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CONTRACEPTIVE PROCUREMENT POLICIES, PRACTICES, AND LESSONS LEARNED

BRAZIL

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DELIVER
No Product? No Program. Logistics for Health

CONTRACEPTIVE PROCUREMENT POLICIES, PRACTICES, AND LESSONS LEARNED

BRAZIL

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Abstract
This study of Brazil has been commissioned by the Commodity Security and Logistics Division of the Global Health Bureau of the United States Agency for International Development (USAID), with Global Leadership Project funding, to identify important lessons learned following USAID's phaseout of Brazil as a recipient of contraceptive donations and other family planning funding. This document reports on the state of contraceptive security in Brazil, more than five years after USAID stopped donating contraceptives to the country. The report is based on interviews with key informants from the public, non-governmental organization and commercial sectors, a review of public policy and published documents, and databases of pricing information. In addition to lessons learned about phaseout, a summary of the current country situation, procurement practices, laws, policies, and regulations is presented. This information will help in the preparation of a procurement strategy for USAID presence countries and help these countries prepare for their eventual phaseout from USAID donations.

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ACRONYMS

ABEPF	Brazilian Association of Family Planning Institutions
ABONG	Brazilian Association of NGOs
ABNT	Brazilian Association of Technical Norms
ANS	*Agência Nacional de Saúde Suplementar* (Supplementary Healthcare Agency)
ANVISA	*Agência Nacional de Vigilância Sanitária* (National Health Surveillance Agency)
ATSM	*Área Técnica de Saúde da Mulher* (MOH Technical Area)
BEMFAM	*Sociedade Civil Bem-Estar Familiar no Brasil* (Brazilian Family Welfare Society, IPPF affiliate in Brazil)
CEME	*Central de Medicamentos* (Federal Center for Drug Purchases)
CEPEO	Commodities Procurement Organization Project
CGRL	General Coordination of Logistics Resources
CMED	*Câmara de Regulação do Mercado de Medicamentos* (Chamber for Regulation of the Pharmaceutical Market)
CIF	cost, insurance, and freight
CIT	Tripartite Management Commission
CNPD	National Commission for Population and Development
CNPJ	tax number
COFINS	social security financing tax
CPAIMC	Research Center for Integrated Maternal and Child Health Care
CEPEO	Commodities Procurement Organization Project
CPR	contraceptive prevalence rate
CSO	Civil Society Organization
DHS	demographic and health survey
FDA	Food and Drug Administration (USA)
FEFO	first-to-expire, first-out (as in rules)
FP	family planning
FPB	*Farmácia Popular do Brasil* (People's Pharmacy)
GDP	gross domestic product
IBGE	*Instituto Brasileiro de Geographia e Estatistica*
ICMS	value-added tax (on circulation of goods and services)
IEC	information, education, and communication

INMETRO	Institute for Measurement, Standardization, and Industrial Quality
IPI	industrialized product taxes
IPPF	International Planned Parenthood Federation
IUD	intrauterine device
IOC	*Instituto Oswaldo Cruz*
IRPJ	*Imposto de Renda de Pessoa Juridica* (income tax on organizations and businesses)
ISO	International Commission for Standardization
MEFP	Ministry of Economy, Agriculture and Planning
MOH	Ministry of Health
MPOG	Ministry of Planning, Finances, and Management
NACP	National STD and AIDS Program
NGO	nongovernmental organization
NOAS	Health Care Norms of Operation
NOB	Basic Norms of Operation
OCP	Product Approval Body
PAFIE	*Programa de Assistência Farmacêutica e Insumos Estratégicos* (Program of Assistance with Pharmaceutical and Strategic Supplies)
PAISM	*Programa de Atenção Informatizada à Saúde da Mulher* (Program for Integrated Women's Health Care)
PHPN	*Programa de Humanizacao no Pre-Natal e Nascimento* (Program of Improvement of Prenatal Care and Delivery)
PIS	*Programa de Integração Social* (social contribution tax)
PITS	*Programa de Interiorização do Trabalho em Saúde*
PPGAR	Program for Prevention of High-Risk Pregnancy
PROQUALI	*Programa de Melhoria de Desempenho e Reconhecimento da Qualidade*
SDP	service delivery point
SES	State Secretariats of Health
SMS	Municipal Secretariat of Health
STD/STI	sexually transmitted disease/infection
SVS	*Secretaria de Vigilancia Sanitaria* (Health Surveillance Secretariat)
SUS	*Sistema Único de Saúde* (Unified Health System)
TFR	total fertility rate
UNFPA	United Nations Population Fund
UN	United Nations
USAID	United States Agency for International Development
WHO	World Health Organization

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The report is based upon information collected in Brazil on procurement regulations and laws as well as actual contraceptive prices from 2005. This paper is available in English and may be obtained directly from the JSI/DELIVER website (www.deliver.jsi.com).

EXECUTIVE SUMMARY

This document reports on the state of contraceptive security in Brazil, five years after USAID phased out its involvement in providing contraceptives to the country. The report is based on interviews with key informants from the public, non-governmental and commercial sector, a review of public policy and published documents, and databases of pricing information.

Brazil is the largest country in Latin America, both in size and in population. Income is distributed very unevenly, both across and within regions. Gross domestic product (GDP) per capita is $7,762, however 11.6% of the population lives below the poverty line. Total annual per capita expenditure on health is $611, and government annual per capita health spending is at $280.

FAMILY PLANNING IN BRAZIL

The total fertility rate (TFR) in Brazil is estimated at between 2.2 and 2.6 children per woman. The modern contraceptive prevalence rate (CPR) is 70%, and the overall contraceptive prevalence rate is 76%. Access to contraceptive commodities and family planning services is weaker in less developed and more impoverished areas such as the northeast region of Brazil, where the reported CPR is 62%.

Public policies on family planning and contraceptive security have fluctuated over the past 40 years. During the military dictatorship (1964-1985), family planning was not among top priorities of the government, although USAID and other international donors did work with non-governmental organizations in the country during at least part of that time period. The federal government gradually began to put more emphasis on women's reproductive health and rights, and to provide its states with some contraceptives since the early 1980's. Brazil's constitution formally charged the individual states with responsibility for family planning in 1988.

In the 1990s, federal laws strengthened rights of access to family planning and established quality control bodies for health commodities, including contraceptives. The primary responsibility for providing commodities, however, remained with the states and municipalities (decentralized procurement). In 1992, USAID began its family planning phaseout process, with initiatives focused on two states: Ceará and Bahia. The goal of USAID's phaseout was to assist in the transition to self-sustainability, and shift the focus of family planning from curbing population growth to increasing the available contraceptive method mix, building capacity of health care professionals, and improving family-planning services. In 2000, USAID ended its formal involvement in family planning activities in Brazil.

Following the phaseout of USAID funding for family planning, the federal government took the lead in trying to improve the availability of contraceptives and develop supply chain management systems. Consequently, in 2000, procurement and distribution were centralized in hope of expanding supply and gaining better control over distribution. Lack of sufficient progress, however, led to abandonment of the centralized procurement in the following year (2001). The Ministry of Health (MOH) assumed responsibility for supplying 30 to 40 percent of contraceptives, with the rest of the need to be met with the help of coordinated management at the federal, state and municipal levels. Low performance indicators, however, once more forced the MOH to adjust its policies in 2004, and to begin progressively re-centralizing procurement. MOH has pledged to gradually increase the provision of contraceptive commodities [from 30%] to meet 100% of the need. The federal government has also recently published guidelines about sexual and reproductive rights, which it intends to make a priority for 2005–07.

CONTRACEPTIVE PROCUREMENT

The key public sector actors engaged in contraceptive procurement are the MOH, Ministry of Planning Finances and Management (MPOG), State Secretariats of Health (SES), and Municipal Secretariats of Health (SMS). MOH participates through a variety of its national-scale programs including *The Program of Assistance with Pharmaceutical and Strategic Supplies* (PAFIE), *The National Program for STDs and AIDS* (NACP), and *the Health Care Program for Strategic Populations.*

Within the non-governmental organization (NGO) sector, only a small number of organizations working with reproductive and sexual health [RSH] issues procure and provide contraceptives as part of their counseling and care services. Essentially, there are only two major NGOs, of those formerly supported by USAID, that remain consistently involved in commercializing contraceptives (BEMFAM and CEPEO).

From among the international-level bodies, Brazil only relies on the contraceptive procurement services of UNFPA, even if in a rather limited capacity, and almost exclusively when condom procurement is concerned.

METHOD MIX

In principle, the majority of the existing modern contraceptive methods are now available in Brazil, especially within the commercial sector. Yet the access to them remains limited due to constraints such as the income of the user, technical capacity of health care professionals, lack of proper information and education on both client and service levels, and deficiencies in the logistics system. As a result, despite the relative increase in the use of the other contraceptives [i.e. diaphragms and IUDs], the most prevalent methods remain sterilization (40%), and oral contraceptives (20%).

In the face of the AIDS epidemic, condoms benefit from special regulations, some of which can be credited with helping increase both demand and supply. Among such regulations are tax exemptions and various incentives for NGOs and other commercial establishments to sell condoms. As a result, about 425 million condoms are sold commercially per year. The Government of Brazil intends to increase its public condom procurement from 50 million to 1 billion per year.

In 1998, the MOH approved use of oral emergency contraception for victims of sexual violence and more recently they began to distribute the method within the public health care network. The policies for effective provision of emergency contraception through the public sector, however, still need improvement.

PRICING

All drugs considered essential are subject to government price regulations, and the National Health Surveillance Agency (ANVISA) maintains a reference list of prices for all these medicines. Due to the volume of purchases and the ability to create special circumstances, or exceptions, for its purchases, the public sector attains lower prices than the commercial sector.

Price variation of contraceptives in the commercial sector is persistent, both within and across product lines, and pharmacies are still the main outlet for the purchase of contraceptives. Access and method choice, however, are often limited, especially for women in remote (rural) regions, poor (urban) areas and for youth. A primary determinant of price for imported products is a series of taxes and duties assessed. Condoms, but no other contraceptives, are exempt from value added tax. The Chamber for Regulation of the Pharmaceutical Market (*Câmara de Regulação do Mercado de Medicamentos*, or CMED) and ANVISA determine annual price ceilings for all medicines, including hormonal contraceptives.

CONCLUSIONS

While the government of Brazil is making serious efforts to improve public family planning services, the implementation process has been slow, and many weaknesses remain, sometimes reinforced by frequent shifts in policy. Decentralizing health services without adequate resources, financial autonomy and capacity-building, for example, made it unrealistic for the municipal level to improve quality of care. In response, procurement has been centralized recently even though the federal government itself doesn't yet have sufficiently strong financing or logistics systems to procure and distribute all the needed commodities. Furthermore, the lack of proper forecasting and planning capacity contribute to unpredictability in the government's demands, thus jeopardizing its reputation vis-à-vis the manufacturing sector.

In the light of Brazil's socioeconomic realities, it would be naive to expect the government to meet the entire population's contraceptive needs within a short period of five years. Yet, with a more consistent approach, better policy implementation and coordination, adequate needs assessments, realistic forecasts and a focus on logistics, more substantial progress could have already been made, especially in relation to lowering prices and increasing availability and access to a wider range of contraceptive methods to the general population.

INTRODUCTION

This document contains results obtained from a qualitative assessment of contraceptive procurement practices in Brazil. The assessment followed the phase out in 2000 of family-planning assistance by the United States Agency for International Development (USAID).

The study, carried out in Brazil over a three-month period between September and November 2005, examined important developments in family planning, reviewed the current federal legislature, and researched state and municipal planning and contraceptive procurement policies and mechanisms.

METHODOLOGY

Multiple sources were used to collect data and evidence about the current reproductive health situation and related policies in Brazil. Relevant data were collected by reviewing literature on family planning, public documents, internet sources, and databases with product-pricing information, and specific government policies and regulations, as well as through conducting key informant interviews with representatives of private, public, and nongovernmental organization (NGO) sectors.

The literature review provided background about historical developments that influenced the current policy framework, while the public documents review offered a general look at the public policy environment. Both undertakings also helped to improve development of research instruments, identify key interview candidates, and reveal further information requirements.

To maximize the scope of the assessment, the interview sessions were conducted in public, private, and NGO sectors, with current as well as former stakeholders. About 24 strategic institutions were approached in four Brazilian states (the Federal District [Brasilia], São Paulo, Rio de Janeiro and Ceará), and interviews were conducted with 34 key informants.

REPORT STRUCTURE

Analysis of primary and secondary sources was conducted to produce a report containing the following:

- A summary of key developments affecting contraceptive procurement practices in Brazil in order to better understand the trade and regulatory environment in which contraceptive procurement policies have been established. The analysis in this section explains the basic structure and operations of the Brazilian health care system (the Unified Health System [Sistema Único de Saúde], or SUS) and how SUS has shaped the environment in which contraceptive procurement takes place. To complete the profile, in addition to providing socioeconomic and demographic information, this chapter presents a brief description of historical developments in family planning in Brazil and the main events that have influenced contraceptive procurement in recent years. Annex A provides a family-planning timeline.

- A review of laws and regulations that identify the main procurement mechanisms used in each sector in order to learn how they influence procurement decisions. This section discusses the actors, policies, and main procurement mechanisms that exist at all levels of the public, private, and NGO sectors. This chapter analyzes the method mix available in the country, as well as the origins and pricing of contraceptives. It touches on issues of quality, and provides data on government investment in contraceptive methods after the USAID withdrawal. See also Annex B, which details relevant legislation, and Annex C, which shows the pricing and origin of contraceptives. Annex C also contains a detailed commodity price analysis for each level for which data were available.

- The closing section brings together the main findings of the Brazil contraceptive procurement analysis and offers the research team's observations and conclusions.

As the key informant interviews were an indispensable source of information, it should be noted that a higher number of public servants from the federal level were originally selected for this study. Due to unforeseen events within the federal government, coinciding with the timing of the interviews, several of the informants withdrew their participation. Additional local and state level government perspectives were sought to overcome this limitation. A list of institutions that provided key informants can be found in Annex D.

PART I.

BRAZIL: A PROFILE

COUNTRY INFORMATION

Brazil is the largest and most populated country in Latin America. It is a federal republic with 26 Federal Units (States) and 1 Federal District (Brasilia).The country is further divided into five distinctive regions (north, northeast, center-west, southwest, and southeast) and has more than 5,500 municipalities. Most Brazilians (80 percent) live in urban areas, predominantly (46 percent) in cities of the more industrialized southeast region (São Paulo, Rio de Janeiro, and Belo Horizonte).

Brazil has significant economic and regional differences. São Paulo in the south is one of the wealthiest states and Ceará in the north is one of the poorest states. The wealthier states in the southeast region are said to have a per capita income seven times higher than the poorest states in the northeast region. In addition, Brazil continues to have one of the most unequal income distributions of any country in the world (HDR, 2005). Selected economic indicators for Brazil are shown in Table 1.1.

Table 1.1. Selected Economic Indicators

GDP per capita (International dollar, 2002)	**$7,762**
Annual GDP growth rate	4.5%
Population below the poverty line	11.6%
Total expenditure on health (as a percentage of GDP 2002)	7.9%
Public/private breakdown of health expenditure	3.6 / 4.3
Per capita total expenditure on health (2002)	$611
Per capita government expenditure on health (2002)	$280
The size of the Brazilian contraceptives market is estimated to be US$305 million per year, with the sale of 90 million units[1] per year.[2]	

[1] A unit is defined here as 1 condom, 1 cycle of pills, 1 diaphragm, or 1 IUD.
[2] IMS Health data: http://www.progenericos.org.br/noticias/noticias2.asp?id=497.

Table 1.2. Selected Demographic Information[3]

Total population estimate	**178,470,000**
Annual population growth rate (1993–2003)	1.4%
Total fertility rate (per woman) estimated (1993/2003)	2.6/2.2
Maternal mortality (2000)	260 per 100,000 live births
Infant mortality	30 per 1,000 live births
Life expectancy	68.3 years
Women of reproductive age[4] (10–49 years)	58,623,000
Married women of reproductive age (2000)	29,020,000
Contraceptive prevalence (modern methods)	70%[5]
Contraceptive prevalence (any method)	76%[6]
The northeast's contraceptive prevalence rate	62.3%[7]

Important demographic and reproductive health indicators are shown in Table 1.2. Historically, much of the high (70 percent) contraceptive prevalence rate (CPR) in Brazil was due to the private sector. With the public sector not providing services for many people, much of the initial impetus for increasing family planning (FP) services came from nongovernmental organizations (NGOs) and from private pharmacies. Even with an increased government role since the 1990s, the public sector contribution to modern contraceptive method use is relatively small. Although there has not been a demographic and health survey (DHS) in Brazil since 1996, estimates suggest the public sector accounts for only 11 percent of oral contraceptive use (the most popular method) and 60 percent of locally manufactured intrauterine devices (IUDs). Despite the high CPR, Brazil's extreme income inequalities mean important segments of the population have no access to private sector sources of supply while at the same time they only have limited access to the public sector.

THE HEALTH SYSTEM IN BRIEF

Familiarity with health service delivery in Brazil is helpful for understanding the environment and mechanisms that influence contraceptive procurement.

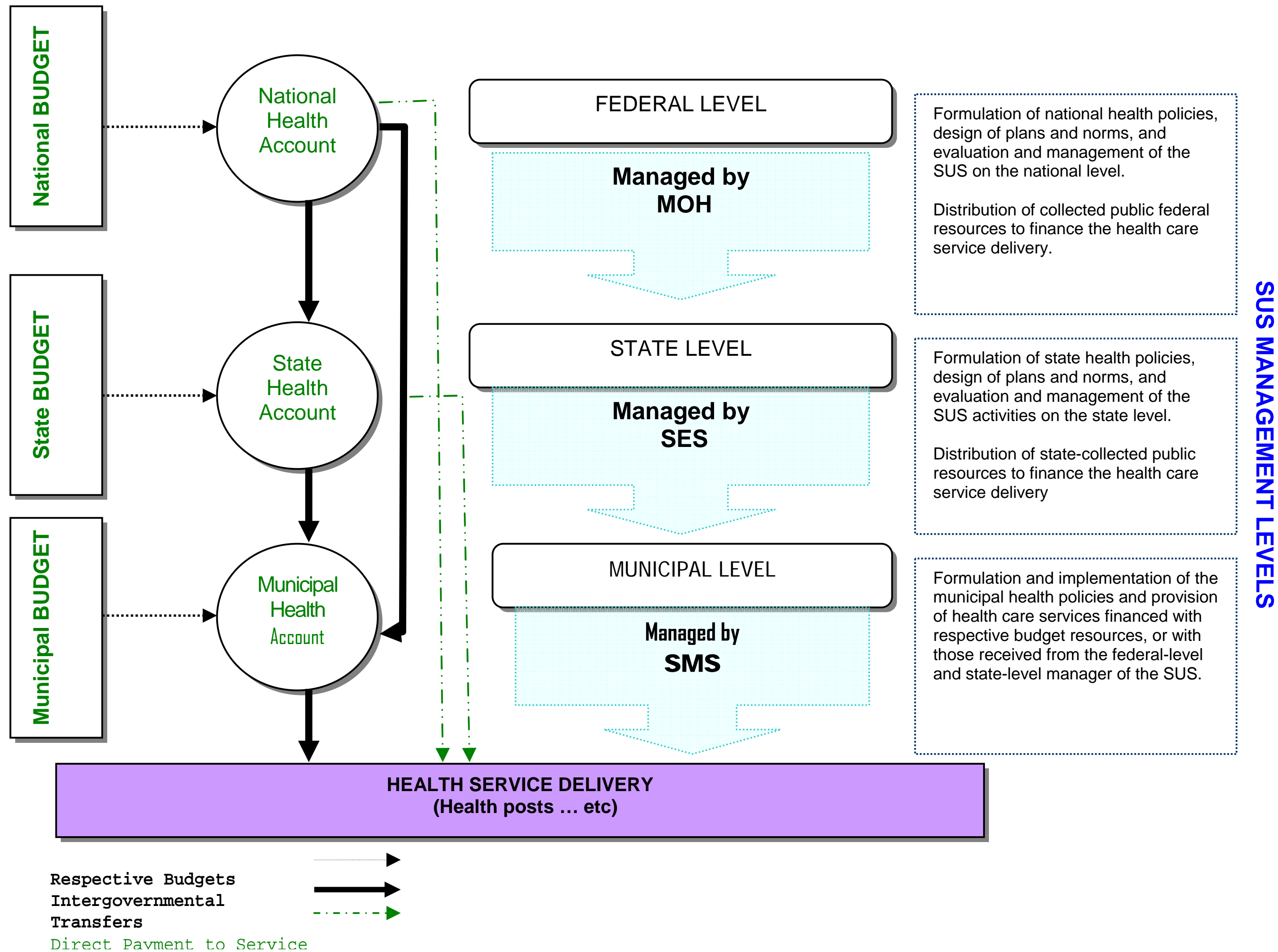
The Unified Health System (*Sistema Único de Saúde*, or SUS) is currently the main mechanism for public health care delivery in Brazil. Based on the 1988 federal Constitution and regulated by Law 8.080 and Law 8.142 since 1990, the SUS was established with the objective of improving access to health services and quality of care, as well as enhancing the country's overall health situation. The SUS is tasked with guaranteeing free and complete basic health care to the entire Brazilian population.

The SUS is financed by government subsidies derived from general taxes, payroll social security tax contributions paid by the formally-employed population, and a special tax imposed on banking transactions. In 2000, a constitutional amendment (EC-29) defined how income should flow among the national, state, and municipal levels and throughout the system. Federal resources consisting of more than 70 percent of SUS's total budget revenue are gradually being passed on to states and municipalities as direct transfers from the National Health Fund to state and municipal accounts (Figure 1.1). The funds are now increasingly being transferred in this manner, as opposed to the alternative where the federal level would reimburse service providers directly.

[3] World Health Organization 2003 data. (Last actual DHS was carried out 1996.)
[4] *Instituto Brasileiro de Geographia e Estatistica* (IBGE) data.
[5] UN World Contraceptive Use Chart 2003.
[6] UN World Contraceptive Use Chart 2003.
[7] 1996 Demographic and Health Survey (DHS) data.

Each of the government players (federal, state, and municipal) in the SUS has assigned functions, roles, and competencies in relation to the others, and with respect to the management of the system at their own level of responsibility (Figure 1.2). Legal provisions, which govern health care system operations, allocate primary responsibility for SUS management and administration to municipalities, while financial and technical assistance comes from federal and state governments. A Tripartite Management Commission (CIT), composed of representatives from each government level, oversees the overall integration and coordination of the system.

Figure 1.1. Flow of Finances



Source: De Souza Renilson Rehem. "O Sistema Público De Saúde Brasileiro." At the conference: "Seminário Internacional Tendências e Desafios dos Sistemas de Saúde nas Américas." São Paulo, Brasil, August 11-14, 2002.

Figure 1.2. Institutional and Decision-Making Structure of SUS

Level	Manager	Intermanagerial Commission	Participatory College
NATIONAL	MOH	TRIPARTITE COMMISSION	NATIONAL COUNCIL
STATE	STATE SECRETARIAT	BIPARTITE COMMISSION	STATE COUNCIL
MUNICIPAL	MUNICIPAL SECRETARIAT		MUNICIPAL COUNCIL

Source: De Souza Renilson Rehem. "O Sistema Público De Saúde Brasileiro." At conference: "Seminário Internacional Tendências e Desafios dos Sistemas de Saúde nas Américas." São Paulo, Brasil, August 11-14, 2002.

The SUS includes a large network of public health care institutions and services at the federal, state, and municipal levels (Figure 1.2). It incorporates health posts, hospitals, university health centers, laboratories, blood banks, and research centers. Basic health needs (and simple procedures) are to be met at the local level (i.e., the center in closest proximity to the user's residence). More specialized or complex procedures are outsourced, as needed, via a referral process, to a more expert service delivery point or hospital. The private sector's involvement in SUS is said to be complementary and provided in the form of contracts and service agreements when public health care facilities do not have the capacity to provide services for all the population in a particular region.[8] Additionally, private (voluntary) plans, group health plans, self-managed health plans (employee enrollment), and insurance companies compose a second system known as the "supplementary medical system."[9]

FAMILY PLANNING IN BRAZIL

1960–2000

USAID channeled financial assistance to Brazilian family planning through sponsorship of select NGOs (e.g., Population Council, Family Health International, Population Services International, and the Pathfinder Fund) that provided family-planning activities over a 30-year span. The historical development of this process is summarized next.

Initial public policies that spread around the world in the 1960s and which eventually influenced Brazil focused almost exclusively on matters of demographic control because the main concern at the time was that, by the turn of the century, some eight billion people would be living on Earth and there would not be enough resources to sustain them all.

Family planning was first implemented largely by the international organizations and by Brazilian NGOs such as the Sociedade Civil Bem-Estar Familiar no Brasil (BEMFAM), which was founded in 1965 and financed by the International Planned Parenthood Federation (IPPF). About 6 percent of BEMFAM's budget was supported by USAID between 1987 and 1991,[10] and this funding coincided with the beginnings of USAID's formal involvement in family planning in Brazil. BEMFAM's primary objective

[8] SUS website: http://www.sespa.pa.gov.br/Sus/sus.htm.
[9] Lobato and Burland (2000).
[10] Medici and Beltrao (1996).

was curbing birth rates, which was also apparent in a few government programs, such as the Program for Preventing High-Risk Pregnancies (PPGAR).

The military dictatorship (1964–85) provided little or no incentives or technologies whatsoever to improve reproductive health care. In addition, the military thought women had an inferior social status, with their position in society limited largely to procreation and homemaking. Thus, little advancement in reproductive health occurred at the public level during the 1960s and 1970s, and family planning activities focused exclusively on population control.

Before the 1980s, social needs assessments were not used to inform public policy development. The first national population policy that considered research, needs assessment, and women's health issues was created in 1983. The national Program for Integrated Women's Health Care (Programa de Atenção Informatizada à Saúde da Mulher, or PAISM), although centralized, was developed in cooperation with representatives of the feminist movement, state-level managers, and academic researchers. It was the first significant step toward improving the health and well-being of women. PAISM, although important for being the first official effort to bring issues of women's reproductive health and rights into policy focus, encountered serious implementation problems. Its evaluation pointed to management inefficiencies and confirmed that the program's distribution of contraceptive methods was poor.

Aside from PAISM, two other notable developments took place in the 1980s: first, the federal government began distributing contraceptives to states, and later the new Constitution of 1988 formally handed over the responsibility for family planning to the individual states.

In 1990, the federal government established the Unified Health System (or SUS). The 1990s also brought about additional national legislation that continued delegating family planning responsibilities to states and municipalities. Law 9.263/1996 was created to regulate family planning and to guarantee equal rights to both genders. Female sterilization was approved as a procedure to be offered by public hospitals, a practice that was previously performed only with (and under the cover of) a caesarian section.

In respect to quality control, Law 9.782/1999 established a National Health Surveillance Agency (ANVISA). This administratively autonomous agency cooperates with the Ministry of Health (MOH), specifically with its Department of Sanitation Monitoring (SVS), to regulate and monitor the quality of contraceptives in the country at the federal and state level.

The last eight years of USAID's support (1992–2000) were considered phase-out years, and activities were concentrated exclusively in the states of Ceará and Bahia. In addition to assisting programs in their transition to self-sustainability, the official objective of the last phase of support was to shift the focus of the family planning strategy from controlling the population to increasing the available method mix, building capacity of health care professionals, and improving family planning services.

In addition, USAID sponsored DKT International, a social marketing firm, to implement its strategy to sell condoms in Brazil. Among other responsibilities, DKT lobbied for removing the sales tax on condoms. As a consequence, an agreement signed between the Ministry of Economy and all state Secretaries of Economy in 1997 exempted all commercial operations related to condoms from value-added (Impostos Sobre Circulação de Mercadorias e Prestação de Serviços, or ICMS) taxation on condoms.

2000–05

In 2000, because of insufficient progress on family planning within the decentralized system, the federal government returned to centralized procurement of contraceptive methods (orals and injectables, as well as IUDs and diaphragms) with the objective of expanding supply and intensifying its control over the distribution of contraceptives within the SUS. The government aimed to reduce abortion-related mortality

and to increase the contraceptive method mix. At this point, the government considered including emergency contraception in the available method mix.

However, in 2001, evaluation of government family planning programs in 10 Brazilian states revealed serious deficiencies in logistics (storage and distribution, especially between states and municipalities) and a lack of technical capacity among state health coordinators to provide adequate reproductive health services in municipalities.

> **Regional Lesson Learned:** Decentralization of authority without proper local capacity building or communication of the implications of change will undermine product availability. Recentralization of the FP supply chain, while overcoming local capacity issues, may also undermine product availability if the central level does not address underlying weaknesses in the supply chain.

Influenced by those findings, the centralized distribution of contraceptives, started only the previous year, was interrupted. The Tripartite Management Commission (CIT) defined a new strategy of decentralizing contraceptive distribution once again. Additionally, in the same year, the National STD/AIDS Coordination Committee was charged with the responsibility of implementing a new MOH strategy for both male and female condom distribution.

Until 2004, the MOH was responsible for supplying 30 to 40 percent of contraceptives, with the understanding that municipalities and states would cover the rest of the need. Underperformance on the contraceptive supply front has forced the MOH to adjust its policies, and it has recently pledged to gradually meet 100 percent of contraceptive need. For the states visited for this analysis, the feasibility of this objective will depend on the MOH's addressing fundamental logistics and service delivery issues in a more systematic way than attempted previously.

NEW POLICY GUIDELINES ON SEXUAL AND REPRODUCTIVE HEALTH (2005–07)

In its most recently issued guidelines about sexual and reproductive health rights, the government confirms the improvement of those rights as the priority for 2005–07. The MOH will once again assume the chief responsibility for procuring and distributing contraceptives and for improving available method mix in the country. The government vows to guarantee (1) the right to make decisions about contraception and (2) access to contraceptive means and methods for all men and women of reproductive age, including both adults and adolescents, who so desire.[11]

The initial investment in 2005 is said to have reached R$40 million (approximately U.S.$20 million), which should correspond to 40 million people assisted. The government started implementing new procurement policies in February 2005 and says that 5,200 municipalities have already begun to receive kits with contraceptive methods.

The guidelines further specify:

- Contraceptives are included on the essential drug list for basic health care; their acquisition is to be the federal level's responsibility.
- Contraceptives will be procured at a rate to progressively meet 100 percent of the need of the federation's 5,561 municipalities for two types of oral methods: (low-dose) combination pills and progestin-only pills.
- Oral emergency contraception and injectable methods (monthly and trimestral) will be provided to the federation's 5,223 municipalities that—until March 2004—maintained registered teams of family health care providers or participated in the Program to Improve Prenatal Care and Delivery (Programa de Humanizacao no Pre-Natal e Nascimento, or PHPN).

[11] Government Guidelines on Sexual and Reproductive Rights, 2005. [*Direitos sexuais e direitos reprodutivos - Uma prioridade do governo, Cartilha*. Série A. Normas e Manuais Técnicos. Série Direitos Sexuais e Direitos Reprodutivos - Caderno no. 01. Ministério da Saúde, Brasília/DF, Brasil, 2005.]

- IUDs and diaphragms will be provided to gradually meet 100 percent of need, initially in 1,200 municipalities (in 2005), with expected yearly increases of 350 municipalities during 2006 and 2007.

The federal government's intention is to show commitment to effectively procure, distribute, and facilitate the use of contraceptives by creating better policies related to contraceptive procurement at all levels (federal, state and municipal). Previous experiences in these areas, however, point to the continued need to improve the infrastructure and logistics systems to be able to provide quality services and products to the entire population, especially those in the central parts of the country where the government reach has traditionally been less effective.[12]

RECENT EVENTS WITH IMPLICATIONS FOR PROCURING HEALTH COMMODITIES

INCENTIVE PROGRAM FOR PURCHASING PHARMACEUTICALS (1999)

Following the national drug policy guidelines, the MOH (in its Decree GM/MS 176/1999) created a financial assistance program for purchasing medicines. The MOH established qualification criteria and corresponding funding amounts to be transferred to eligible states and municipalities to assist them in purchasing essential drugs.

GENERIC DRUGS APPROVAL (1999)

Law 9.787/1999 (amending Law 6.360/1976 regulating the sanitation and establishment of generic forms of drugs, generic names of pharmaceutical products, and other related matters) increased the focus on generic formulations. In reference to government procurement of medications, the law now mandates that, when available and given the same price conditions, generic formulations must be given priority.

"OPERATION VAMPIRE" (2004)

A scandal involving several NACP staff relating to irregularities with invoicing and procurement of hemoderivatives occurred between 1990 and 2002. A federal police investigation confirmed corruption at senior levels of the MOH and the NACP and resulted in severe disciplinary actions. The outcome also stimulated a process of further inquiry into general procurement practices of the MOH related to medical products, and led to the abolition of the NACP's procurement office, which used to be independent from the MOH. The aftermath of the corruption scandal also brought about temporary suspensions of federal-level tenders, which caused significant delays in procurement and distribution processes (including those of contraceptives) to which some of the reported product shortfalls can be attributed.

Regional Lesson Learned:
There was a similar corruption scandal in Costa Rica with medical products. Collusion was discovered between pharmacies, suppliers, and public sector procurement, with several individuals getting kickbacks for selecting specific suppliers.

PROGRAM "FARMÁCIA POPULAR DO BRASIL" (2004)

Farmácia Popular do Brasil (FPB, or People's Pharmacy) is a government program created to improve public access to basic medications. Oswaldo Cruz (Fiocruz) Foundation, the MOH body charged with the program's operation, has been authorized to acquire certain drugs directly from public or private pharmaceutical laboratories and to provide them to the public (upon presentation of a medical prescription) within the FPB chains at production prices.

The contraceptive methods bought and made available throughout Brazil's 60 FPB pharmacies include Depo Provera, Mesigyna, ethinyl estradiol plus levonorgestrel (combined oral), and levonorgestrel (emergency contraception).

[12] Government Guidelines on Sexual and Reproductive Rights, 2005.

NEW GENERIC FORMULATIONS OF HORMONAL CONTRACEPTIVES (2005)

The Brazilian pharmaceutical industry is planning to introduce a new series of generic medications that will include certain formulations of hormonal contraceptives. The entry of those generics is expected to significantly reduce (up to 45 percent) the average price of the pill. The current average cost per pack of pills is between R$10 and R$20 (U.S.$4.88 to U.S.$9.76) and could be reduced to about R$5.50–R$13 (U.S.$2.68 to U.S.$6.34). The formulations are said to still be undergoing testing and rigorous review to ensure that their quality and desired effects are satisfactory and in accordance with quality standards.

A supplementary chronological list detailing some of the main events related to family-planning development in Brazil between 1960 and 2005 can be found in Annex A.

PART II.

CONTRACEPTIVE PROCUREMENT IN BRAZIL

This chapter provides information specific to contraceptive procurement in Brazil. It analyzes different processes, participants, tendencies, and procurement mechanisms that exist at each government level. It further describes the regulatory framework and functioning of procurement mechanisms in the public, private, and NGO sectors. It discusses the origins of respective methods on the market and provides data on government investment in family planning since USAID's withdrawal. Annex C contains a detailed analysis of the pricing of contraceptives within public, private, and NGO sectors.

MAIN ACTORS

PUBLIC SECTOR

Ministry of Health (MOH)

The MOH participates in 35 programs, 25 of its own and 10 in partnerships with other ministries. Three of these programs involve contraceptive products in some way: (1) The Program of Assistance with Pharmaceutical and Strategic Supplies (*Programa de Assistência Farmacêutica e Insumos Estratégicos*, or PAFIE*)* includes hormonal contraceptives. (2) The National Program for STDs and AIDS (*Programa Nacional de DST e Aids*, or NACP) provides condoms through state and municipal prevention programs to prevent sexually transmitted diseases (STDs) and acquired immune deficiency syndrome (AIDS) and through direct supply to the National Council for Women's Health. (3) The Health Care Program for Strategic Populations (*Programa de Atenção à Saúde de Populações Estratégicas)* also includes the National Council for Women's Health. The National Council for Women's Health defines the national women's health strategy, its guidelines and its implementation plan. It establishes periodic forecasts and needs assessments of contraceptives as part of planning the commodities supply for its programs, and it discusses acquisition plans with the PAFIE.

The PAFIE coordinates the acquisition and distribution of strategic health commodities and those on the essential drug lists. The essential drug list category is further divided into centralized and decentralized purchases. Even though the federal government now centralizes the procurement of all contraceptives, some municipalities do purchase additional contraceptive methods on their own. Procurement plans are passed on to the Ministry of Planning (MOP). Once reviewed by the MOP, the plans return to the MOH, which has to follow internal rules as well as regulations of the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, or ANVISA) and the Unified Health System (*Sistema Único de Saúde*, or SUS) to be able to implement them.

The PAFIE also coordinates management of the national pharmaceutical assistance policy and, as part of this responsibility, developed two drug lists: (1) the list of essential drugs, provision of which is the responsibility of the MOH; and (2) the list of drugs that are approved but for which government has no obligation to purchase or reimburse through the SUS.

In 1992 and 1994 respectively, spermicides and oral contraceptives were included on the MOH's essential drugs list. Those decisions reflect increased emphasis on improving the availability of contraceptive supplies. Other changes included reimbursement by the SUS for IUD and diaphragm supplies, as well as the costs of medical consultation and of insertion and fitting procedures.

PAFIE proposes guidelines and coordinates development of intergovernmental activities related to the production of health goods and medicines at the national level, as well as government involvement in the national pharmaceutical market. PAFIE is further charged with coordinating and overseeing procedures related to supply and production of medicines in the pharmaceutical market.

After the procurement plans are completed, they are sent to the General Coordination of Logistics Resources (*Coordenação Geral de Recursos Logísticos* or CGRL), which manages the procurement process and contracts with national and international contraceptives suppliers. This program coordinates the logistics of distribution, warehousing management and, in the case of imported products, importation and customs clearance processes.

Ministry of Planning, Finance and Management (MPOG)

The Ministry of Planning, Finance and Management (*Ministério do Planejamento, Orçamento e Gestão* or MPOG) creates norms for the federal level procurement process but does not directly engage in purchases. It sets up standards and contract rules (before and after purchasing) and assigns procurement responsibilities to different actors. MPOG's role is to provide guidelines but not deal with details of specific tenders. The responsibility for tenders is left to the respective ministries. For contraceptive procurement, the ministry's decrees and orders refer primarily to the types of contraceptives to be purchased by the MOH and to general, macro-level procedures and regulations such as:

- Multi-year plans, which are created by Law 10.933/2004, set objectives, identify expected outcomes, and forecast corresponding funding needs for the four-year period to follow;
- Budgetary guidelines, within multi-year plans, set priorities for each following year. Those priorities are decided by the ministries and are brought to Congress for approval;
- Annual budgetary laws, which are within the multi-year plans, establish budgetary and spending limits for the priority activities of the year to come.

The MPOG decides only on the qualitative (indicators, objectives, justifications) and quantitative (resource limitations) requirements of the programs. On the other side, between the MOH and municipalities, specific qualification criteria are established for municipalities to become eligible to receive commodities. Those criteria serve as general certification guidelines and give qualified municipalities a degree of liberty in decision-making. For example, diaphragms are distributed to municipalities that have a population of more than 50,000. Should a municipality that does not meet this criterion desire to receive this product, it must follow a series of procedures in order to receive MOH's approval and certification.

State Secretariats of Health (SES)

Each state is responsible for organizing, planning, monitoring, and evaluating the health service provision to its municipalities. The SES are tasked with providing high- and medium-complexity health services or high-cost services, with the exception of services provided by municipalities with an administrative status of Gestao Plena (i.e., a higher level of autonomy in management). In addition, the SES are responsible for purchasing high-cost medicines or other strategic commodities.

As a consequence, the SES are not directly responsible for providing family planning services or contraceptives, because those are not considered strategic commodities. In other words, the SES do not generally purchase contraceptives. Nevertheless, an exception within some state health units allows them

to provide family planning services (along with their other health services) to the population in their coverage region.

Each SES, along with the MOH, defines its state pharmaceutical policy, which regulates the essential drugs lists (including hormonal contraceptives). The Municipal Health Secretariat (*Secretaria Municipal da Saúde* or SMS) purchases those medicines on the list. The procurements are funded by SES allocated funds after being approved by the Bipartite Committee, which includes representatives from the SES, SMS, State Health Council and Municipal Health Council as well as other local CSOs. The actual purchasing takes place though at the municipal level. If the essential drugs list of the state already includes pills and injectables, for example, and if the SMS has available funds, the municipality may use its own funds to purchase other contraceptive methods (diaphragms, IUDs, etc.).

States are generally organized by their health secretariats into regional bodies (Regional Health Districts), which are managed by the most central municipality of the district (also called município polo) or by a municipality that has the higher autonomy status in administration—Gestão Plena.

Municipal Secretariat of Health (SMS)

The recent restructuring of the health sector, or "municipalization of health," resulted in decentralizing services to municipalities. The state level was charged with devising overarching strategy while municipalities were tasked with providing basic health care.

Municipal health centers are all obligated to provide basic health care. Any additional services (medium- and high-complexity), however, are provided only when the municipality has sufficient financial and technical capacity to do so. Each municipality has different priorities and has the autonomy to decide which services to provide. In addition, each municipality can use its discretion in procurement decisions according to those priorities. For example, if a small municipality has a significant senior population and a small population of reproductive age, it will likely identify services and corresponding medical needs (including product purchases) that focus on the needs of the prevailing (senior) population. In other words, such a municipality will be less likely to use its resources to purchase contraceptives.

Synopsis of Decentralization:

1997	health care and family-planning (FP) logistics decentralized
2000	FP logistics recentralized
2002	FP procurement centralized but distribution decentralized
2005	FP procurement and distribution recentralized as part of the Government's Guidelines on Sexual and Reproductive Health Rights

Some municipalities such as São Paulo (capital of São Paulo State) and Fortaleza (capital of Ceará State), which are more financially secure and able to carry out their own epidemiological surveillance as well as provide highly complex health procedures, have the status of higher autonomy in administration—Gestão Plena. Such municipalities are able to procure contraceptives to cover demand in their area or to increase method mix availability on their own. Only about 10 percent of Ceará State municipalities have this authority, whereas more than 30 percent in São Paulo State have it. Other municipalities have to wait to receive their contraceptives through the federal distribution system, as well as meet certain qualification criteria to receive commodities.

Government distribution criteria are based on demographics and functioning family health programs, but differ depending on method. Theoretically, according to government assessments, no municipality should be without at least one method supplied by the central distribution system. For example, all municipalities are qualified to receive the pill. In the cases of injectables and emergency contraceptive pills, about 90 percent of municipalities should meet the criteria and be eligible.

Only 25 percent or less of the needs for diaphragms and IUDs are covered by the central distribution system. Economically weaker municipalities (without Gestão Plena) or those in underserved areas often

rely completely on centralized procurement and, depending on their eligibility to receive different methods, may not be able to provide adequate contraceptive method mix.

NGO SECTOR

The latest Brazilian Association of NGOs (ABONG)[13] catalog indicates that a variety of organizations are working with women on reproductive health and gender issues. Among them, only six organizations reported supplying contraceptives as part of their counseling and medical services. Overall, the procurement and sale of contraceptives in the NGO sector does not happen in a systematic or sustainable manner, especially among smaller NGOs.

Thus, commercialization of contraceptives does not represent a significant source of their income. Their product supply depends largely on external (public or private) donations (either financial or in-kind).

Sociedade Civil Bem-Estar Familiar no Brasil (BEMFAM)

BEMFAM is one of the two NGOs remaining from the group of organizations previously sponsored by USAID that is still actively involved in selling contraceptives. Most NGOs did not manage to sustain themselves, and even in cases where they still sell contraceptives, they tend to do so on a very small scale or only as part of their counseling and family planning services. The Commodities Procurement Organization Project (CEPEO) which is the other organization formerly funded by USAID, is now involved in the sale of imported IUDs and some other contraceptive methods, primarily to public sector institutions and on a small scale through its website store.

BEMFAM sees its role as complementary to government activities. It often works through cooperative agreements with the SMS and SES and that allow it to directly influence municipal management in two important areas: (1) diversification and expansion of contraceptive method mix as a demonstration of respect for women's choices in family planning and (2) discussion of important issues related to women's health (gender, poverty, youth, etc.). In this context, BEMFAM provides technical assistance to diversify and increase contraceptive method mix and advice on how management of health care could be improved. In the past 12 years, BEMFAM attended more than four million clients and patients through municipal cooperative agreements.

BEMFAM also operates six reproductive health clinics that are meant to be models for how women's health care needs can and should be provided in Brazil. These clinics focus on providing high-quality health services, sound infrastructure, and a diversified contraceptive method mix. This last point gets special emphasis because it is believed to be a great way to guarantee a woman's free and informed choice in selecting the contraceptive method that best suits her. BEMFAM includes men in its programs throughout the decision-making process and in all other matters of sexual and reproductive health. BEMFAM would like to see this model replicated by other health services and health care providers in the Brazilian public sector.

INTERNATIONAL LEVEL

UNFPA[14]

The United Nations Population Fund (UNFPA) facilitates procurement of contraceptives and condoms on a global scale, and its Copenhagen office is charged with management and logistics of contraceptive procurement. In Brazil, however, with the exception of condoms, the government does not use UNFPA's procurement services, despite the organization's offers.

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[13] ABONG (Associação Brasileira de ONGs). ONGs no Brasil: Perfil e Catálogo das Associadas à ABONG. Serie Desenvolvimento Institucional. Sao Paolo, Brazil: ABONG, 2002.

[14] A recent development, discovered after the conclusion of this report in December 2005, is that UNFPA has become more actively involved with the NACP in condom procurement activities.

In Brazil, UNFPA participates in reproductive health mainly through various feminist and NGO-management networks. It collaborates with the MOH on developing technical norms for the Department of Women's Health. With the NACP, UNFPA also participates in condom social marketing initiatives, free condom distribution, and condom procurement activities.

Recently, the MOH contracted with UNFPA to conduct a study on contraceptive users' opinions and perspectives. UNFPA was asked to survey users' experiences with availability and access to information about the quality of contraceptive methods distributed by the MOH. The research is ongoing.

The next UNFPA activity cycle is expected to start in 2007. The organization plans to base its reproductive health needs and forecasts on the results of the Demographic Health Survey (DHS), which was originally scheduled for 2004 but being implemented in 2007.[15] The last DHS was completed in 1996 and was carried out by BEMFAM.

REGULATORY FRAMEWORK AND PROCUREMENT MECHANISMS

PUBLIC SECTOR

Article 37 of the federal constitution indicates that public works and purchases of goods and services should be contracted through a public process of bidding and tenders. The relevant regulations are established under Law 8.666, dated June 21, 1993 (Box 1), which applies to government procurement at the federal, state, and municipal levels, as well as to public agencies. There is no central procurement agency in Brazil. Procurement is the responsibility of each individual government body, including state enterprises. This law amended various criteria that formerly regulated procurement in order to avoid irregularities in the tender offer. Also, with Law 8.666, the lowest price is the core criterion of the bidding process, and this criterion applies for all contraceptives.

[15] This updated information is based on a conversation between one of the author (C. Studart) and a representative from UNFPA on May 8, 2007. It could not be confirmed which organizations are responsible for the
Study.

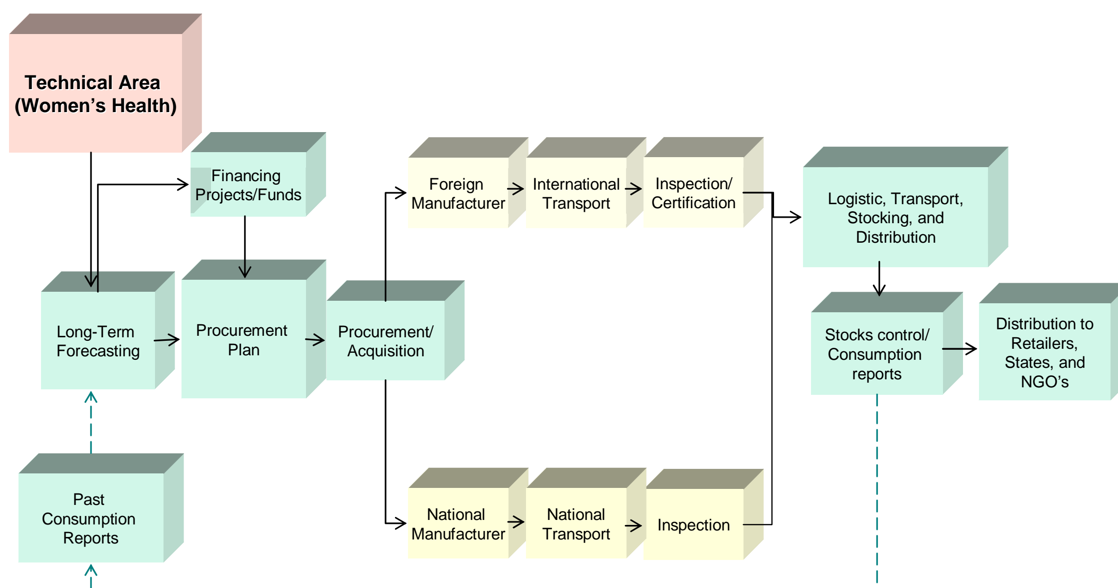
Box 1. Innovations of the 1993 Law 8.666[1]

1. The entire bidding and contract execution procedure is public. The principal acts—invitation, announcement of the award, and contract signing—must be published and the public must have free access to information concerning bidding procedures and contracts. Any interested party can administratively or judicially challenge government actions.
2. The object of the bidding must be described in sufficient detail as to allow for predetermination of its quality. Consequently, the specification or quality of the object of the bidding is not the responsibility of the participants in the competition and is no longer a criterion in weighing proposals.
3. Participating companies are required to provide financial guarantees, capital, access to market financial resources, and access to equipment and technical personnel. The law does not require prior experience with respect to the object of the bidding. The required amount of capital that would guarantee performance of the contract is set at 10 percent, a non-exorbitant level that will not limit participation in the bidding.
4. The company that submits the lowest bid is automatically awarded the contract. This provision reduces the discretionary authority of public officials.
5. The company may be required to demonstrate its capacity to perform the contract in advance, if it is suspected that the company cannot carry out the contract. Delays in contract performance are subject to financial penalties and to a prohibition against participating in other bidding procedures.
6. Additions to contracts are limited.
7. The bidding procedure can be waived only in narrowly defined cases and with detailed justifications. Suppliers must be paid in chronological order. This requirement means that the order of payments no longer depends on the contractor's influence in the public sector and prevents the advance "sale" of accounts receivable.
8. Penalties and sanctions are established for public officials who disobey the law.
9. All bidding and contract execution procedures must be duly registered and are subject to internal and external audits.

Following the forecasting of contraceptives (including condoms) and demand-estimation, a public invitation for registration of product prices is issued to potential suppliers (Figure 2.1).

Some pre-qualification procedures must be met in order to participate in the bidding process. All potential suppliers have to be officially registered firms and must provide evidence of their technical and financial situation, fiscal standing, and legal status. In the case of foreign firms, official registration or authorization to operate in Brazil is also required. This process implies that firms have their products registered at ANVISA, a condition that should, in theory, attest to the quality of the products that are being registered.

Figure 2.1. Purchase and Distribution through the Federal Government



Source: Presentation on Condom Social Marketing by EAESP/FGV–GVConsult, 2003 (Financed by the NAPC, MOH, UNDCP).

The price registration process gives the government a chance to reserve funds needed for procurement, and once the funds are allocated for this purpose, public tender may be announced through four modalities:[16] (1) bidding among any interested parties, (2) acceptance of prices from officially registered firms, (3) invitation by the administrative authorities, and (4) public auctions of goods (electronic or live auctions).

Electronic auction has become the mechanism that is being used more, if not most, of the time for public procurement and price registration. Federal authorities recommend electronic auction, especially in the case of medicines (including hormonal contraceptives). There are a large number of suppliers; this modality takes advantage of broader choices, discourages cartels, and provides cheaper prices. In addition, it significantly minimizes the operational costs of the process, compared with live auctions, for example.

Regional Lesson Learned:
Costa Rica is also looking at an e-commerce solution for handling government procurement to improve efficiency and transparency, and to broaden the international scope of procurement.

Once a company has won an auction, it registers its product at the winning price and the contract is generated. Such a contract is generally valid for one year, with the possibility of renewal for one more year. The contract obligates the company to provide the agreed amount of contraceptives at the winning

[16] See http://www.wto.org/english/tratop_e/gproc_e/brazil.pdf.

price when requested by the government, which can be any time during the life of the contract. The government, however, is not obligated to actually buy the minimum or the total quantity estimated. Furthermore, three times the estimate agreed upon at the auction can be requested by the government.

This approach is known as the Strategic Management of Supply and Demand. This strategy attempts to compensate for the lack of systematic forecasting by requesting the product according to current demand and by procuring according to an estimate of price and quantity without having to actually buy the whole quantity. This strategy is said to minimize the risk of product expiration and inadequate forecasting (see Box 2 for example).

Box 2. Emergency Contraceptive Procurement and Use

Last year, Levonorgestrel (an oral emergency contraceptive method) was the second most purchased contraceptive on the MPOG drug list. Demand was estimated and a significant quantity was purchased. Unfortunately potential users did not request the product in the public health care network (e.g., People's Pharmacies) to the extent expected, because all medicines acquired through that network require a prescription. A medical consultation is a prerequisite to receiving a prescription, which in the public health system often takes several days. In the case of emergency contraception, the long process is not acceptable because the method needs to be taken within 72-hours of unprotected sex. As a consequence, large quantities of Levonorgestrel purchased last year had to be donated to CSOs.

All procurements (tenders, invitations, and auctions—both live and electronic) must be published in the federal government's official publication (Diario Official) and in state-level equivalents of that publication. Information pertaining to every step of the process—from the announcement of price registration, to the details of the bidding documents, to the results and provisions of the competition—must be made available to the public.

The same procedures apply to the Internet, to specific websites of governmental institutions, and to the main public procurement website: www.comprasnet.com.br or www.licitações.com.br.

Box 3. Condom Procurement

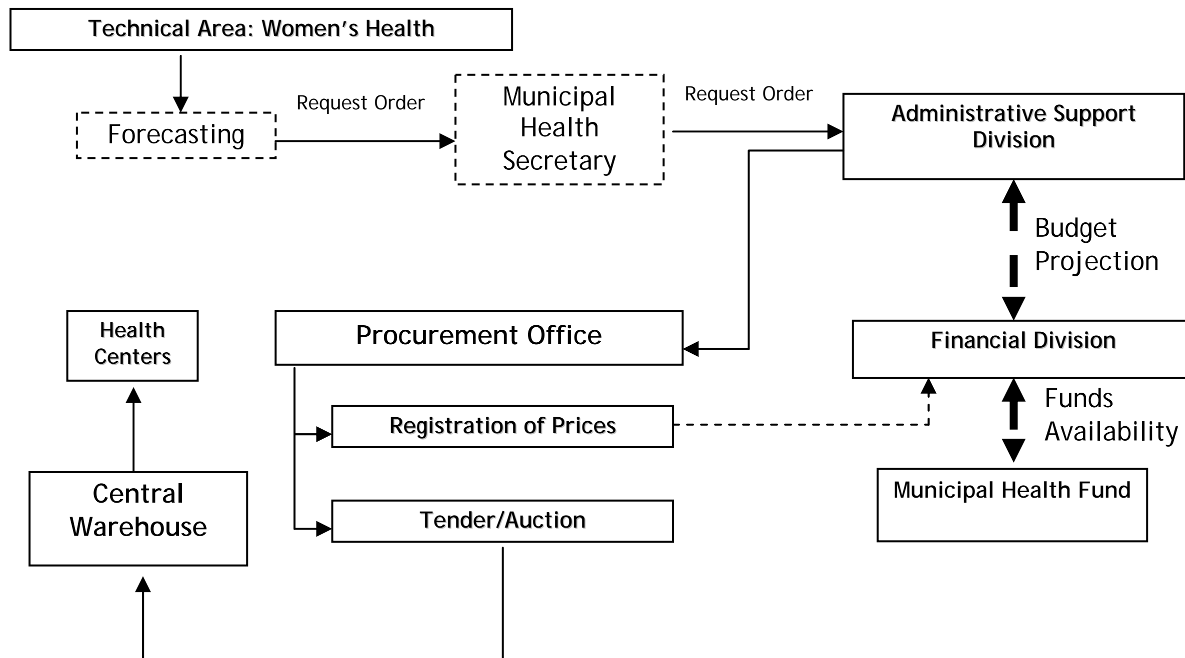
With respect to condom procurement, before 2002, the combination of price and quality— not merely price—was the deciding factor in making an award. Condoms were purchased through a strict process that involved prequalification. Suppliers were considered only after their product had been registered with ANVISA, and evaluated by a quality-assessment committee. Only pre-qualified companies were able to participate in procurements, and quality—rather than price—had the deciding weight in winning the bid.

The NACP's Procurement Office was closed in 2002 as a result of "Operation Vampire," and the responsibility for the procurement of condoms returned to the MOH's General Procurements Office. Condoms automatically became regulated (like any other contraceptive product purchased by the MOH) by Law 8.666—under which the deciding factor for purchase is the lowest price offer. The MOH has since faced several crises that arose because of low quality and inadequate production capacity on the part of manufacturers who were awarded the tenders. Some of the winning companies either did not have the needed production capacity or did not supply products of acceptable quality. Thus, adopting the lowest price criterion negatively affected quality and contributed to an enormous shortage of condoms in 2005.

In retrospect, it seems unfortunate that the NACP did not create a database of reliable suppliers (from the pre-qualified group), because that move could have served as a safeguard for quality assurance once its Procurement Office was closed. Without such a database, any new and unknown firm is allowed to enter into each new condom procurement process, as long as it is registered with the Brazilian authorities (ANVISA). This registration process (as compared to the previous one that required pre-qualification) now simply asks for product samples, leading the companies, unsurprisingly, to use their best ones. There is no follow up on product quality once the bidding is over; hence, it is not possible to prevent companies from sending lower quality products if awarded the tender. Such incidents have been reported since the NACP's Procurement Office was closed.

All information on pricing, bidding, and procurement process details are public, and the tender may be contested by any Brazilian citizen. Law 8.666 forbids: (1) preferences based solely on the domicile of bidders; or (2) differential treatment between Brazilian and foreign firms. However, when all other factors are equal, national suppliers may be selected. In an emergency situation (e.g., a condom shortage), the bidding process can be bypassed, and the product can be obtained through an Emergency Situation Acquisition.

Figure 2.2. Flow of Procurement Process at the Municipal Level (3-month period)



Special Case: Government's Program "Farmácia Popular"[17]

The Oswaldo Cruz Foundation ("Fiocruz") manages and oversees the process of acquiring and distributing medicines and contraceptives offered by the Farmácia Popular. There are 17 official (public sector) laboratories that are exempted from having to enter the auction (in accordance with Law 8.666), and Fiocruz has the option of bypassing the auction if it procures directly from those sources. Medicines produced by private pharmaceutical companies are procured in an auction process organized and implemented by Fiocruz, details of which are published on its website: www.saude.gov.br/farmaciapopular.

All the medicines acquired in the auction process are selected according to the lowest price in combination with the fulfillment of Good Manufacturing Practice requirements. Logistics, warehousing, and distribution for FP products are subcontracted to a firm—Duas Alianças—which oversees the construction and maintenance of pharmacies in municipalities (i.e., their infrastructure and cold chain management).

Farmácia Popular does not have a special focus on providing contraceptives or expanding contraceptive method mix. Its objective is to focus on improving people's access to essential drugs (which now includes

[17] After the conclusion of this report, in December 2005, the *Farmacia Popular* program started a new nation-wide initiative of partnering with commercial drugstores. Today, most Brazilian drugstore chains can also be involved in providing medicines within the *Farmacia Popular* framework.

contraceptives). There are 60 popular pharmacies functioning in the country, 40 of them registered under the Fiocruz umbrella and 20 in partnerships with municipal governments and philanthropic hospitals. The pharmacies are set up like franchises but do not generate their own revenue, and all units receive R$10,000 (approximately U.S.$4800) in financial assistance for maintenance of operations and staff salaries.

NGO SECTOR

With the exception of BEMFAM (see Figure 2.3), the NGO sector does not seem to have solid procedures for forecasting or mechanisms for procuring contraceptives. For many NGOs, product purchases are usually an ad hoc response to a deficiency of the commodities in their stocks. Internal estimates of the amount of contraceptives to be bought are taken to the administrative department, which then enters into contracts with suppliers.

A formal bidding process is rarely held, although NGOs have the ethical principle of looking for the most economical way to purchase goods. Because the number of contraceptives sold or delivered to their clients is very small (generally done as part of a consultation), NGOs do not have the bargaining power to buy at reduced prices. Many NGOS receive their contraceptive supply as donations from the MOH, private companies, or entities such as Fiocruz.

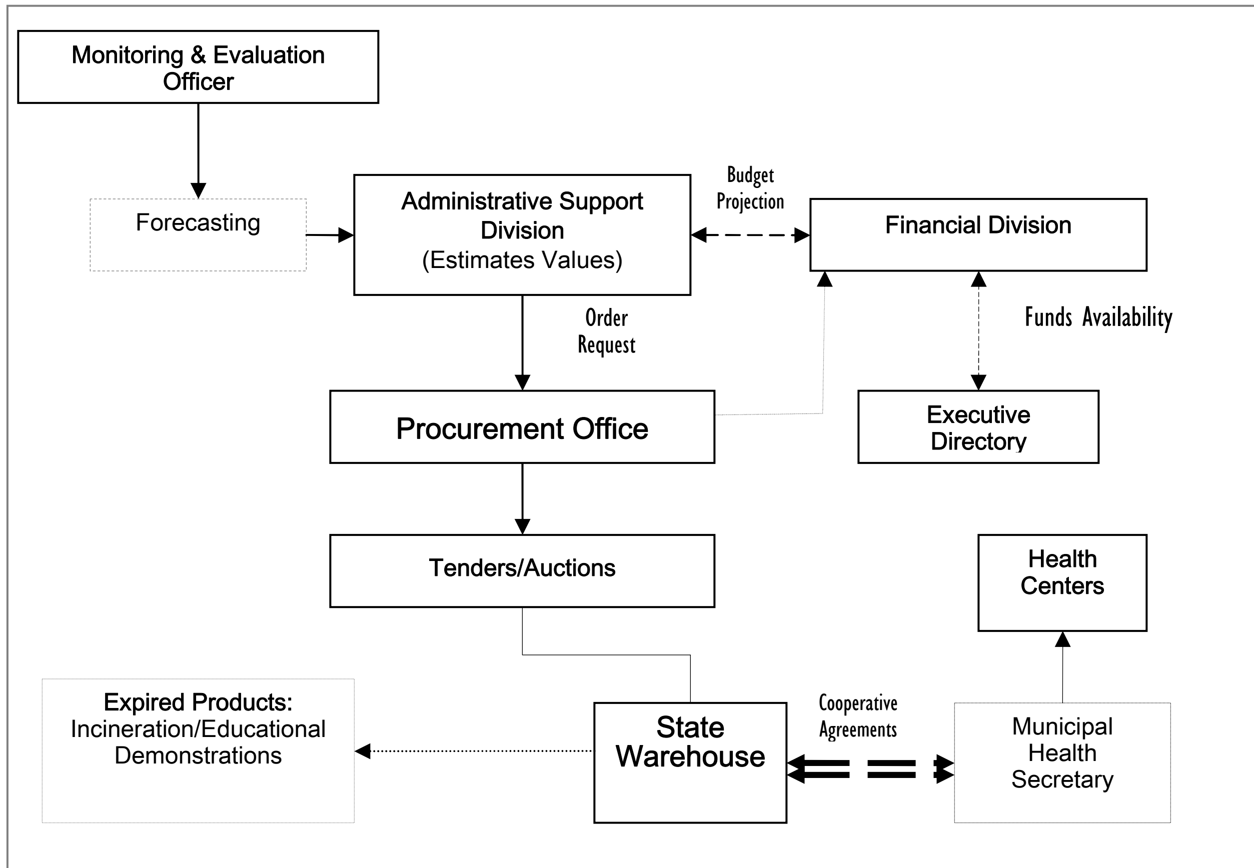
In the case of BEMFAM, because it possesses years of experience with contraceptive procurement, the situation is different. BEMFAM has a solid logistics system and the capacity to forecast its needs using different data sources such as the previous year's consumption rate, demographic indicators, and future expectations. Every year in October, BEMFAM analyses its situation and outlines an estimate of its future needs. These needs are later prioritized in accordance with the organization's financial capabilities.

BEMFAM has a specific department focused on supply chain management and logistics. All its processes comply with good forecasting, acquisitions, logistics, and stock-keeping practices. Its documents in those areas are shared with all the regional agencies in order to guarantee quality logistics at all the institution's service delivery points.

BEMFAM acquisition is not subject to a specific law or regulation, other than its own internal rules. BEMFAM's acquisitions are not formally regulated by the government's procurement law (as it is not a governmental body), but because BEMFAM is heavily involved in providing contraceptives to the government, for practical purposes, they have adopted the government regulations. In other words, BEMFAM is not obligated to adhere to government procurement regulations, but by 'association' or "in practice" they adhere to the government procurement rules. Therefore, all of BEMFAM's procurement processes follow existing rules established for government procurement (Law 8.666). As an NGO, BEMFAM is subject to annual auditing by the Ministry of Justice. Given that BEMFAM operates largely through cooperative agreements with the government and its contraceptives pass on to the government, the organization obeys the governmental procurement regulations in order to avoid any problems with the health departments and secretariats during the yearly audits.

BEMFAM usually invites three suppliers to submit proposals and the lowest price offer is accepted once a year. The contract prices already include transport, so the stock is passed to the states where BEMFAM has a regional office and warehouses. Its logistics system is automated; it tracks stocks to prevent shortages and follows first-in, first-out (FIFO) rules to avoid product expiration. One month before expiration, the product moves within the system from the active to the passive list. Once on the passive list, the product can be used for demonstrations or educational purposes or will be incinerated as per ANVISA procedures.

Figure 2.3. Flow of Procurement Process at BEMFAM



Annex B provides supplementary information on the main regulations governing contraceptive procurement in Brazil.

CONTRACEPTIVE METHOD MIX

The majority of existing modern contraceptive methods are available in Brazil (Table 2.1). Most methods are distributed through formal commercial outlets, with the exception of diaphragms and IUDs, which are sold exclusively at public and private clinics or by NGOs. Hormonal contraceptives are regulated in Brazil as medicines, and reversible or mechanical contraceptives fall under the category of health products at ANVISA.

Table 2.1. Contraceptive Methods Provided by Various Sectors

Method	Commercial Sector	Public Sector	NGO	Social Marketing
Spermicides	X			
Male Condom	X	X	X	X
Female Condom	X	X	X	
Oral Contraceptive	X	X	X	
Emergency Contraceptive	X	X	X	
Patch	X			
Diaphragm			X	X
Vaginal Ring	X			
Implant	X			
Injectable	X	X		
IUD		X	X	

CONTRACEPTIVE METHODS

The variety of contraceptives available is considerable, especially in the case of oral contraceptives and condoms. More than 39 ANVISA-registered brands and types of pills are on the market, as well as more than 27 brands and sub-brands of male condoms. The most prevalent methods used are sterilization and the pill (see Box 4).

Box 4. Use of Contraceptive Methods among Women of Reproductive Age

Sterilization - 40%
Oral - 20%
Traditional - 7%
Barrier Methods - 4%
Vasectomy - 2%
Injectables - 1.5%
IUD - 1.5%
None - 24% (including women who are pregnant or infertile and those who are trying to become pregnant)

(Source: DHS, 1996)

Condoms

Until the latter part of the 1990s, importing condoms was too expensive, and the risk of inadequate product quality was high. Only two brands were available on the market, and both were extremely costly. In 1996, the NACP decided to increase free distribution of condoms with a guarantee of high quality. In the same year, members of the International Commission for Standardization, or ISO began to design condom quality standards and to conduct assessments of governmental procurements by the National STD and AIDS Program (a governmental program that belongs under the Health Surveillance Secretariat, SVS, and the Sexually Transmitted Diseases Coordinating Body).

Brazil intended to adopt the World Health Organization's (WHO) existing guidelines for condom procurement. Brazil started with small purchases (50 million) and was planning to increase to one billion per year. In addition, the MOH announced the National Social Marketing Policy in 2004; however, its implementation has been slow.

In addition to the decrease in the price of condoms (see Box 5), two other developments have had a significant effect on the increase of supply and demand: (1) motel/hotel condom-provision laws, which make the free distribution of condoms in motels mandatory; and (2) permission and incentives[18] to sell

[18] The law allows the sale of condoms in any commercial establishment, without restrictions. No monetary incentives were given directly to commercial establishments that engage in the sale of condoms, but, at times, funding was given to NGOs to help them

condoms in any establishment, provided it meets certain minimum sanitary conditions and safety standards.

Box 5. Condom Prices

The petition to exempt condoms from value-added sales taxes was accepted, and its ratification came in 1997 when the condom tax exemption was granted by all states of the Brazilian federation. This action significantly lowered the price of condoms, even though it did not lower any import taxes or prices of raw materials. It has contributed to increased competition in the condom market, which has resulted in wider variety and lower prices.

The consumer has benefited from more choices in both quality and price. Both supply and demand of condoms in the market have increased, with 425 million condoms sold per year in pharmacies and drugstores (70 percent), supermarkets (25 percent), and other small outlets (5 percent).

Oral Contraceptives

The oral contraceptive market represents 6 percent of the total Brazilian pharmaceutical market, which has reached the 13.5 billion mark for yearly sales of one cycle of pills (prescription medicines only). The market leader in production of oral contraceptives is Schering, with 47 percent of market share of the Brazilian market. Second in size is Organon with 17 percent of market share in oral contraceptive methods. The market has grown notably in the past five years, mainly as a result of constant innovation, but also thanks to some national public policies that influence production companies.

Oral contraceptives are part of the essential drugs list, and it is estimated that the government is responsible for the purchase of approximately 11 percent (in units) of market production. The pill continues to be the prevalent temporary method of choice. Some people believe that the preference for oral contraceptives is reinforced by the strong pharmaceutical industry lobby which influences opinion formers, medical community leaders, and distributors.

Diaphragm

Demand for the diaphragm, despite the advantages the method has to offer, is still insignificant when compared to the pill. The hormonal contraceptive manufacturers' lobby, as well as a serious lack of information on the part of medical practitioners and public health care providers, helps maintain low demand for this method. Semina, the only national diaphragm manufacturer, has been making a serious effort to invest in educational materials and participate in various conferences and meetings that allow it to present its product to the public and call attention to the existence of this barrier method. After a strong advocacy effort, carried out in cooperation with social organizations trying to promote alternatives to hormonal contraceptives, the MOH has agreed to include, once again, the diaphragm in the contraceptive kit packages that are sent to municipalities.

Emergency Contraception

The provision of emergency contraception continues to be an issue of controversy, even though its entry into the reproductive health framework dates back to 1996, when it was first accepted by MOH rule as a family planning method. A strong opposition movement exists, especially from the Catholic Church, which brought charges against the MOH for subsidizing abortive practices by allowing the method to be distributed.[19]

Regional Comparison:
There is a similar controversy in Costa Rica where Congress is currently discussing whether the public sector will provide emergency contraception.

set up systems to sell condoms. Many NGOs, funded by USAID and the MOH, have taken on such activities later defined as condom social marketing strategies—NGOs selling subsidized condoms to commercial establishments or directly to customers.

[19] See Trussel, James and Elizabeth Raymond, 2007 for a detailed explanation of the mechanisms of action associated with emergency contraception. The article states that "ECPs do not interrupt an established pregnancy, defined by medical authorities such as the United States Food and Drug Administration/National Institutes of Health and the American College of Obstetricians and Gynecologists as beginning with implantation. Therefore, ECPs are not abortifacient."

In 1998, the MOH approved the use of emergency contraception in programs providing services to victims of sexual violence. Later that year, the method's commercialization in drugstores was first approved. In 2000, the MOH itself started buying the emergency contraceptive pill to be distributed in programs assisting victims of sexual violence. In 2002, the MOH first procured this method for distribution in the public health care network. Finally, in 2005, the MOH confirmed emergency contraception as part of its national contraceptive policy approach and is now including this commodity in its basic kits distributed nationwide (see Tables 2.2 and 2.3).

Table 2.2. Expenditures for Emergency Contraceptive Pills in Brazil

Commercial Sales and Acquisition by the MOH			
	Reais (in millions)	U.S.$ (in millions)	AYER*
2000	445.0	243	1.831
2001	500.0	210	2.379
2002	593.0	200	2.972
2003	821.8	264	3.113
2004	877.3	300	2.924
2005**	747.3	305	2.450

Source: ANVISA website (www.anvisa.saude.gov.br).
*Average Yearly Exchange Rate; **indicates incomplete year.

Table 2.3. Distribution of Emergency Contraceptive Pills in Brazil

Commercial Sales and Acquisition by the MOH				
Year	**Commercial Outlets ***	**Acquisition by the MOH ****		**Total**
Sept.–Dec. 1999	250,000			
2000	750,000			
2001	1,086,000			
2002	1,493,000	100,000	(sent to 439 municipalities)	1,593,000
2003	1,976,000	120,000	(sent to 2,000 municipalities)	2,096,000
2004	2,329,000			
as of July 2005	2,695,000			

* Source: IMS Health website (**www.imshealth.com.br**) and Aché Laboratory website (**www.ache.com.br**).
* *Source: MOH—Women's Health Program, 2004 and 2005.

Despite visible efforts by the public sector to provide the method, the emergency contraception strategy still shows discrepancies between policy and implementation. Those discrepancies lead to a lack of clear directives to public health care providers. A common problem, for example, has been that distribution of this method requires a medical appointment, which is often not available immediately or soon enough for a method that must be distributed within 72 hours of unprotected sex. This lack of availability creates a difficult situation, given that the method's effectiveness is time-sensitive.

The same constraint applies for the Farmácia Popular network. Emergency contraception is available at a very affordable price; however, it requires a medical prescription from the public health care network, which, in turn, means delays in obtaining medical appointments. The NGO network that offers this method to its clients has a limited reach but, where available, seems to provide more timely assistance.

Private medical care offers adequate service in providing emergency contraception, but is only accessible to those with relatively high incomes.

IUD

There are currently two suppliers of IUDs in Brazil: Injeflex and CEPEO. CEPEO, which was initially supported by USAID, works with imported IUDs from India and the United States. It participates in federal and municipal contraceptive procurements and has been a major supplier of IUDs. Injeflex, a Brazilian factory using Canadian technology, is the only national producer of IUDs in Brazil and throughout Latin America. In Brazil, it is able to compete with imported IUDs because its prices are up to 50 percent lower than the imported brands. About 60 percent of its in-country commercial sales are with the public sector, which represents only about 30 percent of its total production. Injeflex exports the majority (70 percent) of its annual production (3 million units per year). Its production capacity is 8 million units per year.

IUDs, compared to other methods, still have a low prevalence of use (only 1.5 percent). The Brazilian market averages 10,000 per month, and even with a positive growth trend, the market for IUDs is small. Many barriers impede demand for IUDs, including a lack of correct information, a considerable level of misinformation about the method, low availability and too few health care professionals trained to insert the device. The public sector faces similar obstacles, and states and municipalities find it difficult to increase demand and use of IUDs. Doctors seem to prefer prescribing oral contraceptives rather than IUDs, and this reluctance is often caused by their lack of training in proper IUD insertion. Last, but not least, there is a shortage of qualified medical staff in many regions of Brazil, which contributes directly to the low demand for the method, as only authorized medical professionals are permitted to insert IUDs.

ORIGINS

The majority of contraceptives available in Brazil are produced nationally (65 percent). , Almost 85 percent of hormonal contraceptives (orals and injectables) are produced by local industries or multinationals with established facilities in Brazil. Because of heavy import duties, importation of contraceptives is not only expensive, but also more complicated because of strict ANVISA regulations. All health products and medicines must be registered by ANVISA, and the registration requirements include proof of authorization to commercialize the product in the country of origin. The registration of new contraceptives by ANVISA can take from 6 to 12 months.

For details of the contraceptive method mix origins, see Annex C.

QUALITY CONTROL

Every health product to be sold or distributed in Brazil (national or imported) must be registered with ANVISA. The registration requires a quality test based on a sample analysis. Once the product is registered, it is allowed to enter the Brazilian market and to participate in governmental procurements. Compulsory quality control is not the same as quality testing at the time of registration. This quality testing provides an additional control that is required for some products—condoms, for example are subject to a mandatory quality testing. This means that quality control is done batch by batch for all condoms being sold in Brazil (imported or national). Other contraceptive methods don’t need to be tested by batch produced or imported. The registration of health products at ANVISA is a different matter entirely and requires a quality test on all products to be registered.

In addition to the registration (which applies to all products), there are different quality requirements for different goods. For some, the quality certification is mandatory; for others, it is not. Among the contraceptives studied for this report, the only product that is currently subjected to compulsory quality control is the condom, and that process is regulated by the Institute for Measurement, Standardization, and Industrial Quality (INMETRO) Rule 50 and Resolution RDC 03 (08/01/02) from ANVISA (Mercosul Regulation).

The procedures for testing condom quality differ further, depending on the producer's location. Imported brands are all tested by production lot, a requirement that is not applied to locally produced condoms. Although foreign manufacturers' condoms are subjected to control tests in laboratories (sampling from each batch to be commercialized), national manufacturers' products are tested through inspections of the factory premises (which also involve sample collection and testing, but not of every single batch) and through annual evaluation of the facilities.

Initially, INMETRO was responsible for condom quality control processes. However, because it did not have the capacity to meet the high level of demand, the Product Approval Body (OCP), established in 1992, started to handle the quality control procedures in 1995. OCP's unique role is to analyze laboratory results and to issue a stamp of approval for the product. This simple procedure has a direct effect on increasing the price of condoms, because it translates into additional bureaucratic expenses that must be covered by the importer or manufacturer and the consumer.

Brazil has yet to draft quality regulations for the non-latex diaphragm produced by SEMINA. The Brazilian Association for Technical Norms (ABNT) is working on the ISO 4047/WG16 to be presented to the INMETRO for adoption.

IUDs are currently subject to the Ministry Rule No. 6, dated 1984—a somewhat outdated regulation that does not take product development and modernization into account. ABNT is also working on ISO 7439/WG with the aim of presenting it to INMETRO for adoption.

GOVERNMENT INVESTMENT IN FAMILY PLANNING SINCE 2000

Overall amounts invested in procuring contraceptives over the past five years, indicate that the Brazilian government is aware of growing demand and is trying to increase its involvement in this area. However, adjustment needs—including more efficient logistics systems and improved capacity of municipal governments to forecast and procure contraceptives—that arose from changes in procurement mechanisms (centralized to decentralized and back to centralized) have yet to be fully addressed. The inconsistencies and irregularities in procurement processes have had an evident effect on the quantities of contraceptives purchased by the government (Table 2.4).

Table 2.4. Federal Government Contraceptive Distribution (in units/packaging specification)

Year	Dispatch	Nº of Municipalities Covered	IUD (units)	Injectable (ampoules)	Emergency Pill (blister packs)	Pill (blister packs)	Diaphragm (units)	Condoms (units)
2001	2001/01	4,200	158,300	582,300	0	6,210,600	30,000	43,000,000
2001	Total Federal Investment: US$3,692.950.00							

Year	Dispatch	Nº of Municipalities Covered	IUD	Injectable	Emergency Pill	Pill	Mini-Pill	Condoms
2002	2002/01	4,568	166,920	500,760	100,000	27,126,000	1,808,400	130,204,800
2002	Total Federal Investment: US$10,851,686.00							

Year	Dispatch	Nº of Municipalities Covered	IUD	Injectable	Emergency Pill	Pill	Mini-Pill	Condoms
2003	2003/01	4,920	87,120	261,360	120,000	12,000,000	800,000	57,600,000
2003	Total Federal Investment: US$5,017,327.30							

Year	Dispatch	Nº of Municipalities Covered	IUD	Injectable	Emergency Pill	Pill	Mini-Pill	Condoms
2005	2005/01	1,388		439,000	352,300	3,400,000	750,000	
2005	2005/02	3,844				7,500,000	750,000	62,000,000
2005	2005/03							
2005	2005/04							
2005		5,232	0	439,000	352,300	10,900,000	1,500,000	62,000,000
2005	Total Federal Investment: US$5,917,917.10							

This table is a compilation of data from various sources done by the authors of the report. Main website consulted was www.**comprasnet**.gov.br

PRICING ANALYSIS

PRIVATE SECTOR

Most notable, within the private sector, is the huge diversity of prices. The variation is present not only among companies and brands, but also within the product category of a single manufacturer. For example, Schering sells the oral contraceptive Miclovlar for R$4.50 (U.S.$2.20) and Mirelle for R$22.50 (U.S.$10.98). INAL, a local condom manufacturer, sells one condom brand at R$1.90 (U.S.$0.93) and another at R$1.20 (U.S.$0.59). Disparity in prices also exists among drugstore chains that sell the same product—from the same manufacturer—at considerably different prices. In addition, costs vary for the same products offered across different cities and states.

Taxes and, in the case of imported products, high importation duties, are the primary factors influencing price. All contraceptives (with the exception of condoms, which are exempt from value-added taxes (ICMS), are taxed the same as any other commercial product by a series of duties and taxes: 18 percent on ICMS; 8 percent on industrial product taxes (Imposto Sobre Produtos Industrializados, or IPI), social

contribution tax (Programa de Integração Social, or PIS), and social security financing tax (Contribuição para o Financiamento da Seguridade Social, or COFINS); and approximately 5.93 percent income tax on organizations and businesses (Imposto de Renda de Pessoa Juridica , or IRPJ).

All hormonal contraceptive prices are regulated by the Chamber for Regulating the Pharmaceutical Market (Câmara de Regulação do Mercado de Medicamentos, or CMED) and ANVISA, which establish annual price ceilings for all medicines for both the manufacturer and the vendor: the maximum manufacturer price and the maximum consumer price. Those limits vary among states as a result of different taxation policies. ANVISA allows and adjusts the ceilings according to the percentage of the sales tax, which can vary from 11 to 18 percent. It appears that certain big pharmacy chains are able to buy their product in states with a lower sales tax and distribute at that price throughout the chain, which gives them a more competitive price. Further, the retail price of a product (which already includes the pharmacy markup that can be up to 40 percent) was, in some cases, lower than the price listed as the maximum for the manufacturer. In other words, in some cases commercial pharmacies—the large chains, for example, that are present in several states—are able to buy products in states where the taxation is different (lower e.g.11%) from those states where they will sell the product. Then when they come with the product to a state with a higher tax (e.g.18%), their price listing for the product to consumer (which already includes the pharmacy markup) can still be even lower than that of the official price ceiling to the manufacturer in that state.

Price structure in pharmacies and drugstores is usually established by adding a 30 to 40 percent markup to the price the vendor paid. Given the variety of retail prices for the same product within drugstore chains, it is safe to assume that different chains are able to negotiate the purchase of the same product from the same manufacturer at different prices. The average difference between the manufacturer and the consumer price ceiling is about 38 percent. Using the ceiling price as the regular list price for the product in their catalog allows drugstores and pharmacies to create attractive offers and discounts to their clients. In the case of contraceptives, the “discount” is generally about 10 percent; with generic drugs, it can be as much as 30 percent below the list price.

The commercial sector tends to have better logistics than the public sector. There are about 60,000 independent drugstores in Brazil, and transportation costs are high (given the size of the country). Pharmaceutical distributors work with a margin of 25 to 30 percent, which includes warehousing, transportation, and other detailed services for distributing products to a large number of outlets. Some major manufacturers and companies have their own transport and logistics system, but if suppliers are to handle such a large number of pharmacies in a country the size of Brazil, it is more common—and more economical—to subcontract or outsource logistics services. Logistics and transport costs are equivalent to almost 10 percent of the manufacturer’s or importer’s invoice.

Imported products are subject to the following taxation: 8 percent IPI, 18 percent ICMS, 14 percent importation taxes, and 9.25 percent PIS and COFINS. In the case of condoms, the product is exempt from ICMS and IPI, and the importation tax is 12.5 percent, which has a significant effect on the price and allows imported brands to compete with national ones.

PUBLIC SECTOR

Price Regulations

All the drugs considered essential are subject to government price regulations. ANVISA maintains a list of prices for all medicines available on the market, which provides a reference for the maximum allowed prices (ceilings) from the manufacturer to the end consumer. In addition, the policy also defines reference prices for the acquisition of medicines found on the lists of products purchased and distributed to the public through SUS.

Procurement Pricing

Most manufacturers and importers operate with two different sets of prices: one for government and the other for commercial partners. The public sector's high-volume purchases allow it to benefit from economies of scale. A comparison of the public and commercial list prices suggests that high-volume purchases enable the government to negotiate directly with manufacturers or their specific public sector sales representatives and to buy at the price level corresponding to the maximum manufacturer price or less.

In terms of price, the public sector has other advantages because of its ability to create special circumstances or exceptions for its purchases that are protected by law. The law allows the government to buy medications (including contraceptives) under very specific conditions (that is, directly from producers) only to supply the Farmácia Popular program. By skipping "the middle man," this process significantly reduces the cost of the medicines, and the products are offered for sale in the public sector at the most competitive price on the market.

Federal and municipal procurement officials also negotiate prices (for procurement contracts) with national manufacturers so that the contracts include all transportation costs and delivery to the central or municipal warehouse.

When procurement involves imported medical products, suppliers enter with offers at the base price (the cost of the commodity plus freight charge, or CIF, which means cost, insurance, and freight) or warehouse prices. If their bid is successful, the cost of importation procedures and taxes is covered by the MOH, which, in such cases, assumes the responsibilities of the importer.

For pricing data in the private and public sectors, including information on CIF prices, markups, logistics costs, and final consumer prices on contraceptives, see Annex C.

OBSERVATIONS AND CONCLUSIONS

In spite of major limitations, since USAID phased out its activities five years ago, the government of Brazil has made serious efforts to take on responsibility for family planning and for providing contraceptives. While there certainly have been considerable advances in national policies pertaining to sexual and reproductive rights and to women's health and family planning, implementation and integration of these policies into health care services has not been satisfactory. The reproductive health legal framework still needs fine-tuning, and the logistics system for distribution of contraceptives is far from adequate.

Delivering health care through a large structure such as the Unified Health System (*Sistema Único de Saúde*, or SUS) is a challenging task that involves not only coordinating administratively and financially at different structural levels, but also maintaining standards of quality in health service delivery.

Decentralization and "municipalization" of health services may have formally given more power to municipal governments; however, the resources, financial autonomy, and capacity building that should go along with such a transfer of responsibilities have not been proportional. The use of federal resources for procurement by the lower levels is controlled by a series of criteria agreed upon by the Tripartite and Bipartite Management Commissions. Medication selection is restricted to pre-approved lists, which limits the municipalities' decision-making autonomy. Finally, not all municipalities have the needed infrastructure and capacity to take on their new responsibilities in providing and managing health care and contraceptive procurement.

Frequent changes in the contraceptive acquisition system can be destabilizing. Also, it is unrealistic to set a goal to meet 100 percent of the demand when no logistics system is in place to ensure the goal can be met. Currently, the government does not have the capacity to deliver on its promise, and there are delays in both the purchase and distribution of contraceptives. A substantial effort to address the serious deficiencies in the logistics and delivery of contraceptives seems overdue and should be made a priority.

In terms of method mix, there is widespread awareness of the existence of a variety of methods. However, general availability of the entire mix in the public sector is less ample. In the commercial sector, a broad method mix is found. Nonetheless, access continues to be limited by the user's income. Finally, despite the relative increase in use of other methods in recent years, the most prevalent methods continue to be oral contraceptives and female sterilization. Many factors contribute to the status quo. Beyond income constraints, limitations include the poor technical capacity of health care professionals, the lack of proper information and education about different methods at both the client and service provision level, and a gravely inadequate logistics system. All of these shortcomings prevent women, especially those residing in the underserved urban and remote rural areas of the country, from being able to exercise their right of method choice and family planning as guaranteed by the Brazilian Constitution.

With regard to information, education, and communication, only a few specifically targeted campaigns exist, and most strategies seem to address only family planning. With growing fertility rates among adolescents, few communication strategies provide correct and complete information about contraceptive use and methods to reach adolescents and young people who are not yet married or in stable relationships.

Price variations of commercial sector contraceptives are considerable and persistent, despite the government's effort to regulate the cost of essential drugs (which now includes all hormonal

contraceptives). With the exception of condoms, which benefit from tax exemptions that significantly reduce their cost and that increase both supply and demand, and hormonal contraceptives (orals and injectables) provided by the Farmácia Popular, which benefit from a special regulation that allows them to be bought and sold at production prices, there have been few tangible incentives to increase contraceptive availability, improve access, or stimulate demand.

Some regulations, such as those concerning product quality assurance, need revisions to become more effective. The registration process at ANVISA, for example, is based merely on the assessment of a random product sample. The problem is that although the submitted sample may meet the quality requirements, it does not truly attest to the quality of the products that will later be supplied in the bid. There is a serious risk of compromising the quality of the products in the government supply if the procurement process continues to be based on the premise that all products are equal in quality simply because they all have been registered by ANVISA.

With regard to distribution policies, the centralized procurement strategy set up criteria for municipalities to become eligible to receive centrally procured contraceptives. This policy, however, does not specify any strategy for meeting the needs of women of reproductive age who live in municipalities but do not qualify to receive government-purchased contraceptives or who, for any other reason, were unable to receive them. In Ceará, for example, close to 30 percent of municipalities did not receive any contraceptives from the federal government in 2005.

There is a history of inconsistencies in the public sector's behavior that has, to some degree, affected its reputation and inconvenienced the people who depend on it for contraceptive supplies. The level of federal investment in procurement of contraceptives has not steadily increased in response to growing market needs and new policies on reproductive rights. Instead, funding has reflected political situations and constraints (i.e., elections and corruption scandals).

Because the government has a spotty record in procurement planning and timely payments, the manufacturing sector tends to prioritize investment and production planning according to the needs of the private or commercial sector and to respond to federal government demands in a reactive manner. Public procurement processes have often been a source of discouragement for manufacturers because irregularities make it difficult for them to conduct proper systematic production planning. Given the unpredictability of the government's demands, companies regularly initiate informal discussions with the government to assess the potential interest of the government in their products. These communications take place despite the fact that, for purposes of transparency, formal relationships between potential suppliers and government employees are restricted.

In conclusion, there is no doubt about the seriousness of the government's intentions to meet the contraceptive needs of the population, but real progress has been sluggish, demand remains unmet, and considerable differences still exist among social classes with regards to reproductive health services. Pharmacies are still the main outlet for the purchase of contraceptives, but access to pharmacies is often limited, especially for women in remote (rural) regions and poor (urban) areas and for young people.

Naturally, given socioeconomic realities, it would be unrealistic to expect that the government would, within just a few years, manage to meet the contraceptive needs of the entire population. Nevertheless, with a more consistent approach, better policy implementation and coordination, adequate needs assessments, realistic forecasts, and a focus on logistics, more substantial progress could have already been made, especially in relation to lowering prices and increasing availability and access to a range of contraceptive methods.

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www.comprasnet.gov.br

www.anvisa.gov.br

www.semina.com.br

www.consultaremedios.com.br

www.planejamento.gov.br

www.saude.gov.br

www.planalto.gov.br (fonte de legislações - consolidação de toda a legislação vigente no Brasil)

www.dicas.com.br

Farmácia Popular
www.saude.gov.br/farmaciapopular/

Ministry of Health website
http://portal.saude.gov.br/saude/

Ministry of Planning website
http://www.smp.org.br/atualizacao/view.php?id=1168

WHO World Health Report
http://www.who.int/whr/2005/annex/indicators_country_a-f.pdf

UN Human Development Report 2005
http://hdr.undp.org/reports/global/2005/pdf/HDR05_HDI.pdf

Sistema Único de Saúde
http://www.sespa.pa.gov.br/Sus/Sus/sus_oquee.htm
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ANNEXES

ANNEX A: FAMILY-PLANNING TIMELINE

ANNEX B: SYNOPSIS OF RELEVANT LEGISLATION

ANNEX C: LIST OF INTERVIEWED KEY INFORMANTS

ANNEX A

FAMILY-PLANNING TIMELINE

Family Planning in Brazil (1960–2005)
TIMELINE

1960s

1962 – The Pill becomes available for commercial sale in Brazil.

- Two years after its approval by the United States Food and Drug Administration, a hormonal contraceptive (pill)—ENOVID—is produced by Searle laboratories.

1965 – International Planned Parenthood Federation (IPPF) begins financing the *Sociedade Civil Bem-Estar Familiar no Brasil* (BEMFAM).[14]

- During the 1960s, an increasing number of private entities (sponsored by international agencies aiming to reduce population growth) initiate activities in Brazil to help people plan ans space births so that each child could be a wanted child. Public sector involvement in family planning remains negligible. Discussions about concepts and differences between human sexuality and reproduction intensify within academic circles.

1970s

1973 – United Nations Population Fund (UNFPA) initiates its activities in Brazil.

- Prior to 1992, UNFPA invested a total of approximately U.S.$20 million in various individual projects. A majority of the funds (about 85 percent) were allocated to support MOH's Maternal and Child Health Program, and some went to training health professionals in contraceptive procurement. The MOH's Maternal and Child Health Program was created in the mid-1970s, when family planning was considered only within the context of "responsible parenthood."

1973 – National Institute of Measurement, Standardization, and Industrial Quality (INMETRO) is created out of the National Weights and Measurements Institute (of 1971).

- INMETRO is a federal agency responsible for technical quality and measurements. Currently, INMETRO, together with the Department of Sanitation Monitoring (Secretaria de Vigilancia Sanitara, or SVS), sets up test standards for male condoms.

1975 – Research Center for Integrated Maternal and Child Health Care (CPAIMC) is founded.

- CPAIMC is financed primarily by the U.S. Agency for International Development (USAID) and a USAID-sponsored network of organizations (Pathfinder, Family Health International (FHI), etc.).

1977 – Social Development Council approves Program to Prevent High-Risk Pregnancy (PPGAR)

- This program met with opposition from various social movements who perceived it to be discriminatory. The high-risk identification criteria the program adopted seemed to them to be directed primarily at curbing population growth among poor, black, and other groups considered "dispensable."[20] Within the scope of the program, oral hormonal contraceptives were distributed for the first time.

1979 – Public communications and advertising about contraceptives are legalized and their distribution is authorized.

1980s

1981 – Brazilian Association of Family Planning Institutions (*Associação Brasileira de Entidades de Planejamento Familiar,* or ABEPF) is established.

1983 – MOH develops the Women's Integrated Health Care Program (PAISM).

- This program was developed in collaboration with representatives of feminist groups, state managers and academic researchers. PAISM brought women's health into the focus of public policies and emphasized

[20] [Ana Maria Costa. *"Planejamento Familiar no Brasil."* Revista Bioética, Simpósio: Política Demográfica, 4:2 (1996)].

integrated and equitable services, proposing a comprehensive care approach to women's health over the entire life cycle, not just during pregnancy. It proposed considering women's overall health needs, including conception and contraception. An MOH assessment carried out in 1989, however, revealed that—with the exception of São Paulo where it was introduced relatively effectively—the program was not properly implemented and it declined over time.

Mid-1980s – International entities and NGOs working in family planning start planning their phase-out activities.

1985 – MOH begins distributing contraceptive methods to states.

- These initial methods were donated by the United Nations as part of the cooperation agreement with UNFPA. The distribution, however, was not consistent or sustained.
- Guidelines for the National AIDS Control Program are established (MOH Ruling no. 236 of May 2, 1985).

1988 – New Brazilian Constitution is adopted.

- The Title VII, Chapter VII, Art. 226, § 7º of the Constitution charges state governments with responsibility for family planning: "Based on the principles of human dignity and responsible parenthood, family planning is to be a free decision of the couple, and it is the responsibility of the State to provide resources for exercising this right; simultaneously, any form of coercion by official or private institutions is prohibited."

1990s

1990 – Federal government establishes the Unified Health System (SUS, or *Sistema Único de Saúde*)

- The federal Constitution by its Laws no. 8.080/1990 (*Lei Orgânica da Saúde*) and no. 8.142/1990 establishes a Unified Health System (SUS). With the intention of resolving the problem of inequality in access to health care, it obligates all service delivery points within the system to provide basic health care to any citizen free of charge.
- Federal Center for Drug Purchases (*Central de Medicamentos,* or CEME) begins acquisition of oral hormonal contraceptives.

1993 – IUD and diaphragm are included among the method mix offered by the public sector.

- **MOH Orders no. 115 and 118, respectively, include these methods on the list of contraceptives provided by SUS.**

1996 –- On January 12, Law no. 9.263 is adopted.

- Article 2 of this law, regulating family planning (FP) in Brazil, establishes FP as a combination of activities of fertility control and guarantees equal constitutional rights of decisions about having or not having offspring to a woman, a man, or a couple.

1997 – MOH suspends acquisition of contraceptives.

- Acquisition is suspended following a decision to decentralize federal resources to states and municipalities to provide for basic pharmaceutical care. As a consequence, only a few states and municipalities included contraceptives on their essential drugs procurement list. Research carried out in 1992 by M. Costa[21] confirmed that family planning services offered met less than 10 percent of the people's needs in about 45 percent of municipal and 50 percent of state health departments.

1997 – Female sterilization is approved as a procedure to be offered in public hospitals.

- Female sterilization was approved in August 1997, (previously it was illegal), though the cost was not covered by the national health system (see new legislation).

1992–1997 – UNFPA program invests US$12 million.

- Objectives of the program were reducing morbidity and maternal and child mortality rates, strengthening reproductive health services, reducing unwanted pregnancies, strengthening the technical capacity of the government to carry out demographic analysis, and improving the legal and social status of women.

1999 – National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária,* or ANVISA) is established by Law no. 9.782 of January 26.

- ANVISA is an administratively and financially autonomous regulatory agency managed by a five-member board of directors. MOH, through its Department of Sanitation Control Monitoring (SVS), is responsible for controlling condom quality. ANVISA cooperates with SVS to set up norms for product registration, commercialization, and production monitoring. Products wanted by MOH are given priority registration. Registration decisions are made by a commission of 10 scientists, chaired by the president of the Brazilian Medical Surveillance Society, who are leaders of the medical and pharmaceutical community. The state-level counterparts are responsible for implementing production standards. The states themselves can also set up norms that are stricter than those established at the federal level.

[21]Costa, Ana Maria, *ibidem*

1998–2001 – UNFPA Cooperation Program in Brazil.

- This program was developed in cooperation with the government and in accordance with population policies defined by the National Commission for Population and Development (CNPD).

2000–2005

2000 – USAID phases out FP financing in Brazil.

– MOH re-adopts a contraceptive procurement strategy.

- Starting in 2000, the MOH decides to return to the strategy of procuring contraceptives at the federal government level and distributing them to the state health departments. This decision was taken with the intention of meeting 30 percent of potential demand for these methods within the SUS during the first year (2000), 60 percent in the second (2001), and 100 percent of the potential demand in 2002. During the two-year period (2000–01), state and municipal departments in state capitals received 6,210,600 cycles of oral hormonal contraceptives (combination pill), 582,300 ampules of trimestral injectables, 158,300 IUDs (TCu 380 A), and 30,000 diaphragms.[22]

– MOH offers an initiative to incorporate emergency contraception ("morning after pill") into the method mix.

- With the intention of increasing the use of reversible methods offered within the SUS system (and to reduce female sterilization rates), an incentives program (bidding, procurement, and distribution) of reversible methods within SUS has also been initiated.
- The MOH begins acquisition of emergency contraception and supplies it to programs assisting victims of violence.

– Supplementary Healthcare Agency (*Agência Nacional de Saúde Suplementar,* or ANS) is created.

- ANS's objective (created by Law no. 9.961 on January 28, 2000) is to "promote and defend public health interest in supplementary health care by regulating the operations of the sector and improving relations between service providers and consumers, in order to contribute to development of health care activities in the country." ANS's principal function is to oversee and regulate matters related to private health care providers, as well as to evaluate their services and relationship with citizens using those services.

2001 – Evaluation of MOH's contraceptives distribution strategy is undertaken and contraceptive distribution is interrupted.

- A 10-state sample is chosen for conducting an evaluation of the MOH's contraceptive distribution strategy (started in 2000) and its family-planning program. The results point out considerable problems in a majority of the assessed states: deficiencies in logistics (storage and distribution, especially between states and municipalities), as well as lack of state health coordinators' technical capacity to provide adequate reproductive health services in municipalities. As a consequence, the MOH contraceptives distribution strategy is brought to a stop.

– MOH adopts a condom distribution strategy

- A condom procurement and distribution strategy is adopted by MOH, which is also charged with the responsibility for the National STD/AIDS Coordination Program and its implementation.

– MOH institutes a new health agenda.

- The MOH in its decree (GM/MS no. 393 of March 29, 2001) instituted a new health agenda to address the need for reform and institutional improvements in managing the Health Care System, or SUS. In addition to improving health service delivery, the agenda dealt with decentralization and improving management.

– Tripartite Management Commission sets out a new strategy to improve the supply of reversible contraceptive methods within SUS.

- The Tripartite Management Commission (CIT), comprising representatives of state and municipal health departments and the federal government, defines a strategy to increase the supply of reversible contraceptive methods. Under this strategy, the MOH would procure contraceptives for SUS, and decentralize their distribution (every three months) to the municipalities if they fulfill the following conditions: (1) have at least one trained team within the family health program, (2) are approved to participate in the Program to Improve Prenatal Care and Delivery (PHPN), or (3) have at least one functioning team from the *Programa de Interiorização do Trabalho em Saúde* (PITS).[23]

  Under the strategy, contraceptives are dispatched as different kinds of kits: basic kit (contains low-dose combination pill, progestin-only pill, and condom); supplementary kit (contains IUDs and injectable methods). The supplementary kits are sent only to municipalities with a population at or above 50,000 or to those that have medical professionals qualified to perform IUD insertions.

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[22] Ministério da Saúde. "Direitos sexuais e direitos reprodutivos—Uma prioridade do governo, Cartilha." *Série A. Normas e Manuais Técnicos.* Série Direitos Sexuais e Direitos Reprodutivos - Caderno no. 01. Brasília/DF, Brasil: Ministério da Saúde, 2005

[23] Program with objective of decentralizing certain health services to in-state and interior country SDPs.

2002 – FP kits are dispatched to the municipalities.

- In 2002, two series of shipments distributed 40,000 basic kits to 4,568 municipalities and 2,659 supplementary kits to 433 municipalities. In addition, the MOH—for the first time—distributed emergency contraceptives (morning-after pill) to about 439 municipalities, and 59 service delivery points (SDPs) in order to assist women who were victims of sexual violence.[24]
- In 2003, two series of shipment distributed a total of 45,210 basic kits to 4,920 municipalities and 2,782 supplementary kits to 474 municipalities.[25] The MOH also sent all of them updated technical manuals for managing and providing family planning services, including information about how to use emergency contraception methods. MOH also organized capacity-building activities, for medical and basic health care professionals, focused on reproductive health and sexual and reproductive rights, as well as on dual protection (integrating FP and STD/AIDS prevention) and sexual violence issues.

2004 – *Farmácia Popular do Brasil,* or People's Pharmacy, is created.

- "People's Pharmacy" is a governmental program created to improve people's access to basic medications. Oswaldo Cruz (Fiocruz) Foundation, the MOH partner and the body charged with program operations, is authorized to acquire certain drugs directly from public or private pharmaceutical laboratories and to make them available to the public (with a medical prescription), within the *Farmácia Popular* chains at production prices. The medical supplies include selected contraceptive methods.

– MOH institutes national policy guidelines on health care provision specific to women's health needs (2004–07).

- Through its Women's Health Focused Programmatic Area (*Área Técnica de Saúde da Mulher,* or ATSM), MOH established national policy guidelines (2004–07 Action Plan) to provide complex health care services and improve Brazilian women's health and life conditions: that is, to guarantee their legal rights and increase their access to such services as promotion, prevention, health care, and health recovery throughout Brazil. Activities for implementing this plan include: investment in various strategies, including research, publicity, and education to fill the knowledge gap and increase the women's and adolescents' understanding of their rights; and to meet their health needs in an adequate and dignified manner.

2005 – Government launches guidelines on sexual and reproductive rights

- The Government announced that improving these rights would be its priority for 2005–07. According to the guidelines, the MOH will take on the primary responsibility for using government funds to procure and distribute contraceptives and improve the contraceptive method mix available nationally in order to increase access to family planning services. Today, the MOH assumes 40 percent of the contraceptive procurement costs, with the rest to be covered by states and municipalities.

  Two types of kits will be available. This year injectables should be added to the method mix. The basic kit to be offered to the Family Health Programs will contain condoms, morning-after pills, and the progestin-only (mini-pill), as well as combination pills. The supplementary kits will contain IUDs, diaphragms, and injectables. According to the MOH[26] the procurement has already started. R$39.1 million (U.S.$19.1 million) has been allocated in the 2005 budget for this purpose.

– Government expands public acquisition of emergency contraception.

- Government decides to increase the supply of emergency contraception to the basic health care networks of all municipalities, attempting to meet the demand through centralized procurement and distribution.

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[24] Ministério da Saúde, *ibidem*.
[25] Ministério da Saúde, *ibidem*
[26] Ministério da Saúde, *ibidem*

ANNEX B

SYNOPSIS OF RELEVANT LEGISLATION

Regulation Reference	Date of Publication at DOU*	Object of Regulation	General Observations
Federal Constitution of 1988: Article 226, Paragraph 7	October 5, 1988	Family planning	Chapter VII of the Federal Constitution discusses the family, children, adolescents, and the elderly. Article 226 establishes the family as the base of society and assures the family will have special protection from the state. Paragraph 7, states: "Founded on the principles of human dignity and responsible parenthood, family planning is a free will of the couple, and the State will provide scientific and educational resources to enable couples to exercise this right. Any kind coercion by official or private institutions is forbidden." Common Law 9.263/1996 regulates this paragraph and stresses the free will of the couple regarding family planning, as well as the responsibility of the state to provide all needed services.
Law 6.426/1989	July 21, 1989	Obligatory condom distribution in motels	It obligates motels and similar establishments to provide, free of charge, male condoms to its clients. In addition to providing free condoms, the motels must also distribute leaflets or some other kind of IEC (information and education) materials from municipal health authorities, regarding sexually transmitted diseases. It also requires the local authorities to provide further regulations.
MOH Rule MEFP[27] no. 106: Plan Color I	April 16, 1990 February 1991	Price regulations (medicines)	Interministerial Price Control Council oversaw "freezing" of prices of medicines (and imposed some other price ceilings in the economy) in an attempt to control inflation.

* *Diário Oficial da União* – Official Government Daily (government bulletin)
[27] Ministry of Economy, Agriculture and Planning

Plan Color II			In August 1990, the price ceilings began to be liberated, and by October 1990, all medicines became subject to the price control. Because this period brought about a new inflationary wave, it ended in a new price regulation ("freezing of prices") in February 1991—Plan Color II.
Law 8.142/1990	September 19, 1990	Transfer of resources from the federal government	The law governs the transfer of resources from the federal government but does not seem to specify responsibilities related to the different agencies and levels of government.
MOH Rule MEFP no. 418 MOH Rule MEFP 37	May 29, 1991	Liberation of the pharmaceuticals from government price control	This rule started the period of liberation of prices. Chambers for different sectors of the economy were instituted, including the Pharmaceutical Industry Chamber, which at its first meeting discussed new price re-adjustments and approved a flat 8 percent increase for all medical products. A gradual liberation of prices of selected medicines followed (through a series of ministry rulings such as no. 430, 594, and 156…).
Law no. 8.666/1993	June 6, 1993	Rules of public procurements and public administration contracts	The law regulates article 37, item XXI, of the federal Constitution and creates rules for public procurement and contracts for public administration. This law denotes all rulings regarding public procurement of goods and services. It sets all the standards and procedures for purchasing and hiring services, as well as establishing penalties for those who break the law. The standards include price limits for each and every kind of purchase. This law also regulates all modalities of procurement, including: 1. Public competition, 2. Price gathering (bidding different from auctioning), 3. Invitation, 4. Public selection, and 5. Auctioning. (Please see end of Annex B for further details on this particular legislation.)
MOH Rule no. 115/1993 and MOH Rule no. 118/1993	September 9, 1993	**IUDS AND DIAPHRAGM**	IUDs and diaphragms are included on the list of contraceptive methods offered by the SUS.
Law 9.263/1996	January 15, 1996	Family planning	The law regulates paragraph 7 of the federal Constitution's article 226 that discusses family planning, sets penalties, and provides guidelines for other rulings on the matter. According to this law, family planning includes all actions of fertility regulation that ensure equal rights under the constitution of the woman, man or couple to limit or increase their family size. The law forbids the use of these fertility regulations for the purpose of demographic control.

			It ensures services related to conception, contraception, prenatal care, delivery, (all situations), STDs (sexually transmitted diseases), and all related cancer care. The Central Unified Health Care System (SUS) will manage all family planning actions and directions. Prevention and education actions can be provided by public or private institutions, as well as NGOs. The law also permits the participation of foreign companies and capital, under the supervision of the SUS. The law also defines all crimes and penalties for any actions that contravene this legislation.
Basic Norms of Operation (NOB) 1996	1996	Basic norms of operation of SUS	Implementation of the Basic Norms of Operations consolidates the "municipalization" process of health service delivery in the country. The reorganization and decentralization of SUS management to the municipal level includes basic health care provision, with a focus on women's health needs and corresponding guidelines for their provision.
Technical Norm, MOH	1996	Emergency contraception	MOH issues a technical note that regulates the use of emergency contraception in the oral form (pill) within the family planning framework.
ICMS[28] Agreement 87	October 6, 1997	Tax exemption agreement on commercializing male condoms	In regard to the complementary Law 24/1975, this agreement authorizes state administrations to exempt operations related to commercializing condom sales from ICMS taxes. This agreement is signed between the Ministry of Economy and all state economy secretaries, and exempts all condom commercial operations from ICMS taxation, in order to lower prices and make the product more accessible to more people.
MOH Rule no. 144	November 20, 1997	Approval of male and female sterilization in public hospitals	Vasectomy and female sterilization are approved and included among the procedures provided by SUS. Previously (see new legislation), sterilization within the public health network was considered illegal, and the procedure's cost would not be covered by the national health system.
Ministry MOH Ruling GM/MS no. 3916	October 1998	Definition of national medication and drug policies	This ruling sets all guidelines for the medicines and drugs to be used in Brazil. The regulation's purpose is to "guarantee the necessary safety, effectiveness and quality of the products; to promote their rational use and improve people's access to the essential drugs." The guidelines deal with the pharmaceutical industry's activities, matters relevant to establishing essential drugs lists, stimulating the production of medicines and sanitation regulations. This ministry ruling sets all guidelines for the medicines and drugs to be used by the Brazil's medical system.

[28] ICMS is an abbreviation for the value-added tax on the circulation of goods and services.

Technical Note, MOH	1998	Commercialization of emergency contraception	This MOH technical note makes emergency contraception available to programs providing services to victims of violence. As of this year, the National Health Surveillance Agency (ANVISA) authorizes commercialization of the first brand of emergency contraception (pre-packaged dosage) in pharmacies.
Law no. 9.787, amending Law no. 6.360 of September 23, 1976	February 1999	Approval of generic formulations of medications	This law approves the establishment and production of generic drugs, generic names of pharmaceutical products, and other related matters. It mandates that, when available and under the same price conditions, the generic formulations be prioritized in government procurements.
MOH Rule GM/MS no. 176,	March 8, 1999	Program for assistance with procurement of pharmaceuticals	The MOH creates a program of government incentives (assistance with purchasing medicines), and establishes qualification criteria and corresponding financial incentives to be transferred to the [eligible] states and municipalities to assist them in purchasing essential drugs. It further specifies respective managerial responsibilities for each level of the government (federal, state, and municipal) within SUS.
MOH Rule no. 85/1999	March 15, 1999	Record keeping and reporting on sterilization procedures	MOH establishes a new information-sharing requirement, mandating that all female and male sterilization procedures be recorded (obligatory).
Health Care Norms of Operation (NOAS) 2001	2001	Health care norms of operation (SUS)	Norms were written to refine and increase the roles and responsibilities of municipalities in providing basic health care, to define the regionalization of the health care, and to create management mechanisms to strengthen SUS. In respect to women's health needs, the norms mandate the responsibilities of the municipalities to provide very basic health care, pre-natal care, and family planning assistance.
Law 10.191/2001	February 16, 2001	Registration of prices and product acquisition	The law addresses product acquisition for implementing MOH health actions. It establishes the price index (registration of prices) modality for the acquisition of products, in accordance with what is stated in the government procurement law 8.666/1993.
Law 10.449/2002	May 10, 2002	Male condom commercialization	The law deals with the commercialization of latex preservatives (male condoms). This law allows the trade of condoms at any kind of commercial location in order to facilitate public access to this product.
MOH Rule no. 1.356/2002	July 25, 2002	Contraceptive methods and basic pharmaceutical care	**MOH RULES APPROVE AN INCENTIVE PROGRAM PROVIDING ASSISTANCE WITH ACQUISITION OF BASIC PHARMACEUTICALS AND INCLUDING THE CONTRACEPTIVE METHODS FOUND IN THE BASIC HEALTH CARE BASKET OF DRUGS.**
Law 10.520/2002	July 18, 2002	Creates, at all administrative levels, in regard to article 37, item	This law creates the modality of public auction, wherein interested suppliers of goods and services can present their price offers to the public auctioneer after a first round of sealed qualification documents and first prices are presented.

		XXI, of the federal Constitution, the procurement method of public auction for acquiring common goods and services	Prior to this law, this public competition was restricted to the presentation of one price offer where the lowest price would win the procurement. This law takes into account the rulings of government procurement Law 8.666/1993, meaning that all principles governing public purchases shall be complied with under this legislation.
MOH Rules no. 2313 and no. 2314	December 19 and 20, 2002	Incentives for implementation of HIV/AIDS activities	These rules approve an incentive program—for the federal government, states, federal district and municipalities—to implement STD/HIV/AIDS prevention activities.
Decree 4.542/2002	December 26, 2002	Approves the reference table for industrialized products tax (IPI) exemptions	This decree eliminates the IPI tax (tax on industrialized products) for chemical preparations for hormone-based contraceptives, some other products and spermicides. This decree also eliminates the IPI tax for natural latex rubber, even if it is pre-vulcanized.
Provisional Measure 123 Decree no. 4.766	June 26, 2003	Pharmaceuticals price regulation	This measure creates the Chamber for Regulating the Pharmaceutical Market (CMED) and establishes annual price adjustments for medications. The price regulations apply only to essential drugs. The policy also defines reference prices (ceilings) for acquiring medicines found on the lists of products distributed to the public by SUS. Decree no. 4.766, further specifies the functions and competencies of the CMED, which consists of representatives of the Ministries of Health, Justice, and Revenue and the President's Cabinet. It regulates the market price of pharmaceuticals (including new formulations) and defines adjustment criteria. Price adjustment are (and as of March 3, 2004 can only be) made once every 12 months.
Ministry Rule 110/2004	April 29, 2004	Creates the public auction modality within the Ministry of Health	This ministry ruling creates the public auction modality for the Ministry of Health in accordance with Law 10.520/2002, listed above.
Decree no. 5.090, [regulating Law no. 10.858 of 13 April 2004	May 20, 2004	Creation of the *Farmácia Popular do Brasil* program	*Farmácia Popular* (FPB, or People's Pharmacy) is a governmental program created in order to improve public access of the population to the basic medications. The Oswaldo Cruz (Fiocruz) Foundation, the MOH partner and body charged with the program's operations, is authorized to acquire certain drugs directly from public or private pharmaceutical laboratories and to make them available to the public (requires a medical prescription), in the *Farmácia Popular* chains at production prices.
MOH\ Rule 1099/2004	June 3, 2004	Regulates the procedures for document analysis in the Ministry of Health's legal advisory	This Ministry ruling states that the legal advisory, before being published in the DOU, should analyze all requests for proposals (RFPs or *Editals*) for procurement.

NOTES ON LAW 8.666

Following are comments on the articles of Law 8.666 dealing with procurement. (See http://www.v-brazil.com/business/government-purchases.html for additional information.)

Article 1 mentions the entities subject to the law: all three branches of government; all three levels (federal, state and municipal); all agencies and foundations; all public companies, including those with private participation. This means that big businesses like Petrobras, Banco do Brasil and others are subject to the law.

Article 3 mentions that the nationality of bidders will be considered only as a tie-breaking criterion; otherwise, Brazilian and foreign companies compete equally. Also, article 3 states that the entire bidding process is open to the public except for bid values.

Article 4 states that all bids are to be in national currency except in the cases prescribed in article 42 (international purchases); article 42 also mentions other conditions applying to international bids.

Articles 7 through 12 detail the procedures to be followed when public works and respective services are the subject of bidding.

Article 14 states the guidelines for purchasing goods.

Articles 20 and 21 establish the way bids must be publicized and the deadlines thereof.

Article 22 establishes the bidding modalities: depending on the value and subject of the bidding, more or less bureaucratic controls must be included.

Article 24 notes the situations where bidding is not mandatory. Examples include: purchases of small value (as defined by law), emergency situations which put people or premises at risk, when previous bidding processes had no bidders, the purchase or rent of specific buildings, and others.

Article 25 states the situations when a bidding process is not feasible, for example, if there is only one possible contractor for a given product or service (as is the case with electricity supply, which is still a monopoly in Brazil), or if a professional is so much better than all the others that a bidding competition would be meaningless (famous architect Oscar Niemeyer has won several contracts based on this idea).

Articles 27 through 33 establish the documentation necessary to participate in the bidding processes. The number of documents depends on the bidding modality. A tax number (CNPJ) is required for national bidding.

Articles 38 through 53 define how the Bidding Commission must perform: who must be disqualified and why, who the winner is, how to publicize the results, and so on. Article 45 states that, in addition to price, technical factors may help determine the winner.

Articles 54 through 64 specify the guidelines for the terms of the contract to be signed with the winning bidder.

Article 65 establishes the situations when the contract can be modified; these include cases where the price can be changed.

Articles 77 through 80 explain how breaches of contract are dealt with.

Articles 81 through 99 detail the administrative, civil, and penal punishments for acts of misconduct.

ANNEX C

LIST OF INTERVIEWED KEY INFORMANTS

ORGANIZATION	AREA/DIVISION
Federal Government Authorities	
Ministry of Health	Public Relations Advisory
Ministry of Planning and Budgeting	Secretariat of Logistics and Information Technology
Ministry of Planning and Budgeting	Secretariat of Logistics and Information Technology
Farmácia Popular	Technical Management Division
Oswaldo Cruz Foundation (Fiocruz)	Pharmaceutical Assistance Program
National Institute of Technology	Polymeric Materials Technological Laboratory (condom certification)
International Organizations Authorities	
UNFPA—United Nations Population Fund	**GENERAL OFFICE, BRAZIL**
UNIFEM—United Nations Development Fund for Women	**REGIONAL PROGRAM**
São Paulo Government Authorities	
State Health Secretariat	Public Relations Advisory Advisor
State Health Secretariat	Women's Health Reference Center
State Health Secretariat	Adolescent Center
State Health Secretariat	Program of Assistance with Pharmaceuticals and Strategic Supplies
Ceará Government Authorities	
State Health Secretariat	Reproductive Health
Municipal Health Secretariat (Fortaleza)	Technical Area in Women's Health and Gender
Municipal Health Secretariat	Technical Area in Women's Health and Gender
Municipal Health Secretariat	Pharmaceutical and Strategic Supplies Division
SEMINA Indústria e Comércio	Executive Office
SEMINA Indústria e Comércio	Government Procurements
Injeflex	Production Management
CEPEO	Government Procurements
For All Consultoria	Executive Office

NGOs—Third Sector	
Centro Vergueiro de Atenção à Mulher	**EXECUTIVE SECRETARIAT**
BEMFAM	**EXECUTIVE SECRETARIAT**
BEMFAM	**EVALUATION AND STATISTICS DIVISION**
Coletivo Feminista Sexualidade e Saúde	Sexual Health Division
Coletivo Feminista Sexualidade e Saúde	Financial and Administrative Division
Other Key Informants	
BEMFAM	**REGIONAL OFFICE (CEARÁ)**
National AIDS Coordination Program	Evaluation and Health Planning Division
Municipal Health Secretariat (São Paulo)	Secretariat of Planning and Evaluation
PSI/DKT	Social Marketing Division
Ministry of Health	National Women's Health Council
University of Brasília	Center for Women Health Studies
John's Hopkins University/Center for Communications Program (JHU/CCP)	Center for Communication Programs

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