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Mother- to - Child Transmission of HIV and congenital syphilis: A snapshot of an Epidemic in the Republic of Panama

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Mother-to-Child Transmission of HIV and Congenital Syphilis: A
Snapshot of an Epidemic in the Republic of Panama

By

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A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science in Public Health
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DEDICATION

I dedicate my thesis to my family and friends for their endless support and for encouraging me to reach the stars. Thanks as well to those who were not as supportive, because they give me an extra reason to look at the sky to find my star.

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ABSTRACT

Background

This is an epidemiological descriptive study of pregnant women or girls in 2008 who are living with HIV or Syphilis diagnosis, and the outcome of their offspring after the 18 month follow-up period in the Republic of Panama. HIV and Syphilis are sexually transmitted diseases, and have been used as an indicator of sexual risk behavior; as more women get infected in reproductive ages, unborn fetuses are more at risk to get any of these diseases.

Despite all the efforts in the Latin American Region and the Caribbean (LAC), by 2010 LAC was the most affected world region for Congenital Syphilis and the third most affected for HIV/AIDS. Due to the lack of information about vertical transmission of HIV and syphilis we considered it necessary to conduct a baseline clinical chart review to identify the prevalence of young positive females and the outcomes on their offspring in the Republic of Panama.

Methods

The study collected data for 2008 from secondary sources of information: bulletins of epidemiologically surveillance of the ministry of

health, birth records, and miscarriage records. The study compared the outcome of the pregnancies with the data available in the Children's Hospital clinical charts (the national anti-retroviral therapy clinic for children) and "Albergue de Maria" (a non-governmental organization that provides care to orphans).

Results

The current study found 290 clinical charts from pregnant women or girls who were living with HIV/AIDS in 2008 and prenatally exposed children to HIV born between January 2008 and September 2009. There were more clinical charts of prenatally exposed children (174) than pregnant women or girls (116).

The clinical charts from the 2008 pregnant women and girls living with HIV/AIDS revealed that most of the cases are located in the metropolitan health region, followed by San miguelito and Colon. During the 2008 pregnancy 81.67% received HAART, the viral load test result was available in 41.67% of the cases prior to delivery, and 28.33% of the cases had viral load count below 1000 copies, and 83.33% of the pregnancies ended in a live birth.

During pregnancy 58.05% of the mothers received HAART, and 68.39% received intravenous zidovudine during labor. The 81.03% of the offspring's received oral zidovudine the following six weeks after birth, and 54.02% were feed with infant-adapted formula. During the follow-up period 12.64% were diagnosed as positive and 36.36% of the HIV positive children had an older seropositive sibling.

Variables such as receiving HAART during pregnancy, intravenous zidovudine during labor, being born through caesarean, receiving oral zidovudine the following six weeks after birth, and been feed with infant-adapted formula are variables statistically significant when compared to the dependent variable final diagnosis of the prenatally exposed children to HIV.

Conclusions

The Republic of Panama has made efforts to face Mother-to-Child HIV transmission. The current study shows the improvements on availability and proper usage of medications to avoid mother-to-child HIV transmission, laboratory tests to diagnose pregnant females and children, and the free provision of formula-adapted milk; as well as opportunities for improvement such as the late start date of prenatal control and laboratory testing, availability of viral load results prior to delivery, and determining the delivery method of the pregnant women.

This information will contribute to the ministry of Health to draft strategies to achieve the UNAIDS goal of zero HIV-positive children secondary to perinatal exposure and zero new cases of HIV by 2015.

CHAPTER ONE: INTRODUCTION

Panama is a country located in Central America; it is the isthmus that connects North and South America. The country is mostly known because of the Panama Canal, its watershed and harbor-related activities. Because of the abundant economic opportunities, more than half of the population lives around the Panama Canal Area.

Panama has been divided into 14 health regions, five of which are located near the Panama Canal area (Metropolitan Region, San Miguelito Region, Colon Region, East and West Panama Region). Within these five regions, the two main ports of Panama are located. Due to the nature of the activities related to ports there are mobile populations, uniformed forces and female and male sex workers, all populations identified as 'Most-At-Risk Population'.

The rate of women with HIV/AIDS was 2.4/100,000 in 1993 and by 2010 it was 30.2/100,000 females (Epidemiology, 2011), and the proportion of HIV positive children secondary to vertical transmission (between 0.4 and 0.9) were located in the health regions by the Panama Canal area and the shores (Epidemiology, 2011).

For 2010 there was an estimated 0.3% (N = 189) seropositivity in pregnant women, which means that for every 1,000 pregnancies there were 3 positive pregnant women living with HIV. From those 189 pregnant women in 2010 the national department of epidemiology only has the data on 57 deliveries: 24 of them were vaginally delivered (Epidemiology, 2011). There is no data about the circumstances of the delivery and lack of information about the immunological status of the newborns perinatal exposed to HIV.

The first case of congenital syphilis was recorded in 1984, and since then there have been 452 reported cases, with a mean of 17 cases per year and a stable rate of 0.3 (Department of Epidemiology, 2010). The highest rates of congenital syphilis are found in the Metropolitan health region, San Miguelito, and the West Panama Region; coincidentally these are three of the five health regions that report the highest rates in HIV/AIDS.

HIV and Syphilis are both sexually transmitted diseases, and have been used as a predictor of sexual risk behavior. The presence of the characteristic sore (chancre) of syphilis might increase up to five times the risk of transmission of HIV (Gray, et al., 2001).

In efforts to control HIV/AIDS and congenital syphilis in 2007, Panama developed guidelines for the therapeutic management of people living with HIV and syphilis during pregnancy, including guidelines for improving the care of pregnant women. In 2009 the National Plan for multisectoral prevention of mother to child transmission of HIV and syphilis in Panama

were published; both publications emphasized the screening with rapid tests for HIV and non treponemic tests on two occasions during pregnancy: before the 20th week and in the third trimester of pregnancy. Those guidelines state that after a pregnant woman is detected positive she should be referred to a high-risk obstetrics clinic for follow-up and programming of a caesarean and then referred to a antiretroviral therapy clinic (ARVTC) for immune monitoring, initiation of ARVT with a scheme including AZT. If the presence of active syphilis is detected, the treatment can be applied at a primary care center, to her and the sexual partner, free of charge.

The purpose of this epidemiological descriptive study is to provide baseline information, utilizing clinical charts of seropositive women who have been pregnant and/or had congenital syphilis during 2008 to discover the resulting outcomes of the pregnancy and if the national guidelines on HIV/AIDS and Gestational Syphilis for pregnant women are being followed in the Republic of Panama. Another goal is to identify potential avenues for strengthen the Panamanian Health Service.

Objectives

General objective

Provide concrete epidemiological knowledge about the situation of mother-to-child HIV transmission and congenital syphilis in Panama to develop programmatic strategies to eradicate mother-to-child HIV transmission and congenital syphilis.

Specific Objectives

1. Identify women who were HIV positive and pregnant between January 1, 2008 until December 31, 2008.
2. Describe epidemiological characteristics of pregnant women in 2008 living with the diagnosis HIV and/or syphilis in Panama.
3. Quantify the obstetric outcome (live birth, miscarriages and stillbirth) of pregnant women living with HIV and/or syphilis in 2008.
4. Describe compliance of the Panamanian National Guidelines to prevent mother-to-child transmission of HIV and/or syphilis in 2008.
5. Describe sero-positivity of children prenatally exposed to HIV, born between January 2008 and September 2009.
6. Describe the outcome of newborns exposed to gestational syphilis, looking for early signs of congenital syphilis such as prematurity, intrauterine growth restriction, fever, and irritability, early or later rash or watery discharge from the nose, in a 30 day period after delivery.

CHAPTER TWO: BACKGROUND

HIV/AIDS

The first AIDS case was diagnosed in Panama in September 1984, and the most affected population were men who have sex with men (MSM) and hemophiliacs (Epidemiology, 2011). In 2010, 11,585 were diagnosed with AIDS and 6,419 with HIV, prevalence was estimated at 0.8%, and the male-female ratio was 3:1 (Epidemiology, 2011). The population between 25 and 49 years of age were the most affected (69.7%). Panama has a concentrated type epidemic, where the most at risk population (MARPS) is over 5% (MSM: 12.4%) and among pregnant women the risk is less than 1.0% (0.3%) (Epidemiology, 2011).

The global summary of the AIDS epidemic states that there are 33.3 million people infected with HIV; 92.49% (30.8 millions) are adults and from those 51.62% (15.9 millions) are women (UNAIDS, 2011). Over the years HIV / AIDS has suffered a feminization and rejuvenation: 6,000 new infections of HIV are taking place per day in adults, 51% are women, and 41% are people between 15 and 24 years old (UNAIDS, 2011). In Panama since 1993 the incidence in women has increased from 2.4/100,000 up to 30.26/100,000 in 2010 (Epidemiology, 2011). Similarly, in the same period

incidence has doubled in people less than 24 years of age: from less than 5% in 1993 to 9.1% in 2010. In this age group the male-female ratio is 1:1.7 meaning, there are two women for every man in this age group (Epidemiology, 2011).

HIV can be mainly transmitted by unprotected sexual contact, by sharing contaminated needles, maternal-to-child transmission, and is less likely to be transmitted due to blood transfusion or organ transplantation (American Academy of Pediatrics, 2012). In Panama the transmission mechanisms described in 2010 were: sexual contact with 67.0% (12.4% homosexual, 3.8% bisexual and 50.8% heterosexual), blood transmission in 1.2% (0.2% blood recipients, 0.1% hemophiliacs, intravenous drug users 0.9%) and perinatal transmission was reported in 3.0%. There is also a quarter of the population with unknown mechanism of infection (26.7%) (Epidemiology, 2011).

The risk of mother to child transmission or perinatal transmission of HIV can occur during pregnancy (in utero from 25 up to 40% of the time), during labor and delivery (60-75%) and through breastfeeding (15-30%) (World Health Organization, 2011). The first data on the perinatal transmission in Panama was described in 1998 in 14% (Nieto, 2006), but after the introduction of Zidovudine (AZT) on the Panamanian regimen of pregnant women living with HIV/AIDS in 2002, mother to child transmission was reduced to 5% in 2008, and described as 3.0% in 2010 (Epidemiology, 2011).

Congenital Syphilis

Treponema pallidum is a spirochete bacterium that transmits syphilis. It was first described between 1493 and 1495 during an outbreak in Italy, but the agent was recognized in 1905 using the dark ground microscopy. Due to the discovery of penicillin and its effectiveness to treat syphilis, the incidence of the disease declined during the 19th and 20th centuries (Quetel, 1992). Surprisingly, the rate of these STDs has been increasing in the last century, affecting pregnant women and their unborn children.

The problem was addressed as a Public Health Problem in Latin-American countries since 1994 during the XXIV Pan-American Sanitary Conference. During the 116th executive board meeting in 1995 (Pan-American Health Organization, 2010), wrote a document in which they designed an action plan, methodology and strategies to achieve the elimination of congenital syphilis. The rate of congenital syphilis in Panama by that date was 0.6/1000 live births and the Latin American region was the region with the second highest sero-prevalence worldwide with 3.9% (range from 0.7% to 7.4%) (Department of Epidemiology, 2010); the most affected region is sub-Saharan Africa (World Health Organization, 2011).

The LAC is ranked the most affected region by congenital syphilis despite all the efforts held in the region to decrease the congenital syphilis, such as:

- Publication of frame reference for the elimination of congenital syphilis in the Americas in 2005 by PAHO
- The ratification from regional ministers of health in favor of the elimination of congenital syphilis initiative in 2007
- The publication of the basic documents for the elimination of congenital syphilis initiative in December 2009 that includes the clinical guidelines and the regional monitoring strategy

By 2010, the Latin American region reached the highest rate of congenital syphilis worldwide (Pan-American Health Organization, 2010) and Panama reported a rate of 2.2/1000 live births (not including perinatal deaths secondary to in-utero exposure to syphilis) (Department of Epidemiology, 2010).

Syphilis is transmitted by unprotected sexual contact and during pregnancy from an infected mother to the fetus (American Academy of Pediatrics, 2012). Most of the times disease is transmitted during weeks 16 – 28 that leads to miscarriage (30-50% of the cases) and other complications of the pregnancy that ranges from stillbirth, *hydrops fetalis*, intrauterine growth restriction and perinatal death (80%) (American Academy of Pediatrics, 2012) (Quetel, 1992).

Congenital syphilis is the direct consequence of a mistreated sexually transmitted disease that has an inexpensive screening test and a low cost treatment. Although health campaigns and publications available in the

region related to this topic, congenital syphilis continues with a positive trend (Pan-American Health Organization, 2010).

Facing the Epidemic of Mother-to-Child HIV Transmission and Congenital Syphilis

The 189 countries that signed the Millennium Development Goals (MDG) in 2000, Panama included, are committed to promote gender equity and empower women, to reduce infant mortality, to improve maternal health, and to combat HIV/AIDS, malaria and other diseases. Studying mother to child HIV transmission and Gestational Syphilis provides scientific information that will help to achieve the MDGs.

The sanitary code of the Ministry of Health in its fifth article states that diseases which represent a major risk for Panamanian population should be notified immediately to the epidemiological department (Ministry of Health, 1947). Since 1994 the HIV/AIDS report form includes the name, identification number and the address. The HIV/AIDS report form was designed to strengthen the active epidemiological surveillance activities (Ministry of Health, 2003). In 2000, the law number 3 addressed STD/HIV/AIDS as a national problem that should be addressed through education, prevention and early diagnosis. The second chapter of the law, regarding prevention, in the article 6 related to early diagnosis, states that HIV test in pregnant women is mandatory, even if the women or girl doesn't

want to know the result; the clinicians need the test results on behalf of the unborn children. The title 3 of the same law, article 45 states that any health care practitioner that doesn't notify the presence of an HIV positive test might be sanctioned with two to five years in jail (Ministry of Health, 2000).

In 2007, Panama developed a national multisectoral plan to prevent mother-to-child transmission of HIV and syphilis, which states that all pregnant women will receive integral attention free of charge, including prenatal control and screening tests. It says that in every medical record per each pregnancy two rapid HIV test and VDRL or RPR for syphilis should be reported. Before week 20, and one month prior to the delivery, if there is no evidence of any of those tests in the prenatal chart, the physician should request one during labor to identify HIV and/or Syphilis in prenatally exposed cases and start treatment, it also states to refer pregnant women living with HIV/AIDS to antiretroviral clinics and high risk OB-GYN unit, they should receive counseling regarding the diagnosis to increase the adherence to treatment. The offspring's of women living with HIV/AIDS needs to be feed with infant-adapted formula, for such reason the provision of such milk is free of charge (PTMI, 2010).

MEGAS (*Medicion y Analisis del Gasto en SIDA from the initials in Spanish*) in 2008 reported 21,077,738 USD spent on HIV/AIDS programs. From those 12,154,872 USD (57.67%) were used to provide screening and treatment to prevent mother-to-child transmission of HIV and/or syphilis nationwide. On prevention programs 8,233,218 USD (39.8%) was spent,

including the purchase of condoms. The money used for at risk children and orphans was 229,666 USD which represents 1.1% of the overall spent (USAID-PASCA, 2008).

Due to the feminization and rejuvenation of STD/HIV/AIDS in Panama, key strategies need to be developed to strengthen the Panamanian response to HIV/AIDS. This study aims to identify the real scenario on vertical transmission of HIV and congenital syphilis in the Republic of Panama during the 2008-2011 period, to develop programmatic strategies to eradicate mother-to-child HIV transmission and congenital syphilis.

CHAPTER THREE: METHODS

Design

This is a non-experimental descriptive study that provides an epidemiological description retrospectively about pregnant women living with HIV/AIDS and those with gestational syphilis from January 1st, 2008 to December 31, 2008, as the outcome of prenatally exposed newborns to HIV (until the end of the 18 month follow up period March 2011) and congenital syphilis. The study verified the information in the national epidemiological surveillance department of the Ministry of Health (electronic database in Epi-info 2000, Centers for Disease Control and Preventions, Atlanta, GA, USA), and clinical charts from the Mother and Children Hospitals that provides for such patients (12 Antiretroviral Clinics for Adults, one pediatric clinic, and an orphanage). Because the study was looking to track the obstetric outcome and the serological child status after recommended test in these cases the data cycle was in a 27-month period.

Our research question required the linkage of the data from clinical charts from HIV positive mothers and their offspring. The clinical charts were classified based on the Panamanian Country Resident Identification Number (CRIN). This CRIN is used for identification during any government interactions by all Panamanians; this includes healthcare. However,

precautions were taken, including but not limited to assigning a consecutive number to the actual health-related data collected (not the actual CRIN) and using a password protected linkage file with identifiers as described herein. In addition, the linkage file containing the identifiers was deleted after the data collection was completed at each site. The deletion of those identifiers at that time was to fulfill Panamanian law number 3 of January 2000. The data collection started once received clearance from the inter-institutional review board from Panama and the University of South Florida.

Phases

- a. HIV and/or syphilis-positive pregnant cases were obtained from the statistics department, specifically the epidemiological surveillance of STD / HIV / AIDS of the Ministry of Health. The study got the epidemiological data of every case in 2008, such as age and date of the HIV diagnosis.
- b. The study audited the clinical charts of pregnant women diagnosed with HIV or syphilis from January 2008 to December 2008 from the ARVC looking for educational level, the trimester in which the prenatal control starts, the results of the screening test, compliance with the national guidelines to treat pregnant women living with HIV and/or syphilis, the outcome of the pregnancy and the date of the delivery, miscarriage or stillbirth.

- c. After identifying the newborns exposed prenatally to HIV or syphilis from January 2008 to September 2009, the clinical charts from the national ARTC for children and from the orphanage "Albergue de Maria" were reviewed looking for information regarding the compliance with the national algorithm to treat such children, the delivery history (vaginal, caesarean-section, weight, breastfeeding), and also followed the evolution of the laboratory results of PCR DNA Pro-viral and ELISA after 18 months up to the final diagnosis of HIV and/or syphilis of the prenatally-exposed children.

Sample Size

Based on the national STD/HIV/AIDS surveillance department of the Ministry of Health in 2008 there were 153 pregnant women living with HIV/AIDS and girls and 32 cases of congenital syphilis. There was incomplete information regarding the outcomes of the pregnancy or how many newborns were prenatally exposed to HIV and what their immunological statuses are.

After the data collection phase was completed the study reviewed 290 clinical charts: 174 from newborns prenatally exposed to HIV and Syphilis, and 116 belonging to pregnant women living with HIV/AIDS.

Inclusion and Exclusion Criteria

Inclusion criteria

1. Pregnant women and girls of any age for whom an HIV and/or syphilis test was reported as positive in the national epidemiological surveillance for STD/HIV/AIDS from the Ministry of Health of Panama from the January 1st, 2008 through December 31, 2008.
2. Clinical charts available from pregnant women and girls of any age for whom an HIV and/or syphilis test was performed and positive results are found from the January 1st, 2008 through December 31, 2008.
3. Clinical charts available from infants prenatally exposed to HIV born between the January 1st, 2008 and September 31, 2009.

Exclusion criteria

1. Records from pregnant women and girls living with HIV/AIDS and children prenatally exposed to HIV not available during the data collection phase.

Data Collection Instrument

A survey data collection instrument was designed for the study. It was applied to the clinical charts only, with closed-ended answers. The study gathered:

- Socio-demographic data
- Data of when an HIV or syphilis diagnosis of the mother was made
- Compliance with the national guidelines of mother-to-child HIV transmission and congenital syphilis (initiation of antiretroviral therapy or antimicrobial therapy, laboratory testing during pregnancy, procedures for childbirth delivery, provision of milk formula and breastfeeding, referring to antiretroviral therapy clinic for both adult and newborns, counseling for adults about adherence to antiretroviral therapy in adults and newborns).

Variables

The study collected data from the clinical charts concerning each case of pregnant women and girls who receive an HIV and /or syphilis screening test which reported positive results in the national epidemiological surveillance for STD/HIV/AIDS in Panama during January 1st, 2008 up to December 31, 2008. All the variables were considered discrete for analysis purposes (Pan-American Health Organization, 2011). All the variables were considered categorical as listed in the code book. Variables were describe according to a regional initiative conducted by the Panamerican Health Organization to evaluate mother-to-child transmission of HIV and congenital syphilis.

Table 1. Investigated variables from pregnant women and girls living with HIV/AIDS

#	Variable name	Variable definition	Codes
1	Health_R	Panama is divided by 14 health regions; subjects were classified in any of those regions	1. Bocas del Toro
			2. Chiriquí
			3. Coclé
			4. Colón
			5. Comarca Gnabe Bugle
			6. Comarca Guna Yala
			7. Darién
			8. Herrera
			9. Los Santos
			10. Panamá Este
			11. Panamá Metro
			12. Panamá Oeste
			13. San miguelito
			14. Veraguas
		-6=Missing	
2	DT_Birth	Date of Birth	Month/day/year
3	Educ	Number of years approved by the pregnant women or girl who filled the inclusion criteria to participate in the study	1=LESS THAN FOUR YEARS 2= FIVE TO TEN YEARS 3= MORE THAN TEN YEARS 6= OTHER -6 = MISSING
4	O_Educ	Other Education	
5	START_PNC	Trimester where the Pre-natal Control Starts	1= First trimester (0-13 w) 2= Second Trimester (14-27 w) 3= Third trimester (28-41 w) -6 = MISSING
6	VDRL/RPR	Syphilis Test during Prenatal Control	0=NO 1= YES -6 = MISSING
7	VDRL/RPR_Res	Syphilis Test during Prenatal Control Result	0= Non-Reactive 1= Reactive -6= Missing

8	VDRL/RPR_Tx	Did the women receive treatment according to national guidelines	0=NO 1= YES -6 = MISSING
9	VDRL/RPR_Tx_P	Did the partner receive treatment according to the national guidelines	0= NO 1= YES -6 = MISSING
10	Counselling	Did they receive any counseling about STD	0= NO 1= YES -6 = MISSING
11	Condoms	Did they receive condoms	0= NO 1= YES -6 = MISSING
12	HIV_Dx	Was the HIV Diagnosis made during pregnancy	0= NO 1= YES -6 = MISSING
13	HIV_Trim	In which trimester the HIV diagnosis was made?	1= Before 20 w 2= Greater or equal to 20 w -6 = MISSING
14	REF_ARVC	Was the pregnant women or girl referred to a antiretroviral Clinic?	0= NO 1= YES -6 = MISSING
15	REF_OBS	Was the pregnant women or girl referred to a High Risk obstetric Clinic?	0= NO 1= YES -6 = MISSING
16	HAART	Did the women receive TARV according to national guidelines?	0= NO 1= YES -6 = MISSING
17	Prior_Dx	When was the diagnosis made	
18	Counseling_RR	Did the women receive counseling about reproductive rights and sexual health?	0= NO 1= YES -6 = MISSING
19	Planned_Preg	It is reported that it was a planned pregnancy	0= NO 1= YES -6 = MISSING
20	Change_ARV	Did the physician change the ARV according to national guidelines	0= NO 1= YES -6 = MISSING

21	VL_Req	Was the Viral Load Test Requested?	0= NO 1= YES -6 = MISSING
22	CD4_Req	Was the CD4 Test Requested?	0= NO 1= YES -6 = MISSING
23	VL_DD	Was the Viral Load Result available at the delivery date?	0= NO 1= YES -6 = MISSING
24	Viral_load below 1000 copies	Was the Viral Load Result below 1000 copies?	0= NO 1= YES -6 = MISSING
25	Date_outcome	Date of Outcome	Month/day/year
26	Outcome	Which was the Outcome of the pregnancy?	0= Abortion 1= Misscarriage 3= Stillbirth 4= Live birth -6=Missing
27	AZT_LB	It is reported the use of AZT during labor on the live births?	0= NO 1= YES -6 = MISSING
28	WAY_LV	Way of delivery of the live birth?	1= Vaginal Delivery 2= Emergency Caesarean 3= Programmed Caesarean -6= Missing

Table 2. Investigated variables from prenatally exposed children to HIV

#	Variable name	Variable definition	Codes
1	Health_R	Panama is divided by 14 health regions; subjects were classified in any of those regions	1. Bocas del Toro
			2. Chiriquí
			3. Coclé
			4. Colón
			5. Comarca Gnabe Bugle
			6. Comarca Guna Yala
			7. Darién
			8. Herrera
			9. Los Santos
			10. Panamá Este
			11. Panamá Metro
			12. Panamá Oeste
			13. San miguelito
			14. Veraguas
			-6=Missing
#	Variable name	Variable definition	Codes
2	DT_Birth	Date of Birth	Month/day/year
3	Where	The delivery was at the Hospital?	0= NO 1= YES -6 = MISSING
4	37 weeks or above	The gestational age at birth was 37 or above?	0= NO 1= YES -6 = MISSING
5	W_A_B	What was the weight at birth?	0= PEG 1= AEG 2= GEG -6 = MISSING
6	WAY_LV	What was the way of delivery of the live birth?	1= Vaginal Delivery 2= Emergency Caesarean 3= Programmed Caesarean -6=Missing
7	AZT_LV	It is reported in the clinical chart the use of AZT during labor on live birth?	0= NO 1= YES -6 = MISSING
8	HAART	Did the women receive TARV according to national guidelines?	0= NO 1= YES -6 = MISSING

9	VL_DD	Was the Viral Load result available on the delivery date?	0= NO 1= YES -6 = MISSING
10	Viral_load below 1000 copies	Was the Viral Load Result below 1000 copies?	0= NO 1= YES -6 = MISSING
11	Feeding_Hx	What was the feeding history of the newborn?	0= Formula 1= Breastfeeding 3= Mixed -6= Missing
12	AZT_P	Did the newborn receive AZT prophylaxis per 6 weeks?	0= NO 1= YES -6 = MISSING
13	PCR_1	What was the result of first PCR or Pro-Viral DNA?	0= Negative 1= Positive -6= Missing
14	PCR_2	What was the result of Second PCR or Pro-Viral DNA?	0= Negative 1= Positive -6= Missing
15	ELISA_18M	What was the result of ELISA test?	0= Negative 1= Positive -6= Missing
16	Final_Dx	What is the final diagnosis?	0= Negative 1= Positive -6= Missing
17	OTH_SIB	Is there other Siblings with HIV Diagnosis	0= NO 1= YES -6 = MISSING

Analysis plan

The study used a customized database in Microsoft ACCESS 2010 for Windows (Microsoft office, USA) to input the data. The database was analyzed with SAS software version 9.3 (SAS Institute, Cary, NC, USA). Because the study was analyzing categorical variables, the information was summarized as frequencies, proportions and ratios. At the end of the data

collection phase the database was password-protected and encrypted to preserve its confidentiality. The encryption is an internal procedure of Access 2010 (Microsoft office, USA) to encode the information included in a given dataset and make it unreadable for unauthorized users without the encryption key. This procedure was needed to ensure law number three of January 2000 (Ministry of Health, 2000).

The data collected was used for further analysis and was group according to the type of answer coded. They were classified as frequencies, proportions and ratios.

Frequencies

1. Distribution of pregnant women or girls according to the start date of prenatal control.
 - a. First Trimester 0 to 13 weeks
 - b. Second Trimester 14 to 27 weeks
 - c. Third Trimester 28 to 41 weeks
2. Distribution of pregnant women and girls living with HIV/AIDS in 2008 according to age range.
 - a. 15-24 years
 - b. ≥ 25 years
 - c. 26 - 29 years
 - d. ≥ 30 years

3. Distribution of Educational level among pregnant women and girls living with HIV/AIDS.
 - a. <4 years;
 - b. 4 to 10 years;
 - c. >10 years approved
4. Distribution of HIV positive test performed in pregnant women or girl
 - a. Before or equal to 20 weeks of gestation
 - b. 20 weeks and above of gestation
5. Distribution of pregnant women and girls living with HIV/AIDS who received counseling about HIV and pregnancy.
6. Distribution of syphilis in pregnant women or girls in 2008 according to age range.
 - a. 15-24 years
 - b. ≥ 25 years
 - c. 26 - 29 years
 - d. ≥ 30 years
7. Distribution of educational level among syphilis positive pregnant women or girl.
 - a. <4 years;
 - b. 4 to 10 years;
 - c. >10 years approved
8. Geographical distribution among the 14 health regions in Panama of HIV cases among female pregnant women from January 2008 to December 2008.

9. Geographical distribution among the 14 health regions in Panama of congenital syphilis cases among female pregnant women from January 2008 to December 2008.
10. Geographical distribution among the 14 health regions in Panama of HIV secondary to prenatal exposure among children born between January 2009 and September 2009 after the follow-up period (18 months).
11. Geographical distribution among the 14 health regions in Panama of congenital syphilis cases among children born between January 2008 and September 2009 after the follow-up period.
12. Distribution of obstetric outcomes among pregnant women living with HIV/AIDS reported between January 2008 and December 2008.
 - a. Numerator # of specific obstetric outcome among pregnant women or girls living with HIV/AIDS between January 2008 and December 2008
 - b. Denominator # of positive pregnant women and girls living with HIV/AIDS between January 2008 and December 2008.
13. Distribution of the method of delivery among the pregnant women or girls living with HIV/AIDS with reported live births between January 2008 and September 2009
 - a. Numerator # of specific delivery method from the HIV positive women or girls between January 2008 to September 2009.
 - b. Denominator # of HIV pregnant women or girls with a reported live birth.

14. Distribution of delivery assisted by health care personnel
 - a. Numerator # of delivery assisted by health care personnel among HIV positive women or girls between January 2008 to September 2009.
 - b. Denominator # of pregnant women or girls living with HIV/AIDS with a reported live birth.
15. Distribution of birth weight among the live births among the prenatally exposed to HIV between January 2008 to September 2009
16. Distribution of children prenatally exposed referred to a ARV Clinic

Proportions

17. Proportion of counseling for syphilis pregnant women or girl about STD.
18. Proportion of pregnant women or girls that tested positive to HIV in which clinical chart is consigned the provision of condoms.
19. Proportion of pregnant women or girls that tested positive to Syphilis that receive proper treatment, according to national guidelines.
20. Proportion of pregnant women or girls with previous knowledge of being HIV positive.
21. Proportion of pregnant women or girls that tested positive to HIV that receive proper treatment, according to national guidelines.

22. Proportion of gestational age (below 37 weeks vs above or equal to 37 weeks) at delivery among the live births among the prenatally exposed to HIV between January 2008 to September 2009
23. Proportion of type of feeding among prenatally exposed children born between January 2008 and September 2009
- c. Numerator # of Type of feeding (breastfeeding vs formula vs mixed) among children prenatally exposed children to HIV born between January 2008 and September 2009
 - d. Denominator # of live births prenatally exposed to HIV born between January 2008 and September 2009

Ratios

24. Vertical transmission rate of HIV in children born from January 2008 to September 2009
- e. Numerator: # of HIV positive children confirmed by ELISA at 18 months of age
 - f. Denominator: # of live births prenatally exposed to HIV from January 2008 to September 2009.
25. Rate of newborns receiving ARV treatment according to national guidelines
- g. Numerator # number of children prenatally exposed to HIV that receive treatment according to national guidelines

h. Denominator # of live births prenatally exposed to HIV born between January 2008 and September 2009

26. Rate of seroreversion

i. Numerator # of children that seroconverts among prenatally exposed to HIV that receive treatment according to national guidelines

j. Denominator # of live births prenatally exposed to HIV born between January 2008 and September 2009

CHAPTER FOUR: RESULTS

The bulletins of epidemiological surveillance of the Ministry of Health reported there were 153 HIV/AIDS pregnant women in the Republic of Panama between January 01, 2008 and December 31, 2008 (Epidemiology, 2011).

During the data collection phase all 290 existing clinical charts were reviewed. In the antiretroviral clinics there were 116 clinical charts belonging to women who were pregnant and living with HIV/AIDS in 2008 and 174 from prenatally exposed children. From the reviewed clinical charts 61 (39.87%) of the pregnant women or girls charts include the information regarding the 2008 pregnancy as were 170 (97.70%) from the prenatally exposed children and were subject to further analysis. Each clinical chart represents a case; clinical charts from children whose mother's clinical chart was not found were not excluded.

Socio-demographic characteristics among 2008 pregnant women living with HIV/AIDS are shown in Table 3. The study found that pregnant women living with HIV/AIDS are distributed mostly at Colon health region (32.03%), followed by the Metropolitan health region (24.84%), San Miguelito health region (19.30%), and Panama-west health region (9.15%). The remaining

health regions reported less than two percent of the cases each. The educational level was missing in 47.37% of the clinical charts, in 28.07% of the 2008 pregnant women living with HIV/AIDS had education level for more than ten years of education, 21.05% received from five to ten years of education and 3.51% of the cases received less than four years of education. In examining the age distribution of pregnant women and girls cases with 25 years or younger represents 8.20%, 11.47% of the women were between 26 and 29 years and 50.82% of the women were 30 years old or above.

The proportion of women in the study who knew their HIV status prior to becoming pregnant was 38.33%, 3.33% of charts were missing the date of diagnosis and 58.33% of the women were diagnosed during their 2008 pregnancy. The proportion of pregnant women or girls that tested positive for HIV before the 20th week of gestation were 50%, 38.33% tested positive after the 20th week of gestation, and 11.67% of the cases did not report the date of diagnosis (Table 4).

Table 3. Socio-demographical description pregnant women living with HIV/AIDS in the Republic of Panama between January 01, 2008 and December 31, 2008.

Variable	N	Percentage
Health regions		
Bocas del Toro	4	2.61%
Cocle	-	-
Colon	49	32.03%
Chiriqui	3	1.96%
Darien	1	0.65%
Gnobe Bugle	2	1.31%
Guna Yala	3	1.96%
Herrera	-	-
Los Santos	1	0.65%
Panama-East	1	0.65%

	Panama- Metropolitan	38	24.84%
	Panama-West	14	9.15%
	San Miguelito	28	18.30%
	Veraguas	5	3.27%
	Missing	4	2.61%
	Total	153	100.00%
Educational level			
	Less than four years	2	3.51%
	Five to ten years	12	21.05%
	More than ten years	16	28.07%
	Missing	27	47.37%
	Total	57	100.00%
Age ranges			
	<= 25 years	5	8.20%
	26 - 29 years	7	11.47%
	>= 30 years	31	50.82%
	Missing	18	29.51%
	Total	61	100.00%

The start date of prenatal control among pregnant women or girls living with HIV/AIDS in 2008 is missing from the clinical charts in 63.79% of the women. The prenatal control was initiated during the first and second trimester in 15.52% of women, and 5.17% of women started their prenatal control during the third trimester.

The proportion of pregnant women and girls with an HIV positive diagnosis who received counseling regarding sexually transmitted diseases was 53.33%. The provision of condoms among pregnant women or girls living with HIV/AIDS was reported in 47.46% of the cases, 6.78% refused to accept condoms, and in 45.76% of the clinical charts the information was not available (Table 4).

Table 4. Prenatal history among pregnant women living with HIV/AIDS in the Republic of Panama between January 01, 2008 and December 31, 2008.

Variable	N	Percentage
Prior HIV diagnosis		
Yes	23	38.33%
No	35	58.33%
Missing	2	3.33%
Total	60	100.00%
Variable		
Start of prenatal control		
	N	Percentage
First Trimester (0-13w)	9	15.52%
Second Trimester (14-27w)	9	15.52%
Third trimester (28-41w)	3	5.17%
Missing	37	63.79%
Total	58	100.00%
Tested HIV positive		
Before 20 th week	30	50.00%
After 20 th week	23	38.33%
Missing	7	11.67%
Total	60	100.00%
HIV and pregnancy counseling		
Yes	32	53.33%
No	0	0.00%
Missing	28	46.67%
Total	60	100.00%
Provision of condoms		
Yes	28	47.46%
No	4	6.78%
Missing	27	45.76%
Total	59	100.00%
Referred to ARVC		
Yes	39	65.00%
No	19	31.67%
Missing	2	3.33%
Total	60	100.00%
Referred to high risk OB-GYN unit		
Yes	53	88.33%
No	5	8.33%
Missing	2	3.33%
Total	60	100.00%
HAART		
Yes	49	81.67%
No	9	15.00%
Missing	2	3.33%
Total	60	100.00%

Pregnant women and girls living with HIV/AIDS should be referred to antiretroviral clinics and to a high risk OB-GYN unit from the health care facility that made the diagnosis. The study found the reference to the ARVC in 65% of the clinical charts, in 31.67% the diagnosed was during labor and they were not referred prior delivery, and in 3.33% of the clinical charts the information was missing. They were referred to a high risk obstetric unit in 88.33% of the cases, in 8.33% of the cases they were diagnosed during labor, and in 3.33% of the clinical charts the information was not available. The pregnant women and girls living with HIV/AIDS received in 81.67% of the cases a treatment including Lopinavir/Ritonavir, 15% of the schemes didn't include it, and in 3.33% of the clinical charts the information was not available.

A viral load test was requested from 86.67% (N=52) of the pregnant women or girls who were pregnant in 2008, and the information was missing in 13.33% of the cases. The results of the viral load was available prior delivery in 41.67% of the cases (N=25), while 46.67% of viral load results arrived after the birth (N=28) and in 11.67% (N=7) of the cases couldn't be performed the test due to lack of laboratory materials to perform the test. Among the women and girls who were pregnant in 2008 and a viral load test result was available before birth, 68% were below 1000 viral copies (N=17/25), 32% were above 1000 copies, and in 4% of the cases the information was not recorded at the clinical chart (Table 5).

Table 5. Delivery characteristics among pregnant women living with HIV/AIDS in the Republic of Panama between January 01, 2008 and December 31, 2008. N=60

Variable	N	Percentage
Viral load (VL) requested		
Yes	52	86.67%
No	4	6.67%
Missing	4	6.67%
Total	60	100.00%
VL available		
Yes	25	41.67%
No	28	46.67%
Missing	7	11.67%
Total	60	100.00%
VL <1000 copies		
Yes	17	28.33%
No	26	43.33%
Missing	17	28.33%
Total	60	100.00%
Obstetric Outcome		
Abortion	3	5.00%
Miscarriage	1	1.67%
Stillbirth	1	1.67%
Live birth	50	83.33%
Missing	5	8.33%
Total	60	100.00%
AZT during labor		
Yes	24	40.00%
No	12	20.00%
Missing	24	40.00%
Total	60	100.00%
Delivery type		
Vaginal delivery	12	20.00%
Emergency caesarean	3	5.00%
Elective caesarean	33	55.00%
Missing	12	20.00%
Total	60	100.00%

The pregnancies of the HIV positive women or girls ended with a live birth in 83.33% of the cases, 5% ended in abortion and both miscarriages and stillbirth, each representing 1.67%. The information was absent in 8.33% of the cases. During labor 48% of the cases received intravenous AZT, 14% did not, and the information is not included in 38% of the clinical

charts. The distribution of the method of delivery was 55% with elective caesarean-section, 20% with vaginal delivery and 5% emergency caesarean-section (Table 5).

When the data regarding the prenatally exposed children was evaluated, the geographical distribution of the live births were 48.28% in the Metropolitan health region, 9.77% in the Colon health region, 8.62% West Panama health region, 8.39% in San Miguelito health region, in the 4.02% in the East Panama health region, in the 3.45% Cocolé health region, 1.15% in the indigenous community of Gnabe Bugle, and below 1% of the cases nationwide in the rest of the health regions. The geographical distribution of the resulting HIV children was 7.47% in the metropolitan region and 1.15% of the cases were in the Colon, San Miguelito, Panama west region each (Table 6).

Live births occurred in 84.48% of the cases in a hospital, and the proportion HIV positive children that were born in the hospital were 9.77%. Vaginal delivery was present in 37.36% of the prenatally exposed children and 50.58% were delivered through caesarean. Among the children that ended positive at the end of the follow-up period, 8.05% were delivered vaginally and 4.02% were delivered through caesarean. The information regarding the delivery method was missing in 12.07% of the cases. Among the prenatally exposed children the gestational age above 37 weeks was 55.75%, and below 37 weeks 8.05%, and 36.21% of the clinical charts does not include the gestational age at delivery among the live births in the

prenatally exposed to HIV between January 2008 to September 2009. Among the HIV positive children secondary to prenatal exposure the gestational age at birth above or equal 37 weeks was 5.75%, below 37 weeks was 40.23%, and the information was missing in 9.75% of the cases (Table 6).

Among the live births the weight at birth was adequate for the gestational age in 61.49%, 2.30% were recorded with low weight at birth, and the information was missing in 36.21% of the clinical charts. Within the HIV positive children secondary to prenatal exposure to HIV 0.57% were with low weight at birth, 6.32% with adequate weight at birth and the information was missing in 5.75% of the clinical charts. Among the children that tested negative at the end of the follow-up period, 1.72% were with low weight at birth, 43.10% were with adequate weight at birth and 18.39% of the cases did not include the information in the clinical chart (Table 6).

Table 6. Distribution of characteristics of prenatally exposed children to HIV during January 01, 2008 and September 31, 2009 by HIV status.

Variable	Total %(N)	HIV + %(N)	HIV - %(N)	Missing
Health regions				
Bocas del Toro	0.57% (1)	0.57% (1)	-	-
Cocle	3.45% (6)	0.57% (1)	2.30% (4)	0.57% (1)
Colon	9.77% (17)	1.15% (2)	8.05% (14)	0.57% (1)
Chiriqui	-	-	-	-
Darien	0.57% (1)	-	0.57% (1)	-
Gnobe Bugle	1.15% (2)	0.57% (1)	0	0.57% (1)
Guna Yala	0.57% (1)	-	0.57% (1)	-
Herrera	-	-	-	-
Los Santos	-	-	-	-
Panama-East	4.02% (7)	-	3.45% (6)	0.57% (1)
Panama- Metro	48.28% (84)	7.47% (13)	31.61% (55)	9.20% (16)
Panama-West	8.62% (15)	1.15% (2)	5.75% (10)	1.72% (3)
San Miguelito	8.39% (32)	1.15% (2)	10.34% (18)	6.90% (12)
Veraguas	0.57% (1)	-	0.57% (1)	-
Missing	4.02% (7)	-	-	4.02% (7)
Total	100% (174)	12.64% (22)	63.22% (110)	24.13% (42)

Hospital delivery				
Yes	84.48% (147)	9.77% (17)	60.92% (106)	13.79 (24)
No	4.02% (7)	1.15% (2)	2.30% (4)	0.57% (1)
Missing	11.50% (20)	1.72% (3)	-	9.76% (17)
Total	100% (174)	12.64% (22)	63.22% (110)	24.13% (42)
Method of delivery				
Vaginal delivery	37.36% (65)	8.05% (14)	23.56% (41)	5.75% (10)
Caesarean	50.58% (88)	4.02% (7)	38.05% (67)	8.04% (14)
Missing	12.07% (21)	0.57% (1)	1.15% (2)	10.34% (18)
Total	100% (174)	12.64% (22)	63.22% (110)	24.13% (42)
Gestational age ≥ 37 weeks				
Yes	55.75% (97)	5.75% (10)	40.23% (70)	9.77% (17)
No	8.05% (14)	1.15% (2)	5.17% (9)	1.72% (3)
Missing	36.21% (63)	5.75% (10)	17.82% (31)	12.64% (22)
Total	100% (174)	12.64% (22)	63.22% (110)	24.13% (42)
Gestational weight at birth				
Small for gest. age	2.30% (4)	0.57% (1)	1.72% (3)	-
Adequate for gest. Age	61.49% (107)	6.32% (11)	43.10% (75)	12.07% (21)
Missing	36.21% (63)	5.75% (10)	18.39% (32)	12.06% (21)
Total	100% (174)	12.64% (22)	63.22% (110)	24.13% (42)

Regarding the interventions to prevent mother-to-child transmission, 58.05% of mothers received HAART during pregnancy, 32.76% did not receive HAART during labor, and the information was missing in 9.20% of the clinical charts. Among the cases that received HAART, 4.02% of the children were diagnosed as HIV positive and 46.55% were negative, among those that did not receive HAART during pregnancy, 8.62% tested positive and 16.67% tested negative. During labor, 68.39% received intravenous AZT, 20.11% did not receive AZT during labor, and the information was missing in 11.50% of the clinical charts. Among the children that were diagnosed as HIV positive 4.60% of the mothers received AZT during labor and 7.47% did not receive AZT during labor, the children which final diagnosis was HIV

negative 51.72% receive AZT during labor and 10.92% did not receive AZT during labor.

Among the prenatally HIV exposed newborns, 81.03% received oral AZT for the six following weeks, 6.90% didn't receive oral AZT for the six following weeks after date of birth, and 12.07% of the clinical charts did not contain the information. Out of the children that received oral AZT for a six week period, 7.47% were diagnosed positive, 59.77% were diagnosed as negative at the end of the follow up period, and in those children that did not receive oral AZT 4.60% were diagnosed as HIV positive and 1.15% as HIV negative. Regarding the feeding history among prenatally exposed children born between January 2008 and September 2009, 54.02% were fed with formula, 8.05% received breast milk, 6.32% received a mix between formula and breast milk, with the information missing in 31.61% of the clinical charts. Among the children that were feed formula 4.02% tested HIV positive, and 40.80% were diagnosed HIV negative; within those that were feed with breast milk, 2.87% were diagnosed as positive and 4.60% were diagnosed negative and those children that were feed with a mix of breast milk and formula 1.72% tested positive to HIV and 2.87% were diagnosed negative (Table 7).

During the 18-month follow-up period, physicians requested the first DNA-Pro Viral to 84.48% of prenatally exposed children to HIV, among those 76.05% were negative, 11.98% test results were positive, and in 11.98% of

Table 7. Perinatal history of prenatally exposed children to HIV during January 01, 2008 and September 31, 2009.

Variable	Total %(N)	HIV + %(N)	HIV – %(N)	Missing
Pregnant women w/HAART				
Yes	58.05% (101)	4.02% (7)	46.55% (81)	7.47% (13)
No	32.76% (57)	8.62% (15)	16.67% (29)	7.47% (13)
Missing	9.20% (16)	-	-	9.19% (16)
Total	100% (174)	12.64% (22)	63.22% (110)	24.13% (42)
AZT during labor				
Yes	68.39% (119)	4.60% (8)	51.72% (90)	12.07% (21)
No	20.11% (35)	7.47% (13)	10.92% (19)	1.72% (3)
Missing	11.50% (20)	0.57% (1)	0.57% (1)	10.34 % (18)
Total	100% (174)	12.64% (22)	63.22% (110)	24.13% (42)
AZT during six weeks				
Yes	81.03% (141)	7.47% (13)	59.77% (104)	13.79% (24)
No	6.90% (12)	4.60% (8)	1.15% (2)	1.15% (2)
Missing	12.07% (21)	0.57% (1)	2.30% (4)	9.19% (16)
Total	100% (174)	12.64% (22)	63.22% (110)	24.13% (42)
Feeding history				
Breast-feeding	8.05% (14)	2.87% (5)	4.60% (8)	0.57% (1)
Formula	54.02% (94)	4.02% (7)	40.80% (71)	9.20% (16)
Mixed	6.32% (11)	1.72% (3)	2.87% (5)	1.72% (3)
Missing	31.61% (55)	4.02% (7)	14.94% (26)	12.64% (22)
Total	100% (174)	12.64% (22)	63.22% (110)	24.13% (42)

the clinical charts the first DNA Pro viral test result was missing. The second DNA-Pro Viral test was performed in 71.84% of the cases, and 74.85% of the test results were negative. After the 18-month follow-up period, the ELISA test was negative in 65.87% of children prenatally exposed to HIV; with 13.17% positive cases and 20.96% of the cases had not completed the lab tests to determine their immunological status (Table 8). Out of the 22 cases HIV positive, eight (36.36%) has older siblings with the same diagnosis.

Table 8. Laboratory progressions during the 18 month follow up period of prenatally exposed children to HIV during January 01, 2008 throughout March 31, 2011. N=167

	PCR-1	PCR-2	ELISA	Final Diagnosis
Positive	20	0	6	22
Negative	127	125	98	110
Missing	20	22	43	35

During January 01, 2008 and September 31, 2009 there were 174 children prenatally exposed to HIV, and at the end of the 18-month follow-up period there were no cases of seroreversion.

Table 9. Perinatal history of prenatally exposed children to HIV during January 01, 2008 and September 31, 2009 by final diagnosis.

Variable		HIV - %(N)	HIV + %(N)	Total %(N)
Hospital delivery	No	4.26 (4)	2.13 (2)	6.38 (6)
	Yes	81.91 (77)	11.70 (11)	93.62 (88)
	Total	86.17 (81)	13.83 (13)	100 (94)
Method of delivery	Vaginal	35.11 (33)	8.51 (8)	43.62 (41)
	Caesarean	51.06 (48)	5.32 (5)	56.38 (53)
	Total	86.17 (81)	13.83 (13)	100 (94)
AZT during six weeks	No	2.13 (2)	6.38 (6)	8.51 (8)
	Yes	84.04 (79)	7.45 (7)	91.49 (86)
	Total	86.17 (81)	13.83 (13)	100 (94)
Feeding history	Formula	73.40 (69)	7.45 (7)	80.85 (76)
	Breastfeeding	8.51 (8)	4.26 (4)	12.77 (12)
	Mixed	4.26 (4)	2.13 (2)	6.38 (6)
	Total	86.17 (81)	13.83 (13)	100 (94)

Direct interventions on the infant prenatally exposed to HIV are being delivered at the hospital including the method of the delivery and if the infant received oral zidovudine for six weeks in addition to the feeding history. We dropped the missing data and among the children that were born

at the hospital 81.91% (77) were HIV negative versus 11.70%(11) with a final diagnosis of HIV positive. Of those delivered by caesarean 51.06%(48) were HIV negative and 5.32% (5) diagnosed HIV positive. Of children that received oral zidovudine for six weeks 84.04% were negative, versus 7.45% who ended with a positive diagnosis. Prenatally exposed children that were fed with formula in 73.40% of the cases ended with an HIV negative diagnosis versus 7.45% with an HIV positive diagnosis. (Table 9).

Descriptive statistics regarding the interventions to prevent mother-to-child HIV transmission and the outcomes on the prenatally exposed children of this study show that pregnant women who received HARRT during pregnancy, and intravenous AZT during labor is statistically significant to reduce the transmission rate to their offspring. If the newborn is delivered by caesarean, received oral treatment with zidovudine, and is fed exclusively with infant-adapted formula the incidence of an HIV positive decreases, with statistical significance. Events such as having an older HIV positive sibling and being delivered outside the hospital are not significant in the HIV rate of the children prenatally exposed to HIV (Table 10).

Table 10. Descriptive statistics regarding preventing mother-to-child transmission interventions by outcome on the prenatally exposed children to HIV in the pregnancies of 2008 and their offspring's.

Variable		HIV+	HIV-	Total	X²	p value
Did the pregnant women receive HAART?	Yes	7	81	88		
	NO	15	29	44		
	Total	22	110	132	14.43	p<0.01
Did the pregnant women receive AZT during labor?	Yes	8	90	98		
	NO	13	19	32		
	Total	21	109	130	18.77	p<0.01
Did the newborn was delivery through caesarean?	Yes	7	67	74		
	NO	14	41	55		
	Total	21	108	129	5.92	p<0.05
Did the newborn receive oral AZT first six weeks?	Yes	13	104	117		
	NO	8	2	10		
	Total	21	106	127	31.68	
Did the newborn was feed with formula?	Yes	7	71	78		
	NO	8	13	21		
	Total	15	84	99	10.91	p<0.01
Did the prenatally exposed children to HIV have siblings HIV positive?	Yes	1	3	4		
	NO	11	74	85		
	Total	12	77	89	0.4762	p>0.05
The delivery was held in a hospital?	Yes	17	106	123		
	NO	2	4	6		
	Total	19	110	129	1.73	p>0.05

CHAPTER FIVE: DISCUSSION

Findings

This study found more cases of prenatally exposed children to HIV than pregnant women reported living with HIV/AIDS and being pregnant because the screening coverage for those women or girls in 2008 was 75.80%, the national surveillance department missed approximately one out of four cases for diagnosis resulting in under reporting. Because there were only two pediatric ARVC in the 2008-2009 period, their coverage among the pediatric population was higher. According to the Summary Progress Report, 2011, the coverage on HIV-testing in low and middle country ranges between 8–35% (UNAIDS, 2011) which means that in this study, Panama is above its peer countries at 75.8% coverage.

Pregnant women or girls living with HIV/AIDS were located mostly at Colon health region (32.03%), secondly in the Metropolitan health region (24.84%), San Miguelito health region (19.30%), and Panama-west health region (9.15%). The remaining health regions reported less than two percent of the cases each. Coincidentally the health regions with the highest proportions of pregnant women or girls living with HIV/AIDS are the same with the highest rates of HIV nationwide (Epidemiology, 2011).

The distribution of pregnant women or girls living with HIV/AIDS in 2008 according to age range in the Republic of Panama was 11.63% younger than 25 years old, .28% of the pregnant women were between 26 and 29 years old and most of the cases were in the age group older than 30 years (72.09%). According to (Florida, et al., 2006) the age range found was 17-32 years old, the mean was 32.2 years old, and the median 32 years. In Panama based on the results of this study the age group more affected is above 30 years old.

Educational attainment among pregnant women living with HIV/AIDS in the study with more than 10 years of education was 28.08% among those clinical charts that included this information. Educational attainment and the presence of HIV has been discussed widely; the literature prior to 1996 shows no correlation between educational level and the presence of HIV, nor does it show that people with higher academic degrees are at more risk of being HIV positive (Hargreaves, J.R.; Glynn, J.R., 2002); after the year 2000, studies show less risk with higher educational attainment (Hargreaves, et al., 2008).

The distribution of pregnant women or girls living with HIV/AIDS according to the start date of prenatal control was 15.52% during each the first two trimesters, and 5.17% in the last trimester. Most of the clinical charts did not have this information available. Compared with available literature most of the pregnant women living with HIV/AIDS start their prenatal control during the first trimester (57.6%), followed by the second

trimester (26.3%), and there are fewer diagnoses during the third trimester (16.1%) (Florida, et al., 2006).

The distribution of HIV positive tests performed in pregnant women or girls was 50% before the 20th weeks of pregnancy and 38.33% after 20 weeks. International HIV screening guidelines mention the relevance of having the diagnosis as early as possible to avoid vertical transmission (CDC, 2006). Based on the findings of this study, there is not a clear trend in the early diagnosis of HIV during pregnancy.

The absence of prenatal counseling about HIV for pregnant women or girls was reported in the clinical charts reviewed for this study at 35.6% in Italy (Florida, et al., 2006), and in 30% in the United States of America (Mofenson, 2000). In this study conducted in the Republic of Panama the absence of counseling for HIV was found at 46.67% which is above the proportion reported in the literature.

Pregnant HIV positive women or girls were referred to the ARVC in 65% of the cases, 31.67% were not referred, and in 3.33% of the clinical charts the information was missing. They were referred to a high risk obstetric unit in 88.33% of the cases, in 8.33% of the cases they were not referred, and in 3.33% of the clinical charts the information was not available. The proportion of women referred to ARVC is lower than the one expected in the Panamanian health system, which established a series of interventions to warranty free access to prenatal care among pregnant women living in the Republic of Panama (Ministry of Health, 2000).

The proportion of pregnant women or girls who previously knew their HIV diagnosis was at least 38.33%.

According to the World Health Organization the proportion of pregnant women or girls living with HIV/AIDS that receive treatment including Lopinavir/Ritonavir in low to middle income countries is 33% (Wilcher & Cates, 2009); this study found that 81.67% of the pregnant women or girls living with HIV/AIDS received proper treatment according to national guidelines during January 1, 2008 until December 31, 2008, which is greater than the peer countries.

The distribution of the obstetric outcome among pregnant women living with HIV/AIDS reported from live births between January 2008 and September 2009 was 83.33% ending in a live birth, 5.00% of the cases were abortions, and 1.67% were stillbirths, and 1.67% were miscarriages. The literature reveals that 0.033% of pregnant women living with HIV/AIDS experienced a stillbirth (DIGEST, 2008) with a range between 2%-8%. Panama's proportion regarding stillbirth is below that reported in the current literature. In low and middle income countries, the proportions of live births has been reported as 36% (Massad, et al., 2004), Panama presents more than twice that value. Abortions are reported in approximately one out of four pregnancies among HIV positive women or girls (Massad, et al., 2004). In the current study, 5% of the pregnancies in women living with HIV/AIDS during 2008 ended in an abortion, which is below what has been reported in

the available literature. This might be related to under-report of the cases because abortion is illegal in Panama.

Among the 174 HIV seropositive pregnant women or girls who presented a live birth between January 2008 and September 2009, 40.63% (n=65) were vaginal deliveries, 34.38% (n=55) were emergency caesarean-sections and 20.63% (n=33) were elective caesarean-sections. There were seven clinical charts without the delivery method and 14 missing files. The delivery mode in recent studies shows that elective caesarean-sections are present in 51% of pregnant women or girls living with HIV/AIDS, 34% are vaginally deliveries (European Collaborative Study, 2010). The current study reveals scheduled caesareans are less frequent than what is recommended and what happens in peer countries.

The proportion of gestational age at birth among those prenatally exposed to HIV between January 2008 to September 2009 was above 37 weeks of gestation 60.63% (n=97), below 37 weeks was 8.75% (n=14), 49 files did not include the information, and there were 14 missing files. Most of the cases reported in this study were above 37 weeks, despite literature describes prematurity related to HIV/AIDS (Sibiude, et al., 2012).

The distribution of birth weight among those live births of the prenatally exposed to HIV between January 2008 to September 2009 was 61.49% (n=107) with adequate birth weight and 2.30% with low weight for gestational age; in 36.21% of the cases the information was missing in the clinical charts. Current literature describes low weight at birth present in

children born from HIV women at 29% (Markson, et al., 1996), a much higher proportion than the one reported in the current study (2.30%) and it might be result of the missing data related to this question.

The proportion of newborns receiving prophylaxis treatment according to national guidelines to prevent mother-to-child transmission of HIV was 81.03%, while 6.90% did not receive oral AZT for the six weeks after birth, and 12.07% of the clinical charts did not contain the information. According to UNAIDS's report, 42% of the newborns prenatally exposed to HIV received prophylaxis in low-middle income countries such as Panama (38%-48%) (UNAIDS, 2011). This study shows that Panama provides twice the percentage in comparison with its peer countries regarding prophylaxis coverage against HIV.

Regarding the feeding history among prenatally exposed children born between January 2008 and September 2009, 58.75% were fed with formula, 8.75% received breast milk exclusively, 6.88% received a mix between formula and breast milk and the information was missing in 25.63% of the clinical charts. In low-middle income countries the proportion of HIV positive women and girls that breastfeed their offspring were 21.42%, provide formula were 28.49%, and children that were fed with a mix between breast milk and formula were 50.09% (Coutsoudis, et al., 2001). This study reveals that prenatally exposed children are fed mostly with formula-adapted milk in Panama than its peer country (58.75% vs. 21.42%). Between 56% and 76% of prenatally exposed children to HIV were fed in Africa exclusively with

breast milk (Bork, et al., 2013), in the Republic of Panama 8.75% of the children are fed with breast milk which is lower than expected in peer countries.

At the end of the 18-month follow-up period, 13.17% of the prenatally exposed children were positive for HIV, 65.87% were negative, and 20.96% of the cases had not completed the lab tests to determine their immunological status. Compared with others low-middle income countries the vertical transmission rate with PMTCT is 3.5%, which means that Panamanian prenatally exposed children to HIV have four times more risk of becoming HIV positive. The World Health Organization goal of 5–15% transmission rate with ARVT and no breastfeeding intervention (Shaffer, 2010). It is important to mention that if a children DNA-Pro viral results are positive the confirmatory test is RNA Pro viral test which count viral load.

The interventions to prevent mother-to-child HIV transmission that were statistical significant in this study were the used of HARRT during pregnancy ($0.000146 < 0.05$), the use of intravenous AZT during labor ($1.5 \times 10^{-5} < 0.05$), being delivered by caesarean ($0.014948 < 0.05$), received oral treatment with zidovudine for six weeks ($\text{null} < 0.05$), and being feed exclusively with infant-adapted formula ($0.000954 < 0.05$). This interventions has been described as protective factors by the World Health Organization (World Health Organization, 2010), Pan-American Health organization (Pan-American Health Organization, 2010) and studies that promote the use of zidovudine during pregnancy (National Institutes of Health, 1996). The

overall reduction of mother-to-child HIV transmission with the aforementioned strategies is up to 50%, with a transmission rate below 5%.

Missing data

The current study showed a high rate of under report, especially in pregnant women and girls clinical charts. The national surveillance department missed 24.20% of the cases, and the antiretroviral therapy clinics missed 24.18% which is consistent the local level versus the national level. Out of the existing clinical charts 47.71% provided only minimum registration information and it was recorded the antiretroviral therapy clinic lost to follow up due to lack of response of the pregnant women or girl rendering them excluded from the study. Only health region and age information was collected from the cases reported at the national epidemiology department because there is no other information relevant to this research. At the ARVC 60.00% of the cases were missing files or the information regarding a pregnancy in 2008 was not included. Because of the amount of missing data, especially among the clinical charts belonging to pregnant women living with HIV/AIDS, the information only reflects the reality of the women included in the study. Health care personnel need to be more conscious about the relevance of the quality of the data input in the clinical charts rather just to be focused on the quality of the health care provision.

The progress in any epidemic is measured by monitoring indicators, which need to reflect the quality of the service provided in the clinic. To

improve the quality of the reports, we need to decrease the amount of missing data. To do so we will need to perform exploratory qualitative research to identify potential threats at the individual, interpersonal and organizational level. Based on those threats then develop interventions to engage health care personnel to achieve a common goal of better quality of the service provided, and better data quality to improve the quality of national reports. To address the obstacles at the individual level the Transtheoretical model will be helpful in recognizing the rationalization of highly skilled health care personnel. Monitoring their activities by their peers will help to maintain certain behavior. At the interpersonal level it would be relevant to work with the social cognitive theory because it is dynamic, and multidimensional, similar to the relationship between different health care providers involved in the care of pregnant women living with HIV/AIDS and newborns exposed to HIV. Lastly, to overcome the obstacles within the health care system, the organizational culture theory explains, the effort to engage all co-workers on the values of the organization with a dynamic definition constructed by the personnel involved in taking care of such patients (Coreil, 2010) (Green & Kreuter, 2005).

To look at the accuracy and the quality of the sources of the information the study performed analysis to compare the amount of data input among the variables the use of HAART during pregnancy, the use of intravenous AZT during labor and the caesarean delivery method by health region. The sources compared were the clinical charts form pregnant women and from the newborns (Table 11). Clinical charts belonging to live births

from HIV women that were pregnant in 2008 had less missing information than the clinical charts from the pregnant HIV women or girl from 2008. The information reported within the clinical charts of the children was similar among the three variables collected from the clinical charts, which can be interpreted as consistent information from the prenatally exposed children to HIV. The information in the clinical charts from the pregnant women does not have the same proportion along the three variables, and can be interpret as not consistent. The information from Cocle, Panama-east and San miguelito health regions is similar along the clinical charts from the 2008 pregnant women living with HIV/AIDS and the newborns prenatally exposed to HIV. Colon and Panama-metropolitan are the health regions with the biggest information gap between the three variables compared from the clinical charts in this study.

Table 11. Comparison of data input per health region by variable among the clinical charts reviewed from pregnant women or girls living with HIV/AIDS in 2008 and newborns from women who were pregnant and HIV positive in 2008.

	Number of cases		Received HAART during pregnancy		Received Intravenous AZT during labor		Caesarean Delivery method	
	P	LB	P	LB	P	LB	P	LB
Bocas del Toro	4	1	-	-	-	-	-	-
Cocle	-	6	1.64%	1.72%	-	1.72%	1.64%	1.72%
Colon	49	17	52.46%	7.47%	34.43%	7.47%	40.98%	7.47%
Chiriqui	3	-	-	-	-	-	-	-
Darien	1	1	-	-	-	-	-	-
Gnobe Bugle	2	2	-	-	-	-	-	-
Guna Yala	3	1	-	-	-	-	-	-
Herrera	-	-	-	-	-	-	-	-
Los Santos	1	-	-	-	-	-	-	-
Panama-East	1	7	1.64%	2.30%	-	2.30%	1.64%	2.30%
Panama-Metro	38	84	9.84%	31.61%	3.28%	37.93%	4.92%	26.44%
Panama-West	14	15	3.28%	6.32%	-	5.75%	-	3.44%
San Miguelito	28	32	9.84%	8.05%	-	12.64%	8.20%	8.62%
Veraguas	5	1	-	0.57%	-	0.57%	-	0.57%
Missing	4	7	4.92%	9.20%	40.98%	11.50%	21.31%	12.07%
Total	153	174	83.62%	67.24%	78.69%	79.88%	78.69%	53.44%

Note: P= Pregnant women or girl, LB= Live birth

Study Limitations

The national coverage of screening for HIV and syphilis in 2010 among pregnant women and girls has a mean of 74.9% (with ranges between 23.0% for indigenous communities like Gnabe bugle and up to 94.2 % in the indigenous community of Guna Yala) which make it difficult to identify pregnant women living with HIV/AIDS between January 1, 2008 and December 31, 2008. Because the national screening service during 2008 was low there was an under-report of pregnant women or girls living with HIV/AIDS during that year, but later on, pediatric health services in the Republic of Panama were able to find more prenatally exposed children than pregnant mothers HIV positive during 2008.

This study was based on a secondary source of information such as the epidemiological bulletins from the national epidemiological surveillance for STD/HIV/AIDS department from the Ministry of Health, relying in the accuracy of the data such as name and identification numbers. When the clinical charts were reviewed, there were with different identification numbers or names, which made it difficult to locate them.

The clinical charts from the ARV clinics of each health region, the national ARV clinic for children located at the children's hospital, and an NGO "Albergue de Maria" which cares for orphans were incomplete. The largest amount of missing data was found in the adult's antiretroviral clinics.

The procedure to triangulate the pediatric cases with the pregnant women cases in the adult ARV clinics was not possible because during the

first half of 2008 in the pediatric clinical chart the identification number of the mother was not listed. The study tried to triangulate by the birth date, but in most of the mothers, clinical charts the birth date was not available. Based on the previous limitation the study could not follow the complete cycle for all of the cases.

In Panama the diagnosis algorithm includes a RNA viral test once a prenatal exposed child tested positive for HIV, to account the viral load in plasma. Late seroreversion cases (children that tested positive in their DNA por-viral test and negative after 12 month follow-up period) were not found in the current study because of the current national algorithm which is a limitation of the study.

The information regarding Syphilis cases was not available in a timely manner to include them in the current study.

Conclusions

The Republic of Panama has made efforts to reduce Mother-to-Child HIV transmission, such as development of legislation to mandatory notification of pregnant women and girls with the HIV positive diagnosis, as well as to provide medical service free of charge for pregnant women during prenatal control and labor, and designing the national guidelines to prevent vertical transmission of HIV and Congenital Syphilis. The current study shows the improvements on certain topics such as the availability of treatment, the proper usage of medications to avoid mother-to-child HIV transmission,

laboratory tests to diagnose mothers and children, and the free provision of formula-adapted milk.

The study shows opportunities for improvement such as the late start date of prenatal control, the uncertainty of HIV screening pregnant women during the first 20 weeks of gestation, because the earliest the HIV positive diagnosis is made, the earliest the onset of treatment that will decrease the risk of mother-to-child HIV transmission. The screening with non-treponemic tests which is an inexpensive screening test use as a predictor of sexual risk behavior, and ending the pregnancy with viral load results available which will help the health care personnel to decide the delivery method of the pregnant women.

Recommendations

- It is necessary to strengthen the surveillance system to increase the number of cases identified by HIV screening of pregnant women or girls, with the aim of measuring the impact of the interventions already drafted by the Panamanian government and clinical guidelines to avoid mother-to-child HIV transmission and Congenital Syphilis (World Health Organization, 2010).
- Increase access to family planning counseling for women living with HIV/AIDS in reproductive ages and their couples (World Health Organization, 2010).

- Evaluate if it is cost-effective that pregnant women living with HIV/AIDS shall continue ARVT after delivery (UNICEF, 2012).
- In order to improve the quality of the information obtained from the clinical charts it is necessary to decrease the amount of missing data and non-available information. It is necessary to explore the reasons why the health care personnel are not documenting adequately the information of pregnant women and girls living with HIV/AIDS. Once the exploratory research is conducted it will be necessary to draft an awareness campaign to promote adequate data input in clinical charts, systematic collection and processing of data that will leverage the evidence-based decision making by the Panamanian stakeholders (Gliklich & Dreyer, 2010).
- Further quantitative and qualitative research is necessary to design a comprehensive health program focus on the sexual health and reproductive rights of the HIV positive population.

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APPENDICES

Appendix A: Institutional Review Board



DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
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October 4, 2012

Lorna Jenkins Sanchez, M.D.
Environmental and Occupational Health
4301 Shire Court, Box 19
Tampa, FL 33612

RE: **Expedited Approval** for Initial Review
IRB#: Pro00008278
Title: Mother- to - Child Transmission of HIV and congenital syphilis in Panama: A
snapshot of an Epidemic in Republic of Panama.

Dear Dr. Jenkins Sanchez:

On 9/27/2012, the Institutional Review Board (IRB) reviewed and **APPROVED** the above referenced protocol. Please note that your approval for this study will expire on 9/27/2013.

Approved Items:

Protocol Document(s):

[Mother-to-Child HIV and/or Syphilis Transmission in Republic of Panama](#)

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review category:

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.116 (d) which states that an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after