EVALUATION OF THE EPIDEMIOLOGIC IMPACT OF A NATIONAL PRIMARY HEALTH CARE POLICY ON INFANT HEALTH OUTCOMES IN BRAZIL, FROM 1999 to 2002

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TABLE OF CONTENTS

TABLE OF CONTENTS-Continued

TABLE OF CONTENTS-Continued

LIST OF TABLES

TABLE **Pg.**

LIST OF TABLES-Continued

TABLE **Pg.**

LIST OF TABLES-Continued

TABLE **Pg.**

LIST OF TABLES-Continued

TABLE **Pg.**

LIST OF GRAPHS

GRAPH **Pg.**

LIST OF FIGURES

FIGURE **Pg.**

ACRONYMS

BC- Central Bank
CHW- Community Health Worker
CMS- Municipal Health Council
DATASUS- Brazilian Ministry of Health Information System
DENATRAN-National Traffic Department
HMP- European Community Health Monitoring Program
IBGE- Brazilian Institute of Geography & Statistics
INEP-National Institute of Educational Policies
MCH- Maternal & Child Health
MF- Brazilian Ministry of Economy
MSB- Ministerio da Saude do Brasil
PAB- Primary Care Fund
PACS- Community Health Worker Program
PAHO-Pan American Health Organization
PHC- Primary Health Care
PROESF- Program of Expansion and Consolidation of Family Health
PSF- Family Health Program
SES- Socio-economic status
SESA- State Health Department
SI-PNI- Information System for the National Plan of Immunization
SIAB- Primary Care Information System
SIM- Mortality Information System
SINASC- Live Birth Information System
SMS- Municipal Health Department
SUS- Brazilian Health Care System
TPD- Tetanus, Pertussis & Diphtheria
USF-Family Health Unit
WHO- World Health Organization

ABSTRACT

Programa de Saude da Familia-PSF was initially proposed as a novel model of primary health care in Brazil in 1994 as it was implemented in several Brazilian municipalities. This national policy embraces different dimensions of primary care, but has a primary reliance on maternal and child health, especially on the survival of infants, given the unfavorable Brazilian child health scenario. This study has proposed that an improvement on infant health is expected to occur through three major mechanisms: overcoming of socio-cultural and geographical barriers of access to maternal and child health services; integrality of care; and community empowerment. An ecological longitudinal study design was utilized to assess the impact of the policy implementation on municipal indicators of infant health of 1201 municipalities, from 1999 to 2002. A group of municipalities that first implemented PSF in 1999 and were covered continuously from 1999 from 2002 were compared to a group of municipalities that didn't implement this policy within the same time period. This study has found that PSF has had an overall positive impact on infant health. Overall, it might be concluded that PSF implementation has brought an important short-term improvement on municipal indicators of infant health from 1999 to 2002, especially on the infant mortality rate. Such beneficial impact tended to be stronger in socially disadvantaged municipalities, commonly with unfavorable health care scenario. Thus, the expansion of primary health care capacity and overcoming of major gaps within the access to MCH services might explain such beneficial impact of PSF implementation in Brazilian municipalities.

1. INTRODUCTION

1.1 Project Overview

Infant health has been a core component of the majority of international primary health care (PHC) initiatives worldwide. Given the unique vulnerability of such a population group, the considerably lower costs of primary health care compared to more complex levels of health care, and its potential impact in increasing access to essential maternal and child health services; there is a nearly universal belief that PHC is an effective strategy to improve infant health outcomes (Williams, 1988; Hart, 1999).

In general, the existence of an effective PHC system might provide an opportunity for improved pre-natal care; better birth delivery assistance and neonatal care; promotion of breastfeeding; children nutritional follow-up; monitoring of children growth & development; enhanced compliance with the children immunization schedule; and adequate management of common illnesses of childhood such as respiratory and gastrointestinal conditions (Pedreira, 1986; PAHO, 1991; Hart, 1999). Improvements on those areas have strongly impacted indicators of children health worldwide over the past decades (Abel, 1994; Avery, 2002; Rosales, 2002).

In addition, such initiatives should ideally be culturally competent and community-based, thus potentially shaping PHC services that are more responsive to the local demands and consistent to maternal & child health practices and beliefs. In summary, the availability and appropriateness of maternal and child health-MCH interventions and their respective utilization define the impact of a PHC policy on infant health outcomes.

A PHC system focused on maternal and child health activities is especially relevant among less developed countries that are struggling with the impact of poverty, low literacy levels, undernourishment and poor child health indicators (WHO, 1978; Muller, 1980; Magelsdorf, 1988; Moore, 2003). Such conditions have also long been recognized as critical to the social progress strived for by the countries of the Americas (PAHO, 1987). Improving access to essential MCH services in underserved geographic areas and impacting environmental and social determinants of child health are common goals of a PHC in the developing world (Muller, 1980; PAHO, 1993; Ehiri, 1999). Thus, primary health care has been considered the most important element of a national health care system in underserved regions of the globe (Roemer, 1980; Walt, 1982; Belmar, 1990).

Several different international PHC models have been implemented worldwide, mostly covering the seven major areas of action recommended by the World Health Organization-WHO (e.g. food and nutrition; water and sanitation; maternal and child health care; immunization; prevention and control of endemic diseases; management of common diseases and injuries; and provision of essential therapeutic) (WHO, 1978), and ultimately concerned in overcoming major health care disparities. In other words, universal access to basic health care services and focused attention on disadvantaged population groups represent fundamental components of a PHC system seeking social justice, health equity and improved population health outcomes.

However, although the large majority of international PHC initiatives have been consistent with WHO directions and have primarily addressed health inequalities as a

major policy goal, they also have important distinctions. These include the organization and financing models, the relation with other levels of health care delivery within the national health system, the extension of coverage of diverse population groups, the number and type of professionals involved, and the priority areas of actions.

A unique model of national primary health care system was initially proposed by the Brazilian government in 1994. After focused implementation in underserved areas of the country, such a policy that is widely known as *Programa de Saude da Familia*-PSF (Family Health Program) was established in 1998 as a comprehensive national policy. Essentially it is a national primary care policy developed as means to impact population health outcomes and reinforce the *Sistema Unico de Saude*-SUS (National Health System) principles of universality and equality of access to health care, decentralization of health care management to the municipal level, and integrality[1] of health care delivery and social control over health-related decision making processes (Bodstein, 2002).

Programa de Saude da Familia has been voluntarily implemented by municipal authorities in well-circumscribed geographic areas, defined as local units of socio-cultural similarities and geographic contiguity. This policy is characterized by health activities primarily focused on the family unit and sensitive to community social-economic, epidemiologic and cultural specificities. It is conducted by an interdisciplinary team of health care professionals who work 40 hours/week and commonly live at the municipality where the PSF was implemented (MS/PSF&PACS, 2000; MS/Inf.AB, 2004).

[1] Quality of being integral; "wholeness" (Webster Dictionary)

Usually a single PSF team is responsible for the coverage of 600 to 1,000 families (MS/Inf.AB, 2004). Such teams are primarily responsible not only for the entire spectrum of primary health care of families living at the covered geographic areas, but also for coordinating the referral system to other more complex levels of health care delivery within SUS. In addition, each PSF team is required to partner its planning and assessment activities with members of the local communities in order to promote mechanisms of social control over the implementation and conduction of health initiatives.

Although the *Ministerio da Saude do Brasil*-MSB (Brazilian Ministry of Health) is responsible for setting the national agenda for this policy, establishing major national goals and also for sponsoring the large majority of its activities; each program is shaped uniquely at the municipal level. Each municipality has to be in charge of conducting local assessments, setting the municipal PSF agenda, contracting personnel, providing health care facilities, establishing the mechanisms of social participation and to make primary choices regarding the modes of local PSF implementation (MS/PSF&PACS, 2000)(MS/Inf.AB, 2004).

In addition, this policy inaugurates an inversion of the traditional model of access to health care services. Instead of expecting patients to come to medical offices in order to receive preventive/curative services, health care facilities are brought into local communities and health care professionals into family homes in order to help developing a healthy familial and community environment. Such initiatives expand the traditional curative responsibilities of medical care and make PSF a more pro-active model of PHC.

Moreover, it potentially generates a stronger attachment and sustainable relationship between health care teams and community members.

Although it is not a mandatory policy, PSF municipal enrollment has grown greatly since its initial formulation in 1994, since it represents an opportunity to obtain good technical assistance from the national and state governments, expand the municipal health care budget and transfer relevant managerial functions to the municipal authority.

As PSF population coverage has increased and the federal government has expanded its investment on the consolidation of this policy during the last decade, it has gained a positive reputation throughout the country as a health care strategy that enables communities impact the health of their populations (MS/Custos, 2001)(MS/PSF&AB, 2002). In addition, since PSF targets primarily families and their respective vulnerable groups, such as women in reproductive age and children, a beneficial effect of PSF especially on population indicators of infant health is expected to be achieved.

Three major mechanisms are likely to influence such a positive impact of PSF on infant health. At first, given that infant health is importantly determined by the availability and appropriateness of maternal and child health (MCH) services, *overcoming socio-cultural and geographical barriers of access to MCH services* seems to represent a mechanism through which PSF might impact infant health. Secondly, given the enhanced mechanisms of community participation and social control promoted by the implementation of PSF, *community empowerment* may play a fundamental role in improving child health. Communities become more aware and self-responsible for health issues affecting children and different networks of family and social support are

mobilized to address individual- and community-specific needs. Thirdly, an enhanced *integrality of care* is achieved, as PSF is concerned with comprehensiveness of care and regional coordination with other levels of needed health care (e.g specialty physicians, diagnosis clinics, neonatal care units, pediatric units…). Hence, it is more likely that pregnant women and children receive a more integral health care delivery in areas covered by PSF.

Governmental evaluation reports have indicated such an improvement on infant health outcomes nationwide since PSF initial implementation, especially a coincident trend of increased PSF population coverage and improvement on indicators of access and outcome of child health among diverse Brazilian municipalities (MS/PSF&AB, 2002; MS/Evol, 2002; MS/SIAB, 2003; DATASUS, 2005).

For instance, as the PSF population coverage increased nationally from 1.1% in 1994 to 29 % in 2002, within the same period the absolute number of pre-natal care appointments has grown from less than 4 million/yr to approximately 10.1 million appointments/yr; the DPT immunization coverage within the first year of life has changed from 74% to 95% of the total population of children < 1 yr old; and the infant mortality rate has decreased from approximately 41 to 19.26 infant deaths per 1,000 live births (MS/SIAB, 2003; DATASUS, 2005).

In addition, among geographic areas covered by PSF, the level of exclusive breastfeeding among children under 4 months old has reached over 65% and the proportion of women starting the pre-natal care within the first trimester of the pregnancy reached over 60 % in 2002 (DATASUS, 2005). Although such an improvement on

population indicators of infant health has occurred concurrently with a process of PSF access expansion, it has not been established as a causal association yet since no scientific evaluation of the real impact of PSF on child health has been conducted.

Furthermore, although the MSB has published reports monitoring PSF trends at the municipal level (e.g. physical capacity, implementation process and population health indicators) and several studies have explored a qualitative assessment of PSF implementation process, no large scale quantitative evaluation has been developed previously. In other words, there is not a clear understanding regarding the real effectiveness of PSF in impacting population health outcomes and the circumstances under which such a program is more likely to succeed. Thus, such a research study will aim to fulfill this knowledge gap as it has conducted a nationwide quantitative evaluation of the impact of PSF municipal implementation on population health outcomes, focusing on indicators of infant health. It is going to compare infant health indicators of municipalities that have implemented PSF in 1999 with those of municipalities that have not implemented the policy within the study period, 1999-2002.

In summary, such a study is concerned with the assessment of the epidemiologic impact of PSF on municipal indicators of infant health. Epidemiologic impact is essentially a measure of policy effectiveness, commonly used in health policy analysis conducted to assess the extent to which a program has caused changes on a specific set of health outcomes (Rossi_&_Freeman, 1993). In addition, this study is essentially concerned in assessing population-based indicators of infant health, since municipalities are the unit of analysis. Although the concept of infant health embrace dimensions of

health that go beyond the simple evaluation of the presence of disease and/or death (e.g. quality of life, life style, social functioning, mental well-being), the population health indicators used in developing countries for the most part address ultimate health outcomes such as morbidity, mortality and important precursors of both (Larson, 2004).

Given the scientific goals of this research study, three major hypotheses were raised, suited for statistical testing, in order to assess the impact of PSF on municipal indicators of infant health:

1) Municipalities that have initiated PSF implementation in 1999 and were covered by this policy from 1999 to 2002 are more likely to reduce their respective infant mortality rates from 1999 to 2002, than municipalities that have not implemented PSF during the study time period

2) Municipalities that have initiated PSF implementation in 1999 and were covered by this policy from 1999 to 2002 are more likely to reduce their respective neonatal mortality rate, low birth weight rate; and increase the proportional coverage to selected MCH services (coverage to pre-natal care and tetravalent immunization) from 1999 to 2002, than municipalities that have not implemented PSF during the study time period

3) The effects of PSF on these infant health indicators are influenced by municipal contextual characteristics (population size, regional location, proportion of rural population, income/capita, Gini income coefficient, illiteracy, hospital beds/capita, physicians/capita, health care expenditure/capita, and proportion of access to safe water)

The remaining part of this introductory chapter will present the infant health scenario in Brazil during the last decade; discuss the uniqueness of the PSF model of primary health care established in Brazil, presenting definitions and concepts in primary health care, exploring the foundation and respective evolution of this policy, and highlighting the relevance of this policy within the Brazilian health care arena; and finally present a theoretical framework explaining the potential impact of this primary care policy on the infant health of Brazilian municipalities.

1.2 Infant Health in Brazil

Many social and economic factors affect maternal and child health care in Brazil. The effects of poverty, low education status, major geographical and social inequalities in health care, overall poor health care infrastructure and shortage of health care professionals in some areas of the country represent major challenges to appropriately deliver maternal and child health services throughout Brazil (Beckmann, 1987). In some areas of the country, women still reach labor delivery without previous antenatal care; birth deliveries are performed with very rustic apparatus and no medical support; children face serious undernourishing conditions; and the impact of diarrheal and respiratory diseases within the first year of life is remarkable.

Several policies aimed at improving infant health have been implemented over the years, with various degrees of success. In Brazil, such intersectoral policies have been claimed to promote an important decline in infant and childhood mortality rates (respectively under 1 and 5 years old) over the last decades (Alves, 2004; Machado, 2005). Such improvements were largely attributed to a rise in sanitation, education and per capita income over this time period (Pires, 1992; Alves, 2004). However, changes on the organization of the national health system and public assistance policies to low-income youth during the last decade have also contributed to improve overall children health status in Brazil (Barros, 2001; De Mendonca, 2002).

For instance, there was an important overall improvement on national infant mortality rates (IMR) over the last 30 years, despite important regional disparities that were mostly kept during this time period, as shown in table 1.

Table 1. National and region-specific infant mortality rates (per 1,000 live births), from 1970-2000, based on IBGE estimation (Alves, 2004)

REGION	1970	1980	1991	2000
North	180	135	49	41
Northeast	112	71	74	64
Southeast	97	61	34	27
South	81	52	29	24
Middle-West	92	60	39	31
TOTAL (BRAZIL)	**124**	**85**	**49**	**34**

Such a disparity is a serious issue among Brazilian municipalities, as the estimated IMR in 2000 varied from 5.4 to 109.7 deaths per 1,000 live births within different areas of the country (Alves, 2004). Familial economic struggle; inadequate living conditions; early reproductive behavior; limited local supply of SUS services; and low access to essential maternal and child health; especially to childbirth and neonatal care conditions, appear to have shaped such important regional disparities throughout the country (de Andrade, 2000; Dytz, 2002).

In spite of an overall positive change on such an indicator of child health, IMRs in Brazil are still fairly high compared to international standards, as shown in Table 2. Hence, despite the steady decline trend over the last decades, infant mortality still represents a major health challenge for the Brazilian government.

Table 2. International infant mortality rates (per 1,000 live births); World Development Index, World Bank, 2001 (Alves, 2004)

COUNTRY	INFANT MORTALITY RATE
India	70.2
Bolivia	58.8
Brazil	**32.2**
China	30.2
Argentina	20.2
Chile	10
Hungary	8.4
USA	6.9
Portugal	5.6
Canada	5.3
France	4.8
Finland	4.1
Japan	3.6

It is important to mention that Brazilian national rates utilized in tables 1 & 2 were based on indirect estimation from the national demographic census performed by the *Instituto Brasileiro de Geografia e Estatistica*-IBGE (Brazilian Institute of geography & Statistics). They are discordant and obviously less precise than the rates estimated directly from the *Ministerio de Saude do Brasil*- MSB (Brazilian Ministry of Health) annual counts of live birth and infant death records. However, the IMRs presented in

table 1 are fairly comparable among themselves given the similarity of the estimation methods, thus allowing a long historical perspective of infant mortality in Brazil.

A more recent national trend of IMR can be observed in table 3, which is based on the MSB direct estimation method and corroborates such a continuing decline trend.

Table 3. National infant mortality rates (per 1,000 live births), from 1999-2002 (DATASUS, 2005)

YEAR	INFANT MORTALITY RATE
1999	21.3
2000	21.3
2001	19.9
2002	19.3

Moreover, other indicators of child health such as neonatal mortality rate[2], proportion of children under one-year old compliant with the required immunization schedule, exclusive breastfeeding up to 4 months old, prevalence of undernourishment, and hospital admission rate by dehydration among children under 5 years old have also experienced an important improvement during the last decade, as presented in table 4. The only exception was the proportion of low birth weight[3], which has actually slightly increased from 1999 to 2004.

[2] Neonatal deaths are those occurring within the first 28 days of life
[3] Birth weight below 2,500 grams

Table 4. Evolution of national indicators of child health, from 1999 to 2004 (DATASUS, 2005)

INDICATOR	1999	2004
Neonatal Mortality Rate (per 1,000 live births)	13.49	12.64 (2002)*
Low Birth Weight Rate (per 1,000 live births)	7.56	8.07 (2002)*
Prevalence of children undernourishment (underweight) < 2 years old (%)	14.8	5.7
% of children w/ exclusive breastfeeding (< 4 months old)	57.9	69.5
% children compliant with immunization schedule (< 1 year old)	78.2	90
Hospital Admission rate for dehydration (caused by diarrhea) < 5 years old (per 1,000)	18.3	11.4

* National NMR and LBWR are not available for years 2003 and 2004 yet. Thus, rates were presented only for years 1999 and 2002.

Hence, it might be inferred that there has been a steady trend of overall improvement on the population indicators of child health conditions in Brazil since 1999, after consolidation of PSF as the national model of primary health care. It might be associated to the emphasis PSF has given to MCH issues.

1.3 *Programa de Saude da Familia*-PSF: A National Model of Primary Health Care Policy

1.3.1 Essentials of Primary Health Care (PHC)

National health care systems should have the common goals of reducing health disparities among diverse population groups and optimizing population health through the utilization of the best knowledge regarding etiology and management of diseases (Starfield, 1998). The WHO Declaration of Lubliana has defined valued-based principles that should guide health care systems to achieve those goals (Starfield, 1998). Such a Declaration proposes that systems should be:

- Guided by values of human dignity, equity, solidarity and professional ethics
- Directed to protect and promote health
- People-centered, allowing citizens to influence the system and take responsibility for their own health
- Focused on quality, including the cost-effectiveness relationship
- Based on sustainable financing mechanism that allow universal coverage and equal access; &
- Directed to primary health care

Although awareness has been generated regarding the importance of these principles for any national health system, several nations have faced unique logistic, political, financial and cultural constraints to fully attain such principles, especially those

related to the egalitarian perspective of health. However, the importance of an effective PHC within the national health care system, primarily directed to protect and promote health, appeared to be universally legitimized as an effective and socially just strategy to enhance the performance of the systems and ultimately impact population health.

For instance, access to primary health care services has been considered the most fundamental policy issue within the management of national health care services, since a comprehensive primary care system integrated to a local supportive referral system can address the large majority of health-related problems affecting communities (WHO, 1978). In addition, the potential impact of PHC on the mitigation of adverse associations of social inequalities on population health has been reported as a fundamental mechanism to overcome health disparities (Shi, 1999; Shi, 2001). Such a section will further explore the basic principles & concepts of primary health care and its respective relation with population health outcomes.

* **Basic Principles & Concepts of Primary Health Care**

Primary health care is essentially a strategy to guarantee adequate integration of different levels and complexities of the health care delivery chain, promotion of community participation on the planning and monitoring of health policies, effective decentralization of health-related decisions to the community level, universal access to a basic package of health care services and, thus, amelioration of health inequalities, (WHO, 1978; Belmar, 1990; Starfield, 1998). Such services should include health-related actions related to: food and nutrition; water and sanitation; maternal and child health

care; immunization; prevention and control of endemic diseases; management of common diseases and injuries; and provision of essential therapeutic drugs (WHO, 1978).

Primary health care should be understood as the first of the three levels of care of any health care system, primarily responsible for handling health care preventive actions, cultural-specific health promotion programs, and curative & rehabilitative services for common diseases not requiring the utilization of advanced medical services (Belmar, 1990). It has been estimated that an effective primary health care system can respond directly to approximately 85% of total health-related demand (Starfield, 1994; Monteiro de Andrade, 2004)

Moreover, it should organize the demand for secondary and tertiary cares, which are distinguished by their duration as well as by the relative uncommonness of problems that justify them. Secondary care is consultative, usually short-term, and utilized to clarify diagnostic and therapeutic questions. Whereas tertiary care is characterized by caring to unusual disorders that usually demand technologically advanced diagnostic and therapeutic procedures, besides unique specialized competence to handle that (Starfield, 1994).

A very complete definition of primary care, based on its normative functions, is presented by Barbara Starfield, who characterizes that as the *"…aspect of a health service system that assures person-focused care over time to a defined population, accessibility to facilitate receipt of care when it is first needed, comprehensiveness of care in the sense that only rare or unusual manifestations of ill health are referred elsewhere, and coordination of care such that all facets of care are integrated"*

(Starfield, 1998). The elements of *focus on people* (not on illnesses); access at the *first contact*, *longitudinality* of care, *comprehensiveness* and *coordination* are also present at the large majority of official PHC definitions and seem to represent the core of PHC functions (Millis, 1966; Alpert, 1974; WHO, 1978; Kimball, 1994; MCH, 1994).

Hence, *first contact* involves both accessibility to a PHC provider/facility and the actual utilization of PHC services whenever it is needed. *Longitudinality* refers to the degree to which individuals relate to their PHC provider/facility over time for all but referred care. *Comprehensiveness* requires that PHC services offer a broad range of services that meet nearly all common needs in the community. *Coordination* is essentially the extent to which information is effectively shared among different levels of care and utilized to improve management of individual cases (Starfield, 1994).

*** Primary Health Care & Population Health**

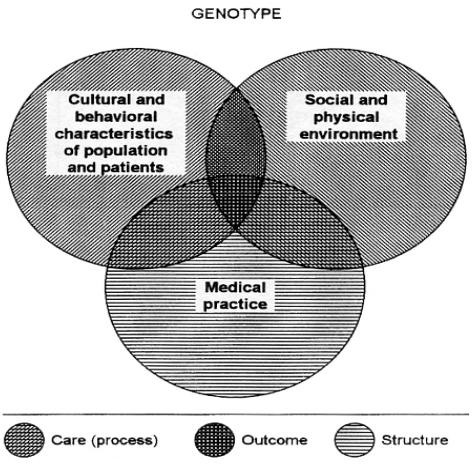
The strength of the primary care approach by a national health care system is commonly determined by specific PHC dimensions such as geographic regulation, longitudinality, coordination and community control. Previous studies have shown that a primary care orientation of a country's health care system is associated with lower costs of care, higher satisfaction of the population with its health services, better population health status, and lower medication use (Starfield, 1992; Starfield, 2002; Macinko, 2003).

Most of these previous analyses of the impact of primary health care on different dimensions of population health status at the national level have assessed the association between the magnitude of the primary health care orientation of the system, based on

PHC functional dimensions, and indicators of population health (Starfield, 2002; Macincko, 2003). Other studies have assessed the association between local availability of PHC providers and indicators of population health (e.g crude mortality rate; age-specific mortality rate, life expectancy, neonatal mortality rate and low-birth weight) (Farmer, 1991; Shi, 1994; Shi, 2004). In general, there is a fairly consistent argument that an increased local availability of PHC providers is associated with better population health status, based on such aggregated indicators of health (Starfield, 1998).

Furthermore, individual and population health are determined by genetic combination, but largely modified by the social and physical environment, culturally-and/or socially-determined behaviors, and by the nature of the health care offered (Starfield, 1998). This is illustrated by the figure 1 presented below, which highlights that health outcomes are ultimately determined by a combination of: genotype, social & physical environment, cultural and behavioral characteristics and medical practice.

Figure 1. Determinants of Health Status (Starfield, 1998)



Such a determinant role of the nature of the health care can not be simply defined by the total amount of health expenditure/ capita, since it is not homogenously associated to improved health status (Berkman, 2000), but it should rather be defined by the type of services offered and their respective effectiveness in affecting health outcomes (Starfield, 1998) Thus, health care services that reinforce equality of access, rather than selected access to high-technology procedures might actually be more important determinants of population health status.

Thus, as a PHC system is able to expand access to disadvantaged population groups, offer scientifically appropriate, locally relevant and culturally-specific health services, embrace a broader dimension of health within its practice, and guarantee financial sustainability; an expected positive impact on population health outcomes is expected to occur.

Thus, PHC might impact potentially infant health outcomes through an effective reorganization of community-based health activities. These activities include better coordination of the entire health care delivery spectrum; longitudinal assistance to infants since their birth; development of cultural specific interventions; enhanced participation of local community within the planning of health care programs/policies; and empowerment of families and mothers, as they gain control and knowledge over children health care process (Kroeger, 1982; Roemer, 1986; Nicholas, 1991; Starfield, 1998; Hart, 1999).

1.3.2 Description of the PSF model of primary health care

Programa de Saúde da Família-PSF can be simply defined as a national primary health care model primarily based on preventive and health promotion activities focused on the family unit. In order to better understand such a novel perspective introduced by PSF, core concepts guiding PSF philosophy of care are reviewed here below:

*** Interdisciplinary Teams**

Each local program is composed by a team of health care professionals who are primary responsibles for the entire continuum of health care, either directly delivering services or indirectly as they conduct referrals to other needed modalities of care. Usually, a PSF team is composed by a primary care physician, a nurse, a nurse assistant and four to six community health workers who normally live at the focused municipality and have complimentary job assignments (MS/GUIA, 2003).

Such an interdisciplinary team seems more likely to have a wider diversity of professional skills (e.g. educational, managerial, relational, social, cultural competency, preventive and curative) required for an appropriate PHC system to exist than a single family practitioner office. Finally, there is a recent effort to also include dentists within such teams in order to PSF embrace dental public health activities as well.

There is coordination of the interdisciplinary team and a physical facility that help integrating their respective actions as health care professionals. In addition, frequent team meetings with their respective communities provide an opportunity to refine individual assignments and activities. Such a perspective expands the common view that

a single PHC provider can be responsible for a comprehensive delivery of primary care services.

*** Integrality**

Integrality essentially means addressing systematically and effectively all types of health-related demands, regardless the complexity of that. It is defined as the availability of a variety of services that can respond to the different dimensions of health conditions such as physical, behavioral and social (WHO, 1978; Rifkin, 1986; Starfield, 1998). In other words, it consists of developing health services that are coherent to the disease-health process, which intrinsically demands a broad spectrum of individual and collective actions.

Such health care actions are usually classified in a hierarchical level determined by the degree of human, physical and financial resources required for the diagnostic procedures and therapeutic interventions. Thus, as PSF proposes a comprehensive delivery of primary care services and also a better integration with secondary and tertiary care services, it takes the primary responsibility for the integral health assistance of their covered populations.

*** Family Unit**

It is essentially the social and biologic cell under which reproductive behavior; socialization patterns; emotional development; and community relationships are forged. Reproduction and development of physical and mental wellness are basic family

functions, which are also determined by the existence and quality of local health care services (WHO, 1976). Thus, such a policy has an interest for the family that goes beyond the individual characterization of the group of associated people sharing the same geographic space. It depends not only on the demographic composition of the family, but also the history of family organization, their collective socio-economic situation and the physical features of the household where they reside.

*** Community**

It represents the socio-cultural sphere where each PSF team will concentrate their efforts. It is essentially defined by geographic limits, but also determined by similar patterns of organization and common dependence on governmental and social institutions. The process of identifying and describing the communities where each PSF team will develop its activities is a fundamental aspect of this policy, since it allows an in-depth initial community assessment. Such an initial assessment will identify major barriers and potential for program implementation, the population groups at higher risk and their respective health–related needs. It, thus, shapes the local implementation of health care interventions.

An interesting distinction between the hegemonic health care model previously existent in Brazil and the novel approach proposed by PSF is presented by Monteiro de Andrade et al., as shown in table 5.

Table 5. Differences between the hegemonic and PSF model of health care (Monteiro de Andrade, 2004)

HEGEMONIC MODEL	PSF MODEL
- Health defined as absence of disease	- Health defined as quality of life
- Health care delivery as a political favor and not as citizen right	- Health care delivery as a citizen right
- Individual-centered care	- Collective perspective of care (community- and individual- centered)
- Centered on curative practices	- Centered on integral health care assistance, including prevention, health promotion, cure and rehabilitation
- Hospital as predominant health care service	- Hierarchy of the health care delivery network, guaranteeing different levels of care
- Health Care services concentrated within large urban centers	- Better geographic distribution of health care services
- Medical sovereignty	- Focus on interdisciplinary health care
- Lack of consideration of local epidemiology profile on planning strategies	- Planning based on epidemiology data bases, prioritizing risky population groups
- Absence of mechanisms of community participation; and lack of attention to local cultural and socio-politcal reality	- Promotion of community participation, guaranteeing a certain level of local autonomy on the planning of health care strategies
- Functioning mostly based on the spontaneous demand	-Functioning mostly based on organized demand and assistance to the problems of focused communities

The functioning of this policy is also unique in several aspects, as it has been organized within a public national health system, which contracts health care professionals as public workers, has its own public facilities to provide health care services and is primarily financed with federal resources. In order to comprehend the

operationalization of this policy in practical terms, an explanation about the professional role of each team member, the physical infrastructure needed for each team, the health services provided, the strategies of community control, and financing mechanisms is going to be provided.

Professional Roles: Each PSF team composed by a physician, a nurse, a nurse assistant and four to six community health workers is primarily responsible for covering 600 to 1,000 families (MS/PSF&AB, 2002), thus being in charge for addressing the health needs of a given geographic area containing in average 2,400 to 4,500 individuals (MS/PAB, 2001; MS/PAF&AB, 2002).

However, a normative evaluation of the PSF implementation performed during 2001-2002 has identified that only 79% of the teams were actually attaining such a requirement and approximately 17% of the teams were overseeing a population above the suggested size limit (MS/Aval.Norm, 2004). Such a wide range of the proportion of population covered is explained by extreme differences among geographic areas regarding road access, demographic concentration and the actual size of the area.

The interdisciplinary composition of the PSF team requires that each member shares information and knowledge with the rest of the group; helps training other new team members; and knowing and assessing collectively major group tasks (MS/GUIA, 2003). A qualitative evaluation has confirmed that there is an appropriate level of integrated actions and coordination over PSF activities regarding the existence conflicting relationships within some professional teams (MS/Aval.Impl, 2002). The Brazilian

Ministry of Health has defined collective responsibilities for each PSF team, which essentially consist of (MS/GUIA, 2003):

- Recognizing the reality of all the families they are responsible for, especially the assessment of their demographic and epidemiology characteristics
- Identifying prevalent health problems and risky situations for the covered population
- Outlining, with community participation, a plan to address the major local needs
- Providing integral health assistance, as the team should respond continuously and systematically to the organized and spontaneous health-related demand. Such health care provision should be done at the "*Unidade de Saude da Familia"*-USF (Family Health Facility), community, household and following-up referrals to other health care facilities.
- Developing educational and inter-sector actions in order to face the problems identified during the assessment
- Executing sanitary and epidemiologic surveillance
- Performing home visits according to the established local plan
- Guaranteeing continuity of care as individuals should be referred to other health services whenever needed
- Promoting mechanisms of systematic community participation

Besides such collective responsibilities, each team member has specific assigned duties that are mostly specific to their educational background. The community health

worker-CHW is usually responsible for accompanying approximately 150 families living at the area under his supervision. He/she should necessarily be a local resident that is identified with community values, costumes and language. Nurse assistants are responsible for preparing individuals for appointment, laboratorial exams and treatment. In addition, he/she is in charge of the active search for individual cases of tuberculosis, Hansen's disease and other focused diseases. Nurses are responsible for promoting the training of nurse assistants and CHWs, administering the *Unidades de Saude da Familia*-USF (Family Health Facilities) and also providing care to a given set of health conditions. Physicians should be responsible for directly providing regular home visits, handling spontaneous demand, coordinating referral to other health services and participating of health education activities (MS/GUIA, 2003). Although each PSF team might distribute tasks differently, the federal government has suggested a set of responsibilities for each team member, which are specified as appendix.

Finally, a fundamental stakeholder for the successful functioning of PSF at the municipality is the Head of the *Secretaria Municipal de Saude*-SMS (Municipal Health Department). Besides having the discretionary power regarding local program implementation, he/she is the ultimate responsible for the operation and maintenance of all PSF teams functioning at the municipality (MS/GUIA, 2003). In addition, he/she should guarantee the integration of the different local PSFs with rest of the health service delivery chain.

Physical Infrastructure: The PSF strategy is structured based on the *Unidade de Saude da Familia*-USF (Family Health Facility)- a local health facility that serves as the environment primarily utilized by the interdisciplinary team to deliver primary health care services. Depending on the size and structure of the USF, its location, and size of the geographic areas covered by each PSF team; a single USF may serve up to four different teams assisting contiguous geographic areas (MS/GUIA, 2003).

Ideally an USF should have the basic technology and equipments necessary to respond to common health problems affecting covered populations. An immunization room; gynecology exam table and pap smear materials; equipment for suture, curative and minor procedures; and individual offices for the physician and nurse represent the major infrastructure required for each PSF team (MS/GUIA, 2003). The majority of these USFs consist of existent small community health centers that were provided by either the state or municipal governments (MS/Aval.Impl, 2002).

In addition, depending on the extension of the geographic area covered and local quality of road access, transportation might be needed for the health care professionals. Especially for the community health workers who commonly utilize bicycles, boats and animals as alternative transportation in order to make home visits.

The minimum USF structure recommended by the Brazilian Ministry of Health for the adequate implementation and maintenance of a PSF team consists of:

- Reception room (ideally should be equipped with TV and VCR to provide educational lectures)
- Storage for medical charts and files

- Room for minor procedures (e.g. suture, curative and other nursing procedures)
- Immunization room
- Physician office
- Nurse office
- Bathrooms
- A space for specific patient group activities (e.g. pregenant women, hypertensive patients, diabetic…) and continuing education classes for health care professionals.

Although it is recommended that each team has such an individualized infrastructure, some of these spaces are frequently shared by different PSF teams occupying the same USF.

A previous study has assessed family opinions regarding the adequacy of the USF infrastructure and identified that the majority of families would rather use such facilities than the previous primary care facilities. However they believe USFs need to improve the comfort of its physical installations and technology is needed to provide adequate primary care assistance (MS/Aval.Impl, 2002).

The accessibility of these USFs was also assessed by previous studies that identified that over 90% of the families covered had utilized services at the USF at least once, and more than 50% of the families had utilized services at the facility within the previous thirty days. Moreover, it was identified that the percentage of families who

access the USF as the first contact health facility for a new health event ranged from 33% to 77% within the municipalities studied (MS/Aval.Impl, 2002).

Finally, the percentage of PSF physicians who agreed that USF function as the entrance gate for the national health system ranged from 37% to 86% within the focused municipalities (MS/Aval.Impl, 2002). In summary, such findings indicate that USF seem to represent a fairly accessible facility for the PSF covered families, although there are important differences among the municipalities studied.

Besides the provision of several different primary care services at the USF, PSF teams also utilize community facilities (e.g. churches, schools and governmental buildings) to minister educational lectures and less frequently to provide out-patient appointments, especially for special population groups. Moreover, home visits are an essential component of the program. For instance, a previous formative evaluation conducted in a sample of selected municipalities identified that 78% to 96% of physicians and/or nurses had performed home visits during the previous week and 55% to 86% of the community health workers had participated in community meetings during the same time period (MS/Aval.Impl, 2002).

Package of Primary Health Care Services: As a supposedly comprehensive primary health care policy, PSF aims to have an impact on different dimensions of primary care. These include improvement of water quality and sanitation facilities; access to proper food and achievement of better nutritional status, especially among children; chronic disease prevention and management; infectious disease control and maternal and child

health are the major target national areas of action (MS/SIAB, 1998). Reproductive health, children health, hypertension, diabetes mellitus, tuberculosis and leprosy have received differential attention in the implementation of PSF, given that the federal government has established national goals to improve them (MS/PSF&PACS, 2000; PSF/Aval.Impl, 2002).

For each of these major issues, the Brazilian Ministry of Health has suggested a list of tasks that should be developed locally in order to achieve the prescribed national goals. However, the level of implementation and quality of the services vary largely at the local level and seem to depend on the level of municipal commitment with the policy, local acceptability, and the availability of enough municipal resources to guarantee program sustainability. Table 6 provides a list of maternal and child health services recommended by the federal government as the appropriate package of services to be addressed regularly at the local level.

Table 6. PSF major responsibilities and services within maternal & child health area, suggested by the Brazilian Ministry of Health (MS/GUIA, 2003)

FOCUS	RESPONSIBILITY	SERVICE
CHILD HEALTH	**Nutritional surveillance**	-Nutritional & developmental follow-up -Combat of major nutritional deficiencies -Promotion of breastfeeding
	Immunization	-Attainment of the basic infant immunization schedule -Active search for children missing the schedule -Development of community campaigns
	Assistance to prevalent diseases during infancy	-Assistance to acute respiratory infections (ARI) in children below five years old -Assistance to diarrhea in children below five years old -Education activities for prevalent diseases -Referral to specialized and hospital care
	Oral health actions	-General oral hygiene education, dental decay prevention and treatment of major oral pathologies

MATERNAL HEALTH	**Pre-natal care**	-Pregnancy diagnosis -Classification of pregnancy risk within the first appointment; follow-up of low risk pre-natal care and referral for high risk pre-natal care in other facilities -Nutritional supplementation for pregnant women with low weight -Tetanus immunization schedule -Post-birth follow-up -Routine laboratorial exams
	Family Planning	-Provision of a variety anti-conception drugs and methods -Routine laboratorial exams

Community Control: The federal government has established new definitions in order to facilitate the assignment of PSF coverage and better monitoring the policy locally. The population group and geographic area covered by each community health worker is called PSF micro-area, while the set of micro-areas under the responsibility of each PSF team is known as PSF area (MS/SIAB, 1998).

Therefore, usually there are series of PSF areas within a same municipality. Since the implementation of PSF is primarily a political decision of the municipal government, commonly a given municipality has several different PSF teams covering its population.

Usually it occurs progressively, and after an initial limited implementation in selected areas, the municipal government might decide expanding PSF access to other population groups and geographic areas.

Two major mechanisms are utilized to guarantee local population control over PSF and adequacy of the policy tasks and activities to the reality of local communities, the *Conselhos Municipais de Saude*-CMS (Municipal Health Councils) and the community health workers (CHWs). They are considered two fundamental elements for the successful policy implementation at the local level.

The MSB has defined the existence of a functioning CMS as a required criterion to transfer funds in order to sponsor PSF. Such a mechanism of social control is aimed to guarantee an adequate level of community participation and monitoring over the implementation, planning and management of this policy.

Such councils should be composed of elected citizens from the municipality and have a *veto* power over major policy decisions made by the municipal government. Ideally it should take part of the municipal health plan and oversee major policy initiatives such as *Programa de Saude da Familia*. However, the level of community representation, the methods for CMS member selection and the role of those councils vary largely throughout the country and they have not been frequently engaged in pro-active and politically independent planning and monitoring activities.

The primary reliance of PSF on the work of CHWs is based on the need of developing culturally sensitive primary health care actions that are responsive to community demands and accessible to them. Ideally CHWs should facilitate the

establishment of trustful and sustainable linkages between PSF teams and community members; identifying major community resources; translating local health-related practices and beliefs to PSF team members; and educating community members regarding the existence, location and importance of diverse health services (MS/PACS, 2001). In summary, the level of community responsiveness to PSF local initiatives will rely strongly on the professional roles exercised by CHWs locally.

Financing Mechanisms: As *Piso de Atencao Basica*-PAB (Primary Health Care Fund) became effective in 1998, it was assured an automatic and systematic financing mechanism for PSF. These financial resources are transferred directly from the federal government to a municipal government account. The fixed component of PAB is transferred monthly and it is calculated by the following formula (MS/PAF&PACS, 2000; MS/Custos, 2001):

PAB fixed component = (Number of municipality residents (based on IBGE* estimation) x per capita value) /12

*IBGE: Brazilian Institute of Geography and Statistics

Such a per capita value ranges from R$ 10 to R$ 18 based on the history of primary care service utilization (Per capita value = sum of all primary care procedures paid to the municipality in the previous year / Municipality population in the current year). Such a fixed amount of resources should be utilized to finance capital and maintenance costs related to the provision of primary care services proposed by the municipal health plan (MS/PSF&PACS, 2000; MS/PSF&AB, 2002). PAB fixed

component reaches nearly all Brazilian municipalities and represents a historical commitment of the national government with primary care actions.

The variable component of PAB is the core strategy to stimulate municipal governments to implement and expand access to PSF. Besides an incentive for the initial implementation of the program, which is approximately R$ 10,000 per each new PSF team established, and the resources transferred to support the payment of community health workers (approximately R$ 2,200 per CHW/year), an annual amount of resources is added per team a year (MS/Custos, 2001). These range from R$ 28,008 to R$ 54,000 per team, divided into twelve monthly payments. The wide range is reflective of the level of municipal coverage (MS/Custos, 2001). The levels of population coverage and the respective PSF financial incentive received are described in table 7.

Table 7. Annual financial incentive for each PSF team, per different levels of population coverage (MS/Custos, 2001).

CLASSIFICATION OF THE LEVEL OF POPULATION COVERAGE	LEVEL OF POPULATION COVERAGE (%)	VALUE OF THE INCENTIVE/TEAM/Yr
1	0 to 4.9	28,808
2	5 to 9.9	30,684
3	10 to 19.9	33.360
4	20 to 29.9	38,520
5	30 to 39.9	41,220
6	40 to 49.9	44,100
7	50 to 59.9	47,160

8	60 to 69.9	50,472
9	Over 70	54,000

In order to make this estimation, each team is considered to be responsible on average for 3,450 individuals. Thus, the total number of covered individuals in a given municipality would be *3,450 x Number of PSF teams*. In order to estimate the percent population coverage, the total number of covered individuals should be divided by the total municipal population. Such a formula is shown here below:

Municipal coverage = [(Number of PSF teams x 3,450)] / municipality population (based on IBGE)] x 100

In addition, the Brazilian Ministry of Health provides an incentive to partially sponsor primary care drugs, which is R$ 1/per resident a year and requires counterparts of R$ 0.5 from the state and municipal governments. Furthermore, the federal government also reimburses municipalities for their costs for immunization and diagnostic exams used in primary care services.

Thus, such a PAB variable component is simply a financial incentive for municipalities to implement and expand population access to PSF since it represents an opportunity to increase the total amount of municipal health budget to be used within primary care. In addition, it is also attractive for local health authorities as they gain autonomy to manage such resources based on major PSF priorities identified locally.

1.3.3 A Historical Analysis of the PSF

The reasons leading to the foundation of the *Programa de Saude da Familia*-PSF and its respective evolution in Brazil can only be understood if contextualized within the history of the *Sistema Unico de Saude*- SUS, the Brazilian public national health system. Thus, such a section intends to provide an overall perspective of SUS guiding principles and organization, and how primary health care initiatives have evolved within such a system until the launching and respective evolution of PSF as the national model of primary health care.

*** The foundation & evolution of the *Sistema Unico de Saude*- SUS**

The Brazilian health care system has a unique developmental history. After twenty one years of military dictatorship, the Brazilian society passed through a process of social mobilization, which culminated with the national redemocratization in 1985. Along with this process, different human right movements advocated reforms on diverse public issues and sectors, requiring social justice and the democratic process of popular participation.

Such movements culminated with the official foundation of the *Sistema Unico de Saude*- SUS in the national constitution of 1988. As a consequence of its developmental process, this system is extensively ideological, is built upon principles of social justice and is claimed to be responsible for increasing citizenship awareness. Nevertheless, it has not been able to fully accomplish some of its most basic duties (Monteiro de Andrade, 2002).

The 1988 Brazilian Constitution has a statement in its Health Chapter that summarizes very adequately the main motive behind the development of such a system: "…health, a right for all and the state's duty" (CFB, 1988). It has been considered a major human right advance for Brazil, as all citizens would have the constitutional guarantee of integral assistance to health.

In addition, such a humanistic concept of health care introduced by SUS has gathered strong popular support within the country and has also been internationally recognized as an egalitarian approach of addressing health as public policy. However, its translation in actual policies and programs has been a slow and very contradictory process. Furthermore, the ambition and magnitude of SUS principles and goals have frequently been criticized as too ideological and paternalistic.

Although the 1988 Organic Health Law has brought several different basic directions for the health system, SUS has actually been developed based on five major doctrinaire principles: universal access to health care; equality of health care; integrality of care for different levels and complexities of health needs; decentralization of planning, management and health care delivery to the municipal level; and community participation through *Conselhos Municipais de Saude*-CMSs (Municipal Health Councils), which are responsible for monitoring and assisting the planning, implementation and assessment of policies at the local level (Monteiro de Andrade, 2002). These principles are better explained in table 8.

Table 8. SUS major doctrinaire principles, Brazilian Federal Constitution of 1988

DIMENSION	GOAL
UNIVERSALITY	Universal access to all needed health-related services
EQUALITY	Equal opportunities to access health services and achieve a satisfactory health status regardless gender, age, race and political/religious choice
DECENTRALIZATION	Municipalities should have autonomy to plan and manage the local health system and respective health-related policies
INTEGRALITY	An integral assistance to health should be provided as all dimensions and complexities of health-related needs are addressed by a coordinated delivery system
SOCIAL CONTROL	Local citizens should monitor the municipal government as the *Conselho Muncipal de Saude* have control over health planning and management decisions.

The implementation of such principles has been progressive, but very inconsistent. In addition, the full achievement of some of these principles, especially universality and equality of care face major structural barriers to their full achievement such as financing, and represent major challenges for the system.

In summary, despite SUS relative success in implementing differential managerial strategies such as mechanisms of popular participation and decentralization, and legislative bills to realign and finance individual policies; it has struggled in achieving increased access to quality health care services and improved population health outcomes.

The financing of the system is primarily based on income tax and there are different obligations for each of the three hierarchical levels of the government; federal, state and municipal (Monteiro de Andrade, 2002). Given the system emphasis on

decentralization, the municipal level has acquired a progressively higher level of autonomy to plan, deliver and especially to manage health care programs and budget locally. The state government serves more frequently as a sphere of technical assistance for municipal governments and as an intermediary between local and federal government arrangements, whereas the federal government is responsible for setting the national agenda, establishing major policy directions and defining financing criteria for resource transferring to municipalities (CFB, 1998).

In general, *Secretarias Municipais de Saude*-SMS (Local Health Departments) are the agencies ultimately responsible for integrating and delivering services at the local levels. The large majority of hospitals and community health centers providing services for the system are public institutions and contract health care professionals as public workers. However, SMS can also contract services from private clinics and/or hospitals whenever it believes the public facilities do not have enough capacity to respond to the local demand.

Although SUS has been considered an important political conquer for the Brazilian population and a more dynamic managerial climate has been generated within the health care arena, its functioning has still been somewhat problematic and has generated some dissatisfaction among clients, especially because of factors affecting adequate access to services and quality of health care.

Thus, as a direct consequence of such system inefficiency, a growing private market has been established especially through independent physician associations and health insurance plans. Such a private system is primarily intended to provide complex

health care for those seeking prompt medical services and more sophisticated hospital facilities. Currently it has been estimated that approximately 90% of the Brazilian population is an eventual client of SUS, 26.5% of the population is a constant user of SUS and about 61.5% are clients of SUS and any other type of private delivery system (MS/SUS, 2003).

Given such a scenario of logistic difficulties to respond adequately to the multiplicity of health demands throughout the country and at the same time keep consistency with the SUS guiding principles, the MSB has prioritized primary health care policies during the last decade to expand access to a minimum level of health care and to consolidate the decentralization process (Bodstein, 2002).

*** The context of *Programa de Saude da Familia*- PSF foundation**

During the second half of the nineties, primary health care policies became the core of SUS efforts, policies and financial investments, as several different governmental initiatives were launched with a primary care direction such as the *Programa de Agentes Comunitarios de Saude*-PACS (Community Health Worker Program) (Boedstein, 2002; Monteiro de Andrade, 2004).

In September of 1994, the Brazilian Ministry of Health released the first official document regarding PSF. Besides describing the policy itself, it defined the details of the agreement among *Ministerio da Saude do Brasil*-MSB (Brazilian Ministry of Health), *Secretarias Estaduais de Saude*-SESA (State Health Department) e *Secretarias Municipais de Saude*-SMS (Local health Department) needed to implement PSF at the

municipal level. Such an agreement describes the requirements for enrollment, the financing mechanisms and the criteria for municipal selection. This document represents the legal hallmark of the foundation of PSF in Brazil.

Thus, in 1994 PSF arises as a national health policy within a context of institutional influences, which were the major determinants of its incorporation as a priority policy for the federal government. The Institutional Theory explains that governmental programs/policies are mostly a product of different pressures from the institutional environmental, rather than a purely technical decision towards the most cost-effective solution to identified problems (Oliver, 1991; Galvin, 2002). Such a theoretical argument is consistent with the process of PSF foundation in Brazil.

The context determining the foundation of PSF as the national model of primary health care is characterized by the SUS evolution and its respective contradictions & uncertainties; the previous experiences of innovative models of health care in Brazil; the Brazilian epidemiology profile; and the international institutional pressure for national systems of primary health care. A detailed discussion of the role of each of these contextual determinants is presented here below and summarized in table 9.

Table 9. Institutional context preceding PSF foundation in 1994.

DETERMINANT	INFLUENCE
SUS evolution	- Need of expanding access to health care - Need of consolidating decentralization - Seeking integrality of health care delivery - Effective incorporation of social control
Innovative Health Care Models * "Em Defesa da Vida" * "Ação Programática em Saúde" * "Silos"	- Tension with the hegemonic health care model - Maturation of models centered on a collective health care perspective
Brazilian Epidemiology Profile	- Need of overcoming regional health care disparities - Seeking universal improvement of population health indicators
International Context	- Popularity of international primary health care models focused on the community - Financial pressure from international health agencies

SUS Evolution: The PSF implementation occurred clearly as a consolidation strategy of SUS major guiding principles. The brief existence of SUS and the respective pragmatic conflicts originated from its innovative aspects generated an environment conducive to the implementation of health policies that could better structure its doctrinaire principles and transform them in effective action. In summary, PSF implementation represented an

opportunity to reinforce SUS guiding principles of achieving universality of access; decentralization of management and delivery duties; integrality of health care; and social control (Martins, 2003; Monteiro de Andrade, 2004).

Brazilian Innovative Health Care Models: The PSF gestation can not be simply described as a replication of international models of family health care. The PSF construction in Brazil was a slow and continuing process of tension with the hegemonic health care model, characterized by a focus on the disease instead of the individual, curative approach, physician sovereignty, emphasis on hospital care and lack of community-directed care actions (Monteiro de Andrade, 2004). Therefore, given the inability of the traditional model to adequately respond to individual and collective demands, several experiences had either a theoretical discussion or practical application that preceded and inspired the current PSF model.

Three major national initiatives seemed to have a fundamental influence on the formulation of PSF. *"Em Defesa da Vida"* (Defense of Life) proposed a assistance model based on democratic management, health as a citizen right and public health service directed to the defense of individual and collective health (Mehry, 1979). "*Açõo Programática em Saúde"* (Programmatic Action in Health) offered an innovative managerial and organizational perspective within the health care arena. It focused on the collective definition of health and on the improvement of the planning, assessment and organization practice seeking enhancement of efficiency (Schraiber, 1993; Mendes-Goncalves, 1994). However, only a program known as *"Sistema Locais de Saúde"*-Silos

(Local Health Systems) could be operationalized on a large scale. Such a proposal was focused on two basic concepts, territory and problems. It has proposed that all the health-related management and planning actions should be developed locally and aimed to better organize the supply of services and respond adequately to the identified demand (Andrade, 1992; Mendes, 1994; Silva, 1998). In summary, it was intended to reinforce the decentralization process proposed by the system.

These previous national initiatives represented a clear demonstration of public dissatisfaction with the traditional model of curative medicine and seeking for theoretical solutions centered on a more collective and holistic health care perspective. They have definitively influenced the conceptualization of the recent Brazilian primary care initiatives.

Brazilian Epidemiology Profile: The epidemiology context preceding this new national primary health care system was typical of a developing country marked by profound regional inequalities, which is characterized by important health-related disparities. In addition, population indicators of primary health care, both of access and outcome, demonstrated the lack of political commitment to health promotion initiatives (DATASUS, 2005).

During the early nineties Brazil faced a profound regional health disparity in different health dimensions such as access to care, service supply, financing and outcomes, as shown in table 10.

Table 10. Illustration of regional inequalities related to supply of health services, access to health care, health outcomes and financing (Nunes, 2001).

REGION	ESTIMATIVE
SUPPLY (Number of SUS hospital beds / 1,000 residents ; 1992)	
North	1.91
Northeast	2.87
Southeast	3.71
South	3.85
Middle-West	3.82
ACCESS (Number of outpatient appointments / resident; 1995)	
North	1.23
Northeast	1.61
Southeast	2.24
South	1.94
Middle-West	1.88
OUTCOME (Infant Mortality Rate per 1,000 live births, 1994)	
North	37.73
Northeast	61.96
Southeast	26.56
South	23.07
Middle-West	26.25
FINANCING (Average expenditure per hospital admission- R$ value in1999; 1995)	
North	202.07
Northeast	298.87
Southeast	396.08
South	411.36
Middle-West	392.94

PAHO has declared that equity in health, although fundamental to achieve an improved national health care system, represent an especially difficult action to be operationalized in Latin America (Nunes, 2001; Duarte, 2002). Thus, PSF arises supposedly as a technically feasible proposal to expand access to primary health services and potentially overcome major health disparities within the country, as its implementation was initially focused on underserved regions of the nation, more heavily in the North and Northeast regions.

International Context: The principles of the World Health Assembly in 1977, which were announced at the Alma Ata Conference, represented the first formal initiative from an international health agency in advocating for primary health policies as fundamental means to achieve better health status worldwide (WHO,1978). At this Conference, primary health care was recognized as an "integral and permanent portion of a formal health care system" (Basch, 1991).

As a direct consequence of the proposals from this Conference, several countries reorganized their respective health care services in order to consolidate the essentials of primary health care. For instance, community-oriented primary care (COPC) model has been developed mainly in underserved populations to integrate public health objectives and primary care through interdisciplinary approaches, with active involvement of the target populations (Illife, 2003). Since its inception in rural, prior to end of apartheid in South Africa, COPC has served to educate public health and primary care leaders worldwide. COPC has influenced such programs as the US community health center

movement, the general practice movement in the United Kingdom, and recent reforms in the public health system of South Africa (Mulan, 2002). In addition, other countries inverted the logic of health care professional training, opting for increasing the training of generalists instead of specialists in order to provide enough human resources for the primary health care interventions (Starfield, 1998).

At the same time, a series of evaluative studies were developed in order to better understand the impact of PHC financial investments on individual and population health indicators. The international health agencies were essentially seeking an effective model of PHC that could be reproduced in developing countries at a low capital and maintenance cost (Starfield, 1998)

Within such a process of better understanding and structuring PHC models worldwide, which was initially motivated and financed by international agencies of social development, a discussion regarding the need of establishing an effective primary health care system arises in Brazil.

*** The consolidation of *Programa de Saude da Familia*-PSF as a national model of primary health care**

Although the initial PSF implementation has been successful and has acquired a wide legitimacy as a focused health policy, there was a need of consolidating PSF as a comprehensive national PHC model consistent with SUS guiding principles. Only a large-scale implementation of a consistent PHC policy, coherent with SUS guiding

principles, could signify a real paradigm change of the Brazilian traditional health care model.

In spite of the publication of several governmental documents during the year of 1997 expressing new PSF directions as a strategy to reshape the traditional assistance model, it was not until the official implementation of the *Piso de Atencao Basica*-PAB (Primary Health Care Fund) in 1998 that such an expansion and consolidation of PSF as a national PHC model was actually undertaken (MS/Aval.Impl, 2002).

As discussed earlier in this section, instead of transferring resources locally based on the number of primary care out-patient appointments, such a financing mechanism transfers a fixed amount of resources per capita directly to municipalities, which are ultimately responsible for the entire continuum of PHC delivery. In addition, a variable amount of resources is also sent to localities to promote PSF access expansion. Thus, such a new financing system was ultimately intended to emphasize preventive and health promotion initiatives rather than simply assistance to diseases, while promoting an expansion of access to specific primary health care initiatives such as PSF (MS/SIAB, 1998; MS/PAB, 2001).

In other words, PAB implementation enabled a positive change on the primary health care practice; expanding its population access and broadening its focus of attention (MS/PAF&AB, 2002; MS/Inf.AB, 2004). In addition, PSF became an attractive opportunity for municipalities as SMS would receive financial incentives to plan, manage and deliver such a policy locally.

The steady trend of growing access to PSF throughout Brazil highlights the relevance of this primary care policy to the country. The four initial years of the program, from 1994 to 1998, are understood as a trial period during which a focused implementation characterized a governmental priority for underserved areas, especially those with poor health care capacity and geographic isolation. During this time period there was a clear trend of prioritizing municipalities with small population size, low socio-economic status and with a partially rural population (MS/Evol, 2002; MS/Aval.Impl, 2002) (see table 11).

Table 11. Evolution of the number of PSF teams, population assisted (million of residents) and percentual of population covered 1994-1998 (MS/PSF&AB,2002)

YEAR	NUMBER OF PSF TEAMS	POPULATION ASSISTED	% POPULATION COVERED
1994	328	1.1	0.7
1995	724	2.5	1.6
1996	847	2.9	1.8
1997	1,622	5.6	3.5
1998	3,083	10.6	6.5

After such a focused implementation, a large municipal enrollment in all geographic regions of the country characterized a new phase of PSF in Brazil, as it was conceived as the national model of primary health care policy. By January of 2002, there were 13,661 PSF teams covering 3,740 municipalities and approximately 29% of the national population; whereas by December of 2004 there were approximately 19,000 PSF

teams covering about 4,656 Brazilian municipalities and 37% of the national population (DATASUS, 2005). Table 12 summarizes such an evolution of PSF national coverage since 1999, stratified by geographic region.

Table 12. Cumulative PSF population coverage (%), by geographic region (1999-2004)(DATASUS, 2005)

REGION	1999	2000	2001	2002	2003	2004
NORTH	4.31	10.59	19.92	25.6	28.15	30.66
NORTHEAST	9.38	21.95	32.26	40.36	45.73	52.82
SOUTHEAST	4.38	9.81	15.45	21.45	24.8	26.72
SOUTH	3.5	11.75	21.21	25.53	32.31	35.95
MIDDLE-WEST	1.55	11.32	26.74	34.77	36.31	39.95
TOTAL (BRAZIL)	**5.45**	**13.67**	**22.13**	**28.58**	**32.85**	**36.59**

Although such an access expansion was very important, it was not homogeneous across municipalities of different population sizes. Municipalities of smaller population size tended to have higher population coverage than those with a larger population, as seen in table 13. Given the usual poorer health care capacity of smaller cities, the local implementation of PSF in those places represented an opportunity to overcome the great inability to address even basic local health care demand and possibly regional health care disparities.

Table 13. Cumulative PSF population coverage (%), by geographic region and population size in year 2004 (DATASUS, 2005)

REGION	**POPULATION SIZE (number of residents)**	
	< 80,000	**≥ 80,000**
NORTH	31.22	30.08
NORTHEAST	60.03	42.42
SOUTHEAST	46.88	18.61
SOUTH	48.76	23.25
MIDDLE-WEST	66.6	21.08
TOTAL (BRAZIL)	**52.12**	**24.9**

Concurrently to such a growing PSF population coverage over the last decade, a larger financial commitment from the federal government has occurred. A historical perspective of the total amount of resources spent by the federal government on the financing of PSF & PACS nationwide further illustrates the increasing relevance of primary care in Brazil, as shown in table 14.

Table 14. Evolution of resources applied by Brazilian Ministry of Health on PSF & PACS, 1994-2002 (MS/PSF&AB, 2002)

YEARS	R$ (MILLIONS)
1994	55.8
1995	78.6
1996	11.8
1997	161.4
1998	225.6
1999	323.9
2000	655.5
2001	986.5
2002	1.300

In order to better illustrate such a financial commitment, this section provides an estimation of the average annual federal cost for each PSF team. Based on the details of the PAB financial mechanisms presented previously in this section, and assuming that each team covers in average 3,450 individuals, a conservative estimation of the total annual federal investment on PSF is shown below (MS/Custos, 2001):

Type of Cost:	**R$***
FIXED PAB (3,450 x R$ 10**)	= 34,500
VARIABLE PAB	= 28,808 to R$ 54,000
FOUR to SIX CHWs	= 8,800 to R$ 13,200
PRIMARY CARE PHARMACY (3,450 x R$ 1)	= 3,450
AVERAGE COST OF VACCINES/yr	= 2,532
AVERAGE COST OF EXAMS/yr	=13,582

TOTAL: Minimum: R$ 74,758/yr + vaccines + exams = 90,874

Maximum: R$ 105,150/yr + vaccines + exams = 121,266

* U$ 1,00 is equivalent to approximately R$ 2.3

** It was assumed the lowest per capita value the federal government can transfer to municipalities as the PAB fixed component

PS: It has been not included the incentive (R$ 10,000/team/yr) for the implementation of each new PSF team

Therefore, assuming that the average annual cost of a PSF team has been estimated in R$ 214,836 and the MSB finances a maximum of R$ 121,266 (including vaccines and exams), the federal government is responsible for approximately 56.4% of the total PSF financing. The remaining costs, about 43.6% of the total, are financed by municipal and state governments. Such resources are usually directed to complement health professional salaries; maintain equipment; provide physical infrastructure; guarantee availability of drugs; train team members; and make overall investments (MS/Custos, 2001).

However, after PAB implementation and its consecutive impact on the consolidation of PSF as a comprehensive PHC policy, new challenges were imposed to the management of PSF such as duplication of philosophy of care, lack of local health care capacity and restricted access in large urban areas (MS/PROESF, 2002).

Therefore, in order to overcome such barriers that were preventing the further consolidation of PSF, a series of national policy initiatives were implemented, these include establishing continuing education mechanisms for managers and health care professionals in order to guarantee consistency within policy organization, directions and

goals among different municipalities nationwide; promoting the organization of regional networks of health care delivery among contiguous municipalities in order to improve the limited capacity of some municipalities and an appropriate response to the municipal demand load; and expanding access in large urban areas.

A description of the historical evolution of PSF in Brazil, detailing hallmark events, since its initial formulation until the implementation of more recent policies has been summarized as appendix.

2. THEORETICAL FRAMEWORK:

Programa de Saude da Familia-PSF & Infant Health

2.1 PSF & Infant Health: Current Body of Evidence

It has been scientifically established that effective primary health care systems have a positive impact on population indicators of infant health, as it has an influence on different dimensions of children health, especially on the accessibility to essential preventive and promotional maternal and child health services (Macinko, 2003; Moore, 2003).

Several international ecological studies have attempted to address the association between primary care systems and population indicators of infant health. These ecological studies have supported the existence of such an association as they assessed the relationship between primary care practices and indicators of child health, mostly comparing the strength of primary care direction and/or availability of primary care personnel among different geographic areas (Starfield, 1998; Macinko, 2003; Moore, 2003; Villalbi, 2003; Shi, 2004).

For instance, Starfield et al established a comparison among twelve developed countries regarding the strength of the primary care direction of their respective national health systems and its potential association with global indicators of health. Such a study identified that the benefits of a strong primary health care orientation were striking and higher for the younger population, especially among those within the infancy and the

school age group. For instance, countries with stronger primary health care systems tended to have better low birth weight and postneonatal mortality rates (Starfield, 1998).

Furthermore, Moore et al utilized aggregated data from the World Bank and UNICEF in order to identify factors, both within and outside the health care system, associated to childhood mortality rates in 22 countries of Latin America and the Caribbean during the 1990s**.** Three of the five factors that were found to be independent predictors of lower childhood mortality rate are fundamental elements of primary care systems; immunization coverage, use of oral rehydration therapy and access to safe water (Moore, 2003).

Villalbi et al have developed an evaluation of the impact of the primary health care reform in Barcelona on the population health. The authors also established an ecological comparison of mortality rates for the 1984-96 period in twenty three areas of Barcelona, which were divided in three major zones of homogeneous socioeconomic level. They have developed an uncontrolled pre- & post-comparison of population health outcomes in all three areas. It was found a clear association between the consolidation of primary care services and reduction of perinatal mortality in all three zones of low socioeconomic level. Authors suggest that such a primary care reform might have impacted perinatal health of the population of lower socio-economic status (Villalbi, 2003).

A different approach was utilized by other authors who have compared the level of local access to primary care professionals and population indicators of health (Shi, 1994). For instance, Shi established a comparison between the proportion of primary care

physicians of different geographic regions and the respective population health indicators, including neonatal mortality rate and low birth weight rate, as coefficients of linear correlation were estimated. It was identified that primary care is correlated to better overall health status, and slightly associated to lower neonatal mortality rate and lower low birth weight (Shi, 2004).

Another ecological study utilized pooled cross sectional design, time series analysis of secondary data (1985-1995). It assessed the extent to which primary care physician supply moderates the association between social inequalities and infant mortality and low birth weight throughout the 50 U.S. states. It identified that an increased supply of primary care practitioners-especially in socially unequal geographic areas-is negatively associated with post-neonatal infant mortality rate and low birth weight (Shi, 2004).

Although such international studies present appealing evidence in favor of a positive effect of PHC on population health outcomes and the Brazilian governmental agencies have claimed a beneficial impact of PSF on child health, the influence of this Brazilian primary care policy on health outcomes has not still been scientifically studied. Only a few studies have actually attempted to explore the potential impact of PSF implementation on population health outcomes (MS/Aval.Impl, 2002; Connil, 2002; Moura, 2003; MS/Aval.Norm, 2004; Araujo, 2004). Most of these previous evaluative initiates have consisted of either governmental formative evaluations of the PSF at the national level or qualitative assessments of the process of PSF implementation in focused localities.

For instance, the Brazilian Ministry of Health conducted a formative evaluation during years 2001 and 2002, which was primarily concerned with the impact of PSF implementation on the access to routine primary care services (MS/Aval.Norm, 2004). It was identified that approximately 54% of the PSF teams throughout the country performed medical appointments to monitor children (under 2 year old) growth and development; 64.1% of them delivered the children immunization schedule proposed by the *Programa Nacional de Imunizacao*-PNI (Immunization National Program); 86.5% delivered medical appointments to assist prevalent illnesses of childhood (e.g. diarrhea and acute respiratory infection); 89.6% assessed nutritional status of covered children and 70% of them performed medical appointments for undernourished children; 70.5% provided family planning counseling to women in reproductive age and 70% distributed contraceptive methods locally (MS/Aval.Norm, 2004).

Another national formative evaluation of the impact of PSF on primary care indicators nationwide was conducted in 2002, which identified increased national access to essential maternal and child health services and improvement on specific population indicators of child health (MS/Aval.Impl, 2002).

For instance, the absolute number of pre-natal appointments in municipalities with a PSF population coverage over fifty percent, increased from 227,990 to 322,606 from 1999 to 2001; and approximately 65.6% of the pregnant women living within areas covered by PSF were initiating their pre-natal care within the first trimester of the pregnancy. In addition, the prevalence of nutritional & protein malnourishment among infants (under 1 year old) decreased from 9.53% to 6.63% within areas covered by PSF

during the same time period. Finally, the infant mortality rate within areas covered by PSF has decreased from 37.4 to 31.4 deaths per 1,000 live births within the same period of time. In addition, such a positive change of IMR in PSF areas was largely due a relevant reduction on infant deaths caused by either diarrheal diseases (6.47 to 4.15 deaths per 1,000 live births) and acute respiratory diseases (4.54 to 3.38 deaths per 1,000 live births) (MS/Aval.Impl, 2002).

Furthermore, Moura et al have developed an analysis of the quality of prenatal care provided in a micro-regional health system in the State of Ceara, Brazil. Such a study utilized data from different sources such as review of patient records, direct observations and Ceara State health care information systems, and was primarily aimed to assess the population of pregnant women covered by PSF teams. It identified that a high level of PSF coverage in those areas was associated to increased access to pre-natal care, higher numbers of prenatal appointments, improved vaccine coverage, and early diagnosis of pregnancy complications among the studied locations (Moura, 2003)

Morever, Araujo et al discussed practices developed by community health centers in the *Programa de Saude da Familia*-PSF of Divinopolis—MG, specifically on the areas of health promotion and disease prevention, including those related to maternal and child health. Authors utilized different methods of data collection such as survey, direct observation of work and open interviews with community health workers. It was concluded that community health centers were appropriately compliant with MSB health promotion and disease prevention directions. However, there is a special emphasis on

specific disease prevention programs, individual actions and health education for groups at risk (Araujo, 2004).

Finally, Connil et al established a discussion regarding the evaluation of primary health care policies based on a case study of the *Programa de Saude da Familia*-PSF in Florianopolis, Santa Catarina, Brazil (Connil, 2002). Authors present two different dimensions of perceptions regarding accessibility and comprehensiveness of PSF. It was assessed from the perspectives of the administrative personnel involved with the policy and also from a sample of five PSF teams. Then, it was created a three item scale to rank the two dimensions of access (physical and psycho-social link between community & human resources) and two of integrality of care (comprehensiveness and continuity). The physical access was considered adequate; however there were concerns about the psycho-social linkage with the local communities, as it was assessed as inadequate. The comprehensiveness of care was considered adequate, whereas continuity of care was assessed as moderately adequate. There were also concerns regarding the reference to other more complex levels of care and with the regularity of home visits. Finally, it was concluded that PSF has been useful to redefine the national health care model towards more rationalization and democratization of services (Connil, 2002).

Although such studies indicate an overall benefit on the access to essential PHC services and on some health outcomes, when establishing before and after policy implementation comparisons, there is not agreement over the positive impact of the policy on population health yet. Since all of these previous PSF studies were descriptive by nature, there is a lack of quantitative scientific approach to better understand the

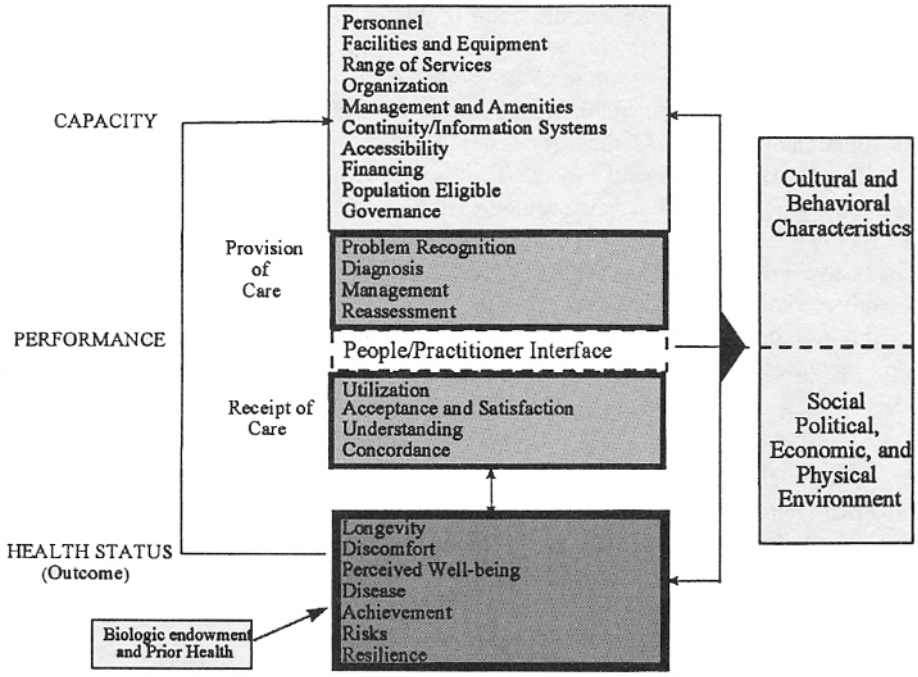
population-based effects of the implementation of this primary health care policy on health outcomes, particularly on aggregated outcomes of infant health.

2.2 The Theoretical Framework

Typically, program evaluation models are primarily intended to identify the outcomes of specific public programs and require the measurement of the level of attainment of selected program goals and objectives. Since policies are usually compared in relation to evaluation criteria associated to policy goals (e.g. impact on indicators of global health), such type of evaluation research is mostly concerned with health outcomes. However, "process" and "structure" information are also important to understand the extent and quality of policy implementation process (Hass_&_Springer, 1998). In summary, "structure" and "process" information are important to improve and refine on-going programs, whereas "outcome" information is fundamental to ascertain the effectiveness of implemented policies.

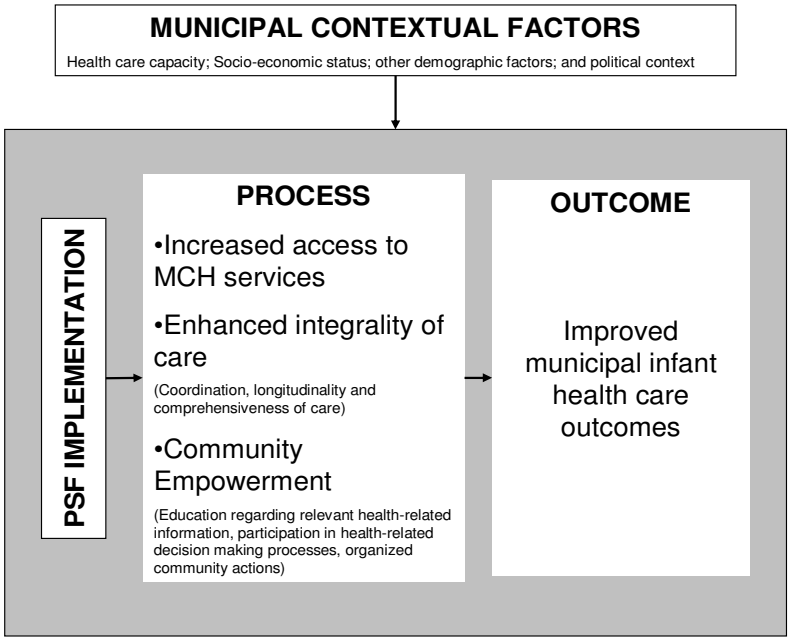
Although "structure' and "process" evaluations are important to provide a comprehensive analytical perspective of a given health policy, other authors have highlighted the unique importance of assessing outcomes since they are ultimately intrinsically related to a set of structural and process factors producing them (Perrin, 2002); thus representing fair proxies of policy overall success. Starfield has developed a didactic illustration of the different components of health care systems and how health outcomes are associated to structural and process factors within the health care arena, as presented in figure 2 (Starfield, 1998).

Figure 2. Structure (capacity), process (performance) and outcome components of health care systems (Starfield,98)



Particularly this research study is essentially concerned in assessing the impact of a primary care policy on municipal outcomes of infant health. In other words, it is aimed to understand the effects of PSF municipal implementation on aggregated indicators of infant health, given the impact this policy on three processes potentially leading to improvements on infant health. A logic model was developed to provide a theoretical explanation for the mechanisms influencing such beneficial effects on the health of infants living in areas covered by PSF, as shown in figure 3.

Figure 3. Logic model proposed to explain PSF impact on infant health outcomes at the municipal level.



Primary care interventions in underserved areas might increase access to essential health care services, enhance coordination and longitudinality of care and also impact the level of community awareness regarding local health issues (Muller, 80; Roemer, 86; Starfield, 2002). Thus, it has been assumed that PSF implementation positively influences population indicators of infant health through three major channels; increasing access to fundamental maternal and child health-related services, improving integrality of care and impacting community empowerment over health-related issues.

In addition, such PSF effects on infant health outcomes, moderated by those processes, appear to be influenced by several contextual characteristics such as municipal

health care capacity, socio-economic status, other demographic characteristics and political context. As well covered by previous authors, infant health outcomes are commonly a result of the influence of several dimensions of health determinants, including those from political and social nature (Avery 1992; Bird, 1998; De Mendonca 2002; Ahmed 2002), which might moderate the impact of health policies directed to impact infant health (Dillon, 2003).

Furthermore, this research study suggests that PSF has not only a short-term impact on infant health, through an initial expanded access to primary care services in areas lacking such services, but also a sustained effect as it promotes conditions for the system to deliver integral health care to covered families and to partner decision-making processes with respective communities, especially when direct mechanisms of community participation are developed. For instance, previous studies have found that simple expansion of the availability of health care providers is associated to short-term increased access to primary care services and improvements on health outcomes (Starfield, 1992; Shi, 1994; Shi, 2001), however it seems that the such an impact will rely on the opportunities created to offer enhanced integrality of care and community participation (Starfield, 1992; Goya, 2003; Martins, 2003).

From an evaluative perspective, increased access to MCH services, community empowerment and integrality of care are fundamental PSF processes indicating satisfactory policy implementation and ultimately necessary to impact health outcomes, however it might be influenced by the socio-economic and political context of each

municipality. Each one of these factors presented on the logic model is further discussed here below:

Increased Access to MCH services: As presented in table 4, PSF is responsible for providing local access to essential maternal and child health services that are needed to impact child health outcomes. However, access to health care services depends not only on the availability of human and material resources, but on the manner in which these resources are allocated to the population (PAHO, 1993). In other words, the simple presence of health care facilities and health professionals locally does not guarantee adequate access to essential MCH services. Two major barriers of access need to be overcame in order to effectively impact the local patterns of health service utilization; physical and socio-cultural.

As PSF establishes local infrastructure and provides health care at the community level, it supposedly overcomes major physical barriers of access to basic MCH services, especially in geographically isolated communities lacking appropriate road access and any other type of health care facility. In addition, PSF has proposed a new model of health care, which is aimed to partner health care planning responsibilities with the local communities, develop cultural sensitive interventions and closing ties between health care professionals and covered population. Thus, it is expected to develop health care services and interventions that are consistent to community real needs and are considered culturally and socially acceptable. In summary, local PSF implementation address major

geographic and socio-cultural constraints of access to MCH services, especially for isolated communities.

Finally, since a national trend for covering preferentially disadvantaged population groups has been identified, such a focused PSF implementation also plays a potential role in diminishing major disparities in access to basic primary care services, especially in municipalities with large rural areas and geographically distant from major health care centers.

Enhanced integrality of care: Primary care system is considered integral as health care professionals are able to share health-related information and fully integrate health assistance at different levels of care; individuals and communities are followed-up prospectively by the same team of professionals; and the system can either directly address all the community and individual health needs or refer that to other facilities and/or professionals. It is a consequence of an appropriate level of coordination, longitudinality and comprehensiveness of care.

As PSF has been implemented in municipalities, there has been occurring a reorganization of local health care systems. As each team control referrals to other levels of health care, follow-up the outcome of such referrals and coordinate the local database containing client records of health care service utilization and health-related outcomes; they essentially take full responsibility for coordinating the entire spectrum of health care needs of their respective covered populations.

In addition, the establishment of stable relationships between health care providers and community members is supposedly one of the major characteristics of this policy, as PSF providers should work full time and live in the municipality they cover, in order to strength linkages with local families. Such sustainable relationships are more likely to generate positive responses from the clients regarding health care recommendations. In addition, this policy recommends longitudinal health assistance to family members and especially to children, from birth to adult life, which also is conducive to long-term follow-up of individuals and respective families. Hence, both closer and more durable patient-provider relationship and long-term follow-up of covered families represent two fundamental features of longitudinality of care, which plays an important role in determining integral assistance to children.

Finally, comprehensiveness of care represents essentially the guarantee of response to the large majority of community- and individual-specific health needs. Besides the direct provision of MCH services at the local level and the referral to needed MCH services in other facilities, such a model of primary care also address important dimensions of community health. Thus, since PSF provides a comprehensive package of primary care services that affects multiple dimensions of infant health; it might have a positive influence on infant health outcomes.

Community Empowerment: Community empowerment allows sufficiency within the process of recognizing factors affecting their lives and also ability to gain access over power and other mechanisms that enable them to transform their realities. In addition, it

might impact the sustainability of policies considered effective and the generation of their own strategies to deal with identified problems (Matins, 2003; Goya,2003).

Within the health care arena, community empowerment might be beneficial to health outcomes as community members acquire knowledge and develop awareness regarding health issues affecting them; have active participation within health care decision-making processes; monitor the quality of health care delivered locally and are able to take collective actions to address relevant health problems such as the development and reinforcement of familial and/or social networks to impact specific health problems.

Community empowerment might be forged within areas covered by PSF as it is required the existence of a CMS in every municipality applying to PAB; the municipality must submit a municipal health plan that should be developed collectively; community health workers are usually recruited from informal leaders of local communities; and several other mechanisms of direct community participation are promoted to facilitate the delivery of services to specific population groups, the provision of health promotion programs and the assessment of the appropriateness of local primary care interventions.

In summary, since the implementation of this policy promotes effective decentralization of health-related decisions to the community level and active community participation on the planning and monitoring of health policies, it might promote community empowerment within these health care areas. Moreover, community empowerment seems especially relevant for maternal and child health issues, since empowered communities commonly utilize social networks of women in order to support

pregnant women and children obtaining adequate nutritional intake, emotional and social support, and physical resources in order to guarantee adequate infant survival and development. In other words, it might address other important determinants of infant health not directly influenced by the increased access to health care such as political, social and environmental ones (Ehiri, 1999).

Contextual Factors: Such factors are those not within the causal pathway leading municipalities implementing PSF locally to impact their respective infant health outcomes, but rather are municipal contextual conditions influencing population indicators of infant health in areas covered by PSF.

For instance, overall indicators of municipal health care capacity (e.g. physicians per capita, number of hospital beds per capita, number of intensive neonatal care beds per capita and health care expenditure per capita) are considered a direct determinant of aggregated outcomes of infant health (Berkman, 1990). Besides such a direct influence, it might also mediate the impact of PSF on infant health. Since this policy is supposedly responsible for reorganizing the local health care demand, a local supportive referral system is needed to respond to the emergent secondary and tertiary demand that arises in consequence of PSF coordination of care. Therefore, the existence of such a supportive system affects the coordination and integration responsibilities of the PSF and ultimately the continuum of infant health care delivery.

In addition, aggregated proxy measures of SES (e.g. per capita income, income Gini coefficient and educational attainment level) are also considered major direct

determinants for several different indicators of child health (Berkman, 1990). In addition, the level of socio-economic development of a given municipality may affect the manners which PSF teams are implemented locally. For instance, municipalities of low SES might face more serious infant health challenges and usually find difficulties in guaranteeing adequate physical infra-structure for primary care services and sustainability of working contracts with health care professionals, thus affecting the organization and delivery of PSF services.

Other municipal demographic characteristics seem to exercise an important influence on the successful achievement of child health outcomes in areas covered by PSF, at least from a short-term perspective. For instance, population size, geographic location and proportion of the total population living in rural areas are examples of such contextual demographic characteristics. The benefits of PSF are believed to be stronger in municipalities of small population size, located in North and Northeast geographic regions and with a large portion of its population living in rural areas.

Such areas typically have major problems of access to health care services and at same time seem to have developed different channels of community mobilization and actions to mitigate the perverse effects of poor access to health care. Thus, PSF implementation in those areas represent an opportunity to increase access to health care, organize the local health care system and reinforce such mechanisms of community participation within the health care process. However, from a long-term perspective, these municipalities would still need to address improvements on local health care

capacity in order to guarantee a more integral level of health care and consequently sustain the beneficial impact of PSF on population health outcomes.

Finally, since the initial implementation of PSF and its respective management are fundamentally political decisions of the municipal authority, the successful implementation and consolidation of this policy will strongly rely on the local political climate. For instance, the municipal authority leadership role, previous political capital and existence of mechanisms of citizen participation might definitively impact the processes of direct community participation, establishment of the CMSs and ultimately the organization of culturally specific health care interventions. Thus, such local political climate seems to exercise an important influence on how PSF implementation might actually attain community empowerment and overcoming socio-cultural barriers of access to MCH services. In addition, the personal behavior and attitude of the Head of the SMS towards consolidating primary care locally is also a fundamental determinant of PSF success (MS/GUIA, 2003).

3. METHODOLOGY

3.1 Methodology Overview

This study is essentially a longitudinal study of the health impact of a primary heath care policy, focused on outcome evaluation of PSF at the municipal level. It is particularly intended to investigate whether PSF implementation in Brazilian municipalities has changed aggregated outcomes of infant health at the municipal level or not, and under which circumstances it is more likely to succeed. The infant health outcomes monitored as indicators of primary care by the MSB were primarily focused in this research project, such as infant mortality rate, neonatal mortality rate and low-birth weight rate. In addition, indicators of access were also studied such as proportional coverage to specific maternal and child health services.

This study has used a longitudinal analysis of secondary data from a sample of Brazilian municipalities selected from the *Pacto de Atencao Basica*-PAB (Primary Care Agreement) database. Such municipalities had their infant health outcomes recorded during the period 1999 to 2002. Data came primarily from different MSB information systems, and also from *Instituto Brasileiro de Geografia e Estatistica*-IBGE (National Institute of Geography and Statistics) databases. These two distinct national databases containing the variables of interest were then converted into a single database that was utilized for analytical purposes. Finally, an ecological approach was utilized as the analysis was conducted in order to establish inter-municipal comparisons of the policy impact on aggregated outcomes of infant health.

3.2 Evaluation Research Framework

Health care interventions are usually complex, multidimensional and context dependent. The evidence for their effectiveness should be compelling and comprehensive enough in order to encompass such a level of complexity (Rychetnik, 2002). Thus, sound epidemiologic and evaluative research approaches are essential for national health care systems to better monitor and assess the outcomes of health policies for optimal allocation to improve health planning and management processes.

Such evidence-based approaches have gained increasing relevance especially within international agendas for health policy and health service research. For instance, as improvement of indicators of population health became a major goal within the health policy arena, evidence-based approaches have provided the necessary information and methodological tools to help set health policy priorities influencing such indicators (Niessen, 2000).

In general, evaluation processes in health research have become a fundamental managerial mechanism to better understand the impact and usefulness of different policy initiatives influencing health outcomes. Rossi & Freeman (1993) have defined evaluation research as the "…arena of activity directed at collecting, analyzing, and interpreting information on the need for, implementation of, effectiveness and efficiency of intervention efforts". It is usually conducted to assess the progress of on-going programs; assess the utility of new initiatives; enhance the management knowledge and methods of

on-going programs; and attain the accountability requirements of sponsoring agencies and societies in general.

Policies in general can be analyzed before they are undertaken or after it has actually been implemented. This former prospective form of policy analysis, known as *ex-ante*, essentially compares the potential impact of different health policy options on multiple dimensions of interest. It serves as a fundamental tool to guide decision-making process, as it enhances the understanding about the issue in question and its respective policy choices. The latter mode of retrospective analysis, called *ex-post* analysis, aims to identify and compare the outcomes of specific policies/programs (Patton_&_Sawicki, 1993; Hass_&_Springer, 1998). It seeks either the comparison of different policy options in respect to the attainment of the same set of goals after their actual implementation or the assessment whether a single policy option has achieved the prescribed goals/objectives or not (Hass_&_Springer, 1998). The utilization of both modes of policy analysis has greatly impacted the quality and effectiveness of public programs throughout the world (Hass_&_Springer, 1998). This study utilizes retrospective longitudinal analysis.

The process of establishing the evaluation criteria is a particularly critical aspect of this policy analysis process. Such criteria are commonly a function of the nature of the problem and policy purpose, and should be developed in concert with population groups and individuals involved in the decision-making process (Patton_&_Sawicki, 1993; Bardach, 1977).

The purpose of the evaluation research, which can be distinguished in three major classes: *Analysis related to the design of interventions*; *monitoring of program implementation* and *assessment of program effectiveness*. The first serves to better understand and define the policy issue in order to design appropriate interventions. The second is basically aimed to understand the efficiency of the implementation and management process such as actual utilization of resources, number and diversity of services delivered and other measures of operational effectiveness. The third is critical to determine whether the policy attains the expected outcomes or not, and has also been known as summative evaluation (Rychetnik, 2002).

The later purpose of evaluation, the assessment of program effectiveness, has frequently been the core of policy analyses within the health care arena, especially those concerned in understanding the appropriateness of different health policies. In addition, three major dimensions of policy effectiveness have been used by previous assessments; efficiency, utility and impact (Rossi&Freeman,93). Efficiency and utility have more commonly been utilized as criteria to select health policies *a priori* among a set of potential alternatives, whereas the assessment of policy impact has been frequently utilized to assess the extent to which a program has caused changes in the desired direction (Rossi_&_Freeman, 1993).

In order to summarize the different definitions and modes of health policy analysis, table 15 presents distinct types of policy analyses based on its temporal perspective, purpose of the evaluation and measure of effectiveness.

Table 15. Classification of health policy analysis based on three different dimensions

DIMENSION	TYPE OF HEALTH POLICY ANALYSIS
TEMPORAL PERSPECTIVE	*Ex-ante*
	Ex-post or Program Evaluation
PURPOSE OF THE ANALYSIS	Analysis related to the policy design (Diagnostics)
	Monitoring of implementation process (formative evaluation)
	Assessment of program/policy effectiveness (summative evaluation)
MEASURE OF EFFECTIVENESS	Efficiency
	Utility
	Impact

Assessments of the impact of health policies have been particularly used when there is a specific interest in understanding the influence of a given policy/program on the causality/prevention of a specific set of health outcomes. In other words, it might determine if a policy has contributed to improve certain health-related evaluation criteria. In summary, the major purpose of such type of assessment is to influence decision makers as it provides information about the potential positive and negative health-related impacts of the policy (Quigley, 2004).

In general, a large portion of previous initiatives to evaluate health care system performance and/or specific national policies have utilized an *ex-post* framework and have been interested in assessing the effectiveness of such health system changes and/or

specific policies, mostly utilizing the impact dimension. Most of these previous large-scale evaluative attempts were program evaluations (*ex-post* analysis) focused on the policy impact on specific population-based indicators of health (Macinko, 2003; Shi, 2004).

Since this study is aimed to understand and estimate the four-year impact of PSF implementation on population indicators of infant health, it has essentially established an *ex-post* policy analysis with the major purpose of assessing a specific dimension of policy effectiveness; impact on infant health. The remaining of this section will further explore the fundamental role of the epidemiology discipline within the health policy analysis process.

*** Epidemiology & Program Evaluation**

The development of "causal" research within the analysis of health policies requires a methodological approach that allows appropriate investigation of the health policy or its respective constituents as potential risk or protective factors for specific health outcomes. Epidemiology provides such a methodological framework for assessing the determinant role of health policies/programs on population health (Greenland, 2005).

For instance, analytical epidemiology studies are concerned in identifying the determinants of health events within different population groups. One set of relevant determinants includes policies that organizations and societies follow in order to achieve expected goals (Koepssel_&_Weiss, 2003). Therefore, epidemiology contributes to understand and estimate the potential causal role of different health policies on

population health (Rothman, 2002)(Koepssel_&_Weiss, 2003). Such a convergence of goals and common proposals between analytical epidemiology and health policy analysis focused on outcome evaluation has been highlighted by other scholars (Matida, 2004)(Greenland, 2005).

Moreover, epidemiology has been used as an approach to assess health policies in two major scenarios, when exposure to the policy/program varies within the subgroups being compared or when it is assumed that there is little or even no variation in exposure within the studied subgroups. For instances, policies of major scope (e.g. DUI regulation, health system reform) are typically an example of the latter. In such situations, specific epidemiology methods address preferentially the overall impact of policy implementation on aggregated health outcomes, rather than assessing the association between the individual level of exposure to the program/policy and individual health outcomes (Koepssel_&_Weiss,03).

In this case, a retrospective *ex-post* analysis of a health care policy that varies within sub-group has been conducted; it focused on the assessment of effectiveness (e.g. impact on health outcomes) that utilizes the analytical epidemiology framework in order to understand the potential policy impact on population health. Table 16 summarizes the characteristics of the method of analyzing health policy utilized by this research study.

Table 16. Characteristics of the health policy analysis utilized by this research study based on the different analytical dimensions

DIMENSION	TYPE OF HEALTH POLICY ANALYSIS
TEMPORAL PRESPECTIVE	Retrospective *(Ex-post* analysis and evaluation)
PURPOSE OF THE EVALUATION	Assessment of policy effectiveness
MEASURE OF EFFECTIVENESS	Impact on child health outcomes
CAUSAL RESEARCH	YES (Hypothesis: PSF has a positive epidemiologic impact on aggregated outcomes of infant health)

3.3 Population Indicators of Infant Health

Population health indicators, as classified by Larson, could be distinguished in two major classes, proximal and distal health indicators. They are respectively characterized by either directly measuring health-related events (e.g. death, disease, proxy measures of health status and/or utilization of health services) or indirectly measuring that (e.g. educational attainment level, poverty levels, access to safe water and sanitation) (Larson, 2004). The definition clarity and straightforward interpretation of proximal indicators make them much more appealing whenever there are information systems in place that allow their adequate utilization in the analysis.

In addition, in order to measure the impact of health services & policies on population health, it has been proposed the utilization of health indicators based on preventable mortality, especially those medically evitable (Gomez-Rodriguez, 1996; Villalbi, 1999; Passarin, 2002). The utilization of such indicators in relation to territorial units is present in different processes of health policy evaluation (Gomez-Rodriguez, 1996; Juncosa, 1999; Passarin, 2002).

Population indicators of infant health are particularly important to assess the health status of children up to 1-year old within specified population groups to determine the allocation of health–related resources to address determinants of infant health and to monitor the impact of health policies and programs aimed to influence different dimensions of infant health.

Such measurements are relevant for two reasons: first, because infants are not able to act as self-advocates, particularly at the population level; and second, because

their health ultimately shapes the future population health status (Rigby, 2004). In addition, there is a broad recognition of the importance of obtaining improved reports of infant health status, especially in a systematic, population-based manner (Riley, 2004). In summary, this study utilizes population indicators of infant health that have been important for recognizing problems and priorities, and are important for monitoring trends over time within different population groups in Brazil (Rigby, 2004).

An in-depth classification of such indicators of child health was presented by the European Community Health Monitoring Program-HMP, as it classified each child health indicator based on its respective dimension of impact on health (e.g. determinant, process or outcome) (Rigby, 2004). Additionally, for each of the three dimensions, indicators were further classified in four major categories (Demographic & Socio-economic; Child Health Status & Well-being; Health Determinants, Risks, and Protective Factors; and Child Health System & Policies), as shown in table 17.

Table 17. HMP Child Health Indicators of Life & Development, classified by their respective health-related dimension (Rigby,04)

DIMENSION	CATEGORY	INDICATORS
OUTCOME	**Child Health Status & Well-being**	Child Mortality Child Morbidity Injuries to Children Mental Health
	Health Determinants, Risks, and Protective Factor	Child Lifestyle Determinants
PROCESS	**Child Health System & Policies**	Health Policies Health System Quality (e.g. number and quality of pre-natal care appointments and neonatal care process
DETERMINANTS	**Demographic & Socio-economic**	Children in Poverty Parental Educational Attainment Children in Single Parent Household Other socio-economic factors
	Health Determinants, Risks, and Protective Factors	Parental Determinants (e.g. breastfeeding, household environmental tobacco…)

	Child Health System & Policies	Social Policies (e.g. anti-bullying policies in schools) Physical Protection Policies (e.g. child transportation safety, exposure to lead)

Such a need of using indicators for assessing and monitoring child health is especially critical for developing countries that still face major challenges to even provide basic maternal and child health services and decent protection to children's health. Such countries still struggle in guaranteeing even the most essential sort of primary care services such as antenatal care, and consequently face very poor children health status. For instance, Pan American Health Organization-PAHO has reported that women and children are the most vulnerable family members in Latin America and the problem of maternal and child health is considered an especially important one in this continent (PAHO, 1979)(PAHO, 1993).

Hence, a series of population-based infant health indicators have been consistently utilized to assess the performance of national health systems and monitor the impact of maternal and child health policies worldwide. The feasible estimation, unambiguous definition, consistency and validity of such infant health indicators have provided an opportunity to establish comparisons among diverse population groups.

Infant mortality rate (IMR), neonatal mortality rate (NMR), low birth weight rate (LBWR) and proportional population coverage to maternal and child health services (e.g. first trimester entry into prenatal care, exclusive breastfeeding until either 4 or 6 months

old and compliance with immunization schedule) are indicators that have been largely used across different groups in previous studies (Martens, 2002; Cesar, 2002; Dillon, 2003; Chang, 2003; Kvale, 2004; Rigby, 2004; Ahmed, 2004; Larson, 2004; Bhutta, 2005).

As PSF has been implemented throughout Brazil, a set of primary care indicators have been monitored at the municipal level in order to assess the local impact of the policy on population health. Infant mortality rate, neonatal mortality rate, low birth weight rate and proportional coverage to specific health services are among such a set of primary care indicators. The remaining of this section will further explore such infant health indicators, focusing on the explanation of its estimation method and causal determinants.

*** Infant Mortality Rate (IMR)**

Infant mortality rate along with life expectancy and years of potential life lost have been frequently used to assess the level of human development and the health status of different geographic areas worldwide. It is simply defined as the probability of dying within the first year of life. In reality, newborns are not followed-up prospectively for the occurrence of death up to 1 year of age. Alternatively, IMR is calculated on the basis of the number of reported infant deaths during a calendar year divided by the reported number of live births occurring within the same time period (Larson, 2004). It is actually a ratio that is commonly presented as “rate” per 1,000 live births. For a given year, IMR is estimated as presented in the following formula (Larson, 2004):

IMR = (number of deaths from 0 to 365 days of life / number of live births) x 1,000

Infant mortality has declined substantially over time both in developed and developing worlds (Kramer, 2003). The major determinants of change included focused improvements on the social-political climate, enhancement of neonatal intensive care, control of infectious diseases, appropriate management of prevalent childhood diseases (e.g. oral hydration for diarrheal diseases), better comprehension regarding nutritional requirements of preterm infants and knowledge about events around the time of birth. Moreover, an increased awareness about the advantages of breastfeeding for the newborn infant and the importance of maternal bonding and involvement of both parents in care of the infant have been considered important in impacting IMR over the last decades(Lithell,91). Finally, improvements on the prenatal diagnosis technology have also impacted child survival as some serious disorders of the fetus could receive early diagnosis (Lithell, 1991)(Avery, 1992).

However, there are still large infant mortality inequalities among different geographic regions of the globe (Kramer, 03)(Larson,04). For instance, WHO figures indicate that about 95% of the world's infant deaths take place in developing countries (Dicfalusy, 1992). IMR is about 6 per 1,000 live births in Canada, while it may reach over 100 per 1,000 live births in some sub-Saharan African countries (WCF, 2001). Unsafe occupational conditions; the large amount of women and children living in poverty; adolescent pregnancy; the increasing number of women with acquired immune

deficiency syndrome; the effect of population and immigration trends; and the lack of adequate reproductive and neonatal care technology appear to exercise a fundamental role in sustaining such profound disparities among nations (Quimby, 1994).

As mentioned earlier, infant deaths are associated to a multitude of factors including familial socio-economic status, maternal risk factors, newborn characteristics and risk factors, and health system/service organization. Such risk factors are better explicated in table 18. Among all the specified risk factors, birth weight is identified by several authors as the most important predictor of infant survival; survival increases exponentially as birth weight increases to its optimal level (Hogue, 1989).

Table 18. Major factors associated to infant deaths, classified by respective health dimension (Hogue, 1989; Lithell, 1991; Avery, 1992; Dicfalusy, 1992; Pires, 1992; Quimby, 1994)

DIMENSION	FACTOR
Familial SES	-Parental educational attainment level -Household income level -Household/neighborhood sanitation facilities & water quality -Access to health insurance

Maternal risk factors	-Reproductive history (e.g. Age of pregnancy[4], number and outcome of previous pregnancies[5]) -Personal behavior (e.g. alcohol, tobacco smoking, illegal drugs) -Malnourishment -Infectious diseases (e.g. AIDS, STDs…) -Pregnancy-specific conditions (e.g. gestational diabetes, hypertension) -Other concurrent health conditions
Infant characteristics and risk factors	-Birth defects -Low-birth weight (< 2,500 grams) -Prematurity (< 37 weeks of gestational age) -Birth order[6] -Inadequate breastfeeding -Familial instability and lack of parent-child bonding -Perinatal complications -Diarrheal and respiratory conditions -Malnourishment - Common neonatal conditions (e.g. sepsis; asphyxia; hypothermia and hypoglycemia) -Other concurrent health conditions
Health system/service organization	-Pre-natal factors (e.g. lack of psychological and social support, late start, lack of comprehensiveness) -Incomplete immunization schedule[7]

[4] Both teenage and late pregnancy might represent risk factors for infant death

[5] A higher number of previous pregnancies might indicate an increased risk of infant death. Additionally, previous unsuccessful birth outcomes might also represent a risk factor for future birth outcomes

[6] A higher birth order might indicate an increased risk of infant death

	-Delivery-related (e.g. medical assistance, type of facility) -Lack or inadequacy of neonatal care facilities - Other factors related to health care services (e.g. lack of access to oral hygiene therapy

*** Neonatal Mortality Rate (NMR)**

The infant mortality rate is composed of two components, neonatal and postneonatal mortality rates. The neonatal mortality rate consists essentially of the probability of dying within the period from birth to 28 days of life, expressed as "rate" per 1,000 live births (Larson, 2004), as presented by the following formula:

NMR = (Number of deaths from 0 to 28 days of life / Number of live births) X 1,000

Similarly to infant mortality rate, there are large NMR inequalities among different areas of the globe. For instance, the NMR may range from 4 to 6 deaths per 1,000 live births in Canada and other developed countries to commonly over 40 deaths per 1,000 live births in developing countries (WCF, 2001). It is important to highlight that approximately three quarters of these deaths occur within the first week of life (Lawn, 2005) and are particularly associated to perinatal conditions. Therefore, although it is also related to multidimensional risk factors, neonatal deaths are mostly a function of poor antenatal assistance, inadequate obstetric care to labor delivery and lack of

[7] Each country commonly establishes national immunization priorities. The Brazilian immunization schedule is attached as appendix

appropriate neonatal care infra-structure (Ezeaka, 2004; Chowdhury, 2005; Feresu, 2005). In summary, gaps within access and quality of maternal and child health services explain largely such disparities within NMR throughout the globe.

Given the common occurrence of births at home in developing countries, the causes of neonate deaths are usually difficult to determine in those areas. However, it has been largely attributed to low birth weight, birth injury, hypoxia/asphyxia, hypothermia, neonatal tetanus and other infection events (Lawson, 2004; Lawn, 2005). In other words, it is commonly caused by preventable conditions that commonly arise in areas with inadequate organization and delivery of maternal and child health services, where preventing neonate deaths has not been a focus of child survival or safe motherhood programs (Lawn, 2005).

On the other side, postneonatal mortality rate usually provides a different picture of children health conditions of a determined region. It is simply defined as the probability of dying from 29 days of life to one year old, and is more commonly associated to family socio-economic and demographic factors affecting conditions for adequate child growing and development. Thus, poor nutritional status, migration, higher susceptibility to infection events, family size and instability, and lack of access to health care are important determinants of post neonatal deaths (Hessol, 2005).

*** Low Birth Weight Rate (LBWR)**

It is defined as the birth weight less than 2,500 grams, which commonly indicates intrauterine growth retardation and/or prematurity (Kramer, 2003; Larson, 2004). The LBW "rate" is actually a proportion estimated as the total number of low birth weights divided by the total number of live births occurring within the same calendar year, as presented in the following formula:

LBWR = (Number of LBW* / Number of live births) x 1,000

* Defined as live birth < 2,500 grams

A potentially large estimation error might occur in some developing countries where the majority of deliveries occur at home, and/or where no scale is available to weigh newborns. In those areas, such a rate may be overrepresented by hospital-based birth weights, which generally are associated to mother of higher SES. Even assuming such an underestimation of low birth weight in some developing countries, there is also a large disparity throughout the world. For instance, in some developing regions such a "rate" may reach over 30% of all births, mostly associated to intrauterine growth retardation; whereas in Canada it reaches approximately 6% of the births and it is mostly related to prematurity (Lawson, 2004).

It is considered an indirect marker of nutritional status of women at childbearing age, since such a birth outcome is strongly associated to maternal nutritional condition (Kramer, 2003; Larson, 2004). Moreover, it is thought that maternal and familial risk

factors such as stress, smoking, drug abuse and deprived living environment are considered causative factors of low birth weight (Dejin-Karlsson, 2004; Okha, 2005; Ashdown-Lambert, 2005; Lasker, 2005). In addition, several other circumstantial factors might indicate increased vulnerability to LBW such as familial maternal educational status, teenage pregnancy and domestic violence (Dejin-Karlsson, 2004; Ashdown-Lambert, 2005; Gisselman, 2005).

Although low birth weight does not necessarily mean premature birth delivery, there is obviously a clear association between weeks of gestational age and birth weight. In order to better define newborn risk based on birth weight, a scale was defined to establish normal weight ranges for each given gestational age. Then, newborns could be classified as small, appropriate, or large for gestational age. However, given the common imprecision of establishing gestational age, especially in developing countries, birth weight itself has been commonly utilized as a more stable factor to define subsequent risk of infant morbidity and mortality. The one caveat concern is that the number of LBW may actually increase when increased services are provided to an area and it becomes measures regularly.

*** Population Coverage of MCH Services**

The level of proportional coverage to several maternal and child health services have also been utilized as population indicators of children health, more specifically as

indicators of resources and service performance (Larson, 2004). Such indicators usually express the level of commitment of the health system with maternal and child health issues, besides also being an indirect measure of access and overall quality of health actions directed to impact children health.

For instance, percent of assisted deliveries (at least assisted by a birth attendant or midwife), percent of exclusive breastfeeding at 4 months old (sometimes at 6 months old), percentage of children compliance with basic immunization schedule (BCG, polio, 3 dosages of DPT vaccines, and measles vaccines by 12 months age), percent of population with access to safe water, and percent of households connected to latrines are commonly utilized as indicators of global MCH health (Larson, 2004). In addition, the percent of pregnant women initiating the pre-natal care within the first trimester and/or having at over 6 pre-natal care appointments during each pregnancy have also been utilized as important indicators of health system performance regarding maternal and child health services (MS/SIAB, 1998; MS/SIAB, 2003).

In summary, high levels of population coverage to such services indicate that given geographic areas and/or population groups have addressed geographic and cultural barriers of access to health services and also prioritized maternal and child health services that are essential to impact children health. In other words, it indicates that mothers and infants are actually utilizing the real essential services to the health of children.

3.4 Study Aims, Impact and Statistical Hypotheses

Given the large amount of efforts and resources invested on this policy over the last decade and the respective lack of enough accountability, there was a need for better understanding the impact of this national primary care policy on population health outcomes. Moreover, given the preferential focus of PSF on maternal and child health activities; there is a particular interest in assessing the effects of municipal PSF implementation on population-based indicators of infant health.

- **Aims**

More specifically, this research study has the following short-term aims:

- Describing the patterns and trends of PSF municipal coverage and aggregated infant health outcomes over the time period 1999-2002, based on municipal demographic, socio-economic and health care capacity characteristics.
- Comparing the impact on diverse population indicators of infant health (e.g IMR, NMR, LBWR and proportional coverage to MCH services), during the time period 1999-2002, between municipalities that have initiated PSF implementation within during 1999 and were covered by this policy from 1999 to 2002 versus those that have not implemented the policy within the study time period (1999-2002).
- Determining the role of municipal contextual characteristics (e.g. population size, regional location, proportion of rural population, income/capita, Gini income coefficient, illiteracy, hospital beds/capita, physicians/capita, health care

expenditure/capita, and proportion of access to safe water) as potential effect modifiers and/or confounders for the studied association.

- Determine if there is an differential impact of PSF on infant health indicators, depending on the level of population coverage
- Determining if there is any time-dependent (since initial implementation) differential impact on child health indicators.

The major long-term aims of this research study are presented below:

- Generate a profile of municipalities based on socio-demographic and health care-related characteristics, where PSF is more likely to succeed in impacting child health outcomes, which might be used to guide future policy initiatives.
- Generate baseline information, for the municipalities initiating policy implementation within 1999, in order to allow a longer longitudinal assessment of the effects of PSF implementation on indicators of child health.
- Guide next evaluative attempts based on the theoretical model of PSF impact provided by this study and the scientific methodology utilized. More specifically, such a theoretical framework might be useful to further assess the potential relevance of proposed policy processes on child health.
- Further understanding regional health care disparities, more specifically on access and outcome indicators of infant health, and guiding specific actions to deal with that.

*** Study Hypotheses**

Since this program evaluation has important epidemiological and health service research component, as noticed within the description of the study aims, such a quantitative study has proposed hypotheses suitable for statistical testing. In order to address the hypotheses aimed to establish such an inter-municipal comparison, study groups were classified as exposed and non-exposed to policy implementation, respectively defined as those municipalities that have initially implemented PSF anytime within year 1999 and were covered by this policy during the entire within study period and those who have not had any level of implementation during the same time period, 1999-2002. Thus, the comparison group ("control") of those hypotheses is composed of municipalities from the same database[8], which did not implement PSF until the end of the study period (December of 2002).

Moreover, given the wide utilization of infant mortality rate as indicator of global health and human development worldwide, and the special emphasis PSF has given to develop actions towards improving that indicator, this study has focused such a child health indicator as the study primary outcome.

Thus, in order to address major study aims, this study has proposed the following major study hypotheses:

[8] *Pacto de Atencao Basica*-PAB (Primary care Agreement) database

1) Primary Hypothesis

a) Municipalities that have initiated PSF implementation in 1999 and were covered by this policy from 1999 to 2002 are more likely to reduce their respective infant mortality rates from 1999 to 2002, than municipalities that have not implemented PSF during the study time period

2) Secondary Hypotheses

a) Municipalities that have initiated PSF implementation in 1999 and were covered by this policy from 1999 to 2002 are more likely to reduce their respective neonatal mortality rate, low birth weight rate; and increase the proportional coverage to selected MCH services (coverage to pre-natal care and tetravalent immunization) from 1999 to 2002, than municipalities that have not implemented PSF during the study time period

b) The effects of PSF on these infant health indicators are influenced by municipal contextual characteristics (population size, regional location, proportion of rural population, income/capita, Gini income coefficient, illiteracy, hospital beds/capita, physicians/capita, health care expenditure/capita, and proportion of access to safe water)

*** Impact**

From a longer temporal perspective, the results obtained from this research project might have an important impact on SUS and on the respective reorganization of this policy nationwide, as it will contribute to:

- Generating further awareness and understanding about the relevance of primary health care actions on infant health
- Determining whether further investments to increase national PSF coverage in specific resource-rich areas (e.g. large urban areas is likely) is likely to impact as much on infant health outcomes as investments elsewhere, since there is a large amount of resources being currently invested in order to expand access in these resource-rich areas
- Refine the process of PSF implementation and management in areas where it is less likely to succeed in its current form
- Assess the appropriateness of current national directions of maternal and child health services that contribute to improved infant health and those that might further contribute

3.5 Study Design

As described earlier, the large majority of the previous studies assessing PSF is of a descriptive nature, does not utilize a control group and lacks external validity. In addition, some of them used solely qualitative methodology and were mostly interested in process evaluation, aimed to assess the delivery of maternal and child health services and patterns of utilization by local population, rather than focusing on outcome evaluation.

In other words, no large-scale, longitudinal quantitative evaluation of the epidemiologic impact of PSF on population health outcomes has been performed previously. In addition, no analytical statistical methods have been applied in previous assessments in order to define whether such an improving trend of national indicators of infant health is significant or not. In summary, there is a need for sound scientific methodology to understand the real effects of PSF on child health and the major municipal contextual factors influencing that.

In order to address such a knowledge gap, a controlled longitudinal evaluation of municipal PSF implementation on aggregated indicators of infant health has been developed. Given the logistic impossibility of undertaking a truly experimental study in the current Brazilian primary care scenario, an ecological observational study was developed. More specifically, municipalities were followed-up from 1999 to 2002. Annual data from such municipalities were collected for such a time period. A summary description of the epidemiologic study design developed is presented in table 19.

Table 19. Characteristics of this epidemiologic study design based on the purpose of the research project, presence of randomization, temporal perspective and unit of analysis

DIMENSION OF THE DESIGN	TYPE
Purpose	Analytical
Randomization	No (Observational Study)
Temporal Perspective	Longitudinal (Retrospective Cohort)
Unit of Analysis	Ecological (Municipalities as unit of analysis)

The remainder of this section will further explore the utility and advantages of undertaking an observational ecological design while assessing the epidemiology impact of health policies *a posteriori*.

Observational Study Design: It has been widely assumed that randomized controlled experimental designs are the soundest epidemiologic evidence to establish causal relationships, especially because it might guarantee control over potential threats to study internal validity such as selection bias and confounding. However, there are serious obstacles that researchers have to face often while planning a randomized experiment to assess the impact of health policies such as cultural, political, and social characteristics related to the policy issue. In addition, randomized designs may actually prove unnecessary, inappropriate or inadequate in some scenarios (Black, 1996). As definitive

policies are implemented in large-scale based on strict governmental criteria, as in the case of PSF in Brazil, it becomes practically impossible to develop a randomized experiment.

At the program design stage, impact evaluations may be undertaken to test the most effective way to develop various program elements (Rossi_&_Freeman, 1993). Alternatively, either reflexive and/or shadow controls or observational designs are recommended (Rossi _&_Freeman, 1993). The utilization of reflexive and/or shadow controls are particularly useful when there is full policy coverage. In other words, when all individuals or population groups of determined geographic region are covered by the policy and no feasible matched control is possible. Thus, temporal comparisons might be performed as outcomes are assessed before and after policy implementation within the same geographic areas. However, such designs suffer of fundamental internal validity threats.

In addition, although not guaranteeing controlling for selection bias and confounding as well, observational studies allow the concurrent comparison of health outcome variables between an "intervention group" (exposed to the policy) and a "control group" (not exposed to the policy), which is more likely to increase the credibility of findings when compared to simple pre- & post-evaluation designs utilizing either reflexive or shadow controls. In addition, known baseline differences between studied groups might be controlled for during the statistical analysis.

In this particular study, an observational design was developed since the level of PSF coverage varied within the study sample chosen and it was possible to determine an

intervention and control group. In addition, the existence of a comparison group consisting of municipalities without any PSF experience during the study time period enhances the validity of the findings.

Ecological Study Design: Ecological studies are those essentially concerned in assessing the exposure-outcome association among groups of peoples, rather among individuals. It is commonly undertaken for two major reasons; only aggregate information on exposure in each group is available for the study, or the focused exposure varies only at the population level, rather than among individuals (Rothman, 2002; Koepssel_&_Weiss, 2003). In this study, as municipalities are focused as unit of analysis and the exposure (municipal PSF coverage) varies only at the population level, an ecological design is appropriate to understand the population-based impact of this policy at the municipal level. For instance, this study is especially concerned in understanding whether PSF implementation is a positive predictor of improvement on population indicators of infant health or not.

This type of design might be particularly subject to ecological fallacy, which occurs when inferences from individual-level data are different and sometimes even in the opposite direction as inferences made from associations observed within the population-level data. However, since such a study is primarily based on population-level measures of exposure (municipal PSF coverage) and outcome (population health indicators) and is intended to make inferences only at population level, it should not be a pitfall for this project.

In addition, confounding operating at the population level also represents a major source of internal validity threat for ecological studies assessing the population-based effects of group-level exposure such as policy implementation. In order to address that, this study has conducted statistical analysis adjusted for the effects of such potential confounders.

Thus, many of the potential biases associated to ecological designs are diminished when the study is intended to assess the effects of exposure that apply to an entire group and is particularly useful to evaluate health policies and programs.

3.6 Study Sample

Given the lack of previous research studies focused on the impact evaluation of PSF implementation and the exploratory nature of this research project, a pilot analysis was developed among all twenty seven Brazilians states previously to this study. Such a pilot study has served to provide at least a rough estimation of the sample size needed to address the primary study hypothesis, at 80% power. It has utilized state-based population data in order to assess the overall association between PSF population coverage and IMR during the time period 1999-2002.

Such data were available at the MSB website and allowed a national longitudinal perspective of the association between the focused variables. However, since all states had implemented PSF at the time the pilot study was done, no power estimation could be done with a control group of states that has never implemented the policy. Overall the cumulative state PSF coverage in 2002 varied from 7.73% to 72.96% among the twenty seven states and the median coverage was 35.09%. IMR declined 1.95 deaths/1,000 live births (sd = 2.6) among those below the median coverage (PSF coverage < 35%), whereas among states above the median coverage (PSF coverage > 35%) the IMR declined 2.4 deaths/1,000 live births (sd = 3.6). The large standard deviations are especially due the small sample size and large variability within this pilot initiative.

Power Calculation: Assuming such parameters, smaller standard deviation (respectively 1.3 and 1.8 to control and exposed groups), alpha = 0.05; power = 0.80 and a two-sided t-test, such a research project is expected to need at least a total of 440

municipalities in order to find the expected difference on the reduction of IMR over the time period 1999-2002.

In order to guarantee a nationally representative study, very inclusive eligibility criteria were chosen. Moreover, since this project is primarily based on secondary data, most of the eligibility criteria were based on the availability, appropriateness and quality of the data. The inclusion and exclusion criteria for the municipalities be included in this study are listed here below:

*** Inclusion Criteria:**

- Geographic areas officially recognized as Brazilian municipalities by the Federal Government until the end of year 1999. Such municipalities should be part of the National Demographic Census conducted in year 2000
- Municipalities included within the PAB database since 1999. In order to be part of this database, municipalities must receive any type of primary care fund from the federal government (e.g. PSF, PACS or traditional out-patient primary care services).
- Municipalities providing information to the *Sistema de Informacao da Atencao Basica*-SIAB (Primary Health Care Information System), *Sistema de Informacoes de Mortalidade*-SIM (Mortality Information System), *Sistema de Informacoes Sobre Nascidos Vivos*-SINASC (Live Birth Information System) during the time period 1999-2002.

- Municipalities with complete exposure information (level of annual population coverage) available for each year of the study period, 1999-2002

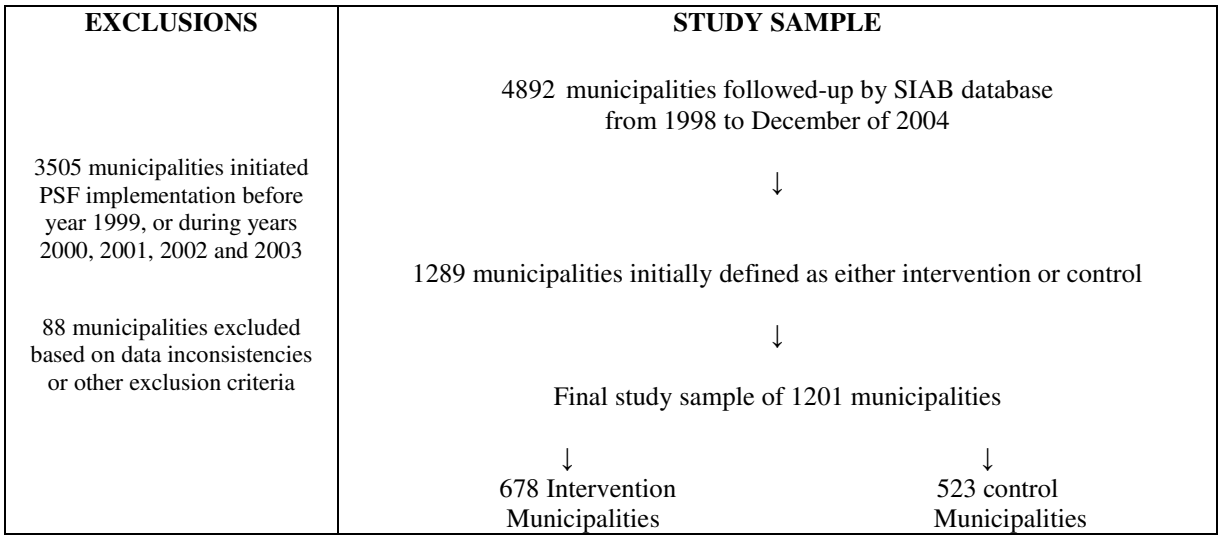
*** Exclusion Criteria:**

- Suspension of coverage for at least one year, among municipalities that have initiated PSF implementation in 1999. Such suspension was identified based on the cross-sectional annual percent of municipal PSF coverage provided by PAB database
- Lack of information reporting to SIAB for a period longer than one year
- Temporary or definitive exclusion from any of the focused databases (e.g. SIAB, SINASC, SIM) for any given reason

Among a total of 4892 municipalities followed-up by SIAB, which have eventually implemented PSF from 1998 to December of 2004, a total of 1289 municipalities initially fulfilled the inclusion criteria; 727 of those have first implemented PSF within 1999 (intervention group), whereas 561 initiated PSF implementation only within the time period 2003-2004 (control group) but were still federally funded for other modalities of primary care within the study period. It is important to highlight that all the municipalities that have implemented PSF at any level of coverage before year 1999, even temporarily, could not be included as intervention municipalities.

However, four municipalities (e.g. Juazeiro do Norte-CE; Quixelo-CE; Araxa-MG and Jacarezinho-PR) that were listed on SIAB as having implemented PSF in 1999, had actually no report of coverage that year on the PAB database. Another municipality (e.g. Araguana-TO) had an extreme value for coverage during year 2000 that proved to be inconsistent and, thus, was excluded given the inability to double check that with the raw data. In addition, 45 municipalities that initiated PSF coverage in 1999 had an absence of coverage at least for one year, from 2000-2002, as reported by PAB indicators, and were then excluded from the study. Given these 50 exclusions, the intervention group was finally composed of 678 municipalities. Furthermore, 38 municipalities that have implemented PSF during years 2003 & 2004, initially selected as control group, were not still officially defined as municipalities in 1999. Given such exclusions, the final control group was then composed of 523 municipalities. Thus, the final study sample was 1201 Brazilian municipalities (see figure 3).

Figure 4. Description of the study sample based on selected inclusion and exclusion criteria.



Some limitations are present. It is important to note that elections for municipal mayors occurred in November of 2000 throughout Brazil. Thus, since a leadership change has possibly occurred in 2001, they might be potentially subject to secular trends as new ideological direction and health care priorities were established locally. Furthermore, ideally such a study should utilize an even longer follow-up period in order to better understand the longitudinal impact on child health; however SIM and SINASC have information available at the municipal level only until the end of year 2002, which dictates the period of this study.

Intervention Group: The selection of the cohort of municipalities that initiated PSF implementation in 1999 to be the intervention group was based on a series of determinants. At first, although PAB became a national policy in 1998, not until the end

of the year PSF started being consistently funded by the federal government under the new financing mechanisms. Secondly, the information system responsible for collecting primary care-related information (SIAB) started generating annual indicators at the municipal level only in 1999. Thirdly, such a longitudinal analysis will allow a longer assessment of the effects of increased PSF coverage over time on population-based child health indicators.

Comparison group ("control"): In order to minimize the potential effect of demographic and socio-political variables determining the decision of implementing PSF locally, a group of municipalities that had eventually implemented PSF after the study period was chosen to compose the control group. Thus, it might reduce the possibility of selection bias and the potential confounding effect of those variables, improving the validity of the study findings. In addition, these municipalities have received primary care fund within the time period studied, which was utilized to finance other modalities of primary care initiatives.

3.7 Data Management

This study has converged and collated different national information systems containing aggregated data at the municipal level in order to generate a study database that could serve the purposes of the research project. Municipal data from different information systems from MSB (e.g. SIAB[9], SIM[10] and SINASC[11]) and IBGE[12] were primarily utilized by this research project in order to address the proposed study hypotheses.

As PSF is implemented locally, a fair monitoring system is established by the Brazilian Ministry of Health. Compliance with data reporting requirement is necessary in order to municipalities receive the PAB variable component to fund PSF locally. In other words, municipalities are eligible to receive federal PSF fund only if they fill out SIAB, SIM and SINASC monitoring forms monthly and send those to MSB within the established deadlines. Similar requirements are imposed to all municipalities that receive any type of primary care fund (e.g. Community health workers; immunization; other prevention activities…), even if there is not any level of PSF implementation at the municipality.

The MSB has aggregated all that information at the municipal level and generated a primary care database (PAB) containing indicators of primary health care for the universe of municipalities that have received any type of primary care fund. This is the database primarily utilized by this research study.

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[9] *Sistema de Informacao da Atencao Basica*-SIAB (Primary Care Information System)
[10] *Sistema de Informacao de Mortalidade*-SIM (Mortality Information System)
[11] *Sistema de Informacao de Nascidos Vivos*-SINASC (Live Birth Information System)
[12] Instituto Brasileiro de Geografia e Estatistica-IBGE (National Institute of Geography & Statistics)

In addition, IBGE has generated a national database with municipal information based on a series of governmental information systems, but mostly relying on information from the national demographic census conducted in year 2000. Such database provides very rich municipal description based on demographic, social and economic indicators. In addition, IBGE has developed an extensive survey on medical assistance nationwide that covered all Brazilian municipalities and has provided a separate database containing such information.

Utilizing electronic access to these databases, the relevant variables were chosen from each of them for the target study period, 1999-2002. Then, all the selected variables had to be converged into a single excel database. The final database containing selected variables for the eligible sample of 1201 municipalities was finally generated in a SPSS 11.5 format.

General data quality monitoring procedures were undertaken in a sub-sample of observations, while range checking was conducted in all variables of the entire study sample. Extreme values and missing observations were identified during this process. Only the variable PSF coverage had problematic extreme values, since the coverage in some municipalities extrapolated 100%. This phenomenon has occurred in areas with universal coverage that have actually assisted residents from neighbor municipalities. For all these municipalities, any coverage value higher than 100% was defined as universal coverage and corrected to 100%. In addition, only a few variables had an important number of missing observations, which were assumed to be missing at random (number of physicians/capita, neonatal mortality rate and infant mortality rate had respectively 53,

38 and 15 missing observations). One of the secondary study outcomes, homogeneity of immunization coverage had 160 missing observations, which might have occurred since in order to define child compliance with immunization schedule, it was needed information in three different time points for all children below 1-yr old (two, four and six months old), which added complexity to the PSF monitoring process.

A brief description of each of these databases is presented here below:

***1) Indicadores do Pacto de Atencao Basica*-PAB**

(Primary Care Agreement Indicators)

The Brazilian Ministry of Health has generated primary care indicators at the municipal, state, regional and national level in order to monitor the progress of such initiatives. Information from a series of national databases has been aggregated in order to produce a national database containing such indicators.

PSF annual population coverage; monthly average of home visits/ family; -annual average of primary care physician appointments/resident; infant mortality rate; neonatal mortality rate; low-birth weight rate; % of live births with 6 or more pre-natal care appointments; homogeneity of immunization coverage (DPT + *H. Influenza*) in children 1 year old[13]; rate of hospital admission by acute respiratory infection diseases in children < 5 years old; maternal mortality rate; leprosy and tuberculosis detection/incidence rates; and rates of hospital admission and mortality rate for different chronic diseases (e.g. cardiovascular disease, certain cancer and diabetes mellitus) are the primary care

[13] Homogeneity of immunization (DPT and Haemophilus Influenza) < 1yr-old is defined by the MSB as at least 95% coverage for all children younger than 1 yr-old at a given year

indicators tracked by the MSB (MS/SIAB, 2003). Since this study has focused on the impact of PSF on infant health outcomes, all the governmental primary care indicators related to infant health were utilized.

Such indicator database is generated based on crude data collected by different national health care information systems. Particularly for the outcomes focused by this research project, three information systems (SIAB, SIM and SINASC) have provided needed information to estimate such indicators. A brief description of each one of these systems is provided here below:

***Sistema de Informacoes da Atencao Basica*-SIAB**

(Primary Health Care Information System)

SIAB is essentially an information system which data are generated by health care professionals. Such information is collected both at family homes and at primary care facilities within areas covered by PSF and/or other modality of primary care (MS/SIAB, 1998). The major data collection tools are national forms of three major types (MS/SIAB, 1998):

- Family registration and survey of socio sanitary conditions. This form is filled out by the CHWs at the initial family enrollment and should be updated regularly
- Follow-up of risky population groups and primary care priority areas, which should be filled out monthly by CHWs at the moment of home visits
- Reporting of activities, services provided, procedures and health events, which are produced monthly by all health care professionals

The data generated by these three data collection forms are aggregated before launched into the information system. After processing such data, three types of reports containing SIAB indicators are generated (MS/SIAB, 1998):

- Registered Family Indicators- presents the demographic and socio-sanitary indicators at the PSF microarea, PSF area, municipal, state and regional level
- Health Condition & Family Follow-up Indicators- consolidates information about major family health conditions in a monthly basis at the PSF area, territorial segment, zone (urban/rural), municipal, state and regional level
- Production & Evaluation Indicators- presents monthly information about overall service utilization/provision and occurrence of diseases and other health events at the PSF area, territorial segment, zone (urban/rural), -municipal, state and regional level

The Brazilian Ministry of Health is the ultimate responsible for providing training regarding the appropriate administration of the data collection forms and entry into the data system. Municipalities lacking enough computer technology infrastructures submit the hard copy of such reports to the MSB, which are then included in the information system. In addition, MSB is also responsible for managing such a national database and publish yearly monitoring reports.

Sistema de Informacoes de Mortalidade-SIM

(Mortality Information System)

SIM is essentially an information system that monitors the occurrence and causes of death nationwide. Infant and neonate deaths have been a major concern for this information system, which has national coverage but still cannot reach the entire universe of infant deaths, especially in isolated areas of the Northeast and North regions lacking any local access to health care (MS/SIM, 2001; MS/SIM&SINASC, 2004).

Death information is directly generated by physicians or other health care professional as the death certificate must be filled out explicating at least the date and time of the occurrence; age and race of the infant; place of occurrence; mother residency; general birth-related conditions (e.g. type of delivery, medical assistance…) and major cause of death (MS/SIM, 2001). In municipalities lacking trained health care professionals, such a certificate should be filled out by a public notary at the presence of two witnesses.

A copy of those certificates should be kept at the health service where the death occurred, a second copy should be sent to the family in order to officially report that, while a third copy should be sent to the SESA (MS/SIM, 2001).

At the state level, such certificates are reviewed and coded based on CID-10 in order to identify the cause of those deaths, although it is not necessary for the direct estimation of either infant or neonatal mortality rates. Then, such reviewed statewide information is sent directly to the national SIM, which will integrate all state-based death

information sent by SESAs (MS/SIM, 2001). In other words, SIM will mainly serve to regularly monitor the occurrence and causes of deaths nationwide.

Sistema de Informacoes Sobre Nascidos Vivos

(Live Birth Information System)

WHO has defined a live birth as the complete expulsion or extraction of the gestation outcome from maternal body, regardless of the gestation duration, who can breathe or present any other life sign such as heart beating, umbilical cord beating or effective movements of the voluntary contraction muscles (MS/SIM&SINASC, 2004).

Similar to SIM, SINASC is primarily based on municipal collection of data from all local health services, both public and private. The live birth certificate should be filled out just after delivery by a trained health care professional. This certificate should contain information about date and time of birth; place of occurrence; mother residency; mother-related information (e.g. previous pregnancy outcomes, age, race, education…); gestation and birth-related information (e.g. pre-natal care, type of birth delivery, type of medical assistance…); and finally about the newborn (e.g. gestational age, race, weight, Apgar index…) (MS/SINASC, 2001)

Three copies are generated as well. A copy is kept by the health service where the birth occurred; a second one is given to the family in order to allow civil registration of the newborn; while a third one is sent directly to the SMS. Then, such municipal information is sent electronically to SESAs that review the statewide information and forward that directly to the information system (MS/SINASC, 2001).

When the birth delivery is conducted by a local midwife, he/she should contact the closest health service in order to report the birth occurrence. Then, a health care professional will be the ultimate responsible person for filling the certificate out and addressing the three required copies (MS/SINASC, 2001; MS/SIM&SINASC, 2004).

2) IBGE

IBGE has an extensive database containing a wide diversity of demographic and socio-economic information called *Censo* 2000 (IBGE, 2005). Such a database has aggregated municipal information that is primarily based on the national demographic census undertaken during year 2000 by IBGE. The national demographic census has utilized a systematic sampling approach to select households within all Brazilian municipalities. In addition, remote sensor techniques were utilized to guide the household selection. Trained interviewers administered the household and individual surveys locally, the data entry process was based on scan reading, and systematic data quality monitoring was undertaken. Such a database containing the crude information at the municipal level is available electronically and in a CD format.

The demographic and socio-economic covariates in this study were mostly gathered from this database. Since the national demographic census was conducted in year 2000 there was no baseline information for year 1999 available for those variables. Thus, several covariate data from year 2000 have been utilized as baseline information.

In addition, IBGE has another database containing health service information at the municipal level for all Brazilian municipalities. Such a database (IBGE-PAMS, 2005)

is based on a survey administered in all types of public and private health care facilities located at the national territory during year 1999. It was primarily aimed to investigate all physical, human and material resources available at those facilities. There were two types of official questionnaires, one for health care facilities (e.g. primary, secondary and tertiary) and another for facilities specialized only in radiological and/or laboratorial diagnostic. Trained interviewers have visited each facility and administered the questionnaire locally, either electronically or using a hard copy.

All socio-economic IBGE variables aggregated at the municipal level that were related to education status, income level, income inequality, access to safe water and distribution of rural population were included within the study database. In addition, all the information related to health care capacity (e.g. physicians/capita, beds/capita, health care expenditure/capita) were also gathered from IBGE databases and included within the final study database.

3.8 Study Variables

In order to assess the impact of PSF on infant health outcomes, this research project has selected a series of primary care indicators tracked by MSB, which are essentially markers of policy impact on aggregated infant health outcomes. Since it is essentially a retrospective observational study utilizing municipalities as unit of analysis, most of the variables are aggregated data at the municipal level. In addition, such data are aggregated yearly for each of the municipalities.

Moreover, since this study is intended to assess the longitudinal impact of the policy, it is necessary to generate baseline information not only to identify initial differences between study groups, but mainly to better understand the longitudinal effect on the study outcomes as well. Given the lack of availability of critical information for year 1998 and inconsistency on the data collection methods before 1999 for some variables, aggregated outcome information for year 1999 was utilized as baseline information.

The choice of variables followed the theoretical framework presented on the logic model (see figure 2). Besides municipal indicators of infant health, several variables were selected to depict the socio-economic and health care context of each municipality. However, it is important to highlight the impossibility of measuring community empowerment and integrality of care, given the lack of availability of needed information on the national databases. Access to primary care services was the only PSF process that could be assessed in this study. It doesn't seem to represent a major problem for this research study, given its primary focus on outcome rather than process evaluation.

Therefore, availability and reliability of the municipal indicators on the PAB and IBGE databases oriented the choice of variables in this study. An explanation of the method of estimation, source of data and time period of the independent and dependent variables are presented here below:

MAJOR INDEPENDENT VARIABLE

Variable[14]: Yearly average PSF municipal coverage

Method of Estimation: Total registered population covered by PSF in December of a given year / Total estimated population for the same year. Then, the yearly average coverage for the study period (1999-2002 will be estimated.

Source of data: Numerator: SIAB; Denominator: PAB (from IBGE direct estimation method)

Time Period: primarily from 1999 to 2002.

PRIMARY DEPENDENT VARIABLE

Variable: Infant Mortality Rate*

Method of Estimation: (Number of infant deaths < 1 year old in a given year / Total number of live births during the same year) x 1,000

Source of data: PAB database (Numerator: SIM; Denominator: SINASC). Infant death is defined by place of mother residence and not by place of occurrence

Time Period: from 1999 to 2002

* In order to address the statistical hypotheses, the reduction on infant mortality rate within such a time period was utilized. It is estimated as: (1999 IMR – 2002 IMR)

[14] It is primarily a dichotomous variable, defined either as municipalities that have implemented PSF in 1999 (intervention group) or those that did not experience PSF implementation within the study period 1999-2002 (control group).

OTHER DEPENDENT VARIABLES

Variable: Neonatal Mortality Rate*

Method of Estimation: (Number of infant deaths 0-28 days of life in a given year / Total number of live births during the same year) x 1,000

Source of data: PAB database (Numerator: SIM; Denominator: SINASC). Neonatal death is defined by place of mother residence and not by place of occurrence

Time Period: from 1999 to 2002

* In order to address the statistical hypotheses, the reduction on neonatal mortality rate within such a time period was utilized. It is estimated as: (1999 NMR – 2002 NMR)

Variable: Proportion of Low Birth Weight*

Method of Estimation: (Number of live births < 2,500 grams in a given year / Total number of live births during the same year) x 1,000

Source of data: PAB database (Numerator: SINASC; Denominator: SINASC).

Time Period: from 1999 to 2002

* In order to address the statistical hypotheses, the proportional reduction on the proportion of low birth weight within such a time period was utilized. It is estimated as: (1999 LBWR – 2002 LBWR)

Variable: Proportion of live births from mothers having more than 6 pre-natal appointments (recommended pre-natal care coverage)

Method of Estimation: Number of live births from mothers having more than 6 pre-natal appointments during a given year/ number of live births with informed number of pre-natal visits during the same year

Source of data: PAB database (numerator and denominator: SINASC)

Time Period: From 2000** to 2002

*In order to address the statistical hypotheses, the improvement on such a variable for the study period will also be estimated (Proportion in 2002 – Proportion in 2000).
** Year 2000 is utilized as baseline since the SIAB forms for year 1999 did not collect information on number of appointments, after the mother completed her fourth pre-natal visit.

Variable: Homogeneity of immunization coverage (*Diphteria, Pertussis & Tetanus + H.Influenza)*

Method of Estimation: Number of third doses of the vaccine applied in children < 1 year old during a given year/ total estimated population of children < 1 year during the same year. Then, if the coverage level reached over 95%, it was considered homogeneous coverage.

Source of data: PAB database (Numerator and denominator: SI-PNI[15])

Time Period: 2002[16]

A brief description of the remaining covariates that were utilized by this research project is presented in table 20. The database source and time period of each variable is described in the table 20. As described previously, some variables had information available only for year 2000.

Table 20. Description of study covariates; database source and time period.

VARIABLE	SOURCE	TIME PERIOD
Total Municipal Population	IBGE (National Demographic Census)	2000
Geographic region	PAB	1999
Monthly average of home visits performed by a health care professional/family (at the municipal level)	Numerator & Denominator: SIAB (PAB)	1999-2002

[15] SI-PNI- Information System for the National Plan of Immunization

[16] Since it is a binary outcome, such an analysis will focus solely among the municipalities with lack of homogeneity in 1999.

Proportion of the local population living in officially defined rural areas (at the municipal level) x 100	Numerator & Denominator: IBGE (National Demographic Census)	2000
Proportion of households connected to the public water system (at the municipal level) x 100	Numerator & Denominator: IBGE (National Demographic Census)	2000
Proportion of population older than 10 years old receiving a monthly salary (formal and/or informal) below the national minimum wage[17] (at the municipal level) x 100	Numerator & Denominator: IBGE (National Demographic Census)	2000
Proportion of literacy among people > 5 years old (at the municipal level) x 100	Numerator & Denominator: IBGE (National Demographic Census)	2000
Gini income coefficient[18]; estimated based on the household income (at the state level)	IBGE (Based on data from the National Census)	2000
Number of physicians/capita* (at the municipal level); estimated as: (Total n of physicians/ population in 1999) x 100,000	Numerator: IBGE (PAMS) Denominator: PAB	1999
Number of hospital beds/capita* (at the municipal level) *(Total n of hospital beds/ population in 1999) x 10,000	Numerator: IBGE (Pesquisa de Assistencia Medico-Sanitaria) Denominator: PAB (estimated from IBGE)	1999
SUS Health Care expenditure (in R$[19])/capita* (at the state level) * Based on IBGE 2000 census population	DATASUS-SIOPS[20]	2000

[17] Brazilian monthly minimum wage is R$ 300
[18] Index of income inequality that ranges from 0 to 1. Values close to 0 indicate a low level of inequality, whereas values approaching 1 indicate a high level of income inequality within the state
[19] Brazilian currency- real (R$). U$ 1 corresponds approximately to R$ 2.3
[20] National Information System for Public Budget in Health Care

3.9 Statistical Analysis

The statistical analysis attempted not only to describe the evolution of PSF coverage and population indicators of infant health for the time period 1999-2002, but also to assess the potential impact of PSF implementation, and of its respective increased level of population coverage, on outcomes of infant health. The municipality has been used as unit of statistical analysis, which has been conducted longitudinally for annual data within the four-year period. SPSS 11.5 for Windows and Intercooled STATA 9.0 were utilized as the statistical analysis software.

Initially, histograms for all outcomes variables were generated in order to identify the distribution of the outcome variables, which are all continuous, except for homogeneity of tetravalent immunization coverage that is a binary outcome. Since the continuous study outcomes are all changes on rates from 1999 and 2002 that have a Gaussian distribution, no data transformation was needed.

In order to address the short-term study aims, different descriptive and analytical statistical methods were utilized:

Descriptive Approaches

At first, the study sample was characterized based on study major independent variable and baseline covariates. Tables and graphs were used to describe the trend of PSF municipal coverage from 1999 to 2002 and the socio-economic and demographic profile of municipalities that have initiated PSF implementation in 1999. In addition, in order to identify any difference on the means or proportions of covariates between the

two study groups at baseline, series of Mann-Whitney and Chi-square statistical tests were conducted. The statistical tests were all performed at 0.05 level of confidence.

In order to assess the adequacy of PSF implementation, a proxy measure of appropriate delivery of primary care activities in Brazil (monthly number of home visits performed by a health care professional/family) was graphically described from 1999-2002. Independent sample t-tests were conducted in order to test whether there was a significant difference on the average number of home visits between study groups each year from 1999-2002 or not. Moreover, ANOVA was conducted in order to identify if the average number of home visit/family would vary by quartile of average municipal PSF coverage, from 1999-2002. All these statistical tests were performed at 0.05 level of confidence.

Finally, since this study has utilized several socio-economic, demographic and health care-related baseline variables, Spearman correlation coefficients were estimated for each pair of covariates in order to identify any important correlation among such covariates at baseline. The significance of each coefficient was tested at α=0.05.

Analytical Approaches

In order to assess the epidemiological impact of PSF implementation on the focused municipal indicators of infant health, different bivariate and multivariate analytical methods were performed for each study outcome.

a) Bivariate Analysis

Initially the study outcomes were described each year and the mean absolute and proportional changes on the outcome (from 1999 to 2002) were estimated for each study group. In addition, such absolute and proportional changes on outcome were compared among control group and each quartile of average municipal PSF coverage from 1999 to 2002 (0-35.8%; 35.8-60%; 60-78.1%; 78.1-100%) in order to identify any differential impact on infant health outcomes by average level of PSF municipal coverage.

The temporal trend of all outcome variables for the time period 1999-2002 was graphically depicted as a regression line was developed for each study group. Then, simple linear or logistic regression models were conducted for each study outcome. The characteristics of the regression models conducted for each study outcome is described below:

Hypothesis 1.a) Municipalities that have initiated PSF implementation in 1999 and were covered by this policy from 1999 to 2002 are more likely to reduce their respective infant mortality rates from 1999 to 2002, than municipalities that have not implemented PSF during the study time period.

Dependent variable: change on IMR (IMR 1999 – IMR 2002)- Continuous variable
Independent variable: PSF implementation- Binary variable
Regression model: Simple linear regression model (Method of Least Squares)

Hypothesis 2.a) Municipalities that have initiated PSF implementation in 1999 and were covered by this policy from 1999 to 2002 are more likely to reduce their respective neonatal mortality rate, low birth weight rate; and increase the proportional coverage to selected MCH services (coverage to pre-natal care and immunization) from 1999 to 2002, than municipalities that have not implemented PSF during the study time period.

Dependent variables:
- Change on NMR (NMR 1999 – NMR 2002)- Continuous variable
- Change on the proportion of LBW (LBW 1999 – LBW 2002)- Continuous variable
- Change on the proportion of live births with >= 6 prenatal care appointments (Coverage2002- Coverage2000)- Continuous variable
- Homogeneity of Immunization coverage (DPT + *H. Influenza*) < 1-yr old- Binary variable

Independent variable: PSF implementation- Binary variable

Regression model:
-Simple linear regression model (Method of Least Squares)
-Simple logistic regression model (for Homogeneity of immunization coverage)

For all the regression models developed in this research project, the coefficient (slope) of the variable "study group" (0: Control; 1: Intervention) was estimated and statistically tested at $\alpha=0.05$[21]. For the simple linear regression models, the absolute value of the coefficient is defined as the average difference of change on the study outcomes (1999-2002) between control and intervention groups[22] (Pagano_&_Gauvreau, 2000; Selvin; 2004). For the simple logistic regression models, the value of the coefficient is simply defined as the average difference between the study groups on the log odds that a municipality achieves the outcome (e.g. homogeneity of immunization) in 2002. In other words, such a model allows the estimation of the odds ratio of achieving the outcome between study groups[23](Pagano_&_Gauvreau, 2000; Selvin; 2004)

For instance, the mathematical expressions of the simple regression models conducted in this research project are described below:

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[21] Ho: $\beta=0$ (t-test with N-2 degrees of freedom; N= sample size) for the linear models;
Ho: $\beta=0$ (Z-test) for the logistic models.

[22] β is the difference for the change on the outcome for the intervention group. If it is positive, the intervention group has a higher reduction (e.g. IMR, NMR, LBW) or improvement (e.g. Pre-natal Coverage), while if it is negative the intervention group has a smaller reduction or improvement

[23] Odds ratio (P intervention/ 1 – P intervention / P control / 1- P control) = exponential.β ;
where P= probability of achieving the outcome.

LINEAR REGRESSION MODELS:

Change on IMR (IMR1999 – IMR2002) = α* + β. Study Group (0: Control; 1: Intervention)

Change on NMR (NMR1999 – NMR2002) = α* + β. Study Group (0: Control; 1: Intervention)

Change on LBW (LBW1999 – LBW2002) = α* + β. Study Group (0: Control; 1: Intervention)

Change on Recommended Pre-Natal Coverage (Coverage2002 – Coverage2000) = α* + β. Study Group (0: Control; 1: Intervention)
* Intercept = Average change on the outcome for the control group

LOGISTIC MODEL:
Ln (P/1-P) = α* + β. Study Group (0: Control; 1: Intervention); where p= probability of achieving homogeneity of immunization coverage
* Intercept= Average log odds of achieving the outcome for the control group

Moreover, in order to identify any differential temporal trend of the impact of PSF on municipal outcomes of infant health, similar linear regression models were conducted for the time periods 1999-2000 and 1999-2001. Since, pre-natal coverage information wasn't available before 2000; only the period 2000-2001 was further investigated for this particular outcome. Finally, given that homogeneity of immunization coverage started being monitored only in 2002, the analysis of temporal trend wasn't conducted for this study outcome.

Stratified analyses were also performed for all baseline covariates to identify any differential impact of the policy on infant health outcomes by level of the baseline covariates. In order to perform such stratified analyses, all continuous baseline variables were categorized in quartiles and simple regression analyses were conducted to each stratum of the covariate. Then, series of two-factor ANOVAs (factors: covariates and study group) or tests of linear trend were conducted at $\alpha=0.05$. Potential effect

modification was identified by assessing the mean difference or odds ratio among each stratum of baseline covariates.

b) Multivariate Analysis

Rationale

As mentioned previously, infant health is strongly influenced by unfavorable socio-economic and demographic scenarios that determine exposure to risky social and environmental conditions, unhealthy maternal behavior, and lower access to adequate maternal and infant care (Avery, 1992; PAHO, 1993; Rigby, 2004). For instance, education attainment level, especially maternal education, has been considered a fundamental determinant of infant health, especially in the developing world (Bird, 1998; Sharma, 1998)

Therefore, the implementation of a primary health care policy that has a fundamental impact on increasing access to MCH services, facilitating integration of care and empowering local communities seem to be especially relevant in underserved areas of Brazil with poor infant health outcomes, which are typically characterized by higher levels of poverty, income inequality and illiteracy; lower access to safe water; poor health care capacity and located in Northern and Northeastern Brazil (Cervantes, 1991; Alves, 2004; Andrade, 2005; Ribeiro, 2005).

However, such socio-economic and demographic variables seem to be strongly correlated in Brazil. For instance, there is a close association among poor health care capacity, low access to safe water, low household income and high illiteracy levels,

especially in largely rural municipalities. Whereas larger urban areas, although presenting some improved socio-economic indicators, still face the struggle of perverse income inequality (Duarte, 2002; Andrade, 2005). Regional disparities are also a unique Brazilian trace (Duarte, 2005). In addition to important cultural peculiarities and unique health practices & beliefs within the five regions; there are also very distinct socio-economic profiles among the regions, North and Northeast being the most socially disadvantaged areas of the country.

Therefore, multivariate regression models were conducted based on this epidemiologic knowledge about the determinants of infant health outcomes in Brazil and on the potential correlation among diverse socio-economic and demographic predictors of infant health. Such regression models aim understanding the impact of PSF implementation on municipal infant health outcomes, adjusted to the effects of other important predictors of such outcomes.

Process of Variable Selection

The baseline covariates included in this study might be classified in three major categories, as specified below:

1) DEMOGRAPHIC: population size; region; and percentage of rural population

2) SOCIO-ECONOMIC: Gini income coefficient (at the state level); percentage of population (<10-yr old) living below 1 minimum wage a month; percentage of households connected to a public water system; and percentage of literate population (>5-yr old)

3) HEALTH CARE CAPACITY: Health care expenditure (at the state level); number of physicians /capita (x 100,000); and number of hospital beds/capita (x 10,000)

Given the high levels of correlations among variables within each one of these classes (see tables 25 & 26) and the aim of keeping parsimonious models, the regression analyses have preferentially included only one variable from each category mainly to avoid collinearity within the regression model. Region location, % literate population and number of hospital beds/capita were preferentially selected as the proxy for each category of baseline covariates, when none of the variables or more than one variable in the same category significantly predicted the outcome of interest. Since the policy implementation itself might have affected the baseline variable "number of physicians/capita", collected in 1999, and health care expenditure in aggregated at the state level; number of hospital beds/capita was considered a more stable proxy of health care capacity to be adjusted for.

Initially all variables considered to be influential on infant health outcomes, based on statistical criteria (Pearson correlation coefficient or chi-square significant at α=0.05), were identified. The decision was based on the Pearson correlation coefficient for the continuous covariates since the outcome variables are normally distributed and the linear regression models are based on the assumption of linearity of association between outcome and independent variables. It is important to highlight that even variables not significantly affecting the outcomes were included in the final model when there was enough scientific evidence justifying the adjustment for them. Regression models were

conducted for all outcomes, but proportion of low-birth weight, which has gathered unadjusted results that might indicate a problematic information bias.

Regression Models

A different regression model was developed for each one of the study outcomes, based on the criteria just explained. The final regression model for each outcome and the respective explanation are described below:

a) Change on Infant Mortality Rate (IMR99- IMR02)

Four baseline covariates were found to independently influence the reduction of infant mortality rate from 1999 to 2002 (e.g. region location, % rural population, % literate population and Gini income coefficient), see table 33. However, given the high correlation between % rural population and other demographic variable (region location), and between % rural population and % literate population (see table 25 & 26), % rural population wasn't included within the final regression model given the effect of collinearity.

Furthermore, since % literate population and Gini income coefficient are two socio-economic variables strongly correlated (see tables 25 & 26), and the latter is aggregated at the state level, % literate population was the only socio-economic variable included in the model. Number of hospital beds/capita was included as a proxy of health care capacity. The final model is shown below:

Change on IMR (IMR1999 – IMR2002) = α + β1. Study Group(dummy) + β2. %Literacy + β3. Hospital beds/capita + β4. Region (dummy)

b) Change on Neonatal Mortality Rate (NMR99- NMR02)

Only one baseline covariate was found to independently influence the reduction of neonatal mortality rate from 1999 to 2002 (% rural population), see table 39. However, two other variables, from different categories, socio-economic and health care capacity, were included in the final model. Thus, the final model for the change on neonatal mortality rate between study groups included % rural population, % literate population and hospital beds/capita. The final model in shown below:

Change on NMR (NMR1999 – NMR2002) = α + β1. Study Group(dummy) + β2. % Rural + β3.%Literacy + β4. Hospital beds/capita

c) Change on Recommended Pre-natal Coverage (Coverage 2002 – Coverage 2000)

Only one baseline covariate was found to independently influence the reduction of infant mortality rate from 1999 to 2002 (% population with monthly income below 1 minimum wage), see table 48. However, two other variables, from different categories, socio-economic and health care capacity, were included in the final model. Thus, the final model for the change of pre-natal coverage between study groups included % population with monthly income below 1 minimum wage, region location, and number of

physicians/capita. Number of physicians/capita was chosen rather than hospital beds/capita, since this study outcome is simply a measure of access that seems to be more related to the availability of providers than in-hospital care capacity.

Change on Coverage (Coverage2002 – Coverage200) = α + β1. Study Group(dummy) + β2. % population with monthly income <= 1mw + β3.region (dummy) + β4. Physicians/capita

d) Homogeneity of Immunization Coverage

Three baseline covariates were found to independently influence the homogeneity of immunization coverage in 2002 (region location, % literate population, and Gini income coefficient), see table 52. Since % literate population and Gini income coefficient are two socio-economic variables strongly correlated (see tables 25 & 26), and the latter is aggregated at the state level, % literate population was the only socio-economic variable included in the model. Moreover, number of physicians/capita was chosen rather than hospital beds/capita, since this study outcome (homogeneity of immunization coverage) is simply a measure of access that seems to be more related to the availability of providers than in-hospital care capacity. The final model is shown below:

regression model for this outcome will be adjusted for all three of them.

$$\text{Ln}\ (p^*/1\text{-}p) = \alpha + \beta 1.\text{Study Group (dummy)} + \beta 2.\%\ \text{literacy} + \beta 3.\text{region (dummy)} + \beta 4.\text{physicians/capita (x100,000)}$$

*p= probability of achieving homogeneity of immunization coverage

4. RESULTS

4.1 Descriptive

The level of municipal PSF coverage has grown steadily within the group of 678 municipalities that initiated the policy within 1999. The average population coverage has changed from 38.70% in 1999, to 54.26% in 2000, 65.05% in 2001 and 70.38% in 2002. The four-year average coverage in this study group was 57.10%, ranging from 1.43% to 100% within this time period; whereas the control group was composed of 523 municipalities that have not implemented the policy during the four-year study period (see table 21).

Table 21. Proportion of PSF municipal coverage during each year, and the average coverage for the study period (1999-2002) stratified by study group.

YEAR	DESCRIPTIVES	STUDY GROUP	
		INTERVENTION GROUP	CONTROL GROUP
1999	Mean (%)	38.70	0
	(Minimum-Maximum)	(0.01-100)	0
	Sample Size	678	523
2000	Mean (%)	54.26	0
	(Minimum-Maximum)	(0.68-100)	0
	Sample Size	678	523
2001	Mean (%)	65.05	0
	(Minimum-Maximum)	(0.03-100)	0
	Sample Size	678	523
2002	Mean (%)	70.38	0
	(Minimum-Maximum)	(0.08-100)	0
	Sample Size	678	523
FOUR-Yr AVERAGE	Mean (%)	57.10	0
	(Minimum-Maximum)	(1.43-100)	0
	Sample Size	678	523

Municipalities from all twenty seven Brazilian states were included in the study sample. However, the state of *Amapa* had no intervention municipality; while *Alagoas, Ceara, Distrito Federal* and *Mato Grosso* had no control municipality. The states of *Minas Gerais, Ceara, Rio Grande do Sul and Bahia* had respectively the largest number of municipalities included in the study sample; *Ceara* and *Minas Gerais* having the largest number of intervention municipalities (see table 22). Table 22 shows the geographic region and population size at baseline (IBGE, 1999) of each Brazilian state along their respective frequency of municipalities in each study group.

Table 22. Frequency of municipalities in each study group for all twenty seven Brazilian states.

STATE (region) Population Size	**STUDY GROUP**		**TOTAL (Relative Frequency)**
	Intervention	**Control**	
ACRE (North) 527,926	8	2	10 (0.83%)
ALAGOAS (Northeast) 2,713,175	26	0	26 (2.16%)
AMAZONAS (North) 2,580,839	11	6	17 (1.42%)
AMAPA (North) 439,783	0	3	3 (0.25%)
BAHIA (Northeast) 12,993,000	18	111	129 (10.74%)
CEARA (Northeast) 7.106,612	139	0	139 (11.57%)
DISTRITO FEDERAL (Middle-West) 1,969,867	1	0	1 (0.08%)
ESPIRITO SANTO (Southeast) 2,938,050	4	4	8 (0.67%)
GOIAS (Middle-West) 4,848,759	9	8	17 (1.42%)
MARANHAO (Northeast) 5.418,354	14	47	61 (5.08%)
MINAS GERAIS (Southeast) 17,296,065	114	52	166 (13.82%)
MATO GROSSO DO SUL (Middle-West) 2,026,628	5	5	10 (0.83%)
MATO GROSSO (Middle-West) 2,375,581	8	0	8 (0.67%)
PARA (North) 5,866,463	14	21	35 (2.91%)

PARAIBA (Northeast) 3,375,600	14	14	28 (2.39%)
PERNAMBUCO (Northeast) 7,580,807	64	1	65 (5.41%)
PIAUI (Northeast) 2,734,158	35	5	40 (3.33%)
PARANA (South) 9,375,665	31	33	64 (5.33%)
RIO DE JANEIRO (Southeast) 13,807,368	14	3	17 (1.42%)
RIO GRANDE DO NORTE (Northeast) 2,654,464	7	18	25 (2.08%)
RONDONIA (North) 1,296,832	15	3	18 (1.5%)
RORAIMA (North) 266,914	1	2	3 (0.25%)
RIO GRANDE DO SUL (South) 9,971,738	19	115	134 (11.16%)
SANTA CATARINA (South) 5,098,440	26	18	44 (2.16%)
SERGIPE (Northeast) 1,712,745	12	1	13 (1.08%)
SAO PAULO (Southeast) 35,816,704	32	45	77 (6.41%)
TOCANTINS (North) 1,134,879	37	6	43 (3.53%)
TOTAL	678	523	1201 (100%)

As shown in table 23, this policy seemed to be implemented in 1999 within municipalities of unfavorable socio-economic scenario. The intervention group tended to have larger population sizes; larger income inequality; larger proportion of the population with a monthly income below 1 minimum wage; lower proportion of rural population; and higher levels of illiteracy than the control group. However, the intervention municipalities tended to have a higher number of physicians/capita, which might be an effect of the policy implementation that same year (1999). Proportionally, the intervention group had a much larger number of municipalities from the Middle-West and Northeast regions (see table 23).

Comparing to such a study sample, the national sample of Brazilian municipalities tends to have a similar percentage of illiteracy[24] (12.9%); similar percentage of population living below 1 minimum wage (24%); lower Gini income coefficient (0.555); lower percentage of rural population (18.75%); much higher rate of physicians/capita (277.5 per 100,000) and higher rate of hospital beds/capita (27.45 per 10,000) (IBGE, 2005).

Table 23. Comparison of means and proportions of municipal baseline characteristics between study groups.

VARIABLE	STUDY GROUP		P-Value
	Intervention Mean or proportion (N) (Minimum-Maximum)	**Control** Mean or proportion (N) (Minimum-Maximum)	
Population (1999)	37,726 (957-1,969,867)	23,467 (1,126-349,581)	0.0352*
Health expenditure/cap (in million of R$)	167.88 (111.43-472.09)	168.72 (111.43-372.58)	0.2142
Gini income coefficient	0.604 (0.548-0.628)	0.591 (0.548-0.618)	< 0.0001*
Percentage of population with monthly income below 1 minimum wage (>10-yr old)	74.53 (32.75-93.77)	71.42 (29.04-93.92)	0.0007*
Physicians/cap (x 100,000)	132.13 (5.44-977.24)	123.87 (0-1,031.73)	0.003*
Hospital beds/cap (x 10,000)	22.85 (0-177.26)	24.13 (0-345.03)	0.821
Percentage of rural population	40.83 (0-98.44)	46.63 (0-93.16)	<0.0001*
Percentage of household connection to public water system	55.92 (0-98.84)	54.73 (0-98.09)	0.7424
Percentage of literacy (> 5-yr old)	74.89 (48.13-99.12)	78.61 (40.64-97.60)	<0.0001*
Region **-North (1)** **-Northeast (2)** **-Middle-West (3)** **-Southeast (4)** **-South (5)**	 57% 62.5% 79.5% 59% 31.4%	 43% 37.5% 20.5% 41% 68.6 %	< 0.0001*

[24] Illiteracy among people > 15-yr old

All baseline covariates (e.g. demographic, socio-economic and health care capacity) are significantly correlated, and, more importantly, within the same category of covariates (see table 25). Especially high Spearman correlation coefficients (rho) were found between: % literate population & % population with monthly income < 1mw (rho = -0.900); % literate population & Gini income coefficient (rho = -0.756); % population with monthly income < 1mw & Gini income coefficient (rho = 0.738); and % percentage of households connected to the public water system & % rural population (rho = -0.732). In summary, among the municipalities studied, lower literacy levels are associated to higher income inequality, lower monthly income and lower access to safe water; reduced expenditure on health care and lower number of physicians and hospital beds/capita; and smaller population sizes & higher proportion of rural population (see table 24).

In addition, as shown in table 25, there are also large differences on the means of baseline covariates among national regions, which indicate profound regional inequalities. Municipalities from North and Northeast regions have consistently the worst socio-economic indicators (e.g. % literacy; % monthly income below 1 mw; and % household connection to public water system). Moreover, these regions have the lowest number of physicians and hospital beds/capita, besides having the highest proportion of rural population. Finally, states from the Northeast region have the lowest health care expenditure/capita and the highest Gini income coefficient.

Table 24. Spearman correlation coefficients (rho) among baseline variables and the respective significance of the correlation coefficient[25]

VARIABLE	Population	Health Expend. /capita	Gini Income Coeffic.	Populat. with monthly income <1mw (>10-yr old)	Physicians /capita (x100,000)	Hospital beds per capita (x10,000)	Rural Popul. (%)	Household Connection to Public Water (%)	Literacy (%) (> 5-yr old)
Population	1	-	-	-	-	-	-	-	-
Health Expenditure Per capita	-0.093* (<0.001)	1	-	-	-	-	-	-	-
Gini Income Coefficient	0.184* (<0.001)	-0.528* (<0.001)	1	-	-	-	-	-	-
Population With monthly income <1mw (>10-yr old)	-0.060* (0.04)	-0.585* (<0.001)	0.738* (<0.001)	1	-	-	-	-	-
Physicians Per capita (x100,000)	0.122* (<0.001)	0.349* (<0.001)	-0.358* (<0.001)	-0.572* (<0.001)	1		-	-	-
Hospital beds per capita (x10,000)	0.261* (<0.001)	0.144* (<0.001)	-0.14* (<0.001)	-0.258* (<0.001)	0.429* (<0.001)	1	-	-	-
Rural Population (%)	-0.383* (<0.001)	-0.271* (<0.001)	0.223* (<0.001)	0.555* (<0.001)	-0.463* (<0.001)	-0.299* (<0.001)	1	-	-
Household Connection to Public Water (%)	0.223* (<0.001)	0.225* (<0.001)	-0.284* (<0.001)	-0.51* (<0.001)	0.461* (<0.001)	0.2363* (<0.001)	-0.732* (<0.001)	1	
Literacy (%) (> 5-yr old)	0.0318 (0.283)	0.554* (<0.001)	-0.756* (<0.001)	-0.90* (<0.001)	0.555* (<0.001)	0.272* (<0.001)	-0.479* (<0.001)	0.488* (<0.001)	1

* Statistically significant at α=0.05

Table 25. Comparison of baseline variable means among five different national regions[26]

VARIABLE	Population	Health Expend. /capita	Gini Income Coeffic.	Populat. with monthly income <1mw (>10-yr old)	Physicians /capita (x100,000)	Hospital beds per capita (x10,000)	Rural Popul. (%)	Household Connection to Public Water (%)	Literacy (%) (> 5-yr old)
REGION									
North	46,652	206.8	0.592	75.69	55.79	18.77	51.63	32.15	76.56
Northeast	30,039	143.2	0.616	84.18	91.60	19.83	48.79	50.17	65.56
Middle-West	68,409	202.5	0.603	67.86	159.08	31.79	29.01	61.11	82.35
Southeast	29,490	182.3	0.588	63.56	184.86	23.41	30.92	71.74	85.03
South	23,463	183.2	0.572	59.35	165.43	33.36	42.41	60.50	89.95
F (p-value)	4.01* (0.003)	143.12* (<0.001)	744.12* (<0.001)	401.47* (<0.001)	55.06* (<0.001)	14.32* (<0.001)	38.26* (<0.001)	73.05* (<0.001)	541.60* (<0.001)

* Statistically significant at α=0.05

[25] Spearman correlation coefficient
[26] One-Way ANOVA

The monthly average of home visits/resident performed by a health care professional has grown steadily in both study groups, from 1999 to 2002 (see graph 1). However, the intervention group had a significantly higher annual average of home visits/resident each year, from 1999 to 20002, when compared to the control group (see table 26). In addition, such a proxy measure of adequate delivery of primary health care is significantly associated to the average level of PSF coverage (1999-2002) each year and during the entire four-year study period, as shown in table 27. In other words, the higher the level of average PSF coverage, the higher the monthly average of home visits/resident performed by a health care professional.

Graph 1. Monthly average of home visits/resident performed by a health care professional, stratified by study group (0: Control; 1: intervention)

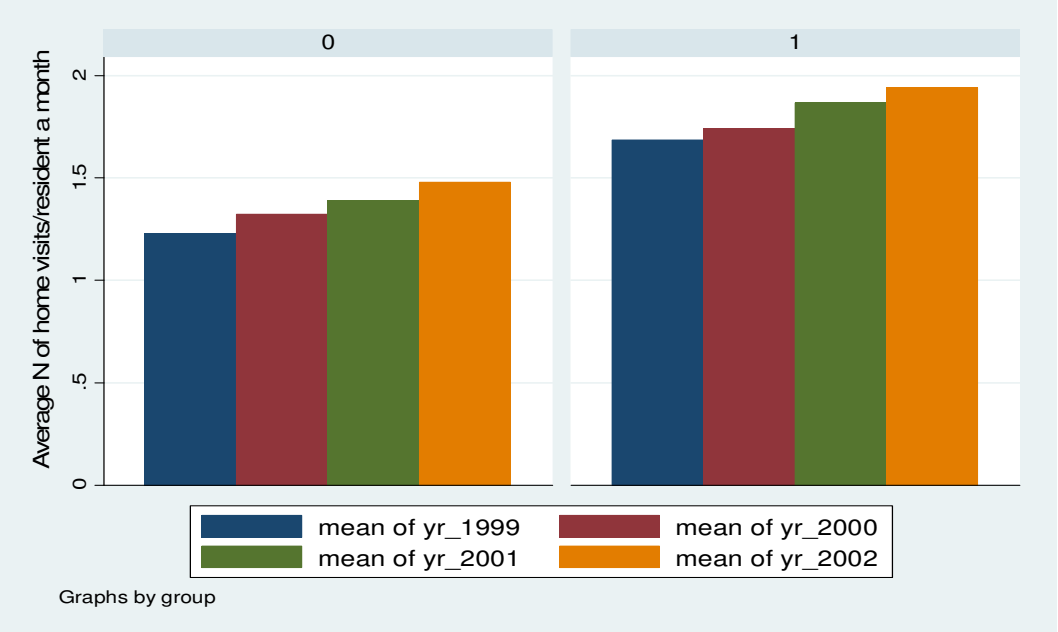


Table 26. Comparison of the average number of home visits/resident (performed by a health care professional a month) between the two study groups, each year and for the four-year average (1999-2002).

YEAR	STUDY GROUP		MEAN DIFFERENCE (Intervention – Control)	P-VALUE
	Intervention	Control		
1999	.671	.356	.315	< 0.0001
2000	.712	.393	.319	< 0.0001
2001	.753	.434	.319	< 0.0001
2002	.799	.483	.316	< 0.0001
Four-yr Average (1999-2002)	.737	.417	.317	< 0.0001

Table 27. Comparison of the average number of home visits/resident (performed by a health care professional a month) among control group and quartiles of average PSF coverage (from 1999 to 2002), each year and for the four-year average (1999-2002).

YEAR	AVERAGE % PSF COVERAGE (1999-2002)					F (p-Value)
	Control (0%)	0-35.8%	35.8%-60%	60%-78.1%	78.1%-100%	
1999	0.357	0.479	0.742	0.718	0.742	40.3 (<0.0001)
2000	0.393	0.502	0.751	0.770	0.824	46.7 (<0.0001)
2001	0.434	0.545	0.774	0.809	0.881	49.0 (<0.0001)
2002	0.483	0.583	0.790	0.907	0.916	53.7 (<0.0001)
Four-yr Average (1999-2002)	0.417	0.528	0.764	0.801	0.841	62.2 (<0.0001)

4.2 Analysis

Infant Mortality Rate (IMR)

The average infant mortality rate for the entire study sample has changed from 24.14 deaths per 1,000 live births in 1999 to 21.28 deaths per 1,000 live births in 2002. Municipalities from the intervention group had a higher IMR in 1999 and a higher absolute change inn IMR from 1999 to 2002 than did control municipalities: 4.79 and 0.34 deaths per 1,000 live births, respectively. The proportional change was also higher for intervention than for control municipalities; respectively 17.16% and 1.77% change (see table 28). However, such a reduction of IMR was not associated with the average level of PSF coverage from 1999-2002 (see table 29)

Table 28. Evolution of the yearly average and range of neonatal mortality rates (per 1,000 live births) and its respective change from 1999 to 2002, for all municipalities and stratified by study group.

STUDY GROUP	INFANT MORTALITY RATE (IMR) (per 1,000 live births)				Absolute Change on IMR*	Proportional Change on IMR**
	1999 Mean (range)	2000 Mean (range)	2001 Mean (range)	2002 Mean (range)		
All Municipalities (N=1186)	24.14 (0-346.2)	24.56 (0-285.7)	22.06 (0-185.7)	21.28 (0-136.4)	2.86	11.85%
Control Group (N=515)	19.21 (0-346.2)	21.89 (0-285.7)	20.55 (0-185.7)	18.87 (0-87.7)	0.34	1.77%
Intervention Group (N=671)	27.92 (0-238.8)	26.62 (0-263.2)	23.23 (0-152.2)	23.13 (0-136.4)	4.79	17.16%

* Absolute change= IMR 1999 – IMR 2002
** Proportional change= (IMR 1999 – IMR 2002)/ IMR 1999

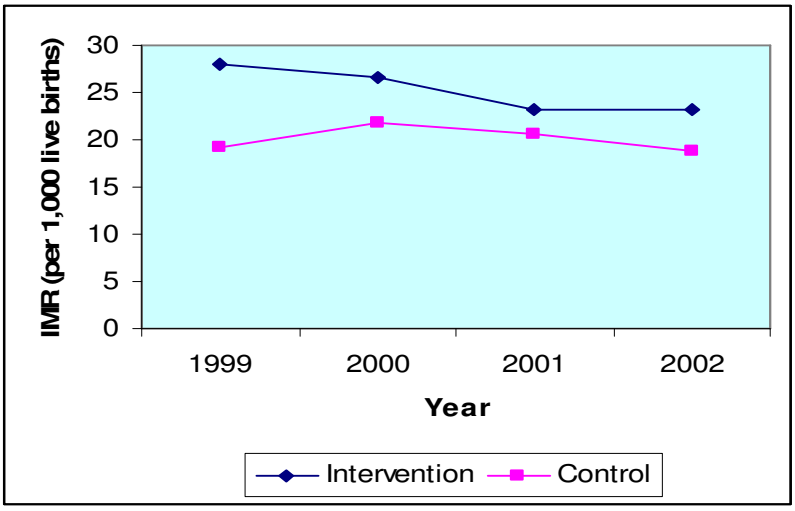
Table 29. Evolution of the yearly average of infant mortality rates (per 1,000 live births) and absolute & proportional change of IMR (from 1999 to 2002) for the control group and quartiles of average PSF coverage (from 1999 to 2002).

YEAR	AVERAGE % PSF COVERAGE (1999-2002)				
	Control (0%)	0-35.8%	35.8%-60%	60%-78.1%	78.1%-100%
1999	19.21	23.67	33.00	26.49	28.45
2000	21.89	23.33	27.98	26.99	28.16
2001	20.55	21.79	24.67	23.72	22.71
2002	18.87	20.84	23.75	25.12	22.81
Absolute Change in IMR*	0.34	2.83	9.25	1.37	5.64
Proportional Change in IMR**	1.77%	11.96%	28.0%	5.17%	19.8%

* Absolute change= IMR 1999 – IMR 2002
** Relative change= (IMR 1999 – IMR 2002)/ IMR 1999

In addition, as shown in Graph 2, intervention municipalities present a consistent reduction trend of IMR from 1999-2002, especially from 1999 to 2001; whereas control municipalities tended to have their IMR reduction primarily from 2000 to 2002.

Graph 2. Trend of the mean infant mortality rates for both study groups, from 1999-2002



The following simple linear regression models were conducted for the change on infant mortality rate between study groups within the study period, 1999-2002:

Regression lines for the change on infant mortality rate (IMR t0- IMR t1):

IMR CHANGE (1999-2000) = -2.68 + 3.99.Study Group (0: control; 1: intervention)
IMR CHANGE (1999-2001) = -1.35 + 6.04. Study Group (0: control; 1: intervention)
IMR CHANGE (1999-2002)= 0.34 +4.46. Study Group (0: control; 1: intervention)
Note: None of the intercepts are statistically significant at α= 0.05

It indicates that intervention municipalities had a higher reduction on IMR than control municipalities from 1999 to 2002 (slope = 4.46; intercept = 0.34). The intercept indicates that the control group has actually had its IMR decreased from 1999 to 2002 in 0.34 deaths per 1,000 live births; while the slope indicates that difference between the changes on IMR between the intervention and control group was 4.46 deaths per 1,000 live births. Such a reduction was also higher for the intervention group from 1999 to 2000 (slope = 3.99), and from 1999 to 2001 (slope= 6.04), see table 30.

Table 30. Comparison of study group slopes for the change on infant mortality rate, within three different time periods (1999-2000; 1999-2001; and 1999-2002)

Time Comparison	β (slope) for Study Group	SE (β)	P-value
1999-2000	3.99	1.79	0.027*
1999-2001	6.04	1.66	<0.0001*
1999- 2002	4.46	1.61	0.006*

* Statistically significant at α= 0.05

In addition, the analysis of the association between PSF implementation and change on IMR (1999-2002) stratified by baseline covariates indicates that the impact of PSF on the reduction of infant mortality rates is higher for municipalities in the first and third quartile of population size; higher for the two highest quartiles of Gini income coefficient; higher for municipalities with larger proportions of poor population, especially in the third and fourth quartiles; higher for municipalities within the second and fourth quartiles of proportion of rural population; higher for the two lowest quartiles of proportional connection to the public water system; higher for municipalities within the lowest quartile of literate population; higher for the two lowest quartiles of health care expenditure/capita; higher for the lowest category of number of hospital beds/capital; and higher for the lowest quartile of physicians/capita (see table 31).

Furthermore, the highest positive impact of PSF on IMR was on Northeast and South regions (see table 31). It is important to highlight that the statistical test, two factor anova, was significant only for population size; health expenditure/capita; Gini income coefficient; percentage of rural population; percentage of connection to public water system; percentage of literacy and region.

Table 31. Slopes of the absolute change on infant mortality rate from 1999 to 2002, stratified by baseline covariates; followed by a two-factor ANOVA

VARIABLE	B Intervention (IMR1999 – IMR2002)	P-value	F-test (Model) (p-value*)
Population (1999)			
<= 6099	6.04	0.140	2.63
6100-12539	0.85	0.805	(0.033*)
1240-25442	8.11	0.017*	
> 25442	3.25	0.024*	

Health expenditure/cap (in million of R$)			
<= 144.95	3.61	0.373	5.55
144.96-155.72	7.39	0.060	(0.002*)
155.73-201.65	-0.48	0.898	
> 201.65	1.01	0.624	
Gini income coefficient			
<= 0.586	2.51	0.275	3.28
0.587-0.599	-0.31	0.935	(0.010*)
0.600-0.612	4.34	0.309	
> 0.612	6.37	0.040*	
Percentage of population with monthly income below 1 minimum wage (>10-yr old)			
<= 62.43	5.37	0.008*	2.19
62.44-76.38	-1.36	0.702	(0.068)
76.39-85.22	5.87	0.102	
> 85.22	7.21	0.043*	
Physicians/cap (x 100,000)			
<= 60.17	6.42	0.084	1.97
60.18-102.63	2.76	0.419	(0.097)
102.64-163.89	4.68	0.121	
> 163.90	2.67	0.397	
Hospital beds/cap (x 10,000)**			
<= 19.38	6.24	0.017*	2.51
19.39-33.70	0.12	0.964	(0.057)
> 33.70	4.83	0.090	
Percentage of rural population			
<= 23.96	2.06	0.419	2.71
23.97-44.69	5.63	0.135	(0.029*)
44.70-61.35	3.67	0.302	
> 61.36	5.9	0.060	
Percentage of household connection to public water system			
<= 37.45	6.49	0.030*	2.61
37.46-56.95	6.95	0.031*	(0.034*)
56.96-74.64	1.68	0.678	
> 74.64	2.19	0.411	
Percentage of literacy (> 5-yr old)			
<= 65.34	10.39	0.003*	3.5
65.35-77.88	0.08	0.982	(0.007*)
77.89-88.14	3.23	0.273	
> 88.14	3.68	0.203	
Region			
North (N=86)	2.45	0.492	2.92
Northeast (N=520)	8,85	0.001*	(0.012*)
Middle-West (N=92)	-13.49	0.040*	
Southeast (N=248)	-4.45	0.284	
South (N=234)	6.65	0.097	

* Statistically significant at α=0.05

** Given the large number of no beds in the municipality, this covariate was categorized in 3 groups

In addition, the change on IMR from 1999 to 2002 was independently predicted by four key baseline covariates (see table 32). Higher levels of income inequality, lower levels of literacy and lower proportion of rural population predicted a larger reduction on

infant mortality rate from 1999 to 2002. In addition, the reduction of IMR was larger in the Middle-West and Northeast regions.

Table 32. Level of correlation between baseline variables (Pearson correlation coefficient) and change on infant mortality rate from 1999 to 2002*
*IMR 1999- IMR 2002

VARIABLE	Change on Infant Mortality Rate (IMR 1999- IMR 2002)	P-Value**
Population	0.031	0.916
Health Expenditure/ capita	-0.039	0.172
Gini Income Coefficient	0.075	0.01*
Population with monthly income <1mw (>10-yr old)	0.030	0.288
Physicians/ capita (x100,000)	0.014	0.647
Hospital beds/ capita (x10,000)	0.048	0.868
Rural Population (%)	-0.060	0.044*
Household Connection to Public Water System (%)	0.028	0.327
Literacy (> 5-yr old) (%)	-0.062	0.034*
Region* **	F=2.40	0.049*
Average IMR change (1999-2002)		
North	2.81	
Northeast	3.84	
Middle-West	3.96	
Southeast	2.01	
South	-1.03	

** Statistically Significant at 0.05
*** ANOVA statistical test was conducted, since region is a categorical variable

Even after adjusting for baseline covariates (% literate population <5-yr old, number of hospital beds/capita x 10,000, and region location), municipalities that have implemented PSF have a higher reduction of IMR (1999-2002) than control municipalities (see table 33).

Table 33. Slopes of the absolute change on infant mortality rate from 1999 to 2002, between the study groups, respectively unadjusted and adjusted for baseline covariates.

ASSOCIATION	β Intervention group (IMR1999 – IMR2002)	SE (β)	P-value*
Unadjusted Association	4.46	1.61	0.006*
Adjusted Association**	3.62	1.67	0.031*

* Statistically significant at α=0.05

** Adjusted for % literate population (<5-yr old), hospital beds/capita (x10,000) and region location

Neonatal Mortality Rate (IMR)

The average neonatal mortality rate for the entire study sample has not varied significantly from 1999 to 2002, since it was respectively 13.34 and 13.35 deaths per 1,000 live births. Municipalities from the intervention group have had a slightly higher absolute reduction of NMR (NMR1999- NMR 2002) than control municipalities; respectively 0.27 and - 0.34 deaths per 1,000 live births. The proportional reduction was also slightly higher for intervention than for control municipalities; respectively 1.84% and -2.90% reductions (see table 34). Such a change on NMR was not associated to the average level of PSF coverage from 1999-2002 (see table 34).

Table 34. Evolution of the yearly average and range of neonatal mortality rates (per 1,000 live births) and its respective change from 1999 to 2002, for all municipalities and stratified by study group

STUDY GROUP	**NEONATAL MORTALITY RATE (IMR) (per 1,000 live births)**				**Absolute Change in NMR***	**Proportional Change in NMR****
	1999 Mean (range)	**2000** Mean (range)	**2001** Mean (range)	**2002** Mean (range)		
All Municipalities (N=1186)	13.35 (0-222.2)	14.94 (0-285.7)	13.74 (0-88.2)	13.34 (0-111.1)	0.01	0.075%
Control Group (N=515)	11.54 (0-222.2)	13.94 (0-285.7)	13.45 (0-85.7)	11.88 (0-76.1)	-0.34	-2.90%
Intervention Group (N=671)	14.71 (0-134.5)	15.70 (0-157.9)	13.95 (0-88.2)	14.44 (0-111.1)	0.27	1.84%

* Absolute change= NMR 1999 – NMR 2002

** Proportional change= (NMR 1999 – NMR 2002)/ NMR 1999

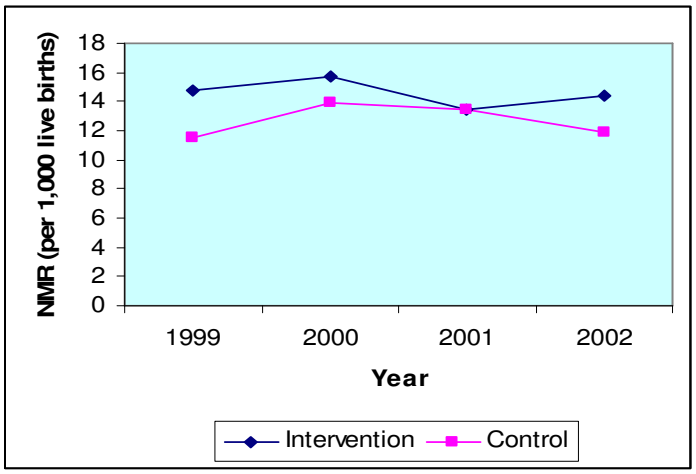
Table 35. Evolution of the yearly average of neonatal mortality rates (per 1,000 live births) for the control group and quartiles of average PSF coverage (from 1999 to 2002).

YEAR	AVERAGE % PSF COVERAGE (1999-2002)				
	Control (0%)	0-35.8%	35.8%-60%	60%-78.1%	78.1%-100%
1999	11.54	14.54	16.05	12.35	15.82
2000	13.93	13.86	15.48	15.96	17.56
2001	13.45	13.46	14.16	14.27	13.9
2002	11.88	13.15	14.79	14.73	15.08
Absolute Change on NMR*	-0.34	1.39	1.26	-2.38	0.74
Proportional Change on NMR**	-2.90%	9.56%	7.85%	-19.27%	4.68%

* Absolute change= NMR 1999 – NMR 2002
** Relative change= (NMR 1999 – NMR 2002)/ NMR 1999

In addition, as shown in Graph 3, both groups do not present a steady trend of reduction on NMR from 1999-2002. Both study groups have their NMR actually increased from 1999 to 2000, and only after that they have experienced a trend of NMR reduction.

Graph 3. Trend of the mean neonatal mortality rates for both study groups, from 1999-2002



The following simple linear regression models were conducted for the change on neonatal mortality rate between study groups within the study period, 1999-2002:

Regression lines for the change on infant mortality rate (NMR t0- NMR t1):

NMR CHANGE (1999-2000) = -2.39* + 1.40.Study Group (0: control; 1: intervention)
NMR CHANGE (1999-2001) = -1.91* + 2.67. Study Group (0: control; 1: intervention)
NMR CHANGE (1999-2002)= -0.35 + 0.62. Study Group (0: control; 1: intervention)
Note: Intercepts are statistically significant at α= 0.05

The results indicate that intervention municipalities had a higher reduction in NMR than control municipalities from 1999 to 2002 (slope= 0.62; intercept= -0.35). As observed in the regression expressions above, the intercept is negative for the time period 1999-2002, indicating that the control group has had its NMR actually increased within this time period, while the slope indicates that the difference of the change on NMR between intervention and control groups was 0.62 deaths per 1,000 live births. The intercept was negative for the other two time periods, while the slopes were higher for the same time periods (1999-2000 & 1999-2001), respectively 1.40 and 2.67. However, except for NMR change from 1999 to 2001 (slope=2.67), none of the other two slopes were statistically significant (see table 36).

Table 36. Comparison of study group slopes for the change on neonatal mortality rate, within three different time periods (1999-2000; 1999-2001; and 1999-2002)

Time Comparison	β Study Group	Se(β)	P-value
1999-2000	1.40	1.29	0.277
1999-2001	2.67	1.10	0.016*
1999- 2002	0.68	0.11	0.584

* Statistically significant at α= 0.05

In addition, the analysis of the association between PSF implementation and change on NMR (1999-2002) stratified by baseline covariates indicates that the impact of PSF on the reduction of neonatal mortality rates tended to be higher for municipalities within the third highest quartile of population size; higher at the lowest and highest quartiles of Gini income coefficient; higher within the two lowest quartiles of proportion of rural population; higher at the second quartile of proportional connection to public water system; higher at the first and third quartiles of proportional literacy; higher at the first and third quartiles of proportion of population living under one minimum wage/month; higher for the first and fourth quartiles of health care expenditure/capita; higher for the second and third quartile of physicians/capita; and higher for the lowest quartile of hospital beds/capita (see table 37). Furthermore, the highest positive impact of PSF on NMR was in the South and North regions. However, none of the slopes for this stratified analysis was statistically significant at $\alpha = 0.05$ (see table 37). It is important to highlight that the statistical test, two factor anova, was not significant for any of the covariates.

Table 37. Slopes of the absolute change on neonatal mortality rate from 1999 to 2002, stratified by baseline covariates; followed by a two-factor ANOVA

VARIABLE	B Intervention (NMR1999 – NMR2002)	Se(B) (p-value*)	F-test (Model) (p-value*)
Population (1999)			
<= 6099	-2.44	0.354	0.91
6100-12539	0.95	0.950	(0.456)
1240-25442	3.72	0.050*	
> 25442	0.24	0.703	

Health expenditure/cap (in million of R$)			
<= 144.95	1.18	0.606	0.97
144.96-155.72	0.66	0.812	(0.422)
155.73-201.65	-2.53	0.384	
> 201.65	1.31	0.409	
Gini income coefficient			
<= 0.586	1.67	0.383	1.02
0.587-0.599	-0.43	0.884	(0.397)
0.600-0.612	0.41	0.889	
> 0.612	0.98	0.575	
Percentage of population with monthly income below 1 minimum wage (>10-yr old)			
<= 62.43	2.88	0.093	0.60
62.44-76.38	-1.39	0.606	(0.662)
76.39-85.22	1.95	0.350	
> 85.22	-0.59	0.803	
Physicians/cap (x 100,000)			
<= 60.17	0.03	0.991	1.73
60.18-102.63	1.42	0.516	(0.141)
102.64-163.89	2.45	0.268	
> 163.90	-2.06	0.385	
Hospital beds/cap ** **(x 10,000)**			
<= 19.38	1.01	0.548	1.60
19.39-33.70	-1.85	0.401	(0.188)
> 33.70	-1.83	0.378	
Percentage of rural population			
<= 23.96	1.30	0.404	0.99
23.97-44.69	1.93	0.409	(0.414)
44.70-61.35	-1.78	0.525	
> 61.36	0.51	0.825	
Percentage of household connection to public water system			
<= 37.45	-0.10	0.963	0.39
37.46-56.95	2.55	0.284	(0.815)
56.96-74.64	-0.91	0.738	
> 74.64	0.825	0.631	
Percentage of literacy (> 5-yr old)			
<= 65.34	2.09	0.308	0.99
65.35-77.88	-1.71	0.484	(0.412)
77.89-88.14	4.87	0.037*	
> 88.14	-0.95	0.680	
Region			
North (N=86)	2.92	0.232	0.84
Northeast (N=520)	1.42	0.367	(0.521)
Middle-West (N=92)	-7.76	0.069	
Southeast (N=248)	-3.11	0.356	
South (N=234)	4.04	0.095	

* Statistically significant at α=0.05

** Given the large number of no beds in the municipality, this covariate was categorized in 3 groups

In addition, the change on NMR from 1999 to 2002 was independently predicted only for one baseline covariate (see table 38). A lower proportion of rural population

predicted a larger reduction on infant mortality rate from 1999 to 2002. Moreover, the reduction of NMR was larger in the North and Middle-West and regions.

Table 38. Level of correlation between baseline variables (Pearson correlation coefficient) and change on neonatal mortality rate from 1999 to 2002*
*NMR 1999- NMR 2002

VARIABLE	Change on Neonatal Mortality Rate (NMR 1999- NMR 2002)	P-Value**
Population	0.02	0.491
Health Expenditure/ capita	-0.001	0.959
Gini Income Coefficient	-0.006	0.834
Population with monthly income <1mw (>10-yr old)	-0.048	0.100
Physicians/ capita (x100,000)	0.032	0.288
Hospital beds/ capita (x10,000)	0.045	0.124
Rural Population (%)	-0.064	0.029*
Household Connection to Public Water System (%)	0.023	0.443
Literacy (> 5-yr old) (%)	0.035	0.228
Region* **	F=1.01	0.402
Average NMR change (1999-2002)		
North	2.46	
Notheast	-1.04	
Middle-West	1.73	
Southeast	0.30	
South	-0.71	

** Statistically Significant at 0.05
*** ANOVA statistical test was conducted, since region is a categorical variable

Even after adjusting for baseline covariates (% rural population, % literate population and number of hospital beds/capita x 10,000), municipalities that have implemented PSF have a higher reduction of NMR (1999-2002) than control municipalities (see table 39). However, such an adjusted association is not statistically significant at $\alpha = 0.05$ (see table 39).

Table 39. Slopes of the absolute change on neonatal mortality rate from 1999 to 2002, between the study groups, respectively unadjusted and adjusted for baseline covariates.

ASSOCIATION	β Intervention group (NMR1999 – NMR2002)	SE (β)	P-value
Unadjusted Association	0.616	1.126	0.584
Adjusted Association**	0.434	1.129	0.709

* Adjusted for % rural population, % literate population, hospital beds/capita (x10,000

Proportion of Low-Birth Weight

The average proportion of low-birth weight for the entire study sample has increased from 6.53% in 1999 to 6.96% in 2002. Municipalities from the intervention group have actually had an absolute increase on the proportion of LBW (LBW1999-LBW 2002) than control municipalities; respectively -0.54% and - 0.30%. The proportional change was also slightly worse for intervention than for control municipalities; respectively -8.27% and 4.55% (see table 40). Such a worsening on the proportion of LBW was higher for municipalities with an average PSF coverage (1999-2002) between 35.8%-100% (see table 41).

Table 40. Evolution of the yearly average and range of proportion of low-birth weight and its respective change from 1999 to 2002, for all municipalities and stratified by study group

STUDY GROUP	PROPORTION OF LOW-BIRTH WEIGHT				Absolute Change in LBW*	Proportional Change in LBW**
	1999 Mean (range)	**2000** Mean (range)	**2001** Mean (range)	**2002** Mean (range)		
All Municipalities (N=1186)	6.525 (0-33.3)	6.428 (0-25.4)	6.744 (0-28.1)	6.964 (0-23.5)	-0.439	-6.72%
Control Group (N=515)	6.523 (0-33.3)	6.609 (0-25.4)	6.820 (0-28.1)	6.820 (0-23.1)	-0.297	-4.55%
Intervention Group (N=671)	6.530 (0-25.0)	6.290 (0-25.4)	6.68 (0-20.0)	7.07 (0-23.5)	-0.540	-8.27%

* Absolute change= LBW 1999 – LBW 2002
** Proportional change= (LBW 1999 – LBW 2002)/ LBW 1999

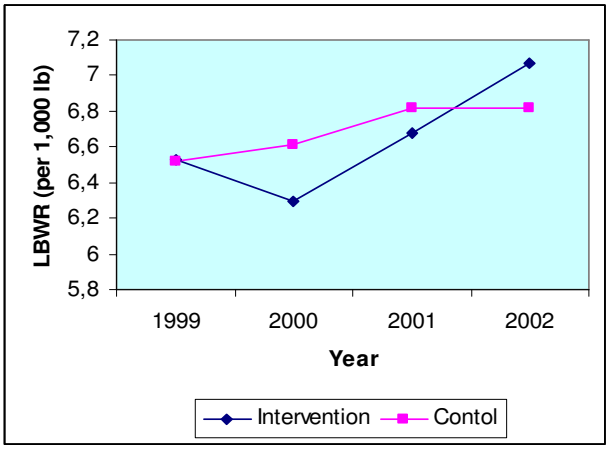
Table 41. Evolution of the yearly average of the proportion of low-birth weight for the control group and quartiles of average PSF coverage (from 1999 to 2002).

YEAR	AVERAGE % PSF COVERAGE (1999-2002)				
	Control (0%)	0-35.8%	35.8%-60%	60%-78.1%	78.1%-100%
1999	6.523	6.931	6.365	6.284	6.521
2000	6.609	6.539	6.054	6.322	6.238
2001	6.818	7.030	6.422	6.591	6.708
2002	6.820	7.216	6.699	7.183	7.22
Absolute Change on LBW*	-0.297	-0.285	-0.334	-0.898	-0.690
Proportional Change on LBW**	-4.55%	-4.11%	-9.15%	-14.29%	-10.58%

* Absolute change= LBW 1999 – LBW 2002
** Relative change= (LBW 1999 – LBW 2002)/ LBW 1999

In addition, as shown in Graph 4, both groups have experienced an important increasing trend on the proportion of LBW, especially from 2000 to 2002. The intervention group has actually had a steady increase in trend, after a little decline from 1999 to 2000. However, none of the slopes were statistically significant at $\alpha=0.05$ (see table 42).

Graph 4. Trend of the average proportion of low-birth weight for both study groups, from 1999-2002



The following simple linear regression models were conducted for the change on the proportion of low birth weight between study groups within the study period, 1999-2002:

Regression lines for the change on the proportion of low-birth weight
(LBW t0- LBW t1):

LBW CHANGE (1999-2000) = -0.09 + 0.33.Study Group (0: control; 1: intervention)
LBW CHANGE (1999-2001) = -0.29 + 0.14. Study Group (0: control; 1: intervention)
LBW CHANGE (1999-2002)= -0.29 - 0.26. Study Group (0: control; 1: intervention)
Note: None of the intercepts are statistically significant at α= 0.05

The results indicate that intervention municipalities had a higher increase on the proportion of LBW than control municipalities from 1999 to 2002 (slope= -0.26; intercept= -0.29). As observed in the regression expressions above, the intercept is negative for the time period 1999-2002, indicating that the control group has had its proportion of LBW actually increased within this time period, while the slope indicates that the difference of the change on the proportion of LBW between intervention and control groups was -0.26 LBW per 100 live births. The intercepts were negative for the

other two time period, however the slopes were positive for the time periods 1999-2000 and 1999-2001; mainly due an important decline from 1999 to 2001 (see graph 4). Nevertheless, none of the slopes were statistically significant at α=0.05 (see table 42).

Table 42. Comparison of study group slopes for the change on proportion of low-birth weight, within three different time periods (1999-2000; 1999-2001; and 1999-2002)

Time Comparison	β Study Group	SE (β)	P-value
1999-2000	0.33	0.22	0.144
1999-2001	0.14	0.22	0.541
1999- 2002	-0.26	0.23	0.262

Recommended Pre-Natal Care Coverage
(Proportion of live births with ≥ 6 appointments)

The average proportion of live births with ≥ 6 appointments (recommended pre-natal care coverage) for the entire study sample has not varied from 33.5% in 2000 to 38.9% 2002. Municipalities from the intervention group have had a slightly higher absolute increase on the recommended pre-natal coverage (coverage in 2002 – coverage in 2000) than control municipalities; respectively 5.46% and 5.35%. The proportional improvement was also slightly higher for intervention than for control municipalities: 16.57% and 15.61% reductions, respectively (see table 43). Such an improvement on pre-natal coverage was not clearly associated to the average level of PSF coverage from 1999-2002, although the highest quartile of coverage had the highest proportion of absolute and proportional change (see table 44).

Table 43. Evolution of the yearly average of proportion of appropriate pre-natal coverage and its respective change from 2000 to 2002, for all municipalities and stratified by study group

STUDY GROUP	APPROPRIATE PRE-NATAL COVERAGE (Proportion of live births >= 6 appointments)			Absolute Change on Prenatal Coverage*	Proportional Change on Prenatal Coverage**
	2000 Mean (range)	**2001** Mean (range)	**2002** Mean (range)		
All Municipalities (N=1186)	33.53 (0-98.4)	35.98 (0-98.9)	38.9 (0-100)	5.37	16%
Control Group (N=515)	34.28 (0-97.8)	36.83 (0-97.4)	39.63 (0-97.4)	5.35	15.61%
Intervention Group (N=671)	32.96 (0-98.4)	35.33 (0-98.9)	38.42 (0-100)	5.46	16.57%

* Absolute change= Coverage 2002 –Coverage 2000
** Proportional change= (Coverage 2002 – NMR 2000)/ Coverage 2000

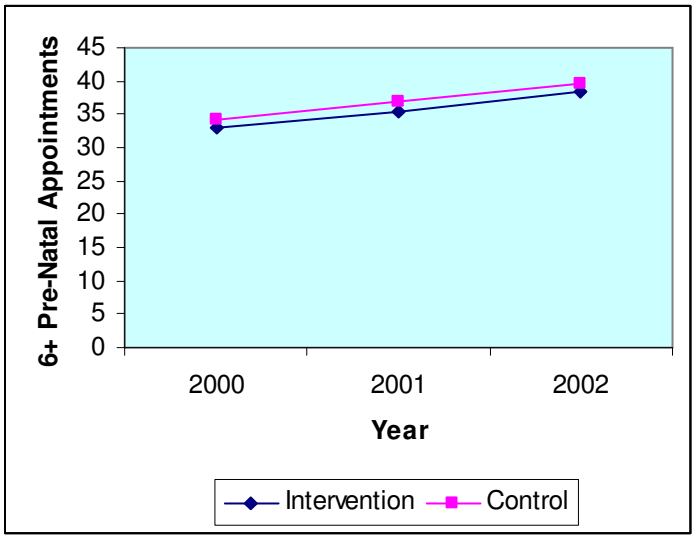
Table 44. Evolution of the yearly average of the appropriate pre-natal coverage (%) for the control group and quartiles of average PSF coverage (from 2000 to 2002).

YEAR	AVERAGE % PSF COVERAGE (1999-2002)				
	Control (0%)	0-35.8%	35.8%-60%	60%-78.1%	78.1%-100%
2000	34.282	33.866	29.631	34.123	34.242
2001	36.829	35.944	32.111	35.515	37.764
2002	39.631	38.189	35.473	38.756	41.273
Absolute Change on Coverage*	5.349	4.323	5.842	4.633	7.031
Proportional Change on Coverage**	15.60%	12.76%	19.72%	13.58%	20.53%

* Absolute change= Coverage 2002 – Coverage 2000
** Relative change= (Coverage 2002 – Coverage 2000)/ Coverage 2000

In addition, as shown in Graph 5, both groups have experienced an important increasing trend on the proportion of recommended pre-natal coverage, which were essentially very similar.

Graph 5. Trend of the recommended pre-natal coverage for both study groups, from 2000-2002



The following simple linear regression models were conducted for the change on the proportion of recommended pre-natal coverage between study groups within the study period, 2000-2002:

Regression lines for the change on the proportion the proportion of appropriate pre-natal coverage (Coverage t1- Coverage t0):

COVERAGE CHANGE (2001-2000) = 2.54* - 0.18.Study Group (0: control; 1: intervention)
COVERAGE CHANGE (2002-2000) = 5.35* + 0.11. Study Group (0: control; 1: intervention)
Note: Intercepts are statistically significant at α= 0.05

The results indicate that intervention municipalities had a higher increase on the proportion of recommended pre-natal coverage than control municipalities from 2000 to 2002 (slope= 5.35; intercept= 0.11). As observed in the regression expressions above, the intercept is positive for the time period 2000-2002, indicating that the control group has had its proportion of recommended pre-natal coverage actually increased within this time period, while the slope indicates that the difference of the change on the proportion of recommended pre-natal coverage between intervention and control groups was 0.11%. The intercepts for both time periods (2000-2001; 2000-2002) were positive, indicating that the control municipalities improved this outcome during both periods of time; while the slope for the time period 2000-2001 was negative, indicating that the improvement of the intervention group was actually smaller than the control for this period of time. Nevertheless, none of the slopes were statistically significant at α=0.05 (see table 45).

Table 45. Comparison of study group slopes for the change on the proportion of appropriate pre-natal coverage (2000-2001; 2000-2002)

Time Comparison	β Study Group	SE(β)	P-value*
2000-2001	-0.18	0.64	0.784
2000-2002	0.11	0.81	0.811

*None of the coefficients are statistically significant at α= 0.05

In addition, the analysis of the association between PSF implementation and change on pre-natal coverage (2000-2002) stratified by baseline covariates indicates that the impact of PSF on the recommended coverage tended to be higher for municipalities of smaller population size, especially those within the first and second quartiles of population size; higher Gini income coefficient; lower average of income level; larger proportion of rural population; lower literacy levels, lower access to public water system; with lower health care expenditure/capita, lower number of physicians/capita, and lower number of beds/capita (see table 46). Furthermore, the highest positive impact of PSF on pre-natal coverage was in the Northeast and South regions. It is important to highlight that the statistical test, two factor anova, was significant only for health expenditure/capita; and Gini income coefficient (see table 46).

Table 46. Slopes of the absolute change on the coverage of pre-natal care from 2000 to 2002, stratified by baseline covariates; followed by a two-factor ANOVA

VARIABLE	B Intervention (coverage2002- coverage2000)	Se(B) (p-value*)	F-test (Model) (p-value*)
Population (1999)			
<= 6099	0.93	0.617	0.48
6100-12539	1.18	0.401	(0.754)
1240-25442	-0.82	0.627	
> 25442	-0.73	0.629	
Health expenditure/cap (in million of R$)			
<= 144.95	0.84	0.588	8.25
144.96-155.72	-3.83	0.118	(0.0001*)
155.73-201.65	-0.68	0.668	
> 201.65	-1.39	0.379	
Gini income coefficient			
<= 0.586	-0.44	0.803	2.57
0.587-0.599	-2.27	0.229	(0.004*)
0.600-0.612	-3.02	0.142	
> 0.612	3.51	0.007*	
Percentage of population with monthly income below 1 minimum wage (>10-yr old)			
<= 62.43	-1.81	0.268	1.32
62.44-76.38	-2.63	0.159	(0.259)
76.39-85.22	2.52	0.084	
> 85.22	2.72	0.072	
Physicians/cap (x 100,000)			
<= 60.17	2.71	0.066	0.38
60.18-102.63	0.38	0.829	(0823)
102.64-163.89	-0.47	0.763	
> 163.90	-1.93	0.297	
Hospital beds/cap (x 10,000)**			
<= 19.38	2.84	0.011*	0.52
19.39-33.70	-1.78	0.280	(0.670)
> 33.70	-3.52	0.042*	
Percentage of rural population			
<= 23.96	-1.42	0.408	0.78
23.97-44.69	-1.49	0.359	(0.539)
44.70-61.35	2.25	0.170	
> 61.36	1.04	0.518	
Percentage of household connection to public water system			
<= 37.45	1.26	0.443	1.19
37.46-56.95	1.11	0.452	(0.312)
56.96-74.64	-2.85	0.078	
> 74.64	1.01	0.556	
Percentage of literacy (> 5-yr old)			
<= 65.34	2.91	0.050*	0.93
65.35-77.88	2.61	0.080	(0.445)
77.89-88.14	-3.39	0.081	
> 88.14	-0.47	0.773	
Region			
North (N=86)	0.97	0.679	5.47
Northeast (N=520)	3.09	0.007*	(0.081)
Middle-West (N=92)	-5.71	0.076	
Southeast (N=248)	-1.53	0.440	
South (N=234)	1.24	0.555	

*Statistically significant at α=0.05;
** Given the large number of no beds in the municipality, this covariate was categorized in 3 groups

In addition, the change on the recommended pre-natal coverage from 2000 to 2002 was independently predicted only for two baseline covariates (see table 47). Larger proportions of the population >10-yr old and with monthly income < one mw (minimum wage) predicted improvement on the proportion of live births with ≥ 6 appointments from 2000 to 2002. Moreover, the increase on the recommended pre-natal coverage was larger in the South and Northeast regions (see table 47).

Table 47. Level of correlation between baseline variables (Pearson correlation coefficient) and change on recommended pre-natal care coverage from 2000 to 2002*
*Coverage 2002 - Coverage 2000

VARIABLE	Change on Recommended Pre-Natal Care Coverage (Coverage 2002- Coverage 1999)	P-Value**
Population	-0.009	0.735
Health Expenditure/ capita	0.015	0.599
Gini Income Coefficient	-0.016	0.571
Population with monthly income <1mw (>10-yr old)	0.058	0.040*
Physicians/ capita (x100,000)	0.006	0.844
Hospital beds/ capita (x10,000)	0.013	0.644
Rural Population (%)	-0.029	0.304
Household Connection to Public Water System (%)	0.039	0.181
Literacy (> 5-yr old) (%)	0.030	0.295
Region* **	F=6.44	<0.0001*
Average Coverage change (2002-2000)		
North	-0.19	
Notheast	5.63	
Middle-West	2.73	
Southeast	5.14	
South	8.33	

** Statistically Significant at 0.05
*** ANOVA statistical test was conducted, since region is a categorical variable

After adjusting for baseline covariates (% population <10-yr old, % population with a monthly income < mw, physicians/capita x100,000, and region location),

municipalities that have implemented PSF have a even higher increase in the proportion of live births $\geq$ 6 appointments (2000-2002) than control municipalities (see table 48). However, such an adjusted association is not statistically significant at $\alpha = 0.05$ (see table 48).

Table 48. Slopes of the absolute change on the recommended pre-natal coverage from 2000 to 2002, between the study groups, respectively unadjusted and adjusted for baseline covariates.

ASSOCIATION	β Intervention group (Cov.2002– Cov.2000)	Se (β)	P-value
Unadjusted Association	0.111	0.809	0.891
Adjusted Association**	1.265	0.847	0.136

* Adjusted for % population (<10-yr old) with a monthly income below 1 minimum wage, physicians/capita (x100,000), region location

Homogeneity of Immunization Coverage (DPT+ H. Influenza) < 1-yr old

About 72.3% of the municipalities studied have achieved homogeneity of immunization coverage for infants in 2002. Municipalities from the intervention group have achieved 76.7% of homogeneity of immunization coverage, while control municipalities only 66.8% (see table 49). Such a difference on the proportions of homogeneity of coverage is statistically significant at $\alpha = 0.05$ (see table 49).

Table 49. Proportion of homogeneity of immunization coverage within the entire cohort and stratified by study group in year 2002

VARIABLE		STUDY GROUP		TOTAL N=1041
		Intervention N=622	Control N=419	
Homogeneity of Immunization	N	477	280	757
	Frequency (%)	76.7	66.83	72.72

Pearson chi2 (1) = 12.2744, p = 0.000
Fisher's exact = 0.001; 1-sided Fisher's exact = 0.000

In addition, the analysis of the association between PSF implementation and change and homogeneity of immunization coverage stratified by baseline covariates indicates that the impact of PSF on the immunization coverage tended to be higher for municipalities of larger population size, especially within the third quartile of population size; larger income inequality; for municipalities within the second and third quartile of proportion of rural population; lower average of income levels; lower literacy levels; lower access to a public water system; with lower health care expenditure/capita, especially among municipalities within the second quartile; larger number of

physicians/capita, especially among the third quartile; and intermediary number of beds/capita (see table 50). Furthermore, the highest positive impact of PSF on homogeneity of immunization coverage was in the Northeast and South regions (see table 50). It is important to highlight that the statistical test, test of homogeneity of odds-ratio, was significant only for region (see table 50).

Table 50. Odds ratio for the association between homogeneity of immunization in year 2002 and study group, stratified by baseline covariates; followed by test of trend.

VARIABLE	Intervention/Control Odds Ratio (p-value*)	Test of Homogeneity Chi-Square (p-value)
Population (1999)		
<= 6099	1.53 (0.119)	2.31
6100-12539	1.24 (0.443)	(0.511)
1240-25442	2.26 (0.005*)	
> 25442	1.76 (0.049*)	
Health expenditure/cap (in million of R$)		
<= 144.95	1.76 (0.079)	3.97
144.96-155.72	2.73 (0.010*)	(0.264)
155.73-201.65	1.30 (0.314)	
> 201.65	1.13 (0.635)	
Gini income coefficient		
<= 0.586	1.50 (0.163)	7.34
0.587-0.599	1.24 (0.426)	(0.060)
0.600-0.612	0.98 (0.979)	
> 0.612	2.97 (0.0001*)	
Percentage of population with monthly income below 1 minimum wage (>10-yr old)		
<= 62.43	1.13 (0.640)	5.86
62.44-76.38	1.77 (0.038*)	(0.118)
76.39-85.22	1.35 (0.319)	
> 85.22	2.90 (0.0005*)	
Physicians/cap (x 100,000)		
<= 60.17	1.14 (0.656)	6.92
60.18-102.63	1.91 (0.037*)	(0.141)
102.64-163.89	2.70 (0.006*)	
> 163.90	1.09 (0.762)	
Hospital beds/cap (x 10,000)**		
<= 19.38	1.52 (0.038*)	1.45
19.39-33.70	2.22 (0.004*)	(0.484)
> 33.70	1.45 (0.176)	
Percentage of rural population		
<= 23.96	1.29 (0.331)	2.34
23.97-44.69	1.79 (0.046*)	(0.501)
44.70-61.35	2.24 (0.004*)	
> 61.36	1.38 (0.273)	

Percentage of household connection to public water system		
<= 37.45	2.39 (0.004*)	3.06
37.46-56.95	1.43 (0.221)	(0.383)
56.96-74.64	1.79 (0.031*)	
> 74.64	1.22 (0.472)	
Percentage of literacy (> 5-yr old)		
<= 65.34	3.19 (0.005*)	6/65
65.35-77.88	1.81 (0.039*)	(0.085)
77.89-88.14	1.14 (0.644)	
> 88.14	1.23 (0.433)	
Region		
North (N=86)	1.14 (0.830)	9.75
Northeast (N=520)	2.62 (0.001*)	(0.044*)
Middle-West (N=92)	0.83 (0.789)	
Southeast (N=248)	0.90 (0.716)	
South (N=234)	1.84 (0.670)	

* Statistically significant at α=0.05
** Given the large number of no beds in the municipality, this covariate was categorized in 3 groups

In addition, homogeneity of immunization coverage was independently predicted by three baseline covariates (see table 51). Municipalities with homogeneity of immunization coverage were more likely to have higher income inequality and smaller proportion of literacy. Moreover, municipalities from Middle-West and Northeast regions were more likely to achieve homogeneity of coverage (see table 51).

Table 51. Association between mean and proportional value of baseline variables and homogeneity of immunization in 2002

VARIABLE	HOMOGENEITY OF IMMUNIZATION YEAR 2002		P-VALUE (N=1041)
	No (N=284)	Yes (N=757)	
Population	33,478	32,676	0.869
Hexp/cap	170.82	170.97	0.864
Gini_inc	.595	.598	0.005*
< 1 minim. wage(%)	71.67	72.32	0.513
Phys/cap	139.99	133.83	0.874
Hbeds/cap	22.56	24.68	0.536
Water(%)	58.40	56.58	0.138
Rural(%)	42.36	41.80	0.749
Literacy(%)	78.79	77.02	0.030*

Region (N)			<0.0001*
North	20	33 (62.3%)	
Northeast	94	342 (78.4%)	
Middle-West	18	72 (80%)	
Southeast	86	139 (61.8%)	
South	66	171 (72.25)	

*Statistically significant at α=0.05 (Mann-Whitney & Chi-Square statistical tests)

Even after adjusting for baseline covariates (% literate population >5-yr old, physicians/capita x 100,000, and region location), municipalities that have implemented PSF in 1999 are approximately 59% more likely to achieve homogeneity of immunization coverage (among infants < 1-yr old) than control municipalities (see table 52). Such an adjusted association is statistically significant at $\alpha = 0.05$.

Table 52. Odds ratios for the association between homogeneity of immunization and study group in 2002, respectively unadjusted and adjusted for baseline covariates.

ASSOCIATION	**Odds Ratio (Intervention/ Control)**	**Se (β)**	**P-value****
Unadjusted Association	1.633	0.229	<0.0001**
Adjusted Association**	1.587	0.296	0.003**

* Adjusted for % literate population (>5-yr old); number of physicians/capita x 100,000 and region location
** Statistically significant at α= 0.05

5. DISCUSSION

5.1. Overview

Overall the group of municipalities that have initiated PSF implementation in 1999 experienced a steady trend of increasing population coverage from 1999 to 2002, which has been associated to an increased delivery of home visits, a marker of adequate policy implementation since it is a nationally recommended primary health care activity. Thus, it indicates that the quantitative increase on PSF coverage has actually been accompanied by enhanced delivery of recommended primary health care services.

This group of municipalities that implemented PSF in 1999 was more likely to reduce infant mortality rates from 1999 to 2002 than the group of municipalities that haven't implemented the policy from 1999 to 2002. Such a beneficial impact of PSF was stronger in socio-economically disadvantaged municipalities (e.g. higher income inequality, in those with lower access to safe water, higher illiteracy rates, lower average income levels) and in those with poor health care capacity (e.g. lower health care expenditure/capita and lower number of beds/capita). Moreover, this association was also significant after the adjustment to baseline covariates embracing municipal socio-economic, demographic and health care capacity dimensions. However, the positive impact of this policy on infant mortality rate was not actually associated to the average level of PSF coverage from 1999-2002 within the intervention group, indicating that the quantitative increase on population coverage might be a less important determinant of prevention of infant deaths than the quality of the delivery and organization of PSF

services. In addition, the largest impact of the policy implementation on infant deaths occurred within the time period 1999-2001.

Furthermore, the group of municipalities that implemented PSF in 1999 was also more likely to reduce neonatal mortality rates; to enhance access to recommended pre-natal care coverage (proportion of live births with $\geq$ 6 appointments) and to achieve homogeneity of immunization coverage under 1-year old (DPT + *H. Influenza*). However, of these only the positive impact on the homogeneity of immunization coverage in 2002, and the reduction of neonatal mortality rates from 1999 to 2001 were statistically significant. In addition, both groups have largely improved the access to recommended pre-natal coverage; however the difference between groups although larger after adjustment to baseline covariates, was not statistically significant. Finally, the proportion of low birth weight has actually increased in both study groups, consistent with the overall national rates within the same time period. this might be a result of potential positive surveillance bias, since surveillance has increased importantly in areas that have experienced change on the supply of primary health care providers.

This chapter will further explore the study findings as a discussion about the process of PSF implementation and its respective impact on infant mortality rate and other aggregated outcomes of infant health (e.g. neonatal mortality rate, proportion of low-birth weight, proportion of live births with $\geq$ 6 appointments, and homogeneity of immunization coverage under 1-yr old) is conducted. Then, general conclusions and final are presented.

5.2. PSF Implementation

Although all Brazilian municipalities are eligible to receive federal funds to sponsor such a modality of primary health care, typically socio-economically disadvantaged municipalities with low health care capacity were more likely to implement the policy in 1999, when compared to control municipalities that have eventually implemented PSF within the time period 2003-2004. The increased number of physicians/capita in the intervention group in 1999 might be a direct consequence of the policy implementation, since there is a major expansion of the number of local health care providers as PSF is initiated. In addition, the other two dimensions of health care capacity (e.g. health care expenditure/capita and hospital beds/capita) indicate that municipalities implementing PSF in 1999 have actually a worse health care capacity.

Therefore, the availability of such federal funds seemed to represent an attractive opportunity for municipalities struggling to overcome lack of access to basic health care services and major socio-economic risky situations. Sometimes, in the most extreme scenarios of poor access to health care, it has even represented an opportunity to have a physician and a nurse working locally. Wealthier municipalities, especially those located in larger urban areas, seem not to be initially attracted by this federal program since it would not represent any major change in their health care capacity, besides establishing a novel philosophy of care that conflicts to the mainstream medical care typically found in those areas. In addition, the legitimacy of PSF as a “cost-effective” model of primary care policy was not yet consolidated in Brazil at that time.

Thus, federal financial incentives, and opportunity of enhancing autonomy of municipal health care systems and expanding the number of health care providers seemed to be more important than the technical assessment of PSF effectiveness to determine the decision made by managers of Local Health Departments to implement *Programa de Saude da Familia* in 1999.

In addition, although the Brazilian Ministry of Health has sought a universal coverage of PSF nationwide, such a policy was initially implemented mostly in underserved areas of the country (MS/Aval.Impl, 2002), serving as a mechanism to ameliorate the major national inequalities in access to health care nationwide. As a direct consequence of this unintended initial focus on underserved municipalities, PSF is still stigmatized as a modality of primary health care for impoverished populations, which makes universal access to PSF a major challenge for the Brazilian Ministry of Health.

Furthermore, although municipalities that have initiated policy implementation might decide not to expand its population coverage or even eventually cancel it, this study has observed a steady trend of growing PSF municipal coverage, which has actually increased from 38.7% in 1999 to 70.38% in 2002 among intervention municipalities. It indicates an overall sustainable commitment of the federal and municipal spheres of government with this primary health care policy within the study time period, 1999-2002. The financial incentives received by municipalities seem to be a major factor determining such an expansion of coverage (MS/Custos, 2001); whereas the federal government seemed to be stimulated by national assessments indicating overall improvement in some population health outcomes nationwide (MS/Evol., 2002;

MS/SIAB, 2003; MS/InfAB, 2004). This finding is consistent with the national trend of PSF coverage that has also grown from 5.45% in 1999 to 37% in 2004 (DATASUS, 2005).

Finally, the increased quantitative PSF municipal coverage does not necessarily mean that residents have been actually assisted by the policy. In order to assess the adequacy of PSF implementation, a nationally recommended primary care activity was assessed - home visits. These home visits are usually performed by community health workers, but are also done by physicians and nurses. They serve to provide educational messages, deliver preventive care and also to assist special population groups (e.g. pregnant women, children, elderly and disabled) (MS/Guia, 2003). This study has found that such a quantitative impact on the PSF municipal coverage has actually been accompanied by an increased number of home visits performed by a health care professional. Such study findings indicate that the intervention group has performed a higher average number of home visits a month than the control group; and that the average number of visits increases by each quartile of PSF average coverage (1999-2002). Thus, based on this marker of primary health care appropriateness, study findings suggest that the policy has been overall adequately implemented.

5.3. Infant Mortality Rate

The type of low-complexity maternal and child health services provided by PSF (e.g. antenatal care, immunization, management of diarrhea and respiratory diseases; nutritional follow-up; and breastfeeding education); its priority on coordination and integration of maternal and infant health demand with other levels of care either within the municipality or at other municipalities; and its strong community focus, concerned with education and empowerment of women in reproductive age, might explain the beneficial impact of PSF on the reduction of infant mortality rates. Study findings are consistent to other authors that have found a positive impact of primary health care systems on infant mortality rate, especially post-neonatal mortality rates (Starfield, 1998). Such improvement on infant deaths has been mainly attributed to an enhanced access to essential maternal and child health services (e.g. oral hydration therapy, immunization, antenatal care) and increased local availability of primary health care providers (Starfield, 1998; Moore, 2003; Shi, 2004).

In addition, given such an increased supply of primary care providers locally, intervention municipalities seemed more likely to identify and report infant deaths that would not be normally recorded by the official system of death record in some municipalities. Therefore, such a potential differential bias on the infant death data collection system might have actually diluted the real association between PSF intervention and reduction of infant mortality rate.

Moreover, the differential effects of primary health care interventions on the reduction of infant deaths, found in socially disadvantaged areas with poor health care

capacity, have also been reported by other authors (Villalbi, 2003; Shi, 2004). Such municipalities typically have a worse infant health scenario characterized by poor health outcomes (e.g. IMR, NMR, LBW) and insufficient access to maternal and child health services. Therefore, a larger and more rapid increase on the access to MCH services might explain the better performance of this policy in underserved municipalities. In other words, since these municipalities had high infant mortality rates and poor health care capacity before policy implementation, the intervention will tend to result in larger slopes of change between study groups.

The difference on the reduction of infant mortality rate between study groups was actually higher for the time period 1999-2001 than for 1999-2002. It could also be simply a result of the high rates of infant mortality in the intervention group in 1999, which had been rapidly impacted by a short-term increase on the supply of primary care providers and access to essential maternal & child heath services. However, a longer assessment of the effects of this policy would be needed before establishing any definitive conclusion regarding this matter.

In addition, there was no linear association between average level of PSF coverage and reduction of infant mortality rate from 1999 to 2002. Actually, the second quartile of average PSF coverage for the time period 1999-2002 (35.8%-60% average coverage) had the largest reduction of infant mortality rate. It might indicate that the quality of the implementation process (e.g. organization of primary care services; delivery of services; integration & coordination of services; mechanisms of community

participation) is a better predictor of IMR improvement than simply increased population coverage.

Furthermore, the adjusted analysis has suggested that even controlling for socio-economic, demographic and health care capacity factors that might predict this study outcome, PSF implementation still had a significant impact on the reduction of infant mortality rate from 1999 to 2002. However, since the impact of the policy has been diluted after adjusting for the baseline variables, it might be inferred that % literate population, number of hospital beds/capita and region location altogether are effect modifiers for the association between PSF and reduction of infant mortality rate. It is important to mention that % rural population and Gini income coefficient have also been independently associated to the reduction of infant mortality rate, corroborating that lower socio-economic status at baseline was a good predictor of change on infant mortality rate from 1999 to 2002. However, their inclusion in the model would challenge the assumption of no collinearity of and within multivariate linear regression models.

Finally, given the characteristics of the PSF policy, it will very likely have an effect only on a portion of infant deaths that can be typically prevented by the delivery of low-technology primary health care services. Thus, as reported by Starfield_&_Shi (2001), primary health care initiatives seem more relevant to the post-neonatal period, since the management of prematurity, low birth weight and neonatal complications usually requires a more complex type of health care, which this policy does not address directly. For instance, delivery of complicated pregnancies, management of premature newborns and neonatal care in intensive units are examples of secondary and tertiary care

interventions determining infant mortality, under which PSF does not have a direct influence. It has been corroborated by the study findings on neonatal mortality rate, which are further discussed in this chapter. However, in order to provide a more in-depth understanding of the impact of PSF on infant mortality rate, future research studies should ideally investigate the gestational age-specific and birth-weight specific infant mortality rates.

In addition, the logic model has proposed that such a short-term impact on infant mortality rate is largely due an expanded access to comprehensive primary care services in areas lacking such services, especially enhancement of maternal health services and appropriate management of conditions affecting infant in the post-neonatal period (Shi, 2004). However, PSF would also have a sustained effect as it promotes conditions for the health care system to deliver integral health care to the covered population and also partner decision-making processes with respective communities, especially when direct mechanisms of community participation are developed. Only a longer study would fully understand the sustainability of the impact of this policy on infant health outcomes. Obviously, since a large reduction of infant mortality rate has already occurred in covered municipalities, such mechanisms of sustainability will likely have a less accentuated impact on IMR. Future research studies could address that following-up prospectively the group of municipalities that have implemented PSF in 1999.

5.4 Other Infant Health Outcomes

a) Neonatal Mortality rate

The impact of the municipal implementation of PSF on the reduction of neonatal mortality rate from 1999 to 2002 was not statistically significant. Such an association was not significant even within different strata of the baseline covariates. As the association between PSF implementation and reduction of NMR from 1999 to 2002 was adjusted to socio-economic, demographic and health care capacity baseline covariates (% rural population, % literate population and number of hospital beds/capita x 10,000), the slope reduced slightly and was not significant as well. Only % rural population was actually an independent predictor of poor change on neonatal deaths. It is a reasonable association, since a larger proportion of a rural population is commonly associated to impaired geographic access to secondary and tertiary care services, more specifically to needed maternal and neonatal care facilities.

Both groups had actually a slight increase on the rates from 1999 to 2000, however the intervention group had an important decrease on NMR from 2000 to 2001 (see graph 3). Thus, for the time period 1999-2001, there was a significant association between intervention and reduction of NMR. As an exploratory adjusted analysis was conducted for the time period 1999-2001 and the multivariate linear regression model included the same set of baseline covariates (% rural population, % literate population and number of hospital beds/capita x 10,000), the slopes did not change importantly and the association between PSF implementation and change of neonatal mortality rate (1999-2001) was still significant (Appendix).

The lack of association found for the period 1999-2002 is fairly consistent to other ecological studies that have found either no association between primary health care and neonatal mortality rate (Starfield 1998; Starfield, 2001; Shi, 2004), or only a slight cross-sectional linear correlation between high availability of primary health care (PHC) providers and low neonatal mortality rate (Shi, 1994). Since this latter study hasn't established any type of longitudinal analysis of the impact of availability of PHC providers on the change of NMR rates, no definitive conclusion can be established. Another study that utilized a longitudinal assessment of the impact of primary health care reform on NMR has actually found a significant temporal change on neonatal mortality rate within a period of thirteen years; however this was an uncontrolled study and authors have simply compared rates in three different time periods.

Although the majority of infant deaths occur within the neonatal period in Brazil (e.g. 13.5 neonatal deaths out of 21.3 infant deaths per 1, 000 live births in 1999) (DATASUS, 2005), the impact of primary health care on the prevention of neonatal deaths is less accentuated than on the prevention of post-neonatal deaths (Starfield 1998, Shi, 2004). Neonatal deaths are more commonly a direct result of sepsis, asphyxia, hemorrhage, hypothermia, and/or hypoglycemia; health conditions that usually require a more complex type of medical care, usually neonatal intensive care units, in order to effectively prevent deaths (Hort, 1985; Levene_&_Tudehope; 1993; Ondoa-Onama 2003). Improvement on breastfeeding and correct management of diarrheal and respiratory diseases are essential primary health care activities that might prevent a portion of neonatal deaths caused by early infection and dehydration within the first 28

days of life (Mota-Hernandez, 1990; Khalique, 1992; Moore, 2003; Davanzo, 2004). In addition, enhancement of pre-natal care with early recognition of risky pregnancies and management of maternal healthy problems that are associated to birth complications (e.g. smoking, alcoholism, drug use, poor weight STD, poor nutrition) might also prevent complications during the neonatal period (Shi, 2004). However, the lack of significant impact found on the pre-natal care coverage (2000-2002) suggests that the short-term effect found on neonatal mortality rate, from 1999 to 2001, seemed to be more a result of rapid changes in the access to the adequate prevention and management of early infections and enhancement of breastfeeding than simply a result of improved pre-natal care. Since the change on overall infant mortality rates were also more profound within the time period 1999-2001, it suggests that the most likely explanation for both the reduction of overall infant deaths and also neonatal deaths was the rapid overcoming of major gaps within access to essential MCH services.

As suggested by the logic model, the consolidation of PSF implementation would lead to a better coordination and integration of care, which might also have a positive role on the prevention of neonatal deaths in the long run. For instance, if there is a good integration between primary health care and other levels of complex care, complicated pregnancies could be adequately referred to secondary level maternities and risky labor could be appropriately handled. Similarly, early signs of neonatal complications could be timely identified and referred to more complex centers of neonatal care. However, in order to understand such integrative and coordination roles of PSF, a longer study needs to be conducted.

It is important to mention that the power estimation performed was based on the primary study outcome, infant mortality rate. Thus, since neonatal mortality rate is a sub-component of the IMR, the sample size might not be sufficient to identify any effect of this policy on the prevention of neonatal deaths from 1999 to 2002, after the important decline from 1999 to 2001. In addition, given the increased supply of primary care providers in intervention municipalities, a potential differential bias might also be playing a role, since neonatal deaths are more likely to be identified and reported in municipalities with a larger number of providers living in the communities. Therefore, such a potential differential bias might have also diluted the real association between PSF intervention and reduction of neonatal mortality rate.

b) Proportion of Low-birth weight

Low-birth weight is mainly caused by prematurity and intrauterine growth retardation (UN, 2000). The latter is the most important cause of low-birth weight in developing country and is intrinsically associated to the maternal environment (e.g. anemia, chronic infections, risky behavior, nutritional status…), especially to poor nutritional status at conception and poor weight gain during pregnancy (Levene_&_Tudehope, 1993; UN, 2000). Therefore, primary care interventions that directly address pre-natal care adequately and also target other important social determinants such as water quality, sanitation and hygiene, and maternal education are likely to impact low-birth weight positively. Given the focus PSF on maternal education,

management of anemia and mal-nutrition and immunization during pre-natal care, besides also targeting community major environmental risks (MS/GUIA, 2003); an improvement on the proportion of low-birth weight was expected to occur, at least in a long-run; however, study findings do not show it during this period.

Brazilian national rates of low-birth weight in live births have actually increased slightly from approximately 7.56% in 1999 to 8.07% in 2002 (DATASUS-PAB, 2005). Such a trend of increasing low birth weight was also found in this study, as both groups of municipalities have increased the proportion of low birth weight from 1999 to 2002. Intervention group had a higher increase on LBW than control group and such an increase was even more accentuated for the two highest quartiles of average PSF coverage from 1999-2002 (60%-100% average coverage), suggesting that municipalities that have increased supply of primary care providers have actually worsened their proportion of live births.

Such results have also contradicted the findings from a previous eleven-year longitudinal analysis that have found a beneficial effect of increased availability of primary health care providers on low-birth weight (Shi, 2004). Authors attributed such lower low-birth weight rates in these areas to a better management of maternal health, especially adequate handling of maternal risk factors (e.g. smoking, alcoholism, drug use, poor weight gain, poor nutrition and infections during pregnancy). In addition, they suggest that this beneficial impact on LBW might be due a "…continuous, comprehensive person focused care over the life span of women"; and also that

consolidation of strong primary care systems in socially disadvantaged areas may influence important social determinants of low-birth weight in a long run (Shi, 2004).

Given the inconsistency of this finding in relation to all other infant health outcomes studied in this research project and also to findings from other studies, the steady trend of growing LBW in the intervention group from 2000 to 2002, and the increased probability of LBW within the two highest quartiles of average PSF coverage (60%-100% coverage from 1999 to 2002), reporting bias is suggested as an explanation for this unexpected study finding. In other words, increased availability of local health care providers in areas typically underserved and regular weighting of newborns that would not be normally weighted might explain it, since PSF has been implemented more frequently in municipalities of unfavorable socio-economic scenario and poor health care system. Such a phenomenon has actually been reported even in developed countries that have implemented more effective data collection systems or health care interventions that have intensified the process of weighting live births for some risky population groups (Phelan, 1998).

The majority of infants born in developing countries are not weighed at birth and those who are weighed are more likely to be from privileged social background, to be born in wealthier areas, and to be assisted by medically trained personnel in medical care facilities (Blanc, 2005). Thus, commonly a large number of low-birth weight in underserved areas are not appropriately identified and officially registered; especially very low birth weight infants who die soon after birth (Muller, 2005) Some authors have actually reported that even in some developed areas of the globe, about 25% of stillbirths

and 15.4% of neonatal deaths didn't have any report of birth weight (Wen, 2002). In other words, population estimates of low-birth weight are commonly subject to bias as the data usually is limited to reports from health facilities, and therefore do not represent the overall population of neonates (Boerma, 1996).

Since municipalities that implemented PSF have been able to identify and weigh newborns that are commonly not delivered in hospital facilities, and those municipalities tended to have worse socio-economic profile; a larger proportional number of low-birth weight are likely to be registered in municipalities after initial PSF implementation. It does not necessarily mean that the proportion of LBW has increased, but rather a more complete recording system is in place. However, a longer assessment of the trends of proportion of low-birth weight of the same group of municipalities may confirm such an explanation for this unexpected finding. If the policy is really effective in reducing the proportion of LBW, it is likely that this increasing trend will eventually stabilize and will experience a more accentuated decrease than the group of municipalities that did not implement PSF.

c) Population Coverage of MCH Services

Two fundamental elements of appropriate assistance to infant health were utilized to understand the impact of this policy on the access dimension. Both access to adequate pre-natal care and infant immunization coverage are determinants of infant health outcomes, and are also indicators of appropriate infant health protection themselves (Pedreira, 1986; PAHO, 1991; Abel; 1994; Bhutta, 2005). The levels of population

coverage of these MCH services indicate a commitment of the municipality with the protection of their infants' health.

- **Pre-Natal Care**

Pre-natal care is typically a continuous and comprehensive maternal health service that is a direct predictor of newborn outcomes, when performed with the correct frequency and provision of quality care (WHO, 1969; Pedreira, 1986, PAHO, 1991). In addition, the Brazilian government has established in 2000 the goal of six pre-natal appointments performed by either a nurse or physician for each pregnant woman. Such a quantitative goal, instead of looking at the quality of the pre-natal care (e.g. tetanus immunization, glycemia and blood pressure monitoring, nutritional follow-up, ultrasound monitoring…), was targeted as the study outcome, since assessing the quality of the pre-natal encounters would be a challenging task for this research study that was based on official national databases.

Both study groups have actually improved steadily the proportion of live births with $\geq$ 6 appointments from 2000 to 2002; the intervention group having a very slightly higher improvement. Although the magnitude of the slope between study groups have increased largely after adjustment to baseline covariates, the difference between groups was not still statistically significant.

Such a lack of significance suggest that the primary care fund received to sponsor other modalities of PHC has been roughly as effective as PSF in increasing utilization of

pre-natal care. The large majority of municipalities in the control group have community health workers that might be acting as critical facilitators in the scheduling and coordination of pre-natal care, what could explain such an important improvement in the control group as well. Alternatively, the sample size or length of study time could not be large enough to identify a significant impact on this outcome, if it actually exists.

It is also important to mention that, consistent to the findings for infant mortality rate, low socio-economic status (e.g. higher proportion of population living with < 1 minimum wage a month) at baseline predicted higher improvement on pre-natal coverage, very likely because those areas would likely have a very low coverage at baseline and any type of primary care investment, either PSF or other modalities of PHC, will result in a important absolute coverage change. Moreover, the stratified analysis identified a significant slope between study groups for underserved municipalities (e.g. higher Gini income coefficient; lower average income; higher illiteracy, from Northeast region). Thus, as also observed for the other study outcomes, PSF implementation has been more effective in disadvantaged areas lacking access to basic health care capacity.

A final comment should be made about the quality of the pre-natal care provided. Although intervention municipalities had an overall non-significantly higher pre-natal coverage though a significant one for underserved municipalities; the differential impact of that on the actual prevention of newborn complications and infant deaths will largely depend on the quality of the care provided. Although the number of appointments is a good proxy of coverage; only antenatal care that addresses adequate maternal education, early recognition of maternal risk factors, correct handling of pregnancy complications

and timely referral to specialized care whenever needed will impact birth outcomes (Abel, 1994; Shi, 2004; Feresu, 2005). Thus, future research should investigate whether higher larger numbers of appointments are actually associated to the provision of adequate pre-natal services (e.g. maternal education, nutritional monitoring, tetanus immunization, ultrasound follow-up…).

- **Immunization Coverage (DPT + *H. Influenza*)**

Given the high rates of immunization coverage for infants achieved in Brazilian municipalities since the early nineties, commonly over ninety percent of coverage (DATASUS, 2005); the Brazilian Ministry of Health has actually sought universality of coverage as a major national infant health goal. Such a universality of coverage is also defined as homogeneity of immunization coverage. Until the end of 2001, the three recommended dosages of DPT immunization were tracked in order to define compliance with the DPT vaccine schedule. Given the inclusion of the vaccine for *Haemophillus Influenza* in 2002 as a national primary care priority, a new goal was established for that year, which consisted of DPT + *H. Influenza*.

As expected, intervention municipalities were approximately 63% more likely to achieve homogeneity of immunization coverage than control groups. In addition, such an association was still significant after adjustment for baseline covariates (% literate population >5-yr old; number of physicians/capita x 100,000 and region location). Consistent to the findings of other outcomes in this study, socially disadvantage (e.g. high

Gini income coefficient and higher illiteracy) has also determined a higher probability of achieve homogeneity of immunization coverage.

Moreover, the stratified analysis identified several significant associations between PSF and homogeneity of immunization coverage within different strata of baseline covariates. However, such odds-ratios were slightly higher among municipalities with larger number of physicians and intermediary number of hospital beds/capita; which might suggest that in municipalities with a better overall health care capacity, PSF is more likely to actually receive the vaccine vials timely and administer them appropriately at the required infant age. This holds true if municipalities of better health care capacity are more likely to obtain, adequately conserve and distribute vaccines promptly to PSF teams.

Although other vaccines are also regularly administered during the infancy in Brazil (see appendix), only these vaccines are tracked as national indicators of primary care, in order to assess municipality commitment with national immunization schedule. Overall, such an increased coverage among municipalities that have implemented PSF is an important indication that this policy has actually attempted to provide fundamental protective services to infants.

5.5 Final Conclusions

The development of such a controlled longitudinal study has allowed for the first time an evaluation of the epidemiologic impact of PSF on population health outcomes. The large study sample size; the utilization of a control group of municipalities of fairly similar socio-economic and demographic similar profile; the adjustment for baseline covariates that are potential predictors of infant health; and the diversity of infant health outcomes studied allowed a methodologically sound and comprehensive assessment of the impacts of this primary health care policy on municipal outcomes of infant health. In addition, the intervention variable was set a dichotomous outcome, defined as any level of continuous PSF coverage from 1999 to 2002. It has prevented the potential circularity in results, given that differential PSF coverage might be associated to the outcome variables. However, it is important to highlight that several methodological weaknesses have limited the scope of the study findings.

At first, it has essentially been an outcome rather than a process evaluation, what has limited the ability of understanding which PSF processes (e.g. community empowerment; integrality of care) have been actually implemented and useful to impact infant health outcomes. It has prevented any attempt to fully test the validity of the logic model presented on figure 3. Secondly, the impossibility of collecting information about political and social capital at baseline for all studied municipalities, given the primary reliance on official national databases, has limited the understanding of the potential impact of such socio-political variables on the success of the policy in improving infant health outcomes. Thirdly, the short length of the longitudinal analysis, also limited by

unavailability of outcome data on the national database after 2002, has prevented a longer assessment of the impact of this policy on infant health. In addition, the lack of real baseline measures of the outcomes variables in the national databases, previous to year 1999, might have affected the study findings. Since measures of outcome for year 1999 were used as baseline measures, the real impact of PSF should actually be larger than those found in this study; given that the policy has already brought some level of impact during 1999 within municipalities that first implemented the policy during that year.

Other limitations might have affected this study at different levels. At first, given that some municipalities have implemented PSF at different times during year 1999 and there was a wide diversity of level of PSF coverage among the intervention municipalities, not all municipalities had universal coverage (see table 22); it might be inferred that study findings were actually diluted and PSF should have an impact greater than the observed in his study. Secondly, some of the socio-economic variables (e.g. gini income coefficient and health expenditure/capita) were aggregated at the state rather municipal level and other municipal contextual variables had limitations on their measurements. For instance, literacy level was estimated using population above 5-yr old rather above 14-yr old, as in other studies, as the denominator; whereas income level was measured as percentage of population living under one minimum wage/month rather than mean per capita income. It might have prevented the possibility of having a measure of adult literate population and a more reliable measure of population income. Moreover, since this study design is typically ecological, it wouldn't be correct to make inferences of the impact of PSF implementation on individual outcomes of infant health, given the

risk of ecological fallacy. Future studies can address that looking at individual rather than aggregated data at the municipal level.

Nevertheless, it might actually be concluded that overall PSF implementation has brought an important short-term improvement on municipal indicators of infant health from 1999 to 2002, especially on infant mortality rate (most likely within the neonatal period) and homogeneity of immunization coverage in infants (*DPT + H. Influenza*). Such beneficial impact was actually stronger in socially disadvantaged municipalities, commonly with unfavorable health care scenario. Thus, the expansion of primary health care capacity and overcoming of major gaps within the access to MCH services might explain such short-term beneficial impact of PSF implementation in Brazilian municipalities.

In addition, the typically disadvantaged profile of municipalities that implemented the policy in 1999 and the respective overall positive impact of the policy in those areas indicate that the policy has served as an instrument of social justice, as it has diminished major infant health disparities, especially among different national regions. Especially the Northeast region, which has municipalities with the worst national social indicators and very low IDH-Index of Human Development, has been particularly impacted by the implementation of PSF. Therefore, it indicates that the recent governmental efforts of expanding PSF coverage in wealthier urban areas of the country should take into consideration that the current modes of PSF implementation do not seem equally effective in those areas. It should be adapted to the needs and level of organization of health care systems in those areas in order to be an effective primary health care system.

Although the logic model has proposed three major channels of actions through which PSF would have a positive impact on infant health outcomes, the restricted length of longitudinal follow-up might have affected the complete assessment of the proposed policy theory. Study findings suggest that most of the benefits of policy implementation came from the rapid increase on the access to important maternal and child health services, although some level of integration and coordination of care and community empowerment have also potentially played a role. However, such latter PSF processes seem to be consolidated slowly and their effects on municipal infant health outcomes need a longer follow-up to be perceived. As proposed, it would guarantee the sustainability of the policy and have a long-term impact on health outcomes (see figure 2).

However, complete integrality of care is going to be achieved only if major gaps within local health care capacity are addressed. The integration and coordination of care in order to be effective needs the support of a network of secondary and tertiary services that can respond timely and effectively to the demand referred by the primary health care system. It seems an especially critical challenge for neonatal health, especially for complicated pregnancies and neonatal care, which need appropriate management in more advanced levels of care. Since the large majority of municipalities do not have such a self-sufficiency to address that locally, they need to rely on regional networks that struggle in conciliating political differences among representatives of Local Health Departments, and usually are ineffective bureaucratic agencies. Therefore, PSF needs investment on human and physical resources in order to expand traditional MCH primary

care activities and guarantee an enhanced capacity to handle common obstetric complications and neonatal intercurrences that would normally be referred to other levels of health care. In addition, community empowerment seems also to rely solely on the formal implementation of the mechanisms of community participation, such as the Municipal Health Council. True empowerment will arise only if the Local Health Departments forge a culture of participatory decision-making and PSF teams establish collective planning processes (Martins, 2003; Goya, 2003). Such empowerment seems especially relevant for the community to address social and environmental risky conditions that determine infant health outcomes, such as access to safe water, adequate sanitation and hygiene and appropriate food supply (WHO, 1978; Belmar, 1990; Starfield, 1998).

Future studies might address some gaps found in this research project. At first, as mentioned repeatedly, a longer longitudinal assessment will help understanding the longer impact of this policy on infant health outcomes, especially on neonatal mortality rate and low birth weight, and also the sustainable effect on infant mortality rate and access to MCH services. Such future evaluative attempts could also not be restricted solely to an outcome evaluation, and aim understanding the level of consolidation of the proposed PSF structure (e.g. attention focused on the family unit; sustained financing mechanisms; establishment of local physical infrastructure; multidisciplinary team of health care professionals; sustainability of health care professionals within the team; variety of primary care services; community participation) and processes (e.g. access to MCH services, integrality of care, community empowerment).

Secondly, there is a major concern with the future of infants that have survived risky socio-economic and environmental conditions in developing countries (Muller, 1980; PAHO, 1987; PAHO, 1993; Ehiri, 1999). As important as looking at infant health from a survival perspective would be assessing the long-term outcomes of infants who have survived. Poor nutritional and socio-psychological outcomes seem common in those areas and any policy really concerned with the protection of infant health should address not only determinants of infant deaths, but also their appropriate development. Thus, future analysis should be conducted in those areas in order to assess measures of quality of life (e.g. physical, mental and social well-being) among children.

Finally, since some of the primary care activities that are relevant to prevent infant deaths seem also important to prevent childhood mortality under 5-yr old (e.g. breastfeeding; immunization, nutritional follow-up and mainly management of gastrointestinal and respiratory infections) (Moore, 2003), future evaluative attempts might expand the focus of attention from infant to childhood health outcomes.

Overall *Programa de Saude da Familia* has been primarily concerned with the development of healthier communities; overcoming national gaps within access to PHC services and better organizing local health care systems. Although such a project has only a restricted focus on infant health, this study indicates that this policy has been effective in positively impacting municipal health outcomes, while keeping consistency with the egalitarian principles guiding the SUS-*Sistema Unico de Saude.*

APPENDICES

1) List of historical events related to the consolidation of PSF as a national primary health care policy (MS/Inf. AB, 04)

TIME PERIOD	EVENTS
1985-1988	-Democracy is reestablished in Brazil -Series of human right movements have exploded throughout the country -Movement of *"reforma sanitaria"* (Sanitary Reform) gain political strength
1988	-Constitutional foundation of "*Sistema Unico de Saude"*- SUS -Governmental commitment with health as a citizen right and governmental duty (universality and equality of access to health care are constitutionally defined)
End of the 1980s	- Initial experience of the *"Programa de Agentes Comunitarios de Saude"*-PACS in focused municipalities
1991	-Official launching of PACS as a national health policy
1994	-First PACS qualitative evaluation -Idealization and focused implementation of "*Programa de Saude da Familia"*-PSF -First official document regarding PSF -Federal government reimbursement for out-patient services provided by PSF & PACS at the local level
1996	-Federal laws promoting the effective consolidation of the decentralization process proposed by SUS -Municipalities were officially classified by the level of autonomy to manage the local health system -It is published the first issue of "Cadernos de Saude da Familia: construindo um novo modelo" (Family Health Notebook: building a new model)
1997	-Implementation of centers of continuing education for development of human resources within the family health area -Second official document regarding PSF (PSF: A strategy to reorganize the assitencial model) -PACS & PSF are officially defined as national health policy priorities -Publication of the governmental approval of a law creating the *"Piso de Atencao Basica"*-PAB (Primary Health Care Fund) -Publication of federal government regulations for the functioning of PSF
1998	-Scholars and governmental personnel consider PSF a "structuring strategy" for SUS organization

	-PAB becomes effective and federal resources are transferred directly to municipalities -Creation of the "Sistema de Informacoes da Atencao Basica"-SIAB (Primary Care Information System) that became a requirement for all municipalities covered by either PSF or PACS -First large-scale event (I Seminar of International Experiences on Family Health) -The first official manual for the local organization of primary care, based on PSF & PACS strategies, is published by the federal government -For the first time it is created a special fund on the national budget in order to particularly fund PSF nationwide
1999	- Definition of primary care national indicators -Second large-scale event (I National Demonstration of Family Health Production: building a new model) -First issue of the "Revista Brasileira de Saude da Familia" (Brazilian Journal of Family Health) -First national normative evaluation of the implementation and functioning of PSF -Financial incentive to expand municipal PSF coverage is established by the Ministry of Health
2000	-Brazilian Ministry of Health creates the Department of Primary Care primarily intended to consolidate PSF as the national model of primary health care -Publication of 1999 national primary health care indicators
2001	-Emphasis is given on the training of PSF health care professionals -Incorporation of dentists and oral health actions within PSF -Third large-scale event is developed (II Seminar of International Experiences on Family Health/Primary Care) -Strengthening of the governmental support to primary care drug distribution -Strengthening of initiatives promoting the development of regional health care delivery networks among municipalities
2002	-Fourth large-scale event "PSF-Saude mais perto de 50 milhoes de brasileiros" (PSF- Health closer to 50 million of Brazilians) -Fund to sponsor *"Projeto de Expansao & Consolidacao do Saude da Familia"*- PROESF is approved
2003	-PROESF becomes effective -Although there was a change on the ideological direction of the federal government (a new republic president was elected), expansion and consolidation of PSF as a national health policy is considered a priority for the Brazilian Ministry of Health -Publication of 1999 national primary health care indicators -New directions within continuing education initiatives for PSF health care professionals

2004-2005	-PSF access expansion, especially in large urban centers -Several medical schools promote curriculum reforms towards a more generalist and primary care-centered medical education -Brazilian Ministry of Health funds expansion of secondary and tertiary care capacity in several different states

2) Task assignments for each member of the PSF team, Brazilian Ministry of Health (MS/GUIA, 03)

PHYSICIAN	**NURSE**	**NURSE ASSISTANT**	**COMMUNITY HEALTH WORKER**
-Out-patient appointments for the population covered	-Provision of nursing care in urgent health conditions	-Execute nursing procedures (within its legal competencies)	-Mapping the geographic area covered
-Integral health assistance to all life cycles: children, adolescent, women, adults and elderly	-Integral health assistance to all life cycles: children, adolescent, women, adults and elderly	-Prepare clients for appointments, exams and therapeutic procedures	-Registration of the families and respective updating of that information
-Appointments and procedures at the USF, and occasionally at the client homes	-Health actions in different environments, at the USF; and at homes whenever necessary	-Execute nursing procedures in different environments; at the USF, and at homes (as defined by the local planning)	-Identify individuals and families at risk
-Conciliate clinical & public health practice	-Conciliate clinical & public health practice	-Active search to tuberculosis, hanseniasis, and other diseases considered epidemiologic	-Identify risky areas

		relevant for the community	
-Promote the development of patient groups for specific pathologies (e.g diabetes, hypertension,…)	-Out-patient appointments, solicitation of laboratorial exams; and prescription for specific conditions	-Conduct health education classes for specific patient groups and risky families	-Conduct health education classes (emphasis on specific disease prevention)
-Eventual urgent care	-Coordinating local sanitary and epidemiology surveillance	-Guarantee cleaning and infection control of the USF and equipments; and adequate storage of materials	-Educate families regarding the existent health services, and schedule appointments
-Referral of clients to other health services	-Plan, manage, coordinate, execute and assess the USF		-Monthly follow-up of families through home visits
-Indication of hospital admission	-Organize and coordinate patient groups for specific pathologies (e.g diabetes, hypertension,…)		-Undertake primary care activities (as defined by the local plan)
-Solicitation of laboratorial exams	-Supervise and coordinate training activities for nurse assistants and CHWs		-Promote community mobilization and education, especially focused on environment and sanitation issues

-Responsibility for death certificates -Clinical activities within primary care priority areas defined by the federal government*	-Perform activities within primary care priority areas defined by the federal government*		-Translate to the team the local social dynamics -Identify potential community partners and resources for health actions

* Maternal & child health; hypertension; diabetes; hanseniasis; tuberculosis; and dental health

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