Birth Outcomes of Diabetic Health Start Participants in 2010

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Abstract:

In Arizona, the Health Start program, a home visiting program, aims to identify at risk (for Low-birth-weight-for-gestational-age babies) women, and educate them about maternal, child, and fetal health, and refer them to medical care throughout their pregnancy and two years post-partum. The goals of the program are to reduce low birth weight infants, reduce the number of infants and young children affected by childhood disease, and increase the number of pregnant women receiving prenatal care. During the years 2009-2010, 2,168 pregnant women received a visit from in the Health Start (HS) program. After matching and exclusions, 808 pregnant women who gave birth in Arizona in 2010 were included. Of the 808 matched HS clients, 3% (n=23) of women were identified as having diabetes (gestational, type I or type II); this group of women was examined for birth outcomes and compared to a matched 2:1 control group of non-HS Arizona women who gave birth in 2010. Known diabetic complications were compared between the groups using chi square tests. Additional birth outcomes that were measured in both groups were congenital abnormalities. The hypothesis was that women with diabetes in the HS program would have better birth outcomes as compared to the control group. The results comparing the groups were not statistically different.

Table of Contents

List of Figures and Tables:

Introduction and Significance:

The goal of this project was to evaluate women with diabetes in the Health Start program, and compare their birth outcomes to that of matched controls (2 controls for every HS client). Diabetic women were a focus of the study due to the increasing incidence of diabetes in the US. The HS program is administered by the Arizona Department of Health Services, through the Bureau of Women and Children's Health. The funding for the program comes from monies allocated to the ADHS from the Arizona State Lottery. HS serves pregnant women, post-partum women, their children, and their families in 11 counties.

At present, there are 26 million Americans who have a diagnosis of diabetes (Type 2 DM, or Type 1 Diabetes Mellitus [DM]), and it is estimated that approximately 79 million more are at risk of developing it within the next few years (Zhuo 2012). Diabetes is a metabolic disorder that affects all parts of the body. Uncontrolled diabetes can have devastating consequences on the health of an affected individual. Furthermore, poor glucose control during pregnancy impacts not only the mother, but the growing fetus as well. During pregnancy, the body's physiology undergoes a series of changes in order to meet the necessities of the growing fetus; as a result, pregnancy itself can lower the rates of HgA1C (Han 2012, Schwartz 2000). Congenital cardiac anomalies, such as transposition of the great arteries, persistent truncus arteriosus, visceral heterotaxia with single ventricle, among others have been well studied in diabetic mothers (type 1, type 2) with poor first trimester control of their glucose levels (Bell, 2007; Lisowski, 2010). Additionally, as much as a five-fold increase in cardiac anomalies has been noted in the children of diabetic mothers, as compared to the general children of the non-diabetic mothers (Suhonen 2000; Bradley 2007).

Immediately after birth, the baby has the risk of becoming dangerously hypoglycemic, possibly leading to detrimental consequences if not recognized right away (Chamberlain, 2011; Gandhi, 2008; Gandhi 2012). Often type 1 diabetic mothers, as compared to type 2, may have the risk of having Low-birth-weight-for-gestational-age babies, and this too may lead to other detrimental outcomes (Holmes 2011). Other peri-natal morbidities include low APGAR scores[1]

[1] *An APGAR score is one given to the newborn at 1 minute of age and 5 minutes of age. APGAR is an acronym for Appearance, Pulse, Grimace, Activity, and Respirations. Scores are based on a scale of one to ten, where seven and above

(peri-natal hypoxia as the leading culprit), birth trauma (Erb Palsy, Clavicle fractures), respiratory disorders, and hyperbilirubinemia. Later in life, the child has a higher risk of obesity as well as risk of developing Type 2 DM (Weintrob 2007; Persson 1993; Persson 2012). The consequences of uncontrolled diabetes can also affect the mother- macrosomic babies, (large babies for gestational age), most likely indicate adverse outcomes for mothers, as macrosomia has been associated with increased risk of c-section, prolonged labor, vaginal cuff tears at delivery (Chamberlain, 2011).

The goal of this project was to evaluate women with diabetes in the Health Start program, and compare their birth outcomes to that of matched controls. The Health Start Program is funded by the state of Arizona and serves pregnant women, post-partum women, their children, and their families. Women can qualify for the Health Start Program if they have at least one social risk factor plus one or more medical risk factors. The medical risk factors as well as social risk factors are listed in the table 1.

is normal, four to six is low, and less than three is critically low. APGAR scores are an indicator of a newborn's wellbeing and therefore important for this study.

Table 1: Medical and Social Risk Factors for Health Start Program

Medical Risk Factors	**Social risk factors**
Preterm birth/labor	Prenatal/postpartum Depression
Low birth weight (<2200g)	
High birth weight (>4500g)	Domestic violence
Birth Defects	Lack of social/family support
Cocaine or other illicit drug use	
Alcohol use	
Tobacco Use	
Miscarriage	Lack of basic needs: food, shelter, transportation, unsafe neighborhood
Previous birth complications	
Previous termination	
Kidney disease in mother	No OB/GYN or primary care providers in area
Anemia in mother	
Diabetes in mother (type I, II, or gestational)	
Weight of mother (<100lbs or obese)	Unemployment/lack of job opportunities
Height <5 feet	
High blood pressure in mother	
HIV/AIDS, sexually transmitted infections	Less than high school education
Previous or current multiple births	
Birth Spacing <2 years	
Age 18 or less, 35 or greater	
Bacterial Vaginosis	
Urinary tract infections	
Vaginal hemorrhaging	
Lack of dental care	

Community health workers (CHWs) provide many essential services to women and their families by having home visits, educational group classes and referring them to health care services such as the state Medicaid program called AHCCCS if they qualify. The program is designed such that once the women are enrolled, they are provided with services for the remainder of their pregnancy and until their child is two years old. The CHWs know their communities well, making it easy to identify possible candidates for the program. The women self-disclose their risks and if they agree to participate, they are enrolled in the program.

Benefits of the Health Start Program:

- Refer women to health care services like primary care physicians and OB/GYNs; also WIC, High Risk Prenatal Program, Healthy Families Program, First Things First, and other programs
- Referring the women for the State Medicaid program called AHCCCS, if they qualify/need health insurance
- CHWs ask the mothers if their child's immunizations are up to date, educating them about the importance of immunizations, and make appropriate referrals
- Providing Education through home visits and group classes involving myriad topics (Exercise, Emotions, Maternal Diet, Changes during pregnancy, Labor and Delivery, Community Resources, Healthy Weight, Medications, Vitamins, Folate, Health Insurance, Breastfeeding, Finances, and Family Planning/Birth Spacing among others)
- Identifies women with self-reported medical and social risks, and provides them with connections to solutions to better the outcome of their offspring (for example, a major goal of the program is to prevent, identify, and improve the outcomes of very low birth weight babies and low birth weight babies; another goal is to reduce the number of babies who require more than seventy two hours of neonatal intensive care.)

The Health Start Program does not emphasize diabetes prevention, it identifies and educates women who self-report diabetes as a medical risk factor. Due to data collection methods, women who self-reported diabetes were unable to report their specific type of diabetes, only that they had the disease. Therefore, the information about diabetes from the database, does not necessarily indicate if the women developed diabetes during their pregnancies (either before enrollment or after). The goal of this project was to evaluate women with diabetes in the Health Start program, and compare their birth outcomes to that of matched controls.

Research Methods and Materials:

The sources of data for this project were obtained from the two Arizona HS databases (due to database transition in 2010), and the 2010 Arizona birth certificate dataset. The information was linked between prenatal visits and birth certificates as follows. Pregnant HS women who had a prenatal program visit in 2009 or 2010 (2, 168), were linked to 2010 Arizona resident birth certificate data (86,978). Various combinations of the following variables were used to link HS clients to birth certificate data: direct spelling of name: first name, first last name, second last name, maiden name, and direct phonetic sound of names; date of birth, and address. A total of 827 HS women were linked to birth certificate data. The control group was chosen as follows. Controls (non HS clients who had a baby in 2010) were matched to HS clients on the following five variables, which make up the control group demographics: ***Diabetes status****:* yes/no, ***Age:*** <20, 20-34, 35+ ***Race/Ethnicity:*** Asian, White non-Hispanic, Hispanic, Black non-Hispanic, American Indian, and Other, ***Method of payment:*** AHCCCS (Arizona's Medicaid program), Indian Health Services, private Health Insurance, out of pocket, and unknown, ***Maternal county of residence:*** Apache, Cochise, Coconino, Gila, Graham, Greenlee, La Paz, Maricopa, Mojave, Navajo, Pima, Pinal, Santa Cruz, Yavapai, and Yuma. In cases where more than two non HS clients were matched to an HS client, a simple random sample was used to select the number of controls needed to keep the 2:1 match. The HS clients were then matched to the control group. After matching, in some cases, there were not enough matched controls to keep the 2:1 ratio to HS clients, so those HS clients were removed (n=19). The final sample size consisted of 808 HS clients and 1,616 matched controls. The Health Start group was calculated using SAS 9.3. The HS group and the control group were analyzed using SPSS version 20. See figure 1. See table 2.

Figure 1: Methods

Table 2: Independent Variables
The table below demonstrates the variables that were controlled for in the study, as demonstrated in the left hand column, with the Health Start and the Control group values in percentages.

Variable controlled for	**Health Start Participants (%)**		**Arizona Control Group (%)**	
Diabetes		3		3
Method of Payment	AHCCCS	82	AHCCCS	82
	Indian Health Services	1.5	Indian Health Services	1.5
	Private health insurance	14	Private health insurance	14
	Out of Pocket	2	Out of Pocket	2
	Unknown	0.5	Unknown	0.5
Race/Ethnicity	Asian	1	Asian	1
	White non-Hispanic	23	White non-Hispanic	23
	Hispanic	58	Hispanic	58
	Black non-Hispanic	2	Black non-Hispanic	2
	American Indian	15	American Indian	15
	Other	1	Other	1
Maternal Age Group	<20	22	<20	22
	20-34	71	20-34	71
	35+	7	35+	7
Maternal County of Residence	APACHE	5	APACHE	5
	COCHISE	12	COCHISE	12
	COCONINO	8.5	COCONINO	8.5
	GILA	4	GILA	4
	MARICOPA	25	MARICOPA	25
	MOHAVE	5	MOHAVE	5
	NAVAJO	1	NAVAJO	1
	PIMA	8	PIMA	8
	PINAL	0.5	PINAL	0.5

	SANTA CRUZ	9	SANTA CRUZ	9
	YAVAPAI	6	YAVAPAI	6
	YUMA	16	YUMA	16

All of the risks and descriptors for the women were self-reported; the descriptors included: marital status, race/ethnicity, educational level, and household size. The medical risks included: previous preterm birth, low or high birth weight, birth defects, miscarriage, previous birth complications, previous termination, kidney disease, anemia, diabetes, obesity, hypertension, HIV/AIDS, sexually transmitted infections, previous or current multiple births, birth spacing, age, alcohol and tobacco use, and illicit drug use. Social risk factors such as lack of employment, lack of social/family support, domestic violence, and lack of primary care physicians or OB/GYNs. The women had to have at least one social risk factor in addition to one or more medical risk factors. The women were then enrolled in the program by CHWs and followed throughout their pregnancies and two years post partum. Since the main variable of interest was diabetes, in the Health Start program, there were 3% (n= 23) of women with diabetes enrolled in the years 2009-2010 who gave birth in 2010. The original number of women with diabetes was 3.2% (n=27), but 4 women were lost due to the fact that they could not be matched on all of the variables to control subjects. So, for example, if diabetes, maternal age, maternal county of residence, race/ethnicity, and method of payment were not all matched to a control, the women could not be included in the group.

Diabetes was important to match on to allow for comparability of analysis between groups. Method of payment was also chosen to represent socio-economic status (SES). SES could have an impact on the outcome of a pregnancy because people with a lower SES, for example, could have a baseline lower rate of prenatal care of less access to medical care, than someone with a higher SES who could afford to have frequent doctor's visits et cetera (Verheijen 2005). Method of payment was broken down into the following subsections: AHCCCS (Arizona Health Care Cost Containment System, the state's Medicaid program), Indian Health Services, private health insurance, out of pocket payment, and unknown. Race and ethnicity (Asian, White non-Hispanic, Black non-Hispanic, American Indian, Hispanic, and other) were controlled for because some races may have an increased risk of certain conditions, or may be predisposed to certain conditions which could skew the data, as could maternal age (<20 years old, 20-34 years old, or 35 or greater). Maternal county of residence (Apache, Cochise, Coconino, Gila, Maricopa, Mohave, Navajo, Pima, Pinal, Santa Cruz, Yavapai, and

Yuma) was included to account for the environment where a woman lives which could pose unique challenges during pregnancy. For example, women in more rural areas may have less access to medical care due to transportation issues or distance to doctor's offices. The process of obtaining the race and age groups differed from the rest, because they were not taken directly from the birth certificate data. The age group was created by manually re-grouping the woman's age into 3 different categories: if the woman was less than 20 years old she was placed into one group, if she was 21-34 she was placed into another, and the same for 35 or more years of age. The race/ethnicity category was created by manually re-grouping the information as well; the women could identify themselves as being Hispanic, White, Black, Asian or Pacific Islander, American Indian, or other. If the woman at any time identified her tribe, she was placed under the American Indian category. A woman could identify herself as white, but then also as Hispanic, so if she identified as Hispanic at any point she was placed in the Hispanic category and all who identified themselves as White remained in that category. The same process was applied to Black non-Hispanic and Asian or Pacific Islander. Other was kept as a category for women who chose to identify themselves as such.

The data sets were merged to produce the data that was analyzed in this paper. Because of exclusion criteria, the total starting number of birth certificates is short about 100 women as compared to the official Arizona Vital Statistics data. Once the information was gathered, the risks that the woman had were recorded and compared. Additionally the frequencies of various congenital abnormalities, birth weights, APGAR scores, among others were recorded and entered into the statistical analysis program SPSS, version 20. Using SPSS, the Chi square test was used to compare the multiple variables between the two groups of women's babies.

Results and Statistical Significance:

Overall, the birth outcomes were not statistically different in the HS population as compared to the control group. See table 2, 3, figures 1, 2, 3, 4, 5, and 6. Furthermore, the results of the birth outcomes in the HS diabetic group, vs. those in the control diabetic group were also not statistically different. Additionally, there were no recorded cases of the following diseases in either group, so no analysis was conducted: Fetal alcohol syndrome, Anencephalus/Spina Bifida, Heart Malformations, Tracheoesophageal Fistulas, Malformed Genitalia, Renal Agenesis, Newborn Anemia, Polydactyly, and Diaphragmatic Hernia.

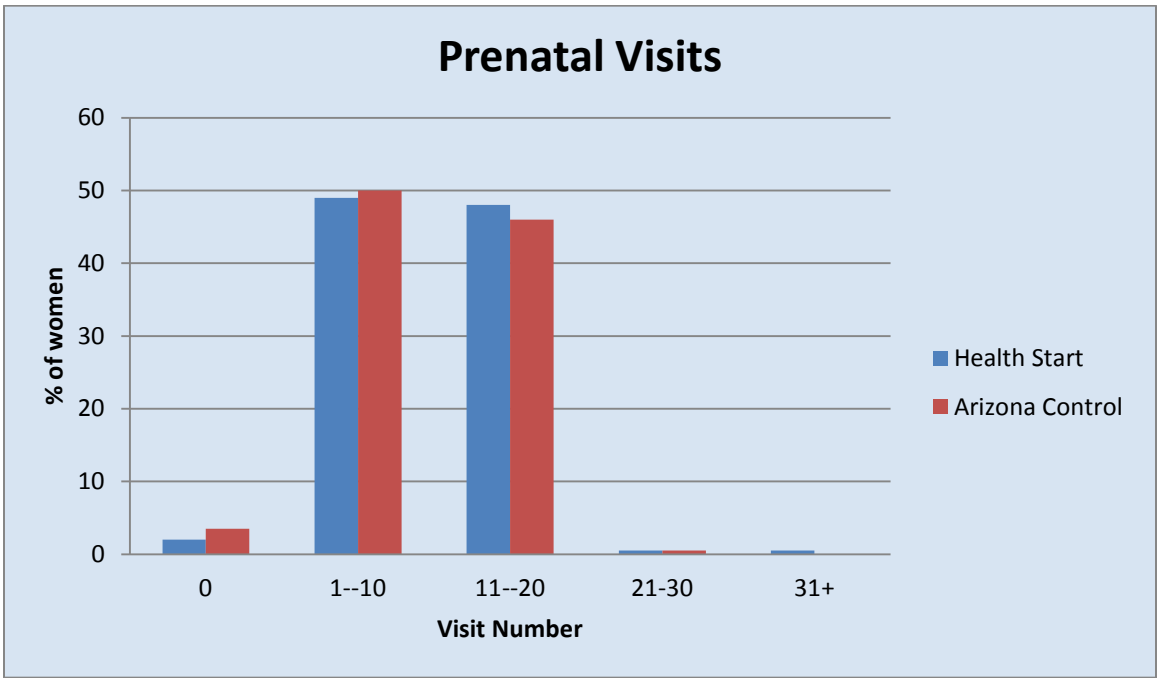
Health Start Diabetic Group versus Control Diabetic Group; Control Non-Diabetic vs. Control Non-Diabetic:

Table 3: The following are breakdowns of APGAR scores at 1minute and 5 minutes for Health Start Participants with and without diabetes and the control group with and without diabetes. The health start group and the control group are not statistically different with p-values of 0.467 and 0.131 for 1 minute and 5 minutes respectively.

Health Start Group	**Diabetes (%)**	
	Yes	**No**
APGAR Score 1 minute Control		
<3 critically low	0	2
4-6 low	0.5	4
7+ normal	2.5	91
APGAR score 5 minutes		
<3 critically low	0	0.5
4-6 low	0	0.5
7+ normal	3	96

Control Group	**Diabetes (%)**	
	Yes	**No**
APGAR Score 1 minute Control		
<3 critically low	0	3
4-6 low	0	4
7+ normal	2	91
APGAR score 5 minutes		
<3 critically low	0	1
4-6 low	0	1
7+ normal	3	95

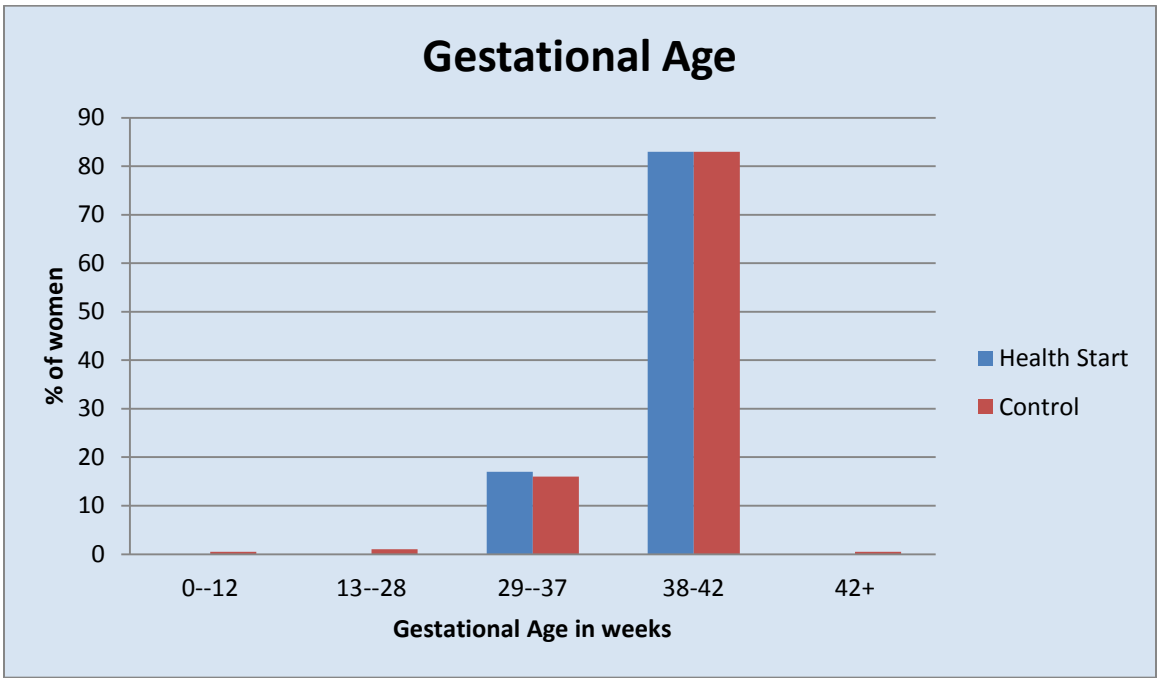
Figure 2: Prenatal Visits



Prenatal Visits. Number of Prenatal Visits in Health Start Group: 10.78 +/- 7.333
Number of Prenatal Visits in Non Health Start Group: 10.09 +/- 4.238

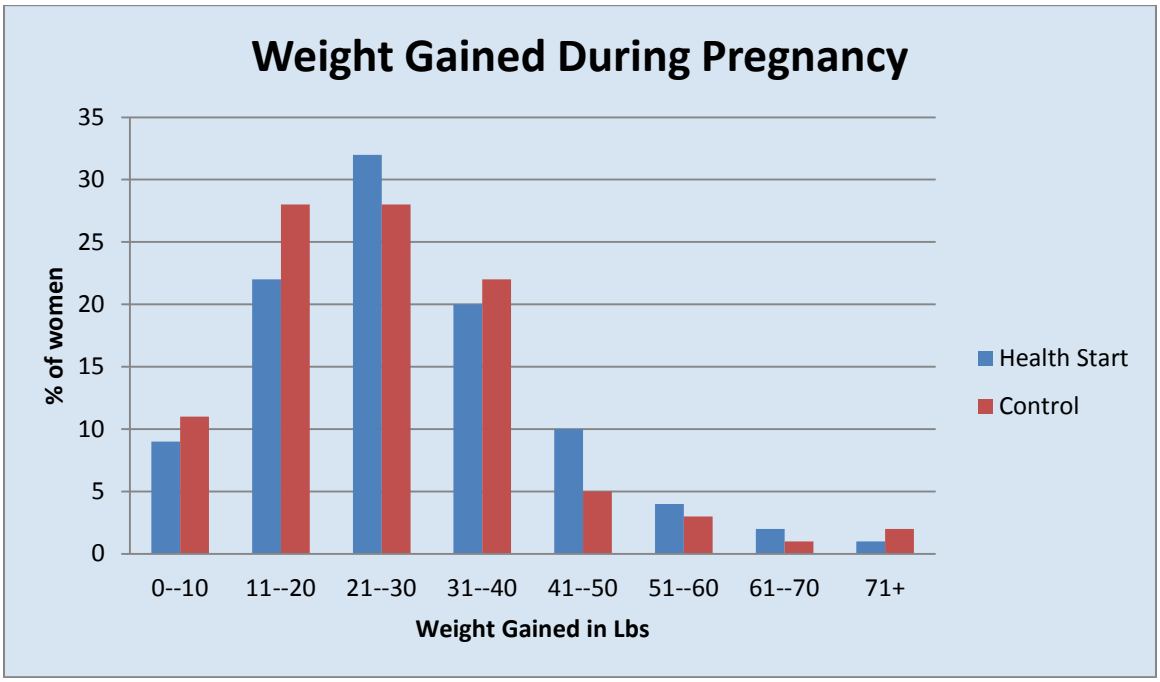
(There is no statistical significance between the two groups p-value 0.058

Figure 3: Gestational Age



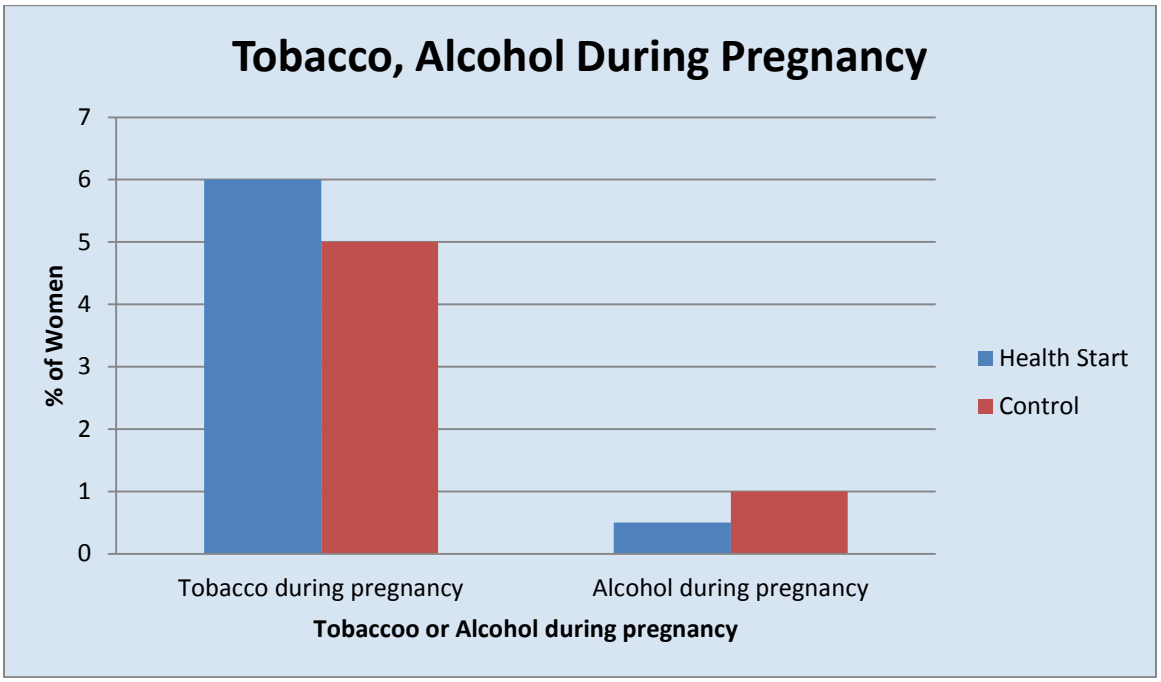
Gestational Estimate in Health Start participants and non Health Start controls. Important to note that most of the health start participants were able to make it to term. P-Value 0.855

Figure 4: Weight Gained During Pregnancy



Weight Gained during pregnancy in Health Start versus Non Health Start Participants; P-value .604

Figure 5: Tobacco, Alcohol Consumption During Pregnancy



P-Value .891, .181 respectively

Figure 6: Birth Outcomes of Health Start Clients and Controls

Birth Outcomes of Health Start and Controls

Outcome	HS in % (n= 808)	Control in % (n= 1,616)	P-Value
Fetal Distress	**0**	**.08 (13)**	**0.486**
Hyaline Membrane disease	**.01 (1)**	**.01 (2)**	**.617**
Meconium Aspiration Syndrome	**0**	**.01 (2)**	**.479**
Newborn Seizures	**.01 (1)**	**0.3 (5)**	**.621**
Omphalocele	**0**	**.01 (1)**	**.479**
Cleft Palate	**.01 (1)**	**0.2 (4)**	**.527**
Club Foot	**0**	**.01 (2)**	**.479**
Down Syndrome	**0**	**.01 (2)**	**.479**

The table depicts the birth outcomes that were reported on birth certificates in both the Health Start clients and the control group, in addition to their p-values. **The diabetic women in the HS group (n=23) and control group (n=46) did not have any fetal anomalies at all, and therefore were not included in the table above**. The results above depict both non-diabetic HS clients, and non-diabetic controls.

Discussion:

This study analyzed women in the HS program with and without diabetes to see if they had any statistically different birth outcomes as compared to case controls. There was no statistical difference among the two groups. This study had several limitations. First, the sample sizes were quite small at 808 HS women, in which 3% (n=23) had diabetes, as well as 1,616 controls of which 3% (n=46) had diabetes. With such a small proportion of subjects with diabetes, it is difficult to determine whether HS was truly effective. Second, the type of diabetes that each woman in the project had was also unknown, so it is difficult to extend generalizations about diabetic outcomes to all types of diabetes. And given that the diabetic status was self-reported, certain patients in the study may not have been classified properly. Third, individuals in the control group were matched on diabetes, and therefore, are not representative of the actual percentage of diabetes in the community. Fourth, confounding variables such as obesity, hypertension, and hypercholesterolemia which may affect birth outcomes, were not controlled for in this study. Finally, the matching criteria may have been too specific and eliminated women who could have had different birth outcomes.

Although this study indicates that there is no statistical difference between HS clients and control clients in specific health outcomes; the HS program may provide benefits in outcomes that were not assessed in this study and may not be apparent from health records. For example, HS provides personalized health care and prenatal education that may subsequently lead to greater patient satisfaction, empowerment, or compliance though these are factors that cannot be analyzed with the data currently available. In addition, HS provides opportunities for assessing future public health improvements by archiving birth outcomes of current clients using birth certificate information. Although the results indicate no statistical difference in birth outcomes for the health start group versus the control group, it is important to note that this does not mean that the health start program is not successful in helping pregnant and post partum women be as healthy as possible. The women in the Health Start group were recruited based on the fact that they were deemed to have increased risks or poorer birth outcomes. Many of the CHWs that recruited the women are located in areas of Arizona that are more rural, underserved, or of lower socioeconomic status. These were some

of the possible confounding factors that were avoided by matching them to the controls. However, the women followed in the health start program perhaps would not have been referred to the necessary resources, such as enrollment in AHCCCS, or other programs (also WIC, High Risk Prenatal Program, Healthy Families Program, and First Things First) to help provide them with medical care. In general, the data suggests that the health start group has comparative results compared to the level of care that the control group received.

In the groups with diabetes, there was no marked difference in any of the outcomes. In general, there is a lower rate of developmental abnormalities in the overall population; however, the literature suggests that they may be slightly increased in women with poorly controlled diabetes, as compared to the general population (Nasrat 1993; Al-Dobbous 1996). Since the sample size of diabetic women in the health start program was only 3% as well as in the Arizona controls, it is difficult to see if there is, in fact, a noticeable difference in the general rates of congenital abnormalities in women with poorly controlled diabetes. However, the lack of statistical difference among the women with diabetes in the health start program and the women with diabetes in the Arizona controls could just be because the women had well controlled diabetes on the whole. Without being able to follow their hemoglobin A1c or knowing if they were placed on insulin/if they were compliant with insulin, it is difficult to extrapolate an answer to the fundamental question in the study. In the future, a larger sample size would be needed to understand the relationship between diabetes and birth outcomes in this population. Although there may have been more women than 3% who had diabetes during their pregnancy, this project only analyzed participants that could be matched to 2010 birth certificate data. Women were not followed to see if they became diabetic during their gestation, as diabetes was a self identified risk factor at the time of enrollment into the health start program. Certainly, a lower census does not give this study a greater power, and therefore, it is difficult to fully analyze the effect that the Health Start Program has on the outcomes of diabetic women, which is a limitation of this study.

Future Directions:

The Health Start Program brings a positive light to the pregnant and post-partum women in Arizona who are able to participate. The program is providing the women with educational material about a wide range of must know subjects concerning motherhood and wellbeing, as well as referring women to health care, that perhaps they would not have been able to obtain had they not been enrolled in the program.

In regards to diabetes, it would be useful to expand data subset to include more than one year, ideally to a span of five or more years to better examine the outcome of diabetic mothers compared to pregnant Arizona controls. Additionally, it would be beneficial to follow blood glucose level of the women closely to determine how the various levels of diabetic control impact their birth outcomes.

The aim of the Health Start program is to create a healthy start for all of the babies involved, and with time, the number of women and babies they have helped will continue to increase and truly have an impact on the growing generations of Arizonans.

Conclusions:

It is difficult to extrapolate answers with a limited sample size. However, the fact remains that the pregnant women in the Health Start program who received a prenatal visit in 2009 or 2010, who also gave birth in 2010, had comparable health outcomes to the control group of non-Health Start Participants with similar demographics. In terms of diabetes, the women did not have better outcomes than their diabetic controls, however, they did not have worse outcomes either.

All the chi square tests among the health start and non health start group concerning hyaline membrane disease, meconium aspiration syndrome, newborn seizures, neural tube defects, omphalocele, heart malformations, rectal atresias, and tracheo-esophageal fistulas were not statistically different. There was also no statistical difference in the weight gained during pregnancy of the women, the APGAR scores of the two groups, or the gestational age. However, the health start group did meet their goal of having most of the women make it to term before giving birth. What was interesting to note was that the women did not gain more weight than the control group, and this was consistent with the fact that there was also not a statistical difference in the cephalo-pelvic disproportion between the two groups. Perhaps part of this can be contributed to the fact that Health Start clients were provided with home visits and group classes that spoke about the importance of a health maternal weight, as well as nutrition during pregnancy.

The hypothesis at the beginning of the study was that the health start women with diabetes would have better birth outcomes than their Arizona controls with diabetes, in addition to the health start program having better birth outcomes in general as compared to their Arizona controls. The data does not indicate a statistical significance between the two groups and therefore the alternative hypothesis cannot be accepted. Although the results are not statistically different, the fact that the outcomes are not worse compared to the control group could mean that the Health Start program provides care to the women that they may not have otherwise sought, such as educational classes about healthy weight, maternal diet, or being referred to a primary care physician or OB/GYN physician. It is important to note that neither the Health Start group nor the control groups are representative of the general

population of Arizona. They are instead, a representation of what the underserved populations of Arizona are, and the results should not be used to make inferences about the general population of pregnant women in Arizona, which is a limitation of the study. The sample size of diabetic women in the group was very limited at 3% of the 808 women, a larger sample size, as well as a greater time span is needed to further investigate any differences that may be present between the Health Start group and the control group.

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