their people. The license will allow local drug industry to manufacture particular patented drugs, of which a percentage of sales must be returned to compensate the patent holders.

experiences and financial assistance from international NGOs. Many of these non-state actors approached the state counterparts directly in meetings and discussions, as well as publicised their proposals through the media, while others provided distant support. In so doing, apart from forming into networks, the treatment advocates learned from others' experiences (Wisartsakul 2004). For example, two NGO leaders pointed to their participation in a campaign for drug price reduction:

*'Before this time, NGOs were only involved with campaigning and training, but with this issue, I had to familiarise myself with ARV medicines, patents, TRIPS<sup>17</sup> and WTO<sup>18</sup>.'* and, *'We had to catch up on the legal details. We had to know what the academics mean. We had to be precise about the medicine formula and its effects.'* (Treemanka and Tienudom, respectively, quoted in Wisartsakul 2004:46)

Although the Health Minister and bureaucrats were mostly amenable to interaction with the NGOs, the imbalance of power between politician-bureaucrat policy makers and the civic alliance counterparts could be observed. The didanosine case offers a good illustration. Although urged to do so by NGOs, the Health Minister refused to issue a compulsory license to produce the drug domestically (Ford et al. 2004; Wisartsakul 2004), and instead sought to procure low-priced original products of didanosine and other ARVs through the government's tendering mechanisms (Chitwarakorn 2001). The Minister also allowed the state laboratory to manufacture didanosine in powder, instead of the patented tablet form (Wisartsakul 2004). This reflected the power (even if only perceived) of Big Pharma in the US.

As in other countries, the pharmaceutical industry was an important actor in the HIV area. In Thailand, transnational companies were accused of using drug patents and other monopolistic measures<sup>19</sup> to set unreasonably high prices of ARVs – the major barrier to treatment (Drug Study Group 2001; Limpananont 2002), in spite of the fact that the local drug industry had the capacity to bring down the prices through marketing of generic versions. A report of the

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<sup>17</sup> The Agreement on Trade-related Aspects of Intellectual Property Rights

<sup>18</sup> World Trade Organisation

<sup>19</sup> In 1980s, the Thai government was forced by the US Trade Representative to enact an administrative measure – known as Safety Monitoring Programme – to grant market exclusivity to research-based companies for marketing pharmaceutical products those were not eligible for the protection under the Patent Act. The programme required original products to be tested for safety in clinical settings for 2 to 4 years after approval by the Thai authority. During this 'safety monitoring' period, corresponding generic products could not be applied for registration (Limpananont 2002).

International Centre for Trade and Sustainable Development (2000) suggests that the fear of trade sanctions was the main reason why the MOPH was reluctant to implement compulsory licensing measures even though the US administration declared no official opposition. In the same report, the Director General of the Disease Control Department argued that, *'We must be very, very careful: considering the livelihood of our 62 million people, not just the 1 million HIV patients.'*

Some key informants said that apart from making use of international trade agreements, research drug corporations employed several tactics to restrict local ARV production and generic prescription in the national programme (interview N13 and N19). As revealed by one scientist, her office was often visited by foreign executives of major pharmaceutical companies and the US Embassy officials to make sure that the government laboratory did not violate patent regulations (The Nation 2002). She went on to note that *'Death threats were common when I began producing these drugs a decade ago.'* Another example of the action of drug industry was illustrated by Wisartsakul (2004:32):

*'Bristol-Myers Squibb made an offer to the Director of the Government Pharmaceutical Organisation to become the distributor for two Bristol-Myers Squibb products, didanosine and stavudine. Bristol-Myers Squibb proposed a reduced price for didanosine of around 29 baht per tablet, still very expensive compared to the one produced by the Government Pharmaceutical Organisation. ...The negotiation did not end in success.'*<sup>20</sup>

However, the involvement of transnational drug companies in the national ART policy during this period, and their relationship with, and influence on, Thai politicians and health officials is unclear as the evidence is limited.

#### **4.1.2 The attitudes of key actors towards ART**

During the 1990s large-scale ART delivery was commonly perceived as unaffordable (Chitwarakorn 2001; Dahlan 1994; Patanasingha 1996). For example, in a press conference in

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<sup>20</sup> This was to prevent the government drug firm to produce generic didanosine. As maintained by a key informant, the offer was based on the condition that if the government laboratory accepted this proposition, it would not sell generic version at the same time.

1992, the Director General of the Disease Control Department emphasised that, *'AZT (zidovudine) – the only antiretroviral offered in public programme – is very expensive: 50 baht per tablet. As the usual dose is 12 tablets a day the total cost is 600 baht per head.'* (Naew Naa 1992). The Director General also maintained that, *'Free drugs are available for only 300 low-income patients. The wealthier who can afford the cost will be asked to pay by themselves. The government cannot support all PLWHA since very large amount of budget would be required in such case.'* (Khoaw Sod 1992). For the bureaucrats responsible for resource allocation across HIV interventions, the 1995 programme evaluation which suggested that ARV-based treatment was significantly less cost-effective than the use of the drugs to prevent mother-to-child HIV transmission also led to another commonly-held official view (see chapter 2): ART did not provide the best value for money, especially in comparing prevention programmes which had been well-established and proved effective (Kunanusont, Phoolcharoen, and Bodaramik 1999).

Gradual changes in the attitudes towards ART of the two networks could be observed with the growing numbers of publications on the effectiveness of highly active antiretroviral therapy (HAART) and the associated cost saving in the West and Brazil after 1996. Treatment advocate coalitions and expert activists deliberately distributed such information: passing on the success stories to health officials, professionals and the general public (Matichon 2001). In addition to the clinical outcomes of medication, NGOs' campaigns for ART access through generic production were motivated by two elements: the introduction of relief strategies for public health implications of the World Trade Organisation's Intellectual Property Right Agreements and the NGOs' experiences on the unsatisfactory results of treatment for opportunistic diseases (interview N15 and N16). Furthermore, the notions of *life saving medication* and *human rights* were increasingly highlighted to encourage treatment extension (Ungphakorn 2001; Wisartsakul 2004). However, owing to the limited capacity of the local drug industry, threats of international trade sanctions, and the absence of global mechanisms to foster ARV price reduction, nationwide treatment remained infeasible in Thailand throughout the 1990s.

#### **4.2 The introduction of universal health coverage and the exclusion of ART**

The shift in the national ART policy towards universal coverage developed in the midst of substantial changes in politics and health system reform. After a long period of political

instability as reflected by short life-span regimes and military coups, the Thai Rak Thai party gained a landslide victory in the general election in January 2001 (Nelson 2001). Given its strong majority in parliament and popular support after the election, the administration implemented several initiatives as pledged in the electoral campaign (Phongpaichit and Baker 2004). This included the introduction of the universal health coverage plan (UC). Rolled out in all 76 provinces by October 2001, the publicly-funded scheme making health care available to everyone was regularly rated as the government's best initiative (National Health Security Office 2004b; Phongpaichit and Baker 2004).

Before the UC was instigated, several health benefit plans existed for different groups of people (Tangcharoensathien, Srithamrongsawat, and Pitayarangsarit 2002). However, there was a significant fraction (30%) of the population who had no benefit coverage (chapter 2). The feature of Thai health insurance system at that time included fragmentation, duplication and inadequacy, and led to inefficiency of resource use and inequity among beneficiaries of different schemes. The introduction of the UC aimed to tackle such problems by consolidating the existing schemes for low-income groups and also expanding health benefits to cover the uninsured (Jindawattana and Pipatrojkomol 2004). The newly established plan allocated funds to health providers for ambulatory care, health promotion and preventive care on a capitation basis, and adopted Diagnosis Related Groups as a tool to subsidise in-patient services (Siamwala 2002). The coverage for health interventions in the UC was restricted to those selected to be part of the scheme's benefit package (Ministry of Public Health 2001a).

For treatment advocates the establishment of the UC underpinned the likelihood of improving ART access (interview N16 and N17). However, although NGO staff expected treatment expansion as one of the UC benefits, ART was actually excluded. The status of ART was officially discussed at a meeting to prepare for the rolling out of the new health insurance initiative convened on 17<sup>th</sup> March 2001 (Ministry of Public Health 2001f). In the meeting chaired by the Prime Minister, the competing proposals of two policy networks: the technocrats and NGOs were presented. Sanguan Nitayarumphong – the Deputy Health Secretary responsible for UC implementation<sup>21</sup> - proposed to exclude ART (interview N02). This proposal was supported by Viroj Tangcharoensathien – a health economist with

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<sup>21</sup> Later, Nitayarumphong became the first Secretary General of the National Health Security Office - an autonomous public agency with a mandate to oversee the UC when the National Health Security Act was effective in early 2003.

expertise in healthcare financing. It was the economist and his research fellows<sup>22</sup> who worked out the projections and related policy recommendations on the financing facets of the UC such as the capitation rate and benefit package (Tangcharoensathien, Wibulpolprasert, and Nitayarampong 2004). Health officials and researchers closely involved in formulating the initiative explained that the reason for the exclusion was the high cost of ARVs and insufficient information on the long-term financial implications for the health plan (interview N02 and N11).

While ART was labelled by the UC officials as costly, the NGO-expert alliance held different perspectives. They accepted that owing to the high ARV prices, it was infeasible for the government to subsidise ART for all afflicted people immediately (interview N15 and N16). They argued, however, that treatment should be adopted as a component of the UC for two reasons. First, as suggested in clinical studies in several settings, ART could significantly reduce morbidity and mortality, as well as improve the quality of life. Second, the exclusion of therapy would be regarded as discrimination against people with a particular health condition which violated the Constitution and human rights (interview N15, N16 and N17). As Ungphakorn (2001:75) asserts:

*‘Those who can afford it are now able to have a good quality of life for a long period of life. This raises the question whether drugs should be considered in the same terms as a commodity ...or should it be considered an essential part of people’s needs and therefore a right. Should it be a right to people in the world to receive the drugs needed in order to support their life?’*

The NGOs raised the Brazilian and Indian experiences in producing low-priced generic drugs and pointed out that the universal coverage for ART would be possible if a similar strategy, i.e. local ARV manufacturing, was introduced. In addition, they proposed that the government commission economic and financial evaluations of treatment in order to inform policy<sup>23</sup> (interview N15 and N16). This proposition, as noted by NGO leaders, was based on the

<sup>22</sup> Tangcharoensathien was a researcher of the Health Systems Research Institute. He also ran a capacity strengthening programme in health economic & financing research. The health economist and fellows focused their works on the implications of and impediments in implementing different health insurance schemes in Thailand.

<sup>23</sup> This demonstrates the culture of respecting evidence-guided policy processes in Thai health systems. Even though the NGOs emphasised the justice and human rights as their major arguments, many of them agreed that the benefits of ART should be proved in empirical studies.

positive cost-saving and cost-benefit parameters of ART programmes in forerunner settings such as Brazil and developed countries (interview N13 and N15). In this regard, the meeting assigned the Health Ministry's research agency – the Health Systems Research Institute (HSRI) – to estimate the financial costs of nationwide ART compared to its potential benefits (Ministry of Public Health 2001f).

While the potential financial burden of ART to the early phase of the UC plan was the centre of debates, other aspects were not taken into account: for example the infrastructure to support rational prescribing, dispensing, administration and monitoring as well as other critical issues like medication adherence and drug resistance (interview N02 and N11). In interview, health officials – mostly health economists or related disciplines – who were involved in the UC establishment, admitted that they had had no experience in HIV and ART areas, thus their concerns focused only on a single element: ARV costs. On the other hand, their treatment advocate counterparts maintained that they considered other potential obstacles, but believed that the treatment was manageable in the Thai context (interview N15 and N16). This suggests that the decision to exclude ART from the UC scheme was not determined by the speculation on the inadequacy of infrastructures and other resources in the health delivery system but rather on affordability.

### **4.3 Agenda setting and adoption of universal ART policy**

The previous section illustrates the roles of the government official cluster and the civil society coalition in ART policy making and the justification proposed by the technocrats that led to the exclusion of the treatment from the UC in March 2001. Yet a mere 8 months later, in November of the same year, the government offered medication to all eligible PLWHA through the newly founded health plan. This section explores the evolution of the national ART policy during this eight-month period in order to understand the factors that account for the provision of nationwide treatment, as well as the process and context in which the policy was innovated.

#### **4.3.1 Stepping towards universal ART access**

The NGO network began communicating with the Thai Rak Thai cabinet even before the discussion about the UC benefit package took place. In February 2001 an important event

relating to ART provision in resource-poor settings developed. Cipla – an Indian generic drug company – announced an offer of ARVs to developing countries at a price between 1,200 and 2,050 baht<sup>24</sup> per patient per month (Reuters 2001). As the monthly cost of the drugs in Thailand was between 7,000 and 10,000 baht, the NGOs promptly conveyed this message to the government. Following the same report, the NGO alliance encouraged the Health Ministry to deal with Cipla for cheaper medicines.

On 5<sup>th</sup> March, NGO leaders met Surapong Suebwonglee – the Deputy Health Minister – and asked him to enact appropriate strategies to lower the prices of all anti-HIV drugs marketed in the country (Bangkok Business 2001c). The Minister was informed about the advantages of purchasing Cipla products and that the drugs had been adopted by HIV programmes in many African countries. The NGOs also urged the Health Ministry to support the GPO to produce non-patented ARVs on an industrial scale. They expected that either the importation or local manufacture of generic drugs could result in a price reduction to 1,000 baht per patient per month. The Minister responded positively: the policy was to strengthen the government laboratory to produce more anti-HIV items and also to extend its facilities for industrial-scale production (Bangkok Business 2001b).

Although local ARV manufacture had never been declared as a government policy before, the Health Minister's vow to encourage its laboratory to produce low-cost drugs was not rhetorical. The GPO's Research and Development Institute had succeeded in formulating a number of anti-HIVs since the early 1990s, so that it could respond promptly to the ministerial request (Kraisintu 2001). Approved by the Governing Board of the GPO on 15<sup>th</sup> March, the proposal to upgrade ARV production from laboratory into industrial scale was submitted to the cabinet and was finally approved in May (Ministry of Public Health 2001e). It was expected that the first batch of drugs could be launched by January 2002. The monthly price of first-line regimen drugs was anticipated to decline to 4,000 baht in the beginning phase and later to 2,000 baht, which would be affordable for inclusion in the UC.

After the exclusion of ART from the UC in March 2001, the network of NGOs and activists continued campaigning for treatment extension. Parallel to the Thai movement were significant milestones in international efforts to attain similar objectives. In April,

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<sup>24</sup> US\$1 equalled 41 baht in early 2001

the South African government's triumph over 39 transnational pharmaceutical companies<sup>25</sup> raised attention worldwide, and was brought to the Thai government, as a role model to address the impediments in large-scale ART delivery (The Nation and Deutsche Presse Agentur 2001). The NGO coalition urged the government to act upon its policy on making generic drugs more available and accessible. This action was immediately undertaken after three NGOs, namely the MSF, Treatment Action Campaign and Oxfam jointly delivered a press release acknowledging the end of the lawsuit in South Africa as a *'powerful precedent set for other developing countries'* (MSF, TAC, and Oxfam 2001). The influence of this particular event on Thai ART policy is unclear; however, it demonstrates a possible influential role of the global AIDS NGO network in policy making in the South.

The relationship between the politician-bureaucrat and civil society networks became closer as it seemed they shared a common destination: improving ART access. A series of discussions to extend publicly-subsidised treatment were convened between the Health Minister; health officials from both the Disease Control Department and those involved in the UC commencement; and NGO-expert alliances (interview N15 and N16). During this period, the major focus of concern of all parties remained on the high drug costs. A NGO leader notes that, in an important meeting organised in May 2001, the Health Minister pledged to integrate ART into the UC benefit if drug costs had decreased to less than 2,000 baht a month (interview N15).

Alongside the development of the public-civic partnership, the context of the national ART policy changed to allow cheaper drugs to be available. After the government laboratory's ARV project had been approved, notable progress was made in accordance with the timeframe. Serious attention was paid by the Health Ministry to implement this initiative as reflected in press releases, speeches and presentation at national conferences and meetings (Ministry of Public Health 2001e; Suebwonglee 2001), and when the Minister visited the laboratory to reaffirm the policy to its governing board and administrators (interview N13). This demonstrated the strong intentions of the government to increase treatment coverage.

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<sup>25</sup> In 1998, 39 pharmaceutical companies filed a lawsuit against South African government over its Medicines and Related Substances Act, which would allow compulsory licensing and parallel import of medicines in a health emergency. On April 19, 2001, the pharmaceuticals companies withdrew their case owing to mounting international pressure mobilised by NGOs.

In this period, many medical and laboratory experts had a supporting role in facilitating access to ART. They provided related information, advice and training to PLWHA and NGO staff. Some were closely involved in formulating the Health Ministry's Access to Care Initiative which was in its first year of implementation. On some occasions, these specialists expressed their views to the general public. In October 2001, for instance, a Thai Professor of Immunology who led an international HIV research network made an assertion through the media that despite higher drug costs in Brazil than Thailand, Brazil had started its nationwide ART programmes (Matichon 2001). Furthermore, he mentioned the net benefits of therapy in Brazil as a consequence of the opportunistic infections averted, hospitalisation reduction, and increased quality of life, as well as recurrent productivity among ARV recipients.

The success of the government laboratory was publicised in October 2001, and it was announced that the first batch of ARV fixed-dose combinations would be launched in December, and that the increased manufacture volume would result in a drug price reduction which allowed a ten-fold increase in treatment coverage from 5,000 to 50,000 PLWHA (Bangkok Business 2001a; Manager 2001). As noted by the GPO Director, two cocktail formulas<sup>26</sup> mainly prescribed in such a programme, could be marketed at the cost of 2,300 baht per patient per month, while the corresponding brand products cost 16,400 to 21,800 baht per patient per month. According to the Director, two other fixed-dose combinations would be launched by April 2002.

The dissemination of such information was critical. Immediately, the NGO coalition urged the government for further action. On 5<sup>th</sup> November, a letter co-signed by the presidents of the Thai Network for PLWHA and Thai Non-governmental Coalition on HIV/AIDS was sent to the Health Minister as well as circulated to the media, proposing the Ministry to designate bilateral task force to oversee treatment extension (Tan-ud and Panichpak 2001a). The letter not only illustrated the ambitious goal proposed by the ART advocates, but also reflected their knowledge and experiences in the HIV field. It was stressed that the task force should have the following responsibilities: (1) to work out a plan to integrate therapy into the UC scheme that would benefit 150,000 PLWHA within five years; (2) to design programmes for human resource and infrastructure development; (3) to supervise HIV prevention campaigns in order to reduce future demands for medication; and (4) to foster research on the

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<sup>26</sup> Zidovudine + lamivudine + nevirapine and zidovudine + didanosine + nevirapine

consequences of treatment extension such as the decline in public spending on opportunistic infections and welfare services for PLWHA<sup>27</sup>.

In addition, the letter suggested that to achieve the target of treating 150,000 individuals the budget must increase over five years, i.e. from 500 million baht for fiscal year 2002 to 3 billion baht for 2006. The NGOs claimed that these figures were justified as it had been expected that drug prices would further reduce owing to negotiations with private drug companies and the capacity of the government laboratory. The estimated budget covered the costs for twice-a-year CD4 testing. Moreover, to develop the training curriculum for health workers and the plan to improve infrastructure, the civic alliance recommended that the task force should take into account the past experiences in providing therapy to 3,000 patients under the first-year Access to Care Initiative. Finally, the letter stated that a thousand PLWHA and NGO representatives from 5 regions of the country would gather at Government House in Bangkok to hear the government's decision on World AIDS Day eve – 30<sup>th</sup> November 2001. At the same time, another letter was sent to the Prime Minister asking the government to adopt the policy to provide free access to ART in the UC (Tan-ud and Panichpak 2001b).

The NGO network also employed other means in their campaigns. Thai NGOs and worldwide partners, for example the International Gay and Lesbian Human Rights Commission, MSF, and Global Treatment Access, called for support from other NGOs and the general public. A draft letter provided as a prototype was posted on these NGOs' websites persuading audiences to endorse and forward it to the Thai government (International Gay and Lesbian Human Rights Commission 2001). The letter requested the Prime Minister to ensure the government's commitment to include ART in the UC. Several arguments including those on human rights, discrimination, equity, and the matters of life and death of PLWHA were presented to convince the politicians and the public. The NGOs' proposal emphasised the obligations to uphold and exercise the principles of many international conventions, as well as agreements and guidelines adopted by the Thai governments in the past. The successful ART programme in Brazil was also highlighted as the best practice.

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<sup>27</sup> This proposal indicates that, on the one hand, the importance of research had been recognised by different parties involved in Thai health policy, and the NGOs believed ART's benefits exceeded the costs, on the other.

In response to such movement, on 28<sup>th</sup> November, a government-NGOs meeting was organised. Those who took part in the discussion included the Health Minister, Deputy Health Secretaries<sup>28</sup>, the Director General of the Disease Control Department, the Director of the Government Pharmaceutical Organisation, HIV experts, NGOs and PLWHA representatives (Ministry of Public Health 2001c). Prior to the meeting, the NGOs prepared information on many facets of a publicly-funded ART programme, such as the potential number of PLWHA currently eligible for therapy and the magnitude of financial implications for the UC plan (interview N15 and N16). With these projections, they tried to convince the Health Minister that integrating ART into the UC would be financially feasible.

Subsequent to the discussion, an agreement was attained. The key resolution was that the Health Ministry agreed in principle to include ART in the UC package, phasing it in gradually. A memorandum was developed to cover all issues concerned by the participants of both sides. First, a remark was made that studies including operational research in different fields were required to support efficient integration of treatment into the health scheme (Ministry of Public Health 2001c; Wibulpolprasert 2001). Second, a task force consisting of health officials, academics, clinicians, NGOs and PLWHA representatives would be designated to formulate a comprehensive work plan. In order to enhance patient adherence to therapy and to assure clinical outcomes as well as programme efficiency, the task force would set up guidelines on drug selection, patient enrolment, treatment regimens, and clinical monitoring. Finally, it was emphasised that multisectoral collaboration would be pursued to maintain the well-established programme for HIV prevention.

Despite the Health Ministry's pledge to integrate ART into the UC plan, the treatment advocates felt the settlement made at the 28<sup>th</sup> November meeting was uncertain (interview N15, N16 and N17). NGO leaders pointed out in interviews, they did not believe that the government would keep the promise, thus they carried on a public demonstration planned before the agreement was reached. On 30<sup>th</sup> November, the Health Minister made a declaration before a thousand PLWHA that the government would expand the UC benefit package to cover ART (Manager 2001; Noikorn 2001).

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<sup>28</sup> There were four deputy health secretaries. The two who participated in the 28<sup>th</sup> November discussion included Sa-nguan Nitayarumphong and Suwit Wibulpolprasert

### 4.3.2 Extending ART coverage versus integrating ART in the UC

The above discussions illustrate a straightforward process that led to policy innovation: ART had been excluded from the UC package in March 2001 owing to the prohibitive ARV costs. Eight months later treatment was pledged to be included in the health plan after substantial drug price reductions. In fact, both policy makers and NGO networks recognised that there were different issues to consider: extending ART coverage and integrating ART in the UC. This section explores the meanings of these two aspects as perceived by each group of policy participants, as well as their implications for the policy development.

#### *Policymakers' perspectives*

According to a senior official responsible for the UC instigation, financial feasibility and the implications of integrating ART into the emerging UC plan, was a major concern, making him reluctant to facilitate such development (interview N02). This was shared by politicians and other technocrats. Since the universal health coverage policy was in the early phase of its formulation and implementation, these personnel felt that the programme had not yet been well established. Thus, they were unwilling to bear the increased risks from ART. For instance, Suebwonglee – the Deputy Health Minister stated that:

*'Not only UC implementation but also the extension of ART coverage under the new scheme resembled the 'Long March' – if the first pace had been unevenly performed, both initiatives might fall down before reaching the destination. Therefore, the initial period must be well prepared. ...ART provision is a really big issue – we have to consider carefully how to maintain the steps forwards'* (Suebwonglee 2001)

On the other hand, the Health Minister and bureaucrats thought that the government could not refuse to improve medication access for two reasons (interview N2 and N11). First, the administration had to keep its promise that treatment would be delivered on greater scale if ARV prices decreased to an acceptable level. Second, the concurrent global initiatives to encourage ART access could not be ignored; otherwise it would result in an undesirable image that the country, and the impression that the Health Ministry, was *left behind*. A high-ranked MOPH official revealed that he had many opportunities to discuss with the minister

about the global mainstream policies and related campaigns, for example the joint declaration issued by the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS in June 2001 (interview N02). Such international policy developments indicated that Thailand could not afford the embarrassment if the government chose the *status quo*. This official maintained that he also raised the successful case of nationwide ART programmes in Brazil to the Minister.

The attitudes towards the potential burden of ART on the UC budget played a key role not only in the exclusion of treatment from benefit package at the beginning, but also in the policy decisions after ARV prices fell. In the former phase, another factor was involved: technocrats felt the urgency to move the UC scheme forward. One said that he saw the window of opportunity opened to reform the country's health care financing system as this issue had failed to catch the government's attention in spite of his efforts to do so for the past ten years (interview N11). Therefore, he and his reformist colleagues did not want to divert attention to study the financial burden of ART because it would delay the UC implementation.

Actually, the projected resources required for the UC were derived from existing data on the total medical care costs of services provided in a number of hospitals (Tangcharoensathien, Teerawattananon, and Prakongsai 2001). None of particular health interventions covered by the new scheme had been assessed for its costs and financial impact on the health scheme. As revealed by an official, owing to the limited timeframe, the preparatory process of the UC was disorganised, especially in the formulation of the fundamental components of programme financing (interview N02). This assertion has been reaffirmed by Siamwala (2002:225): '*... while the UC committee envisages a more leisurely pace of implementation, this has to be confronted with the political drive to show the result quickly, ...*' Because of this haste, treatment and care enlisted to the first version of benefit package were transferred from the benefits provided under the Social Security Scheme without reappraisal of their economic and financial consequences (Jindawattana and Pipatrojkomol 2004; Ministry of Public Health 2001f). That ART had not been covered by the Social Security Scheme was another factor legitimising treatment exclusion from the UC (interview N02).

The perception about the high costs of ART among the UC technocrats remained important even though the government laboratory showed it could produce low-priced generic drugs. At

that time, the Health Ministry's UC task force was occupied by *day-to-day* problem solving (interview N11 and N12). None of the health economists in this team paid attention to estimate the potential costs of ART and its financial implications. An official who led the management of the health care financing reform said he supported a policy for the government to subsidise ART as a component of the UC package (interview N02). This official further argued that, integrating therapy into the health plan in 2001 or even one to two years later, was infeasible since it would severely afflict the constrained budget<sup>29</sup>. Since the additional burden from the anti-HIV medication was seen as '*overwhelming and intolerable*', he suggested that the Health Minister adopt the universal ART coverage, but only gradually integrate it into the UC, without setting up an exact timeframe.

### *Treatment advocates' perspectives*

NGOs and other activists too paid much attention to the status of ART in the UC. Although treatment could be extended to achieve universal coverage by employing the existing management processes of the Disease Control Department, they insisted that the service should be funded as a UC component. NGO leaders argue that the financing mechanism was vital because it affected the sustainability of ART provision (interview N15, N16 and N17). As the Health Ministry's negotiating power with the Budget Bureau was considered to be less powerful than other ministries, leaving any interventions outside the benefit package and funding them as non-UC items would be uncertain, since it meant that the budget item and amount would have to be negotiated year by year. Since the universal health coverage policy proposed in the electoral campaign was one of the most high-profile elements of the Thai Rak Thai's triumph, it was argued that the administration must be accountable to meet the resource needs for any essential services (Kulsomboon, Thanaviriyakul, and Pinyowiwat 2003). Some activists also claimed that excluding HIV therapy from the health benefit scheme would discriminate against PLWHA.

Others pointed out that as ART could reduce medical care costs, ensuring access by integrating treatment into the UC would benefit the health plan itself. The Thai Red Cross Society (2002), for example, argued that the government should include treatment in the UC since it would offer better value for money than the services for many other diseases such as

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<sup>29</sup> This argument is supported by many documents such as Jindawatana and Pipatrojkomol (2004), NHSO (2004), Jongudomsuk (2004).

hypertension, heart diseases, and renal failure. The Red Cross officials compared the quality of life of the elderly patients with chronic conditions with PLWHA on ARVs and concluded that the latter group would gain more. Some academics asserted that ART was more cost-effective than many interventions covered by the UC, especially in comparison with treatment interventions for other chronic conditions. With these perceptions, the NGO coalition maintained to pursue the goal of financing ART in the UC through the policy formulation phase as will be discussed in the next chapter.

### **4.3.3 What others thought about the new policy**

The above discussion illustrates a relatively consensual policy process, resulting in the extension of the national ART programme coverage, and ending the integration of treatment into the UC. However, the discussion was largely confined to the interaction and perceptions of the policy makers and NGO coalition.

Synthesising the information from documents and key informants, it appears that the issues of delivering nationwide ART and including medication in the UC package did not catch the public's attention. Although the evolution of the new policy was published in newspapers and in other media, it could draw little attention of the general public and even journalists (interview N09 and N18). The result of reviewing a range of newspapers suggests that ART-related information disseminated during March to November 2001 mostly came from NGOs and the Health Ministry's or the GPO's press releases. There were only a few analyses in two English-language newspapers which were accessed by a small number of people. Interviews with health officials and NGO leaders also suggested that though it was likely that some people disagreed with the policy, none of them liked to raise conflicting arguments publicly (interview N03, N04 and N19). This is because denial or merely expressing unsympathetic views towards the sick or the underprivileged including PLWHA was an action against social norms of the society where most of the population were Buddhists.

As key informants maintain, the debates for and against the universal ART policy adoption developed within a limited circle – among academics, HIV experts, and AIDS officials (interview N04, N09 and N19). More importantly, the discussions did not aim at absolutely opposing the treatment provision, but focused mainly on the anticipated negative externalities of the national-scale medication programme, especially given the plan to expand rapidly. The

literature and interviews with health personnel in the field suggest that many officials in the Health Ministry and sub-national offices, as well as health workers involved in implementing the Access to Care Initiative articulated their concerns about the undesirable consequences on the health delivery system, owing not only to inadequate preparation but also to administrative hurdles caused by the newly introduced health financing reform (AIDS Division 2001; Kulsomboon, Thanaviriyakul, and Pinyowiwat 2003). However, these caveats were conveyed to particular audiences such as those attended technical meetings or conferences which normally caught neither politicians' nor the public attention.

#### **4.4 Why was the universal ART policy adopted?**

The availability of low-priced ARVs and the NGO movement were generally recognised as the major factors of ART policy innovation in 2001 (Phanuphak 2004). Based on the literature and interview data, however, the government's decision to adopt the new policy was predisposed by many elements internal and external to the health system. According to the Health Minister, in addition to the price reduction, the policy to scale up ART was supported by the notion of human rights: *'the right to equally and universally access health services of Thai people'* (interview N01). Another motivating factor was the potential public interest concerning the desirable implications of treatment for HIV patients, their families and the society. The Minister went on to maintain that Thailand had a well-established health infrastructure and management system, as well as sufficient financial and human resources, compared with many other developing countries. In sum, she stressed that the strong political resolve – which came from this combination of factors – played a crucial role in the policy making. However, she admitted in interview that treatment advocates' campaigns encouraged the cabinet to make the decision. At the same time, she argued that the inclusion of ART in the UC package was in line with other treatments and care adopted under the umbrella of the Thai Rak Thai Party's universal health coverage policy. In response to the question on whether international ART experiences such as Brazil's large-scale treatment programme had had any influence, the Minister denied the role of established models in other countries and emphasised that the policy adoption was solely subject to endogenous factors: the potential benefits to the public, technical feasibility and political commitment.

However, other sources of information provided broader explanation for the policy change. In term of political desirability, it appears that the government as well as the Thai Rak Thai

party might have been concerned about their domestic reputation. Some interviewees illustrated the political importance of the policy, by maintaining that '*...at least, over 50,000 PLWHA who would be on government-subsidised ART and their family members would vote for the party in the 2005 national election.*' This argument was reaffirmed by a journalist who also pointed out that universal access to medication could bolster the country's prominence in the international HIV arena.

*'Politically, the Health Minister knows exactly how to play the game and how to make use of the Bt30 medical scheme<sup>30</sup>, touted as one of the major policies that put the Thai Rak Thai Party into government. The decision is sure to win Thailand praise from the international community again after the globally-recognised success of its programme to reduce the rate of new HIV infections.'* (Sakboon 2001).

However, it could also be argued that, the Health Minister was forced to adopt the policy. The government's pledge to expand ART coverage if drug prices declined to a certain level had been publicised through ministerial statements and other media (Ministry of Public Health 2001e). This allowed the administration very limited choice in responding to the demand made by the NGO alliance when the state laboratory declared the price reduction. Given that it was not unusual for politicians to disregard their own promises, the government's actions were closely watched by treatment advocates who kept up pressure on the cabinet. One senior health official recognised that the political pressure would continue and even increase, and therefore he often reminded the Minister about her promise and the potential consequences of ignoring it (interview N02).

In addition to the domestic circumstances, and in spite of the Minister's denial, the global movement to encourage ART in resource-poor settings played a crucial role. Among several inter-state agreements and affirmations endorsed by Thai government, the declaration of commitment issued by the UNGASS on HIV/AIDS in June 2001 was critical. This set of statements illustrates the commitments of state leaders to address HIV epidemic by every effort to ensure the access to prevention, care, support, and treatment among affected populations (United Nations 2001). At the United Nations Assembly, the Deputy Prime

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<sup>30</sup> The UC was usually called the '30-baht scheme' since patients were required to pay 30 baht per visit or per admission to hospitals

Minister who was the head of Thai delegates asserted that the government fully supported the adoption of this declaration (Intrawityanunt 2001). Key informants argued that the government had to respect the declared commitment to improve ART access as part of their international obligations (interview N11 and personal communication with a Deputy Health Secretary). The mechanism to evaluate the progress in implementing the UNGASS commitments was acknowledged to be an inducement to the administration. This was because the level of national achievement for each of the measure would be regularly appraised and reported to the Annual UN General Assembly. Prior to the UNGASS on HIV/AIDS, Thailand had declared its obligations on HIV prevention and treatment at several regional and international meetings, but the 2001 UN forum was the first high-level intergovernmental conference dedicated to this specific issue (Ministry of Foreign Affairs 2003). There is little doubt that the Thai Government's commitment to treatment extension was in part encouraged by the global trend (Phanuphak 2004).

To be fair, an argument can be made that the ART policy innovation in Thailand was not under domestic or international political pressures but, to some extent, motivated by true public interests. In other words, the government had a strong commitment to improve treatment access. This was reflected in ministerial policies and actions, for example the programme to strengthen the GPO's capacity in order to extend generic ARV production was implemented immediately after the Thai Rak Thai cabinet came to power as aforementioned. Such effort indicates that the government had had clear objectives and strategies to address the treatment impediments. Drug price reduction – a vital factor of the adoption of universal ART coverage – was partly the outcome of the administration's advocacy.

#### **4.5 Summary**

The process of HIV policy making in Thailand comprised a long period of policy continuity followed by a radical policy shift. Over the first decade of national ART programme implementation, incremental changes resulted in limited treatment coverage. When the Government pledged to scale up treatment in late 2001, there were transformations in both the policy network and policy image. Health financing reformists and civil society organisations replaced groups of Disease Control Department officials who had dominated the policy decisions concerning ART delivery since 1992. At the same time, nationwide treatment was

considered feasible owing to the local production of generic ARVs and the associated price reduction.

Reflecting Kingdon's explanation of how issues reach the policy agenda, universal ART coverage took place at a critical moment when problem, politics and solutions came together. The HIV epidemic and its devastating effects had long been recognised as a problem; the Thai Rak Thai administration was elected and committed to universal health care with strong civil society support for political change to improve access to treatment; and affordable drugs were one of the solutions that made scaling-up a feasible national policy.

The 2001 programme renovation could also be seen as an outcome of learning among several groups of policy actors. The Health Minister, reformists, health officials and HIV experts got the information on ART expansion in different parts of the world from many sources, local and international. Meanwhile, NGOs and PLWHA alliance including health professionals in some hospitals obtained direct experiences on service provision through their projects such as the Buyer's Club. Lessons drawn by members of these policy networks had an important role in inspiring and inducing policy change.

## **CHAPTER 5: MOVING TOWARDS UNIVERSAL ART ACCESS: NATIONAL POLICY FORMULATION**

When the Thai government agreed to provide universal coverage for antiretroviral therapy in late 2001, it was understood that the relevant agencies, led by the Ministry of Public Health (MOPH), had the obligation not only to get many more people living with HIV/AIDS (PLWHA) on therapy but also to arrange the integration of treatment into the recently launched health benefit scheme. To achieve these two goals, the national antiretroviral therapy (ART) programme configuration was subjected to modification in several aspects. This chapter provides the overview of the gaps and achievements in improving treatment access in the beginning phase of the programme scale up. Moreover, it sheds light on the concomitant revisions of key elements of the medication delivery and associated resource mobilisation in this period.

### **5.1 Treatment expansion: targets and achievements**

Extending HIV medication on a national scale required a substantial preparatory period and this was initially underestimated. Although the MOPH received extra resources, which would double the target of people on ART for fiscal year 2002, i.e. from 3,000 to 6,000 clients, when the fiscal year ended in September 2002 only half the expected number were on therapy (Chitwarakorn 2003). In the process to draft the budget proposal for 2003, the Health Ministry planned to deliver ART to 12,000 PLWHA (Sirisuthorn 2002). As a result of the continual drug price reductions, the final proposal stated that treatment coverage could be doubled, i.e. to benefit 23,000 patients (Administration Advisory Panel 2002c). However, the national programme was able to meet only 57% of this target by September 2003. Despite the unsatisfactory achievement for 2004, the Health Ministry aimed to have 50,000 PLWHA on therapy. As maintained by a senior official, the Ministry was confident that the programme's performance could be improved and therefore the target could be met by learning from the first-two-year experience of treatment extension (Teeratantikanont 2004).

### **5.2 Major changes in programme configuration**

As the national ART programme was expected to meet the challenge of broadening services for all eligible PLWHA, the policy instruments to achieve the new goal were amended

accordingly. Developments in the initial phase of treatment scale up can be categorised into 6 facets: integrated management; resource mobilisation; designations for the Health Ministry agencies; changes in treatment protocols; revisions of enrolment criteria; and extension of therapy to hospitals external to the Health Ministry.

### **5.2.1 Integrated management of the national programme**

Before the scale up of ART in 2002, treatment delivery had been organised in a fragmented manner, involving several government agencies and non-governmental organisations (NGOs). The Health Ministry had a leading role in providing the medication through many of its departments, but all had different target populations. This included the Department of Disease Control's Access to Care programme for adults and children; the Department of Health's ART for post-delivery women and their family (so called 'PMTCT plus'); and therapy offered under clinical trials and research projects jointly conducted by the Health Ministry and other institutes (ATSI 2003b). To facilitate efficient scale-up, in July 2003 the Disease Control Department's Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections (ATSI) integrated all previously disjointed programmes under an overarching umbrella, entitled 'National Access to Antiretroviral Programmes for People Living with HIV/AIDS (NAPHA)' (ATSI 2003b). A steering committee, comprising representatives from MOPH departments, other ministries, local administrative authorities, publicly-funded health benefit schemes, and civil society organisations (CSOs), was appointed to set up administration guidelines and coordinate different programme components (ATSI 2003b). This aimed to encourage information exchange through the inauguration of common reporting system, standardisation of clinical and management practices, and resource sharing, as well as to improve referral of patients between programmes. However, this move did not cause significant conflicts, which might be because there was no substantial change in programmes' management structures and resource allocation to responsible departments (interview N05).

### **5.2.2 Resource mobilisation**

The increase in the number of targeted clients required additional resources, including funding, personnel, and infrastructure. Promptly after the universal ART policy was announced, the Health Ministry submitted a proposal to the cabinet for an additional budget of 250 million baht for the first-year treatment extension (Assavanonda). At that time, the

fiscal year 2002 had started and the financial allocation to all budget lines had been established. Since ART was not classified as urgent according to the public finance regulation, the Health Ministry received an extra amount of only 50 million baht (Administration Advisory Panel 2002c). However, future budgets were met in full.

The budget required to meet targets for 2003 and 2004 rose sharply to 350 million baht and one billion baht, respectively. But there was no difficulty in getting funding approval from the Budget Bureau and House of Representatives, as there was no dissension on the rationale, and these amounts did not exceed the overall finance for the Disease Control Department's pre-set budget ceiling (Teeratantikanont 2004). The consensus on budget allocation to the treatment programme was likely to have been facilitated by the government party's majority in the legislative institute. Apart from public finance, Thailand got a grant of US\$192 million from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) for HIV programmes including ART between 2002 and 2006 (GFATM 2004). However, the public component accounted for the major portion of treatment programme funding, i.e. 80% of the total in 2003 (Teokul et al. 2004). With this budget, antiretrovirals (ARVs) and laboratory supplies were centrally purchased in bulk and distributed to hospitals through the regional disease control offices (Ministry of Public Health 2003b). In 2004, matching resources from the GFATM facilitated the accessibility to CD4+ cell measurement as the grant included setting up an additional 20 well-equipped laboratories with flow cytometres to make a total of 39 sites throughout the country (WHO-SEARO 2004). However, other tests necessary for ART monitoring such as viral load and drug resistance assays were very limited – available in Bangkok and a few other provinces (Phanuphak 2004).

The demand for qualified hospitals and health personnel to serve more patients also escalated considerably. From its first launch in 2000, the Access to Care programme had been integrated into the existing health delivery system, predominantly run by the Health Ministry (Satasit, Kuaykiatikul, and On-Nom 2002). The Disease Control Department had invited some hospitals, especially those located in HIV-prevalent provinces of the north, to participate. A number of settings volunteering to join the initiative were selected according to the competency of key personnel, including physicians, nurses, counsellors, pharmacists, and medical scientists (Ministry of Public Health 2001b). The principle of voluntary hospital participation ended in 2004 when the Health Ministry issued the policy demanding all its hospitals to provide ART under the national programme.

Regarding human resource development, consultation sessions and training courses were organised for health administrators, hospital directors, and health workers at different levels from 2000 (interview N08). Policy communication was also set out on several occasions including national meetings chaired by the Health Minister or Deputy Minister (interview N05 and N09). These aimed to deepen the understanding and strengthen cooperation between responsible agencies and also to ensure treatment quality. By December 2004, ART in the national programme had been extended to 914 out of 980 government hospitals, with over 3,300 health workers and laboratory scientists trained under newly developed curriculum to deliver the therapy nationally (Thanprasertsuk, Lertpiriyasuwat, and Chasombat 2004).

During 2002 to 2004, the role of NGOs in the national ART initiative was significant. As illustrated in Access to Care guidance from 2002 (Ministry of Public Health 2002a; 2003b), the civic groups were recognised as important partners, and also vital resources, to provide necessary information and mental support to HIV patients before and during therapy administration in order to encourage adherence. Many NGO staff and PLWHA were invited to take part in training courses as consultants and speakers as well as participants (interview N08 and N15). Moreover, with administrative and financial support from the Health Ministry and GFATM, in July 2002 the NGO alliance initiated projects to develop the role of infected persons in providing care for PLWHA as part of an existing Comprehensive and Continuous Care framework (Kumphitak et al. 2004). By May 2004, Comprehensive and Continuous Care centres funded by GFATM monies had been established in 105 hospitals or 12% of the national ART programme settings.

### **5.2.3 Designations for responsible MOPH-affiliated agencies**

Between 2000 and 2003, while the Health Ministry hospitals were being persuaded to join the Access to Care programme on a voluntary basis, these settings were allowed to set their own targets in accordance with their capacity and demands for medication in the catchment areas (Satasit, Kuaykiatikul, and On-Nom 2002). However, owing to the insufficient management of drug procurement, inventory and logistics at the national and peripheral levels, drug shortages occurred in many provinces so that a 'quota' system was introduced to restrict the numbers of treatment enrolees in particular hospitals (Punpanich et al. 2002; Satasit, Kuaykiatikul, and On-Nom 2002). Ironically, there were some un-used ARVs at the central department, and the national targets were not achieved. The revision of the arrangement

commenced in 2004 as the national target of providing 50,000 PLWHA with therapy was shared between 12 health regions according to the number of HIV cases previously reported from each region (Ministry of Public Health 2002b). This meant that the ‘voluntary targets’ set by participating hospitals and the ‘quota’ employed in ARV allocation were superseded by what was perceived as a ‘coercive target’ – a programmatic goal that each regional disease control office and hospital was expected to attain.

#### **5.2.4 Changes in treatment protocol**

A crucial shift in therapy delivery in the Access to Care scheme was the introduction of new standard treatment regimens in 2002. After the universal ART policy was announced, responsible advisory panels advised the Disease Control Department to replace eight existing ARV combinations for adults with three regimens: stavudine + lamivudine + nevirapine, stavudine + lamivudine + efavirenz, and stavudine + lamivudine + indinavir and/or ritonavir (Ministry of Public Health 2001b; 2002a). See table 5.1. Recommended regimens for children also changed, reduced the number from 12 to 6 formula. Triple-drug formula were first regimens of choice. Dual therapy would be prescribed in the cases hypersensitive to both nevirapine and efavirenz.

The drug administration protocol, for adults and children, including dosages, warning and precautions in the treatment guidelines were amended accordingly, and were also clearly illustrated in the operational manuals and training documents. The recommendations on suitable strategies to change regimens were developed and circulated to respective institutes and health professionals (ATSI 2004b).

In addition to ART, the national HIV programme recommended the prophylaxis and treatment of major opportunistic infections (OIs): tuberculosis, *Pneumocystis carinii* pneumonia, and cryptococcal meningitis among PLWHA, especially for those who had not met the enrolment criteria to start ARV medication (Thanprasertsuk, Lertpiriyasuwat, and Chasombat 2004). Corresponding guidelines on drug administration, case management and related laboratory testing were developed at the national level. However, hospitals were responsible for procurement of these drugs and chemical reagents as they were not funded by the Disease Control Department.

Table 5.1: ART regimens prescribed in the national programme before and after the adoption of universal access policy

	Before policy shift (2000-2001)	After policy shift (from 2002)
Adults	<ul style="list-style-type: none"> <li>▪ AZT+3TC+NVP</li> <li>▪ AZT+ddI+NVP</li> <li>▪ AZT+3TC+EFV</li> <li>▪ d4T+ddI+EFV</li> <li>▪ AZT+3TC+SQV/RTV</li> <li>▪ d4T+ddI+ SQV/RTV</li> <li>▪ AZT+3TC+IDV/RTV</li> <li>▪ d4T+ddI+IDV/RTV</li> </ul>	<ul style="list-style-type: none"> <li>▪ d4T+3TC+NVP</li> <li>▪ d4T+3TC+EFV</li> <li>▪ d4T+3TC+IDV/RTV</li> </ul>
Children	<ul style="list-style-type: none"> <li>▪ AZT+ddI+EFV</li> <li>▪ AZT+3TC+EFV</li> <li>▪ d4T+ddI+EFV</li> <li>▪ d4T+3TC+EFV</li> <li>▪ AZT+ddI+IDV</li> <li>▪ d4T+ddI+IDV</li> <li>▪ AZT+ddI+RTV</li> <li>▪ d4T+ddI+RTV</li> <li>▪ AZT+ddI</li> <li>▪ AZT+3TC</li> <li>▪ d4T+ddI</li> <li>▪ d4T+3TC</li> </ul>	<ul style="list-style-type: none"> <li>▪ AZT+3TC+NVP</li> <li>▪ d4T+3TC+NVP</li> <li>▪ AZT+3TC+EFV</li> <li>▪ d4T+3TC+EFV</li> <li>▪ d4T+3TC</li> <li>▪ AZT+3TC</li> </ul>

Source: Ministry of Public Health (2001b; 2002a)

Note: AZT, zidovudine; 3TC, lamivudine; NVP, nevirapine; d4T, stavudine; ddI, didanosine; EFV, efavirenz; IDV, indinavir; RTV, ritonavir; SQV, saquinavir.

### 5.2.5 Revisions of enrolment criteria

In 2001, patient enrolment for adults in the Access to Care Initiative was locally carried out in accordance with the Health Ministry-recommended inclusion and exclusion criteria, which included both clinical and social elements as shown in table 5.2 (Ministry of Public Health 2001b). Following the official guidelines, a panel comprising government officials and

representatives from communities, NGOs and PLWHA groups was expected to make collective decisions on patient enrolment.

Table 5.2: Enrolment criteria for adults in the national ART programme, 2000-2001

Inclusion criteria

- CD4+ cell count < 250 cells per mm<sup>3</sup> or viral RNA > 30,000 copies per mm<sup>3</sup> by b-DNA technique or > 50,000 copies per mm<sup>3</sup> by RT-PCR technique
- The patient understands the treatment objectives and expresses his/her willingness to participate and cooperate in the follow-up process
- The patient who is likely to benefit or contribute to the family, community, or society

Exclusion criteria

- The patient with a history of hypersensitivity to at least one ARV in every available regimen
- The patient with high tendency to exercise unsafe practices such as IDUs (for the IDUs, they must be treated for the addiction before commencing ART)
- The patient with poor adherence and who is unlikely to cooperate in the follow-up process

Source: Ministry of Public Health (2001b)

When treatment protocols for adults were cut down to 3 combinations in 2002, new enrolment criteria were introduced. Therapy was suggested for patients in three categories: infected persons with AIDS-defining illness; symptomatic HIV cases<sup>31</sup> with CD4+ cell count less than 250 cells per mm<sup>3</sup> and asymptomatic cases whose CD4+ cell had dropped under 200 cells per mm<sup>3</sup> (Ministry of Public Health 2002a).

Another revision was the cancellation of the 'social criterion' which favoured individuals who were considered likely to make a contribution to family, community and society. Moreover, it was the first time the Health Ministry spelled out that only treatment-naïve patients were eligible beneficiaries of therapy. Later, in early 2004, this criterion was removed and the national programme began to cover treatment-experienced cases. As the

<sup>31</sup> HIV-infected individuals with unknown chronic fever, diarrhoea with unknown cause longer than 14 days, and/or weight loss more than 15% within 3 months

drug regimens were limited to three combinations, the patients who had been treated with other ARVs prior to the enrolment had to meet another set of conditions on the CD4+ cell and viral load levels, non-resistance to particular drugs, and clinical signs and symptoms to ensure that the regimens could be switched properly (ATSI 2004d).

By contrast, the enrolment of children to receive ART, before and after the policy change, was mainly subjected to clinical justification. In 2000 and 2001, the national programme guidelines suggested that all children aged under 12 months were eligible for treatment irrespective of clinical stage of HIV infection (Ministry of Public Health 2001b). Those between 1 and 12 years old were enrolled if they had mild, moderate or severe symptoms, or if their immune levels indicated moderate to severe suppression, according to the US Centre for Disease Control and Prevention's classification system<sup>32</sup>. Criteria were also set to exclude those with the history of ARV hypersensitivity, potential failure to adhere to medication, or inability to perform normal activities (e.g. bedridden). From 2002, the criteria slightly changed: children of one year of age and over with mild symptoms were not eligible, while other conditions remained the same (Ministry of Public Health 2002a; 2003b).

### **5.2.6 Spill-over effects to other agencies**

Along with the growing participation of MOPH hospitals in ART delivery, the Health Ministry convinced and provided support to the Bangkok Metropolitan Administration – the local government for the capital city – to establish ART clinics in its affiliated hospitals (Ministry of Public Health 2003b). A study in mid 2002 documented the increasing number of local authority hospitals which were supported by the Disease Control Department to deliver treatment as part of the national programme (Administration Advisory Panel 2002d). At the same time, the Health Ministry's AIDS Division sought new partnerships with the Social Security Office<sup>33</sup> through several meetings in 2003 and 2004 (ATSI 2003c; Social Security Office 2004). Dialogue between the two agencies aimed to improve ART coverage among the Social Security Scheme beneficiaries and also to standardise the treatment protocols across the initiatives. Moreover, subsidising treatment in Social Security Plan was expected to help to diminish national programme expenditure as this scheme was funded

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<sup>32</sup> Center for Disease Control and Prevention. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. *MMWR* 1994;43:1-10

<sup>33</sup> Health insurance manager for private-sector employees - Social Security Scheme (SSS)

through 3 sources: government, employers and employees. With technical, management and other support from the MOPH, Government Pharmaceutical Organisation (GPO), academic institutes and NGOs, the Social Security Office agreed to extend its medical benefits to cover ART in late 2004 (Manager 2003; Treerutkuarkul 2004).

### **5.3 Designing the new programme configuration**

The aforementioned changes in the programme features subsequent to the adoption of the universal access goal demonstrate that the government's pledge was not merely rhetorical. The administration also kept its promise to allow the participation of NGOs and PLWHA in policy formulation, and a new form of policy network was formed – appointed by the government. On 4<sup>th</sup> December 2001 – promptly after the declaration of the public commitment to medication – the Health Ministry established an Advisory Committee to develop administrative strategies and technical guidance to facilitate the inclusion of ART in the Universal Health Coverage (UC) benefits (Ministry of Public Health 2001d). Chaired by the Director General of the Disease Control Department, the committee consisted of 21 members, half of whom were from government agencies: including Health Ministry departments; the GPO; HIV experts and academics, and the rest from NGOs and PLWHA networks.

#### **5.3.1 Advisory Panels for treatment extension**

In February 2002, the Advisory Committee delegated its functions and responsibilities to 4 Advisory Panels (Ministry of Public Health 2002c). As illustrated in the Ministerial Order, the first two Panels were assigned to revise the clinical guidelines on ART in adults and children. Mainly, they comprised experts and physicians from medical schools and public hospitals. The third Panel principally encompassed scientists from university and Health Ministry laboratories, and was appointed to work out the detailed procedures of essential tests for ART instigation and outcome monitoring. The appointment of these experts and scientists was not surprising because their expertise had been well recognised, and was task-relevant. In addition, most of them had been involved in rolling out the Access to Care scheme from its first launch. The fourth [Administration] Panel was asked to draw recommendations on the preparation strategies and administrative aspects of the country-scale ART as part of the universal health coverage scheme. The Panel was chaired by Nitayarumphong – the Deputy

Health Secretary who led the establishment of the UC scheme. Crucially, the majority (8 of 15) of the panel members were NGOs and PLWHA leaders, most of whom had played a leading role in the campaigns for universal ART access. AIDS officials, NGO and PLWHA representatives were appointed to be members of all Panels. This included, for instance, the designation of MSF physicians who had experience in treatment delivery in civic-organised programmes in the country.

This collaboration between the Thai government and civil society in health was not unusual. Documents suggest the involvements of NGOs and community-based volunteers in rolling out several public health activities, for example the Primary Health Care initiative<sup>34</sup> and the Family Planning programme from 1970s (Ministry of Public Health 2002d; Nitayarumphong and Mulada 2001). Between the late 1980s and early 1990s, civil society associations such as those previously focused on family planning and sexually-transmitted diseases campaigned for government response to the HIV epidemic. HIV NGO representatives were appointed as members of the National AIDS Committee since its conception in 1991. At the peripheral level, these NGOs played important roles in providing care and support to PLWHA. Close cooperation between civil society, MOPH agencies and hospitals as well as its benefits to HIV patients and families were reported in many parts of the country.

The state and civil society connections developed continually and reached a crucial stage when nationwide campaigns were organised to support the formulation of the National Health Bill during 2000 to 2002 (National Health System Reform Committee 2002). The social mobilisation to facilitate health reforms was extensive, and the participation of the general public as well as the CSOs through series of public hearings was acknowledged as an important element of change (Phoolcharoen 2001). NGOs and PLWHA had been involved as active partners in many fora before and after the National Health Bill was endorsed and put forward through the legislative process. The HIV NGO's participation in these events enhanced the relationships with other NGOs in health and related areas such as consumer protection and human rights organisations (interview N15 and N16). Importantly, they also had many opportunities to meet and discuss their issues with the reformist network at which Nitayarumphong was the forefront.

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<sup>34</sup> The strategy employed by Thai government to achieve 'Health for All by the Year 2000'

In addition to the partnership strengthening through the collaborative movements for health system reform, health officials recognised the capacity of NGOs and PLWHA owing to these civic groups' past experiences, for example in rolling out Buyers' Clubs<sup>35</sup> and co-trimoxazole prophylaxis campaign<sup>36</sup> since 2000 (Thanprasertsuk, Lertpiriyasuwat, and Chasombat 2004). As argued by Kumphitak and colleagues (2004), the two initiatives demonstrated the NGOs' capability to improve HIV treatment and care through patient participation, in collaboration with healthcare providers and well-organised training programmes. A former Director of the MOPH AIDS Division acknowledged that the learned lessons and accumulated skills of the civic groups were helpful in rolling out nationwide ART and thus their representatives were embraced to join the Health Ministry's Technical and Administrative Panels (interview N05).

### 5.3.2 Decisions on the programme's new design

The role of the Administration Panel in introducing the national ART programme revision was crucial. As assigned by the Advisory Committee, its responsibilities were to work out the strategies and guidance on broad issues of the universal ART management – for instance the financing and budgeting; patterns of treatment delivery, logistics, and procurement of low-priced ARVs and laboratory reagents (Ministry of Public Health 2002c). In the single year of 2002, there were regular meetings and substantial outputs from this Panel. The discussions, recommendations, and resolutions made by the Administration Panel had spill-over effects on others as well.

The Administration Panel took into account both the integration of ART into the UC and the improvement of treatment access; however, it made more significant progress in the latter than the former (Administration Advisory Panel 2002c). The decisions made by this Panel were affected by the health system environment, especially the difficulties experienced in the recently-launched UC as provincial and district hospitals struggled with the new healthcare

<sup>35</sup> A project organised by the Thai Network of PLWHA to support private, collective ARV purchasing from India and delivery of the medications by HIV specialists.

<sup>36</sup> This campaign aimed to increase access to co-trimoxazole for the prophylaxis of *Pneumocystis carinii* pneumonia (PCP). The Thai Network for People Living with HIV/AIDS organised training programmes for representatives from 157 interested PLWHA groups to provide information on drug administration, and general knowledge in relation to PCP and other OIs. These trained PLWHA were responsible for screening their group members for signs and symptoms which indicated the needs for PCP prophylaxis, and referring them to receive the drugs in hospitals. They were also expected to offer first aid if common symptoms, such as cough, diarrhea, fever and rash, developed, and refer the patients to health workers if the symptoms persisted (Kumphitak et al 2004).

financing arrangements (Administration Advisory Panel 2002b). During the period of ART programme design, complaints about the UC made by health providers focused on financial constraints and a substantially increased workload (National Health Security Office 2004b). These were considered potential impediments in introducing other radical changes, especially expecting them to deliver additional services to PLWHA.

One of the successes of the Administration Panel was that its proposals, for instance those on the engagement with new partners for ART delivery, revisions of therapy provision profile and human resource development component, were accepted by the authorities, i.e. the Advisory Committee and Disease Control Department, and finally got implemented. Persuading the Bangkok Metropolitan Administration and Social Security Scheme to take part in delivering and financing the medication was one of the recommendations from this Panel (Administration Advisory Panel 2002c; 2002d; 2002f). The motivation to approach these agencies was that their responsibilities could fulfil existing gaps, i.e. the small Health Ministry hospital network in the capital city and the limited ART coverage among private firm employees who were the Social Security Scheme beneficiaries. Another clear illustration of the Panel's role was that its proposals to provide the opportunities for NGOs and PLWHA participation in training and care delivery were adopted by the Health Ministry. Moreover, the extension of ART to treatment-experienced patients in 2004 could also be claimed as a result of this Panel's advice (Administration Advisory Panel 2002f).

The above does not suggest the other three Panels' roles were less important. All shared the ultimate goal to renovate the national programme to suit the massive service delivery. The major revisions of treatment regimens and enrolment criteria were informed by the feedback from previous policy implementation. The Access to Care programme evaluation in 2001 indicated several weaknesses including inefficient procurement, poor inventory and allocation of ARVs to participating hospitals, because as many as eight complicated combinations had been adopted (Punpanich et al. 2002; Satasit, Kuaykiatikul, and On-Nom 2002). This led to frequent drug shortages and health providers' mistrust. See chapter 2. The two Panels for clinical guideline development therefore sought to simplify the protocols, to lessen the problems in treatment administration and drug management (interview N05 and N10).

Although most of the members of the Panel for Clinical Guidelines Development were HIV experts, the discussions to identify the most suitable first- and second-line regimens focused

not only on the clinical outcomes but also on implementation feasibility on a national scale. The Drug Selection Panel considered that the fixed-dose combination stavudine + lamivudine + nevirapine was not the best regimen from the clinical aspect (interview N05 and N10). Despite the drug being effective, local studies had demonstrated that severe side effects developed in 20% of Thai patients. However, as this combination was the cheapest and was well tolerated by 80% of treated individuals, it was selected to be the first-line formula. One Panel member pointed out that the drug was selected because of its *acceptable* efficacy, safety and potentially good adherence (interview N10). Another advantage of this combination was that it could be locally produced by the GPO under the brand 'GPO-Vir' at an affordable price (interview N05 and N10). NGO members of the Panel, for example MSF representatives, supported GPO-Vir choice as this product had been prescribed to hundreds of PLWHA in their projects and caused no serious problems (Kapranis quoted in Agence France-Presse 2002).

Findings from clinical studies in Thailand<sup>37</sup> were seen to have had more legitimacy in the drug selection choice than western-based trials. As asserted by the Panel for Clinical Guidelines Development, there were many reasons indicating that findings from drug studies could not be transferred across settings (interview N05 and N10). For instance, most Thai PLWHA sought institutional care when they were seriously ill, i.e. with CD4+ cell levels much below 200 – the clinical stage which was unacceptable for subject recruitment to clinical trials in western countries. Meanwhile, another two formulas, i.e. effavirenz- and protease inhibitor-containing regimens, aimed to be GPO-Vir alternatives in intolerant and resistant cases were also selected, though they were more expensive.

The modification of the criteria to start ART in adults was a shared responsibility of the Advisory Panel members and officials in the AIDS Division. One official argued that, the change in the CD4+ cell levels as the indicators to commence therapy – from 250 to 200 cells per mm<sup>3</sup> in asymptomatic cases – was recommended by World Health Organisation (WHO) (2002c), and suggested by clinical evidence that the outcomes would be as promising as employing the existing criteria (interview N05). He also observed that starting therapy at lower CD4+ cell levels would significantly decrease the financial burden to the programme

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<sup>37</sup> Studies conducted by Thanomsak Ake-patananon, Siriraj School of Medicine and series of clinical trials of different HAART regimens done by Kiat Ruxrungtham and colleagues under HIVNAT. Ruxrungtham was the chairperson of the technical panel on ART delivery in adults.

because of a smaller number of eligible clients. Unsurprisingly, this assertion was never used as the rationale for the criterion modification.

Regarding the 'social contribution' inclusion criteria, all parties agreed to its cancellation although the issue had not been raised on the agenda of any Panel but discussed in many formal and informal ART-related meetings (interview N05). Eventually, it was the Access to Care programme manager who decided to remove it. This action was mainly justified by the fact that the criterion had been discriminatory (personal communication with a former Provincial Chief Medical Officer and a Regional Disease Control Official). In addition, feedback from health providers and provincial health officials suggested that this selection measure was hardly used in practice due to the difficulties in making the judgement on whether an individual could or was willing to contribute to the society, and how to compare treatment candidates.

Despite the difference in the responsibilities of the Technical and Administration Panels, they shared a fundamental principle in their decision making that treatment would be delivered with adequate quality. The analysis of meeting records suggested that vital issues in ARV administration such as adverse drug reactions, patients' tolerability, and medication adherence had often been discussed. However, individual members addressed particular concerns, which varied widely from clinical- to system-oriented issues. Competitions between different ideas were occasionally evident (personal observation). Two examples on drug procurement and service delivery facilities illustrate this. Some members proposed shifting ARV procurement from national to hospital level in order to solve the problems of delayed logistics and drug shortages, which usually occurred in the early-phase Access to Care Initiative (Administration Advisory Panel 2002a). Others suggested transferring certain ART delivery functions to sub-district health centres, aiming to ease the burden on district hospitals, and to lift the geographical barriers of the treatment access (Administration Advisory Panel 2002b). Agreement could not be reached on these proposed strategies so the two elements remained unchanged. However, as perceived by Panel members, even the discussion on these and other controversial issues, was relatively consensual (interview N04 and N05).

### **5.3.3 Termination of the policy formulation network**

Apart from the influence of contextual factors on the programme modification, the policy formulation network itself was affected by the shift in the policy subsystem's environment. The activities of the four Advisory Panels faded out in late 2002 though they were not officially terminated by the Health Ministry. The major cause of the interruption was the bureaucratic system reform implemented in October 2002 and subsequent reorganisation and staff reallocation in all government agencies, including the MOPH and its departments (interview N05, N08 and N15). The AIDS Division was integrated into a newly founded organisation – the Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections (ATSI) – with a new Director (Ministry of Public Health 2002b). Many AIDS officials who had undertaken the secretariat role in the Advisory Committee and four Panels took new positions with different duties. Some were transferred from technical supervisory to service delivery posts in hospitals (interview N08 and N09). Importantly, when the National Health Security Office – an autonomous agency responsible for UC management and implementation – was established and fully functioning in early 2003, Deputy Health Secretary Nitayarumphong moved to become its first Director General.

### **5.3.4 Who really made the changes?**

As maintained by Marsh and Rhodes (1992), some members of particular networks may play more significant roles than others in policy making. Following the Panels' minutes, ART programme formulation in the scale-up phase intensively involved the NGO network and HIV experts from MOPH and universities. The civic actors as the Administration Panel members actively joined in the process by developing the meeting agendas, drafting strategic plans, and providing ideas in the discussions (Administration Advisory Panel 2002a; 2002b; 2002c; 2002d; 2002e; 2002f; 2002g; 2002h). The meeting records also indicate that many, though not all, NGOs' suggestions were well responded to and accepted by other members. Although NGOs had worked closely with Health Ministry officials and peripheral health providers since the nascent phase of HIV epidemic, interviewees maintained that these actors' participation in the treatment extension period had a more 'forceful' pattern (interview N05 and N09).

At the same time, many significant changes in the ART programme configuration reflected the crucial role of specialists and scientists of different areas. With their expertise and long-term engagement in treatment delivery since the implementation of the Clinical Research Network in the mid-1990s, the policy making process to roll out countrywide treatment was well informed with not only scientific evidence but also the insights from experience, and the difficulties of balancing treatment quality and practicality. Although expert members of each Advisory Panel did not officially represent groups or organisations, their competence and experience had been gained from work and research done in their institutes, and in collaboration with each other. For instance, Kiat Ruxrungham – chairperson of the Panel to develop the guidance for treatment in adults – was a leader in clinical trials of different ARV combinations as parts of a multi-country network – the so-called HIV-NAT. He was also a key person in the Thai AIDS society which was a non-governmental association of HIV clinicians and other health professionals with the main objective to improve access to quality medication among Thai PLWHA (interview N10). In addition, HIV specialists had formed connections with and offered support to NGOs in several ways. Therefore, although the recommendations made by the Technical Panels were likely to be dominated by experts, members of non-specialist networks also had some influence.

Despite the vital roles of civic groups and experts in the policy formulation process, the final decisions were guided and made by bureaucrats. Key informants revealed that every meeting of the Advisory Panels was attended by at least one high-ranking official, such as the Deputy Director General of the Disease Control Department or the Deputy Health Secretary – Nitayarumphong – who facilitated the discussions towards consensus (interview N04 and N05). As the civil servants had insights into all facets of ART delivery including how the service was located in the health and administrative system context, they could influence their civic counterparts with internal information. NGO representatives admitted that it was the first time they learned about the impediments and limitations to organising a large-scale programme in the public sector (interview N15 and N17). A NGO leader asserted in interview that, *'the meetings looked like consultations between partners, and the health officials used these stages to convince others to agree with their proposals.'* (interview N15)

Officially, an Advisory Panel must be accountable to its instigating authority. In this light, the four Panels reported to the Advisory Committee which then forwarded all agreed recommendations to the Disease Control Department and Health Ministry for final decision.

However, for particular resolutions of these Panels – for example the suggestions to revise training curriculum and materials – some formal processes were bypassed (interview N05 and N09). The reasons given by responsible officials included that improving ART access was recognised as the government’s priority thus any unnecessary delay in arrangements should be avoided. In addition, owing to the delegated system of Thai bureaucracy, decisions could be made at different levels depending on the degree of their importance. Therefore, either Nitayarumphong, the Deputy Director General of the Disease Control Department, or the AIDS Division director could endorse many proposed changes in ART strategies and commanded their subordinates to have them implemented (interview N05). In other words, the fact that high level officials attended meetings was very important – not only showing government commitment, but also facilitating the process – making it faster.

#### **5.4 Financing ART through the UC: the unfinished agenda**

Since the national ART programme was established in 1992, treatment had been subsidised by the Health Ministry through the Department of Disease Control budget. When civil society alliances campaigned for universal access to ARVs in 2001, they aimed not only for service scale up but also to include therapy in the UC package. Although the government promised to gradually expand the UC benefit to cover ART, as of December 2004 the treatment advocates’ goal had not been met.

While the Administration Panel was functioning in 2002, representatives of civic coalitions often raised the issue of financing on the meeting agenda (interview N15 and N16). NGO leaders observed that the Panel members from the Disease Control Department were apparently not paying sufficient attention to this issue, but focusing only on the national programme expansion. Excepting the chairman Nitayarumphong, most bureaucrat participants, as well as specialists, academics and health providers who sat on the Panel, were unfamiliar with health financing arrangements and thus should have little interest in it. Some officials and researchers argued that the MOPH and Disease Control Department were not in favour of the change in ART programme funding because it would result in a substantial decline in their annual budgets. For example, once the National Health Security Office became the treatment purchaser the Disease Control Department’s role would shift from programme manager to technical supporter, which meant fewer resources and less power (personal communication, anonymous). This was the experience of the Health Ministry when

a significant portion of its budget was diverted to the UC plan from fiscal year 2002, which was claimed to be a major cause of severe resource shortage in peripheral healthcare settings ever since (National Health Security Office 2004b). Meanwhile, officials in the Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections focused differently: they would have liked more time to prepare infrastructure and health personnel in order to ensure treatment quality before all public hospitals were obliged to deliver ART as part of the UC.

Since Nitayarumphong was one of the founders of the emerging health plan and most likely to get the National Health Security Office Secretary General title, he was the sole government official who had an obvious interest in the alteration of ART financing strategy. Projected demands for the enormous amount of 40 to 50 billion baht to support next-ten-year universal ART access (Administration Advisory Panel 2002f), was of major concern to the Deputy Health Secretary, because of the magnitude of the treatment burdens and implications on the UC's stability. His hesitation might have also been fuelled during that period because protests against the health financing reform among hospital directors, physicians, and medical professional organisations had increased over time (Assavanonda 2002a; Assavanonda 2002b; Khwankhom, Sukin, and Sakboon 2002). However, in spite of all this, he had not shown any sign or attempt to delay the treatment integration until the role of the Advisory Committee and its Panels came to the end in December 2002.

The NGOs' campaigns for financing ART under the UC continued throughout 2003 and 2004, while the Health Ministry's and National Health Security Office's positions became clearer (interview N15 and N16). A public hearing on the UC implementation and performance organised in June 2004 indicated the popular preference that ART should be covered by the UC (Manager 2004a). The National Health Security Office responded positively to this suggestion. Along with these movements, the Health Ministry designated a new Advisory Committee in late 2003 to consider the change in ART financing mechanism (Ministry of Public Health 2003c). The ATSI as the Advisory Committee's secretariat amended the working process – organising a series of consultation sessions which were attended by the committee members and a wide range of stakeholders including NGOs, PLWHA groups, academics, HIV experts, regional and provincial health officials, and health professionals.

Mounting feedback on the impediments in ART expansion and UC implementation resulted in increasing concerns of all parties that the integration of treatment into the health benefit

plan should be carried out cautiously. In 2004, the discussions among policy actors mainly addressed the question '*how to ensure quality and sustainability of ART provision in the UC?*' For instance, in a consultation meeting on 14<sup>th</sup> September 2004 the issues in focus were long-term sources of funding, growing demand for second-line ARVs, variation in therapy offered in the national programme and 3 health benefit plans, capacity and role of CSOs, the need for strengthening HIV prevention, and generic production of new-generation ARVs (personal observation).

Fed with lessons learned from a couple of years of both the UC and national-scale ART, the consultation led to the recommendations that funding ART under the UC would be feasible if the problem of financial uncertainties could be solved, while service quality and programme efficiency must be concomitantly enhanced. Finally, in December 2004 the National Health Security Board agreed to finance ART as a component of the UC benefit package by 2005 (Manager 2004b).

## **5.5 Summary**

In 2002, there was a transformation in the treatment policy network, allowing Disease Control Department officials and HIV specialists, who had a minor role in universal ART policy adoption, to take part in the policy formulation process. It was not surprising that these public servants, health systems reformist and treatment advocacy coalitions were appointed as Advisory Panels members to work out new programme features, because the tasks required both technical and management expertise as well as practical skills necessary for synthesising lessons from past experiences, anticipating future impediments and selecting appropriate policy options. Importantly, all members of the Panels might have been expected by the Health Ministry to steer service expansion and provide support to sub-national offices and hospitals in the policy implementation phase.

The policy development in this period suggests the important role of collective policy learning. Representatives from the MOPH, Disease Control Department, universities, research institutes, hospitals, NGOs and PLWHA groups formed into a network to devise new programme strategies. The experience of network members was a crucial factor accelerating the policy development process: helping the Advisory Panels to reach rapid decisions. Collaboration between health officials, academics, health professionals, and staff

of CSOs had been established since HIV problems became obvious in the late 1980s. The interrelationship was occasionally strengthened through events that demanded multi-sectoral cooperation. Information exchanges across networks were beneficial to learning from each other.

The transfer of lessons from the previous phase of national ART service reaffirms the complexity of policy making, as policy formulation and implementation stages overlapped, rather than ran discretely. Feedback on the obstacles in delivering treatment through the Clinical Research Network and the Access to Care Initiative, as well as the problems faced by health care providers in introducing the UC plan played a considerable role in shaping the new ART programme configuration. In this way, the Thai HIV policy formulation process could be considered to have been influenced by 'bottom-up' policy implementation process.

A key feature of policy formulation in this period was that the level of consensus was high. The harmony of Panel members of different backgrounds might have stemmed from the long-term connection between their own networks, prior to joining the MOPH Panels. In addition, these state and non-state actors shared the same goals and interests: to get more PLWHA on quality therapy. Their awareness of the interdependency among Panel members might also have had a role in fostering agreements upon the issues being discussed. The attendance of high-ranking officials in the meetings and even the leadership of the health system reformist who chaired the Administration Panel, were other factors facilitating the process.

## **CHAPTER 6: SETTING THE CONTEXT OF CASE STUDY PROVINCES**

Antiretroviral (ART) policy innovation between 2001 and 2004 was expected to benefit people living with HIV/AIDS (PLWHA) nationwide. To understand how the policy was activated, two provinces with relatively high human immunodeficiency virus (HIV) prevalence were selected as case studies. In each province, 3 hospitals implementing the national treatment programme are analysed – one provincial, two at district level. This chapter describes the context of the policy execution in the study settings: HIV epidemiology and the features of health delivery systems as well as the responses to the epidemic before ART scaling up. It also appraises the roles of different actors in the hospitals' decisions to sign up to the national initiative in the early phase of expansion. The analysis sheds light on the factors affecting treatment instigation in the study provinces and provides some insight into the evolution of the universal ART policy implementation.

### **6.1 Introduction to case studies**

Pichit and Rayong – the study provinces, are located in different parts of the country. The literature suggests that HIV has long been an important problem in both provinces (Bureau of Epidemiology 2003). However, the features of each province differ in several aspects.

#### **6.1.1 Phichit**

Phichit is a medium-size province located in the lower northern part of the country, 350 kilometres from Bangkok (Phichit Provincial Administration Office 2004). The province is divided into 9 districts, namely Muang; Bang Mun Nag; Pho Prathap Chang; Pho Tha Le; Sam Ngam; Taphan Hin; Thapkhlo; Vajira Baramee and Wang Sai Phun. In 2003, the provincial population was 590,476, the rural portion of which accounted for 80% (Department of Provincial Administration 2003). Most people work in agriculture. The province is relatively poor: its gross product in 2002 was 33,489 baht per capita – ranked 53<sup>rd</sup> of the country's 76 provinces<sup>38</sup> (National Economic and Social Development Office 2002).

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<sup>38</sup> The per capita gross domestic product for 2002 was 85,951 baht

### ***Health delivery system***

Phichit is one of 6 provinces which make up Health Region 9, which comes under the supervision of the Regional Offices of the Ministry of Public Health (MOPH), located in an adjacent province, Phitsanulok. In 2003, public health facilities in Phichit comprised 9 MOPH hospitals, 109 health centres; and in the private sector, 4 hospitals and 45 clinics (Phichit Provincial Health Office 2004). The ratio of beds in public to private facilities was 855: 150 (Bureau of Policy and Strategy 2004a). The number of doctors, professional nurses and pharmacists in the public sector was 64, 638, and 54, respectively (Bureau of Policy and Strategy 2004b). In addition, there were 10 doctors and 25 nurses working in private settings in the same year. In 2003, 93% of the provincial population were covered by health benefit plans (Universal Health Coverage plan 75% of total population, Social Security Scheme 13%, and Civil Servant Medical Benefit Plan 5%). The poverty of the general population, as well as a very small business sector and therefore few formal-sector employees, have limited investment in private hospitals in Phichit (interview R06 and S11).

### ***HIV epidemiology***

Phichit's first acquired immune-deficiency syndrome (AIDS) case was diagnosed in 1987 (interview S11). Like many other provinces, evidence suggests that the provincial HIV incidence reached a peak in the early 1990s (Bureau of Epidemiology 2003). The number of new HIV and AIDS cases diagnosed in healthcare settings and reported to the Health Ministry declined from 285 in 1999 to 106 in 2003. The total number of cases ever recorded between 1987 and 2003 amounted to 2,237, of whom 667 had died by 2003 (Phichit Provincial Health Office 2004). Fifty-five percent of HIV patients were labourers, while farmers and other agriculturalists accounted for 16% of the total. The rest included merchants (6.1%), government workers including civil servants, arm forces and police officers (3.2%), children under 5 years old (3.1%), housewives (2.7%), unemployed (2.5%), and others (11%).

HIV in Phichit has spread widely in the general population. Sentinel sero-surveillance indicated a prevalence rate of 2.8% among pregnant women at antenatal clinics in 2003, against the national figure of 1.3% (Bureau of Epidemiology 2004b). The prevalence rate in commercial sex workers in this province was 6.2%, lower than the corresponding rate of 11.4% of the national average, but HIV officials felt the Phichit figure was an underestimate

because surveillance did not cover indirect sex workers, who were believed to be substantially afflicted (interview R06 and S07). In addition, interviewees pointed to the rising trend in some sexually-transmitted diseases such as syphilis and gonorrhoea in 2003 and 2004 which indicated that HIV infections might also rise.

### **6.1.2 Rayong**

Rayong province is located at the centre of the east coast region, 179 kilometres from Bangkok (Department of Provincial Administration 2003). It comprises 6 districts: Muang, Ban Chang, Ban Kai, Klaeng, Pluag Dang, and Wangchan. In 2003, the provincial population was 523,518, one-third of which were agriculturalist (Rayong Administration Centre 2004). Rayong has maintained high economic growth for many years. In 2002, the per capita provincial product was 515,577 baht – the highest in the country (National Economic and Social Development Office 2002). The economy is boosted by manufacturing industries such as chemical, petrochemical and metallic production, all of which accounted for 56% of the provincial output. Large industrial estates and deep-sea ports expanded during the 1990s, requiring an increased workforce, from other provinces and also neighbouring countries – Cambodia and Myanmar (Interview R07). Almost 60% of the total 1,400 industrial sites in this province are located in 2 districts: Muang and Klaeng (Rayong Administration Centre 2004). Rayong is also famous for tourism thus the province is open to large number of visitors as well as migrant labourers who work in tourism facilities.

#### ***Health delivery system***

Rayong and 6 other provinces in the east fall under Health Region 3. Chonburi is the principal province of this region, where the Regional Disease Control Office and Medical Testing Laboratory are located. In 2002, public healthcare facilities in Rayong included 1 provincial and 6 district hospitals and 127 health centres under the MOPH direction; and 6 private hospitals and 111 private clinics (Rayong Administration Centre 2004). There were 128 doctors, 772 professional nurses and 55 pharmacists practising in the government sector in the same year (Bureau of Policy and Strategy 2004b). Meanwhile, 51 doctors, 143 nurses and 15 pharmacists worked in the private sector. The total number of hospital beds in 2003 was 1,194 (public 868 and private 326) (Bureau of Policy and Strategy 2004a). As the province is home to many private establishments such as factories and business facilities, a significant

portion of the population, i.e. the formal-sector employees are beneficiaries of the Social Security Scheme.

### *HIV epidemiology*

The first symptomatic HIV patient in Rayong was identified in 1987. The number of new cases reported from healthcare settings escalated considerably at the beginning of 1990s – the same period as the expansion of industrial estates and sea ports (interview R07 and S16). Case reports per annum peaked at 1,177 in 1998, followed by a decline to 979 and 682 in 2000 and 2003, respectively (Rayong Provincial Health Office 2004a). In 2003, the morbidity rate in this province was the highest in the country. The accumulated HIV cases reported between 1987 and 2003 amounted to 9,687, while 2,147 had died by 2003. Over half of these patients resided in the main town, and 66% were general labourers. Seventeen percent of PLWHA treated in government and private health facilities in 2003 were migrants from other provinces.

Findings of sentinel surveillance illustrated that Rayong's HIV prevalence in subpopulations such as pregnant women at antenatal clinics and commercial sex workers was amongst the top five in the country over many years (Bureau of Epidemiology 2003). In 2003, despite a declining trends in all monitored groups, disease rates in pregnant women (3.1%) were still the highest compared with other provinces (Bureau of Epidemiology 2004b). Apart from sex workers, fishermen were a population with a high risk to the infection. Labour migration and tourism were seen to be responsible for the sustained HIV epidemic in this province (interview R07 and S16), although HIV officials pointed out that the disease was also prevalent among immigrants from neighbouring countries. Similar to Phichit, the rising trend of gonorrhoea and syphilis was apparent in 2003 and 2004, indicating unsafe sex practice and potential increase in HIV infections (interview S13 and S15).

In summary, both study provinces are afflicted by HIV (table 6.1). However, the problem in Rayong is more severe than its Phichit counterpart. The numbers of HIV-positive persons who are still alive suggests higher demand for medical services including ART in Rayong. Compared to Phichit, Rayong is better off for its health care resources.

Table 6.1: Selected parameters on HIV and health care resources, Phichit and Rayong 2003

	Phichit	Rayong
Population	590,476	523,518
HIV prevalence in pregnant women at ANC, %	2.8	3.1
Accumulated HIV cases (1987-2003)*	2,237	9,687
Accumulated HIV deaths (1987-2003)*	667	2,147
Bed : population	1:588	1:439
Doctor : population	1:7,979	1:2,925
Nurse : population	1:891	1:572
Pharmacist : population	1:10,935	1:7,479

Note: \* as reported by hospitals and other health facilities

## 6.2 The context of study hospitals

A total of six MOPH hospitals in Phichit and Rayong were analysed for their ART implementation. Apart from the two provincial facilities, 2 district hospitals were selected from each province – i.e. Sam Ngam and Thapkhlo in Phichit and Klaeng and Wang Chan in Rayong. Sam Ngam hospital signed up to the Access to Care Initiative, which started in 2001, shortly before the obligatory participation was imposed in 2004. Provincial health officials asserted that treatment delivery in this hospital had been well organised and responsive to clients (interview R06 and S11). In contrast, it was suggested that Thapkhlo hospital which joined the national programme earlier – in 2002 – experienced difficulties in therapy provision in the beginning phase. In Rayong, both Klaeng and Wang Chan hospitals instigated ART service as part of the national programme in 2002.

This section reviews the demand- and supply-side factors relating to HIV and ART delivery in the six study hospitals. This includes the statistics on HIV patients who accessed institutional care; public resources available for treatment provision; steering and supervisory roles of MOPH's regional offices; and the relationship between non-governmental organisations (NGOs), PLWHA groups and healthcare providers.

### 6.2.1 Demands for HIV treatment and care

The information on reported HIV/AIDS cases and deaths suggested that the magnitude of HIV burden in the 6 study settings during the ART scaling up differed considerably between the settings (table 6.2). Large numbers of HIV cases had been identified in Rayong town and Klaeng district before the national treatment initiative started in 2001, while the number of HIV patients who received institutional care in Phichit town was much smaller. In the other three districts, the number of newly diagnosed cases was only 10 per year, on average. By 2003, the accumulated number of deaths among PLWHA in Phichit town, Sam Ngam and Thapkhlo was 179, 55 and 43, respectively. The information on the number of deaths by district in Rayong province was not available.

Table 6.2: Reported symptomatic HIV and AIDS patients in study settings, 2000-2003 (cases)

District	2000	2001	2002	2003	Accumulated HIV/AIDS (1987-2003)	Accumulated HIV/AIDS deaths (as of 2003)
Phichit Town <sup>a</sup>	71	49	81	52	599	420
Sam Ngam <sup>a</sup>	17	24	12	10	181	126
Thapkhlo <sup>a</sup>	19	10	8	14	159	116
Rayong Town <sup>b</sup>	476	421	415	309	5,252	n.a.
Klaeng <sup>b</sup>	237	141	92	109	1,488	n.a.
Wang Chan <sup>b</sup>	20	22	17	22	186	n.a.

Sources: <sup>a</sup> Phichit Provincial Health Office (2002g); <sup>b</sup> Rayong Provincial Health Office (2004a)

The information in table 6.2 was derived from spontaneous case reporting – the disease-monitoring approach generally known to have the major drawback of underreporting. Although more accurate HIV epidemic numbers can be drawn from data from sentinel serosurveillance, the former's advantage is that it suggests the rough number of infected persons who access health delivery systems. The annually reported cases and accumulated figures at a point of time offer a picture of the extent of the HIV burden in particular hospitals. This helps to project the trend of service utilisation which is essential in responding to policy formulation and planning. For instance, hospital directors needed to compare the demands for

services across different diseases in their decision making on the adoption of new treatments and allocation of resources.

### **6.2.2 Health care resources**

Phichit and Rayong provincial hospitals are located in the main towns. In addition to serving people in their catchment areas, they are obliged to provide secondary and tertiary care to patients referred from district hospitals. Apart from general practitioners (GPs), there are specialists in medicine, paediatrics, and obstetrics practising in these provincial facilities (Phichit provincial hospital 2003; Rayong Provincial Health Office 2004c). The health delivery system in Rayong possesses more resources than that of its Phichit counterpart. According to the MOPH hospital categories, Rayong provincial hospital is classified as a regional hospital owing to the number of beds (550), range of subspecialties and services provided. The demand for institutional care in Rayong town is shared with 6 private hospitals with a total of 250 beds (Rayong Administration Centre 2004).

Klaeng hospital – 47 kilometres from Rayong town – is a large district-level facility of 120 beds, with 3 GPs and 7 doctors trained in major sub-specialties such as medicine, obstetrics, paediatrics, orthopaedics, and general surgery (Rayong Administration Centre 2004; Rayong Provincial Health Office 2004c). In contrast, Wang Chan is small and remote – 70 kilometres from the main town. However, Wang Chan is adjacent to Chonburi – the major province of Health Region 3, and people can seek care from the regional hospital. The 30-bed district hospital of Wang Chan is operated by 3 GPs and paramedics including a significant number of nurses (Wang Chan hospital 2003). Like many other small and distant districts, frequent in- and out-movement of doctors is a problem in Wang Chan (interview D19).

Sam Ngam district hospital is 18 kilometres from the main town (Phichit Provincial Administration Office 2004). It is located on the border of Phichit and Phitsanulok – the regional headquarters. In contrast, Thapkhlo is a remote district, 68 kilometres from the main town and 110 kilometres from Phitsanulok. Both Sam Ngam and Thapkhlo hospitals are small, with 30 beds and 2 GPs (Phichit Provincial Health Office 2004). Frequent movement of doctors in and out of these district settings has been common. Although it takes longer from Sam Ngam to Phitsanulok than to Phichit town, some people including those living with HIV prefer seeking care from the regional hospital and regional medical centres for some

diseases such as tuberculosis and sexually transmitted infections (interview R06 and S04). Thapkhlo's remoteness is a barrier for its residents to travel to visit health providers in the provincial and regional healthcare settings.

Table 6.3 summarises selected health care resources of the public sector in study districts. It suggests that, on the whole, the government health service system in Rayong is better resourced, compared to its Phichit counterpart, especially in relation to the doctor to population ratio.

Table 6.3: Selected government's health resources in study settings, 2003

District	Population	Bed: population	Doctor: population	Nurse: population
Phichit Town	142,786 <sup>a</sup>	1:353 (405) <sup>a</sup>	1:4,760 <sup>a</sup>	1:357 <sup>a</sup>
Sam Ngam	45,306 <sup>a</sup>	1:1,510 (30) <sup>a</sup>	1:22,653 <sup>a</sup>	1:1,225 <sup>a</sup>
Thapkhlo	53,015 <sup>a</sup>	1:1,767 (30) <sup>a</sup>	1:26,508 <sup>a</sup>	1:1,433 <sup>a</sup>
Rayong Town	206,249 <sup>b</sup>	1:375 (550) <sup>c</sup>	1:3,683 <sup>c</sup>	1:441 <sup>c</sup>
Klaeng	127,127 <sup>b</sup>	1:1,059 (120) <sup>d</sup>	1:11,557 <sup>d</sup>	1:1,271 <sup>d</sup>
Wang Chan	23,873 <sup>b</sup>	1:770 (30) <sup>e</sup>	1:7,958 <sup>e</sup>	1:468 <sup>e</sup>

Note: the figure in ( ) indicates the number of hospital beds

Sources: <sup>a</sup> Phichit Provincial Health Office (2004); <sup>b</sup> Rayong Administration Centre (2004); <sup>c</sup> Rayong provincial hospital (2004); <sup>d</sup> Klaeng hospital (2004b); <sup>e</sup> Wang Chan hospital (2003)

### 6.2.3 Direction and supervision for ART implementation

According to the Health Ministry's sub-national administration structure, the Department for Disease Control has Regional Offices in 12 health regions. Each Regional Office is responsible for the prevention, surveillance, and control of communicable and non-communicable diseases (Ministry of Public Health 2002d). To carry out these tasks, these offices collaborate with and oversee provincial health authorities and hospitals to implement some programmes, for example the Expanded Programme for Immunisation, and prevention and treatment campaigns for infectious diseases including HIV, tuberculosis and malaria.

When ART was gradually extended during 2002 to 2003, the normal supervision and steering system for disease control was deployed. In addition, the Disease Control Department provided a range of support such as health personnel training and supervision through its 12 regional offices (Ministry of Public Health 2002a; 2003b). Since provincial and district hospitals were under the direction of the Health Ministry's Health Service Department, the connections between the Regional Offices and hospitals usually involved Provincial Health Offices (PHOs) which were in charge of overseeing the health delivery system within provinces.

As the universal ART policy became high priority in 2004, the Disease Control Department introduced intensive supervision and monitoring over the treatment delivery units (Ministry of Public Health 2003a). There were regular visits of senior officials of the Health Ministry and the central Departments to its regional centres, provinces and hospitals, aiming to promote the national ART initiative and to get feedback from health workers in hospitals (interview R04 and R07). The visits were also to facilitate the development of strategies to deal with any recognised obstacles.

In 2004 the Disease Control Department established an advisory board to provide recommendations to improve treatment extension in each region (interview R01, R04 and R06). Chaired by the Ministry Supervisor, the board members consisted of the directors of the Regional Offices for Disease Control and Health Promotion; Provincial Chief Medical Officers; hospital directors; HIV experts; academics; and NGO and PLWHA representatives. This advisory body was expected to develop programme directions in collaborative ways for the entire region. Administrators of regional and provincial offices were involved because it was considered an effective strategy to promote two-way communications and cooperation among these peripheral agencies.

#### **6.2.4 Relationship between NGOs, PLWHA groups and healthcare providers**

The development of partnerships between the public sector and NGOs in Phichit and Rayong was markedly different, probably reflecting the magnitude and burden of HIV epidemic in each area. The very first HIV NGOs founded in the east-coast region from the mid-1990s were faith-based organisations such as the Camillian Social Centre and San Maria Foundation, both of which were in Rayong (interview R08 and S16). Later, this area was relatively

crowded with local, national, and international NGOs offering several sorts of care and assistance for infected persons and families.

With support from the Camillian Centre, the Eastern Regional Network for PLWHA was established in 1999, and thereafter became an active member of the National PLWHA Alliance and also coordinator of PLWHA groups in 7 Eastern provinces (interview R08, R09 and S16). The close collaboration between these NGOs and government agencies especially MOPH hospitals developed some time before the universal ART policy (Contarin 2004; Disease Control Office for Health Region 3 2004a; Eastern Region PLWHA Network 2003). Evidence for links between civil society, private business, and government organisations was apparent in the establishment of, for example, the Provincial HIV Prevention and Control Committee and the Regional Advisory Board on ART Extension (interview R07 and S16).

By contrast, the involvement of HIV NGOs in healthcare delivery in Phichit was only observed from about 2002, and seemed to be less organised than in Rayong. Three CSOs, namely Ruam Pattana Phichit, Phichit PLWHA Network, and PLWHA Network of the Lower-Northern Region, were suggested in interviews as having active roles in Phichit (interview R06, S11 and S12). The first, which mainly focused on agriculture and community development, provided financial support to hospital-based PLWHA groups for occupational training and encouraged group leaders to take part in HIV education activities in secondary schools and communities. For the two PLWHA networks, their substantial role emerged after the national ART programme was instigated. Similar to Rayong, official coordination among actors from different sectors was partly managed through provincial and regional panels (interview R01 and R06). Interviewees asserted that in both provinces, these panels were dominated by government officials.

As delivering healthcare for PLWHA demanded the understanding and cooperation of patients, an important strategy was to offer them essential information (interview S01 and S11). To facilitate this process, Phichit provincial hospital set up a PLWHA group, as early as 1992, aimed at organising education fora and information exchanges among members. The hospital funded group activities which mostly emphasised meetings of patients and with health providers. Later, the group extended its interests to wider areas such as practising self-employed occupations in order to improve income-earning opportunities (interview S04 and

S12). The relationship built among patients, and between patients and health workers through this arrangement was perceived as useful for HIV care in this setting.

In Rayong, the first patient group was established in Klaeng hospital in 1999 (Klaeng Kow Naa Club 2003). Later, in 2000, HIV patients in the provincial hospital formed into a small organisation. The group formation was acknowledged as a product of the cooperation between the hospital and Camillian Social Centre (interview S16 and S17). The analysis suggests that this initiative was underpinned by the remarkable increase in demands for HIV services in this region. The management was similar to that in Phichit in terms of support and range of activities. However, the Rayong group got substantial assistance from the Regional PLWHA Network so that it was relatively stronger and more independent than the former. The success in coordinating ART provision through the Buyers' Club<sup>39</sup> was claimed as empirical evidence for the effectiveness of the group (interview S23 and S24). Furthermore, the patient organisation was well accepted by hospital administrators as witnessed in two observations – the inclusion of the patient group in the hospital's organisational structure on HIV service delivery (interview S16), and the hospital providing a permanent office and meeting room for the group members (Koh Kaew Club 2002). In contrast, the establishment of PLWHA group in Phichit provincial hospital was less formal as it was not recognised as a component of HIV care provision. As of July 2004, the group leaders were still negotiating with the hospital director for a room to organise group activities (interview S04 and S12).

In the district settings, at the time of data collection in July 2004, the establishment of a patient group in Sam Ngam hospital was under consideration (interview D02). The hospital director maintained that since ART had been inaugurated in this facility for only 10 months, there were many uncertainties such as the extent of PLWHA participation, volunteer leaders and demand for incentives, and financial implications for the hospital. By contrast, patient groups were organised and led by health workers in Thapkhlo and Wang Chan, after ART service instigation in the hospitals. PLWHA leaders claimed there were connections between these patient groups and provincial and regional PLWHA organisations as well as other NGOs (interview D11 and D23). Through such linkages, the capacity of the groups was

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<sup>39</sup> Buyers' Club was a programme to promote ART access, offering medicines together with appropriate information and counselling. In June 2002, approximately 1,000 PLWHA received treatment from 21 Buyers' Club sites across the country (MSF 2004). Thereafter, the number of clients continually declined as a result of the National ART Programme extension.

strengthened by the Regional PLWHA Network through many education and training sessions on HIV care, group management, and home visits. In addition, the group leaders learned from the Regional NGO to develop proposals to seek funds from different sources such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM). A grant from this global initiative was allocated through the two regional PLWHA networks in late 2004. With this support, patient groups could run their projects such as prevention and education, home visits, and occupation training. However, the analysis of interview data and personal observation suggest that group activities predominantly depended upon health workers in each hospital.

Regarding the provider-client relationships, Klaeng's HIV clinic was the only study setting criticised for its undesirable approach. The interviews with health officials, NGO and PLWHA leaders suggest poor relations owing to the responsible health workers' personality; lack of cooperation between departments and poor connection with other hospitals (interview R07, R09 and S23). ART and other HIV services offered in this facility left the clients dissatisfied and in some instances, provoked perceptions of stigma and discrimination. Interviewees claimed that these phenomena encouraged PLWHA in this district to seek care from other hospitals.

Although all hospitals, except Sam Ngam which had no group, encouraged patient involvement through group mechanisms, participation was voluntary (interview D07, D13 and D20). For those who refused to participate in groups, the counselling, information, and other services were offered on an individual basis. In 2004, the largest hospital-organised PLWHA group existed in Rayong provincial hospital (table 6.4). The small proportion of the group members compared to the total treatment clients was said to be because most of the patients resided in the main town, and were afraid of coming across familiar persons in the patient group who might unveil their HIV status (interview S04 and S16). Thapkhlo was the only study hospital where the number of PLWHA group members exceeded that of the current ART clients. However, interviewees in all settings suggested that large numbers of members were not associated with active participation, and many patients joined group activities only when they came to visit health workers in HIV clinics.

Table 6.4: Patient groups in study hospitals: year of formation and number of group members comparing with the number of ART clients in 2004

Hospital	Year of group formation	Number of group members	Number of current ART clients
Phichit, provincial	1992 <sup>a</sup>	25 <sup>a,(1)</sup>	46 <sup>b,(2)</sup>
Thapkhlo	2003 <sup>a</sup>	30 <sup>a,(1)</sup>	19 <sup>b,(2)</sup>
Sam Ngam	n.a. <sup>a</sup>	n.a. <sup>a,(1)</sup>	11 <sup>b,(2)</sup>
Rayong, provincial	1999 <sup>c</sup>	151 <sup>d,(3)</sup>	261 <sup>c,(2)</sup>
Klaeng	1999 <sup>c</sup>	50 <sup>d,(3)</sup>	99 <sup>c,(2)</sup>
Wang Chan	2002 <sup>a</sup>	30 <sup>d,(3)</sup>	37 <sup>c,(2)</sup>

Sources of information: <sup>a</sup> key informants in study hospitals; <sup>b</sup> Disease Control Office for Health Region 3 (2004b); <sup>c</sup> Koh Kaew Club (2002); <sup>d</sup> Eastern Region PLWHA Network (2004); <sup>e</sup> Klaeng Kow Naa Club (2003)

Note: <sup>(1)</sup> as of July 2004; <sup>(2)</sup> as of September 2004; <sup>(3)</sup> as of March 2004

### 6.3 Health delivery systems' responses to HIV before ART era

Soon after the first HIV case in Phichit was reported, the PHO in collaboration with the Disease Control Office for Health Region 9 and hospitals in the province developed a system for disease prevention and control, which comprised activities to be undertaken in communities and healthcare settings (interview S11). The first HIV clinic in Phichit was founded as a unit under the Medicine Department in the provincial hospital in 1992 (interview S01). At that time, a counselling service had only recently been introduced to the country's health delivery system, especially in MOPH hospitals. All nurses including those working in district facilities were trained in basic counselling courses annually, which were run at the provincial level (interview S08 and S11). Some counsellors attended the advanced counselling programmes for HIV regularly organised by the Disease Control Department in Bangkok.

In the mid 1990s, the HIV clinic in Phichit provincial hospital offered counselling, testing, and prophylaxis and treatment of opportunistic infections (OIs) (interview S04). Information & education, follow-up, and monitoring were also carried out. The clinic also provided

condoms to clients not only to prevent further infections but also for contraception purposes (interview S08). When zidovudine and breast-milk substitutes for the prevention of mother to child viral transmission became available through the national initiative in 2000, a connection was established between the HIV clinic and antenatal clinic to deliver counselling and testing for pregnant women (interview S01). Family planning services including contraceptives were offered to HIV patients in the Obstetric & Gynaecology clinic.

HIV prevention and control programmes in Rayong had been developed from the late 1980s (interview S15 and S16). Strategies and activities were adjusted over time in accordance with the national policies as well as changes in local HIV epidemic features. The Disease Control Office for Health Region 3, PHO and MOPH hospitals created close collaboration in the areas of disease surveillance, research projects, and the implementation of HIV programmes such as the 100% condom campaigns, information & education, and vertical transmission prevention (interview S16 and S17).

The number of symptomatic HIV and full-blown AIDS patients admitted to Rayong provincial hospital increased markedly from 1993, reaching 40 to 50 cases per month in 1997 (interview S15 and S16). The burden of HIV in Klaeng and Wang Chan became visible a few years later. However, similar to other provinces, the health delivery system in Rayong began preparing to deal with the growing demands for treatment and care in the early 1990s and established anonymous clinics in the provincial and district hospitals in 1992. Following the Health Ministry's policy, all nurses had to be trained in basic HIV counselling irrespective of clinics or wards they were working in, so that they could manage HIV-suspected and infected cases properly.

In 1996, Rayong provincial hospital started a collaboration with Camillian Social Centre (Tangsurakit 2000). With this relationship, bedridden cases who had been rejected by families and communities were referred from the hospital to this NGO's hospice for palliative and terminal-stage care (interview S16). The Camillian Centre also organised training sessions targeting students, civil servants, community members, and factory workers on disease prevention and many aspects of care (Contarin 2004). The provincial hospital also sought partnership with other NGOs in the Eastern region to provide assistance to PLWHA and families (interview S16 and S17).

A different feature of HIV treatment and care provision observed in the two study provincial hospitals is that in Rayong case, there was strong coordination between doctors, nurses and social workers in preventive and outreach activities from the early epidemic. Through this, holistic and multi-sectoral approaches had long been employed to address HIV problems in Rayong town and nearby districts before the national ART programme was extended in 2001. The analysis of the interview data suggests that medical and psycho-social interventions were introduced by the provincial hospital through the partnership with other provincial-level government agencies and local administrations, private companies, NGOs, and PLWHA networks. However, medical services within the hospital and clinical trials in Rayong provincial setting were fragmented, even those activities which were supposed to be well integrated under the supervision of the hospital's Infectious Board (interview S13 and S22). In this hospital, there was no special clinic for HIV, and ART was prescribed by specialists in the Medicine and Paediatrics Departments. Interviewees argued that as these specialists had different subspecialties such as cardiology, nephrology, and gastroenterology, some of them did not pay much attention to national treatment protocols (interview S13 and S18). In contrast, HIV-related activities in the provincial hospital of Phichit in the same period were cohesive since they were led by the sole doctor and more focused on medical care delivered in the facility.

District hospitals in the two study provinces could deliver HIV counselling & screening; however, treatment and care for PLWHA was limited to symptomatic relief in these settings. For expensive OI drugs such as amphotericin B and fluconazole, which were unavailable at district level, patients were usually referred to provincial hospitals (interview D03, D06 and D22). Klaeng hospital was exceptional as this district facility provided a wider range of drugs for OI prophylaxis and treatment (interview D13). This was because according to the Health Ministry's regulations, the number and categories of drug items on hospital drug lists depended on hospital size and specialties of doctors (Commission on Thai Drug System Study 2002). Interviewees in both provinces believed that some PLWHA who could afford the costs sought care in nearby provinces such as Chonburi and Phitsanulok respectively as well as in Bangkok owing to stigma and perception of better services. Stigma also led to HIV patients seeking health services from different districts.

Wang Chan hospital was perceived as an outstanding district facility among other district hospitals in Rayong province, because of its development and quality of HIV service

provision (interview R07 and R09). Despite limited capacity in some services, treatment and care for PLWHA had been well integrated before ART delivery instigation. In 2001, the hospital signed up to a pilot programme of the Disease Control Department aiming to provide integrated, holistic HIV care – the so called ‘Comprehensive and Continuum of Care programme’ (interview D20). All health workers from different departments were trained in a course organised by the Disease Control Department to understand the objectives and concepts of the medical services and psycho-social care offered to PLWHA at particular stages of the disease, in both hospital and community. The programme evaluation in 2002 indicated the success of the Comprehensive and Continuum of Care programme in this hospital in many aspects including patients’ satisfaction and improved quality of life (Yachompoo 2003).

#### **6.4 First introduction of ART in study provinces**

In Phichit, ART was first delivered as dual-drug regimen in the provincial hospital in 2000 through a multi-centred clinical trial coordinated by HIV-NAT<sup>40</sup> (interview S01). The study was managed and funded as a project under the Clinical Research Network. Before the research started, all investigators and respective health workers were trained by the project coordinators in two main aspects, namely ART provision and Good Clinical Practice<sup>41</sup>. They learned about treatment administration and crucial caveats including the importance of medication adherence and drug use monitoring; programme management; data handling and analysis; and techniques for laboratory testing (interview S04, S10 and S11). Fifteen patients were enrolled in this treatment trial according to preset criteria. Close supervision from the HIV-NAT and intensive audit were undertaken throughout the 96-week study period.

It is unclear when ART was first introduced in Rayong. However, it was believed that a number of PLWHA might have been treated with ARVs of different regimens in private hospitals and clinics before the medications were offered in government facilities (interview R07 and S16). Interviewees claimed that treatment was prescribed in Klaeng hospital from 1996 (interview D12 and D13). At that time, the hospital had only 60 beds and a small

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<sup>40</sup> HIV research collaboration between the Netherlands, Australia and Thailand, jointly coordinated by the Thai Red Cross Society and other foreign institutes.

<sup>41</sup> Good Clinical Practice is an international code of conduct in biomedical studies in humans. It covers a wide range of elements aiming not only to assure research quality but also to safeguard subjects from unnecessary adverse effects and other unethical treatments.

number of doctors. Twenty PLWHA received dual ARV regimens, zidovudine + didanosine or zidovudine + zalcitabine, through a clinical trial under the Clinical Research Network. Treatment was prescribed by a GP whose important role in HIV service delivery continued when the Access to Care Initiative commenced in Klaeng in 2002.

In the non-governmental sector, ART access was encouraged by the Camillian Centre. From 1997, the NGO funded some patients in its hospice to receive medications from the Thai Red Cross HIV clinic in Bangkok (interview S16 and S17). At the same time, it supported the establishment of the network of PLWHA groups in Rayong, which was further extended to 6 other provinces in the east-coast region (St. Camillus Foundation of Thailand 2002). Later, the eastern PLWHA association became a member of the Thai Network for PLWHA (interview R09). When the national network, AIDS Access Foundation and Medicine San Frontier (MSF) established the 'Buyers' Club' in October 2000, the eastern network signed up to the programme, through which ARVs were purchased and prescribed to self-funding patients (interview S16).

Rayong and Chonburi provincial hospitals were the major hubs of ART provision through the Buyers' Club in the eastern area. Focusing on Rayong province, health providers in the provincial hospital, Klaeng hospital and a Royal Thai Navy medical centre volunteered to deliver therapy for the programme members (interview S16 and D12). The estimated number of patients who received medication through this mechanism during 2000 to 2002 was between 350 and 400. This included PLWHA not only from different districts but also other provinces. A Wang Chan nurse revealed that since ARVs had not been provided in small hospitals like hers, one of her patients whose CD4+ count was 6 cells per mm<sup>3</sup>, who it was anticipated would not survive until the government's programme was established, sought therapy from the Buyers' Club in the provincial hospital (interview D20).

The Buyers' Club was commented on positively and negatively. NGOs and other treatment advocates praised its ability to provide ART, since treatment was not initially available in the public sector (interview R09 and S24). Moreover, the programme in some way encouraged collaboration and information exchange between health professionals of the Red Cross Society, MSF, Camillian HIV Centre, and the public hospitals (interview S16 and S17). The relationship was also claimed as firm foundation for the scaling up of the national ART programme (MSF 2004a). On the other hand, the project was criticised for many drawbacks

(interview S13). First, therapy was based on personal judgements, in the absence of established guidelines<sup>42</sup>. Second, there was no proper system to guarantee the service quality, i.e. to promote medication adherence and monitor clinical outcomes. Finally, since the Buyers' Club members had to absorb the whole financial burden, occasional income deficits resulted in drug shortages and subsequent treatment interruptions. Interviewees asserted that these pitfalls and the fear of development of drug resistance led many doctors in Rayong provincial hospital to refuse to take part in this programme (interview S13 and S15).

Along with ART prescription in the Buyers' Club, therapy was offered by Rayong Obstetrics & Gynaecology Department under the Perinatal HIV Prevention Trial Project (PHPT)<sup>43</sup>. Rayong provincial hospital and Klaeng hospital participated in this multi-centre study from 1997 (interview S13 and D12). Excluding a small number of those with contra-indications and dissenting cases, all HIV-positive pregnant women were recruited to receive zidovudine for preventive purposes. For ethical reasons, the subjects were promised follow-up over their lifetime and provided with care and dual-ARV therapy, which shifted to triple-drug regimens as recommended by the national ART guidelines later.

In summary, before the government issued the policy to scale up the ART programme in 2001, three study hospitals had had some experience of dual-ARV therapy provision. The largest group of patients received the medication in Rayong provincial hospital through the Buyers' Club. In the other two settings, namely Phichit and Klaeng hospitals, treatment was provided to a small number of infected persons who were enrolled as subjects in clinical trials under the supervision of the Health Ministry's Disease Control Department. Health providers of Klaeng hospital were also involved in treatment delivery through the patients' self-financing initiative, the Buyers' Club.

### **6.5 Introducing universal ART coverage: peripheral-level policy adoption**

After the government adopted the policy to extend its ART programme to meet universal coverage in 2001, the national treatment target gradually increased to 50,000 in 2004. The voluntary participation of hospitals in the programme was maintained during the first two

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<sup>42</sup> Several dual-ARV regimens were prescribed through Buyer's Clubs in different hospitals.

<sup>43</sup> The study was conducted by an international collaborative research group based in Thailand which involved multidisciplinary researchers, experts and health workers from the MOPH, universities in Thailand and the United States, and four institutes in France.

years of scaling up; after that participation became obligatory. This section explains how and why study hospital directors decided to instigate ART service in the national initiative in the early extension period.

### **6.5.1 Persuasive role of sub-national MOPH offices**

As stated in the national ART programme guidelines, Regional Disease Control Offices were responsible for identifying competent hospitals and convincing the directors to join the initiative (Ministry of Public Health 2001b; 2002a; 2003b). Since there were no explicit criteria to assess hospitals' competency, large facilities including regional and provincial hospitals, especially those with experience on HIV care were considered priority (interview R01 and R04). Smaller district hospitals were invited to participate when the programme had been launched for a year (interview D02 and D20).

To scale up ART in Phichit and Rayong, similar arrangements for policy communication were employed by the two Regional Disease Control Offices. Information on the national treatment initiative was circulated through the meetings of hospital administrators and health workers on different occasions (interview R01 and R04). After this, hospitals were invited to join the national programme. Prior to treatment start, three-day training workshops were arranged for health workers who would be involved in the service delivery, namely physicians, nurses, counsellors, pharmacists, and laboratory scientists, from all hospitals in the regions. It was also the Regional Offices' responsibility to organise specific skill-development courses for each profession and also for the staff of NGOs and PLWHA groups. The education, information and training programmes aimed to encourage efficient therapy provision among participating hospitals and also to enable the non-participants to take part in the Initiative later.

Although the guidelines had not suggested that PHOs should have a promotional role in persuading hospitals to join the national programme, in practice provincial-level officials helped to identify the potential hospitals and to convince them to sign on. This was because PHOs and hospitals were under the direction of the Health Secretary's Office and they had had close collaboration with each other in general health service delivery aspects (Ministry of Public Health 2002d). A HIV official observed that since Phichit PHO recognised the importance of the policy to scale up treatment, many elements of the national programme

such as the targets and activities were included on the agendas of the monthly meetings of health administrators within the province (interview R06).

However, the task of convincing hospitals to join the national programme became increasingly difficult over time as most of the competent hospital settings had been enrolled. In late 2003, almost all of the non-participants were 10- and 30-bed district hospitals (ATSI 2004c). Following the universal ART policy in 2004, all MOPH hospitals were obliged to deliver the medication under the national initiative. As a consequence, the role of the Regional Disease Control Centres and PHOs shifted from persuaders to supervisors, collaborators, and ‘trouble shooters’.

Interviews suggested that there was a real need to persuade many smaller hospitals to join the national ART programme before 2004 (interview R01, R06 and R07). Reluctance arose from the fear of treatment implications for the hospitals, for example in the incurred expenditures on ARVs, chemical reagents and staff training. It was also possible that some facilities with few HIV patients hesitated to start the service because the problems were not acute for them. These issues are explored in the next section.

### **6.5.2 Perceptions of healthcare providers on universal ART policy**

The interviewees illustrated that in the early phase of the national treatment programme, directors and health workers of study hospitals were positive to ART extension since it would reduce the burden from repetitive HIV-related admissions and associated medical care costs (interview S11 and S13). In particular, health providers who had got involved in therapy provision showed their support for the government programme owing to their direct experience (interview S01 and D12). For instance, a social worker of Rayong provincial hospital said:

*‘Since we had worked with the MSF and PLWHA network to coordinate patient group activities, we witnessed significant changes. Some of them were bedridden, with CD4 levels of as low as zero. They became healthier...got up from beds and played football with friends...they could return to work. This made us consider that ART delivery would enhance overall care for PLWHA as well.’* (interview S16)

A specialist from the same hospital asserted that ART was essential especially in the settings with large numbers of HIV patients.

*'In some wards, most of the admitted patients were HIV positive. We only treated OIs and other complications ... then let them home. They usually came back to us within 2 to 3 days or a couple of weeks at the longest. If we hadn't offered ARVs, as we all know, they would come back and forth – visited us frequently. This cost us enormous resources ...'* (interview S13)

As suggested by key informants, however, the decisions to participate or not in the national ART programme were influenced by many factors other than the clinical outcomes in infected persons and associated medical care cost reduction. One of the impediments to therapy delivery was the workforce shortage. The inadequate number of health workers and disproportionate workload were chronic problems in many provinces especially in rural areas (interview R04, R06, and S07). In addition, this problem was exacerbated by the reform of healthcare financing including the UC launched in 2001. The UC reform required the reallocation of doctors and paramedics, who also had increased workloads, such as the health promotion campaigns and 'close-to-home' healthcare delivery in community-satellite centres (Srithamrongsawat and Torwatanakitkul 2004). Among the reform's consequences was also the growing number of people seeking institutional care, as well as inefficient budget management and subsequent deficits in financial incentives such as over-time allowances (National Health Security Office 2004a). Evidence suggests that the impact of the UC for health delivery system affected all levels of health facilities; however, the effects on the ART programme participation varied across study hospitals. For instance, in Rayong provincial hospital where the Social Security Scheme was a substantial source of the service budget, financial constraints originating from the UC implementation might have been less severe than hospitals in Phichit. However, the financial consequences of the UC on health facilities of different levels were complicated and involved many administrative and economic factors.

Regarding the subsequent increase in workloads, it was argued that before the 2004 national ART programme, hospitals were allowed to set their own targets; and in some settings like Phichit provincial hospital the number of clients to be treated was decided by considering workforce capacity (interview S01). Thus the additional burden originating from participation in the programme was considered to be manageable. Similarly, Wang Chan hospital was

invited to join the Access to Care Initiative in 2002, when only 20 PLWHA regularly visited the HIV clinic, so they could be absorbed in routine work. Responsible health workers therefore did not hesitate to start treatment delivery (interview D20). Interviewees maintained that despite lacking experience and knowledge, this hospital volunteered to sign up since the health workers expected the training programme organised by the Regional Disease Control Office would be able to fill the gaps.

Sam Ngam was the only study hospital reluctant to take part in the national ART programme because of the concern about negative consequences. The director perceived that it was difficult for such a small facility to handle the potentially increased number of HIV patients and associated financial impact (interview D01). The arguments related to the possibility that ART service would increase the health personnel shortage, since doctors, nurses, pharmacists and medical scientists had to allocate more time to deliver this complex therapy. Moreover, according to the national programme requirements, the Disease Control Department would merely provide ARVs to hospitals and subsidise laboratory costs for enrolees. Other categories of expenditure such as those on home visits, blood specimen transportation and other logistics, data management, and programme administration were left to hospitals. The recently initiated UC plan was also perceived to have had negative effects on the hospital's personnel and financial resources.

An additional concern raised by Sam Ngam director was on the sustainability of the Access to Care Programme. In its beginning stage, the Initiative was perceived as 'another research project' (interview D01). The Director had heard that an unpleasant effect for healthcare settings of joining the Clinical Research Network was that the Disease Control Department failed to continue its support to the participating hospitals when research projects had ended<sup>44</sup>. In the absence of assistance from the central level, it became a burden on the health providers to maintain ART for their patients who used to be study subjects, because of the huge expenditure on ARVs and other supplies. In many settings, medication was terminated owing to financial constraints. The Director also argued that he had consulted the respective Regional Disease Control Office about the long-term status of the Access to Care Initiative, yet received no definite answer. Although only one hospital director mentioned this, another

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<sup>44</sup> This reflected the discrepancy between policy and practice – following national guidance, ART was supposed to continue in all study subjects with financial and technical support from the Disease Control Department.

interview with a former director of the MOPH AIDS Division suggested that this scepticism was prevalent among hospital administrators (interview N05). This concern was justified: treatment interruption as a consequence of the change in the national ART policy was reported in certain parts of Thailand. For instance Phanuphak (2004) reveals that when the Health Ministry changed its policy to support the study of zidovudine + didanosine and zidovudine + zalcitabine combinations in naïve patients in 1998, many ARV-experienced cases could not get free drugs to maintain treatment .

### **6.5.3 Decisions to join the national ART programme**

All study hospitals participated in the national ART programme before it became compulsory; however, the motivations to do so were different. The Sam Ngam hospital director revealed that he decided to take part in late 2003 because of implicit external pressure (interview D01). He experienced the policy communication through the PHO as ‘top-down command’.

*‘We had problems of personnel shortage ... we were reluctant – not sure about our capacity; however, we signed up to the programme. It was the provincial administrators’ policy – they demanded 100% participation. It was a bureaucratic top-down command. I discussed this with friends – other district hospital directors ... we signed up because our hospital was the only non participant.’* (interview D01)

Although the Health Ministry asked for voluntary collaboration from hospitals, the Director of Sam Ngam hospital felt he was forced because at the monthly meetings of health administrators in the province, names of non-participating hospitals had been underscored, which to certain extent embarrassed the Directors of such facilities. One HIV official admitted that it was the PHO’s strategy to put pressure on hospitals by naming the non-participants (interview R06). Before the voluntary participation policy was officially lifted by the MOPH, the hospital obligation to deliver ART had been strongly promoted at the provincial level. Possibly, this was because the proportion of participating hospitals in a province reflected the performance of the PHO in some ways.

In Rayong provincial hospital, although there were almost 400 PLWHA on medication through the Buyers' Club when the scale up of the national programme began in 2001, the hospital did not decide to participate promptly (interviews S16 and S17). The limited staff in the Medicine Department and special arrangements required in treatment delivery were the reasons given for the reluctance to make a long-term commitment. However, interviewees maintained that health professionals and social workers were willing to take part in the national ART programme (interview S13 and S16). It was possible too that the decision made finally by the hospital director was partially influenced by NGOs and PLWHA concomitantly with the concern about the hospital's reputation as a regional facility. A key informant said:

*'It was not only health providers who got the information ... NGOs, patients and PLWHA group leaders got it too. They frequently reminded us that the drugs had been available and allocated to this province. We anticipated the consequences (if we didn't sign up to the initiative) since we were a regional hospital ... large numbers of PLWHA came to us to seek care. I informed the director that the group leaders knew a lot and consulted him on how to respond to their requests.'*  
(interview S17)

For many, participation in the national programme was voluntary. Interviews in the other four study settings suggested strong support for patients' wellbeing. Health workers of Phichit provincial hospital, Klaeng and Wang Chan asserted that the benefits of ART to patients was the major reason justifying their hospital's participation (interview S01, D12 and D18). Likewise, a nurse in Thapkhlo observed that the hospital volunteered to instigate the service because the director expected improved therapy access would benefit PLWHA and families (interview D07). The interviewee perceived no coercion on the part of the provincial or regional offices on her hospital. An argument can be made that, however, there might have been pressure on the hospital director but nurses and other health workers were distanced from such pressure. It is worth noting that at that time, there was no doctor practising in this district and the hospital was overseen by the Deputy Provincial Chief Medical Officer who was assigned to be the acting director. As this senior officer was normally responsible for policy-level issues, he might have signed on to the programme in order to further the profile of the provincial health delivery system. This may have taken precedence over the potential feasibility and costs of the service provision in this hospital.

From interviews, it seems that the decisions to start the ART service were voluntary or only indirectly coercive. Also the decisions involved very few: only the director and a small group of healthcare staff, led by physicians. In the two provincial settings, and Klaeng and Wang Chan hospitals, programme participation was initiated by health workers, who proposed the directors endorsed it (interview S01, S16, D12 and 20). All interviewees said that they found no obstacle in convincing the directors to join the initiative. In contrast, the dominating role of hospital directors in decision making was mentioned in both Sam Ngam and Thapkhlo cases (interview D02 and D07). Regarding Sam Ngam hospital, key informants revealed that the director did not consult staff about applying to join the Initiative but informed respective health workers that treatment delivery in the hospital seemed to be inevitable because he perceived this policy was going to be compulsory shortly (interview D02 and D03).

Despite active involvement of PLWHA groups in HIV treatment and care in Rayong before ART coverage extension, the NGOs' role in deciding to instigate therapy provision in the three study hospitals was limited. As argued by key informants, it was unlikely that PLWHA would appeal for additional or improved hospital services because of the strong stigma attached to HIV (interview R07 and R09). Many hid their HIV status to avoid social isolation and discrimination. Also PLWHA may have perceived they had inferior knowledge about treatment than the health professionals. Given that most PLWHA groups were initiated by hospital staff, they may have been reluctant to make group demands. An interviewee maintained that:

*'We cannot expect PLWHA to challenge even they become increasingly cohesive when gathering in groups. ... it is impossible for them to challenge physicians and nurses because these patient groups have been established and managed by hospitals.'* (interview R07).

From a health official's perspective, NGOs which were independent of the public sector should have been more successful than hospital-organised patient groups in reflecting PLWHA's demands (interview R07). In reality, however, NGOs played a minor role in encouraging programme participation. Although the Eastern Region PLWHA Network had collaborated well with government hospitals to provide support to HIV-infected people, the Network Director revealed that his organisation had largely tried to persuade and support the actions of the health providers, and admitted he had no planned action when the hospital

directors or physicians refused to join the Access to Care Initiative, or limited the number of ART clients (interview R09). In part, this might be because the response from the health authorities was considered justified by the fact that the human resources constraints in public hospitals was well known and affected not only HIV patients but also those with other diseases. In addition, it was accepted that such impediments were not solely encountered at sub-national levels.

## **6.6 Summary**

Phichit and Rayong differed in terms of the demography, economic status, health care resources, and burdens of HIV in the health delivery system. The relatively severe afflictions from HIV in Rayong might have been a factor encouraging civil society participation in treatment and care delivery from the early days of the epidemic. Patient groups in provincial and district hospitals in this province were managed with support from faith-based organisations and regional-level PLWHA coalition. Networks to tackle HIV-related problems had connected Health Ministry hospitals with NGOs, PLWHA groups, and private business long before ART scaling up. The launch of several research studies ARVs, prophylaxis and therapeutics, and NGO-organised treatment through the Buyer's Club in Rayong and nearby provinces, provided many opportunities for health workers and staff of civil society organisations to learn together about the benefits, risks and proper administration of medication. In addition, the substantial fund from Social Security Scheme was an important factor shaping the allocation of the National ART Programme resources.

A different picture was illustrated in Phichit: there was lower prevalence of HIV, less financial support from the Social Security Plan and looser connection between government hospitals and NGOs including PLWHA groups which were fewer in number. However, learning to deliver ART developed in the provincial hospital when it joined the clinical trial project organised by a research institute as part of the MOPH's Clinical Research Network in 2000. As this project was multi-centred, HIV clinic staff in this hospital acquired direct experiences of treatment implementation and also drew lessons from other settings.

The notable improvement in patients' health gained from participating in research projects, apparently motivated some hospital staff to want to take part in the extended National ART Programme. However, concerns about possible failure owing to increasing workload as well

as inadequate resources made some hospital directors hesitate to sign on. This suggests that the policy process in peripheral public agencies resembles that at the national level: the adoption of new interventions relies on the perceived feasibility in the implementation and anticipated implications for the organisations. Information exchange among administrators and health professionals of different settings was an important part of the decision process.

## **CHAPTER 7: IMPLEMENTING UNIVERSAL ART POLICY**

Chapter 6 illustrated the circumstances relating to HIV burden and health services for people living with HIV/AIDS (PLWHA) including antiretroviral therapy (ART) before the universal treatment policy arrived in Phichit and Rayong. Employing the bottom-up policy implementation approach, the present chapter describes the roles played by sub-national actors to get the programme into action. It mainly focuses on how the hospitals reacted to the targets and directions set by national agencies. The issues explored in this respect comprise the integration of therapy into the existing service delivery structure and workforce allocation; hospitals' performance; impediments and coping patterns. The analysis also sheds light on the factors conducive to, and discouraging of, ART scale up in the two provinces.

### **7.1 Integrating ART: structure and staffing**

The introduction of ART policy at national level in 2001 resulted in the restructuring of HIV services in particular study hospitals in one way or another. When the Access to Care Initiative was first introduced in 2000, all hospitals had HIV clients, but not all were offering antiretroviral (ARV) medication. The two provincial hospitals and Klaeng district hospital had already provided medication to a number of patients through other programmes at that time, but the 3 other study settings had not (table 7.1).

In the three hospitals with ART delivery experience, health workers included enrolees in the Access to Care Programme in their routine clinics (interview S04, S16 and D12). As the systems already established in these facilities more or less conformed to the national programme's requirements, minimal changes were introduced. Interviewees indicated that there were attempts to transfer old ART clients from research projects and the Buyers' Clubs so that they could receive free medication in the national Initiative. However, this was contradicted in the enrolment criteria, which excluded those who had already taken ART (Ministry of Public Health 2001b). The exceptional cases were the HIV-NAT study subjects in Phichit. Following negotiation between health providers and the Regional Disease Control Office, all eleven subjects were provided with appropriate ARV regimens on the Access to Care quota (interview S01). The small number of treatment-experienced patients in this setting might have facilitated the regimen adjustment and management processes when they

Table 7.1: Number of ART clients at the time of treatment provision in the Access to Care was instigated (cases)

Hospital	No. of non-ATC ART clients			Year of ATC participation	No. of ATC enrolees, first year
	CRN/ HIV-NAT	Buyers' Club	PHPT		
Phichit, provincial	11	0	0	2001	10
Rayong, provincial	0	382	50-60	2002	75
Klaeng	20	n.a.	n.a.	2002	30
Thapkhlo	0	0	0	2002	3
Wang Chan	0	0	0	2002	5
Sam Ngam	0	0	0	2003	10

Source: key informants in 6 hospitals

Note:

- (1) ATC, Access to Care Initiative; CRN, Clinical Research Network project; HIV-NAT, the HIV Netherlands Australia Thailand Research Collaboration; PHPT, Perinatal HIV Prevention Trial Project
- (2) n.a., the data were not available. The best estimation for the number of the Buyers' Club clients in Klaeng hospital is 20.

were transferred to the national initiative. On the other hand, the larger demands for medication among the Buyers' Club members in Rayong could not be met by the limited provincial quota applied in the first year of the programme.

The scale up of ART in 2004 required staff mobilisation at hospital level: extending involvement to specialists and other health workers in Paediatric and Obstetrics & Gynaecology Departments (interview S04, S16 and D20). To guarantee service quality, Phichit provincial hospital appointed an ART Committee to oversee and integrate therapy delivered by different clinics and wards (interview S01). The Committee issued treatment guidelines, some of which were simplified from the national directions and manuals. Similarly, in Rayong provincial hospital ART provision in different Departments was supervised by a committee on HIV prevention and treatment. By contrast, there was a lack of coordinating body for ART services in adults, children, and women after delivery in Klaeng district hospital.

Different arrangements were introduced in the other three settings with no ART experience. However, the new systems aimed not only to integrate ARV-based treatment but also to

counter some existing problems – mostly involving workforce shortages and movements. In Thapkhlo, Sam Ngam and Wang Chan hospitals, health professionals who had been in charge of HIV prevention and care, were assigned to manage ART services, irrespective of their professional training or job description (interview D02, D07 and D20). A former HIV official said this was common in many other district hospitals owing to insufficient personnel (interview R07 and S11).

Another similarity was that in these settings there were movements or changes in position of personnel as a result of the public administration reforms in 2002 and 2003. Before ART started in Thapkhlo, HIV prevention and treatment was fragmented. There was no focal point to manage the overlapping services, or to carry out the tasks on statistics and reporting (interview D07). When the hospital signed up to the Access to Care Initiative in 2002, an ART clinic was set up and run by a nurse of the In-Patient Department (interview D08). In the hospital reorganisation in 2003, this nurse was transferred to a new position in the Health Insurance Unit, while her responsibility as ART service coordinator was handed to a counselling nurse of the Mental Health Division (interview D07). By the end of the first year of ART, 5 out of 6 health workers who had received the Access to Care Initiative training had resigned, or had been relocated to different jobs (interview D08). The newly-assigned treatment coordinator of Thapkhlo was responsible for coordinating the therapeutic and prophylactic ART services, as well as prevention and alleviation of drug addiction and mental disorders (interview D07).

In Sam Ngam hospital, prior to ART adoption, a clinic was set up in the Sanitary Division to offer pre- and post-test counselling (interview D02). Those who were found to be HIV-positive were referred to receive treatment and care from the Health Promotion Division, where the services to prevent vertical viral transmission were also offered. Almost at the same time as ART arrived in Sam Ngam, a nurse of the Family & Community Health Division was asked to take over HIV-related tasks from a sanitary officer (interview D01). After attending a training workshop organised by the Regional Disease Control Office, this nurse became the coordinator of all activities under the National Treatment Initiative and also played the role of manager, counsellor, and nurse at the monthly ART clinic (interview D02). In addition to the HIV treatment and management, she was responsible to the Family & Community Health Division, and her job description covered health programmes such as mother and child health, nutrition, and prevention and care for chronic diseases in communities.

Compared to Thapkhlo and Sam Ngam, HIV services in Wang Chan seemed to be better organised and more cohesive as most health professionals involved in the prevention and care delivery had worked together for a long time. HIV-related activities in this setting had been coordinated by a nurse and counsellor of the antenatal clinic since 1999 (interview D20). When the hospital signed up to the national ART initiative in 2002, this nurse continued her role and also took the responsibility of managing therapy provision although she moved from the antenatal clinic to the Family & Community Health Division.

In these three hospitals, one general practitioner (GP) was responsible for ARV prescribing; and importantly, the shift in the medication prescribers was a frequently-occurring phenomenon. Sam Ngam director revealed that between the instigation of ART provision in November 2003 and July 2004, his GP staff changed three times (interview D01). The situation was even worse in Thapkhlo hospital. At the time of data collection, the hospital had a new director who had just moved in after it had been supervised by the director of a nearby district hospital for four months (interview D07). The other doctor in Thapkhlo in July 2004 was newly graduated, recently transferred from another district setting, and had started working only two months before. In contrast, the GP who prescribed ART in Wang Chan in 2004 had been trained in the Access to Care preparation programme in 2002 (interview D19). However, this doctor would leave to pursue a specialist internship in the near future. As argued by provincial health officials, the mobility and shortage of doctors in district hospitals had long persisted and was acknowledged as an important impediment to ART scaling up in the two study provinces (interview R06 and R07).

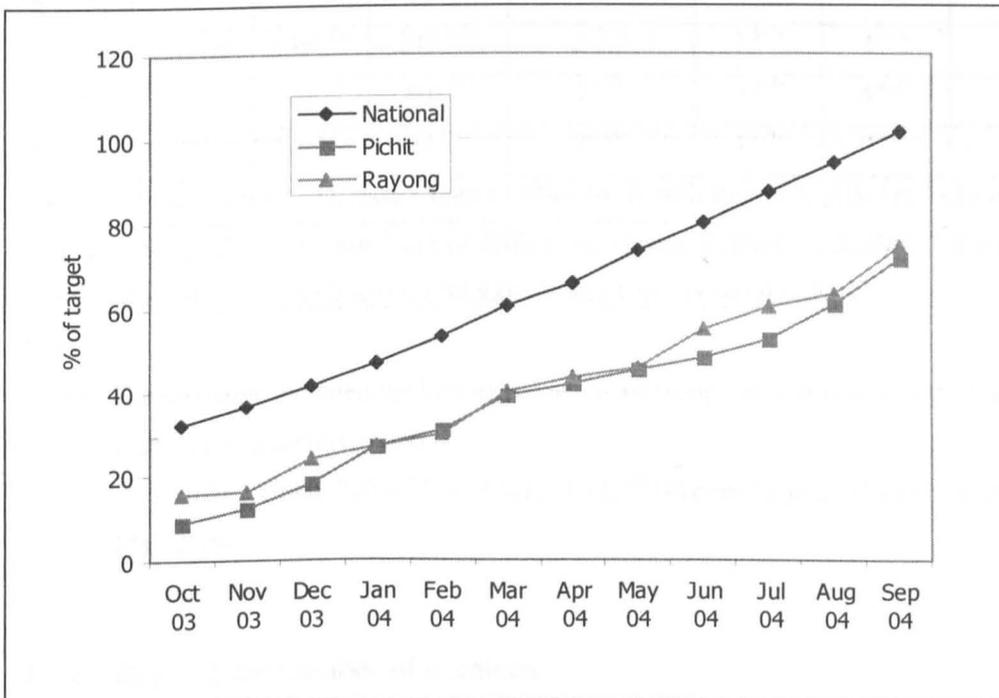
## **7.2 ART scaling up in Phichit and Rayong**

The information on the national ART programme between 2001 and 2003 is too limited to indicate the provincial- and hospital-level achievement. When the treatment ‘quota’ turned to ‘targets’ in 2004, systematic policy monitoring tools were installed including periodic reporting that captured the information from provincial and regional offices and hospitals (Thanprasertsuk, Lertpiriyasuwat, and Chasombat 2004). Based on the data available from the Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections and interview information, this section examines the performance of study settings in expanding treatment coverage in two aspects – quantity and quality of the service provided.

### 7.2.1 The unmet targets

In 2004, the national ART programme set the performance indicators on the number of treatment clients on two different bases – accumulated and current cases (Disease Control Office for Health Region 9 2004b; Rayong Provincial Health Office 2004b). The goal for each implementing setting was to achieve 100% of the target if the accumulated figures were employed, while it was set at 80% if the assessment was based on the numbers of current clients. The 2004 targets for Phichit and Rayong were 332 and 1,213, respectively (Disease Control Office for Health Region 3 2004b; Disease Control Office for Health Region 9 2004c). Parallel to the national figures, the number of treatment enrollees in both provinces steadily increased; however, only about 76% of the targets on the accumulated-case basis were met by the end of September 2004 (figure 7.1).

Figure 7.1: Accumulated number of the national ART programme clients as percent of the targets, Phichit and Rayong, fiscal year 2004



Source: Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections

At the sub-national level, the current-based figures were usually employed to monitor and assess programme development (interview R01). Disaggregated by settings, none of the study facilities could meet their targets. The best performance was observed in the case of Thapkhlo

hospital where 67% of the target was achieved in September 2004. Table 7.2 illustrates the number of PLWHA on treatment at the time of data collection and three parameters: the number of referred-out, dead, and default cases, which impart broader aspects of the ART delivery by hospitals. Some patients were referred to receive therapy in other settings for different reasons. For instance, 6 migrant workers in Wang Chan asked for treatment in their hometowns, while 3 paediatric cases in Phichit were referred back to the hospitals at district level after regimen adjustments were made by specialist in the provincial hospital. The other two parameters – deaths and defaults are discussed in the next section.

Table 7.2: National ART programme clients in study hospitals, 2004 (cases)

Hospital	Target	Number of ART clients				
		Current	Referred out	Dead	Default	Accumulated
Phichit, provincial	80 <sup>a,(1)</sup>	36 <sup>b,(2)</sup>	3 <sup>b,(2)</sup>	0 <sup>b,(2)</sup>	2 <sup>b,(2)</sup>	41 <sup>b,(2)</sup>
Thapkhlo	30 <sup>a,(1)</sup>	19 <sup>b,(2)</sup>	1 <sup>b,(2)</sup>	0 <sup>b,(2)</sup>	0 <sup>b,(2)</sup>	20 <sup>b,(2)</sup>
Sam Ngam	23 <sup>a,(1)</sup>	11 <sup>b,(2)</sup>	0 <sup>b,(2)</sup>	3 <sup>b,(2)</sup>	1 <sup>b,(2)</sup>	15 <sup>b,(2)</sup>
Rayong, provincial	449 <sup>c,(1)</sup>	249 <sup>d,(3)</sup>	3 <sup>d,(3)</sup>	3 <sup>d,(3)</sup>	1 <sup>d,(3)</sup>	256 <sup>d,(3)</sup>
Klaeng	220 <sup>c,(1)</sup>	80 <sup>e,(4)</sup>	1 <sup>e,(4)</sup>	9 <sup>e,(4)</sup>	4 <sup>e,(4)</sup>	94 <sup>e,(4)</sup>
Wang Chan	120 <sup>c,(1)</sup>	28 <sup>f,(4)</sup>	6 <sup>f,(4)</sup>	4 <sup>f,(4)</sup>	0 <sup>f,(4)</sup>	38 <sup>f,(4)</sup>

Sources of information: <sup>a</sup> Disease Control Office for Health Region 9 (2004c); <sup>b</sup> key informants in particular hospitals; <sup>c</sup> Disease Control Office for Health Region 3 (2004b); <sup>d</sup> Rayong hospital (2003 and 2004); <sup>e</sup> Klaeng hospital (2004a); <sup>f</sup> Wang Chan hospital (2004)

Note:

- (1) Default cases included the loss to follow up and drop out or refusing to continue the medication after instigation
- (2) <sup>(1)</sup> as of September 2004; <sup>(2)</sup> as of July 2004; <sup>(3)</sup> between June 2003 and May 2004; <sup>(4)</sup> as of May 2004

## 7.2.2 Beyond the number of enrollees

In addition to the numbers of patients on medication, ART programme performance can be assessed in terms of treatment benefits and service quality (WHO 2003b). Healthcare providers in all study settings expressed their satisfaction with the low default rates and desirable clinical outcomes as indicated by the improved overall health status; escalated

CD4+ cell levels; weight gain; and lowered opportunistic infection (OI) rates (interview S01, S14, D02, D07, D13 and D20). Hospital admissions due to serious adverse drug reactions were required in only a few patients. After treatment instigation, a small number of clients were classified as default cases as they discontinued the medication or never visited the clinics for follow up.

Although treatment adherence was recognised as a vital element in ART and the less-than-perfect adherence suggests a service of deficient quality, there had not yet been any systematic evaluation conducted in study settings on this issue. Rayong Provincial Health Office (PHO) included the goal of assuring adherence in 80% of treatment recipients in its HIV/AIDS prevention and control plan; however, no detailed framework and methodology for the assessment was developed (Rayong Provincial Health Office 2004b). In interviews, health workers in all study settings argued that the improved therapeutic results indicated desirable adherence of their patients.

As shown in table 7.2, deaths among ART clients were reported in 4 hospitals: 9 in Klaeng, 4 in Wang Chan and 3 in Rayong (provincial setting) and Sam Ngam. As health workers explained, the common factor of the fatality was the patients' severe ill-health, as indicated by the very low CD4 cell counts and existing OIs at the time of enrolment (interview D02, D13 and D20). According to hospital database, 66% and 58% of ART recipients in Klaeng and Wang Chan, respectively, started the medication at CD4 cell levels of less than 50 cells per mm<sup>3</sup> (Klaeng hospital 2004a; Wang Chan hospital 2004). The enrollees' condition in these two district hospitals was relatively poor as the Health Ministry AIDS Division's data suggest the national corresponding figure was 53% on average. However, apart from initial low CD4 cell counts there are many factors contributing to treatment outcomes including patient survival, for example experiences of providers, OI manifestation, and medication adherence (Chaisson et al. 1998; Kitahata et al. 1996; Paterson et al. 2000).

As the literature suggests, a potential negative consequence of ART is the sexual disinhibition in clients with improved health, and the magnitude of this problem to some extent indicates the quality of counselling services (Kalichman and Rompa 2003; Katz et al. 2002). Health officials and providers in both study provinces argued that it was difficult to explore sex practices (interview R04, S13, S14, D02). However, they suggested that disinhibition would be an unavoidable aftermath of treatment extension and would need systematic action at

national and peripheral levels to counteract it. A Regional Disease Control official noted in interview:

*'... these patients get well – physically, some look nice. When they become healthier, they look like other people ... as if they have never got infected. Then, they have irresponsible behaviour. Some admit that they don't have protected sex .PLWHA Network asks us to organise educational programmes on this issue, but this relates to life skills and other elements ... it should be managed by the Department of Mental Health. We are going to coordinate necessary activities to deal with the forthcoming downside.'* (interviews R04)

Pregnancies, either intended or unintended, were another important issue mentioned by interviewees not only in ART clients but also in general HIV-positive persons. Although family planning services were offered to all HIV patients, some of them refused to comply to contraceptive instruction since they desired to have children and then got pregnant while they were on ARVs (interview S01, S14 and D13). Some PLWHA treated in study hospitals did not inform their spouse that they were infected. In such cases, the providers asserted that it was patients' right to make their own decisions; and the health workers' responsibility was to provide proper counselling and prevent vertical HIV transmission (interview S01, S13 and S16). One doctor in Rayong provincial hospital revealed:

*'I keep considering we should take it more seriously to address unsafe sex practices. I often remind my patients when they come to the clinic: you must stop the disease at yourself – don't expand it further. It is really bad to destroy other people's lives. ... even though we provide them with information, contraceptives and condoms, some get pregnant. They neither ask their husbands to use condoms nor take the drugs regularly, because they don't want to disclose their HIV status.'* (interview S14)

### **7.3 Quantity and quality of treatment in the study context**

Since universal ART access became the Ministry of Public Health (MOPH) priority in 2004, the policy's progress was on the list to be reported to the monthly inter-departmental meetings of the Health Ministry (Ministry of Public Health 2003b; 2004a). Treatment

extension was closely monitored at different levels of the health system; and the performance indicators mostly emphasised were not about service quality, but the gap between targets and numbers of clients in certain settings (interview R01, R06 and R07). Pressure was put on the regions and provinces where progress was relatively slow. As shown in Figure 7.1, from the beginning of 2004, Phichit's and Rayong's performance in term of the number of ART clients by target could be considered moderate. This section describes the difficulties in enrolling eligible PLWHA to receive therapy in study settings and strategies introduced by these policy implementation units in order to achieve the programme targets. It also explores the perspectives of healthcare providers about the goals and associated measures established by the Health Ministry to scale up medication in this period.

### **7.3.1 Moving patients: moving targets**

An important feature of the national ART programme was that the enrolees were not required to register in particular hospitals thus they could seek medication from any preferred setting. Given the HIV-related stigma and inadequate OI drugs at district level, many PLWHA sought care from health facilities located far from their domiciles. For instance, some patients residing in Sam Ngam and Thapkhlo were willing to travel to get ARVs from Phichit or Phitsanulok provincial hospitals, or even from Bangkok (interview D02 and D07). Health workers argued that owing to the lack of effective HIV registration, responsible agencies could not have accurate data on the current disease status and other information such as address and health provider of each infected person. Interviewees maintained that for these reasons, the number of their clients could change over time, and the treatment targets set on existing information were difficult to achieve if the patients had died or moved freely from one hospital to another.

In contrast, none of the key informants in Rayong expressed the concern about unattainable targets. This does not mean that the information on the number of PLWHA residing in Rayong was considered reliable or no HIV-positive persons sought care from different districts and provinces. However, it might be because HIV prevalence in Rayong was so high that the pool of HIV patients in MOPH hospitals was sizeable and healthcare providers had no difficulties finding cases to be enrolled on the national initiative.

### 7.3.2 Strategies to boost programme uptake

In order to meet ART targets, public relations campaigns were initiated in Phichit (interview R01 and R06). This measure, with a corresponding budget, was put in the regional Access to Care operational plan for fiscal year 2004 (Disease Control Office for Health Region 9 2004b). However, a key informant revealed some reluctance among health officials at the beginning (interview R01). The concern was that the publicised information about ART availability and its efficacy might be misinterpreted, resulting in carelessness and negligence in safe-sex practices. However, when the increase in the number of new enrollees was apparently sluggish, the Regional Disease Control Office got the public relations plan implemented.

The Phichit PHO established an information programme to target the national ART programme messages to people with high risk of HIV infections and PLWHA groups (interview R06). Other government agencies and local administrations were asked to distribute the information to their clients, for example PLWHA who received monthly financial support from the Provincial Social Welfare Office. Apart from the information campaigns organised by the regional and provincial offices, in fiscal year 2004, the Health Ministry allocated 15,000 baht to each hospital for the ART programme administration including public relation activities to encourage treatment demands among isolated or undisclosed PLWHA (ATSI 2003a).

Although Rayong province did not face the same problems in finding HIV cases, the PHO and provincial hospital ran information campaigns about ART service provision in order to promote HIV counselling and testing for early case detection (interview R07). This also aimed to encourage clinical outcomes through prompt therapy initiation in the infected individuals. One interviewee revealed that, like its Phichit counterpart, the campaigns were initially opposed by senior provincial administrators because of the concern about misinterpretation of the content of the information distributed.

*'In a meeting at the Provincial Administrative Office, we proposed to encourage PLWHA to seek proper care, by disseminating the information that AIDS was treatable, but patients had to take medicines until the end of their lives. We were*

*criticised by senior officials – they argued that such information would be wrongly conceived, resulting in misbehaviour ... neglecting prevention.* (interview R07)

Directors and staff of study hospitals in Phichit were concerned about meeting treatment targets. Therefore, they too created mechanisms to boost service uptake, but some expressed professional ethical concerns. In the provincial hospital, health workers tried to verify the figures by reviewing retrospective epidemiological information in order to map the patients according to their current dwellings and also to identify the number of deaths among them (interview S01). Sam Ngam hospital did the same, recognizing however, that this must be done with caution since it might be regarded as disrespectful of the rights of PLWHA who sought anonymity (interview D01). The HIV nurse of this setting revealed that she asked her network, including sub-district health workers, officials of local administration authorities, community leaders and village health volunteers, to support case finding and provide information (interview D02).

Thapkhlo hospital faced similar problems: the gap between the current demand and expected need for ART. The responsible nurse observed that in 2002 – the first year of treatment service, from the target of 10, only 3 clients who resided in the township and other districts were enrolled (interview D07). The interviewee argued that the obstacle arose from the lack of reliable HIV case reporting and there was a marked discrepancy between the information from different sources. The strategy employed to encourage patient enrolment in this district was not case finding in communities but dispatching the programme's information through posters and brochures.

### **7.3.3 Quantity versus quality: health workers' perspectives**

Although healthcare providers in study settings had been positive to the early-phase Access to Care Initiative, their attitudes became more pessimistic when the MOPH set the 2004 target to get 50,000 PLWHA on medication. It appeared that the demands of the Ministry on its sub-national offices and hospitals to enrol more patients distressed responsible health workers since they anticipated a growing workload and threat to service quality (interviews R04 and D06). They feared that the crucial elements of ARV administration such as adequate counselling and follow-up measures to ensure adherence would be neglected if the number of clients surpassed capacity. A regional health official asserted:

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*'ART is presented as another routine, resembling simple antibiotic prescriptions. We cannot expect the services to conform to standard practices ... some essential procedures may fail to be carried out. Patients just come in and receive drugs from our clinics and that's it. When we have to treat a lot more patients, we do not have enough time to give comprehensive counselling – no follow up, no home visit ...'*  
(interview R04)

Although health workers in Phichit worried about failing to meet the national programme targets and introduced corresponding strategies to enhance patient enrolment, they argued that the increase in the number of clients was not their ultimate or sole objective. The provincial hospital's HIV specialist, the Sam Ngam nurse, and the Thapkhlo counsellor all shared concerns that a larger caseload would undermine treatment quality, in particular given provision over a lifetime, complicated medication, and patients who felt stigmatised and isolated (interview S01, D02 and D07).

Despite apprehension about the unmet targets, these ART providers prepared a common explanation to the central department that they had put their best efforts to case finding, running information campaigns, justifying each case against enrolment criteria, and carefully taking care of their HIV patients no matter whether they were or were not ART enrollees. In all study settings including those in Rayong, there were lists of PLWHA at different clinical stages; some of whom were ART eligible according to the enrolment criteria, but the medication had not yet started. Health workers asserted that they did not care about being blamed for not meeting targets and would not enrol the new batch, if treatment quality could not be ensured to their satisfaction. For instance, a Sam Ngam nurse said her hospital could deliver good quality ART to 10 patients at maximum, but the medication target for this setting was 23.

*'I told the director I couldn't bear the frustrations .I asked him to ignore the criticisms made in the provincial meetings when our performance was highlighted with 'red figure'! Service like this couldn't be accelerated. If patients were unprepared, it would be dangerous. In some cases, I had to phone them in the morning and evening to remind them to take the drugs as I wasn't sure about the adherence... – definitely we would fail ... drug resistance would develop.'*  
(interview D02)

In Thapkhlo, the ART coordinator said that she was not actively searching for new cases in the communities, because a 30-bed hospital like hers could not handle more HIV patients (interview D07). She preferred providing the best to the small number she had on the list, which had been much expanded since she took over the task. This health worker welcomed walk-in cases, who she would add to the existing pool, and then systematically monitor their clinical condition until the Access to Care enrolment criteria were met. She argued that ART was not the best therapy for all PLWHA because of its adverse effects; and therefore, to her patients she recommended several health promotion and self-care activities.

Similar concern about the quantity-quality trade off was expressed by treatment providers in Rayong. At the time of data collection in May 2004, none of the study hospitals had got close to the targets. However, ART coordinators in these settings showed no signs of distress about the unmet targets. Although there were a lot of patients on waiting lists, responsible health workers insisted that they would not enrol the next cohort unless both supply and demand side were well prepared (interview S16 and D20). In the interviews, the ways the doctors, nurses and pharmacists discussed specific issues such as case management, training needs, patient group coordination, and programme impediments principally reflected their attitude that service quality was vital. In addition, ART was seen as a component of integrated treatment and care for PLWHA, thus in the perspectives of these providers, the whole range of services and related activities should be concomitantly promoted.

## **7.4 Dealing with constraints**

Respective healthcare providers pointed to many difficulties in maintaining service quality, although evidence suggested acceptable outcomes. This section analyses the overall context in which treatment policy was executed and how contextual factors hindered critical elements of therapy provision. It also explores the measures employed by hospital directors and staff to counter the constraints.

### **7.4.1 The dynamics of change**

In addition to the inauguration of the Universal Health Coverage Plan (UC) in 2001, two national policies were launched subsequently: the public administration system reform in 2002 and national-scale health promotion campaigns in 2004. Both were said to have had

negative implications for ART scaling up (interview R04, R07 and D01). Interviewees claimed that strategies of the former included organisational restructuring; reallocation of personnel within and across agencies; and early retirement opportunities for civil servants<sup>45</sup>, all of which resulted in significant loss of experienced health workers, not only in hospitals but also in the PHOs. The reorganisation of hospitals and changes in HIV clinic coordinators in Sam Ngam and Thapkhlo (section 7.1) were among the reform's consequences.

In early 2004, another large-scale project titled 'Healthy Thailand' was launched by the Health Ministry<sup>46</sup>. This policy aimed to improve the health status of the general population as well as emphasising disease prevention in women and children, in line with the Millennium Development Goals for 2015 (Thaineua 2004). It comprised health promotion activities in 5 areas: diet, exercise, emotion, environment and disease reduction, all carried out at different levels from national to provinces, districts, and villages. Although the project called for public and community participation, fostering these activities were extra tasks on an already overburdened range of health workers (interview S17, D02, D07 and D09).

#### **7.4.2 Providers' competency**

Other than the problem of health personnel shortage, inadequate knowledge and experience to deliver treatment was mentioned by key informants. Similar difficulties have been documented in many health systems when central departments start up new programmes at peripheral level (Gilson et al. 2003; Rees et al. 2004). In Phichit and Rayong, doctors, nurses and pharmacists revealed that ART issues had been discussed very briefly while they were undergraduates (interview S02, S05, S14, and D07). For most of them, the first time they learned about the medication, especially its critical elements, was from the Access to Care training sessions during 2001 to 2003. The exceptional cases included two Phichit provincial hospital specialists – one in Medicine and the other in Paediatrics, who had been trained to prescribe ARVs during internships in a university hospital in Chiangmai – a province with very high HIV prevalence (interview S02 and S03). On the other hand, a doctor who led ART service in Rayong provincial hospital argued that although he was a medicine specialist, he

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<sup>45</sup> This strategy aimed to downsize the bureaucratic system. Government officials 50 years of age and over were encouraged to resign from public work and received a substantial payment, in addition to normal pensions, in return.

<sup>46</sup> The Healthy Thailand policy became national agenda in fiscal year 2005 and was extended to involve government officials from other ministries including Ministries of Interior and Education

had had no experience of prescribing ART during his internship in a medical school in Bangkok (interview S14).

Other providers such as the GP and nurse of Thapkhlo hospital had never received training on ART delivery (interview D06 and D07). The GP maintained that he had no difficulty in prescribing ARVs because he followed the national guidelines (interview D06). Despite this argument, problems arising from this inexperienced doctor were mentioned by other health workers in this setting (interview D07 and D09). By contrast, the nurse expressed her concerns about lacking competency when she first undertook the tasks (interview D07). She received training in the Access to Care course after having been involved in the programme for 6 months. Self study by consulting different sources of information was her coping strategy.

*'I was trained in Mental Health Nursing. I confess I knew almost nothing about ARVs in the beginning. The first six months, being unfamiliar with the drugs and regimens, I found really difficult. I was expected to know everything as I was a coordinator. Therefore, I had to read many books and review several documents. Partly, I learned from patients – the PLWHA Network. The pharmacist also guided me ... she taught me about the drugs and drug actions. Now, it's fine.'* (interview D07)

The problem of inexperienced doctors was also highlighted in Wang Chan. The GP who was responsible for the service had never been trained or got involved in ART delivery. She admitted lacking confidence when the director assigned her this task (interview D19). However, working in an area with very high HIV prevalence such as in Rayong, she was inevitably exposed to large number of cases. Furthermore, the doctor claimed that she gained more knowledge from the Access to Care training sessions as well as the continuing education programmes organised by an NGO – the Thai AIDS Society<sup>47</sup>.

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<sup>47</sup> The Department for Disease Control outsourced the Thai AIDS Society to develop training curriculum and run education programmes for doctors involved in ART provision.

### 7.4.3 Integrating care in the province

In 2004, as the national ART programme demanded hospitals enrol more clients, the obstacles in service delivery became apparent, and required system adjustment. In Phichit, the PHO and the provincial hospital established an inter-hospital network to provide support to district facilities: organising training and education programmes for district health personnel including medical scientists (interview S01 and S03). This aimed to complement the training workshops organised by the Regional Disease Control Office between 2001 and 2003, by offering new cohorts of health workers and those transferred from other positions with the national programme orientation and current information on the detailed technical aspects necessary for each discipline (interview S06, S08 and S10).

Special arrangements were integrated in the existing training programmes set for newly-graduated doctors before they were allocated to district hospitals (interview S01 and S03). While rotating in different departments of the provincial hospital, the GPs were trained in ART administration in both adults and children. The network also allowed consultations between district-level doctors and specialists of the provincial hospital. Moreover, as paediatric ART was considered much complicated, the provincial hospital offered therapy initiation for children from districts and then referred the cases back when the regimens were adjusted and stable. Key informants revealed that the inter-personal connections established in the training period encouraged further collaboration among doctors as well as other professions of the two levels (interview S06, S08 and S10).

While a HIV treatment network was established to coordinate health care providers in Phichit, less structured collaboration between hospitals was observed in Rayong's ART delivery. Interviewees said they used the existing, normal referral system set by the MOPH through which patients were referred from district settings to receive secondary or tertiary care in the provincial hospital (interview D19 and D20). With such a mechanism, paediatric cases and complicated adult patients in Klaeng and Wang Chan were transferred for ART and other HIV medications to the provincial facility. After that, these patients would be referred back to the district hospitals for maintenance therapy. Apart from this, there were case consultations between GPs and specialists in different hospitals. Technical support among doctors was needed not only by GPs at district level; a medicine specialist of the provincial hospital revealed that he consulted a specialist of Chonburi provincial hospital who had long

experience providing HIV medications in this region (interview S14). Treatment advice was particularly requested in the cases in which drug-resistance had developed, for example among Buyers' Club members who had received ARVs for many years.

Inter-hospital collaboration also played a role in inventory management of drugs used in the programme. In the early phase of the Access to Care initiative, shortages and oversupply of ARVs were reported to be prevalent in both Phichit and Rayong (interview S05 and S22). In the case of drug shortages, pharmacists sometimes had to borrow from other hospitals in the same province. Oversupply of nearly expired ARVs from the regional disease control office was also a problem in district hospitals with a small number of ART clients. In such cases, the provincial hospitals might be asked to exchange their newer batches with the older from the district counterparts. This was because in the provincial settings with higher HIV caseloads, drugs inventory turnover was more rapid.

#### **7.4.4 Crossing professional boundaries**

In addition to the collaboration between settings as a strategy to deal with workforce shortage in district facilities, each study hospital set its own mechanisms which to some extent shared common features. Key informants suggested that in addition to doctors, nurses and pharmacists played key roles in ART provision in all study settings, especially district hospitals (interview R01, R06 and S11). However, doctors and pharmacists appeared to be more bound by their professional territories, so that nurses who were more flexible ended up running the clinics and coordinating all treatment partners internal and external to the hospitals, as well as updating the programme's database and report-writing. When the national ART programme was considerably extended in 2004, the two study provincial hospitals allocated more nurses to support the service including related administration work (interview S04, S17, and S20). Even so, the providers argued that this did not meet the substantial increase in the caseload. In district settings, on the other hand, all management tasks of ART delivery remained undertaken, single-handed, by one nurse (interview D02, D07, D13 and D20). Since there were frequent turnovers of doctors in Sam Ngam and Thapkhlo, nurses and pharmacists were expected to assure the service quality including safeguarding patients from severe adverse effects of the medication (interview R01 and R06). The exceptions were Klaeng and Wang Chan hospitals where the GPs had had some continuity.

While it appeared to be a norm that health professionals would support each other, interviewees argued that nurses and pharmacists of district hospitals had to pay particular attention to newly-graduated GPs, by reviewing their prescriptions and providing second opinions in cases considered as irrational prescribing (interview D02 and D07). For instance, a Thapkhlo pharmacist revealed that:

*'It was a pharmacist's responsibility to review the prescriptions because the new doctors didn't know ...some of them had never attended training course – they didn't know what to do, what had changed, what was to be emphasised. A frequent mistake was on drug dosage ...'* (interview D09)

In Phichit, interviewees maintained that since therapy was delivered by paediatricians some of whom were unfamiliar with not only ART but also the whole package of HIV treatment and care, some prescriptions were inappropriate (interview S06 and S08). For example, the drug dosage was not adjusted according to patients' weight, and drugs for OI prophylaxis were not concomitantly prescribed with ARVs. In such cases, responsible pharmacists had to consult the prescribers before dispensing. Although such pharmacy practices could be seen as an intrusion into physicians' professional territory, no tension between the two professions was reported in these settings.

Unlike other study hospitals, Klaeng and Wang Chan pharmacists had no role in ARV dispensing, counselling, and promoting medication adherence as these activities were carried out by nurses (interview D13 and D22). Similar arrangements were described in the two settings, i.e. the drugs were transferred from the Pharmacy Department to dispense in the monthly ART clinics where responsible nurses and PLWHA leaders provided treatment information and drug counselling. Therefore, the prescriptions and dispensed ARVs were not reviewed and rechecked by pharmacists.

Importantly, nurses of all district hospitals in this study were authorised to repeat the prescriptions in the cases without complications (interview D02, D07, D13 and D20). Having screened all patients for certain signs and symptoms, only the cases with OIs or severe adverse drug reactions would be treated by doctors. In Phichit, since more reliance was placed on nurses and pharmacists, the two professions from provincial and district facilities

were invited to attend some continuing education and training programmes originally targeting doctors (interview S08).

#### **7.4.5 Struggling to ensure quality**

Inadequate medication adherence was a matter of great concern to ART providers in all study hospitals. Despite constraints, the efforts of responsible health workers to keep patients on lifetime therapy were strong. As nurses and pharmacists argued, they spent substantial time on individual and group counselling before and after treatment instigation, while their physician colleagues were unable to do so.

Health workers in all study hospitals said they recognised and took into account the characteristics of particular patients, such as willingness to adhere to the medication, education level, occupation, economic status, and social environment, which might affect treatment administration and monitoring. Past compliance to OI medications was regarded as a helpful predictor (interview D20). In all settings, ART was withheld from patients whose adherence was anticipated to be poor. The difficulties in providing treatment instruction to patients and caregivers were considerable in some cases. One example given was of a child with AIDS, who lived with an old, illiterate grandmother and received therapy in Phichit provincial hospital.

*'There was a small child ... her grandmother could not read at all. The kid took AZT and lamivudine syrups. As her granny could not read the figure, I put brightly coloured stickers on the syringes to mark the volume of drugs to be drawn. The granny could not read the labels on the bottles either. It took a long time to explain to her about the instructions – how to prepare the mixture ... when to give the drugs to the kid.'* (interview S06)

In addition to the counselling, adherence strategies were promoted by health workers. For example, they used simplified education & information, unit-dose containers, reminders via telephone calls, and easy-to-reach counselling services. Simple measures such as pill counting, assessing the improvement in CD4 cell levels, body weight, and overall physical appearance in the follow up were used as indicators of treatment adherence in particular patients (interview D20). Staff of Phichit provincial hospital claimed that techniques and pragmatic

lessons learned from HIV-NAT research were adapted to enhance the adherence among the Access to Care clients (interview S04 and S05).

However, monitoring and encouraging adherence of clients in their communities as well as home visits to ART- and non-ART patients was limited. An insufficient workforce and the effects of stigma were two common explanations. As argued by the Sam Ngam nurse, she could arrange regular HIV case visits by integrating them into trips for general home healthcare purposes, but this action was refused by some patients who concealed their HIV status (interview D02). In Thapkhlo, travelling to some distant villages was difficult and time consuming (interview D07), and some ART clients resided outside the hospital catchment area (interview S04). Since adherence encouragement was considered crucial, healthcare providers in study settings organised home visits for disclosed patients through their networks in communities, especially PLWHA leaders (interview D02, D07, D13 and D20). Contribution of health workers at sub-district health centres in these activities was reported in some hospitals, for example Klaeng and Wang Chan.

## **7.5 Discretion in treatment financing**

After the introduction of the health care financing reform in 2001 there were 3 health benefit plans existing in the country: the Civil Servant Medical Benefit Scheme for government workers and dependants; the Social Security Scheme for formal private sector employees and the UC for the rest of the population (chapter 2). The inclusion of ART and OI medications in these schemes differed and changed over time. This section documents the coverage for HIV services by health benefit programmes and practical arrangement introduced in study hospitals.

Table 7.3 summarises the rules on the finance of ART and drugs for OI prevention and treatment through different schemes and practices in Phichit and Rayong provinces between 2001 and 2004. In this period, government workers and dependants could access free HIV medications in any public hospital. On the other hand, those on the Social Security Scheme and the UC plan were covered only for OI drugs. ART was subsidised for Social Security Scheme beneficiaries in late 2004.

Table 7.3: ART and OI medication coverage in the three health benefit plans and national ART programme, and practical arrangement in study hospitals, 2001-2004

	Health benefit schemes			National ART Programme
	Government Employee Scheme	Social Security Scheme (SSS) <sup>a</sup>	UC <sup>a</sup>	
2001				
Official benefits	ART and OI drugs	OI drugs	OI drugs	ART
Rayong practices	ART and OI drugs	ART and OI drugs	OI drugs	No national programme implemented
Phichit practices	ART and OI drugs	OI drugs	OI drugs	<u>ART in provincial hospital</u> for PLWHA who met the enrolment criteria, irrespective of their domicile and benefit scheme entitlement
2002				
Official benefits	ART and OI drugs	OI drugs	OI drugs	ART
Rayong practices	ART and OI drugs	ART and OI drugs	OI drugs	ART for UC members and the uninsured
Phichit practices	ART and OI drugs	OI drugs	OI drugs	<u>ART in provincial hospital, and ART and OI drugs in Thap Khlo hospital</u> for PLWHA who met the enrolment criteria, irrespective of their domicile and benefit scheme entitlement
2003				
Official benefits	ART and OI drugs	OI drugs	OI drugs	ART
Rayong practices	ART and OI drugs	ART and OI drugs	OI drugs	ART for UC members and the uninsured
Phichit practices	ART and OI drugs	OI drugs	OI drugs	<u>ART in provincial hospital, and ART and OI drugs in Thap Khlo and Sam Ngam</u> for PLWHA who met the enrolment criteria, irrespective of their domicile and benefit scheme entitlement
2004				
Official benefits	ART and OI drugs	OI drugs, and ART <u>from late 2004</u>	OI drugs	ART
Rayong practices	ART and OI drugs	ART and OI drugs	OI drugs	ART for UC members and the uninsured
Phichit practices	ART and OI drugs	ART and OI drugs	OI drugs	<u>ART in provincial hospital, and ART and OI drugs in Thap Khlo and Sam Ngam</u> for PLWHA who met the enrolment criteria, irrespective of their domicile and benefit scheme entitlement

Note: <sup>a</sup> registration of beneficiaries to particular hospitals was required

The national ART initiative from its launch in 2000, established clinical and social enrolment criteria, but had not stated which groups of the population would be eligible for treatment with regard to their health schemes and dwelling (ATSI 2004a; Disease Control Office for Health Region 3 2004c; Disease Control Office for Health Region 9 2004a). The variation in HIV treatment coverage across these programmes allowed different interpretations and discretion in providers' practices.

In Phichit, the three study hospitals provided ART in the national programme to all clinically-eligible patients, without taking into consideration their health benefit entitlement (interview S04, D02, and D07). It was not until December 2003 – two years after the Access to Care Initiative was incorporated in the provincial hospital – that an official direction of the Regional Disease Control Office entitled Social Security Scheme members to ART in the national programme (interview R06). The justification of such a solution, as revealed by a PHO official, was that *“the Ministry and provincial health office did not mind who would be enrolled to receive the medication ... otherwise we could not meet the target”*. The main reason then, for extending the availability of ARVs, was to meet MOPH targets.

Another variation relating to patients' rights to inclusion was caused because ART delivered in the national programme in Phichit as well as other provinces in Health Region 9, was opened to PLWHA of all domiciles (Disease Control Office for Health Region 9 2004a). However, the UC and Social Security Scheme beneficiaries were entitled to the health services specified in the benefit package from particular hospitals, mostly located in their residential areas. If patients sought ART from different hospitals, and at the same time required other drugs such as those indicated in opportunistic infections, they had to pay for these drugs themselves. The provincial hospital was strict on this rule, so some patients who received ART freely in this setting were charged for other HIV medicines such as drugs for opportunistic infections and symptomatic treatment (interview S04 and S05).

For Thapkhlo, on the other hand, the hospital's executive board decided to offer all HIV treatment without charge irrespective of the clients' entitlement (interview D07). The ART coordinator in this setting asserted that registering people to certain hospitals deployed by the UC and Social Security Scheme was not friendly for PLWHA since most of them were afflicted by stigma and discrimination so that they could not comply with, or benefit from this insurance management. One key informant argued:

*'We can't counter HIV problems if we always consider whether this or that patient has been entitled to the services of our hospital. Working on HIV/AIDS has no border. Many patients came here from other districts and provinces because they want to hide themselves – there should be a place accepting them and offering care to them. Definitely, we know they are able to transmit the disease, why don't we keep them in our hands? Just don't let them wander uncared.'* (interview D07)

Nevertheless, HIV medications other than ART offered in this district facility were relatively limited because expensive OI drugs were not available in the hospital. In such cases, patients would be referred to the provincial hospital free of charge. Transactions were managed between the two hospitals in accordance with the UC regulations (interview D08).

The financial arrangement for ART in Rayong was different from Phichit. In the provincial facility, it was the hospital's policy not to cross-subsidise therapy between health plans (interview S16 and S22). For the Social Security Scheme beneficiaries and government officials, therapy was delivered through the schemes' funding mechanisms. The drugs supplied by the national programme were dispensed only to the UC members and the uninsured. Interviewees argued that subsidising ART in the Social Security Scheme was fiscally feasible because the pool of over 100,000 Scheme's members registered at MOPH hospitals in this province was large enough to cover the costs. In Klaeng and Wang Chan, according to the agreement made between hospitals, all HIV patients on this plan were referred to receive ART and OI drugs in the provincial hospital (interview D13 and D20). HIV nurses in these districts claimed that if they diverted the Social Security Scheme cases to the national initiative, the toll of the national programme's clients in their hospitals would increase to a certain extent. However, both hospitals insisted on reserving the national ART programme's resources for the UC beneficiaries and the uninsured.

A common problem shared by study hospitals was that a lot of people residing in Rayong were migrants from other areas, thus were not eligible for the UC benefits offered in this province. Some were of Thai nationality, other were migrants from Cambodia and Myanmar and providing care was problematic (Disease Control Office for Health Region 3 2004a; 2004c). In such cases, ART and OI drugs were withheld. However, respective social workers and nurses claimed that, with their help, all Thai patients could overcome the complicated

bureaucratic processes<sup>48</sup> to obtain the UC entitlement in Rayong, and access to ART and other HIV treatments (interview S16 and D20). For non-Thai citizens, an official resolution was enacted in 2004 that foreigner migrants were eligible to ART under the Access to Care Initiative (Disease Control Office for Health Region 3 2004a). While this could be seen as a strategy to boost the number of treatment enrollees, it was argued that the extension of therapy to this population was necessary for public health reasons because many of the migrants had sexual relations with or married Thais, and they were a potential source of HIV transmissions (interview R04). In interview, health providers emphasised that medication might help to encourage HIV screening and care seeking among these individuals. So from 2004, the Cambodian and Burmese labours were treatment eligible if they had permanent residence, essential for the complicated, life-time medications. Community leaders such as head of villages, teachers and monks helped to provide health workers with the information on foreign migrants' settlements. Despite the national ART programme resources sharing out, the Regional Disease Control Office stressed that Thais were priority for medication (Disease Control Office for Health Region 3 2004a).

Another financing issue highlighted in both Phichit and Rayong was the impracticality of following guidelines on laboratory charges. The national ART programme did not cover laboratory assessment of CD4+ levels in the patients who had not met the enrolment criteria. PLWHA who received the tests for monitoring purposes prior to treatment instigation, and were found with CD4+ counts of higher than 200 cells per mm<sup>3</sup> would be charged 200 baht per case (Ministry of Public Health 2001b; 2002a; 2003b). Health workers claimed that the charge of this rate was unaffordable for many patients and might discourage them from visiting HIV clinics regularly (interview D02 and D07). Providers would miss opportunities to keep their clients' health status monitored and also to remind them about safe sex, self care, and other desirable practices. For these reasons, all study hospitals waived the laboratory charges, for the poor if not all cases, and subsidised them with other funds.

## **7.6 The role of PLWHA in ART scaling up**

Following the national guidelines from 2002, PLWHA were recognised as partners in the service delivery (Ministry of Public Health 2002a; 2003b). The patterns of the non-state

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<sup>48</sup> This administrative hurdle was diminished in 2004 when a computerised registration system had been established nationwide.

actors' involvement in Phichit's and Rayong's ART were similar. Health workers accepted that PLWHA significantly contributed to treatment provision (interview S04 and S16). In all study hospitals where patient groups existed, the group leaders and staff were involved in offering essential information on the disease, OI prevention and ART to members. An HIV patient argued that the activity was well-organised in Rayong provincial hospital as it was managed in planned sessions for clients at different stages of treatment (interview S24). In other settings, more casual mechanisms were deployed. For instance, in Phichit provincial hospital, messages were transferred through inter-personal or group conversations arranged while patients were waiting in front of the clinics before service time (interview S04). Apart from the information and education facets, monitoring and promoting adherence were other programme components in which PLWHA played a role (interview S04, S16, D02, D07 and D20). For example, group leaders made home visits to observe drug-taking behaviour and provide psychological support.

The PLWHA group management contributed to ART coverage and its quality in study settings in three aspects. First, the group leaders and staff facilitated the enrolment process as well as treatment adherence through discussions (interview S12, S24 and D11). The lay-language used in the conversations was highlighted as a helpful element to encourage understanding (interview S16 and S23). New enrollees were, to some extent, informed about ARV-related issues at the time they started the medication. However, health providers felt that the patient groups' activity could not substitute for their counselling and other patient preparation procedures (interview D05, D07 and D09). A HIV specialist in Rayong revealed that in random checking, he detected occasional incorrect information provided in PLWHA-organised education programmes (interview S14).

The second benefit was that patient groups' activities that included home visits were regarded as encouragement to keep patients adhering to treatment. Moreover, sharing of undesirable experience such as suffering from adverse drug reactions among ART clients and peer pressure were flagged as factors enhancing therapy adherence (interview S24 and D13). Given the workforce shortage and limitations of the bureaucratic system, the PLWHA groups were perceived to play a useful role. In some settings such as Thapkhlo, Klaeng and Wang Chan, ART service coordinators said that when patients failed to visit HIV clinics as scheduled, the group leaders were asked to follow up the missing cases (interview D07, D13 and D20). Furthermore, it was maintained that the home visits undertaken by lay people were

more appropriate than the providers since the latter's untimely or frequent visits to particular households would be recognised by the public which might break patients' confidentiality (interview S12 and D02).

Finally, ART-experienced PLWHA in groups and individuals had a role in convincing the high risk and the infected persons, who had been reluctant to receive institutional care, to seek counselling and HIV testing (interview S12 and D09). This was because the significant improvement in health status of ART clients was observable and had the potential to motivate reluctant patients:

*'Neighbours frequently asked me how my illnesses were relieved – which kinds of medicines I took. They saw me getting healthier ... some of them had children or relatives who had the disease so they asked me for advice. They were afraid of visiting hospitals and seeing doctors. I told them not to worry... drugs were available and also we had organised as a group. It was better joining the group than staying desperately at home.'* (interview D12)

## 7.7 Summary

This chapter suggests there was a gap between national ART policy intention and actual programme implementation in Phichit and Rayong, including missing provincial treatment targets and many discretionary practices. The disparities between policy expectation and reality were influenced by several factors, for example lack of accurate epidemiology information at local level, inadequate ART experience, administrative and management pressures from concomitant reforms in the health sector and public administration system, stigma against PLWHA and health seeking behaviour of HIV patients.

Although both study provinces could not achieve the programme targets, the attempt made by sub-national health officials and health providers in integrating ART into the health delivery system resulted in substantial progress. As these front-line workers were motivated by clinical benefits of therapy, their prime concern was on service quality rather than merely meeting programme targets. Such interest concomitantly with treatment delivery constraints shaped the professional and management practice to certain extent, which varied from setting to setting.

In all district hospitals, single-handed nurses played a crucial role in service provision and management activities. In contrast, many more health workers were involved in provincial ART clinics. Despite the importance of health care staff in each setting, in this policy stage, there was network formation of regional and provincial MOPH offices, hospitals and civil society organisations including HIV NGOs and PLWHA groups as a key mechanism to deal with treatment impediments. As the two provinces differed in the strength and capability of local civil society organisations, the structure of treatment networks varied: while ART implementation in Rayong was encouraged by the pre-existing public-civic collaboration, scale-up of therapy in Phichit was enhanced through a newly-established network of MOPH hospitals and the Provincial Health Office.

As argued by Marsh and Rhodes (1992), policy networks often function through resource sharing and collective action of network members. ART networks in two study provinces affected treatment integration through similar mechanisms: knowledge and experiences on ARV-based therapy of front-line actors were collaboratively utilised. The joint missions of these partnerships were facilitated by learning of both service providers and supporters, as well as the exchanges of information among them. Lessons drawn from research projects and NGO-organised services helped all members of the network to understand the crucial requirements of ART administration and how to assure therapy quality. In addition, transfer of clinical knowledge and skills from experts to general practitioners within and across settings and policy networks was beneficial to treatment expansion, especially in the areas with few HIV specialists. Communicating with each other in training programmes and meetings to promote treatment scaling up might have been another channel for health care staff to exchange not only their ART experiences but also their perspectives towards the national programme ambition and administration. Sharing the opinions and feelings among treatment providers could have been an effective mechanism to cope with work-related stress including that stemmed from resource constraints and missing programme targets.

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## **CHAPTER 8: DISCUSSION AND CONCLUSIONS**

This thesis has aimed to understand the development of antiretroviral therapy (ART) policy in Thailand. Its objectives were to assess the roles of actors and context in agenda setting, policy formulation and implementation. The influence of networking and learning among policy participants on the policy processes was also examined. This chapter synthesises the overall findings and lessons concerning the introduction of antiretroviral (ARV) medication in this middle-income country. It also explores the strengths and drawbacks of public policy models employed to explain health policy development.

### **8.1 Driving factors of the universal ART policy**

In Thailand, the human immune-deficiency virus (HIV) epidemic and its devastating effects including the growing burden of the disease on the health systems became obvious and recognised by policy makers from the early-1990s. However, although effective ARV-based therapy had been available and implemented in developed countries as well as in Brazil from 1996, a nationwide programme to offer medication was not rolled out in Thailand until late-2001. Like most resource-poor settings, a key impediment in therapy provision was the prohibitive drug costs. Thus, it is clear that the price reduction of ARVs owing to local generic production by the Government Pharmaceutical Organisation (GPO) was a crucial element of the policy shift. However, the availability of low-priced drugs could not have been the sole factor making ART universally available. Limited access to therapy in India and China – the countries with the capacity to manufacture many generic ARVs – supports this argument (WHO 2004a; 2004b). As suggested by the findings of this thesis, the Thai policy process that led to treatment scale up was facilitated through several, highly collaborative networks at national and provincial level, and through a policy learning environment. The agenda setting and policy adoption were also influenced by many contextual factors.

#### **8.1.1 Old and new policy networks**

Resembling the punctuated equilibrium model proposed by Baumgartner and Jones (1993), the dramatic policy change towards the universal treatment coverage developed after a decade of policy stability where the national treatment plan targeted only small fractions of the afflicted population. This study illustrates the transformation of policy networks from a

relatively narrow group that embraced bureaucrats and experts, to an expanded cluster of politicians, reformist bureaucrats, and civil society coalitions. During the policy continuity period of 1992 to 2000, the decisions in relation to treatment delivery in the public sector were dominated by officials in the Health Ministry's Disease Control Department, although HIV experts including researchers, clinicians and laboratory scientists had an increasing role when the national ART programme was replaced by a clinical trial network in 1996. By contrast, support for treatment extension in 2001 covered a much wider group of participants including the Health Minister, ART advocacy alliances, and bureaucrats responsible for the establishment of the Universal Health Coverage (UC) scheme.

The civil society network comprising non-governmental organisations (NGOs), people living with HIV/AIDS (PLWHA), experts and other activists can be regarded as policy entrepreneurs who campaigned for improving ART access, and for assuring long-term service financing by including therapy in the UC plan. Employing several approaches, the coalition rapidly succeeded in raising the treatment scale-up issue on to the governmental agenda in the early 2001. It took a short time thereafter, a few months, for further policy development. However, without support from the Deputy Health Secretary Nitayarumphong, the policy might have evolved in different ways or at a slower pace. This senior official, who had long led the reform of the health system, had good relationships with NGOs in the health sector, as discussed in chapter 5. At the same time, he was trusted by the Health Minister as can be seen in his appointment to lead the initiation of the UC plan, and then in his appointment in 2003 as the first Secretary General of the National Health Security Office. However, although Nitayarumphong supported the NGOs' proposal to extend ART, initially he considered therapy should not be integrated into the UC benefit package since he felt that subsidising such high-cost medication might destabilise the emerging health scheme.

### **8.1.2 The contextual elements**

The ART policy shift was affected by changes in the endogenous and exogenous factors in the health system context. The most obvious element encouraging ART policy adoption was the local capacity to produce generic ARVs. Another positive contextual factor was the relatively well-established health delivery infrastructure and management system throughout the country. Unlike many other countries in the South, Thailand did not face serious problems concerning service provision capacity. Despite no systematic assessment of the health

system's readiness to introduce ART nationwide, from the perspective of the Health Minister, health officials and NGO staff, any shortcomings and emerging requirements would be managed when the programme started.

A non-health system factor that facilitated the policy change was the national political ideology. The universal ART policy was adopted in November 2001 – 10 months after the Thai Rak Thai Party cabinet took office in January. As the Health Minister argued in interview in 2003, the government's commitment to offer free ARV medication was in line with the UC plan – a major social policy pledged in the election campaign. Several populist programmes were instigated by this regime: the agrarian debt relief initiative, the village revolving fund programme, and the health benefit scheme (Phongpaichit and Baker 2004). So the extension of HIV treatment was not surprising in that all these projects shared one characteristic – large policy investments to meet with political party promises, people's expectations and to maintain popularity.

Furthermore, the Thai ART policy innovation was encouraged by exogenous factors. In this study two forms of international influence could be observed. First, as a member of the United Nations (UN) and other transnational organisations, the country took seriously its commitments to international agreements, treaties, and declarations decided by these authorities. Policy directions, technical guidance and best practice recommendations issued by such agencies therefore had legitimacy. Second, the information about ART access and availability of cheap medicines elsewhere was intentionally conveyed to the government by treatment advocates and reformist officials to make the policy change. It was possible that the information also reached policy makers through other channels, for example via international meetings, personal communications and the media. Although there was no obligation imposed on the government, recognizing global efforts to facilitate treatment access might have inspired Thai politicians and bureaucrats to make ARVs more accessible among Thai PLWHA. From another angle, foreign experiences, especially the well-recognised Brazilian ART programme, as well as similar initiatives about to be established in many South American and African countries, might have pushed Thai policy makers to emulate such policies. For instance, a senior official admitted in interview that when NGO alliances campaigned for universal ART access in 2001, he informed the Health Minister about treatment scaling up in other middle-income countries, and encouraged the Minister to extend the national programme by arguing that by not doing so, Thailand would lose its esteem in

the international HIV arena. This can be explained by what Dolowitz and Marsh (1996:349) have observed: a policy implemented in other settings may be adopted '*if political actors perceive their country as falling behind its neighbours or competitors.*' As the country was lauded for its past success in HIV prevention, the perceived need among Thai policy makers to maintain international admiration was likely to have been a factor influencing policy development.

### **8.1.3 How did the policy change?: the process**

Baumgartner and Jones (1993) argue that radical policy change takes place only when there is *positive feed back* in the policy subsystem, for example transformation of monopolistic policy networks as well as the image or definition given to particular proposals. In Thai ART policy, the shift from limited treatment programme to universally accessed medication was introduced by a new administration. The regime brought with it the ideology to offer equitable access to health care including medical services that allowed the entry of a new cluster of policy actors: the Health Minister, reformist bureaucrats and treatment advocates, all of whom shared some fundamental values in relation to equity in health. These participants replaced the pre-existing policy network monopolies – the Disease Control Department officials and HIV specialists – who had dominated the policy subsystem for a long period. The shared ideologies on equity and human rights among the new policy network members likely played a role in the policy innovation. Parallel to the actor network transformation, local manufacture of generic ARV products and drug price reduction resulted in changes in policy makers' perceptions about nationwide therapy, changing the image of the policy from one which was a hugely expensive service to one which was affordable.

Kingdon (1984) explains the agenda setting process in different way, suggesting that a problematic issue can become agenda item at a critical moment when three independent streams of problems, solutions and politics come together, i.e. when particular conditions are recognised as problems; feasible policy solutions are available; and the political environment facilitates policy change. This study argues that in the Thai context, the agenda setting of the universal ART policy developed in the same vein. Although HIV-related problems had been considered significant in the country since early 1990s, it was not until mid-2001 that ARV medication was expected to be affordable and therefore it was perceived to be feasible to deliver on a large scale. This window of opportunity arose when the new government came to

power, accompanied by substantial shifts in ideals and attitudes of politicians and bureaucrats involved in health policy making. The fall of drug prices as well as new groups of policy actors affected how nationwide ART provision was defined and interpreted. Campaigns organised by civil society organisations (CSOs) was political events, which also had a role in treatment extension. Not only was the HIV problem well recognised, but solutions to treatment of PLWHA became apparent, and the change in government facilitated political change. Furthermore, as Kingdon (1984) points out, issue definition and policy entrepreneurs are two important factors in raising previously-neglected problems and corresponding policies on to the policy agenda. The issue was re-defined as drug costs came down, and CSOs acted as entrepreneurs to accelerate change.

It could be argued that the Thai government had anticipated the policy to offer universal coverage for ART before treatment advocates appealed for it, as evidenced from the request of the Health Minister to the GPO to speed up its research on ARV formulation as well as to extend the production capacity in early March 2001. However, without the civic movement, the government might have hesitated to hasten scaling up, especially when the UC bureaucrats argued that this would result in immense financial burden.

The exact moment when the government began to pay serious attention to ART service is hard to identify. However, between March and November 2001 there were continuing interactions between the existing cluster of state actors and civil society alliances. Exchange of information drawn on treatment experience elsewhere furthered the penetration of the policy ideas within this informal, transient network. Assessing the benefits, political desirability, threats and feasibility of the policy proposal in comparison to *status quo*, policy makers began to think the unthinkable: extending the national ART plan and including medication in the UC benefit package.

#### **8.1.4 Spill-over effects/policy momentum**

The rise of universal ART delivery issue on the government agenda and subsequent policy adoption were both a consequence of health care financing reforms and the launch of the UC plan, and were affected by those policies. Reforms had been developed and pushed by health officials and reformists in Thailand for more than three decades before being adopted by the Thai Rak Thai Party, and becoming the government's major policy in January 2001

(Jindawattana and Pipatrojkomol 2004). The ideology behind such policy was based on human rights notions, emphasising the rights to health through equitable access to essential health services (Leechanavanichphan 2004). The shared ideology of the UC scheme and universal access to ART – the two policies adopted almost in tandem – were reflected in many policy dialogues and statements made by NGOs and the Health Minister.

It could be argued that the treatment policy development in Thailand during the one year of 2001 resembled what Walker (1971) calls a momentum phenomenon. In his theory, Walker maintains that when there is a breakthrough in a policy domain previously neglected by the government, it is often followed by a surge of administrative or legislative policies in that domain which has persisted for a long time. An initial policy shift can have spill-over effects. This fits the introduction of the UC plan, followed by ART expansion. Two reasons for the spill-over effects can be applied to understand the mechanisms by which the consecutive policy shifts in the Thai health domain operated. First, exploration and consideration of the first issue (universal health coverage) make others (ART expansion) increasingly specified and well defined. Second, policy makers and interest groups working on similar problems see the opportunity to make themselves knowledgeable and ride on the wave of policy change (Nelson 1978). This study suggests an additional explanation: given that the ART policy proposal was deliberately labelled with the same ideology as the emerging UC scheme – one of the most popular policies at the time – it would have been difficult for the government to find a justifiable argument to reject the expansion of ART. As noted by Kingdon (1984), the success of policy entrepreneurs to promote spill-over in adjacent arenas can be enhanced by underlining similar analogy in legitimising their arguments. China offers a good illustration: reform of the country's disease control strategies and considerable change in AIDS policy in 2003, could be regarded as a response to the outbreak of severe acute respiratory syndrome (SARS) earlier in the same year (Zhang 2004).

## **8.2 Devising the nationwide ART programme**

Since ART service coverage in Thailand before 2001 was limited to small numbers of the population in need, national-scale treatment provision inevitably required modification and preparation in the central departments, sub-national health offices and health delivery facilities, all of which demanded the reformulation of the national programme's strategies. Addressing the question on how such a policy process operated, this study suggests a new

network of policy actors, the importance of *policy learning*, and imbalance of power among programme formulators.

### **8.2.1 Policy formulation network**

A small group of actors involved in the decisions to adopt universal ART policy had a considerable role in policy formulation. The involvement of these participants became official as they were appointed by the Health Ministry to sit on Advisory Committee and Technical Panels. Joining with public servants from the Disease Control Department, clinicians, researchers and scientists in the HIV field who were also assigned to work out the national programme's blue print, this group of policy actors characterised a policy network as defined by Marsh and Rhodes (1992). This policy formulation network had restricted membership and tight integration characteristics such as frequent meetings and sharing core values and interests: not only to improve equitable access to ARV medication but also to assure service quality. However, the stability of the network lasted over a short period, one year only.

While members of this policy network were interdependent, each possessed different resources essential to formulate new strategies for ART provision. These included the technical expertise of HIV clinicians and laboratory scientists, administrative skills of health officials, and implementation experience of CSOs. As Rhodes (1988) argues, members of a policy network may enhance the capacity to pursue their pet proposals as well as their interests by sharing resources with others. In the absence of support from experts and NGOs, the Health Ministry bureaucrats might have foreseen difficulties in both policy formulation and programme implementation. At the same time, the opportunity to connect academic works such as research results with national policies and subsequent action could have been an incentive to specialists to participate in the policy process. For treatment advocacy members, partnership with government agencies and HIV experts provided them with a chance to influence policy, gain more technical knowledge, and also legitimise their future activities.

The features of the dominant policy network in this stage resemble what Howlett and Ramesh (2003:148) have observed: the policy subsystem in which a policy is formulated, which is relatively closed, allowing only relevant actors with some minimal knowledge and experiences in the subject area to participate. This is because these actors are required to

search for policy prototypes, consider and make comments on the feasibility, outcomes, and consequences of different policy options. Networks also provide a channel for policy transfer and lesson drawing (Stone 1999). Findings of this thesis suggest that information and experience exchange among the various Panels' members facilitated treatment programme reform, to the benefit of people who needed medication which was a common interest of the policy network members – that is, learning among network members played an important role in this phase.

### **8.2.2 Role of policy learning in policy formulation**

Policy learning in the universal ART policy occurred at all stage of the policy process: agenda setting, policy adoption and formulation. The inspiration to get more PLWHA on therapy, as well as the discussion about feasibility and affordability of scaling up the service were in major part encouraged by the information circulated in the international health community. In the programme reformulation, members of the four Advisory Panels continued to learn and draw lessons about ART in several respects.

Policy transfer models argue that the motivating factor of policy learning or *voluntary* policy transfer is the policy makers' demand for effective solutions to particular problems (Dolowitz and Marsh 1996; Rose 1993). To obtain such remedies, individuals and groups search for policy ideas or programmes established in other countries, or experiences in their own settings. The Ministry of Public Health (MOPH) appointed Advisory Panels comprising members with relevant expertise and experience to carry out the task of expanding access to ART. Instead of spending resources and time on conducting research to identify the most appropriate practices and instruments, these Panels' members devised the programme's features by drawing lessons from different sources, including their own experiences and some Thai researches. It was the expertise and experience of these actors that led to the examination of several policy choices in order to develop solutions pertinent to problems faced in the Thai context (Considine 2005).

This study points to the many lessons drawn from domestic experience, which played a crucial role in the policy design. As seen in chapter 5, learning about the success and obstacles in earlier phases of ART provision, through public and NGO's initiatives, was highlighted by interviewees and also illustrated in the Panels' minutes. Such feedback was

prepared in the form of meeting documents, and then fed into the discussions by the Panel secretariat and, in some instance, by some members assigned by chairperson. Moreover, in the meetings, participants developed arguments on the basis of their direct experiences as treatment providers, administrators or service clients. Other than the programmes' feedback, findings from locally-conducted clinical trials of the first-line regimen – GPO-Vir, as well as other treatment protocols were raised to consideration by the Panels.

While domestic policy learning had an important role in devising the national treatment programme configuration, foreign country experiences in ART service strategies were neither mentioned by key informants nor recorded in the Advisory Panels' minutes. Although policy transfer from abroad is difficult to trace in non-coercive cases where policy makers in importing countries have the liberty to adopt and adapt policies from elsewhere, it is highly likely that exogenous information on treatment provision and programme management, either from the forerunners, CSOs, or international agencies, affected the decisions regarding the Thai ART initiative. As the Thai policy development took place while ART access in developing countries was strongly promoted at the global level, research results, evidence and other types of information about *what worked* and *what didn't* in foreign settings were reaching and affecting Thai experts, NGOs, and health officials, all of whom had been interested in such issues. Training programmes, conferences, meetings, visits, collaborative projects and personal communications were all vehicles by which Thai policy participants were exposed to international lessons.

### **8.2.3 Imbalance of power**

Although the universal ART programme formulators shared a common goal, and all participants actively contributed to accomplish the tasks as commissioned by the Health Ministry, on many occasions the Deputy Health Secretary and officials in the Disease Control Department dominated the policy process. On the whole, government actors controlled the Panels' agendas, directed the meetings or even furthered their proposals directly to the authorities, bypassing the discussions within the Panels. Despite the fact that, as some observe, the term 'network' refers to *non-hierarchical* relationships between individuals and/or organisations (Considine 2005), some imbalance of power among policy network members is not unusual. Marsh and Rhodes (1992) suggest that unequal resources and powers among members can be found in most policy networks. Public policy scholars have pointed

out that power and influence is distributed unevenly in the policy subsystems, even in tightly-integrated networks defined as policy communities, and that the concentration of supremacy in policy making is found more often in state actors than other interests (Marsh 1998a; Read 1992). *'Governments can seize power over established institutions such as policy communities and networks.'* (Richardson 2000:1009).

However, while civil servants dominated the policy process, NGO leaders revealed that they felt that health officials *'knew best'* about issues such as those on public programme administration. This indicates that the unequal information and experiences possessed by the two parties was a source of power differences. As Hill (1992:1-11 quoted in Howlett and Ramesh 2003:69) has suggested, expertise and access to knowledge and information in particular areas of specialisation are among policy resources commanded by technocrats and professionals. In ART programme renovation, the bureaucrats' influence over NGO representatives and scientists also had different roots. For instance, the Deputy Health Secretary who chaired the Panel on treatment programme management had long been recognised as a dedicated health system reformist. Cooperating with him in other areas of public health, HIV NGOs had developed a sense of respect and trust for this official. This may have emanated from what could have been seen as the authority reflected in an individuals' charismatic personality (Weber 1949, quoted in Hudson and Lowe 2004:195). It can be speculated that owing to the influence of the Deputy Health Secretary, he was able to lead Panel meetings and apparently, also keep the issue of ART finance off the Panel's agenda without significant challenges from the treatment advocacy alliance. This was in spite of the fact that the alliance had strongly-promoted the proposal for including ART in the benefit package in the agenda-setting and policy adoption phases.

#### **8.2.4 Factors facilitating policy formulation**

Although the Advisory Committee and four Panels worked over only one year of 2002, these groups of actors made considerable changes in the National ART Programme strategy. This indicated a low level of conflict among policy formulators, which was unusual for participants with different backgrounds. Apart from the personality of the Deputy Health Secretary, the consensual, rapid policy development process might have been based on three interconnected elements: common interests; the sense of interdependency; and shared experiences among network members. First, the Health Ministry appointed only selected

individuals or groups who had similar attitudes to sit on the Panels in order to smooth the decision processes and therefore rapidly work out the programme configuration. Having worked and learned lessons together, the panel members had developed similar preferences towards the urgent needs for solutions and strategies. Second, one of the lessons these state- and non-state actors might have learned interaction was that they were interdependent: neither MOPH, specialists, nor NGOs alone could move universal ART coverage forward in the absence of support from the others. And third, in addition to the direct experiences in treatment implementation of Panel members, the availability of research on the national ART initiative, feedback from treatment programme evaluation, and documented lessons on NGO-organised service could also have facilitated policy learning and therefore policy formulation.

### **8.3 Implementing universal ART policy**

With regard to the policy implementation stage, this study does not examine the programme's effectiveness, but analyses the factors influencing ART expansion at the provincial and district level.

#### **8.3.1 Policy implementation network**

Howlett and Ramesh (2003) point out that clusters of participants who form into networks to pursue their interests, can be found in every policy stage including policy execution. While most top-down and bottom-up theorists emphasise the interactions between government actors, employing the policy networks concept in this thesis helps to explain the involvement of non-state participants in the integration of ART into the health delivery system. In the study settings, policy implementation networks were dominated by bureaucrats: administrators and health professionals in provincial and district hospitals, who were in direct contact with HIV-positive patients. But, in addition to creating relationships with health workers in other settings, these front-line bureaucrats interacted with regional and provincial health officials, as well as CSOs like PLWHA groups and NGOs.

Despite sharing some characteristics, there were differences between the networks in the two study provinces. In both areas, the Regional Disease Control Offices and Provincial Health Offices provided technical and management support essential to ART provision in hospitals. These MOPH sub-national agencies also operated as mediators for policy communication and

feed back between national policy makers and the implementation units. The relationships between the MOPH organisations at different levels were set along the command and supervision lines of the public administration system. Another common feature of treatment implementation networks was that all patient groups were initiated and managed by hospital staff.

However, the two provinces also differed. While close collaboration of providers at provincial and district levels was formally established in Phichit, hospital-civil society partnerships in Rayong seemed to be more influential than its Phichit counterpart. Furthermore, to carry out some activities such as public relations about treatment availability and case finding, health workers sought cooperation with local organisations such as provincial government offices of other ministries, local administrative authorities and also community leaders. These partnerships developed intermittently and were contingent on particular settings.

The collaboration of state- and non-state actors in ART policy execution was largely conditioned by the need to exchange resources among members of the networks. Obviously, the MOPH's hospitals had a mandate to offer medication and related care to significant numbers of HIV-infected patients. However, as the service was so complicated, in order to achieve the targets and to assure quality at the same time, the providers needed assistance from other public agencies and CSOs. Another reason for networking on the supply side was to overcome implementation constraints, as will be discussed further. Meanwhile, getting more PLWHA on therapy was the shared interest of NGOs, patients themselves, communities and the health professionals. Therefore, it could be expected that the network would benefit all parties involved in the treatment introduction.

### **8.3.2 ART delivery constraints, discretion and context**

Although planned preparation of the health delivery system was introduced at the national and sub-national level alongside the ART programme scale up, many obstacles were stated by health providers as impeding treatment targets, and ensuring quality of care. The lack of reliable HIV registration, complexities of therapy, inadequately experienced staff in district hospitals, increasing burdens of concomitant reforms and so on were reportedly afflicting medication delivery. Insufficient staff may affect treatment service in different ways. In

addition, the additional burdens of ART introduction on health care providers would increase over time, since therapy improves patient survival. Experiences in Thailand and elsewhere suggest that long-term caring of PLWHA accompanied by high workload may cause anxiety, stress and burnout<sup>49</sup> among health workers (Visintini et al. 1996; WHO-SEARO 2005). These psychological conditions tend to develop alongside the growing number of patients on ART in study context, especially in district hospitals where a single nurse ran a HIV clinic and prescribed medication. In fact, administrators of some settings such as Sam Ngam district hospital predicted such impediments, but nevertheless signed up to the national initiative because of the perceived pressure from Provincial Health Office and forerunner participating hospitals.

To address these problems, health facilities generated different coping measures, as seen in chapter 7. Similar situations have been reported in other resource-poor countries, where health providers experience constraints to ART scale up. Example of coping solutions include networking with NGOs and other support groups outside the health systems, encouraging home-based and community-based service delivery, and introducing simplified therapy approaches which allow nurses and other paramedics to substitute for medical doctors (UNAIDS 2003c; Wendo 2005). When front-line civil servants face implementation constraints, ambiguous policy content, uncertainty of work environment, or work-related hazards, they invent several mechanisms to counter such problems (Lipsky 1980). The practice of government workers who directly contact with clients and beneficiaries of a public programme may thus deviate from the expectation of national-level policy makers. However, this operational discretion becomes routinised and maintained in the policy enacting units. Example can be drawn on how treatment providers discretely responded to the unclear elements of the national ART programme. As it had not been spelled out which groups of patients were entitled to the service according to their health benefit plans, different arrangements were introduced in study hospitals: while ART in Phichit was offered to all clinically eligible PLWHA, in Rayong medication subsidised through the national programme was provided only to UC members and the uninsured (chapter 7).

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<sup>49</sup> Burnout syndrome is defined as a loss of motivation in work, response to excessive engagement, dissatisfaction, psychological withdrawal interest and emotional exhaustion (Cherniss 1980 quoted in Visintini et al 1996:184).

This thesis demonstrates that the implementation constraints and coping mechanisms in certain hospitals were understood in general, but were also context driven. Responses to the universal ART policy involved other government policies: the reforms of health financing and public administration system, which worsened the existing district-level workforce shortages among other things. However, many factors and their implications for discretionary practices were province-specific. An illustration can be drawn on the case of Rayong where the existence of a large business sector made it feasible not to provide the Social Security Scheme members with drugs from the national ART programme. Other factors that related to the particular context included the burden of HIV in comparison to other diseases; experiences on treatment delivery; distance between hospitals to regional laboratory; relationships with NGOs and surrounding communities. All these factors affected the decision to sign up to the initiative, allocate health personnel, and organise the service and related logistics.

### **8.3.3 Policy learning in the implementation stage**

ART programme instigation in many countries suggests the need for capacity building and skill development of health workers. The literature shows that individual and organisational experiences on the supply side have a substantial role in assuring desirable professional practice and clinical outcomes (Dudley et al. 2000; Kitahata et al. 1996; Laine et al. 1998). The importance of substantive learning – the process by which policy actors draw lessons from education, observation, analysis and practice (Peterson 1997) – was observed in all study hospitals. This was reflected in the interviews with health workers as they discussed the benefits from training workshops organised by Regional Disease Control Offices; training programmes for new cohorts of health workers in Phichit province; training courses for specialists in Medicine, Infectious Diseases and Paediatric; consultation with HIV experts within and outside hospitals; as well as experiences on treatment delivery as part of research projects, Disease Control Department's earlier initiatives, and programmes previously run by NGOs.

Findings of this research indicate that health professionals in study settings learned to devise coping strategies since they were motivated not only to achieve the national programme targets, but also to meet their goal: offering therapy of high quality. Knowledge about coping with ART service delivery – the intervention new to the hospitals and most health care

workers – was sought in several ways. In addition to the clinical and programme administration guidelines from the Health Ministry, the service providers searched for additional information from different sources. For instance, a HIV nurse in Thapkhlo, who missed the Regional Disease Control Office’s training course, reported self-learning from textbooks and other documents, as well as from discussions with pharmacists and even PLWHA group leaders. Meanwhile, a doctor in Rayong provincial hospital asked for advice on complicated case management from HIV specialists in adjacent province of Chonburi.

However, policy learning also has another critical role in converting policy prescriptions into action. According to Schofield (2004)’s model of learned implementation, to meet new policy goals, street-level bureaucrats seek to obtain necessary information to guide policy execution as well as draw lessons from several sources. Through the learning process, there are 2 categories of knowledge acquired by these service providers: technical and procedural (chapter 3). The learned implementation model suggests that procedural knowledge has an important role in adapting and utilising technical information, by increasing skills and capabilities of front-line workers to deal with impediments. This thesis argues for the existence and usefulness of knowledge of both types in ART scaling up. Apart from commanding clinical knowledge necessary for treatment administration, hospital directors and staff in study provinces possessed the capacity to adapt the undesirable work conditions that afflicted programme achievement. The self-learning of the Thapkhlo nurse and expert consultation by the Rayong doctor earlier mentioned in this section offer illustrations of how these health workers gained technical knowledge on ART administration. In contrast, lesson drawing on adherence promotion among health professionals in Phichit provincial hospital, who had participated in Clinical Research Project, could be regarded as generative learning, since their skills to promote patients’ adherence were developed on past practices.

Learning for policy implementation, as Schofield (2004) points out, is provoked by many elements. Collaboration between hospitals in Phichit offers an example as it aimed to facilitate the learning process through the transfer of knowledge and experiences from provincial experts to district-level practitioners. Other ways learning was facilitated were found in this study: the past experiences on ART administration and other HIV service provision; teamwork of health personnel in the same hospitals; support from respective regional and provincial offices in organising treatment networks and training courses; partnerships with NGOs; and accessibility to relevant information. These learning approaches

can be viewed as the function of policy networks by which the resources, i.e. knowledge and information, were shared and exchanged among implementation agents. As argued by Schofield (2004), when service providers discover the strategies to operationalise new policy prescriptions, they do not hesitate to share such knowledge with others in their formal and informal networks – the so-called ‘communities of policy learning and practice’. In Phichit and Rayong, sharing lessons in relation to ART provision might have taken place in several occasions: for example, discussions and presentation in formal meetings and conferences, training programmes, circulation of provincial or hospital treatment guidelines, and personal communication. It is suggested that collective learning among service providers as members of policy learning networks can encourage and steer a policy through to implementation (Schofield 2004).

Based on the fact that during 2002 to 2004 all study settings took part in the national ART programme and offered therapy to HIV patients, this thesis maintains that certain extent of policy learning happened among health providers and hospital administrators. However, different paces of learning could be anticipated. Learning in Sam Ngam and Thapkhlo hospitals tended to be relatively slow, as it was hindered by the lack of ART experience, accompanied by recent changes in HIV clinic staff, and rapid turnover of GPs (Thapkho), especially when they first participated in the treatment programme in 2002-2003. In contrast, lesson drawing to enact treatment extension in Phichit and Rayong provincial hospitals and Klaeng hospital was likely to develop rapidly. This was because these settings had offered ART through clinical trial projects and/or NGO-organised service before the national programme scale up. The knowledge obtained and skills developed in the previous-phase treatment were compiled in the organisations owing to the continuity of health workers involved in HIV care. Although some doctors recently moved to Phichit and Rayong provincial hospitals, they had exposed to HIV cases while there were on specialist training.

This study also shows that policy learning among ART providers and its results, i.e. the invention of task completion strategies, was not only influenced by contextual elements including the existence of learning facilitators as above mentioned, but actors themselves were also crucial in the process. Despite the central department’s pressure on sub-national offices and health facilities to meet the programme’s targets, health officials, hospital administrators and HIV clinic staff asserted that many of their discretionary practices and coping strategies aimed to avoid the adverse effects of the service on enrollees and the public.

For instance, although a 200-baht charge was recommended in the programme management guidelines, all study hospitals offered free CD4+ cell assessment to PLWHA in order to encourage them to visit hospitals for regular follow-up. The response of the Thai health professionals to ART expansion is typical of the features of street-level policy inventions, bound to professional norms and codes of conduct, and accountable to their bureaucratic and personal responsibilities (Lipsky 1980; Schofield 2004).

#### **8.4 Potential negative outcomes of the universal treatment policy**

This thesis illustrates a satisfactorily picture of ART service in study hospitals: good attitudes and strong devotion of health care providers, as well as acceptable adherence, small default fractions, and improved quality of life among treatment enrolees. However, according to the existing literature, both implementation constraints and coping mechanisms invented by front-line civil servants may have negative implications. As Lipsky (1980:xii) suggests, in the worst cases, street-level bureaucrats adopt discrimination in service provision against selected populations: '*... they give in to favouritism, stereotyping, and routinising – all of which serve private or agency purpose.*' In similar ways, health workers' interventions and discretionary behaviour in HIV care may result in unwanted effects. Poor attitudes including fear of occupational infections amongst health care staff and associated stigma and discrimination practice against HIV patients have been documented in many developed and developing countries (Foreman, Lyra, and Brienbauer 2003; Hsiung et al. 2001; Kermode et al. 2005). Also, substitution of physicians by nurses and other paramedics in ART prescription and monitoring could potentially impose clinical risks as studies in industrialised societies show that service quality and survival time of treated patients are significantly associated with expertise and experience of clinicians (Dudley et al. 2000; Kitahata et al. 1996; Laine et al. 1998).

In addition, studies on treatment extension in other Thai settings in the same period have suggested some sorts of poor performance such as inadequate adherence to therapy. For instance, Punpanich et al (2005) found that among 1,137 ART enrolees in 12 provinces, 4% missed at least one dose of ARVs in the last five days, and 15% had ever failed to take medicines on time. Regarding discrimination in health facilities, other systematic studies suggest the existence of poor-quality and delayed treatment delivered by Thai health professionals to some patients on the ground of their HIV status (Seale 2004; Stringer et al.

1999). Therefore, similar practices among ART providers in Phichit and Rayong cannot be ruled out, although such action was not captured in this thesis.

There are three possible explanations for the underestimated problems in study provinces. First, during field work, the programme was in its early phase of scaling up, thus the undesirable effects might not have happened, or been perceived by interviewees. Second, without a proper study design, it is difficult to examine the causes of poor therapeutic outcomes and other unwanted effects, as they could be resulted from many factors. For instance, there were a number of deaths among patients on ART in all study hospitals, which might be owing to the lack of GPs' competency, nurse prescribing, insufficient information provided by pharmacists and counsellors, or inadequate adherence to medication and late care seeking of the HIV-positive individuals. The third reason involves methodological limitations: this part of research was based only on interview data, and triangulation between sources of information could not be carried out since the results of programme evaluation and research on ART extension in study settings were not available (see chapter 3). As most of the key informants were health workers, they tended not to criticise their own practices, or reveal their unacceptable behaviour, especially stigmatising and discriminating HIV-infected persons. It was also possible that PLWHA interviewed in this study dare not make frank comments on their service providers. However, based on empirical evidence in some study hospitals, for example, inaccurate information provided by PLWHA to treatment enrollees, and poor prescribing by inexperienced doctors, it can be anticipated that treatment quality in these settings may be undermined in the long run.

### **8.5 Weaving the web: policy learning network**

Exploring the changes in Thailand's national ART initiative, this thesis has illustrated that throughout the past decade, the policy development processes were intricate and dynamic, governed by two integral elements: policy networks and policy learning. This section suggests that, in the period and context described, there were *policy learning networks*, and that treatment programme evolution was a consequence of collective learning among several actors as network members.

It was the collective process of learning of policy makers, health officials, professionals, experts and CSOs that, in considerable part, triggered treatment extension and made such

inspiration possible, by guiding the policy formulation as well as leading the service provision at the frontline. In fact, the use of knowledge and scientific evidence to inform policy had been traditional, integrated in Thailand's health systems for a long time prior to the 2001 policy shift. Research in different disciplines of basic sciences, biomedicine, epidemiology, and social sciences conducted in the country were influential in many respects. The case of ART policy was merely one illustration affirming the existence of a strong applied research environment and links to policy.

It has been argued that owing to the research & development capacity of the government laboratory – ARV prices – the major barrier to therapy substantially declined. The strength of local generic production was complemented by clinical trials conducted by Thai experts, which provide the information on the effectiveness and safety of several ARV regimens and alternative medicines. The drug testing involved not only specialists and academics but also health personnel in the MOPH's sub-national offices as well as health providers in district and provincial hospitals. Knowledge and information emerging from domestic research greatly contributed to policy decisions and programme feasibility. Moreover, clinical and management experiences of health professionals obtained through taking part in study projects were reported in interviews as invaluable in getting policy into action.

In collaboration with experts in academic institutes, officials in the Health Ministry usually integrated research into the process of programme development. The start-up of mother-to-child HIV transmission prevention in the late-1990s offers a good example. Based on a clinical study in the country between 1996 and 1998 which demonstrated the efficacy of short-course zidovudine and breast-milk substitutes in reducing perinatal infections, the MOPH organised operational research to assess how such interventions would work when delivered in a pilot programme in 1997 before scaling up nationwide in 2000 (Kanshana and Simonds 2002; Thaineua et al. 1998). In the same vein, when the clinical benefits of highly active antiretroviral therapy were proved in the developed world during the late 1990s, medication was provided in some hospitals through a small initiative – known as the Access to Care Plan, which it was intended to extend further gradually. These two HIV programmes demonstrate how knowledge was generated and used in policy development. Feedback from these operational studies encouraged policy learning among policy makers, formulators and implementers. Some have pointed out that this is a key feature and a factor of success in the country's HIV control policy:

*'Rather than first drafting a comprehensive policy and then designing programmes accordingly, Thailand built large part of its national programme on the groundwork and experiences of a series of early, often province-wide initiatives. These were monitored and assessed, and provided relatively quick proof to policy makers that solutions were available. They also provided early lessons for adapting and improving programmes. Policies could therefore incorporate or draw on this accrual of learning and adaptation.'* (UNDP-Thailand 2004:31)

By this, it does not mean that research findings and other types of scientific evidence from foreign settings were less important than those of domestic origins, but the existence of a lively research community was extremely important.

The above discussion on policy learning networks is confined to those operating in the public sector. Actually, the web of actors keen to use knowledge and evidence to influence ART policy covered a greater range. Chapter 4 illustrates, for instance, the relationships and collective learning of NGOs, PLWHA, specialists, academics, lawyers, scientists of the government laboratory, and international AIDS relief organisations who fought against a trans-national company in the didanosine case. Chapter 6 portrays the partnerships of experts, national-local NGOs, PLWHA alliance, and health providers involved in many activities including in carrying out research, as well as delivering therapy such as the organisation of the Buyers' Club. Furthermore, some NGOs like MSF cooperated with the Health Ministry hospitals in doing studies on treatment regimens and patients' adherence (Frederix et al. 2004; Petdachai and Wilson 2005). Given that these networks had existed before the universal ART policy adoption, and their members overlapped with those of the policy formulation community seen in chapter 5, it cannot be denied that the national policies were also influenced by actors outside the MOPH's Advisory Panels, through the transferring of knowledge and experiences from antecedent learning clusters.

In addition to the complex feature of ART policy learning networks, the interrelations between these participants and their influence changed over time. The period of policy evolution saw the rise and fall of particular learning agents at the core and distant zones of the policy subsystem. For instance, those NGOs and PLWHA groups that previously focused their attention on ART provision through the Buyers' Clubs and had a minor role in the national policy decisions gradually moved closer to the centre of the policy-making stage

from early 2001, and continued their involvement in devising the universal treatment initiative until late 2002. State actors like the Disease Control Department officials also shifted within the learning network. They dominated ART policy decisions throughout the 1990s, then their leading role was taken over by reformists who set up the UC plan in 2001. They eventually returned to central sphere of the subsystem where they regained their policy-driving power from 2002 as they were appointed as members of the Health Ministry's Advisory Committee on ART Expansion.

### **8.6 Policy learning environment**

The development of policy learning networks and their roles in the national ART policy were moulded by many contextual factors. One clear factor was the overall health environment which encouraged the use of evidence and knowledge to inform policy. It can be argued that in addition to the well-educated personnel and adequate financial resources, this was the legacy of a group of intellectual leaders in the Health Ministry and medical schools in the 1970s that contributed notably to knowledge generation and utilisation in policy making (see chapter 2). The roles of research in the health system have been increasingly crucial, particularly in late 1990s when Prawase Wasi – a Professor of Medicine and well-respected reformist – suggested the integration of 3 elements: knowledge management, social mobilisation and political movement into a framework to drive health system reforms – the so-called *Triangle that Moves the Mountain* (Wasi 2000). This framework reflects the viewpoint that not only knowledge but also networks of social and political actors are key elements to policy change.

The introduction of health care financing reform and the Universal Health Coverage Scheme in 2001 is a good illustration of knowledge-based policy that incorporates civil society and political involvement. Some suggest that the remarkable progress of such reforms can be attributed to local health system research capacity, which generated information to identify the weaknesses of the existing health plans and estimated resources needed for the new financing mechanisms as well as potential outcomes of different policy alternatives (Tangcharoensathien, Wibulpolprasert, and Nitayarampong 2004). Others emphasise the credibility of research and close connections between research communities, NGOs and policy makers as key factors encouraging research-policy integration (Alliance for Health Policy and Systems Research 2004; Mills 2004). Mills (2004) suggests that both research

capacity and good relationships including ‘trust’ between Thai researchers, reformists and policy makers required long-term development. It certainly can be argued that these factors had been fostered systematically in the health systems by responsible organisations. For instance, since the Health Systems Research Institute (HSRI) was instigated as a research-granting agency under the MOPH in 1992, one of its mandates was to facilitate health system reforms (Ministry of Public Health 2004b). In addition to commissioning studies, this Institute formed networks with regional universities and set up many affiliated organisations including a programme to strengthen research capacity in related areas such as health economics, financing, human resources and policy analysis (International Health Policy Program 2003; Phoolcharoen 2002b). Research fellows in this programme were exposed to national-level policy making and contact with politicians and bureaucrats in order to understand how policies were made and what evidence was required. Introducing the *Triangle that Moves the Mountain* concept, the HSRI also held a series of consultations to consolidate stakeholders’ opinions and mobilise people’s participation as a vital part of the reform process. Major issues on the HSRI’s agenda included not only research to improve the health system’s efficiency, equity and responsiveness, but also research to promote civil society mobilisation and empowerment (Phoolcharoen 2002a). This Institute involved policy makers from the initial phase of setting the research agenda to the use of research findings in policy formulation and implementation (Grant et al. 1998; Green 2000).

An important feature of the network for health system research in Thailand is that it involves researchers, experts and practitioners at all levels. Capacity strengthening programmes were established by many Health Ministry’s departments to produce researchers with different expertise. An example can be drawn from the Field Epidemiology Training Programme. Organised by the Bureau of Epidemiology in collaboration with the US Centre for Disease Control and Prevention in 1980, this training course provided health workers from all regions with knowledge and skills on disease investigation and surveillance (Laosiritaworn and Jirapongsa 2004). The Epidemiology Bureau also had a programme to support local analysis of surveillance data in order to inform provincial planning and health programme evaluation (Thanaisawanyankoon and Sangwanloy 2005). The strength of Thailand’s disease investigation and monitoring system as well as its contribution to the country’s policy development is reflected in the case of HIV/AIDS control.

Academic institutes in Bangkok and up-country had an important role in conducting studies and building research capacity for the health workforce at sub-national level. The Health Ministry allocated annual budgets to support research projects run by its staff. Findings of these studies have been presented in meetings, published in journals, and disseminated through organisations' websites. Many studies have been accepted by international journals and conferences. For example, at the 2005 International Congress on AIDS in Asia and the Pacific, 37 studies conducted by health workers in MOPH's sub-national offices and hospitals<sup>50</sup> were presented (AIDS Society of Asia and the Pacific 2005). In addition to conducting research in their responsible areas, large numbers of the workforce took part in pilot programme assessments, routine programme monitoring and evaluation, as well as regular epidemiological and health-related behaviour surveillance (Poshyachinda and Danthamrongkul 1999). Experience on data collection, management and analysis acquired by these health personnel was highly likely to have been helpful in systematically drawing lessons from their own work.

As a member of global health community, Thailand also gained knowledge to improve its health systems by learning from foreign experiences. The Thai Government and private organisations offered scholarships for Thai students to study in developed countries. Some scholarships and training opportunities were arranged under collaborative programmes jointly organised by the MOPH and international academic institutes. Green (2000) observes that some researchers and reformists who played important roles in driving health system reform in the 1990s maintained the connection with their post-graduate schools, mostly in Belgium, the Netherlands and the UK, in order to draw technical support to next-generation research fellows. Furthermore, Thai health officials have had many opportunities to engage with heads of states, health ministers, experts, programme managers and NGO representatives from different countries as part of international networks – at conferences and meetings. In addition to formal education and training programmes abroad, health officials and health workers had access to information on health systems and policies in different countries through many channels. These included worldwide media such as the Internet which can be connected from all district hospitals.

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<sup>50</sup> As measured by first authors' institutes.

## 8.7 Government and civil society in the HIV arena

This thesis shows that CSOs were among the key actors in Thai HIV policy. However, the civic sector was not homogeneous: the distinction between NGOs and PLWHA groups could be observed. In the early phase of HIV epidemic, NGOs working on HIV issues comprised existing associations, well-established in health and social welfare areas such as the Population and Community Development Association, Thai Red Cross Society and the Parenthood Association of Thailand (chapter 2). That these organisations had long-term, good relationships with the public sector allowed them to play a considerable role in the decisions and implementation of HIV policies. Despite collaboration with the Health Ministry and other government agencies, the background and involvement of these NGOs indicated that the voluntary sector developed independently from its public counterpart, and therefore can be regarded as the third sector (chapter 3). This argument is based on the fact that NGOs ran several campaigns to support or oppose particular policies issued by the administration. For example, they filed court cases against Big Pharma and the Department of Intellectual Property to revoke didanosine patent in late 1990s, and rallied to promote universal coverage for ART in 2001 (chapter 4). At peripheral level, the roles of HIV NGOs in providing treatment and care to the afflicted individuals were also widely acknowledged:

*'... NGOs' vitality, efficiency and unwavering commitment to social causes have been recognised by many members of society. Even some state officials readily attest to NGOs' contributions to social development in niche arenas such as health care for HIV/AIDS patients and their families, and policies for women and children.'* (Vichit-Vadakan and Anukansai 2004:72-73)

Apart from their involvement in HIV policies, in many instances these NGOs created partnerships with other CSOs to pursue wider interests. For example, the National Network of HIV NGOs and its individual members took part in a series of public fora to facilitate the development of the National Health Bill in early 2000s (chapter 5). The civic campaigns against the regime in 2006, demanding the Prime Minister's resignation and political system reforms in 2006 reflect the power of NGOs to make coalitions across a number of different sectors to demand radical political change.

In addition to NGOs, this thesis shows that groups of persons afflicted by the disease were another type of CSO participating in HIV policy process. In all study settings except Sam Ngam hospital, PLWHA groups had a supporting role in HIV care including ART delivery. Despite their contribution as self-help organisations, a common feature was that these groups were attached to, and organised by Health Ministry hospitals. That the national HIV programme demanded health facilities to foster networks with NGOs and PLWHA to facilitate Comprehensive and Continuum of Care including ART extension (AIDS Division 2000; Ministry of Public Health 2002a; 2003b) might have been the reason for patient group formation in some settings such as Thapkhlo and Wang Chan hospitals. Meanwhile, in other facilities including Phichit and Rayong provincial hospitals and Klaeng district hospital, patients groups were established before ART scaling up. Findings of this thesis suggest that these groups of PLWHA were not self-reliant: they required financial, information and management support from health providers and local NGOs. This is what some have noted that in the developing world, people's responses to HIV were often led and managed by the 'outsiders', i.e. health workers and NGOs (Seckinelgin 2002). Such development was contradictory to AIDS activism in Western societies where HIV-afflicted people themselves initiated and mobilised response.

Although civil society is located outside the public and private sphere, the boundaries between the three sectors are complex and unclear (Centre for Civil Society 2004). In modern societies, CSOs may be set up, managed or subsidised by governments and international organisations for particular purposes. In many countries, governments encourage volunteering and charitable activities of CSOs and businesses through different enabling and enforcing measures (Post and Rosenblum 2002). In Thailand, an example of government-operated voluntary sector could be drawn on the organisation of HIV patients in MOPH hospitals. At the global level, CSOs have been mobilised and integrated into health and development frameworks of transnational agencies such as the UN systems (UNAIDS 2004a; UNDP 2002). Moreover, some civic advocacy is supported by for-profit corporations through their philanthropic divisions: for example, the Bill and Melinda Gates Foundation and some pharmaceutical companies. The findings of this thesis suggest that the growing need for networks and partnerships between government agencies and other organisations has resulted in increasingly blurring lines between the state, market and civil society sectors.

Despite the advantages of policy networks in achieving policy goals shared by government and non-government actors, the unequal power of network members is an important feature (Marsh 1998b). This thesis maintains for the health officials' superior power and dominant role over CSOs throughout the process of universal ART programme formulation and implementation. However, NGOs and PLWHA alliances at national-level were relatively well off as they had the ability to persuade and challenge the regime, as reflected in the development of many HIV policies since the epidemic began. This was totally different from patient groups in study hospitals. The insufficient information, low socioeconomic status, illnesses, stigmatisation and isolation among HIV-infected individuals might have been crucial factors discouraging them from confronting with health workers. Despite organising as groups, it was unlikely for PLWHA to guide ART introduction in order to fulfil their own needs. Since PLWHA volunteered to participate in groups to carry out self- help activities, their organisations resembled others in the civil society sector. At the same time, because of their dependence on resources from service providers, it could be argued that these patient groups acted as extended arms of government: working to achieve policy goals set by the state. Moreover, the involvement of PLWHA in ART scaling up not only benefited front-line providers in carrying out some activities, but also legitimise the national treatment policy as a whole.

### **8.8 Lessons learned from Thailand's universal ART policy**

The primary aim of this research was to increase understanding about the ART policy process through the analysis of treatment programme evolution in Thailand. It was expected that lessons derived from this study may be useful to inform therapy policy in other low- or middle-income countries, recognising that programme configuration introduced in one setting cannot be replicated in other societies owing to the differences in socioeconomic, political and health system environment. The universal coverage for ART in Brazil and Thailand, for example, cannot be adopted in many African settings with many fewer resources. Assuming the policy learning notion, however, this thesis maintains that the Thai experience can be used as a model for adaptation in other resource-constrained settings. This section raises some general issues emerging from this study.

First, although the National ART Programme was a public policy and therefore responsible by government agencies, rolling out such complex therapy nationwide would have been

infeasible without support from NGOs and PLWHA groups. This thesis has demonstrated how the collaboration between state actors and civic volunteers, as members of policy networks, was essential in policy making and execution. Despite the fact that health officials and treatment providers in the public sector often command more resources than the CSOs counterpart, in some aspects of HIV policy decisions and service delivery, NGO staff and PLWHA are relevant to substitute for government workers.

Second, ART scaling up in Thailand was facilitated by a learning environment, from which knowledge could be generated and used to inform policy. Treatment introduction needs regular monitoring and evaluation as vital elements since feedback on programme's strengths and weaknesses is indispensable for further improvement. To avoid and tackle unwanted consequences of service expansion, surveillance of sexual behaviours and drug resistance as well as supply side monitoring should be well operated and carried out as an integral part of therapy initiative.

Third, knowledge-based policy processes existed at all levels of the health system, especially through collective learning of stakeholders. As the formation of a policy network is motivated by efficient use of resources to pursue common interests of all members, empowering CSOs is as crucial as strengthening the capacity of professionals, experts, bureaucrats and policy makers. It is noteworthy that fostering policy learning networks will not only contribute to the use of empirical evidence to shape policies, but also potentially to reinforcing public-civic unity through the collaboration of policy participants.

Fourth, the development of ART policy and its outcomes were facilitated by policies implemented in other domains, either the non-health areas or health-related sectors. Thailand offers an illustration that it might have been infeasible to scale-up therapy to meet the universal access goal if HIV prevention programmes had not been in place and effectively translated into action when the epidemic begun in early 1990s. Moreover, the country enjoyed the benefits from the legacies that resulted in adequate health infrastructure and a relatively well-developed pharmaceutical industry.

Finally, ART implementation requires adequate resources and proper management. This study suggests that although Thailand's health system was better-off compared to many countries in the South, the impediments in ART extension were substantial. In high HIV-prevalent, but under-resourced settings such as some sub-Saharan African nations, the trade-

off between rapid start-up of treatment provision to address the urgency of HIV problems, and service quality as well as the programme consequences should be considerate among local policy makers, international organisations and donors.

## 8.9 Conclusions and future research

Fieldwork for this thesis ended in December 2004. However, the National ART programme developed further. In April 2005, the number of PLWHA on therapy was 56,400 or 83% of the overall enrollees since the programme expanded in 2002 (data from Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections). ARVs and related services including counselling as well as laboratory tests for CD4+ cell count, viral load and drug resistance were included in the universal health coverage plan in October 2005 (Sakulpanich 2005). Treatment offered through this scheme covered 3 categories of PLWHA: ART-naïve, treatment-experienced, and drug-resistant cases, who were UC beneficiaries (Matichon 2005; Srisamit 2006). The Disease Control Department was contracted by the National Health Security Office to continue its role as programme manager, providing technical and administration support to health providers. Meanwhile, PLWHA groups were increasingly involved in service delivery. The Comprehensive and Continuous Care Centres run by HIV patients extended from 105 hospitals in 2004 to 129 hospitals in 2005 (Sakulpanich 2005). It was expected that by September 2006, treatment recipients in the UC plan would amount to 82,000, or approximately 100% of need (Srisamit 2006).

While the numbers of Thai PLWHA on ARV medication were increasing, the learning networks to improve treatment access were maintained. Apart from several ART-related studies including programme evaluation, the GPO's capacity was extended, resulting in the production of many new generic ARVs including indinavir, ritonavir and saquinavir, as well as other drugs in new dosage forms and fixed-dose combinations (Ake-sangsri 2005). The generic protease inhibitors will be beneficial for cost containment if and when first-line regimens are resisted in the wider population. At the same time, from 2004 civil society network comprising HIV NGOs, PLWHA, scientists, lawyers, and academics, most of whom played a vital role in the didanosine case in late 1990s (see chapter 4), campaigned against market exclusivity extension of pharmaceutical products, suggested by the US Government as part of Thai-US Free Trade Agreements (FTA) Proposal (FTA Watch Group 2006). Until March 2006, the two countries had not reached agreement, and the civic movement was still

continuing. When the people's campaign to dismiss Thaksin Shinawatra regime began in late 2005, the Thai-US FTA problems were among several issues raised to justify the petition against the Prime Minister. Certainly, CSOs in the HIV arena joined the civic coalitions in this political event.

This thesis provides insights into ART policy in resource-poor countries through the literature review and the analysis of Thailand's national treatment programme evolution. The Thai experience illustrates the crucial roles of actor networks and policy learning that drove the universal ART proposal on to the government agenda, and thereafter, shaped the process by which the service strategies were devised and translated into action. In each policy stage, the policy process was complex and dynamic, affected by networks' features including their resources, the interactions between participants and context, as well as collective learning among network members. Over a decade of the publicly-subsidised ART programme, there were occasional changes in the groups of dominant actors. Although government officials continued to lead the policy decisions and execution, in some instances their monopolistic influence was shared with others, such as HIV experts, health system reformists, NGOs, PLWHA groups and treatment advocate individuals. The transformation of actor networks took place alongside the growing experiences of local and international ART introduction. At the same time, learning environment including knowledge generation capacity and evidence-based policy tradition fostered the transfer of such treatment lessons. It was the common interests, concerted efforts, learning competence, as well as technical and practical expertise of multiple partners from the government and civil society sector that facilitated ART extension, despite significant impediments.

This study also increases the knowledge on the introduction of policy analysis approaches developed in the northern hemisphere to describe the processes of health policy in the South. The conceptual framework drawn on these public policy models was helpful in several ways. First, the policy triangle backbone provided a fundamental explanation about the influence of actors and context on the development of the national ART policy in particular stages. Second, the punctuated equilibrium model could capture the dynamic features of the treatment programme, both in its stable phase and when the universal coverage idea was adopted, through the understanding of dominant actors and their perceptions towards different policy alternatives. Third, the integration of policy networks and policy learning concepts enhanced the explanatory power of the conceptual framework, as these two notions deliberately address

the questions on how and why state and non-state actors formed partnerships with each other, and drew lessons from elsewhere to inform ART policy making and executing in Thai context. Fourth, the bottom-up theories of policy implementation helped to figure out the process and motivation by which the treatment extension policy was reinvented by front-line service providers. Finally, the overall analytical framework reaffirmed the untidy policy process, as comprising intersections between policy stages: the ART policy innovation developed in parallel to, and was affected by the implementation of existing treatment programme.

This thesis does not aim to appraise the national ART programme's performance and its consequences. Nevertheless, since knowledge-based policy making is a tradition in the country's health system, it is not surprising that the initiative has been systematically scrutinised in several facets, for example epidemiology, biomedicine, economics, and behaviour. However, gaps of public policy research concerning HIV and ART in Thailand remain. Comparative analysis of HIV interventions that succeed and fail is required. For instance, policy analysis would help to explain why it took only a few years to implement perinatal infection prevention on national scale, but by contrast, harm reduction for intravenous drug users has been completely neglected by the government.

With respect to the established initiatives such as ARV medication, more attention should be paid on how to assure their effectiveness, encourage equitable access, and avoid negative impact. One of the areas of research that deserves emphasis is better understanding of health workers' responses to the burdens of several health policies and the implications of the street-level practice for policy outcomes. In addition, given that ART introduction in the country will substantially change the face of the HIV epidemic and the demands for treatment and care among PLWHA, need assessments of supply and demand, and programme revision, as well as epidemiological projections are urgently needed.

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## APPENDIX 1: INTERVIEW GUIDES

Note: The following questions were used as general guideline. They were subject to adaptation in response to particular respondents and emerging situations during interview. Relevant sets of questions were sent to interviewees in advance. Each questionnaire contained generic front page illustrating background information on project, purpose of this interview, confidentiality statement, and signature.

### Section 1: National-level policy process

#### 1. Personal background:

- What was your background?
- When did you first get involved in the antiretroviral treatment (ART) policy? Have you been continually involved? Until when?

#### 2. The National ART Policy before scaling-up (1992 to 2001):

- What were the key determinants of the programme development? How did these factors change over time?
- Was there any attempt to expand the programme coverage? Who were the people who suggested the expansion? Why didn't they succeed? Was there any opposition to the expansion? Who were they? How did these two groups of people get involved in the policy?
- What did the general public think about publicly-subsidised ART provision? (for or against the issue). How and why did the public opinion affect the policy?
- What were the best and worst things about the government's ART policy during this phase? Why? How did you influence decisions?

#### 3. Agenda setting of the universal ART policy:

- Why was the ART excluded from Universal Health Coverage (UC) benefit package when the scheme was first launched in March 2001? What were the government's reasons for the exclusion? How was the exclusion justified in the technical, financial and political aspects? Who was involved in the decision? How were they involved?
- Why did the government adopt the policy to provide universal access to ART in November 2001? What were the key factors influencing policy change? What were the government's reasons for the new policy? How was the adoption justified in the technical, financial and political aspects? Who was involved in the decision? How were they involved?
- At the time of policy adoption, what was the expected source of funding for the programme? Did the information on the establishment of Global Fund to Fight AIDS, Tuberculosis and Malaria affect the government's decision?

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- Who were the people inside and outside the government who advocated universal access to ART? How did they get involved?
  - Who outside the government was involved in campaigning for or against the policy? Who ran the campaign? How and why did the campaign affect the policy?
  - Did the general public think about public-subsidized ART provision? Was there any strong public opinion for or against the policy? How and why did the public opinion affect the policy adoption?
  - What were the barriers and opportunities the adoption of universal ART policy? At the time of policy adoption, was the policy feasible and sustainable? Did you expect any negative effect of the policy (e.g. diversion of budget from HIV prevention programmes, encouraging unsafe sex behaviours among PLWHA, increasing drug-resistant HIV strains)?

#### 4. Policy formulation:

- What was the mechanism through which the policy was formulated? Were health care workers at the provincial and peripheral level consulted?
- Who were the key actors in the policy formulation? How did they get involved? What were the particular policy components focused by each actor? What were their concerns?
- What were the most controversial issues in designing universal ART programme? Who made the final decisions? How did s/he convince other actors involved in the policy making process to accept her or his ideas?
- How were lessons drawn from the pilot ART programme in Thailand, established ART programmes in other countries, and international recommendations affect the design of universal ART programme?
- What were the expected obstacles to implementing universal ART policy? What were the measures to deal with those obstacles?
- How did you get involved in the policy formulation? What were the best and worst components of the universal ART policy? At the time of policy formulation, what did you think about the technical feasibility and political desirability of the programme?

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**Section 2: Sub-national level policy process*****Questionnaire 1: Regional and provincial health officers/hospital directors/NGO staff***

- (1) Personal background
  - What was your background?
  - When did you first get involved in ART delivery? Have you been continually involved?
  - [NGO staff] When was your organisation established? Is it domestic or affiliation of other agency? What are the main objectives and activities?
- (2) What are the major HIV problems in this province – how have they impacted on your organisation? How has this changed since ART became available?
- (3) What have been the main developments in ART policy in this province? [hospital director] When did your hospital join the national programme – why?
- (4) What information have you received from the Disease Control Department on ART? How was the information conveyed? Were you consulted in the process – how? What were your concerns?
- (5) What guidelines did you receive? What follow up support have you received – has it been useful?
- (6) How was the universal ART policy integrated into the provincial health delivery system? Was there any consultation between the Regional Disease Control Office, Provincial Health Office (PHO) and key stakeholders at the peripheral level, e.g. director of district and provincial hospitals, NGOs, PLWHA, community leaders?
- (7) What were the implications of ART for human resources, training, drug distribution, treatment systems, laboratories, and financing in this province/your organisation?
- (8) What has been the outcome of the ART policy monitored: numbers on treatment, proportion of quota met, adherence/dropout rate, PLWHA health, quality of life, productivity?
- (9) What is the relationship between your organisation and others such as Regional Disease Control Office, PHOs, provincial hospital, district providers, NGOs, PLWHA groups, communities? When and how often do you meet formally? Do you have other informal interaction?
- (10) What have been your major constraints to scaling up ART? How have you managed to overcome these constraints? How will they change as the ART programme expands further?
- (11) What have been the positive aspects for you of scaling up ART? Why were they so positive?

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***Questionnaire 2: Hospital health professionals (clinicians, nurses, counsellors, pharmacists, laboratory scientists)***

- (1) Personal background:
  - What was your background?
  - When did you first get involved in ART delivery? Have you been continually involved?
- (2) What have been the main developments in ART programme in this hospital? When did the hospital director decide to participate in the National ART Programme - why? Was there any consultation between the director and key stakeholders, e.g. hospital staff, networking health facilities (district hospitals and health centres), and NGOs?
- (3) What is your responsibility in providing HIV treatment and care – how has it changed with the arrival of ART?
- (4) What information and guideline have you received from the Disease Control Department on ART? How was the information conveyed? Have you ever been trained in ART delivery? What were your concerns?
- (5) What have been the complexities in ART delivery in professional/technical aspects (e.g. prophylaxis and treatment of opportunistic infections, promotion and assessment of treatment adherence, promotion of safe sex practice, home visit, counselling service, drug information provision, performing laboratory test, specimen management)? What are the hospital's measures to deal with them? How effective are these measures? (if not effective) Why?
- (6) What have been your major administration constraints to deliver ART? How have you and your hospital managed to overcome these constraints? How will they change as the ART programme expands further?
- (7) What follow up support, including supervision, have you received from national, regional and provincial agencies – has it been useful?
- (8) What were the implications of ART for work load, case complications, management system in your department, risk of disease transmission to health care workers?
- (9) What support have you received from hospital director, colleagues, external experts, NGOs/patient networks?
- (10) What have been the positive aspects for you of scaling up ART? Why were they so positive?

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**Questionnaire 3: PLWHA group leaders**

- (1) Have you ever sought care from other facilities? What are the supportive factors for you to seek care at the hospital? Have these elements been improved during the past 2 to 3 years – in what aspects?
- (2) How did you get the information on ART provision at this hospital? What was your impression when you first got the information? What were your concerns? Who was the key person encouraging you to seek the treatment? How did this person help you to make the decision?
- (3) How long have you taken ARVs? What is the most important support you have got from hospital staffs, NGOs and your colleagues that encourage the adherence? From your experience, what do you feel about the health effects of ART? Is there any significant improvement or deterioration? What symptoms are serious? Have you got any support to manage these symptoms – from whom?
- (4) If you have a chance to talk to a friend who is HIV infected, will you recommend him/her to receive ARVs at this hospital – why? What information you would like to convey to your friend?
- (5) How long have you participated in this PLWHA group? How often the group meetings are organised? What are the activities carried out by group members? How has this group supported the members to access to treatment and care? What are the constraints in group management? Has your group got any support from the hospital director and health care staff – how?
- (6) What is the relationship between your group and others such as Regional Disease Control Office, PHOs, provincial hospital, district providers, NGOs, PLWHA groups, communities? Has your group got any support from them – how?

## APPENDIX 2: LIST OF INFORMANTS

In this thesis 80 persons were formally interviewed, using the semi-structured questionnaires as interview guide (Appendix 1). Furthermore, 22 persons were consulted by the investigator in order to clarify and triangulate particular points. See tables A1 and A2 for lists of interviewees and other informants.

**Table A1: List of interviewees**

No.	Job title	ID	Interview date
1.	Health Minister	N01	26 November 2003
2.	Secretary General, National Health Security Office	N02	21 January 2004
3.	Expert, Disease Control Department	N03	15 January 2004
4.	Expert, Disease Control Department	N04	27 November 2003
5.	Director, Thai-US Collaborating Centre for HIV/AIDS Research	N05	16 January 2004
6.	Director, Bureau of AIDS, Tuberculosis and Sexually-Transmitted Infections	N06	6 October 2003
7.	Technical Officer, Bureau of AIDS, Tuberculosis and Sexually-Transmitted Infections	N07	5 November 2003
8.	Technical Officer, Bureau of AIDS, Tuberculosis and Sexually-Transmitted Infections	N08	9 April 2004
9.	Counsellor, Bang Rak Sexually-Transmitted Infections hospital	N09	16 December 2003
10.	HIV specialist, Faculty of Medicine, Chulalongkorn University	N10	6 February 2004
11.	Director, International Health Policy Programme	N11	24 December 2003
12.	Research fellow, International Health Policy Programme	N12	17 December 2003
13.	Director, Research and Development Institute, Government Pharmaceutical Organisation	N13	24 December 2003
14.	Deputy Director, Research and Development Institute, Government Pharmaceutical Organisation	N14	12 January 2004
15.	Director, AIDS Access Foundation	N15	18 December 2003
16.	Staff, National Network for PLWHA	N16	23 December 2003
17.	Director, Centre for AIDS Rights	N17	22 January 2004
18.	Columnist, Bangkok Post newspaper	N18	20 November 2003
19.	Associate Professor, Faculty of Pharmaceutical Science, Chulalongkorn University	N19	22 January 2004
20.	Manager, Pond Chemicals, Co. Ltd	N20	15 January 2004
21.	Manager, T.O. Chemicals, Co. Ltd	N21	22 January 2004
22.	Chief, HIV and STI Division, Regional Disease Control Office, Region 9	R01	11 June 2004
23.	Chief, HIV and STI Division, Regional Disease Control Office, Region 3	R02	10 May 2004
24.	HIV specialist, Cholburi provincial hospital and Regional ART programme consultant, Region 3	R03	10 May 2004
25.	Health Official, HIV and STI Division, Regional Disease Control Office, Region 3	R04	10 May 2004
26.	Social worker, HIV and STI Division, Regional Disease Control Office, Region 11	R05	17 November 2003
28.	Health official, Provincial Health Office, Phichit	R06	11 June 2004

No.	Job title	ID	Interview date
29.	Health official, Provincial Health Office, Rayong	R07	23 April 2004
30.	Director, Camillian Social Centre, Rayong	R08	23 April 2004
31.	Director, Thai Network for PLWHA, Eastern Region Office	R09	23 April 2004
32.	Pharmacist, HIV and STI Division, Regional Disease Control Office, Region 3	R10	10 May 2004
33.	HIV Programme Manager, Holt Sahathai Foundation, Southern Region Office, Nakhon Si Thammarat	R11	17 November 2003
34.	Head, Preventive Medicine and Community Health Department, Phichit provincial hospital	S01	23 July 2004
35.	Clinician, Medicine Department, Phichit provincial hospital	S02	21 July 2004
36.	Clinician, Paediatric Department, Phichit provincial hospital	S03	23 July 2004
37.	Counsellor, HIV clinic, Phichit provincial hospital	S04	21 July 2004
38.	Pharmacist, Phichit provincial hospital	S05	23 July 2004
39.	Pharmacist, Phichit provincial hospital	S06	24 July 2004
40.	Director, Phichit provincial hospital	S07	24 July 2004
41.	Nurse, Phichit provincial hospital	S08	22 July 2004
42.	Nurse, Phichit provincial hospital	S09	22 July 2004
43.	Medical scientist, Phichit provincial hospital	S10	24 July 2004
44.	Nurse, Psychiatric Department, Phichit provincial hospital	S11	22 July 2004
45.	Leader, PLWHA group, Phichit provincial hospital	S12	21 July 2004
46.	Director, Sam Ngam hospital	D01	26 July 2004
47.	Nurse, HIV clinic, Sam Ngam hospital	D02	26 July 2004
48.	Pharmacist, Sam Ngam hospital	D03	3 August 2004
49.	Medical scientist, Sam Ngam hospital	D04	27 July 2004
50.	Leader, PLWHA group, Sam Ngam hospital	D05	27 July 2004
51.	Clinician, Thapkhlo hospital	D06	4 August 2004
52.	Nurse, Thapkhlo hospital	D07	4 August 2004
53.	Nurse, Thapkhlo hospital	D08	5 August 2004
54.	Pharmacist, Thapkhlo hospital	D09	4 August 2004
55.	Medical scientist, Thapkhlo hospital	D10	5 August 2004
56.	Leader, PLWHA group, Thapkhlo hospital	D11	5 August 2004
57.	Clinician, OBGYN Department, Rayong provincial hospital	S13	19 May 2004
58.	Clinician, Medicine Department, Rayong provincial hospital	S14	19 May 2004
59.	Clinician, Preventive Medicine and Community Health Department, Rayong provincial hospital	S15	21 May 2004
60.	Social Worker, Rayong provincial hospital	S16	18 May 2004
61.	Nurse, Preventive Medicine and Community Health Department, Rayong provincial hospital	S17	18 May 2004
62.	Nurse, Paediatric Department, Rayong provincial hospital	S18	21 May 2004
63.	Nurse, Ante-natal Clinic, Rayong provincial hospital	S19	19 May 2004
64.	Nurse, Out-Patient Department, Rayong provincial hospital	S20	24 May 2004
65.	Medical scientist, Rayong provincial hospital	S21	18 May 2004
66.	Pharmacist, Rayong provincial hospital	S22	24 May 2004
67.	Leader, PLWHA group, Rayong provincial hospital	S23	20 May 2004
68.	Leader, PLWHA group, Rayong provincial hospital	S24	20 May 2004
69.	Clinician, Klaeng hospital	D12	14 June 2004
70.	Nurse, Klaeng hospital	D13	14 June 2004
71.	Pharmacist, Klaeng hospital	D14	14 June 2004
72.	Medical scientist, Klaeng hospital	D15	15 June 2004
73.	Medical scientist, Klaeng hospital	D16	15 June 2004

No.	Job title	ID	Interview date
74.	Leader, PLWHA group, Klaeng hospital	D17	14 June 2004
75.	Director, Wang Chan hospital	D18	27 May 2004
76.	Clinician, Wang Chan hospital	D19	28 May 2004
77.	Nurse, Wang Chan hospital	D20	28 May 2004
78.	Medical scientist, Wang Chan hospital	D21	27 May 2004
79.	Pharmacist, Wang Chan hospital	D22	27 May 2004
80.	Leader, PLWHA group, Wang Chan hospital	D23	28 May 2004

**Table A2: List of other informants**

No.	Name	Job title
1.	Suwit Wibulpolprasert	Deputy Health Secretary, Ministry of Public Health
2.	Chaiyos Kunanusont	United Nations Population Fund, Thailand office
3.	Waranya Teukul	Technical Officer, Social Division, National Economics and Social Development Office
4.	Samrit Srithamrongsawat	National Health Security Office
5.	Busaba Tantisak	Technical Officer, Bureau of AIDS, Tuberculosis and Sexually-Transmitted Infections
6.	Peeramon Ningsanonda	Technical Officer, Bureau of AIDS, Tuberculosis and Sexually-Transmitted Infections
7.	Taweekiat Bunyapaisal-charoen	Provincial Chief Medical Officer, Ayudhaya
8.	Aphichart Rodsom	Chief, AIDS and Sexually-Transmitted Infections Division, Provincial Health Office, Nan
9.	Supaporn Wattanatorn	Chief, AIDS and Sexually-Transmitted Infections Division, Centre for Disease Control, Region 2
10.	Phanumas Yanavesakul	Chief, AIDS and Sexually-Transmitted Infections Division, Centre for Disease Control, Region 11
11.	Patcharee Si-chapaeng	Nurse, Preventive Medicine and Community Health Department, Phichit provincial hospital
12.	Ladda Thanompreechachai	Nurse, Preventive Medicine and Community Health Department, Rayong provincial hospital
13.	Opas Putharoen	Clinician, Panas Nikom district hospital, Cholburi
14.	Peerachat Chantako	Pharmacist, Pho Prathap Chang district hospital, Phichit
15.	Surachai Pai-pan	Health officer, Pho Prathap Chang district hospital, Phichit
16.	Supornpen Aksornwong	Pharmacist, Nakhon Si Thammarat provincial hospital
17.	Thapanee Karikarn	Nurse, HIV clinic, Nakhon Si Thammarat provincial hospital
18.	Nujaree Tulatharn	Nurse, Camillian Social Centre, Rayong
19.	Churnruethai Kanjanachitra	Professor, Institute for Population and Social Research, Mahidol University
20.	Sukontha Kongsin	Associate Professor, Faculty of Public Health, Mahidol University
21.	Niyada Kiat-ying-angsulee	Associate Professor, Faculty of Pharmaceutical Science, Chulalongkorn University
22.	Jongkol Lertiendumrong	International Health Policy Programme, Thailand

**APPENDIX 3: OUTLINE OF REVIEWED DOCUMENTS**

Category	Source of document	Information obtained
(1) Government documents (e.g. statements, declarations, minutes, guidelines, notices, letters, memorandum, reports, and database)	Responsible agencies, libraries, internet	<p>Policy context:</p> <ul style="list-style-type: none"> <li>▪ Policy-making institution: structures and procedures</li> <li>▪ Government policy</li> <li>▪ Economic and financial status: Gross Domestic Product, government budget</li> <li>▪ The profile of health system: health administration and service delivery, health financing system, health expenditure and sources of finance</li> <li>▪ HIV epidemiology and burdens of disease</li> <li>▪ National HIV/AIDS policy</li> <li>▪ Drug regulations: drug approval, pricing, patent</li> <li>▪ International relations: collaboration between Thai Government and international agencies</li> </ul> <p>Policy content:</p> <ul style="list-style-type: none"> <li>▪ ART policy content at the national and sub-national level: preparatory activities, coverage of ART in health benefit package, drug regimens, patient enrolment, availability and allocation of fundamental resources for ART provision, drug management, programme evaluation and monitoring, expected roles of local authorities, private health care settings, NGOs, PLWH/A networks and communities</li> </ul>
(2) International declarations, recommendations, guidelines, and manuals	Responsible agencies, libraries, internet	<ul style="list-style-type: none"> <li>▪ State of the art of international HIV treatment recommendations, internationally accepted regimens and experiences elsewhere</li> <li>▪ International collaborations and agreements in health, HIV/AIDS, pharmaceutical, and trade</li> </ul>
(3) Domestic and international journals	Libraries, internet	<ul style="list-style-type: none"> <li>▪ State of the art of international HIV treatment recommendation, internationally accepted regimens and experiences elsewhere</li> <li>▪ Efficacy, effectiveness and safety of different antiretroviral regimens</li> </ul>
(4) Books, research reports and other grey literature	Responsible agencies, libraries, internet	<ul style="list-style-type: none"> <li>▪ Socio-cultural parameters: values, norms, and beliefs relating to PLWHA and treatments</li> <li>▪ Political situation: government status, legitimacy, and popularity</li> <li>▪ Political environment of ART policy: public opinion and social movements</li> </ul>
(5) Domestic newspapers	News clipping service	<ul style="list-style-type: none"> <li>▪ Political situation: government status, legitimacy, and popularity</li> <li>▪ Political environment of ART policy: public opinion, social movement</li> <li>▪ Roles of principle actors</li> </ul>

Note: The actual documents are included in the Reference list.