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The Role of Forecasting, Price Negotiation and Procurement Management in Determining Availability of Antiretroviral Medicines (ARVs) in Mexico

By

Adebiyi Ola-Oluwa Adesina

A dissertation submitted in partial satisfaction of the

requirements for the degree of

Doctor of Public Health

in the

Graduate Division

of the

University of California, Berkeley

Committee in charge:

Professor Arthur Reingold, Co-Chair
Doctor Sandra Dratler, Co-Chair
Professor Ralph Catalano
Professor Philip Kaminsky

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Abstract

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Doctor of Public Health

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Professor Arthur Reingold, Co-Chair
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Ensuring an adequate supply of antiretroviral (ARV) medicines is a crucial part of providing uninterrupted treatment to people living with HIV/AIDS (PLWHA). Since adoption of a mandate to provide universal access to HIV care in 2003, Mexico has made considerable effort to provide PLWHA with access to antiretroviral treatment and medicines. In 2008, increasing concerns about supply chain efficiency, ARV availability and rising costs led the Mexican government to create an Inter-Institutional Commission to negotiate prices of ARVs and to improve the efficiency of forecasting, procurement and distribution of these medicines. The aim of this dissertation is to provide a descriptive analysis of ARV forecasting, price negotiation and procurement processes and practices among major health care providers in Mexico with the goal of identifying problems related to supply chain efficiency and ARV availability.

This research utilized estimated demand volume, procurement volume, and procurement price data for the most commonly prescribed ARVs in Mexico from 2003 to 2009. The global optimization model, which draws upon a comprehensive analytical framework, was used to assess performance, information integration, organization, and overall efficiency of the supply chain. The quantitative analysis is linked with qualitative data generated from a review of pharmaceutical and ARV policy documents and interviews with key informants. Interviews were conducted with physicians, pharmacists and program managers involved in decisions surrounding ARV supply at the national and hospital levels. The majority of informants were staff from the *Secretaria de Salud* (SSA) /Ministry of Health and the *Instituto Mexicano del Seguro Social* (IMSS) health systems, which together serve more than 90% of PLWHA in Mexico. Secondary data were also obtained from interview notes with representatives of pharmaceutical companies in Mexico. Findings from the study were presented for two periods – pre-inception (January 2003 – September 2008) and post-inception (October 2008 – November 2009) of the Commission.

Pre-Commission findings indicate a paucity of data on ARV supply chain in Mexico, which reflects the dearth of information on the drug supply chain generally. The limited data available indicate that when patient ARV need is compared to volume procured, both of

Mexico's health systems experience varying levels of shortages and surpluses of ARV. Shortages of ARVs in the SSA health system appear to have been alleviated by the introduction of SALVAR – the patient and ARV management information system (MIS). For IMSS, the lack of a similar standardized MIS and lack of access to forecast and procurement data made it difficult to assess ARV shortages beyond one year. In IMSS, more so than in SSA, procurement of single ARV pills to compensate for combination ARV pills, as well as surplus procurement of ARV, indicate limited integration of information between forecasting and procurement stages of the supply chain that likely leads to waste of resources. Analysis of annual price and volume data from 2003 to 2008 showed that despite a substantial increase in the annual volume of ARVs procured, ARV prices did not decrease. Additionally, a comparison of ARV prices in Mexico to other upper-middle income countries showed that Mexico has been paying substantially higher prices for ARVs. Overall, the findings indicate inefficiencies in the ARV supply that are likely to be detrimental to patient well-being and costly to the health systems, which have limited resources.

Post-Commission findings show that the Inter-Institutional Commission successfully negotiated lower ARV prices in 2008 and 2009. Despite these savings, Mexico continues to pay more for ARVs than comparable countries. Additionally, costs associated with procurement of surplus ARVs and lack of overall changes in organizing and integrating information across stages of the ARV supply chain suggest the Commission has yet to implement a comprehensive approach to improving efficiency in the purchasing and delivery of ARVs. Lastly, the overall estimated cost of surplus ARVs exceeded initial savings from lower prices, further suggesting that there is a need for cost containment strategies that go beyond price negotiation.

In conclusion, factors hindering efficiency of ARV delivery identified in the findings are discussed with recommendations for improving supply chain efficiency. To improve efficiency of ARV delivery and availability the Mexican government should 1) improve data collection and coordination of information across stages of the supply chain by strengthening information management capacity, 2) establish a support system to monitor and provide feedback concerning to the quality of patient treatment and 3) strengthen the Commission's role by providing additional resources and ensuring clarity in its tasks, responsibilities and goals.

While this study is not exhaustive in accounting for every aspect of the ARV supply chain in Mexico, it addresses the need for a better understanding of the delivery of ARVs and identifies areas for future research relating to ARV supply chain management.

Dedication

For my parents, Omolara and Olujuwon Adesina

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I am truly grateful for the assistance of my dissertation committee. Professor Art Reingold provided valuable feedback on my manuscripts ensuring that my research is methodologically sound and written in a clear, appropriate, and accurate manner. When I was struggling with clarifying the details and overarching theme of my dissertation, Professor Ray Catalano took the time to help me lay out the case for why my dissertation was an important addition to research and the field of public health. Professor Philip Kaminsky guided me in translating theory into practice in the form of an evaluation framework and always made himself available. In addition to my dissertation committee, other faculty at Berkeley have been essential in inspiring and mentoring me, especially Norm Constantine, Amani Nuru-Jeter, Cheri Pies, Linda Neuhauser and Michael Jerrett.

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My deepest appreciation goes to my family for their boundless support. My siblings and their families, Adewole, Adebowale, Oyebimpe, Omotunde, Adebusola, Yetunde, Omolara and Olakanmi, were always ready to remind me to appreciate time with loved ones. I have dedicated my dissertation to my parents, who from as far as I can remember encouraged me to always ask questions and be humble enough to understand the answers.

Finally, I thank all of the people who were interviewed for their openness and willingness to speak with me. Each time I read the interviews, I am reminded that there are a number of people who are sincerely committed to improving the lives of the most vulnerable populations in our world. Your lives and your work are truly inspirational.

ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral Medicine
CENSIDA	Centro Nacional para la Prevención y el Control del VIH/SIDA/National Center for the Prevention and Control of HIV/AIDS
GPRM	Global Price Reporting Mechanism
HIV	Human Immunodeficiency Virus
IMSS	Instituto Mexicano del Seguro Social
ISSSTE	Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado
MIS	Management Information System
PAHO	Pan American Health Organization
PLWHA	Person/People Living With HIV/AIDS
PPY	Price per Patient per Year
SALVAR	Sistema para la Administración, Logística y Vigilancia de ARV
SCM	Supply Chain Management
SSA	Secretaría de Salud/Ministry of Health
USAID	United States Agency for International Development
WHO	World Health Organization

CHAPTER I: INTRODUCTION

Over the last decade, there have been considerable global and national efforts to provide people living with HIV/AIDS (PLWHA) access to treatment and care. The scale up of initiatives from the World Health Organization's (WHO) 3 by 5 program to Mexico's Universal Access program has significantly increased the number of PLWHA receiving antiretroviral treatment (ART). Antiretroviral (ARV) medicines reduce the HIV viral load to very low levels and allow the immune system to recover, thereby improving quality of life and reducing the risk of premature deaths (WHO, 2009). Ensuring that ARVs are made available at the right quantity in the right places and to the right people at the right time and at an accessible cost is crucial to improving access to treatment. The drug supply chain is the means by which these essential medicines are delivered to patients. The ARV supply chain is particularly complex because of the nature of ARVs. For example, the majority of ARVs have a shelf-life of 6-24 months; need temperature-controlled storage; have a high purchase price; lack alternative options for buyers due to patent protection, are taken in combination with other ARVs; and are given in treatment protocols that often change as new medicines become available (Deliver, 2006). Efficient management of the drug supply chain is contingent upon systematic coordination of health system resources and mechanisms that ensure adequate supply of ARVs. The purpose of this study is to explore the relationship between the management of key stages of the supply chain: forecasting, price negotiation and procurement, and availability of ARVs in Mexico.

A. Background

1. Mexico and HIV/AIDS

Mexico is a federal republic comprising 31 states, a federal capital district and, as of 2007, a population of 106 million (PAHO, 2007). In that same year, the estimated Gross Domestic Product (GDP) was $1.486 trillion and per capita income was $8,340 (World Bank, 2009). Despite being categorized by the World Bank as the second largest economy in Latin America, Mexico continues to experience persistent poverty and rising rates of poverty and inequality in both income and health status (World Bank, 2009). According to World Bank officials, an estimated 40% of the population live in poverty and 18% live in extreme poverty (2009). Data show that in 2005 Mexico spent 6.4% of GDP or $725 per capita on health expenditure (OECD, 2009), the lowest of the middle and high income countries that constitute the Organization of Economic Co-operation and Development (OECD) (OECD, 2005).

HIV/AIDS is the16th leading cause of death in Mexico. As of December 2006, there were 182,000 known cases of HIV/AIDS, with a population prevalence of 0.3% (CENSIDA, 2007). Although the prevalence of HIV/AIDS is seemingly low, in 2006 Mexico had the third largest population of PLWHA in the Americas after Brazil and the United States. The Mexican government has made considerable efforts to ensure that PLWHA receive care as part of the goal of curbing the spread of the disease. In 2001, the government mandated universal access to treatment that, beginning in 2003, included ART and ARV access for PLWHA through all of its national health systems.

2. Health Coverage and HIV/AIDS Care in Mexico

The health system in Mexico is highly fragmented. As in other Latin American countries, access to health insurance is largely related to employment in the formal sector (i.e. employment for which wages are taxed by the government). The majority of insured persons are covered through a package of employee benefits, also known as "social security" benefits. In 2005, health care systems provided health insurance coverage to approximately 56.4 million people representing 53% of those who received health services (WHO, 2009). Three major health systems provide the majority of care in Mexico. The largest of the three is the *Instituto Mexicano del Seguro Social* (IMSS), or Mexican Institute for Social Security, which covers ~ 79% of people with health insurance. This is followed by the *Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado* (ISSSTE), or the Insurance and Social Service Institute for State Workers, covering about 19% of the insured population. Workers in the informal economy, the rural uninsured, and the unemployed accounted for nearly 45 million people who received health services in 2005. This population receives care through the safety net services provided through the *Secretaría de Salud*, or Ministry of Health (PAHO, 2007).

Each health system has its own financing mechanisms, service delivery structure, and network of clinics and hospitals (Frenk et al., 2003). These three systems, shown in Figures I.1 and I.2, serve the majority of patients receiving ART in Mexico.

The *Secretaría de Salud (SSA) & Seguro Popular* is managed and financed by the Ministry of Health/ SSA. In 2004, the government began offering a new insurance system called Seguro Popular or People's Health Insurance as part of its Social Protection and Health System. The program provides coverage for individuals and families (mostly working in the informal sector) who do not have access to insurance through employment benefits, who are unable to purchase private health insurance, and/or who are paying out of pocket for private health care (Frenk et al., 2003). SSA's structure allows states to have management autonomy from the federal government with some exceptions. For instance, HIV/AIDS care and ARV planning and procurement are centrally managed at SSA's national level by the *Centro Nacional para la Prevención y el Control del VIH/SIDA* (CENSIDA). CENSIDA monitors patient care, forecasts the need for ARVs, and determines the amount of ARVs to be purchased. The cost of ARVs in SSA is covered by the *Fondo Catastrófico* (Catastrophic Fund) and ARV expenditures are not capped. According to SSA, 23,245 patients were on ARVs as of December 2007 (CENSIDA, 2008; Hernandez, 2008; Ortiz, 2008).

The *Instituto Mexicano del Seguro Social* (IMSS) serves private sector employees retirees and their families. IMSS is financed through general federal taxes and employer and employee payroll taxes (Frenk et al., 2003). IMSS operates through a decentralized structure that is similar to ISSSTE; the difference is that autonomy exists at the state level known as the *delegación* (delegation). In IMSS, HIV/AIDS care, as well as ARV planning and procurement, is decentralized. As of December 2007, 20,889 PLWHA were enrolled in the system (Diaz, 2008), of whom 19,836 were receiving ART (CENSIDA, 2006; Ortiz, 2008).

The *Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado* (ISSSTE) provides services to public sector employees (i.e. federal and state government workers), retirees

and their families. It is financed through general federal taxes, as well as through employer payroll taxes. ISSSTE has a decentralized structure, similar to SSA's, that allows for some autonomy at the state level. As in SSA, HIV/AIDS care and ARV planning and procurement is coordinated centrally by the Department of HIV/AIDS and STIs located at ISSSTE's national office. As of December 2007, ISSSTE officials reported that 3,415 of 3,478 PLWHA enrolled in the system were receiving treatment from 40 ISSSTE clinics and hospitals across the country (Ortiz, 2008; ISSSTE, 2008).

According to WHO, people receiving care account for 74% of PLWHA eligible for treatment[1] in Mexico (WHO 2009). About 98% of those receiving care are served by SSA, ISSSTE and IMMS. The remaining 2% of patients receive treatment through private health clinics or health systems, such as the Petroleum Employee Benefits (PEMEX) and the Armed Forces Benefits (SEDENA), or through the private sector (Ortiz, 2008).

B. Problem Statement

Despite efforts to provide ARVs to PLWHA in Mexico, there are concerns about availability of ARVs among the three major providers of care. In 2003, Bautista et al. conducted an analysis of the cost of HIV/AIDS treatment in Mexico and noted that "patients may be forced to stop their medication because of [shortages] in the hospital pharmacy or the inability to pay for medication" (2008). Changes in the nature and treatment of HIV/AIDS have also contributed to significant increases in expenditures for ARVs by Mexico's health care system. An analysis of ARV prices conducted by SSA showed that for some medicines, there was significant price variation across health systems. This analysis also showed that on average, Mexico was paying higher prices for ARVs than developing countries. For example, the average price of lamivudine in Mexico was 45 times more than the average price of the same product in developing countries (Pesqueira-Villegas, 2008).

Spurred by concerns over escalating drug costs and the consequent impact on availability of medicines, President Calderon issued a decree in February 2008 which resulted in the creation of the National Inter-Institutional Commission (DOF, 2008). The newly-created body has been tasked with coordinating price negotiations for patented medicines and medical devices on behalf of the major health systems, as well as providing guidance on how to improve their respective drug supply chains.

The paucity of data on specific aspects of the ARV supply chain in Mexico indicates a clear gap of knowledge about the role supply chain management plays in ensuring availability of ARVs. Additionally, the creation of the Inter-Institutional Commission, particularly its development of policies intended to guide management of the supply chain, indicates major concerns about effective ARV delivery. These concerns are part of a larger set of challenges that include medication shortages, disruption of individual treatment regimens, enhanced potential for

[1] The number of people eligible or in need of ART care is defined by the WHO as the "proportion of people with HIV infection out of the total population of the country or the selected geographical area, the number of people who are estimated to know their HIV status, who access HIV/AIDS care, who need ART according to the guidelines, and who ultimately will take antiretroviral treatment."

the development of drug resistant strains of HIV, high variation in drug costs, and unnecessary system expense (Bautista et al., 2003; Pesqueira-Villegas, 2008). There are problems with the efficient delivery of ARVs to PLWHA resulting in shortages in supply of ARVs and high costs to both patients and health systems. The limited data that exist (Bautista et al., 2005; Gutierrez, 2008; Saavedra, 2008; Sierra Madero, 2008) suggest that these problems are a result of poor management of the supply chain, specifically, problems with forecasting, price negotiation and procurement. Identifying the source of these problems is a crucial first step to developing strategies to improving the availability of ARVs.

C. Specific Aims

The specific aims of this study are four-fold: 1) to describe forecasting, price negotiation, and procurement of ARVs in Mexico; 2) to examine changes to the ARV supply chain being implemented by the Inter-Institutional Commission; 3) to identify supply chain factors that constrain availability of ARVs, and 4) to offer recommendations aimed at improving management of the ARV supply chain.

D. Research Questions

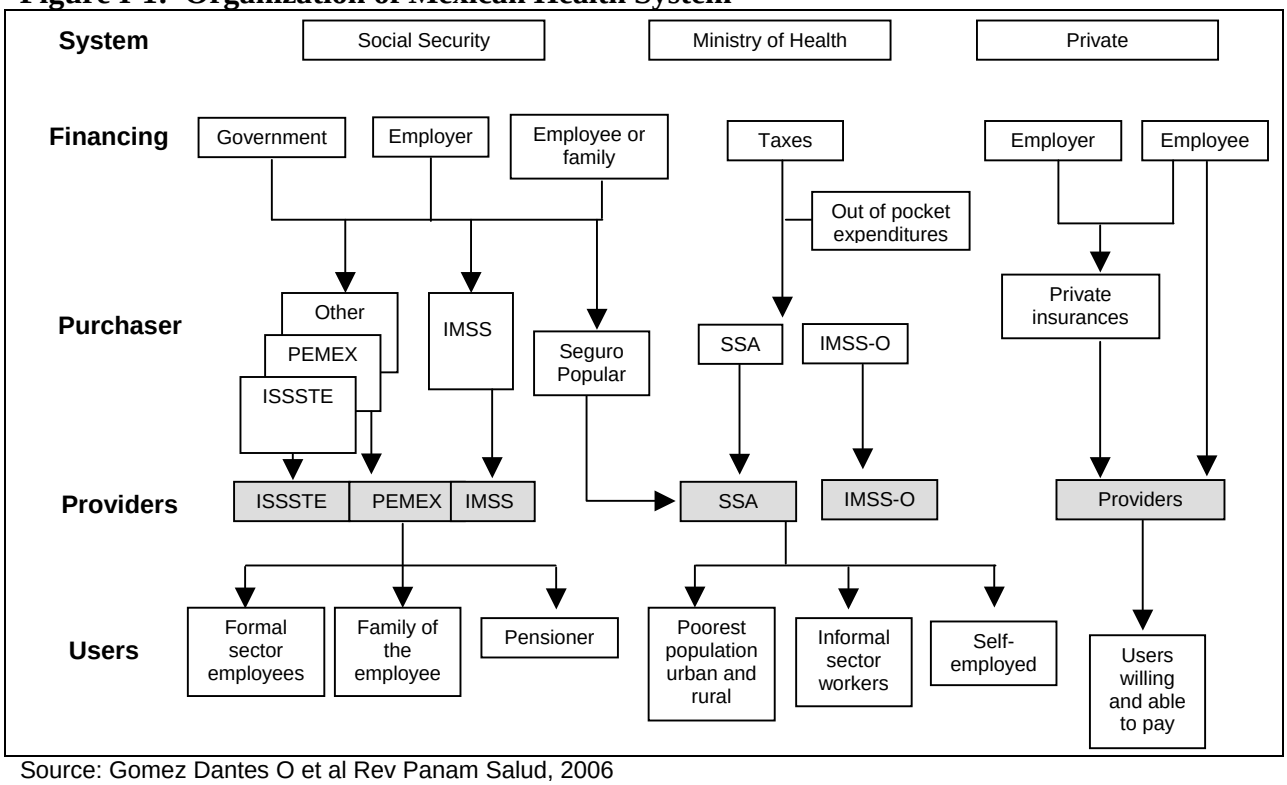
The following research questions and sub-questions were raised in order to address the concerns outlined above. These questions are:

1. How were ARV forecasting, price negotiations and procurement management conducted in each of the three systems before the creation of the Inter-Institutional Commission?
    - 1.1. What forecasting, price negotiation and procurement methods, indicators and performance measures were used before the creation of the Inter-Institutional Commission?

2. What changes has the Inter-Institutional Commission introduced to forecasting, price negotiation, procurement management and overall availability of ARVs in the three health systems?
    - 2.1. What factors hindered supply before the creation of the Inter-Institutional Commission?
    - 2.2. Did the Inter-Institutional Commission address its primary goal of lowering price of ARVs in the three health systems?
    - 2.3. How has the Inter-Institutional Commission changed (current and expected) forecasting, price negotiation and procurement policies and procedures to improve availability of ARVs?

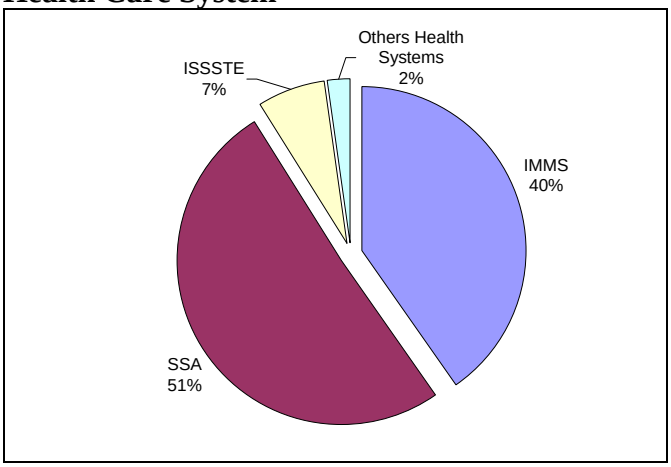
3. What supply chain management factors constrain availability of ARVs?
    - 3.1. What factors continue to constrain supply chain management and ARV availability?
    - 3.2. What policies and procedures can be recommended to improve availability of ARVs through the commission and/or each health system?

Figure I-1: Organization of Mexican Health System



Source: Gomez Dantes O et al Rev Panam Salud, 2006

Figure I-2: Proportion of People Living with HIV/AIDS on Antiretroviral Therapy by Health Care System



Source: CENSIDA, 2007

CHAPTER II: DRUG SUPPLY CHAIN MANAGEMENT

A review of the literature for definitions and measures as well as standards for evaluating the supply chain was conducted. Publications were identified using the following databases and search engines: PUBMED, ISI Web of Science, Institute for Industrial Engineering (INSPEC) and Google Scholar, as well as the websites of international health organizations such as the WHO, United States Agency for International Development (USAID) Project Deliver, John Snow International and Management Sciences for Health (MSH). Search terms used included: supply chain, drug/medicine supply chain, forecasting, price negotiation, procurement, ARV supply, ARV/drug delivery and ARV/drug availability.

The literature search netted 22 published sources – an edited work by MSH in collaboration with the WHO (Quick et al., 1997), a guide by USAID Project Deliver also in collaboration with the WHO (2006), a WHO survey report (2007) on demand and forecasting methods globally and 19 articles published in peer reviewed journals. The edited work and guides focused more on two key factors – 1) highlighting commonly used methods for defining and measuring the different stages of drug supply chain and 2) posing key questions necessary for implementing and enhancing a supply chain system. Of the 19 peer reviewed articles, only five discussed evaluation or assessing efficiency of the supply chain in detailed terms related to one or more of its stages.

A. Stages of the Drug Supply Chain: Forecasting, Price Negotiation and Procurement Management

The drug supply chain or logistics network consists of a system of people, organizations and resources involved in moving medicines from the manufacturer to the patient (Mentzer et al., 2001; Simchi-Levi et al., 2008). From the health system perspective the supply chain includes the manufacturer, which produces the medicines; the distributor, which transports the medicines to the buyer (in this case the health system); and finally, the patient (Mentzer et al., 2001).

Management of the supply chain involves the coordination of "a sequence of functions that guarantee uninterrupted supply of the right quality and quantity of ARV drugs" (Deliver 2006). MSH and USAID describe these functions as a cyclical process that involves 1) selection of medicines based on a nationally approved drug formulary; 2) forecasting/estimating the quantity of medicines required to serve a particular population; 3) procurement of the medicines; 4) distribution/transportation of the medicines from the manufacturer to pharmacies; and 5) use by the patient/consumer (Quick et al., 1997; Deliver, 2006). After delivery is made to the patient/consumer, the supply chain loops back into the forecasting process and the cycle repeats itself. Supply chain management also includes the integration of information by decision-makers within and across the different organizations and the supply chain for efficient delivery.

In light of the Mexican government's creation of the Inter-Institutional Commission and its goals for consolidating the price negotiation process, this paper will address the management of supply chain involved in price negotiations and stages only proximal to price negotiation (i.e., forecasting and procurement).

Forecasting is defined as the process of estimating the type and volume of drugs required to provide treatment for a specified number of people (Quick et al., 1997; Deliver, 2006; Simchi-Levi et al., 2008). The description of forecasting methods falls into two major categories – the epidemiological/consumption approach and the normative/morbidity-based approach (Quick et al., 1997; Deliver, 2006). The epidemiological/consumption approach utilizes data on previous ARV consumption to project future ARV volume for the selected time period. On the other hand, the normative/morbidity method uses a "best-case scenario" approach by combining epidemiological data showing shifts in disease incidence with the number of people expected to receive treatment and assumes full implementation of treatment guidelines. These data are then used to project the number of patients and quantity of medicine expected to receive treatment over the period in consideration.

Price negotiation, the process by which buyers and sellers arrive at an agreed upon price and volume of ARV (Table II-1), was not as clearly illustrated in the literature as forecasting. As described in Quick et al., price negotiation is considered part of the procurement contracting process, in which drug suppliers/manufacturers and buyers arrive at agreements as to the price and quantity of drugs to be acquired (Quick et al., 1997). Methods for creating procurement contracts include: 1) open tender, where suppliers/manufacturers are invited to submit price quotes; 2) reduced tender, where interested suppliers are required to fulfill certain standards before submitting price quotes; 3) competitive negotiations, where a buyer selects a "limited number of selected suppliers (typically at least three) for price quotations" and 4) direct procurement, where the buyer has two choices - direct purchase from a single supplier either at a quoted price or to negotiate the price.

Two of the three sources described procurement as the development of a contract that states a specific quantity, type(s) of drug and unit price (Table II-1). Key deciding factors in the procurement process were noted to be highly dependent on the forecasting process and other crucial factors, such as timing of order and receipt, contract management, logistical systems for monitoring storage, distribution and use, and inventory management (Quick et al., 1997; Deliver 2006; Simchi-Levi et al., 2008).

B. Evaluating Efficiency of the Drug Supply Chain

The review of published literature on supply chain management revealed a dearth of existing theoretical frameworks for evaluating supply chain management of medicines and in particular the forecasting, price negotiations and procurement of antiretroviral medicines.

Agwanda et al. conducted an evaluation of a regional drug supply chain in Kenya (1996). In order to determine whether forecasting and procurement of essential medicines matched morbidity patterns in rural health facilities in the Kirinyanga district, the authors conducted a multivariate analysis of data gathered from out-patient registers, patient clinic use, medical records and staff and patient interviews. Results of the evaluation showed a significant difference between the volume of drugs forecasted and the volume of drugs supplied, indicating that drug supply did not match morbidity patterns. This disparity resulted in a lack of availability of essential drugs. The authors also noted that there was a delay in procurement/distribution due to

the Ministry of Health's tendering process and that lack of transportation added another constraint to drug availability. The authors concluded by recommending a distribution system for essential drugs based on the needs of the two broad regional divisions of the district.

Yusuf and Tayo's evaluation of the Nigerian Drug Supply utilized a qualitative approach (Yusuf and Tayo, 2004). The authors conducted interviews with key informants in the drug procurement unit and central medical store of Department of Food & Drugs in order to identify challenges to the supply of essential drugs to public hospitals and clinics. They found that financing of the drug supply and distribution was "inadequate to ensure sustained availability of essential drugs." Additional factors that hindered the availability of drugs included "late order placement, delay in payment and poor supplier lead-time mainly attributable to lateness in payment for previous drug supplies, poor distribution as a result of vehicle shortage and lack of a functioning drug management information system." These factors led to expiration and spoilage, resulting in significant losses. The authors concluded by suggesting the need for reforms that include the creation of an autonomous drug supply agency to ensure efficiency and sustainability in the delivery of essential medicines.

In their assessment of the impact of decentralization on essential medicines logistics, Bossert et al. showed that certain functions of the supply chain were better suited for a model in which the bulk of decision-making was conducted at the national level (centralized) while other functions were better suited to a model in which the bulk of decision-making was conducted at the local (state/district/hospital) level (Bossert et al., 2006). The centralized model was associated with better supply chain performance with regard to inventory control (i.e. monitoring forecasting and procurement volumes) and information systems (tools for monitoring demand, procurement and consumption of essential medicines). On the other hand, the decentralized model was associated with better performance with regard to planning (assessing number of patients and ARV needs) and budgeting (assessing resources required to meet patient needs). In both models, however, the authors noted decision-makers at different levels played roles in ensuring better performance. In the centralized model, local level decision makers were trained and involved in data collection for inventory control and information systems while in the decentralized model, national level decision-makers were involved in reviewing and approving local plans and budgets.

Vasan et al. studied ARV pricing and procurement behavior using data from The Global Fund to Fight AIDS, Tuberculosis, and Malaria Purchase Report on ARV prices (Vasan et al., 2006). Publicly available data from ARV purchases contained data concerning ARV prices and quantities from which the authors selected ten of the most commonly available ARVs in treatment programs. This study showed higher variability in ARV prices in lower-middle income countries than in lower income countries. Additionally, there were several instances in which the prices of certain ARVs (lopinavir/ritonavir, didanosine, and zidovudine/lamivudine) "were significantly higher" than the highest analyzed prices quoted by the patent-holding company. According to the study results, many lower middle-income countries are often as financially constrained as low income countries when purchasing ARVs. The authors argue that reduction in ARV prices is necessary for scaling-up of treatment programs for PLWHA in a sustainable way. The authors concluded that there needs to be better use of cost-efficient procurement choices. A key strategy suggested for achieving a reduction in ARV prices, was to make ARV procurement

data (such as price and volume of ARVs purchased) transparent and publicly available, giving purchasing bodies access to information needed to negotiate better prices.

Seoane-Vazquez and Rodriguez-Monguio conducted a mixed methods analysis of the 2003 round of negotiations by six Andean countries in order to 1) assess problems faced during negotiations, 2) evaluate the impact of the negotiation on ARV prices and 3) identify factors that hinder countries from being able to purchase ARVs at negotiated prices (Seoane-Vazquez and Rodriguez-Monguio, 2007). Findings showed that 1) despite achieving lower ARV prices, negotiating countries lacked the detailed data necessary to achieve even lower prices, 2) participating countries ended up purchasing the bulk of their ARVs at higher prices than those negotiated, and 3) government purchases did not have contractual clauses necessary to ensure that participating pharmaceutical companies would not raise ARV procurement prices. In future negotiations, the authors suggested better coordination of information (drug procurement data and government policies), coordination of financial resources and increased participation by domestic generic companies (Seoane-Vazquez and Rodriguez-Monguio, 2007).

C. Gaps in the Literature

This literature review identifies two key themes necessary to understanding the ARV supply chain in Mexico. First, it provides a starting point from which the ARV supply chain can be better described, assessed and understood. In the case of Mexico, where there is a lack of published data regarding the ARV supply chain, the literature provides various definitions, indicators and methods for collecting data and assessing performance of the key stages of the supply chain. For example, Agwanda et al. compared forecast volume to procurement volume to assess how procurement meets estimated patient needs. For their analysis, Vasan et al. compared the price of ARVs quoted by manufacturing companies and the actual price at with the ARVs were purchased to assess price variation across countries with similar economic standings. Seoane-Vazquez and Rodriguez-Monguio collected data on negotiated prices and procurement prices of ARVs through interviews and publicly available sources to assess the impact of price negotiation on procurement price. These studies offer a variety of approaches to identify and collect data which describe and assess the ARV supply chain in Mexico.

Second, there is a gap in existing frameworks for evaluating the supply chain. The literature reviewed strongly suggest that performance benchmarks such as price variation between similar buyers or percentage difference in volume between forecast and procurement volumes have to be specific to context. As a result, developing benchmarks requires a preliminary assessment of measures used by program managers in Mexico to assess performance.

Third, a conclusion consistent across the majority of the articles reviewed was the need to incorporate other stages in improving effectiveness in the supply chain. For example, Agwanda et al. proposed implementing a system that informs the procurement process with accurate forecasting. Similarly, Seoane-Vazquez and Rodriguez-Monguio propose the coordination indicators for forecasting, price negotiation, and procurement in a manner that ensures reduced costs and improves availability of ARV. Both of these examples suggest a need for not only

coordinating different functions of the supply chain, but incorporating different indicators that measure performance of the supply chain.

D. Developing a Conceptual Framework and Selecting Indicators and Measures

Given the recent pharmaceutical policy focus on cost minimization, a key question to ask is; "what is the best approach to reduce cost through lower prices and better forecasting and procurement?" Global optimization is the theoretical basis for the comprehensive approach suggested in the reviewed literature and the principle behind the creation of the commission. Global optimization is a concept that argues that components of the supply chain are closely interconnected parts that work together to ensure effective management and subsequently, effective delivery of products (Simchi et al., 2008). Simchi-Levi, Kaminsky and Simchi-Levi (2008) describe this global optimization as a process that "takes into account the interaction between the various levels of the supply chain and identifies strategies that maximize supply chain performance." This concept suggests that optimizing one component of the supply chain without considering the impact on one or more of the other components may not translate into a cumulative enhancement of the supply chain system as a whole. Rather, it is crucial to recognize that stages of the supply chain are closely connected and optimizing individual stages as well as the coordination between them is essential to improving the overall efficiency of the supply chain.

While the proposed framework is limited to three of five stages of the drug supply chain, it captures the essence of global optimization – i.e., when focusing on forecasting, price negotiation and procurement the best approach to minimizing supply chain cost is to understand interaction and integration across these three stages. To this end, it draws from tested indicators and measures of performance from the literature to provide as comprehensive a tool as possible to identify factors that hinder integration across the three stages and to offer recommendations for improving integration and ultimately improving supply chain efficiency. The framework for a global optimization analysis expands the inquiry to assess the integration of the components as they relate to efficiency of the supply chain and ultimately, improved delivery of ARV.

A global optimization framework adds another layer of analysis by providing a lens through which the management of the supply chain can be assessed in conjunction with a description of how information from each stage is sequentially integrated into the decision-making process of other stages in the supply chain. To conduct this type of assessment, concepts from Value Stream Mapping (VSM) will be applied. VSM is a management tool that is used in logistics management to assess organization of the supply chain and coordination of information for enhancing supply chain efficiency (Abdulmalek and Rajgopal, 2007). As a tool, VSM identifies the types of data (indicators and measures) and processes in which these data are used to make management decisions. Table II-2 provides a taxonomy of common supply chain process indicators and performance measures found in the literature as well as additional indicators for assessing how information is organized and integrated into managing the supply chain.

The section on indicators and measures of performance assesses efficiency of delivery while the section on information integration focuses on how information across each stage is integrated to improve efficiency by focusing on two key areas: the organization of the supply chain and the use of tools for managing, monitoring and sharing information.

E. Conclusion

The global optimization framework serves three goals in this study: 1) as a foundation for developing primary data collection tools, such as interview guides and to establish the criteria for secondary data collection 2) as an analytical tool for assessing how established performance goals are being met, as well as how gaps in information integration through each stage of the supply chain can be addressed, and 3) to provide as comprehensive as possible a description of efficiency of the supply chain and availability of ARVs for each health system.

Table II-1: Overview of Forecasting, Price Negotiation and Procurement Definitions and

Supply Chain Stages	Definitions	Method
Forecasting	Estimating type and volume of ARV required for specific number of people.	1. Epidemiological/Consumption 2. Normative/Morbidity 3. Combination of Epidemiological and Normative.
Price Negotiation	Process by which buyers and sellers arrive at agreed price and volume of ARV.	1. Open tender. 2. Reduced tender. 3. Competitive negotiation 4. Direct procurement.
Procurement	Developing contract specifying quantity, type(s) of ARV and unit price of ARV.	1. Dependent on combination of forecasting, timing, contracts management, logistical systems, inventory management and other contextual factors.

Table II-2: Taxonomy of Common Supply Chain Indicators, Performance Measures and Information Integration Indicators

Supply Chain Stage	Common Indicators	Common Performance Measures	Information Integration
Forecasting	1. Annual forecasting formulae. 2. Criteria for treating patients diagnosed with HIV/AIDS. 3. Patient volume by treatment category. 4. Demand based disease and/or consumption patterns. 5. Total annual volume of ARVs forecasted and annual volume forecasted not based on treatment guidelines. 6. Annual volume of ARVs expected to follow standardized treatment protocol.	1. Percentage difference between annual forecast and total. number of patients registered 2. Percentage difference in annual forecast trend. 3. Proportion of forecast that follows standardized protocol.	1. What kinds of data (e.g. disease prevalence, previous annual ARV consumption, vertical data collection process etc) are used in the forecasting formulae? 2. Is forecasting at the hospital level based on standardized treatment protocol? 3. Does price influence forecasting? If so, how?

Price Negotiation	1. Annual volume negotiated. 2. Budget allocation for all drugs. 3. Budget allocation for ARVs 4. Average negotiated price of ARVs (e.g. most common first-line treatment regimens). 5. Average price of ARVs across health systems. 6. Average ratio of unit prices of indicator drugs to international prices.	1. Percentage difference between annual volume forecasted and annual volume negotiated. 2. Average price variation across systems no more than certain percentage. 3. Average price differences between Mexico and other middle income countries like Brazil) no more than certain percentage. 4. Actual expenditure as Percentage of budget allocation for ARVs.	1. Is forecasting data used in the price negotiation process? 2. Are there separate staff involved in forecasting and price negotiation? If so, how is information shared between the two staff groups? 3. What other data (average per unit price across health systems and/or in other economically similar countries etc) are included in the price-negotiation process? 4. Does procurement influence price negotiation? If so how?
Procurement	1. Annual volume procured. 2. Average procurement price of ARVs (e.g. most common first-line treatment regimens). 3. Average lead time between purchasing and receipt of ARVs. 4. Average time for which safety stock will last. 5. Annual type and volume of emergency ARVs procurements. 6. Average price of ARVs purchased through emergency procurement.	1. Percentage difference between annual volume forecasted and annual volume procured. 2. Percentage difference between annual volume negotiated and annual volume procured.. 3. Percentage difference between average negotiated price ARVs and average procurement price. 4. Average lead time between placement of order and receipt no more than average time for which safety stock will last. 5. Frequency of emergency procurements. 6. Percentage difference in average procurement price and average emergency procurement price. 7. Proportion of total annual procurement that is as a result of emergency procurement.	1. Are forecasting and price negotiation data used in procurement? 2. Are there different staff involved in forecasting price negotiation and procurement processes? If so, how is information shared between the different staff groups? 3. What other data are used in procurement?

CHAPTER III: METHODS

This chapter describes the data sources for this study and explains the process in which the conceptual framework was refined given available data and the analytical process.

A. Data Sources

1. Qualitative Data

Qualitative data were obtained from two sources: 1) interviews with key informants and 2) a review of pharmaceutical (particularly ARV) policies and procedures as well as information repositories (databases and websites) containing ARV forecasting, price and procurement data.

Semi-structured interview guides were developed for each of the key informant groups, based on common themes (methods, indicators and measures) culled from the published literature on drug supply chains (see Appendix B for interview guides). These open-ended guides were used to interview key personnel/informants involved in all three stages of the supply chain in all three health systems. Each of the three guides was targeted towards staff who played key roles in the supply chain process – national program managers at the three health institutions/systems, Ministry of Health policy analysts working with the Commission and hospital level program managers (including physicians, program managers, pharmacists and information system administrators).

Secondary data were obtained from interviews of representatives from the Mexican pharmaceutical industry. The interviews were collected as part of a Ford Foundation funded project on drug patents, prices and access to care conducted by Dr. Veronika Wirtz at the Mexican National Institute of Public Health.

2. Quantitative Data

Data on annual ARV procurement price per unit (package of tablets or capsules), annual ARV procurement volume, annual number of patients receiving ARV, and total annual expenditure between 2003 – 2009 were obtained from databases and websites for each institution – CENSIDA (SSA), IMSS and ISSSTE (see Appendix for number of patients, procurement prices and volume of ARV by institution).

To benchmark public procurement prices in Mexico, Mexican ARV prices were compared with international prices. Data were collected on median transaction prices of the same type and dose of ARVs for upper-middle income countries[2] from WHO Global Price Reporting Mechanism (GPRM). The GPRM is a public database containing information on prices of medicines procured by donor recipients of the Global Fund and other organizations that report their drug procurement prices. These prices are reported in United States dollars at Price per Patient per Year (PPY) for the defined daily dose of each medicine required to treat an adult patient for one year.

[2] Defined as countries with a Gross National Income per capita between US$ 3,706 and US$ 11,455.

B. Refining the Global Optimization Framework for ARV Supply in Mexico's Health Systems

A preliminary review of available supply chain data indicators was conducted using IMSS, ISSSTE and SSA ARV price and procurement websites and databases. These data were then incorporated into a framework specific to the Mexican context to assess key areas of the supply chain: indicators and measures of performance and integration and organization of information. Thus, the global optimization framework used to evaluate efficiency of ARV supply chain management was incorporated into Table III-1.

C. Analysis

1. Qualitative Data

A total of 19 health system and Ministry of Health informants were interviewed in 18 interview sessions (see Table III-2). Fifteen interviews were digitally recorded and transcribed, while three interviews were summarized in notes. Informants were recruited using a preliminary list of heads of HIV/AIDS programs at the national and hospital level. Additional informants were recruited using a snowball strategy; informants recruited from the original list were asked to provide contact and/or introductions to HIV/AIDS program managers in other hospitals. All informants were involved in decision-making on ARV supply at the national or hospital level. Informants at the hospital level represented clinical settings that served 300 – 5,000 patients per year.

Secondary data from eight interviews with pharmaceutical representatives were also used. Of the eight, five represented patent-holding companies and three represented generic companies.

All interviews were coded along the three key areas of the global optimization framework (i.e., indicators and measures of supply chain as well as information organization and integration in decision making).

2. Quantitative Data

Patients on Inadequate Treatment:

The number of patients on inadequate treatment – defined as patients on a treatment of less than three ARVs – was calculated for the years 2007 and 2008 by using information from CENSIDA's patient and medicine database SALVAR, which captures individual patient data from all SSA clinics in the country. Similar data for IMSS were obtained for individual patients from all IMSS clinics in the country and uploaded into the SALVAR database.

Annual Estimated ARV Demand Volume and ARV Procurement Volume:

Estimated ARV demand volume for the years 2007 to 2008 was calculated by using information from SALVAR. The data from SALVAR gave information about the ARV drug

combination given to each of patient treated in SSA clinics and hospitals. However, data from National Hospitals which provide tertiary level care in SSA's system were not included in the 2007 SALVAR data on ARV demand volume. SSA National Hospital patients are estimated to be 3,187 or 17% of patients, according to estimates from the Second SALVAR Analysis Report 2007. As a result, projected demand for patients in the national hospitals was calculated by extrapolating the proportion of patients on each ARV in the 31 states to the number of patients in the national hospitals. For example, according to 2007 SALVAR data, 42% of patients in the 31 states were on TDF/FTC. It was then assumed that 42% of patients receiving care at the National Hospitals were on TDF/FTC. Annual estimated demand for SSA for 2008 was for all patients registered in SALVAR.

Data on annual estimated ARV demand volume for IMSS and ISSSTE were provided separately by each respective health system. The total volume per year required to treat all patients was calculated by multiplying the number of patients treated in each institution by the number of treatment courses required, according to National ARV Treatment Guide for Persons with HIV as well as data provided by SALVAR and corresponding information systems in IMSS and ISSSTE.

Annual procurement volume by each institution was provided as the number of units of ARV purchased in one year. A unit of ARV procurement volume is the ARV dosage of the medicine required to treat an adult patient for 30 days (approximated to one month). ARV procurement volume for SSA was provided by CENSIDA for 2003 – 2009. ARV procurement demand volume for IMSS was obtained from IMSS procurement database for 2003 – 2008. IMSS ARV procurement volume for 2009 was projected by calculating the average percent increase in annual ARV procurement volume for each year from 2003 to 2008 and then multiplying by the annual volume of ARV procured in 2008. For example, EFV procurement increased by an average of 127% between 2003 and 2008, thus the volume of EFV procured in 2008 (i.e., 47,787 units) was multiplied by 127% which came to a projected 60,689 units procured in 2009.

Assessing Efficiency:

To assess the efficiency of procurement, the annual estimated demand volume of units to treat the number of patients on the ARV combinations over one year was compared with the actual number of units procured for each health system. Fourteen of the most common ARVs used by SSA – tenofovir/emtricitabine (TDF/FTC), zidovudine/lamivudine (AZT/3TC), efavirenz (EFV), lopinavir/retonavir (LPV/RTV), atazanavir (ATV), Retonavir (RTV), saquinavir (SQV), nevirapine (NVP), abacavir (ABC), abacavir/lamivudine (ABC/3TC), Tenofovir (TDF), emtricitabine (FTC), lamivudine (3TC) and zidovudine (AZT) – were selected for analysis (see Table III.3 for descriptions). The annual estimated demand volume for units was calculated as the total volume of ARV units required to treat the estimated number of patients on each of the selected ARVs for 12 months. Based on informant interviews, it was assumed that patient treatment change (as a result of regimen change, death and new patients) and safety stock accounted for +/- 15% difference between the annual estimated volume demand and the annual volume procured.

For the purposes of this research, ARV procurement shortage is defined as the situation in which the annual demand volume of units was higher than the annual procurement volume, while an ARV procurement surplus is defined as the situation in which the annual demand volume is less than the annual procurement volume. Based on interviews with treating physicians, in cases where there is a shortage for a combination dose (TDF/FTC, AZT/3TC and ABC/3TC), it was assumed that the shortage would be supplemented by surplus of single dose equivalents (TDF, FTC, AZT, ABC and 3TC). The formula for compensating shortages is as follows:

> If Annual Demand Volume (ADV) > Annual Procured Volume (APV),
> then Annual Demand Volume = Annual Procured Volume + Surplus Procured Volume of single dose equivalent.

In other words, where there is a 10% shortage of TDF/FTC and the annual demand volume for single dose TDF and FTC is exceeded by the volume procured, the surplus volume of the single dose was used to supplement the shortage of the combination dose.

Annual ARV Procurement Price:

The annual procurement price is defined as the price at which a unit (30-day/1-month dose) supply of an ARV was procured during that year. All ARV prices were converted into US dollars (based on the Bank of Mexico exchange rate) and adjusted for inflation (obtained from the United States Labor Department) using the average inflation rate for 12 months of each year (Bank of Mexico Exchange Rate 2009 and U.S. Labor Department Bureau of Labor Statistics Consumer Price Index for Prescribed Drugs 2009). In the analysis of pre and post-negotiation prices for 2008, the pre-negotiated inflation rate was calculated as the average inflation rate for January to September 2008, while the post-negotiation inflation rate was the average inflation rate for October to December 2008.

To assess variation in price across health systems, the annual price for each of the selected ARVs for each health system was used to calculate the average price and standard deviation across health systems for each year. The coefficient of variation was then calculated as the ratio of the standard deviation to the average price expressed as a percentage.

ARV Expenditure:

The Price per Patient per Year (PPY) for ARVs in Mexico was compared to the median PPY for upper-middle income countries obtained from GPRM[3]. Using price and procurement data provided by IMSS and SSA, price per unit in Mexican pesos was first converted to PPY by multiplying by 12, then converted to U.S. dollars, and finally, adjusted for the U.S. inflation rate using the Consumer Price Index for Prescribed Drugs (as listed by the United States Department of Labor). IMSS and SSA expenditures on of the selected ARVs were also compared to the hypothetical expenditure of the same kind and quantity of ARVs for the same period assuming the median price for upper-middle income countries provided by the GPRM.

[3] Note: Median Prices of Tenofovir/Emcitrabine and Tenofovir were for Middle-income countries as reported in the Summary Report from the Global Price Reporting Mechanism October 2008.

In addition, the estimated ARV demand expenditure was compared to the procurement expenditure in order to understand the monetary cost of procurement shortages and surpluses. The estimated ARV demand expenditure was calculated by multiplying the annual demand volume for each of the selected ARV times its inflation adjusted price. Similarly, the procurement cost was calculated by multiplying the annual procurement volume for each ARV times its inflation adjusted price. The shortage cost as well as the surplus cost were both calculated as the difference between the estimated ARV demand expenditure and the procurement expenditure.

D. Limitations of the Study

Interviews with HIV/AIDS program managers at the national level, while not substantial in number, were representative of ARV supply chain program managers who have been key decision makers in ARV supply for their respective health systems for at least five years. Interviews with HIV/AIDS program managers at the hospital level were conducted with a convenience sample of informants and thus may not be generalized to their respective health systems. Nevertheless, these informants were heads of HIV/AIDS care at clinics or hospitals serving a broad number of patients (300 – 5,000) with varying needs (patients on first-line treatment, patients on first-line alternative treatment as a result of toxicity, patients with drug resistant infections and those on regimens beyond first-line treatment).

The study's generalizability is limited by the quantitative data collected. Data for 2008 and 2009 annual number of patients, annual required volume, annual price and annual procurement volume were obtained from the two different sources. However, these sources may have obtained their data from the same source. Nevertheless, these data were used in forecasting, price negotiations and procurement decisions by national policymakers and program managers indicating some level of validity of the data.

Third, because data on procurement volume by quantity purchased at a particular time of the year were unavailable, the study was unable to use a more accurate weighted average price. As a result, the inflation adjusted rate may not precisely reflect the actual inflation adjusted price for ARVs. Similarly, ARV expenditures (actual or estimated) may not be reflective of actual expenditures. Furthermore, ARV expenditure was calculated as procurement cost and does not include the cost of distribution or storage; thus, the actual cost of ARVs to the system are likely to be higher than this study's estimates.

Lastly, due to the lack of existing data, the comparison between required volume and procurement volume, the shortage or surplus does not take into account the possibility of existing ARV stocks, which were available at the time of procurement. However, as the analysis shows, if there was existing stock for any ARV, one would expect to see a reduction in surpluses for the same drug or specific regimen from one year to the next and not an increase. Thus, it is likely that either there are no existing stocks or the volume of existing ARV stocks are not being taken into account in forecasting and procurement.

Table III-1: Indicators and Measures for Evaluating Efficiency of ARV Supply Chain

Supply Chain Stage	Common Indicators	Common Performance Measures	Information Integration
Forecasting	1. Annual forecasting formulae 2. Criteria for treating patients diagnosed with HIV/AIDS. 3. Patient volume by treatment category. 4. Demand based disease and/or consumption patterns. 5. Annual volume based on forecast.	1. Annual percentage change in annual forecast trend.	1. What kinds of data (e.g. disease prevalence, previous annual ARV consumption, vertical data collection process etc) are used in forecasting formulae? 2. Is forecasting at the hospital level based on national formula? Does forecast at hospital level follow standardized treatment protocol? 3. Does price influence forecasting? If so, how?
Price Negotiation	1. Average negotiated price of ARVs (e.g. most common first-line treatment regimens). 2. Average price of ARVs across health systems. 3. Average global upper-middle income prices of ARVs.	1. Average price variation across systems. 2. Average price differences between Mexico and median global upper-middle income countries. 3. Actual expenditure as % of budget allocation for ARVs	1. Are forecasting data used in the price negotiation process? 2. Are there separate staff involved in forecasting and price negotiation? If so, how is information shared between the two staff groups? 3. What other data (average per unit price across health systems and/or in other economically similar countries etc) are included in the price-negotiation process? 4. Does procurement influence price negotiation? If so how?
Procurement	1. Annual ARV volume procured 2. Average lead time between purchasing and receipt of ARVs 3. Average safety stock volume and average time for which safety stock will last.	1. Percentage difference between annual volume forecasted and annual volume procured	1. Are forecasting and price negotiation data used in procurement? 2. Are there different staff involved in forecasting price negotiation and procurement processes? If so, how is information shared between the different staff groups? 3. What other data are used in procurement?

Table III-2: Categorization of Informants

Category	Health System Informants			Pharmaceutical Company Representatives
	IMSS	ISSTE	SSA	
Health System Program Managers	3	2	2	
Hospital Program Managers	4		3	
Ministry of Health Policy Analysts	5			
Generic Companies				3
Patent-Holding Companies				5
Total Number of Informants	27			

Table III-3: List and Description of Selected Antiretroviral Drugs

Non-Proprietary Name	Abbreviation	Trade (Brand) Name
Abacavir	ABC	Ziagen
Abacavir/Lamivudine	ABC/3TC	Epzicom
Atazanavir	ATV	Reyataz
Efavirenz	EFV	Sustiva
Emtricitabine	FTC	Emtriva
Lamivudine	3TC	Epivir
Lopinavir/Retonavir	LPV/RTV	Kaletra
Nevirapine	NVP	Viramune
Saquinavir	SQV	Fortovase
Retonavir	RTV	Norvir
Tenofovir	TDF	Viread
Tenofovir/Emtricitabine	TDF/FTC	Truvada
Saquinavir	SQV	Fortovase
Zidovudine/Lamivudine	AZT/3TC	Combivir

CHAPTER IV: ARV FORECASTING, PRICE NEGOTIATION AND PROCUREMENT MANAGEMENT BEFORE THE CREATION OF THE INTER-INSTITUTIONAL COMMISSION

This chapter describes the results of the analysis of data on ARV forecasting, price negotiation and procurement before the creation Inter-Institutional Commission. It focuses on the indicators, measures, organization and integration of each health system's management of their respective ARV supply chain. The ultimate goal is to fill some of the knowledge gap about the role that supply chain management plays in ensuring efficient delivery of ARVs.

A. What forecasting, price negotiation and procurement methods, indicators and measures were used before the creation of the Inter-Institutional Commission?

1. Forecasting

The three major institutions have been using the epidemiological model of forecasting – i.e. historical consumption data from the previous years to project future annual demand. According to the SSA and ISSSTE program managers, these trend analyses looked at annual consumption rates based on the number of patients which was calculated by adding the volume of medicines previously consumed, the number of patients transitioning from regimen to regimen, patients who developed resistance to treatment, new patients and subtracting patients who died (Interview 7, 2008; Interview 12, 2009). These historical analyses were based on one to three years of ARV data. In discussing the historical range used in the trend analysis, an analyst from the Commission's Economic Evaluation sub-committee stated that using consumption data beyond five years in the past "would likely fail because it would not adequately account for introduction of newer, less toxic and more effective medicines" (Interview 10, 2008).

For SSA and ISSSTE, forecasting was managed and monitored centrally, while for IMSS the process was more fragmented. In all three systems, clinics and hospitals that provide ARVs to patients submit their forecasts to state-level drug supply departments, which then submit these forecasts to the supply department at the federal level. Both SSA and ISSSTE have designated bodies responsible for coordinating forecasting (and general HIV/AIDS care program management) at the national level. In the case of SSA, the coordinating body is CENSIDA, while for ISSSTE it is the HIV/AIDS and Infectious Disease Department (Interview 1, 2008; Interview 3 2008). Both ISSSTE and SSA utilize ARV management information systems – SSA uses the ARV Logistics and Surveillance Management System (Sistema para la Administracion, Logistica y Vigilancia de ARV - SALVAR) and ISSSTE uses a customized MS Excel template.

> *"We implemented SALVAR in 2007- many but not all [clinics and hospitals] have it up and running. Those that do not have SALVAR submit almost the same type of data in our old format [MS Excel]… we were able to conduct a first analysis of patient ARV at the end of 2007 and it has been very helpful to managing [HIV/AIDS] care."* (Interview 12, 2009)

"We have our customized MS Excel file that everyone [clinic and hospitals] submits every month. We review it to make sure it is in order and then send them what they need." (Interview 5, 2008)

Both systems allow program managers to monitor forecasts sent from state hospitals to ensure that they are in line with treatment guidelines and that the variation in overall forecasts is within certain standards. For example, each hospital is given a 10% or one-month additional stock in case there are delays in the next procurement cycle. As one physician/ program manager stated,

"[safety stock] allows us to continue to serve our patients when there are disruptions" (Interview 17, September 2009)

However, one hospital program manager noted that for their hospital SALVAR did not capture all the data needed to manage supply and dispensing of ARVs, stating:

"We have created our own information management system from MS Access in April 2005. For us SALVAR is only an information system for CENSIDA and not our primary system. Realistically, our [management information] system has a lot more variables than SALVAR. We are able to provide monthly receipts to our patients for when they come to collect their medicines. In other words, we have a system that matches our patients with the medicines they receive each of which has a unique bar code… basically [we can see] what is being consumed and what we have in inventory". (Interview 16, 2009)

In the IMSS system there is no department responsible for coordinating HIV/AIDS care program management or forecasting guidelines. As one respondent stated:

"No, IMSS does not have a standardized forecasting formula or national guide to forecasting… each state does its own forecast and then sends [the data] to IMSS central for negotiation and procurement". (Interview 21, 2010)

In IMSS, the pharmaceutical supply department is responsible for coordinating ARV forecasting. Forecasting as well as price negotiation and procurement are combined with that for other pharmaceutical products. The pharmaceutical supply department is responsible for coordinating forecasting used in price negotiations and procurement (Interview 7, 2008). In 2008, IMSS established a physician position as part of an effort to develop "an evidence-based treatment guideline and centralized coordination for HIV/AIDS treatment" (Interview 3, 2008). However, according to an IMSS physician/HIV/AIDS hospital program manager "no one reviews the forecast to see if it follows treatment guidelines" and "how much [ARVs] you get depends on your relationship with the pharmacy manager and also on that person's relationship with the state pharmacy manager" (Interview 18, 2009). Based on these responses, it appears that the IMSS forecasting process lacks a standardized monitoring process.

Monitoring Treatment Guideline:

The proportion of patients on less than three ARVs in the SSA system decreased slightly from 0.51% in 2007 to 0.45% in 2008 (see Figure IV-1). Data on patient treatment for IMSS showed that the proportion of patients on less than three ARVs was 6.7% in 2008. While this analysis is limited in its ability to identify and quantify the number of patients receiving inadequate treatment, it does indicate that the proportion of patients who are receiving internationally and nationally recognized triple-therapy treatment is lower in IMSS than in SSA in 2008. This may be a result of a less standardized monitoring system of treatment in the IMSS system.

2. Price Negotiations

All three institutions conduct price negotiations in coordination with their purchasing department. In SSA, CENSIDA coordinates with the SSA procurement department to negotiate with ARV providers and/or their designated distributors. In discussing the negotiations, informants from all three systems stated that each system relied on the volume or quantity as a primary strategy for achieving lower prices for patented ARVs. Additionally, all three institutions are part of a price transparency system, which required that all institutions post price per unit drug purchased. This allows each institution to compare prices across institutions, thus providing another measure for ensuring that negotiated prices are within a range specified by the government for all three institutions. However, a review of publicly available data showed 2008 ARV prices for SSA, while IMSS and ISSSTE ARV price data were only available through official requests.

In order to see the effect of quantity of ARVs purchased on pricing, the annual quantity of ARV procured was compared to ARV PPY (not adjusted for inflation) paid by SSA for ABC, ATV, AZT/3TC, EFV, LPV/RTV, SQV and TDF/FTC for the time period between January 2003 and September 2008 (see Figure IV-2). While the annual procurement volume for each of these medicines is not directly correlated with the increase in annual number of patients, the procurement volume for a number of ARVs increased substantially from 2003 to 2008.

As Figure IV-2 indicates, between 2003 and September 2008, the unadjusted ARV price per patient per year showed marginal decrease, even when the number of patients receiving treatment and the volume of ARVs procured increased substantially. The only ARV for which the price per patient per year showed a substantial decrease was NVP and this was as a result of global discounts offered by Boehringer Ingelheim in May 2007 (Jack, 2007). For the SSA health system, the average annual change in procurement price per patient per year ranged from a decrease by 17% for NVP to an increase of 8% for EFV, with no change in procurement prices on average for all the selected ARVS. In comparison, the number of SSA patients receiving treatment increased by an average of 17% annually, while the average annual ARV volume purchased increased by 126% (see Table IV-1). For IMSS, the average annual price change ranged between a 21% decrease in price for FTC to a 14% increase in price for SQV, and a marginal decrease of 3% in prices on average for all the selected ARVs[4]. On the other hand, annual volumes of ARV procured by IMSS increased by 106% in the same period (as shown in

[4] The average annual change in price analysis for IMSS did not include TDF/FTC or ABC/3TC because data were either unavailable (TDF/FTC) or there were no procurement data (ABC/3TC).

Table IV-2). This seems to indicate that economies of scale (i.e. increased volume of ARVs associated with reduction in prices) were not observed between 2003 and 2008.

Informants also indicated that there were variations in prices paid for some ARVs between the three health systems. An example that was cited was the prices of ARVs paid by ISSSTE. According to one respondent "ISSSTE pays about the same price for 80% of ARVs" but for one particular ARV "ISSSTE is paying more than twice the price what SSA/CENSIDA pays" (Interview 5, 2008). Two informants suggested that this might be reflective of the smaller percentage of patients (8%) served by ISSSTE as compared to SSA/CENSIDA (51%) (Interview 5, 2008; Interview 10, 2008; Ortiz, 2008). Data on the inflation adjusted annual ARV price for 2003-2009 for all three institutions were available for only NVP, SQV, LPV/RTV, and 3TC (2006-2008 for EFV and 2007-2008 for AZT/3TC and RTV). Figure IV-3 and Table IV-3 shows the coefficient of variation of the annual price for seven ARVs expressed as a percentage.

When adjusted for inflation, the available data suggest that variation in price as measured by the ratio of the standard deviation in price to the average annual price for the three institutions appears to have been greater than the expected 10% in only four out of thirty-one data points for which comparison is possible - SQV and NVP in 2007 and 3TC and EFV in 2008. Except for of the prices of 3TC and EFV, price variation appears to decrease over time indicating that ARV prices across health systems were approaching parity.

A previous analysis conducted by SSA showed that on average, Mexico was paying higher prices for ARVs than developing countries (Pesqueira-Villegas, 2008). An example highlighted by this report showed that the average price of lamivudine in Mexico was 45 times the average price of the same product in developing countries In order to understand where Mexico lies in the global procurement price spectrum, SSA's average prices per patient per year between 2004 and September 2008 for nine of the most commonly used ARVs - EFV, 3TC, LPV/RTV, NVP Tablets, SQV, TDF, TDF/FTC and AZT/3TC were compared to median upper-middle income prices per patient per year (WHO – GPRM, 2009) (As shown in Figure, IV-4 and Table IV-4). The data show that on average Mexico paid substantially higher prices (approximately 67% average price difference) for the nine ARVs than the median upper-middle income country between 2004 and October 2008.

In order to understand the impact of price on total ARV expenditure, IMSS and SSA expenditures on nine ARVs - ABC, EFV, 3TC, LPV/RTV, NVP Tablets, SQV, TDF, TDF/FTC and AZT/3TC from January 2004 to September 2008 were compared to hypothetical expenditures assuming median prices procured by upper-middle income countries. Table IV-5 shows both scenarios – Mexico's actual expenditures and what the expenditures would have been assuming Upper-middle Income Country prices.

As shown in both Figure IV-5 and Table IV-5, Mexico's spending on nine of the most commonly used ARVs was significantly higher than the median price offered to Upper-Middle Income Countries. Had Mexico been able to negotiate to pay the median price for Upper-Middle income prices, it would have saved 64% to 85% in ARV costs between 2004 and 2008.

3. Procurement

IMSS, ISSSTE and SSA procured ARVs in roughly the same manner. In all three systems the body responsible for gathering data on ARV volume needs and price negotiations submits procurement orders on behalf of ARV treatment clinics and hospitals across all 32 states/delegation and the federal district. However, the distribution process differs by institution. For SSA and IMSS, each delegation or state receives its ARV procurement directly from the private distributor or vendor. In contrast, the ISSSTE system receives the annual procurement orders from the distributor or vendor in a central warehouse and then distributes the medicines to clinics across the country.

Consumption and Procurement in the SSA Health System:

Procured volumes for 14 key ARVs were compared to the estimated volumes of the same ARVs indicated in the prescription information by SALVAR. Figure IV-6 shows the comparison of procurement volumes with estimated demand volume, expressed in percentage shortage or surplus for 2007 and 2008, respectively.

In 2007, the initial comparison of estimated ARV demand volume to ARV procurement volume showed significant shortages of the combinations TDF/FTC, AZT/3TC and ABC/3TC. These shortages were compensated with surplus single dose equivalents – TDF, FTC, AZT, ABC and 3TC. Despite compensating for combination doses, there were shortages of 26%, 22%, 49% and 21% for TDF/FTC, AZT/3TC, LPV/RTV and ATV, respectively. Also, a significant portion of estimated demand for TDF/FTC (11%) and ABC/3TC (21%) was compensated with single doses. The 2007 comparison of estimated consumption and procurement also shows surplus volumes for SQV (25%), FTC (72%) and 3TC (20%) in 2007. In other words, SSA procured enough ARVs to serve an additional 466 patients on SQV, 851 patients on FTC and 276 patients on 3TC in 2007. Additionally, if the surplus ARVs were procured to provide for an unexpected surge in patient needs, one would expect to see a similar procurement pattern for nucleoside/nucleotide analogues such as TDF (in the case of FTC) or AZT and ABC (in the case of 3TC) recommended by the treatment guidelines. This variation in shortages and surpluses of ARVs highlight the poor translation of forecasting into procurement, which leads to both mismanagement of limited resources and lack of availability of ARVs.

In 2008, it appears translation of forecasting into procurement improved when compared to the previous year's shortages. After compensating for shortages in the combinations doses for AZT/3TC and ABC/3TC (initially at volume shortages of 4% and 50%, respectively), the analysis shows a shortage in ARV supply for only ABC/3TC (31%). There were, however, substantial surpluses of TDF (147%), FTC (85%), 3TC (165%) and AZT (170%). The surplus in ARVs purchased by SSA would be sufficient to serve an additional 1,055 patients on TDF, 1,353 patients on FTC, 1,235 patients on 3TC and 1,300 patients on AZT. Further analysis shows surplus volumes ARVs required for regimen treatment such as EFV (903 patients), SQV (156 patients), and RTV (483 patients). This would seem to indicate that there was a surge in patient volume such that additional volumes of ARVs were procured to meet patient demand. However, without data on actual consumption and the volume of ARV procured through emergency procurement for 2008, it is difficult to assess how surplus procurement was used to meet patient

need. It would, however, appear that the surplus procurement may have gone to waste. According to a national news article on a federal audit of ARVs purchased by CENSIDA:

> *In 2008, CENSIDA purchased a surplus of ARVs for four states at a cost of $231.3 million Mexican Pesos…. This led to additional use of resources and product expiration… 273 expired units that cost $275,000 Pesos were discovered in Veracruz … 236 expired units that cost $407,000 Pesos were discovered in Jalisco* (Vega, 2010)

This audit further highlights the disparity between estimated patient needs and procurement within the SSA health system, indicating that there are still inefficiencies in the supply chain process that are likely to be the result of inaccuracy in forecasting and/or procurement processes.

Using data from SALVAR, the estimated ARV expenditures to ARV procurement expenditures needed were compared to assess costs of surplus procurement. As Tables IV-6 and IV-7 and Figure IV-7 show there are significant costs to the health systems when forecasting is not accurately reflected in procurement.

The procurement of surplus units of ARVs was estimated to cost SSA approximately $5 million (5% of the procurement cost for all 14 ARVs) in 2007. At the same time, SSA did not procure the ARV volume required to meet patient needs. Compensating shortages in combination doses with single drug doses results in added costs for the health system. After adjusting for inflation, SSA paid $334 per unit for ABC/3TC, but paid an extra $154 per patient per month (or $130,000 additional spending) to procure ABC ($263) and FTC ($225) separately. Concerns of cost-efficiency do not seem to have been alleviated in 2008, particularly considering that SSA spent approximately $8 million (or 7% of the procurement cost for all 14 ARVs) more than expected, while it was unable to meet the needs of other patients (e.g. patients on ABC).

Consumption and Procurement in the IMSS Health System:

As discussed in the forecasting section, IMSS does not have a national body to monitor discrepancies between forecasting and procurement. As another IMSS informant stated, “Sometimes you can ask for 10 boxes of X and then you get 5 boxes of X and 5 boxes of Y” (Interview 2, 2008). However, in discussions with informants working at the national level who work with the Commission, it was uncertain if the difference between hospital forecast and procurement was the result of accurate monitoring and/or a lack of oversight (Interview 9, 2008).

The annual procured volume of the same 14 ARVs was also compared to the estimated volume necessary to treat the number of IMSS patients with the combinations of ARV indicated in IMSS prescription data. Due to limited access to forecasting and procurement data, however, only data for 2008 were available for this analysis. Figure IV-8 shows the comparison of procurement volumes with estimated consumption volume, expressed in percentage shortage or surplus for 2008 for the IMSS system.

As with SSA, it was assumed that initial shortages of TDF/FTC, AZT/3TC and ABC/3TC were complimented with surplus single dose equivalents. In order to meet patient needs, a significant portion of TDF/FTC (91%) and ABC/3TC (100%) needs were met using

single drug doses. Even after compensating, the results show some shortage of AZT/3TC (19%) and significant shortages of RTV (33%) and ABC/3TC (60%). In addition, IMSS procured a significant surplus of EFV (66%), TDF (212%) and FTC (154%). The surplus procurement would be sufficient to serve an additional 1,578 patients on EFV, 1,090 patients on TDF and 906 patients on FTC. This suggests IMSS may have had a surge in new patients that required procurement of more ARVs. However, limited data on actual patient consumption and the volume of ARV procured through emergency procurement for 2008 across the IMSS health system, make it difficult to assess how the additional procurement was used to meet patient need. Much like SSA, these figures indicate disparities between the ARV volume required to meet patient need and the volume procured by the system. These disparities also come at a cost to the system. In Table IV-9 and Figure IV-10, estimated expenditures were compared to procurement expenditures in order to assess the cost to the health system.

Based on the cost analysis in TableIV-8 and Figure IV-9, IMSS spent approximately $9 Million USD (9% of the total procurement cost for all 14 ARVs) more than necessary to meet patient need in 2008. This is particularly significant given that the costs of combination dosages for TDF/FTC, AZT/3TC and ABC/3TC were considerably less than the cost of single drug equivalents. After adjusting for inflation, IMSS paid $408 per unit for TDF/FTC, but paid an extra $40 per patient per month (or $500,000 thousand additional purchasing cost) to procure TDF ($346) and FTC ($102) separately. Similarly, combination dose ABC/3TC was procured at $322 per dose, while ABC and 3TC single doses cost $241 and $178, respectively, costing an additional $97 per patient per month ($700,000 thousand additional purchasing cost).

B. Discussion

The results for this chapter are summarized in the two categories of the global optimization framework – 1) Supply chain indicators and performance measures and 2) Information integration.

1. Supply Chain Indicators and Performance Measure

Within the SSA health system, lack of data appears to be the result of limited collection of data regarding key indicators. Of the most common indicators highlighted in the conceptualization of the global optimization framework, only four indicators were available – annual number of patients, annual estimated demand volume of ARV, annual procurement volume of ARV procured and annual procurement price of ARV. Data for the years in which ART had been provided were either unavailable (e.g., annual estimated demand volume were available only for 2007 and 2008) or kept confidential (e.g., annual negotiated price of ARVs, annual expenditure on ARV, and annual expenditure on pharmaceuticals). The lack of indicators and limitations of available data make it impossible to assess demand and supply of ARVs accurately, resulting in added costs to individuals and to the health system (Agwanda et al., 1996; Deliver, 2006; Simchi-Levi et al., 2008; Yusuf and Tayo, 2004). As the largest provider of HIV/AIDS care in Mexico, this is of concern for SSA.

In SSA's ARV supply chain, the available data on prescriptions and volume of procurement indicate that there may be shortages of ARV that would result in treatment interruption. SSA data show that from 2007 to 2008, there were some improvements in addressing ARV shortages. Nevertheless, data for 2008 suggest that that surplus procurement of ARVs are costly and patients are still using single dose pills instead of combination dose pills. The use of single drugs instead of combination drugs raises two major concerns – additional storage costs and possibly reduced adherence as a result of increasing pill burden. The cost of shipping and storage of drugs is increased when two separate pills are procured instead of one, because both the combination and single drug pills require the same storage conditions. As for adherence, some studies show that decreasing the number of pills (or pill burden) for a particular regimen is correlated with "higher adherence rates, potentially better HIV RNA control and improved CD4 T-cell count" (Ammassari et al., 2008; Hogberg et al., 2008; Jean-Baptiste, 2008). Thus, comparing the forecasting and procurement indicators suggests that both SSA patients and the health system are paying a substantial price in balancing the patients' needs with the costs of ARV.

In addition to the cost associated with surpluses and shortages, SSA and Mexico in general pay a substantially higher price for ARVs than the median upper-middle income country. With an average ARV price difference of 67%, the results appear to correspond with those of Vasan et al., showing a higher variation in ARV price among middle-income countries (Vasan et al., 2006). While concerns about price variation across health systems are not borne out by this analysis, ARV price stagnation despite exponential increases in ARV procurement indicate that increased volume does not guarantee lower ARV prices, as shown in Waning et al.'s study of global strategies to reduce ARV prices (Waning et al., 2009). As a result, there are possible limitations to cross-system pooled procurement as a strategy for negotiating discounts in prices of ARVs (Seoane-Vazquez and Rodriguez-Monguio, 2007; Waning et al., 2009; Vasan et al., 2006).

Despite being the second largest provider of HIV/AIDS care in Mexico, the IMSS system appears to have sparser data than the SSA health system. As was the case in the SSA system, only four kinds of indicators were available – annual number of patients, annual estimated demand volume of ARV, annual volume of ARV procured, and annual procurement price of ARV. However, data for the years in which IMSS has been providing ART were incomplete (e.g. annual estimated demand volume was available only for 2008 and annual procurement volume was unavailable for 2009). Similarly, certain data (e.g. annual negotiated price of ARVs, annual expenditure on ARV, and annual expenditure on pharmaceuticals) were considered confidential. Last, only a few IMSS national program managers at the national level were willing to be interviewed to assist with corroborating available data and provide insight and additional data.

The ARV price data for IMSS also appear to correspond with SSA ARV price data. The lack of substantial variations in price across health systems demonstrates that IMSS was purchasing ARVs at prices similar to those paid by SSA. However, this also suggests that IMSS has been unable to use its purchasing clout as the largest provider of all health care in Mexico, to achieve lower ARV prices. Furthermore, both IMSS and SSA are paying prices for ARVs that are at the higher end for upper-middle income countries. These conclusions indicate that there

are limitations to the use of pooled procurement or larger market demand of pharmaceutical products as negotiation strategies in Mexico (Seoane-Vazquez and Rodriguez-Monguio, 2007; Waning et al., 2009; Vasan et al., 2006).

The comparison of forecasting and procurement data for 2008 indicates that IMSS shared common problems with SSA in 2007 – shortages exceeding 15% of estimated need for three ARVs and substantial surpluses for four ARVs. The circumstances surrounding procurement of TDF/FTC and ABC/3TC present a perfect example of this inefficiency. No ABC/3TC and only 10% of the volume of TDF/FTC required to meet patient need were procured in combination pills in 2008. This means that all patients on regimens that included ABC/3TC and 90% of patients on regimens that included TDF/FTC were taking single drug doses. Additionally, the costs of procuring single drugs versus combination drugs were 10% and 30% higher for ABC/3TC and TDF/FTC, respectively. As discussed above, these inefficiencies can be detrimental to patient wellbeing and are costly to a health system, especially one with limited resources (Agwanda et al., 1996; Yusuf and Tayo, 2004; Deliver, 2006).

2. Information Integration

The ARV supply chain in the SSA health system appears to incorporate both the centralized and decentralized models (with more emphasis on centralization) in managing its ARV supply chain. SSA embodies a more centralized model because a greater number of the supply chain functions involve and are influenced by the national HIV/AIDS department – CENSIDA. While hospital level managers are involved in the forecasting and procurement stages of the supply chain by assessing and meeting local patient needs and managing their procurement stock, CENSIDA's role spans all stages of the supply chain. This role includes aggregating and monitoring estimated demand, participating in price negotiation and procurement, and managing ARV distribution across the country.

The organization of SSA's supply chain reflects the results from Bossert et al.'s assessment with one identifiable limitation. Centralized decision making in SSA is more efficient than decentralized decision making such as that used by IMSS. However, at the local level, the capacity of hospital managers to accurately forecast patient ARV needs based on treatment guidelines is heavily dependent on available resources (e.g. monitoring tools and trained staff), which vary from state to state. Although the number of SSA patients who are on two or fewer ARVs is a relatively small portion of the patient pool, the existence of this category of patients indicates that hospital program management at some treatment facilities is unable to monitor patient treatment in accordance with treatment guidelines. The lack of monitoring at the hospital level also indicates that at the national level, where CENSIDA is able to capture and monitor aggregate patient data on the number of patients, there is no adequate mechanism to provide rapid feedback to treating physicians who are providing inadequate treatment (Agwanda et al., 1996; Deliver, 2006; Yusuf and Tayo, 2004; Simchi-Levi et al., 2008).

The implementation of the SALVAR system in 2007 appears to have helped CENSIDA better manage and monitor ARV forecasting and consumption at both the national and local level. Training almost all hospital staff across the country and making the database readily available on the internet appears to have assisted CENSIDA reduce drug shortages between 2007

and 2008 (Bates et al., 2000, Deliver, 2006, Simchi-Levi et al., 2008). However, the failure of SALVAR to reach all SSA HIV/AIDS care sites, the lack of a systematic process for monitoring data validity at the hospital level, and limitations of SALVAR's ability to collect hospital inventory data and patient history (particularly changes in treatment regimen) result in less precision in forecasting and procuring of ARVs and increased challenges in meeting treatment needs (Allers and Riwa, 2001).

Unlike SSA, IMSS uses a more decentralized system to manage its ARV supply chain. The lack of a national central body to aggregate, manage and monitor patient data and the inconsistent use of treatment guidelines across the health system indicate less than adequate performance of the supply chain (Bossert et al., 2006). Furthermore, the lack of a standard method and tools for managing monitoring and integrating data across the stages of the supply chain at both the national and hospital levels, as well as varying capacity at the hospital level to monitor patient treatment, raises concerns about the accuracy of aggregate forecasting and procurement of ARVS and the adequacy of patient care. Without an adequate organizational infrastructure and the tools necessary to integrate information across the supply chain, patients receiving care at IMSS are more likely to face challenges in accessing ARVs (e.g., shortages in availability of ARVs) and the health system is more likely to incur excess costs as a result of inefficiency in the supply chain (Allers and Riwa, 2001; Bossert et al., 2006; Deliver, 2006; Quick et al., 1997).

In the next chapter, questions regarding changes implemented by the Inter-Institutional Commission and how these changes address concerns about the management of the ARV supply chain, ARV prices and the impact on ARV procurement expenditure are examined.

Figure IV-1: Percentage of IMSS and SSA Patients on Less than Three ARVs, 2007-2008

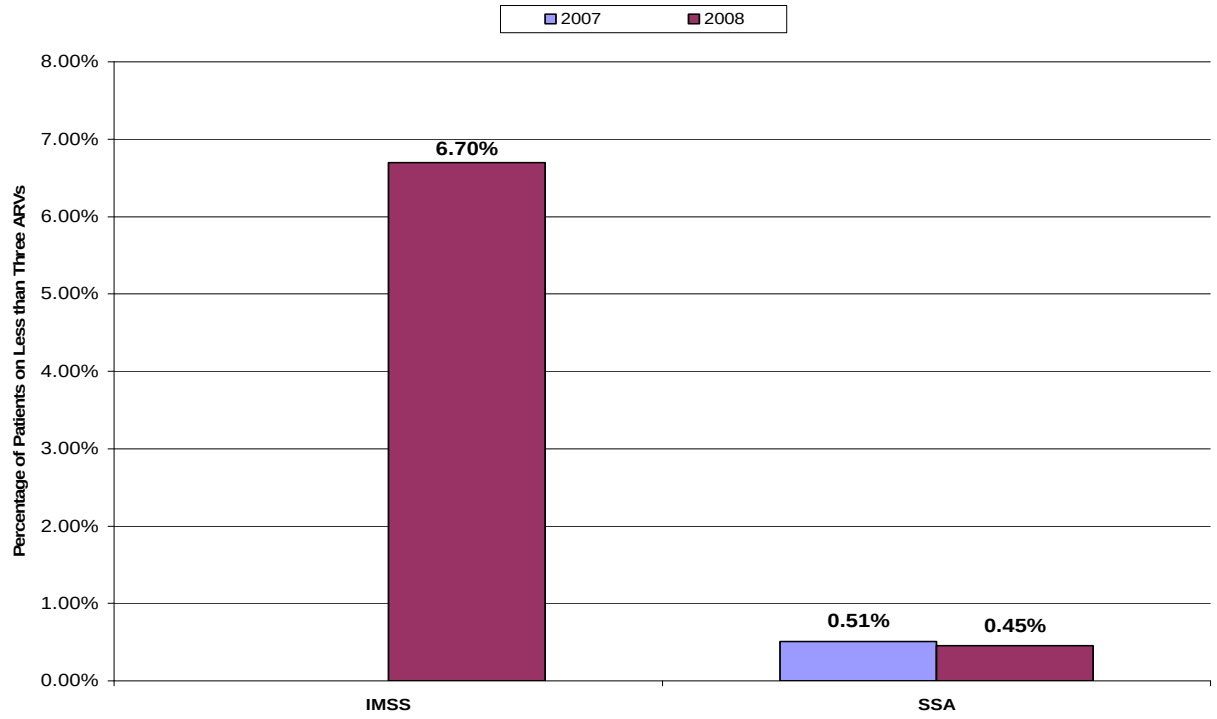
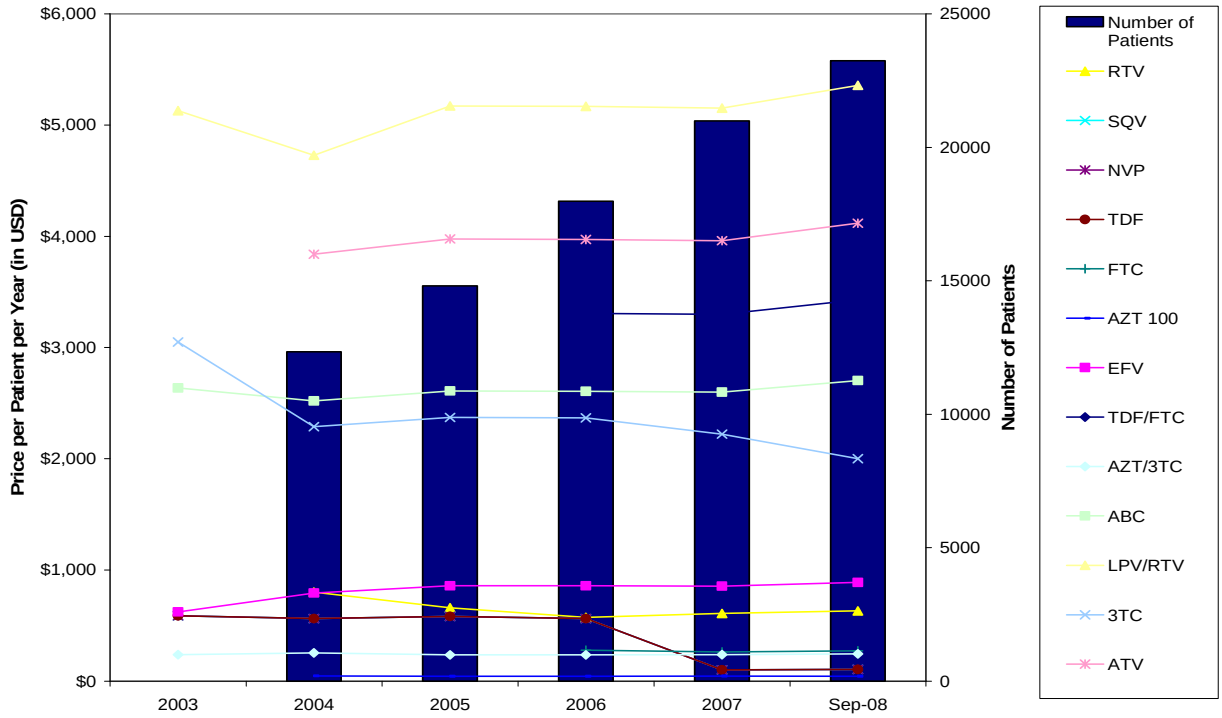


Figure IV-2: SSA Number of Patients and Price per Patient per Year of 13 ARVs. 2004 – September 2008



Note: ARV PPY is not adjusted for inflation.

Table IV-1: Variation in ARV Unadjusted Price per Patient per Year and Quantity in SSA

ARV Medicines	2003 Volume	2008 Volume	Average Annual Percentage Change in Volume	2003 Price	2008 Price	Average Annual Percentage Change in Price
EFV	4,557	129,264	182%	$624	$889	8%
TDF/FTC*	22,000	115,392	141%	$3,307	$3,428	2%
AZT/3TC	50,881	88,834	19%	$2,863	$2,936	1%
ABC	5,967	30,672	41%	$2,636	$2,703	1%
NVP	10172	30,672	26%	$2,452	$445	-16%
SQV	10122	29,628	25%	$1,661	$3,013	16%
LPV/RTV	3,212	51,612	82%	$5,129	$5,357	1%
3TC	10,302	15,826	17%	$3,050	$2,000	-8%
TDF*	695	15,120	842%	$4,403	$2,286	-17%
RTV	4,607	25,968	51%	$2,754	$2,733	0%
FTC*	18,890	24,516	24%	$1,162	$1,143	-1%
ATV*	792	26,916	177%	$3,839	$4,118	2%
AZT 100*	1,812	2,580	11%	$128	$162	6%
Median Change			126%			0%

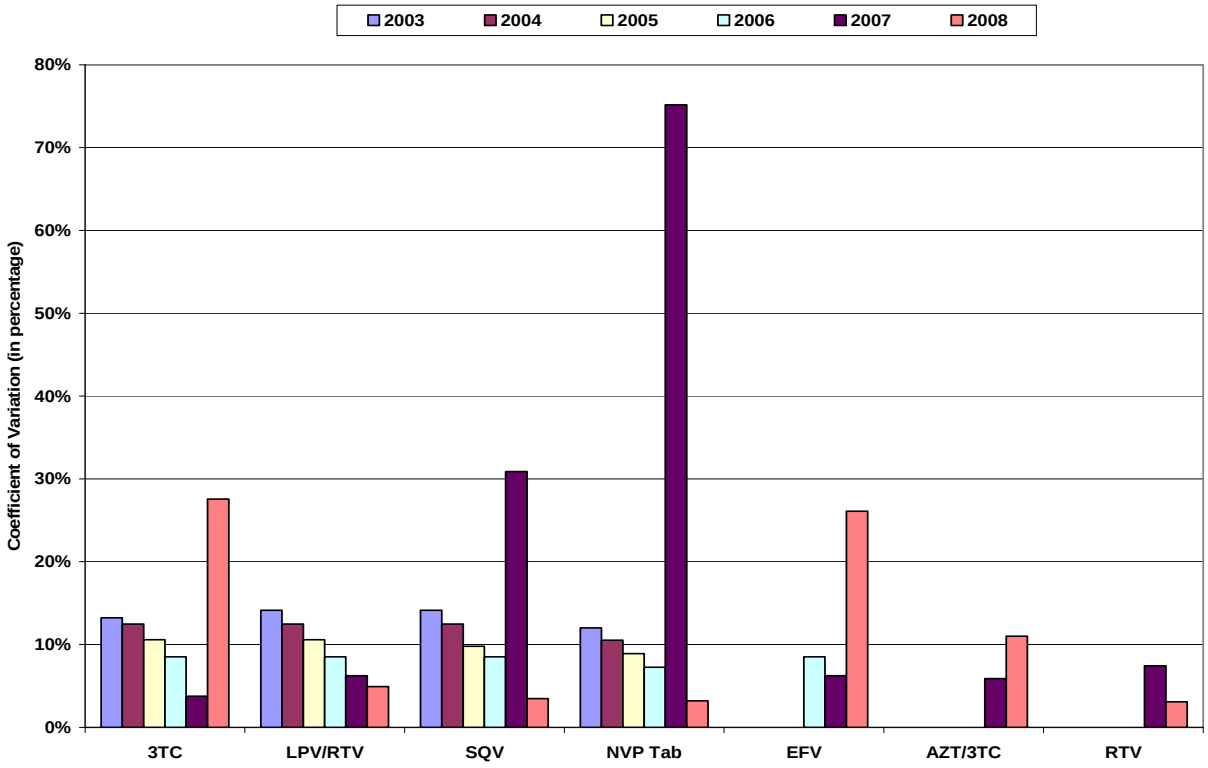
Note: Volume and Price for TDF/FTC and single dose FTC were available starting in 2006, for TDF starting in 2005 and for ATV and AZT 100 in 2004. According to CENSIDA procurement data no ABC/3TC was purchased before 2007

Table IV-2: Variation in ARV Unadjusted Price per Patient per Year and Quantity in IMSS

ARV Medicines	2003 Volume	2008 Volume	Average Annual Percentage Change in Volume	2003 Price	2008 Price	Average Annual Percentage Change in Price
EFV	1,435	47,787	127%	$830	$846	0%
AZT/3TC	5,330	69,020	80%	$2,863	$2,796	0%
ABC	2,160	30,275	96%	$2,636	$2,573	0%
NVP	4,958	22,133	84%	$2,229	$423	-17%
SQV	5,679	36,456	69%	$1,661	$2,870	14%
LPV/RTV	3,535	45,592	106%	$5,129	$5,102	0%
3TC	2,540	35,316	107%	$2,395	$1,904	-4%
TDF*	701	32,726	303%	$4,403	$3,695	-6%
RTV	2,322	18,457	65%	$2,109	$2,577	5%
FTC*	545	31,415	354%	$2,372	$1,088	-21%
ATV	455	12,572	251%	$4,517	$3,921	-5%
AZT 100*	991	1,958	166%	$123	$129	1%
Median Change			106%			-0%

Note: Volume and Price for ATV, TDF, FTC were available starting in 2005. According to IMSS procurement data, no TDF/FTC was purchased before 2008. and ABC/3TC has never been procured.

Figure IV-3: Variation in ARV Procurement Price per Unit across Health Systems, 2003-2008

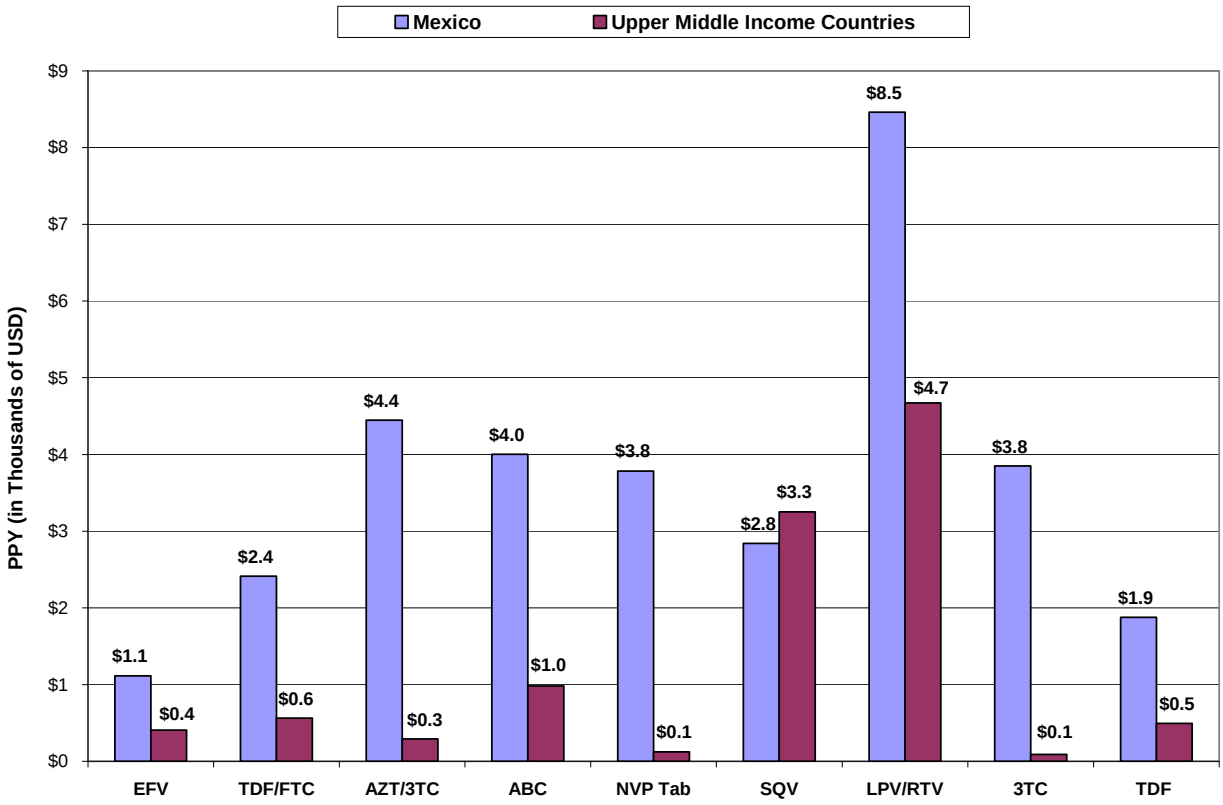


Sources: CENSIDA (2004 – 2008) and Global Price Reporting Mechanism (Median ARV prices paid by upper-middle income countries (2004-2008).

Table IV-3: Variation in ARV Procurement Price per Unit across the Three Health Systems, 2003-2008

ARV Medicines	2003	2004	2005	2006	2007	2008
3TC	13%	12%	11%	9%	4%	28%
LPV/RTV	14%	12%	11%	9%	6%	5%
SQV	14%	12%	10%	9%	31%	3%
NVP Tab	12%	11%	9%	7%	75%	3%
EFV				9%	6%	26%
AZT/3TC					6%	11%
RTV					7%	3%

Figure IV-4: Comparison of Average ARV Price per Patient per Year Paid by SSA and Upper-Middle Income Countries, 2004-September 2008



Sources: CENSIDA (2004 – 2008) and Global Price Reporting Mechanism (Median ARV prices paid by upper-middle income countries (2004-2008).

Table IV-4: Median ARV Price per Patient per Year in Mexico and Upper-middle Income Countries, 2004-2008

ARV Medicines	Mexico	Upper Middle Income Countries	Price Difference
EFV	$1,113	$405	64%
TDF/FTC	$2,414	$563	77%
AZT/3TC	$4,445	$293	93%
ABC	$4,001	$981	75%
NVP Tab	$3,783	$124	97%
SQV	$2,839	$3,253	-15%
LPV/RTV	$8,462	$4,672	45%
3TC	$3,850	$90	98%
TDF	$1,878	$495	74%
Average Price Difference			67%

Figure IV-5: Comparison of ARV Expenditures by Mexico and Upper-middle Income Countries, 2004-2008 (Based on IMSS and SSA Procurement Volume)

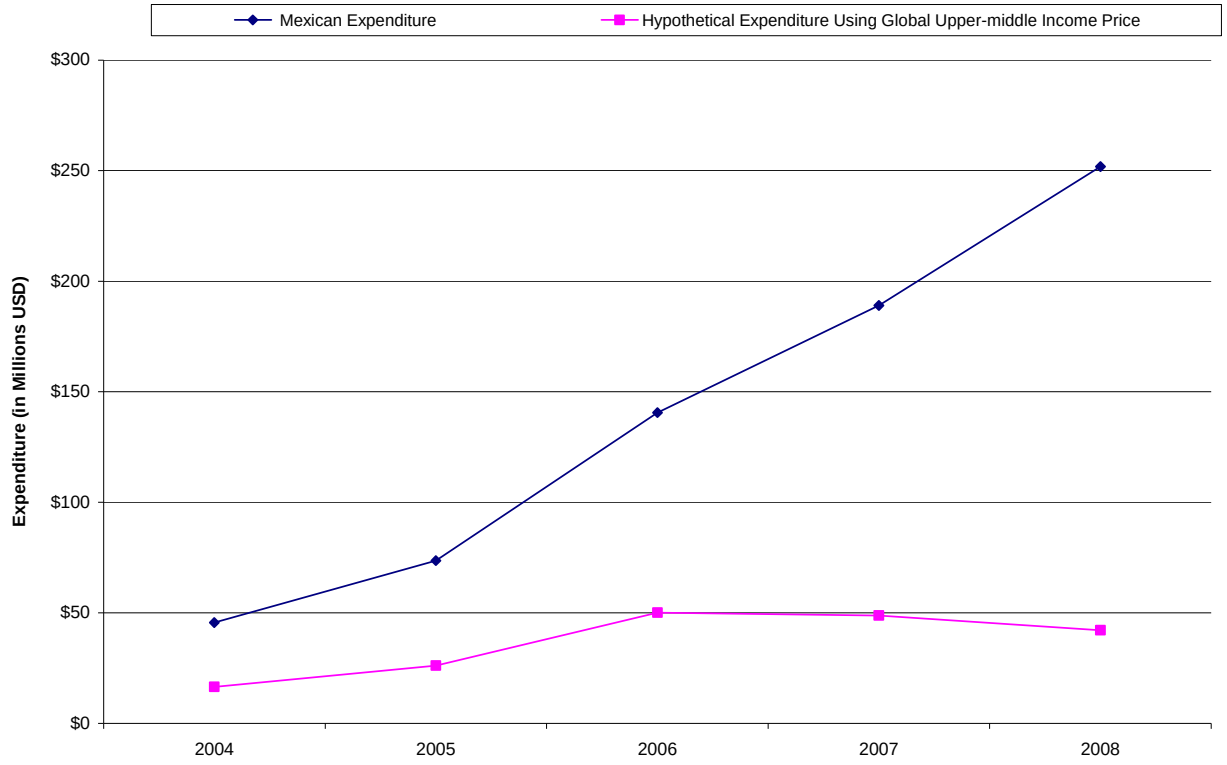


Table IV-5: Comparison of ARV Expenditures by Mexico and Upper-middle Income Countries, 2004-2008 (Based on IMSS and SSA Procurement Volume)

	2004	2005	2006	2007	2008
Mexican Expenditure (in Millions)	$45.6	$73.6	$140.6	$189	$251.8
Hypothetical Expenditure Using UMI Price (in Millions)	$16.5	$26.2	$50.1	$40	$42.1
Savings Assuming UMI Prices (in Millions)	$29.1	$47.5	$90.5	$140.2	$209.8
Percent Savings using UMI Prices (in Millions)	64%	64%	64%	74%	83%

Figure IV-6: Percent of ARV Volume Shortage or Surplus for the SSA Health System, 2007 and 2008

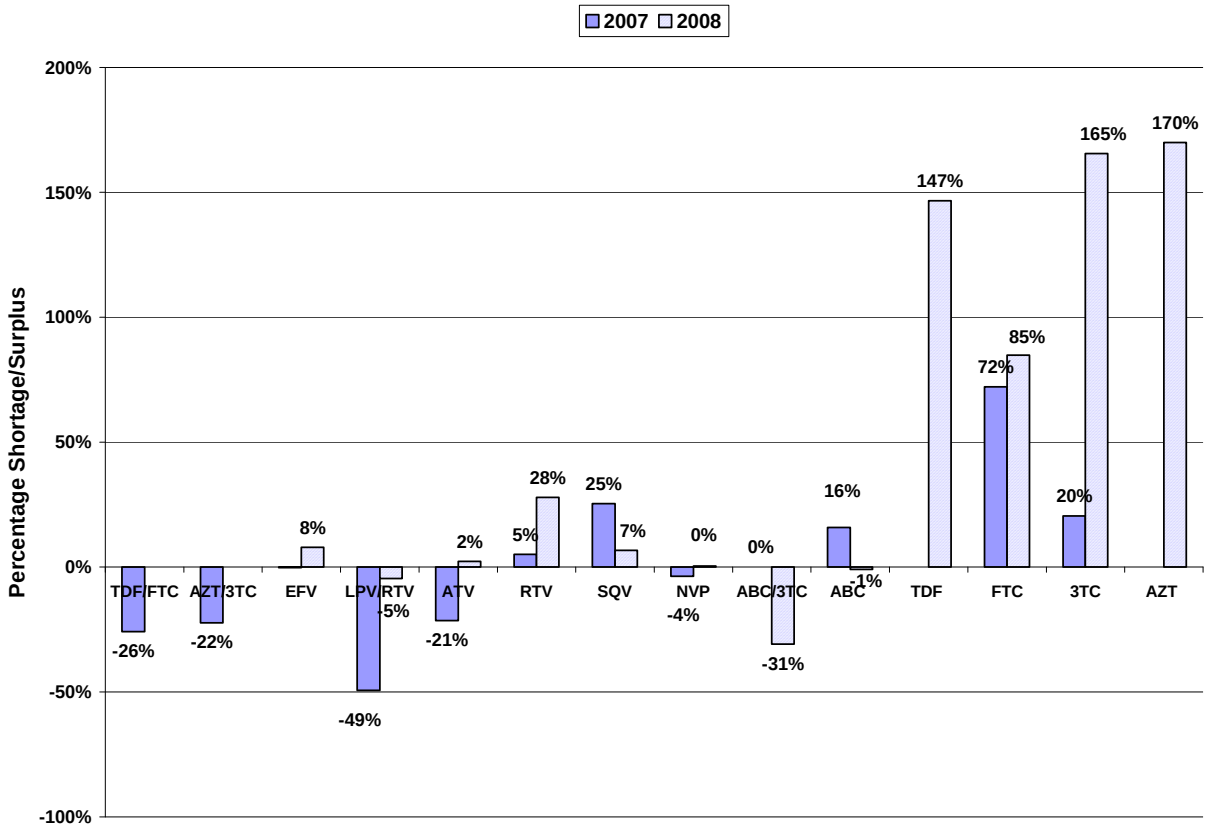


Table IV-6: Estimated ARV Demand and Procurement Volumes and Expenditures for the SSA Health System, 2007

ARV Medicines	Estimated Volume (in units)	Estimated Expenditure (in Millions)	Actual Volume Procured (in units)	Actual Expenditure (in Millions)	Over Expenditure	Under Expenditure
TDF/FTC	105,798	$35.3	78,397	$26.2		$9.2
*AZT/3TC	82,398	$23.9	63,997	$9.7		$14.1
EFV	108,798	$9.4	108,527	$9.4		$0.02
LPV/RTV	46,448	$24.2	23,525	$12.3		$11.2
ATV	23,698	$9.5	18,624	$7.5		$2.0
RTV	55,941	$4.4	17,513	$4.7	$0.2	
SQV	22,042	$6.7	27,640	$8.5	$1.7	
NVP	27,362	$1.1	26,344	$1.1		$0.04
*ABC/3TC	3,990	$1.3	3,990	$0.7		$0.6
ABC	24,646	$6.4	28,540	$7.5	$1.0	
TDF	12,818	$2.9	12,818	$2.9		
FTC	14,148	$1.6	24,357	$2.7	$1.1	
3TC	16,185	$3.6	19,496	$4.4	$0.7	
AZT	2,589	$0.04	2,589	$0.04		
Total		$130.6		$97.5	$4.8	$38.1

Note: Estimated demand volume for all patients in SSA for 2007 is the sum of estimated demand by patients in 31 federal states (17,805) and the projected demand by patients in attending national hospitals in the Federal District (3,187). Projected demand for patients in the national hospitals was calculated by extrapolating the proportion of patients on each ARV in the 31 states to the number of patients in the national hospitals.

Table IV-7: Estimated ARV Demand and Procurement Volumes and Expenditures for the SSA Health System, 2008

ARV Medicines	Estimated Volume (in units)	Estimated Expenditure (in Millions)	Actual Volume Procured (in units)	Actual Expenditure (in Millions)	Over Expenditure	Under Expenditure
TDF/FTC	131,727	$40.6	131,727	$40.6	$0.01	
*AZT/3TC	100,188	$27.6	100,188	$27.2		$0.4
EFV	136,388	$10.6	147,228	$11.5	$0.9	
LPV/RTV	59,144	$28.9	56,458	$27.5		$1.3
ATV	28,553	$10.7	29,186	$10.9	$0.2	
RTV	20,799	$5.3	26,596	$6.8	$1.5	
SQV	28,176	$8	30,047	$8.5	$0.5	
NVP	33,331	$1.4	33,458	$1.4	$5.3	
*ABC/3TC	15,854	$5	10,967	$4.1		$0.9
ABC	25,125	$5.8	24892	$5.7		$0.1
TDF	8,635	$1.8	21293	$4.5	$2.7	
FTC	19,152	$2	35387	$3.7	$1.7	
3TC	8,959	$1.7	23785	$4.5	$2.8	
AZT	9,180	$0.1	24783	$0.3	$0.02	
Total		$149.5		$157.4	$10.7	$2.8

Note: Data on estimated demand volume for lamivudine (3TC) and zidovudine (AZT) were not provided by dosing form. It was assumed that the estimated demand combines all dosing forms. The estimated demand for all dosing forms was then compared to procured volume for the same ARVs.

Figure IV-7: Estimated and Actual Expenditure for 14 Most Commonly Used ARVs, SSA, 2007 and 2008

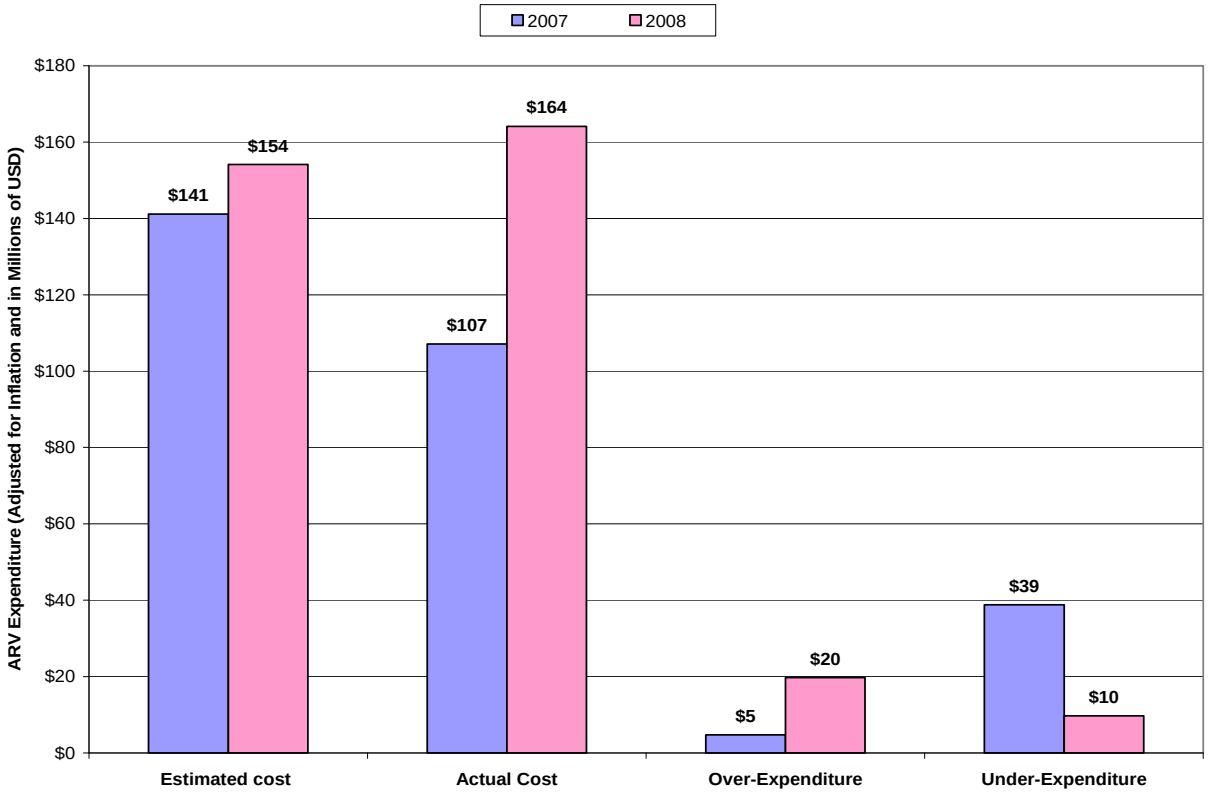


Figure IV-8: Percent of ARV Volume Shortage or Surplus for the IMSS Health System, 2008

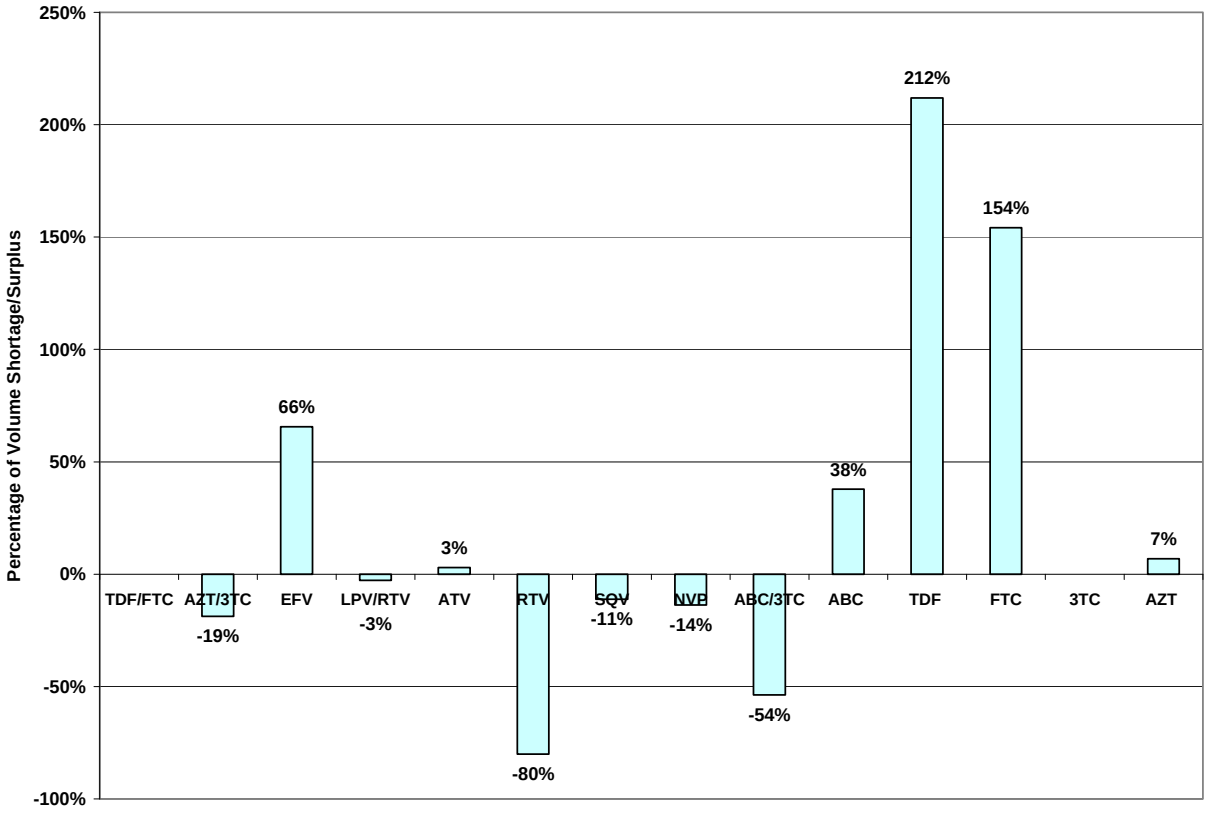
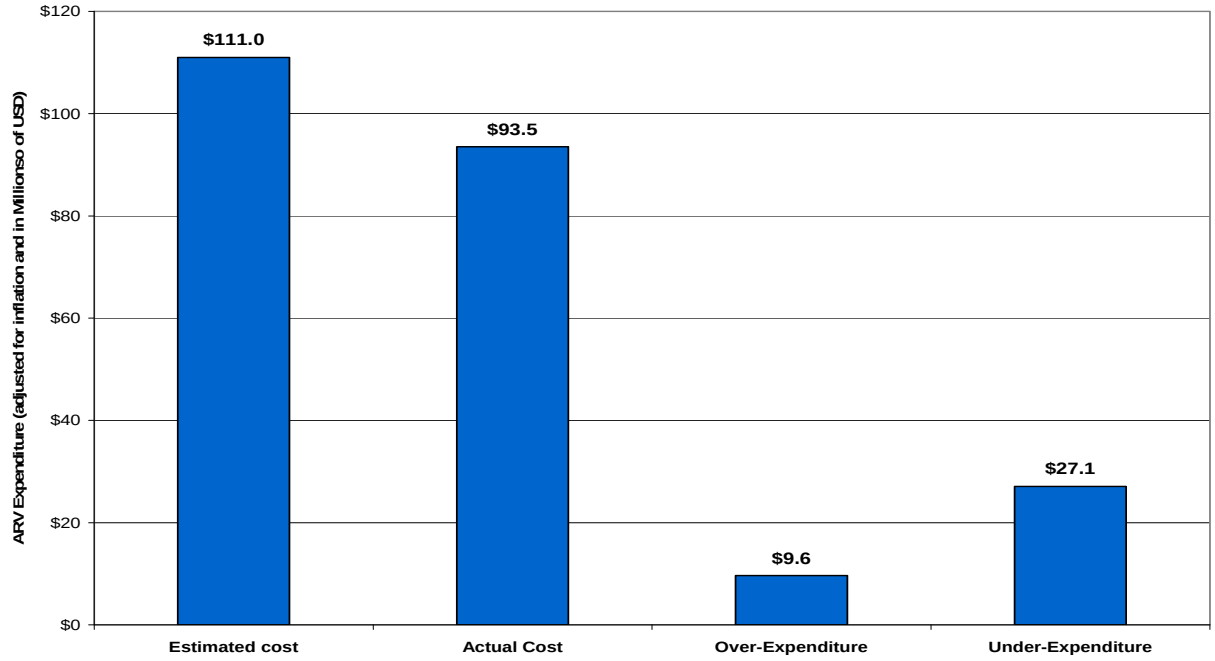


Table IV-8: Estimated ARV Demand and Procurement Volumes and Expenditures for the IMSS Health System, 2008

ARV Medicines	Estimated Demand	Estimated Expenditure (in Millions)	Procurement Volume	Actual Expenditure (in Millions)	Over Expenditure	Under Expenditure
TDF/FTC	14,880	$6.1	14,880	$6.6	$0.5	
*AZT/3TC	94,044	$24.6	77,467	$19.7		$5.1
EFV	28,848	$2.3	47,787	$3.8	$1.5	
LPV/RTV	46,896	$22.4	45,592	$21.8		$0.6
ATV	12,216	$4.5	12,572	$4.6	$0.1	
RTV	27,615	$6.7	18,457	$4.4		$17.9
SQV	41,040	$11.0	36,456	$9.8		$1.2
NVP	25,656	$1.0	22,133	$0.8		$0.1
*ABC/3TC	15,948	$5.1	6,313	$2.6		$2.0
ABC	20,148	$4.9	23,962	$5.7	$1.8	
TDF	6,168	$2.1	19,242	$6.7	$4.5	
FTC	7,056	$0.7	17,931	$1.8	$1.1	
3TC	20,556	$3.7	20,556	$3.7		
AZT	15,504	$0.1	15,504	$0.2	$0.01	
Total		$ 95.3		$92.4	$8.7	$11.6

Note: Data on estimated demand volume for lamivudine (3TC) and zidovudine (AZT) were not provided by dosing form. It was assumed that the estimated demand combines all dosing forms. The estimated demand for all dosing forms was then compared to procured volume for the same ARVs.

Figure IV-9: Estimated and Actual Expenditure of 14 Most Commonly Used ARVs, IMSS, 2008



CHAPTER V: CHANGES TO FORECASTING, PRICE NEGOTIATION, PROCUREMENT MANAGEMENT AND OVERALL AVAILABILITY OF ARVS INTRODUCED BY THE INTER-INSTITUTIONAL COMMISSION TO MEXICO'S HEALTH SYSTEMS

This chapter assesses how the Inter-Institutional Commission introduced changes to the ARV supply chain in the three systems.

The Inter-Institutional Commission was established with the main objective of improving price negotiations for patented medicines, medical devices and supplies included in the inter-institutional drug formulary. The Commission is made up of the representatives of the three public institutions: IMSS, ISSSTE and SSA/CENSIDA. However, it exists in an advisory capacity and does not have a budget. The Commission has three sub-committees – 1) Technical Clinical, 2) Economic Evaluation and, 3) Prices and Patents.

As mandated by a presidential declaration, the primary objective of these sub-committees is to provide technical information to the Commission that informs the negotiation process. At its first meeting in February 2008, the Commission developed the following 11 goals:

1. Annual price negotiation of patented medicines and medical supplies listed in the drug formulary.
2. Gather information on minimum volume demand.
3. Gather information on prices selected for negotiation.
4. Gather information on patents of medicines.
5. Develop strategies for negotiation and procurement to improve drug purchasing.
6. Analyze, develop and propose measurements for improving drug purchasing.
7. Prepare an annual negotiation calendar.
8. Design and develop strategies for drug distribution.
9. Implement evaluation mechanisms for monitoring forecasting and distribution and to ensure government accountability.
10. Issue operating rules.
11. Prepare an annual report.

Source: Federal Declaration, February 26, 2008

During the implementation phase the Economic Evaluation sub-committee was instrumental in developing the operational procedures for the sharing of information between the sub-committees. Due to a limited time schedule, the Economic Evaluation sub-committee proposed providing in-depth cost-effectiveness analyses for only 17 of the 95 patented medicines that the Commission selected for negotiations. According to one of the sub-committee's analysts, the 17

medicines were selected because "they amounted to about 80% of costs of the 95 patented medicines" (Interview 14, 2008; Interview 15, 2008). Of the 17 medicines subjected to this analysis, six were ARVs. The next round of analysis was then conducted by the Technical Clinical sub-committee. This round included an analysis of the safety and therapeutic equivalence[5] of each of these medicines. The role and contribution of the sub-committee on Prices and Patents remained uncertain at the time of the interviews. According to respondents from both the Economic Evaluation and Technical Clinical sub-committees, reports were generated for all 17 medicines and submitted to the Commission. The Commission in turn convened negotiation teams (with representatives from each of the three institutions), which would then negotiate prices for all 95 medicines.

A. Did the Inter-Institutional Commission achieve its primary goal of lowering prices of ARVs purchased by the three health systems?

1. Post-Negotiation ARV Prices

To assess the immediate effect of negotiations on annual ARV prices, the following analysis compares ARV prices (adjusted for inflation) between 2004 and 2009 for SSA and IMSS, the two largest providers in Mexico (see Figures V-1 and V-2 as well as Tables V-1 and V-2). Annual prices for ARV for 2008 for SSA were separated into January-September and October- December, the periods before and after negotiations. Available data for IMSS cannot be separated in the same way and thus only an aggregate analysis is provided for 2008.

When adjusted for inflation, there were no substantial changes in prices of the selected ARVS between 2003 and 2008. That means that ARV prices remained relatively stable between 2004 and 2008. After the first round of negotiations concluded in September 2008, ARV prices were significantly reduced compared to the prices in previous years. Additionally, looking at the average percent change from 2004 to 2009, the highest average percentage reduction in prices occurred after negotiations – after October 2008 for SSA and in 2009 for IMSS (Tables V-1 and V-2). The data strongly suggest that the Commission successfully negotiated lower prices, accounting for an average of 33% and 42% reduction in ARV prices for SSA and IMSS, respectively.

2. ARV Prices in Mexico Compared to Global Prices

To understand how ARV prices in Mexico compared with global ARV price trends of the same period of time, the annual price per patient per year for the most commonly used ARV regimens in the SSA system before and after negotiations was compared to median annual price per patient per year of the same ARVS for upper-middle income countries (see Tables 2A to 4B in the Appendix). As Figure V-3 shows, Mexico, in this case SSA, has consistently paid higher prices for ARVs than the median upper-middle income country, even after joint price negotiations were conducted in September 2008.

[5] An analysis that provides comparisons with other medicines that treat the same ailment.

While both SSA and IMSS achieved average price reductions of 33% and 42%, respectively, they would have achieved even greater price reductions had the Commission been able to reach the median price for upper-middle income countries. In other words, there was a reduction in ARV prices in Mexico after September 2008, but the median ARV prices paid by countries similar to Mexico in economic standing were even lower prices for the same medicines. In addition, between 2007 and 2008, there was a significant drop in median prices of ARVs paid by upper-middle income countries (see Table V-3).

To understand how prices affect total ARV expenditures, IMSS and SSA expenditures for twelve ARVs (ABC, EFV, 3TC, LPV/RTV, NVP Tablets SQV, TDF, TDF/FTC, ATV, RTV AZT and AZT/3TC) from 2004 to 2009 were calculated and then compared to two hypothetical scenarios: 1) the cost of the same ARVs for the same period, assuming the median price for upper-middle income countries, and 2) the projected cost after 2008 had there been no price negotiations. Figure V-4 and Table V-4 show Mexico's actual expenditure, the expenditure assuming upper-middle income prices and the expenditure had there been no reduction in prices after 2008.

Mexico's two largest providers of HIV/AIDS care have been paying substantially higher prices and thus spending more than the median upper middle-income country. More importantly, even though both health systems saved a little over $4.5 Million or 2% after negotiations, had the Commission been able to negotiate the median global middle-income prices for the same ARVs, Mexico would have saved approximately $205.2 Million or 83% in ARV costs for the year 2008. In 2009, as a result of negotiations Mexico spent $169.1 million instead of $245.6 million on ARVs, thus achieving savings of $76.5 million or 45% in ARV costs. However, Mexico would have saved a total of $128.5 million or 76% of ARV costs had the Commission been able to negotiate at median upper-middle income prices for 2009. Additionally, because median ARV prices paid by upper-middle income countries fell between 2007 and 2008, the expenditure for SSA and IMSS for 2008 at upper-middle country median prices was compared to the expenditure for the same quantity of ARVs for the same year, but at median prices paid by upper-middle countries in 2007 (Table V-5). The cost-savings by upper-middle income countries for the same quantity of ARVs between 2007 and 2008 was $23.2 million or 55%. This suggests that the median ARV price for upper-middle income countries also experienced a significant drop in ARV prices during Mexico's first round of negotiations.

B. How has the Inter-Institutional Commission changed (current and expected) forecasting, price negotiation and procurement policies and procedures to improve availability of ARVs?

When asked if they understood how the Commission would implement negotiations for patented medicines, there were varying responses from different groups of informants (see summary of responses in Table V-6). The following paragraphs describe how groups of informants perceived the Inter-Institutional Commission and its roles.

1. Hospital Program Managers

Few program managers at this level were aware of the Inter-Institutional Commission. Those who were aware of the Commission indicated said that it would be involved in reducing prices but were not aware of the changes the Commission would implement outside of lowering ARV prices. Informants in this group were not aware of any changes to forecasting or procurement since the Commission's inception, nor were they expecting any changes in the near future. As an IMSS hospital program manager put it:

> *"Yes, the Commission negotiated in 2008 and 2009. The prices made a difference for everyone. For IMSS each of the regions/delegations still buy apart but they now have the agreed contract from IMSS central in order to procure at negotiated prices. [But] prices are one thing but there are also infrastructure problems that need to be addressed."* (Interview 21, 2010)

2. Health System Program Managers

All the informants in this group understood the premise behind the creation of the Commission – i.e., price variation and increasing cost of medicines across the health systems. While informants knew that the Commission would negotiate prices of patented medicines, the majority believed its primary negotiation strategy would be based on the consolidation of volume across the three health systems.

> *"For prices, ISSSTE [doesn't] negotiate, about 80% of the prices are the same for all the institutions (IMSS, SSA, ETC). In 2009, [the institutions as a] group will negotiate for better prices using total ARV volume and the group will try to pay the same price for each medication.* (Interview 5, 2008)

Only a few of the informants had an in-depth understanding of the negotiation process, indicating that they believed that the Commission's analysts would use methods that include comparison of drug prices with prices paid by similarly-situated countries (in terms of HIV/AIDS prevalence and economic status), therapeutic equivalence analysis, and safety and efficacy studies. These informants also believed that the experts in the Commission had a potential to increase the knowledge and implementation of strategies to negotiate drug prices. As the ISSSTE program manager quoted above puts it:

"They [Commission] has more than people than we do and will be able to do more." (Interview 5, 2008)

3. Ministry of Health Analysts

Informants in this group consisted of people who were directly involved with the Commission or its sub-committees by providing technical support to members of the Commission or sub-committees. This group of informants had the most detailed understanding of the premise for the creation of the Commission, its methods for assessing drug prices, and its potential negotiation strategies. Informants stated that there were two principal reasons for the creation of the Commission – 1) the cost of patented drugs account for a large proportion of the pharmaceutical budget (80%) but the same drugs represented a small proportion (20%) of total drugs purchased, and (2) variation in prices for the same patented drug across health systems, in particular the IMSS health system (Interview 5, 2008; Interview 7, 2008; Interview 10, 2008; Interview 11, 2008; Interview 21, 2010). Informants also indicated that they understood the goals of each sub-committee in providing analyses that would be used to develop negotiation strategies. These informants all stated that the Commission and its sub-committees needed to clarify their respective roles and responsibilities in achieving the goals and objectives laid out in the Mexican President's declaration.

"So you've got a great degree of heterogeneity in the purchasing in the public sector. This fragmentation implies that the purchasing power at the institutional level is quite weakened. So when you have a weak purchasing power so unless you have a reasonable volume you are weakened in the face of the industry…You want to first add volume, and second improve or institutionalize have a more professional process to inform the people who are going to sit down with the industry and negotiate. So it is a matter of having more volume therefore surmounting the limitations from fragmentation and then adding new elements to the negotiation - economic evaluation, consideration of safety and bio-equivalence and also a more professional way of price comparison with other countries with other equivalence and so on. So you want to pursue these two goals, you have to do it necessarily through an entity that connects the different institutions that operate in the public sector and that is how the idea of the commission was developed"(Interview 7, 2008)

"There is still more work but [now] we have more time to think [about strategies]. We should be working/planning what should come up next. [We are going to try] to work out what to do for the next cycle for next year. I am not sure when the next deadline is but I know when the next meeting will be" (Interview 11, 2008)

Beyond mentioning reduction in prices, none of the informants working with the Commission were able to provide any specific and quantifiable objective of price reduction (for instance, at least 30% price reduction from the previous year) laid out by the Commission. Informants either stated that the outcomes of negotiations were confidential or, as stated above, that the Commission's processes and negotiation strategies were still being developed. At the same time, the explanations demonstrated that the commission and sub-committees were

intensively working shortly before the negotiation but not continuously over the year to prepare for the new negotiation phase.

Like health system program managers, Ministry of Health analysts explained that the Commission would incorporate strategies that included cost effectiveness analyses, and comparisons of Mexico's economic level with other countries as ways to assess price differences and Mexico's share of global pharmaceutical consumption. Providing more detail than health system program managers, SSA analysts said that they expected the Commission to focus on negotiations and strategies (i.e., cost benefit analysis, duration of a patented drug[6], therapeutic equivalence analysis, etc.) in choosing drugs for the three health systems.

> *"It is important to understand that the Commission is only a Commission that negotiates. The Commission does not purchase. It is still the responsibility of each institution to do their own purchasing. The Commission will just be involved in negotiation…. Also remember, the Commission does not have a separate budget, it cannot tell the institutions [health systems] how to spend their money."* (Interview 7, 2008)

> *"At the end of the day, what it will adopt as an added value, the Commission, is this key information that perhaps the institutions by themselves don't have. For example, the comparison of prices, at the international level, the information of cost effectiveness and some key ideas about which arguments will be the strongest. In some medications, it will be the volume of purchase, in some others, it will be the fact that their cost effectiveness is not that good so please reduce the price because there are other alternatives, and so on."*(Interview 10, 2008)

However, one informant made a comment that was a departure from the general response of other informants in the group. This senior analyst stated:

> *"The best conditions are not exclusively price? Right? The government's job is to make the best conditions possible for all possible situations, right? To buy medicines and give to the people, in this case, who are unable to afford care, like those without resources. But also I have to consider the development of the [pharmaceutical industry], its employees, so that they create medicines and new medicines. Depending on the situation, these things are things that the Commission has to consider in each and every case in negotiating the price with the patent holder."* (Interview 8, 2008)

Coming from one of the key members of the Commission, this statement suggests that the Commission's approach to negotiation might be limited by the possible impact on the Mexican pharmaceutical market and commercial interests. It was not clear how the Commission members planned to balance the differing positions: on one hand, to lower prices and provide more ARVs to the maximum number of patients needing treatment, and on the other hand to place limitations on private development and potentially economic benefits to the Mexican pharmaceutical industry.

[6] The time a patented drug is protected against infringement from other companies or individuals.

Despite the Commission's stated goal of developing strategies for drug procurement and distribution, both groups of program managers stated that they expect the Commission to focus primarily on negotiation, requiring that the three health systems to manage the other components of the drug supply chain, i.e., conduct forecasting, procurement and distribution.

> *"The rest of the chain in the process will be supervised by other entities. At least that's what I can expect from the Commission. That doesn't limit the fact that perhaps one or two years, the Minister decides well, the Commission should also go into some other parts of the process. At the moment the scope is very limited, and it's only the negotiation of prices."* (Interview 10, 2008)

However, there is the possibility that the Commission might venture into management of other stages of the supply chain and bring its expertise to bear by offering guidance to the three institutes on managing forecasting, procurement and distribution.

> *"Once [the Commission] negotiates, the supplier should respect the negotiation prices. So each institution goes through their own [purchasing/procurement] system. Now one of the conditions for the supplier to respect set prices is to have certainty that the volume offered is accurate. So obviously each institution has to improve the forecasting of volume requirements. This could be the first opportunity to systematically start collecting information on purchases basically and having the chance to gather all the information of everybody and not having a partial view of each institution. So you could provide not only lessons on how to produce forecast but also analytical information of what is being done at the sector level."* (Interview 7, 2008)

Given the limited understanding of the negotiation process on the part of the informants, the interview pool was expanded to include representatives from the pharmaceutical industry. Secondary data on interviews with pharmaceutical industry representatives were then included for additional analysis.

Informants in this group consisted of two groups – representatives of patent-holding companies and representatives of generic companies. Much like the program manager group, informants in the industry group understood that the Commission would negotiate prices for patented medicines on behalf of the three major health systems, but they did not know more than the fact that negotiations would be conducted with the Commission instead of separately with each institution.

In terms of the premise for the creation of the Commission and the process of negotiation, there were distinct differences in the points of view between the informants representing companies producing generic medicines and those representing patent-holding companies.

4. Representatives of Patent-Holding Companies

Patent-holding companies saw the Commission as a cost effective way to conduct negotiations, but they were concerned that the Commission could increase the government's negotiating power disproportionately. These informants described this power as the ability to

make demands that could infringe on the companies' ability to recoup research and development costs and/or infringe on intellectual property rights and Mexico's economy. As two informants described it:

> *"First and foremost, the most important thing is that we cannot agree without understanding the importance of developing new medicines."* (Interview with Patent-holding Pharmaceutical Representative 1, 2008)

> *"As an industry we can not agree if the procurement prices violates patent rights. This we cannot agree to. The procurement of products in theory should follow a particular manner when that product is patented [it] can only be purchased from the patent owner and no one else"*. (Interview with Patent-holding Pharmaceutical Representative 2, 2008)

> *"There is a process of struggle with patenting and the one who gains is the one who develops the medicine. So companies in Mexico must respect patent rights because whenever a product is patented there is a struggle to get it off patent so that it can be sold by many. For this reason COFEPRIS (Mexican Drug Registration Administration) does not recognize patents. The ones that are most affected are the companies that developed the medicines and if you say patents are a limitation to access to medicines I cannot agree and will not see it that way."* (Interview Patent-holding Pharmaceutical Representative 3, 2008)

> *"The government is a very powerful negotiator, no? Why? Because the government is the entire health system. Like volume and everything, it can be coercive no? Let's call it what it is a, a very powerful negotiator. And what are they trying to do? That everyone wins or just them?"* (Interview Patent-holding Pharmaceutical Representative 5, 2008)

> *"About the negotiations and discussions with national (generic) companies etc, etc, the only thing is the recognition of patent of the active ingredient, I'm not talking about the patent of the active ingredient, I'm talking about the patented medicines, no? How should it be? Now if you have a patent for a specific use, then you have to register and apply to use it, but the problem is that in Mexico today, for example Seguro Social (health insurance) tries to get patent [medicines] both ways, where I have exclusivity, no one else can sell because COFEPRIS should not allow you to register but [COFEPRIS] also allows other companies to sell them, no? So, there are big fights with these [national] companies when it comes to registering our patents and this is not a issue about limiting access, this is a question of international intellectual patent right and they are violating an international right, no?"* (Interview with Patent-holding Pharmaceutical Representative 4, 2008)

Overall, representatives of patent holders expected that the Commission would allow for one singular price negotiation process that would reduce the overhead costs related to having to conduct multiple negotiations. These informants also noted that the Commission would have to take factors other than drug prices into consideration. These factors included using negotiation strategies that "respected intellectual property rights," "the contribution of the pharmaceutical

industry to the economy," and the "importance of building a working relationship between the industry and the government."

5. Representatives of Companies Producing Generic Medicines

Representatives of the generic pharmaceutical industry had a less detailed understanding and thus had very few expectations of the Commission, noting that the negotiation process did not involve generic drugs. Also, one particular perspective among this group noted the need for a transparent negotiation process to ensure that Commission acted fairly. As one respondent conveyed

> *"I believe that in our country there really isn't a culture of transparency to change everyday experience with this type concentration of power and decision-making acquired by the Commission. The only thing that can happen is that it is inviting less transparency and less clarity regarding public spending."* (Interview with Generic Pharmaceutical Representative 1, 2008)

Each one of these informants expected the Commission to conduct negotiations with patent-holding companies only. In the long term, however, representatives of companies producing generic medicines stated that the current intellectual property regulations heavily favors patent-holding companies, stifling competition for drug production necessary for lowering prices. As noted by a representative of generic pharmaceutical company:

> *"Well, here the problem is not IP per se but abuses around granting patents. It is very important to grant patents and we all agree about that. That is what it was created for. The problem is that pharma or the innovators are trying to push many IP figures too fast, I mean they are trying to extend IP rights too much. If we consider patents for new knowledge for example, that has inventive step and that is important. But when we are talking about incremental steps about patents of selection and all those patents that really do not have inventive merits. Then we are in a scenario were we will not agree to the granting of those patents. What is really important here is that there is a huge gap between negotiating partners, that is industrialized countries have a lot of power to implement trade agreements."* (Interview Generic Pharmaceutical Representative 3, 2008)

While informants in the industry group all wanted the negotiation process to be fair, each sub-group had its own definition of a fair process. Representatives of companies producing generic medicines wanted the Commission to address the patent process that allows continuous patent extensions for medicines and limits generic competition. On the other hand, representatives of patent-holding pharmaceutical companies considered the Commission powerful because it was part of the government and, as such, had the power to change intellectual property rights in its favor. These statements indicate that the Commission has yet to address a key issue in the negotiation process – i.e., how the patent process maintains limited competition and thus higher drug prices and how the Commission intends to address this complex issue in pursuing the goal of obtaining lower drug prices.

C. Discussion

This chapter's discussion will focus on two main areas – assessing changes to the supply chain of each health system using the global optimization framework and assessing the implications of the Commission's negotiation of ARV prices.

1. Supply Chain Indicators and Performance Measure

The most noteworthy change to the SSA ARV supply chain has been the Commission's success in achieving lower ARV prices across health systems, due to significant improvements in the negotiation stage of the supply chain. Beyond this aspect of the negotiation stage of the supply chain however, there has been little or no change to supply chain indicators and performance measures in the SSA health system. At the same time, limited data collection and access to data persist after the establishment of the Commission. In particular, access to ARV demand and procurement volume for 2009 data were limited, requiring the use of estimates to assess changes in the performance of the supply chain. Similarly, uncertainties associated with limited data continue to prevent improvement of the supply chain after the establishment of the Commission (Allers and Riwa, 2001; Bossert et al., 2006; Deliver, 2006; Quick et al., 1997).

Much like the SSA health system, achieving lower ARV prices was the main improvement to the IMSS ARV supply chain. However, no substantial changes have been made with regard to forecasting and procurement indicators. Furthermore, the limited availability of data for 2009, and thus limited ability to monitor and assess performance, suggests that challenges to improving IMSS health system ARV supply chain remain. As a result, there are still concerns about the availability of ARV and how this impacts patient care and health system costs (Allers and Riwa, 2001; Bossert et al., 2006; Deliver, 2006; Quick et al., 1997).

2. Information Integration

The translation of the Commission's successful negotiation of ARV prices into lower procurement prices indicates some improvement in information coordination and integration between the Commission, SSA (including CENSIDA) and IMSS. The processes for organizing information as well as the tools used in analyzing ARV price data were changed by the inclusion of the Commission and its sub-committees. These changes helped guide decision-making and the introduction of additional analysis in the negotiation process. In the particular case of the IMSS health system, ARV prices negotiated by the Commission were transmitted to regional IMSS bodies as the ceiling prices to use in procurement of ARV. It might be that the combination of cost-effectiveness analyses, therapeutic equivalence studies, and price comparisons with countries with similar economic statuses played an important role in achieving lower ARV prices (Bossert et al., 2007; Waning et al., 2009). Although informants stated that volume was a key factor in negotiations, it is uncertain what role pooled procurement played in achieving lower prices. While the details of the negotiation process, particularly the strategies used to lower ARV price remain confidential, centralizing the negotiation process appears to have alleviated a portion of the cost of purchasing ARVs (Bossert et al., 2007).

Despite the success integrating the Commission into the negotiation stage, it remains unknown what impact this integration will have on other stages of SSA and IMSS ARV supply

chain. For example, the use of forecast data by the Commission in the negotiation process may require improving accuracy in data collection by the health systems and thus more accuracy in the estimation of patient ARV needs. However, because 1) informants stated that they did not expect immediate changes to forecasting and procurement stages of the ARV supply chains in both IMSS and SSA, 2) the Commission has yet to offer specific policy guidelines on forecasting and procurement, and 3) the Commission lacks the capacity to implement policy through resource allocation, it is likely that factors respective to each health system identified in chapter IV will persist in hindering integration of information and ultimately supply chain performance.

3. Assessing the Inter-Institutional Commission

The establishment of the Inter-Institutional Commission to conduct joint negotiations on behalf of the three major health systems has achieved its main goal – substantial reduction in ARV prices through joint negotiations. It is, however, difficult to evaluate the Commission's achievement of other stated goals because the implementation is still evolving.

First, a key aspect of the Commission's development is the lack of specific goals with regards to price reduction. The Commission seems to be adopting negotiation strategies for securing improved prices by mainly using volume and Mexico's economic status. However, as mentioned in Chapter IV, an increase in volume did not lead to reduction in prices for SSA in previous years. Since there does not appear to be a precedent for increased volume as a strategy for reducing ARV prices, it is uncertain how much of an impact pooled procurement will have on ARV price reduction in Mexico, particularly in the long term. Additionally, although the Commission was able to achieve reduced ARV prices, Mexico continues to pay substantially higher prices for ARVs than the average upper-middle income country. In comparison to prices negotiated by the Commission, the decrease in median upper-middle income country prices at the same time suggests that price reduction in Mexico may have been influenced by a global trend and not solely the result of the Commission's work. This further suggests that the Commission's use of global price comparative analysis may not be as effective a negotiation strategy as stated by informants.

Second, the lack of specific goals is also evident in the lack of transparency in the negotiation process and lack of clarity with regard to the roles and objectives of each of the Commission's sub-committees. Information about strategies and goals set out by the Commission in the 2008 and 2009 rounds of negotiations was deemed confidential, making it difficult to evaluate strategy success. Without addressing the issue clearly, defined goals, performance targets, and transparency of the negotiated prices to compare to actual purchasing prices, both IMSS and SSA health systems run the risk of being unable to assess the impact of the Commission's negotiations on health system ARV costs (Seoane-Vazquez and Rodriguez-Monguio, 2007; Vasan et al., 2006).

Third, responses from pharmaceutical representatives raise a key issue that the Commission and its sub-committee on Prices and Patents have yet to address – the complexity of balancing private intellectual property rights with the goal of lowering ARV costs. The lack of a clear role and set of responsibilities of the Prices and Patent sub-committee further proves this point. As a number of informants noted, the intellectual property process in Mexico – registering,

granting, maintaining or extending intellectual property rights – is convoluted and the lack of a functioning Prices and Patents sub-committee is likely to impede the Commission's ability to monitor adequately the impact of the patent process on price negotiations. In addition, concerns about the possibility of the government violating intellectual property rights raised by representatives of patent-holding pharmaceuticals do not bear out, as evidenced by the lack of a functioning Price and Patent sub-committee. However, the opposition to government involvement by the pharmaceutical industry appears to follow a pattern first established in South Africa, where pharmaceutical companies sued the South African government over the creation of a law to reduce ARV prices. This law consisted of policies that included the creation of a pricing committee and banning of pharmaceutical company influence on physician prescription practices (Sidley, 2001). In that case, pharmaceutical companies dropped the lawsuit when the South African government assured the industry it would comply with international trade obligations and intellectual property rights (Sidley, 2001).

Last and most importantly, the negotiation process is only one aspect of managing the supply chain of ARVs in Mexico. As the comparisons between forecast and procurement show, there are still substantial gaps in meeting patient treatment needs. Despite a presidential mandate to "analyze, develop and propose measurements for improving drug purchasing," it is yet to be seen how and when the Commission intends to develop guidelines for improving forecasting, procurement and distribution efficiency in order to lower the cost of managing the ARV supply chain. While it could be argued that requiring that health systems submit ARV volume forecasts is an important first step towards encouraging use of data in decision making, the lack of a formal and systematized procedure for assessing the quality of data submitted by the health systems fails to address concerns about improving efficiency of the supply chain.

The results and discussions from this chapter and the previous chapter will be synthesized in the concluding chapter in order to 1) provide details concerning factors identified as hindering the performance of the ARV supply chain, and 2) offer recommendations for improving management of the ARV supply chain in Mexico.

Figure V-1: Price per Patient per Year for 15 Most Commonly Used ARVs, SSA, 2004 – 2009

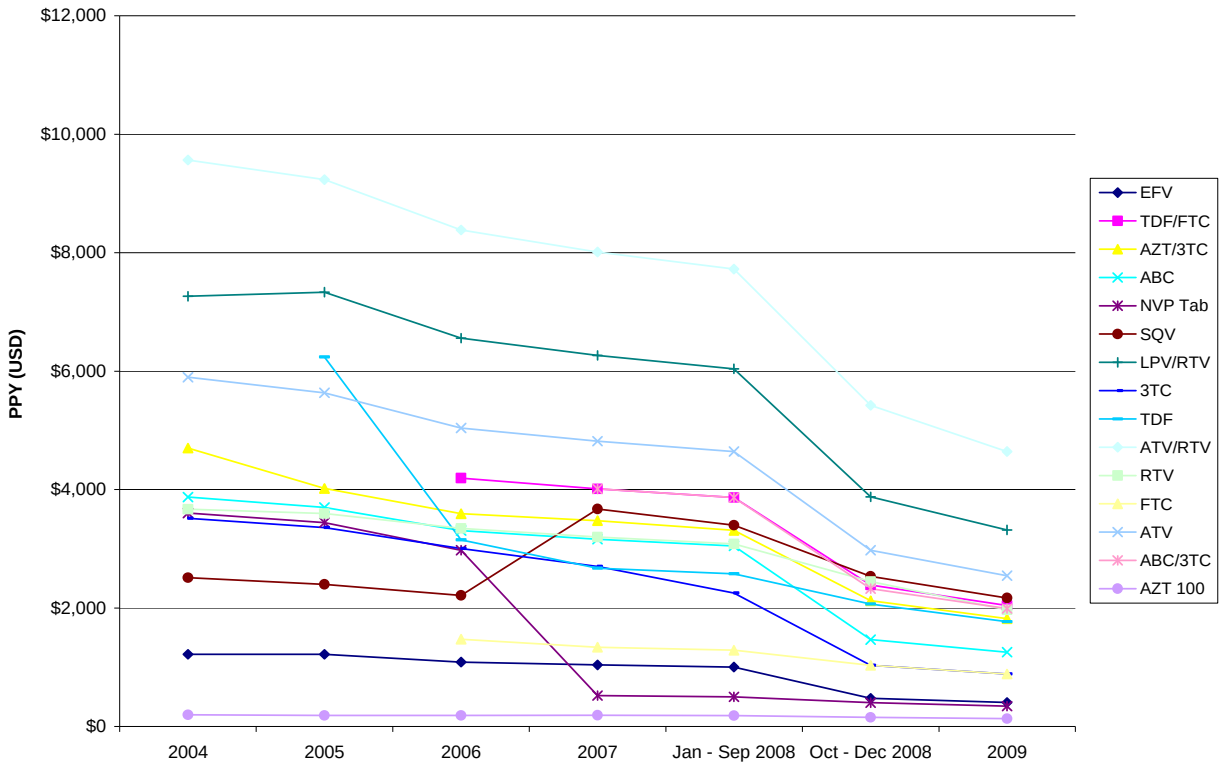


Table V-1: Percent Change in Adjusted ARV Prices Paid by SSA, 2004-2009

ARV Medicines	2004-2005	2005-2006	2006-2007	2007 - Sept 2008	Sept 2008 – Oct 2008	Oct 2008 - 2009
EFV	0%	-11%	-4%	-4%	-53%	-14%
TDF/FTC			-4%	-4%	-38%	-14%
AZT/3TC	-15%	-11%	-3%	-5%	-36%	-14%
ABC	-4%	-11%	-4%	-4%	-52%	-14%
NVP Tab	-4%	-13%	-83%	-4%	-20%	-14%
SQV	-4%	-8%	66%	-7%	-25%	-14%
LPV/RTV	1%	-11%	-4%	-4%	-36%	-14%
3TC	-4%	-11%	-10%	-17%	-54%	-14%
TDF		-49%	-15%	-4%	-20%	-14%
ATV/RTV	-3%	-9%	-4%	-4%	-30%	-14%
RTV	-2%	-7%	-4%	-4%	-21%	-20%
FTC			-9%	-4%	-20%	-14%
ATV	-4%	-11%	-4%	-4%	-36%	-14%
ABC/3TC				-4%	-40%	-14%
AZT 100	-6%	1%	2%	-4%	-16%	-14%
Average Change	-4%	-13%	-6%	-5%	-33%	-15%

Figure V-2: Price per Patient per Year for 15 Most Commonly Used ARVs, IMSS, 2004 – 2009

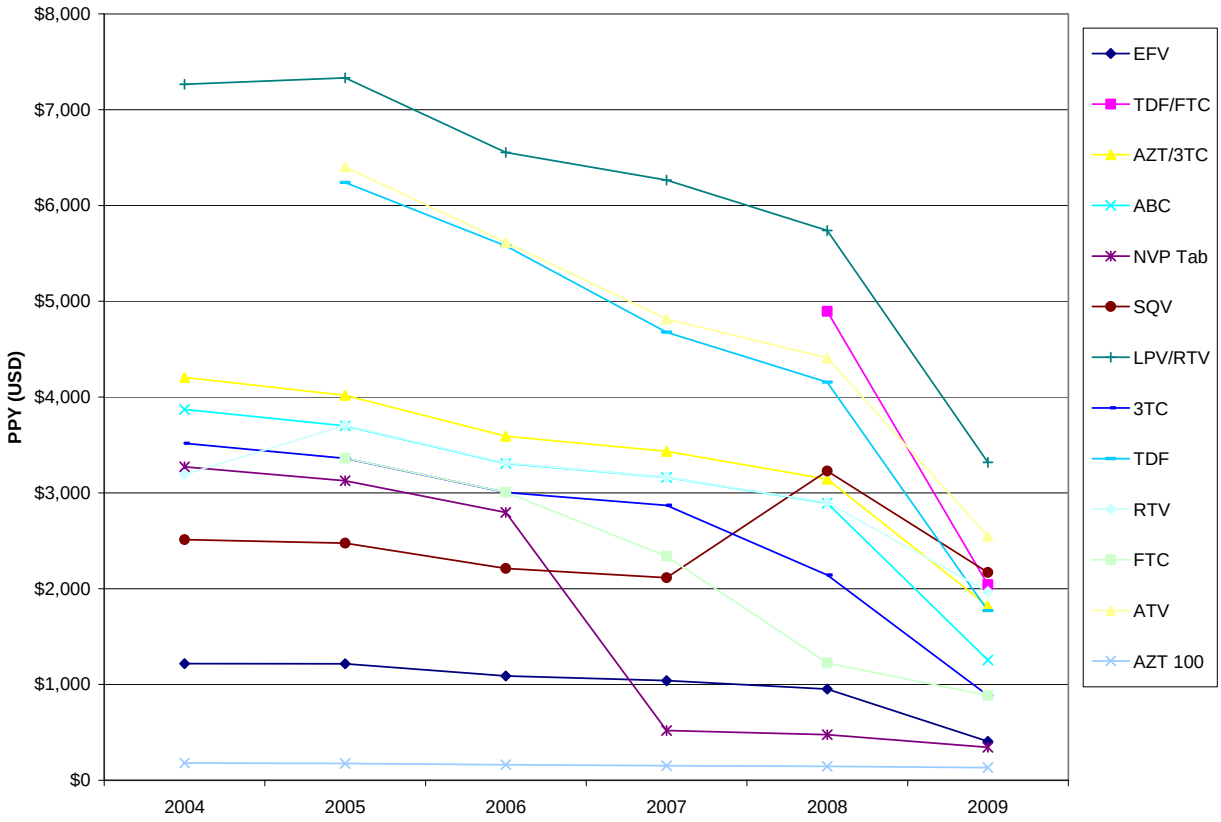
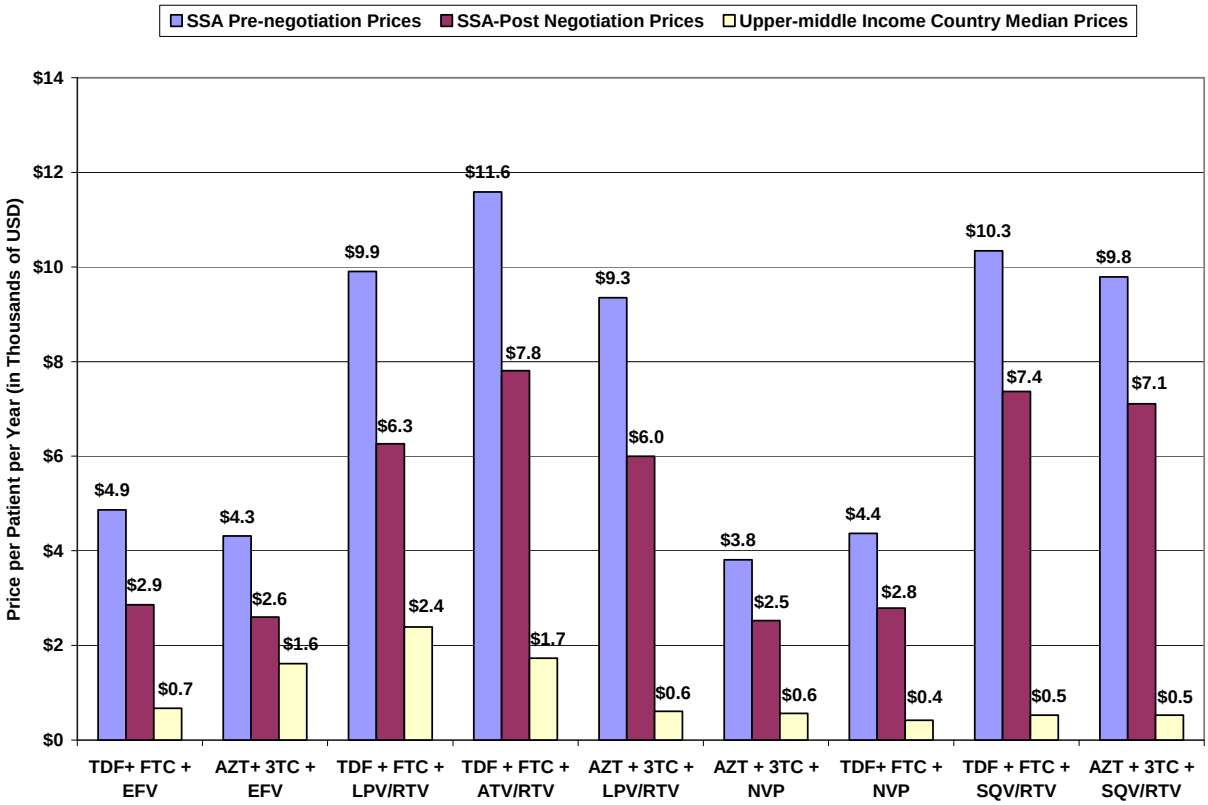


Table V-2: Percent Change in Adjusted ARV Prices Paid by IMSS, 2004-2009

ARV Medicines	2004-2005	2005-2006	2006-2007	2007-2008	2008-2009
EFV	0%	-11%	-4%	-8%	-57%
AZT/3TC	-4%	-11%	-4%	-8%	-42%
ABC	-4%	-11%	-4%	-8%	-57%
NVP Tab	-4%	-11%	-81%	-8%	-28%
SQV	-2%	-11%	-4%	53%	-33%
LPV/RTV	1%	-11%	-4%	-8%	-42%
3TC	-4%	-11%	-4%	-25%	-59%
TDF*		-11%	-16%	-11%	-57%
RTV	16%	-11%	-4%	-8%	-32%
FTC*		-11%	-22%	-48%	-28%
ATV*		-12%	-14%	-8%	-42%
AZT 100	-2%	-9%	-5%	-6%	-9%
Average Change	-1%	-11%	-14%	-8%	-42%

Note: Price data for TDF, FTC and ATV were available starting in 2005.

Figure V-3: Price per Patient per Year of ARVs at Pre-Negotiation, Post-Negotiation and Median Upper-middle Income Country Prices



Note: Regimens shown from left to right in order of highest to lowest frequency in use.

Table V-3: Percent Change in Adjusted Median ARV Prices Paid by Upper-middle Income Countries, 2004-2009

ARV Medicines	2004-2005	2005-2006	2006-2007	2007-2008
EFV	7%	-35%	-10%	-46%
TDF/FTC	-8%	51%	-4%	-24%
AZT/3TC	-8%	-28%	-3%	-41%
ABC	-1%	-25%	-25%	-45%
NVP Tab	-34%	-37%	-3%	-38%
SQV	-1%	-17%	42%	-42%
LPV/RTV	-6%	-17%	-76%	-16%
3TC	2%	-16%	-11%	-33%
TDF	-23%	32%	125%	-73%
RTV	1%	-20%	-14%	-56%
ATV		-47%	122%	-91%
AZT 100	-69%	-64%	-12%	-35%
	-13%	-19%	11%	-45%

Figure V-4: Comparison of Annual Expenditure for 12 Selected ARVs, 2004- 2009 (Based on IMSS and SSA Procurement Volume)

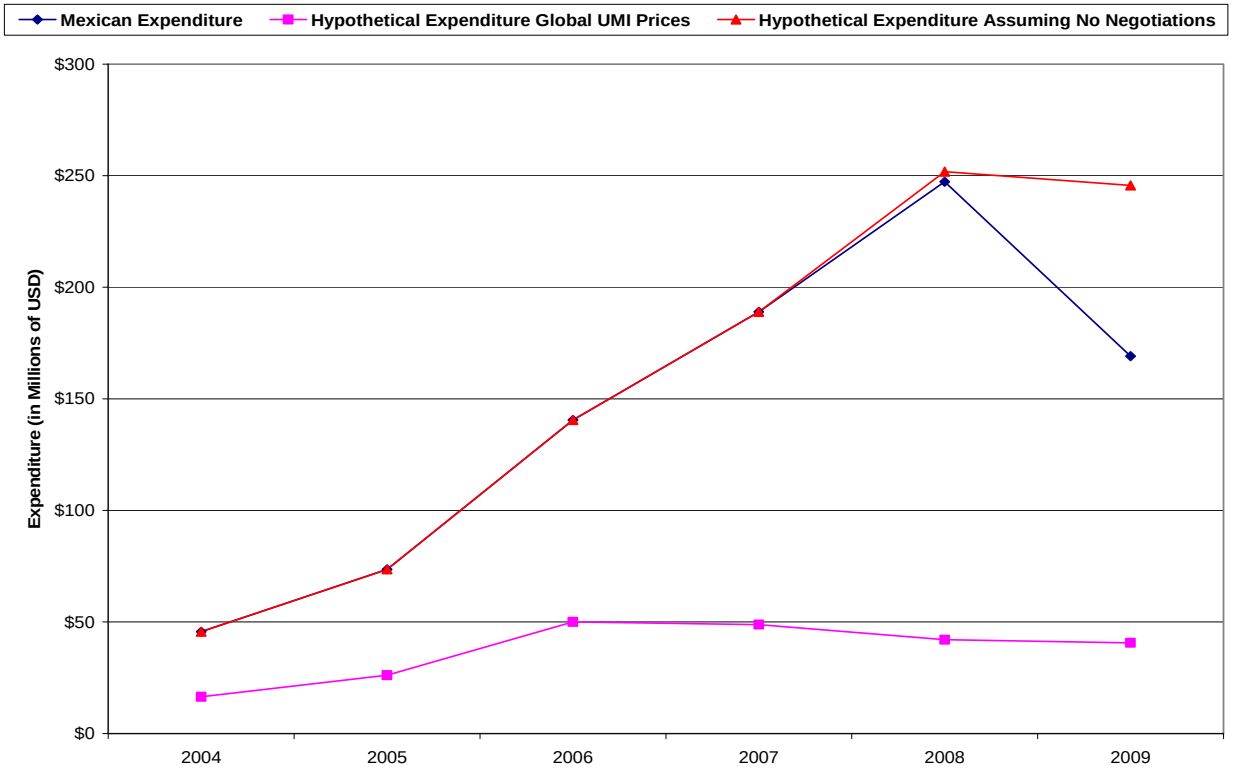


Table V-4: Comparison of Annual Expenditure on 12 Selected ARVs, 2004 – 2009 (Based on IMSS and SSA Procurement Volume)

Cost Scenarios/Percentage Savings	2004	2005	2006	2007	2008	2009
Mexican Expenditure (in Millions of U.S. Dollars)	$45.6	$73.6	$140.5	$188.9	$247.3	$169.1
Hypothetical Global UMI Expenditure (in Millions of U.S. Dollars)	$16.5	$26.1	$50.1	$48.3	$42.1	$40.6
Expenditure Assuming No Negotiations (in Millions of U.S. Dollars)	$45.6	$73.6	$140.5	$188.9	$251.8	$245.6
Global Upper-middle Income Cost-savings (in Millions of U.S. Dollars)	$29.1	$47.5	$90.4	$140.1	$205.2	$128.5
Post–negotiations Cost-savings (in Millions of U.S. Dollars)					$4.5	$76.5
Percent Cost-savings at Post-negotiation prices					2%	45%
Percent Cost-savings at Global UMI Prices	64%	64%	64%	74%	83%	76%

Table V-5: Comparison of Hypothetical Upper-middle Income Expenditure on 12 Selected ARVs, 2007 and 2008 (Based on IMSS and SSA Procurement Volume)

Cost Scenarios/Percentage Savings	2008	2008 (at 2007 prices)
Hypothetical Global UMI Expenditure (in Millions of U.S. Dollars)	$42.1	$65.3
Percent Cost-savings in global price reduction		55%

Table V-6: Summary of Forecasting, Price Negotiations and Procurement Before And After The Establishment Of The Commission

	Health System	Forecasting	Negotiation Strategy	Procurement
Before the creation of the Inter-Institutional Commission	IMSS	Historical consumption model	Large volume for lower prices.	Procurement price set by IMSS pharmaceutical supply department, but different states may be purchasing at different procurement prices.
	ISSTE	Historical consumption model	Large volume for lower prices. Not as successful given lower volume of patients.	Procured centrally by ISSSTE national HIV/AIDS care and procurement.
	SSA	Historical consumption model	Large volume for lower prices.	Procured centrally by CENSIDA and SSA procurement.
After the creation of the Inter-Institutional Commission	IMSS	Unchanged	Negotiation once a year for all public institutions *Using a number of factors that include volume, price comparison with economically similar countries, availability of therapeutic equivalences, Mexico's market share of pharmaceutical consumption, Institutions are not bound to Commission negotiated prices and can seek lower prices on their own.	Procurement price set by Commission and IMSS pharmaceutical supply department. All states purchase pay the set procurement prices.
	ISSTE	Unchanged		Unchanged
	SSA	Unchanged		Unchanged

CHAPTER VI: REVIEWING FINDINGS TO ADDRESS INEFFICIENCIES IN ARV SUPPLY IN MEXICO

This dissertation sought to provide a description of previous and current changes to forecasting, price negotiation, and procurement of ARVs in Mexico. The analyses were based on a global optimization model, which draws from tested indicators and measures of performance from the literature to provide as comprehensive a tool as possible to identify factors that hinder integration across the three stages of the supply chain. This chapter reviews the findings from the two previous chapters and discusses policy recommendations for improving efficiency of the supply chain.

A. What supply chain management factors continue to constrain availability of ARVs in Mexico?

In this section, the discussion returns to the two key categories of assessment of the global optimization framework: 1) Indicators and Performance Measures and 2) Information Integration. It also includes a discussion on the limitations that are specific to the Commission fulfilling its mandate.

1. Indicators and Performance Measures

The Commission introduced performance measures intended to optimize the negotiation stage of the supply chain. However, limited collection of data by the health systems and lack of access to key indicators and performance measures for the forecasting and procurement of ARVs will likely limit the cumulative impact of price savings on overall performance of the supply chain.

The Commission successfully negotiated lower ARV prices in its first round of negotiations by establishing indicators (e.g., price variation across health systems, and prices in economically similar countries) and measures of performance (cost effective analysis, and therapeutic equivalence analysis). Despite the advantage of introducing new performance indicators, both IMSS and SSA are limited by the failure to collect certain types of supply chain data, such as annual number of patients changing treatment, annual emergency ARV procurement, and average price of ARVs procured in emergencies. The major concern is that the ability to reduce ARV supply chain costs is limited by the lack of data concerning total pharmaceutical budget, total ARV budget, procurement delivery cost and storage costs (Allers and Riwa, 2001; Bossert et al., 2006; Deliver, 2006; Simchi et al., 2008; Vasan et al., 2006; Quick et al, 1997). For example, even though the Commission was able to achieve a total cost saving of an estimated $4.5 million across the two systems in 2008, surplus procurement costs for IMSS and SSA were estimated to be $9 million and $8 million, respectively. In other words, cost savings as a result of price reduction of the selected ARVs were less than half of the costs of surplus procurement for both systems. This example highlights a concern that focusing on price reduction is insufficient to judge the overall success of the Commission, a view frequently expressed by the informants.

Another clear example of the need to improve data collection and analysis is the procurement of single drug doses to compensate for combination drug doses patient needs. The potential impact of compensating with single drug doses on patient adherence and long-term care and the cost of this kind of dosage compensation to the health system do not appear to have been addressed by changes to the negotiation process. As a result, it is not clear that savings from the lower prices will translate to more available resources without indicators and measures to assess the supply chain as a global unit. Without improving the accuracy of indicators such as patient consumption, and means of ensuring that patient needs are adequately met, efforts to reduce costs focusing on price reduction may not have as substantial an impact on overall costs as expected. The need for data accuracy highlights a very important aspect of using the global framework as an analytical lens – indicators and performance measures are key aspects in estimating and prioritizing cost saving goals.

2. Information Integration

While the coordination of information and the organization of joint negotiation improved the negotiation process for the major health systems, the lack of similarly coordinated changes to forecasting and procurement procedures within the health systems is likely to limit the impact of the Commission's efforts on overall performance of the ARV supply chains.

The Commission was able to coordinate collection of information (for example, annual demand forecast for patented medicines as well as therapeutic equivalence and cost-effectiveness studies) and organize joint negotiations with the major providers of HIV/AIDS care in Mexico. However, there remains a lack of clarity regarding the role of the Commission in developing standard policies to help IMSS and SSA improve the forecasting and procurement of ARVs. As discussed in Chapter IV, IMSS and SSA organize and coordinate their respective forecasting and procurement processes differently. IMSS employs a more decentralized system, in which forecasting and procurement practices (forecasting formula, information collection tools, procurement procedures and performance monitoring) vary across states. Apart from the recent development of HIV/AIDS care treatment guidelines by a small committee of IMSS staff, there is no one central body at the national level providing patient treatment guidance and monitoring forecasting and procurement procedures. Second, the ability of certain hospitals to compile accurate patient ARV needs, consumption and pharmaceutical inventory depends on a variety of management information systems implemented at the state level. Finally, as results from this analysis have shown, this lack of organization and coordination of accurate information across the IMSS health system suggests that IMSS is unable to properly monitor treatment. As a result, an unknown number of patients may be receiving inadequate medication and/or have their treatment interrupted, placing additional burden on patient and health system resources.

On the other hand, the SSA system balances organization of its ARV supply chain between centralized and decentralized decision-making. The success of this balance is heavily dependent on the SALVAR system, an information management infrastructure that allows both levels to coordinate information and share decision-making. This infrastructure is, however, limited by lack of full implementation and utilization of SALVAR across all SSA/CENSIDA sites. In addition, hospital level program managers are unable to collect and monitor data such as patient treatment history, physician treatment compliance and inventory data (most importantly

level of stock in storage units) that are necessary for decision-making at the local level. This suggests that current forecasting and procurement data that are being aggregated at the national level by CENSIDA may not accurately reflect patient ARV needs at all SSA sites. The lack of coordination and organization in forecasting and procurement of ARVs means that both health systems will be unable to estimate patient need and/or purchase more ARV than needed (Allers and Riwa, 2001; Bossert et al., 2006; Deliver, 2006; Simchi et al., 2008; Vasan et al., 2006; Quick et al, 1997).

3. Factors Hindering the Commission

In the short term, the Commission has been successful in its role as a price negotiator and cost-saving advisory body. Over the long term, however, the Commission's effectiveness in implementing changes and measuring strategic success of the functioning of the ARV supply chain will be limited without clear and measureable objectives, transparency in key negotiation strategies and the ability to allocate resources.

The Commission was successful in using its mandate to bring together the major providers of HIV/AIDS care in Mexico to negotiate lower ARV prices. However, it is difficult to assess success when there is little transparency surrounding negotiation strategies and there are no measureable goals. First, it could be argued that the Commission is still adapting to its role, which may require an incremental approach in order to engage stakeholders with varying and perhaps divergent interests. These interests range from different procurement schedules across health systems to pharmaceutical industry concerns about the Commission's impact on the patented ARVs. However, providing a measureable objective with more specificity than lowering ARV patent prices would provide a better means to assess progress. In addition, making information about the negotiation process available ensures that the Commission's mandate can be independently verified and that its activities are in line with the Mexican government's policy of openness and accountability of government function (Seoane-Vazquez and Rodriguez-Monguio, 2007; Vasan et al., 2006).

Second, without the ability to allocate resources or require that health systems allocate resources, it will be difficult for the Commission to implement policy changes that require significant resource investment. Improving forecasting, procurement and distribution of medicines in the health systems will require implementation of a reliable information system and ensuring that staff have the capacity to manage the supply chain. These are just a few of the crucial steps the Commission will need to take to fulfill the broader mandate of lowering costs and improving the efficiency of the supply of medicines.

Finally, factors hindering supply chain efficiency related to indicators, performance measures and information integration also impact the Commission's ability to successfully negotiate lower prices. Lack of coordination across the three stages of the supply chain is correlated to lack of accurate forecasting, price and procurement data (Bossert et al., 2006; Deliver, 2006; Simchi et al., 2008; Vasan et al., 2006; Quick et al., 1997). The result is that without improving coordination and having accurate data available, the Commission is unable to effectively employ strategies such as ARV demand and procurement volumes in negotiating for lower prices.

B. What policies and procedures can be recommended to improve the availability of ARVs through the Commission and/or each health system?

A number of policy recommendations can be made in light of the results of this study. However, given that the identified challenges to the efficient supply of ARV are inter-related, recommendations for improvement will require a comprehensive approach. The aim of this approach is to address these challenges by paying particular attention to policies that emphasize a process for improving selection of key indicators and performance measures as well as to how information is integrated into decision-making. These policy recommendations will be presented in terms of how they align with two key policy initiatives – 1) the Commission's overall goal of improving forecasting, negotiation and procurement of medicines and, 2) the Mexican government's policy of Universal Access to Treatment for PLWHA. Alignment with these two policy initiatives assumes that the creation of the Commission by presidential declaration is the most recent installment in a series of pharmaceutical policies intended to reduce costs and expand access to care.

1. Recommendations for the Commission

Strengthening the organizational structure of the Commission by establishing goals, outlining clear roles and responsibilities, and granting the authority to allocate resources is necessary for continued successful negotiations.

In order to be able to provide policy guidelines for improving forecasting and procurement, it is vital that the Commission move beyond its advisory and unofficial price regulatory roles and become a more structured body. This process will require developing roles and responsibilities for the Commission and its sub-committees with specific objectives and delivery timelines for the Commission, its sub-committees and the health systems (Yusuf and Tayo, 2004; Seoane-Vazquez and Rodriguez-Monguio, 2007; Vasan et al., 2006). Clearer roles and objectives will also help guide the sub-committees with regard to their responsibilities to one another. For example, information on price and patent timeline from the Patents and Prices sub-committee is made available to the Economic Evaluation sub-committee in order to avoid a situation in which an out-of-patent (or soon to be out-of-patent) medicine is negotiated at patent prices. Similarly, the role and responsibilities of health systems vis-à-vis the Commission should be delineated, with specific timelines to ensure that the burden of work and success are shared by the Commission and its constituents (Seoane-Vazquez and Rodriguez-Monguio, 2007; Vasan et al., 2006). As part of their responsibilities, health systems should provide accurate ARV supply chain forecasting, price, procurement and distribution indicators on time, to ensure that the Commission's technical team is able to generate comprehensive analyses to support the negotiation process. As an indication of the commitment to clarifying roles and objectives, the Commission and its sub-committees could create dedicated staff time to coordinate activities and ensure that objectives are being met on schedule. These positions need not be on a full-time basis, but it is important that the policies being made by the Commission and its sub-committees have coordinating staff to ensure achievement of outcomes in the implementation process (Deliver, 2006; Quick et al., 1997).

Second, the Commission occupies a unique position in which it is able to convene key decision makers from health systems that provide services to the vast majority of the Mexican population. In addition, the Commission is able to bring together technical expertise from within the Ministry of Health as well as the private sector. This allows the Commission to gather information on health services, identify factors hindering access to services, and offer recommendations for addressing these problems. However, to ensure that its policies are implemented, the Commission will need resources or at the very least the authority to allocate resources. While not all policies will require resource investment, policies concerning as information infrastructure and capacity building (to be discussed in detail in the next section on recommendations for health systems) will require some capital and human investment (Deliver, 2006; Quick et al., 1997). Therefore, the mandate to make policy must be strengthened by a complementary mandate to allocate resources, so that cost-saving policy guidelines that require resource investment are not exercises in futility.

Finally, it is vital that the roles and responsibilities as well as specific objectives of the Commission, its supporting bodies and constituent health systems be made known to the public and be independently verifiable. The lack of clarity of roles, responsibilities and objectives limits the Commission's ability to monitor and evaluate the impact of policy implementation.

2. Recommendations for the Health Systems

Developing a dependable information infrastructure that meets the needs of staff is key to informed decision making at both the local and national levels.

An information infrastructure with a reliable Management Information System is fundamental to the functioning of a supply chain (Allers and Riwa, 2001; Bossert et al., 2006; Deliver, 2006; Quick et al., 1997). In the SSA health system, the SALVAR system appears to have provided CENSIDA with a tool to better estimate ARV consumption and thus facilitate procurement of ARVs. The findings from this study indicate that this tool could be improved to inform both central and hospital level decision makers. In order to make SALVAR more useful, CENSIDA will first have to embark on a needs assessment with a representative (if not the majority) of state and hospital level program managers involved in ARV supply chain management, to understand how supply chain data inform decisions at all operational levels (Allers and Riwa, 2001). Information on the capacity of program managers and their hospitals or clinics to collect and manage supply chain data should also be captured as part of this assessment (Waako et al., 2009). Second, important data such as state and hospital level ARV inventory and patient treatment changes should be included in SALVAR's repository to ensure more accurate data concerning patient consumption and stock monitoring, therefore improving forecasting and procurement (Allers et al., 2007). Equipped with a more comprehensive understanding of staff and organizational capacity and data utilization in decision making, CENSIDA will be better able to make appropriate changes to the SALVAR system that will meet the needs of local and national level decision makers. These changes should include – 1) the creation of a piloted-new version of SALVAR that is based on feedback from program managers and accommodates patient treatment transition and pharmacy inventory data, 2) training of staff to manage data collection and monitor patient treatment, and 3) regular tests of data use and validation by CENSIDA.

In the IMSS system, the lack of a central guiding body and the lack of an information infrastructure are intertwined. To address these issues, IMSS should first establish a central body to coordinate HIV/AIDS care and develop standards for collecting data. Second, IMSS should follow CENSIDA's example and implement a national HIV/AIDS patient treatment database that also includes forecast and procurement data. SALVAR's platform can be copied and adapted to IMSS's needs; however, in order to ensure successful implementation, IMSS will need to follow the same needs assessment recommendations as SSA. An appraisal of health system staff and infrastructure capacity should be conducted in conjunction with an assessment of data use by program managers. A standard process for conducting forecasting and procurement should be developed and augmented by retaining patient treatment changes and inventories in a management information repository. The following recommendations should be implemented: 1) establishment of a central care management body/partnering with CENSIDA to manage HIV/AIDS care; 2) the creation of a management information system similar to the SALVAR system and based on feedback from program managers; 3) staff training to build capacity to manage and monitor ARV MIS; and 4) regular tests of data use and validation by central national care management.

Developing a care monitoring system to improve treatment compliance is essential to quality and cost of care.

With a dependable data repository in place, decision makers are better able to assess and improve quality of care (Deliver, 2006; Quick et al., 1997). In the process of surveying staff capacity for data collection and monitoring, SSA should include an assessment of existing monitoring tools to track utilization of the national treatment guidelines, and thus, quality of patient care. This will allow SSA and CENSIDA to identify individuals and clinics or hospitals that are implementing promising practices as well as those with areas in need of improvement. As part of its role in providing support and training to SSA program managers and care providers, CENSIDA should develop a quality care referral network. If a quality care monitoring system does not already exist within CENSIDA, the network should take on this responsibility. Alternatively, if it is more cost effective, the network could be guided by an advisory board composed of program managers and care providers who have established promising quality care practices. Physicians and program managers facing challenges with providing quality care will then be able to refer to the quality care system or advisory board for support such things as case referral and/or supplemental training. The quality assessment tool could be used on a continuing basis to provide feedback to providers in the form of an annual or semi-annual report for hospitals to use for continuous improvement of quality of care.

The lack of a central body guiding and managing HIV/AIDS treatment means there is a lack of a national standard of care, which in turn means there is lack of a standard means of measuring quality of service (Allers and Riwa, 2001; Bossert et al., 2006; Deliver, 2006; Quick et al., 1997; Waako et al., 2009). As part of the process of establishing a central unit at the national level, IMSS should ensure that the unit is charged with developing and maintaining standards and quality of care guidelines. As with SSA, IMSS should first carry out a quality of care assessment to identify areas implementing promising practices and those experiencing challenges. The central HIV/AIDS care unit should then function as the monitor of quality of

care, providing support and training to program managers and care providers. If there are not enough resources to establish a HIV/AIDS care at the national level, IMSS can develop a partnership with SSA in which CENSIDA (as the national coordinator of HIV/AIDS care) can assist with HIV/AIDS care management. In either case, quality assessment should be conducted regularly and feedback in the form of reports should be provided to program managers and care providers as part of continuous improvement of quality of HIV/AIDS care.

C. Conclusion

The Mexican government's creation of the Inter-Institutional Commission follows a series of policies aimed at streamlining supply chain management to guarantee efficient and sustainable delivery of ARVs. The Commission's coordination of negotiations on behalf of the three major health systems has achieved its main goal – substantial reduction in ARV prices through joint negotiations. As the analysis from this dissertation shows, the Commission's focus on price negotiation as a cost minimization strategy is only one aspect of a broader set of factors related to supply chain performance. A more comprehensive approach would use a global optimization framework to identify key indicators, performance measures and gaps in integration across stages of the supply chain. Policies geared towards enhancing the capacity of decision makers to monitor ARV supply and quality of care, and improving collection and coordination of supply chain data are crucial to ensuring uninterrupted access to ARVs and lowering health system costs. The implementation of these policies will not be a simple undertaking. It presupposes agreement by decision makers within and across health systems on improvements in data infrastructure, collection and monitoring, as well as providing decision makers with the training and support to manage the supply chain and improve quality of HIV/AIDS care. These policies will also require extensive resource investment during initial stages of implementation and sustained cooperation between the Commission and participating health systems, which may be time-consuming. However, the long-term benefits of decreasing costs and enhancing access to treatment will likely outweigh the initial investment.

This study provides a limited description of the role of forecasting, price negotiation and procurement management in determining availability ARVs in the largest providers of HIV/AIDS care in Mexico. For a broader assessment of supply chain performance, future research should include other stages of the supply chain - drug selection, distribution and patient use - to the analytical framework. Improving management of the supply chain is a key part of access to ARVs, and a global optimization framework is an important tool for ensuring that the right ARVs are made available at the right quantity in the right places to the right people at the right time and at an accessible cost.

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APPENDICES

Table 1A: SSA 2003 – 2009 Annual Procurement Volume.

ARV Medicines	2003	2004	2005	2006	2007	Before Oct-2008	After Oct-08	Total 2008	2009
EFV	4,557	39,567	48,681	83,224	108,527	129,264	17,964	147,228	165,079
TDF/FTC				22,000	69,955	115,392	14,948	130,340	138,639
AZT/3TC	50,881	34,331	64,020	65,028	63,909	88,834		88,834	26,528
ABC	5,967	8,617	12,327	22,903	29,372	30,672	4,478	35,150	20,643
NVP Tab	10,172	12,060	13,318	21,487	26,344	30,672	2,786	33,458	16,340
SQV	10,122	13,189	13,720	20,912	27,640	29,628	419	30,047	23,442
LPV/RTV	3,212	5,937	13,621	24,023	23,525	51,612	4,846	56,458	45,519
3TC	10,302	20,895	27,371	28,017	20,416	15,826		15,826	3,291
TDF			695	18,347	21,260	15,120	1,013	16,133	8,745
RTV	4,607	11,092	8,577	13,598	17,513	25,968	628	26,596	9,054
FTC				18,890	32,799	24,516	3,116	27,632	11,602
ATV		792	1,392	7,533	18,624	26,916	2,270	29,186	41,916
ABC/3TC					3,158	6,912	497	7,409	18,450
AZT 100		1,812	1,700	2,489	2,677	2,580	589	3,169	4,878

Source: CENSIDA Procurement Tables.

Table 1B: SSA Annual Procurement Price 2003 – 2009

ARV Medicines	2003	2004	2005	2006	2007	Before Oct- 2008	After Oct-08	2009
EFV	$86	$102	$101	$91	$87	$83	$40	$34
TDF/FTC	$0	$0	$0	$350	$334	$322	$199	$170
AZT/3TC	$392	$392	$335	$299	$290	$276	$177	$151
ABC	$361	$323	$308	$276	$263	$254	$122	$105
NVP Tab	$336	$300	$287	$248	$43	$42	$33	$29
SQV	$228	$209	$200	$184	$306	$283	$211	$181
LPV/RTV	$703	$605	$611	$546	$522	$503	$323	$276
3TC	$418	$293	$280	$250	$225	$188	$86	$74
TDF	$0	$0	$520	$263	$223	$215	$172	$147
RTV	$377	$306	$300	$279	$266	$257	$204	$164
FTC	$0	$0	$0	$123	$111	$107	$86	$74
ATV	$0	$491	$470	$420	$401	$387	$248	$212
ABC/3TC					$334	$322	$194	$166
AZT 100		$16	$15	$15	$16	$15	$13	$11

Source: CENSIDA Price Tables

Table 1C: SSA Annual ARV Expenditure 2003 – 2009

ARV Medicines	2003	2004	2005	2006	2007	Before Oct-2008	After Oct-08	Total 2008	2009
EFV	$389,752	$4,017,072	$4,934,211	$7,541,266	$9,399,801	$10,792,740	$709,835	$11,502,575	$4,979,521
TDF/FTC				$7,689,823	$23,372,094	$37,164,457	$2,973,574	$40,138,031	$22,193,005
AZT/3TC	$19,964,887	$13,445,815	$21,435,820	$19,465,352	$18,512,283	$24,500,456	$0	$24,500,456	$13,456,766
ABC	$2,155,306	$2,779,702	$3,799,474	$6,310,967	$7,736,104	$7,787,608	$547,128	$8,334,736	$3,675,978
NVP Tab	$3,417,833	$3,618,936	$3,818,534	$5,330,493	$1,141,271	$1,280,922	$93,329	$1,374,250	$959,348
SQV	$2,303,426	$2,761,412	$2,744,716	$3,854,557	$8,455,792	$8,387,708	$88,475	$8,476,183	$5,430,602
LPV/RTV	$2,257,584	$3,593,894	$8,322,074	$13,121,614	$12,282,163	$25,975,812	$1,565,109	$27,540,921	$15,607,362
3TC	$4,305,304	$6,123,059	$7,663,740	$7,013,086	$4,595,096	$2,973,309	$0	$2,973,309	$1,166,534
TDF			$361,404	$4,819,483	$4,735,337	$3,246,479	$174,471	$3,420,950	$2,378,327
RTV	$1,738,319	$3,390,492	$2,570,977	$3,789,733	$4,665,297	$6,668,536	$128,063	$6,796,600	$4,363,674
FTC				$2,320,171	$3,652,735	$2,631,967	$268,337	$2,900,304	$2,036,755
ATV		$389,247	$653,678	$3,162,496	$7,473,433	$10,411,923	$562,769	$10,974,692	$6,193,292
ABC/3TC					$1,055,094	$2,226,157	$96,299	$2,322,456	$1,228,764
AZT 100		$29,659	$26,180	$38,575	$42,491	$39,331	$7,583	$46,914	$34,921

Table 2A: IMSS 2003 – 2009 Annual Procurement Volume.

ARV Medicines	2003	2004	2005	2006	2007	2008	Projected 2009
EFV	1,435	1,919	5,760	23,346	44,371	47,787	71,145
TDF/FTC						31,415	116,076
AZT/3TC	5,330	9,178	15,927	49,432	77,263	69,020	84,768
ABC	2,160	2,731	4,297	18,297	32,966	30,275	41,175
NVP Tab	4,958	1,728	4,482	17,797	24,978	22,133	25,338
SQV	11	6,726	10,385	28,970	15,103	36,456	100
LPV/RTV	3,535	2,447	5,316	24,579	42,823	45,592	63,987
3TC	2,540	5,337	6,890	33,530	41,083	35,316	36,815
TDF			701	3,746	18,773	32,726	110,528
RTV	2,322	2,625	3,010	8,038	18,531	18,457	30,467
FTC			540	3,028	19,395	1,396	4,521
ATV			455	2,419	9,385	12,572	32,808
AZT 100	991	1,798	631	4,808	4,143	1,958	1,306

Source: IMSS procurement database.

Table 2B: IMSS Annual Procurement Price 2003 – 2009

ARV Medicines	2003	2004	2005	2006	2007	2008	2009
EFV	$114	$102	$101	$91	$87	$79	$34
TDF/FTC						$408	$170
AZT/3TC	$392	$350	$335	$299	$286	$262	$151
ABC	$361	$323	$308	$276	$263	$241	$105
NVP Tab	$305	$273	$261	$233	$43	$40	$29
SQV	$228	$209	$206	$184	$176	$269	$181
LPV/RTV	$703	$605	$611	$546	$522	$478	$276
3TC	$328	$293	$280	$250	$239	$178	$74
TDF			$520	$465	$390	$346	$147
RTV	$289	$266	$309	$276	$264	$241	$164
FTC			$280	$251	$195	$102	$74
ATV			$534	$468	$401	$367	$212
AZT 100	$17	$15	$15	$13	$13	$12	$11

Source: IMSS procurement database.

Table 2C: IMSS Annual ARV Expenditure 2003 – 2009

ARV Medicines	2003	2004	2005	2006	2007	Total 2008	2009 (projected)
EFV	$163,132	$194,828	$583,822	$2,115,476	$3,843,086	$3,790,212	$2,406,240
TDF/FTC						$12,815,262	$19,764,274
AZT/3TC	$2,091,406	$3,216,240	$5,332,838	$14,796,876	$22,106,431	$18,082,185	$12,840,823
ABC	$780,168	$880,938	$1,324,381	$5,041,562	$8,682,337	$7,301,016	$4,306,104
NVP Tab	$1,514,083	$471,277	$1,167,961	$4,146,108	$1,082,094	$878,052	$726,516
SQV	$2,503	$1,408,238	$2,141,154	$5,339,829	$2,660,892	$9,804,142	$18,096
LPV/RTV	$2,484,607	$1,481,263	$3,247,937	$13,425,307	$22,357,452	$21,797,500	$17,688,576
3TC	$833,433	$1,563,952	$1,929,165	$8,393,075	$9,829,579	$6,302,894	$2,713,628
TDF			$364,524	$1,741,458	$7,317,464	$11,330,867	$16,293,979
RTV	$670,973	$698,192	$928,930	$2,217,696	$4,886,953	$4,457,314	$4,998,841
FTC			$151,310	$758,519	$3,779,945	$142,382	$333,249
ATV			$242,763	$1,131,980	$3,766,010	$4,619,813	$6,961,976
AZT 100	$16,649	$26,977	$9,252	$64,422	$52,977	$23,653	$14,395

Table 3A: Global Upper-middle Income Countries Median Annual Procurement Price 2003 – 2009

ARV Medicines	2004	2005	2006	2007	All 2008	Apr 2009
EFV 600	$44	$47	$31	$28	$15	$9
*TDF/FTC	$41	$38	$57	$55	$41	-
AZT/3TC	$33	$30	$21	$21	$12	$13
ABC	$114	$113	$84	$63	$35	$23
NVP Tab	$18	$12	$8	$7	$5	$4
SQV	$305	$300	$250	$356	$207	-
LPV/RTV	$577	$544	$452	$111	$93	
3TC	$9	$9	$8	$7	$4	
*TDF	$36	$28	$36	$82	$22	$13
RTV	$102	$103	$82	$70	$31	
ATV 150	$0	$443	$233	$518	$48	
AZT 100	$152	$47	$17	$15	$10	$8

Source: Global Price Report Mechanism 2004 - 2009

Table 3B: Hypothetical IMSS And SSA Expenditure Assuming Global Upper-middle Income Median Prices

ARV Medicines	2004	2005	2006	2007	All 2008	2009 (assuming 2008 prices)
EFV 600	$1,843,086	$2,578,532	$3,289,141	$4,229,075	$2,887,453	$3,497,600
*TDF/FTC	$0	$0	$1,255,686	$3,820,220	$6,684,764	$10,526,474
AZT/3TC	$1,420,476	$2,389,047	$2,455,922	$2,932,131	$1,937,835	$1,366,282
ABC	$1,288,717	$1,873,208	$3,475,080	$3,928,476	$2,268,482	$2,143,427
NVP Tab 200mg	$252,436	$216,551	$298,960	$379,583	$255,264	$191,377
SQV	$6,068,367	$7,243,129	$12,463,960	$15,195,999	$13,772,834	$4,875,596
LPV/RTV	$4,841,081	$10,306,843	$21,950,871	$7,340,597	$9,505,811	$10,200,288
3TC	$231,737	$307,550	$461,881	$411,238	$230,043	$180,401
*TDF		$38,584	$803,300	$3,269,144	$1,089,711	$2,660,158
RTV		$55,490	$1,793,109	$3,669,957	$1,389,023	$1,389,023
ATV 150		$1,033,291	$1,702,974	$3,530,906	$1,999,633	$3,578,272
*AZT 100	$550,008	$108,478	$122,633	$100,883	$49,487	$59,697

Interview Guides

INTERVIEW GUIDE – Planning staff or program manger

Role:
Location:

Introduction: Thank you for your time. I am a doctoral student from UC Berkeley, working on a joint policy project with researchers from INSP about supply chain management of ARVs in Mexico. We are trying to learn about the forecasting, price negotiation and procurement of ARVs in your health system. We are also interested other practices that may affect availability of ARVs (for example, shortages). We asked to interview you because of your position, experience and/or area of expertise.

Give interviewee the information card which is in the study protocol

"What are the barriers and facilitators to the ARV forecasting and procurement supply chain in the three major health systems in Mexico?"

- Identify and understand forecasting, price negotiation and procurement procedures for ARVs.
- Examine ARV tracking systems

A. ARV forecasting & procurement systems

1. What factors influence forecasting and procurement of ARVs –
    a. Do you utilize a forecasting method and/or formula, if so how is it calculated? What kinds of data (e.g. disease prevalence, previous annual ARV consumption, vertical data collection process etc) in forecasting formula? Does price influence forecasting? If so, how?
    b. Do you utilize forecasting software/information system? Why or why not?
    c. Do you utilize surveillance data that looks at incidence rates by state/regional area, as well tool for projecting patient eligibility and enrollment etc Is forecasting at the hospital level based on standardized treatment protocol?
    d. How do you conduct a tiered drug selection i.e. first line treatment, alternatives to first-line treatments and second-line treatments?
    e. Is forecasting data used in the price negotiation process?

f. Are there separate staff involved in forecasting and price negotiation? If so, how is information shared between the two staff groups?

2. How do you monitor or track dispensing of ARVs? Is there a pharmacy inventory monitoring/tracking system in place that would allow for forecasting? Is there a patient monitoring/tracking system in place that will contribute to more accurate forecasting?

3. Have you heard about the new federal price negotiation coordinating committee?
    a. What is your impression of the new federal price negotiation coordinating committee?
    b. What kind of changes do you foresee with the creation of the federal price negotiation coordinating commission?
    c. Will your agency be required to implement a different forecasting and procurement procedures? If so how?
    d. What other data (average per unit price across health systems and/or in other economically similar countries etc) are included in the price-negotiation process?
    e. Does procurement influence price negotiation? If so how?
    f. If your agency will not be required to implement new forecasting and procurement procedures how do you foresee merging your current procedures to help facilitate better ARV prices?

B. Procurement and Tracking Systems

1. Are forecasting and price negotiation data used in procurement?
2. Are there different staff involved in forecasting price negotiation and procurement processes? If so, how is information shared between the different staff groups?
4. What other data are used in procurement?
5. How are the purchasing systems for ARVs and the purchasing system for other pharmaceuticals linked? Is the distribution system the same or separate?

6. Is there a criteria for selecting patients who receive treatment? If so what is the criteria (i.e. likelihood of adherence, CD4 count & viral load etc)?

7. How often are patients diagnosed with HIV lost to follow-up? Are there any systematic efforts to recapture them?

8. What data is collected on the proportion of patients on ARVs who quit therapy? How do you track them?

9. Is there any data being collected comparing the number of patients who are prescribed ARVs and the number of patients registered in pharmacy dispensary information systems?

C. Wrap-up

10. Have I/we discussed the key issues related ARV forecasting, procurement, distribution and access in your opinion? What else do we need to understand, in your opinion?

Thank you very much for your time and contribution to this project. May we contact you in the future with follow-up questions, if necessary? Is there someone else you think might have more information about ARV price negotiations, forecasting, procurement and/or distribution?

INTERVIEW GUIDE – Clinicians

Role:
Location (Hospital, City and State):

Introduction: Thank you for your time. I am a doctoral student from UC Berkeley, working on a joint policy project with researchers from INSP about supply chain management of ARVs in Mexico. We are trying to learn about the forecasting, price negotiation and procurement of ARVs in your health system. We are also interested other practices that may affect availability of ARVs (for example, shortages). We asked to interview you because of your position, experience and/or area of expertise

"What are the barriers and facilitators to the ARV forecasting, price negotiation and procurement supply chain in the three major health systems in Mexico?"

- Identify and understand forecasting, price negotiation and procurement procedures for ARVs.
- Examine ARV tracking systems, prescription and pharmaceutical practices

A. ARVs forecasting & procurement systems

2. Can you please describe your hospital's procurement process?
    a. How does your hospital forecast and procure ARV?
    b. Do you play a role in forecasting and procuring ARVs?
    c. Is there a particular hospital department(s)/health officer(s) responsible for coordinating funding, forecasting, procurement and shipment of ARVs?
    d. Do you utilize surveillance data that looks at incidence rates by state/regional area, as well tool for projecting ARV volume etc
    e. Are they required to follow guidelines/standardized procedures for forecasting, procurement and monitoring?
    f. How many people typically handle ARV forecasting and procurement at the hospital?
    g. Who do you procure the drugs from? Your health system or a particular distributor?
    h. When are drugs procured? Is there a regular purchasing cycle/schedule?

2. How do you monitor or track dispensing of ARVs? Is there a pharmacy inventory monitoring/tracking system in place that would allow for monitoring distribution from a storage site and dispensing at the pharmacies?

3. If the combination of ARV drugs you prescribe is not available in the pharmacy what is the typical time between when medications are ordered and when they arrive? How often do you experience delays?

4. What is the mechanism by which hospitals report ARV procurement patterns to the larger health system/monitoring body?

5. Do you think that prices of ARVs present a barrier to access? In which way and for whom?

6. Have you heard about the new federal price negotiation coordinating committee?
    a. What is your impression of the new federal price negotiation coordinating committee?
    b. What kind of changes do you foresee with the creation of the federal price negotiation coordinating commission?
    c. Will your agency be required to implement a different forecasting and procurement procedures? If so how?
    d. If your agency will not be required to implement new forecasting and procurement procedures how will do you foresee merging your current procedures to help facilitate better ARV prices?

B. Tracking Systems

7. Is there a criteria for selecting patients who receive treatment? If so what is the criteria (i.e. likelihood of adherence, CD4 count & viral load etc)?

8. What data is collected on the proportion of patients on ARVs who quit therapy? How do you track them?

9. Is there any data being collected comparing the number of patients who are prescribed ARVs and the number of patients registered in pharmacy dispensary information systems?

C. Wrap-up

10. What have been the successes and challenges of following through on Mexico's commitment to provide universal ARV access?

11. Do you think the majority of people who need ARVs in Mexico have access to them?

12. Have I/we discussed the key issues related ARV procurement, distribution and access in your opinion? What else do we need to understand, in your opinion?

Thank you very much for your time and contribution to this project. May we I contact you in the future with follow-up questions, if necessary?

INTERVIEW GUIDE – Pharmacist

Role:
Location (Hospital, City and State):

Introduction: Thank you for your time. I am a doctoral student from UC Berkeley, working on a joint policy project with researchers from INSP about supply chain management of ARVs in Mexico. We are trying to learn about the forecasting, price negotiation and procurement of ARVs in your health system. We are also interested other practices that may affect availability of ARVs (for example, shortages). We asked to interview you because of your position, experience and/or area of expertise

"What are the barriers and facilitators to managing ARV forecasting and procurement supply chain in the three major health systems in Mexico?"

- Identify and understand forecasting, price negotiation and procurement procedures for ARVs.
- Examine ARV tracking systems, prescription and pharmaceutical practices

A. Forecasting and Procurement of ARVs

1. Can you please describe your hospital's forecasting and procurement process?
    a. What role do you or the Chief Pharmacist play in forecasting and procuring ARVs?
    b. How do plan for procuring ARVs for your pharmacy?
    c. Who do you purchase the drugs from?
    d. Is there a centralized purchasing system? If so who is in charge of this?
    e. When are drugs procured? Is there a regular purchasing cycle/schedule?

2. How do you track dispensing of ARVs?

3. Is there a pharmacy inventory monitoring/tracking system in place that would allow for forecasting as well as monitoring distribution and dispensing?

4. Are you seeing an increased demand for second line drugs?

5. What is the typical time between when medications are ordered and when they arrive? How often do you experience delays?

6. How are the ARVs inventoried at the pharmacy?

7. Do you coordinate with the hospital regarding the supply of ARVs?

8. Once ARVs are purchased, how are they transported to your hospital/pharmacy?
   - What is the typical time between when medications are ordered and when they arrive? How often do you experience delays?

9. Can you please describe any stock-outs or shortages of ARVs you have experienced?
   a. How are these handled?
   b. How do they affect individual hospitals/clinics or patients?
   c. What do the patients do if a drug is not available? Are they sent to other pharmacies?

10. Is there any "internal borrowing" of ARVs among the different systems or facilities, if there is a shortage? How is this generally carried out?

11. What are the barriers to forecasting and procurement of ARVs, if any?

12. Have you heard about the new federal price negotiation coordinating committee?
    a. What is your impression of the new federal price negotiation coordinating committee?
    b. What kind of changes do you foresee with the creation of the federal price negotiation coordinating commission?
    c. Will your agency be required to implement a different forecasting and procurement procedures? If so how?
    d. If your agency will not be required to implement new forecasting and procurement procedures how do you foresee merging your current procedures to help facilitate better ARV prices?

B. Tracking Systems

13. Is the pharmacy part of the review process looking at the number of HIV patients lost to follow up? Are there any systematic efforts to recapture them?

14. Is there any data being collected comparing the number of patients who are prescribed ARVs and the number of patients registered in pharmacy dispensary information systems?

C. Wrap-up

15. What have been the successes and challenges of following through on Mexico's commitment to provide universal ARV access?

16. Do you think the majority of people who need ARVs in Mexico have access to them? Who has no access?

17. Have we discussed the key issues related ARV forecasting, procurement and access in your opinion? What else do we need to understand, in your opinion?

Thank you very much for your time and contribution to this project. May we contact you in the future with follow-up questions, if necessary?