Improving birth outcomes among pregnant, Hispanic/Latina adolescents in Gila County, Arizona.

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# Table of Contents

## TABLE OF CONTENTS

---

1. **Specific Aims** .................................................................................. 3

   1.1 **AIM 1: Formative Research** .......................................................... 3

   1.2 **AIM 2: Establish Community-Derived Priorities** ....................... 3

   1.3 **AIM 3: Intervention** .................................................................. 3

   1.4 **AIM 4: Monitoring & Evaluation** .............................................. 4

   1.5 **AIM 5: Reporting** ................................................................. 4

2. **Background & Rationale** ................................................................. 5

   2.1 **Background** ........................................................................... 5

   2.2 **Rationale** .............................................................................. 6

3. **Design & Methods** ........................................................................ 8

   3.1 **Overall Study Design** ................................................................ 8

   3.2 **Formative Frameworks** ............................................................... 10

   3.3 **Formative Research - Specific Aim 1** ....................................... 11

   3.4 **Community Priorities - Specific Aim 2** ................................... 13

   3.5 **Intervention - Specific Aim 3** .................................................. 14

   3.6 **Data Management & Analysis** ................................................. 16

4. **Monitoring & Evaluation - Specific Aim 4** .................................... 16

   4.1 **Inputs & Input Evaluation** ......................................................... 16

   4.2 **Processes & Process Evaluation** .............................................. 16

   4.3 **Outcomes & Outcome Evaluation** .......................................... 17

   4.4 **Impact** .................................................................................... 17

   4.5 **Logframe Matrix** .................................................................... 17

5. **Program Logistics** .......................................................................... 22

   5.1 **Organizational Capacity** ............................................................ 22

   5.2 **Budget** .................................................................................... 24

   5.3 **Reporting - Specific Aim 5** ..................................................... 25

   5.4 **Sustainability** .......................................................................... 25

6. **Conclusion & Limitations** ............................................................... 26

7. **Appendices** .................................................................................. 28

   7.1 **Consent Form** ........................................................................... 28

   7.2 **Sample Surveys** ...................................................................... 30

   7.3 **Protection of Human Subjects** .............................................. 34

8. **References** .................................................................................... 38
1 Specific Aims
This program proposes to reduce infant morbidity and mortality by improving access to prenatal care, increasing care utilization, and promoting healthy behaviors among pregnant, Hispanic/Latina adolescents ages 19 years and under using a community health worker model in Gila County, Arizona.

1.1 Aim 1: Formative Research
To assess baseline prenatal care utilization and describe access barriers using qualitative (key informant interviews) and quantitative (retrospective analysis) methods in order to establish local needs that will inform intervention design and deployment.

Using retrospective data analysis, baseline care utilization and access barriers can be approximated. However, state-level surveillance mechanisms are not designed to capture cultural, behavioral, and environmental access barriers. During program enrollment, pregnant adolescents will be interviewed to establish baseline utilization and confirm access barrier estimations.

Hypotheses:

- Less than 65% of pregnant Hispanic/Latina adolescents will initiate prenatal care during the first trimester (Bureau of Public Health Statistics, 2009b).
- Less than 65% of pregnant Hispanic/Latina adolescents will complete 7 or more prenatal visits (Bureau of Public Health Statistics, 2009b).

1.2 Aim 2: Establish Community-Derived Priorities
To establish community-derived priorities and develop culturally-competent interventional strategies for integration into community health worker training and program design.

Accounting for Aim 1, program priorities should be directed toward alleviating confirmed access barriers. However, cultural relevance is integral for understanding factors influencing these barriers. Through qualitative research (focus groups & key informant interviews), informed strategies can be targeted by the community, rather than at the community.

1.3 Aim 3: Intervention
To implement a community health worker-driven intervention in order to increase prenatal care utilization and promote healthy maternal behaviors among pregnant, Hispanic/Latina adolescents during the course of the intervention.
Intervention activities will include transportation for pregnancy-related appointments; healthy behavior education and support; child care services; insurance acquisition; WIC enrollment; and other referral services as needed.

**1.4 Aim 4: Monitoring & Evaluation**

*To assess intervention effectiveness by comparing pre-, mid-, and post-intervention longitudinal data.*

Program monitoring and evaluation is centered upon decreasing maternal and child health morbidity and mortality, as indicated through the proposed Healthy People 2020 (Office of Disease Prevention & Health Promotion, 2010).

**Hypotheses:**

- The intervention will immediately improve upon baseline programming through:
  
  - Increasing first-trimester prenatal care initiation by 50% (Flynn, Budd, & Modelski, 2008; Leppert & Namerow, 1985; Watkins et al., 1994; Watkins, Larson, Harlan, & Young, 1990)
  
  - Increasing number of mothers who participate in an adequate number of prenatal care visits by 50% (Bray & Edwards, 1994; Flynn, et al., 2008; Lia-Hoagberg et al., 1990; McFarlane & Fehir, 1994; Meister, Warrick, de Zapién, & Wood, 1992; Rogers, Peoples-Sheps, & Suchindran, 1996; Watkins, et al., 1994; Watkins, et al., 1990)

- The intervention will improve mid-term outcomes over baseline programming through:
  
  - Increasing achievement of proper weight gain by 50% (Kogan, Alexander, Kotelchuck, & Nagey, 1994).
  
  - Decreasing alcohol use by 50% (Kogan, et al., 1994).
  
  - Decreasing the incidence of premature births to adolescent mothers by 50% (Nguyen, Carson, & Parris, 2003).
  
  - Increasing breast-feeding within the neonatal period by 50% (Kogan, et al., 1994).

**1.5 Aim 5: Reporting**

*To recommend statewide, regionally-based goals for increasing prenatal care utilization.*

Once program evaluation is complete, thorough report discussing strengths and weaknesses of the program will be generated. This will ultimately lead to a policy brief targeting legislators, communities and state employees.
2 Background & Rationale

2.1 Background

Current United States practice guidelines for routine prenatal care are primarily aimed at improving maternal and fetal health outcomes (Institute for Clinical Systems Improvement, 2009). Ideally, this is accomplished through a series of preventive and interventional tasks scheduled over 8-11 prenatal visits beginning in the first trimester and occurring throughout the pregnancy. Women who fail to receive prenatal care or delay the initiation of care are more likely to have preterm labor, often resulting in premature delivery of low-birth-weight infants (Greenberg, 1983). Additionally, maternal health behavior changes prompted by prenatal care decreases the risk of low birth weight, whether due to, or independent of, premature delivery (Kogan, et al., 1994). These behavior changes target preventable maternal risk factors such as alcohol, drug, or tobacco use, which contribute to low birth weight by induction of preterm labor, intrauterine growth restriction, or both (Mittendorf et al., 1994). Complications relating to low birth weight account for two-thirds of infant deaths during the first month of life and half of infant deaths within the first year of life (Lia-Hoagberg, et al., 1990).

Compared to adult, White non-Hispanic/Latina women, adolescents and women of color are at higher risk of receiving no pre-natal care and delivering low-birth weight infants (Cunnington, 2001). Infants of adolescent mothers are at higher risk for low birth weight and subsequent complications compared to US averages (MacDorman & Kirmeyer, 2009). In 2005, perinatal mortality for mothers between the ages of 15 and 17 was 51% higher than those between the ages of 25 and 29. From 2005 to 2007, birth rates for adolescents ages 15-19 increased by 5%, which was the first increase in nearly 15 years (Martin et al., 2010). This recent rise in birth rate, accompanied by increased risk of morbidity and mortality, underscores the importance of prenatal care for adolescents. Unfortunately, some adolescents are up to seven-times less likely to receive adequate prenatal care compared to women in their thirties.

Among Hispanic/Latina women, Mexican-American women have the lowest rate of first trimester care (Byrd, Mullen, Selwyn, & Lorimor, 1996). Research has been conducted assessing factors associated with failure to initiate prenatal care. Barriers relating to adolescent care include lack of transportation, negative attitudes toward physicians, fear of disclosure, lack of knowledge about available services and confusion regarding health insurance (Kinsman & Slap, 1992). Among Mexican-American women, barriers to prenatal care include lack of transportation, lack of financial resources and lack of information regarding existing services (Zaid, Fullerton, & Moore, 1996).

The Hispanic/Latino population in Arizona is twice that of the United States: 31% vs. 16% (United States Census Bureau, 2009). In 2008, the pregnancy rate among White non-Hispanic adolescents was 17.5 per 1,000 compared to 49.4 per 1,000 among Hispanic/Latina adolescents ages 19 years and under (Bureau of Public Health Statistics, 2009b). Barriers to prenatal care identified by Hispanic/Latina participants from farmworker families in a peer health worker program included “the lack of a consistent medical provider, inability to pay for care, lack of transportation, language barriers between the women and their providers, lack of community based educational resources, and inadequate knowledge about self care during the childbearing period” (Warrick, Wood, Meister, & de Zapien, 1992).
For the purposes of this project, we will target pregnant, Hispanic/Latina adolescents ages 19 years and under in Gila County, AZ. Eligibility will not be restricted to first-time pregnancies. In 2008, Gila County had the highest teen pregnancy rate in state: 45.9 per 1,000 females in Gila vs. 31.6 per 1,000 females in the state (Bureau of Public Health Statistics, 2009a). Furthermore, in 2008 only 64.6% of women in Gila County received prenatal care in the first trimester – only Apache County had fewer women initiate early prenatal care. Compared to other counties, Gila County had the highest incidence of low birth weight. In addition, relative to other Arizona counties, women in Gila County displayed high rates of risky behaviors while pregnant. Rates of selected birth characteristics in Gila County are summarized below (Table 1).

Table 1. Comparison of Rates of Occurrence for Selected Characteristics of Newborns and Mothers Giving Birth in Gila County and the state of Arizona, 2008 (Bureau of Public Health Statistics, 2009a, 2009b).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Gila County Rate per 100 births</th>
<th>State Rate per 100 births</th>
<th>2010 Target Rate per 100 births</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Birth Weight Births (&lt;2500 grams)</td>
<td>10.3</td>
<td>7.1</td>
<td>5.0</td>
</tr>
<tr>
<td>Births to Unmarried Mothers</td>
<td>63.1</td>
<td>45.1</td>
<td>n/a</td>
</tr>
<tr>
<td>Women Giving Birth who Received Prenatal Care in the First Trimester</td>
<td>64.6</td>
<td>79.4</td>
<td>90.0</td>
</tr>
<tr>
<td>Tobacco Use During Pregnancy</td>
<td>14.9</td>
<td>4.9</td>
<td>1.0</td>
</tr>
<tr>
<td>Alcohol Use During Pregnancy</td>
<td>1.3</td>
<td>0.5</td>
<td>n/a</td>
</tr>
</tbody>
</table>

2.2 Rationale

This program will target both in-school and out-of-school adolescents ages 19 years and younger who are pregnant. Adolescents who are having their first, repeat, or any other subsequent pregnancy are eligible for participation. Since this program is aimed toward getting pregnant adolescents into prenatal care, we will collaborate with the Gila County Health Department and receive referrals of pregnant adolescents from their Maternal and Child Health Program, which offers prenatal education and infant/child development assessments for new families. This program will also market through the Gila County Health Department’s Teen Pregnancy Prevention Program which is Gila County’s newest program to reduce adolescent pregnancy.

This intervention is designed to provide targeted, comprehensive services to adolescent mothers in Gila County. Studies have shown that adverse outcomes in this population can be linked to late or absent prenatal care (Koniak-Griffin, Anderson, Verzemnieks, & Brecht, 2000). The program will address many of the barriers to prenatal care identified in the literature, using community health workers.

Community health workers as advocates of change have been effectively used among Hispanic/Latino populations in the United States to reduce health disparities. Community health workers are effective because they possess the same characteristics as the community they serve and are indigenous to the
community in which they serve. Community health workers share the same race, ethnicity, language, culture, socioeconomic background as the people they assist, which allows them to understand the health needs, social networks, the resources available within the community. This allows them to reach out to individuals inaccessible to outsiders (Rhodes, Foley, Zometa, & Bloom, 2007). They have been valuable in health promotion, disease prevention, social support, and connecting individuals to appropriate health care and social services. They offer guidance, counseling, and are trusted within the community. According to Witmer, Seifer, Finocchino, Leslie, and O’Neil (1995), “As community, ethnic group, and family members, community health workers can translate health and system information into the community’s language.” They connect individuals with providers to address the unique health care needs of many in underserved communities. Many studies have been conducted on the effectiveness of using lay health workers among pregnant women and adolescents. Adolescents assigned to a community health worker were more likely to receive adequate prenatal care, had a higher incidence of early prenatal care, and were less likely to have a low birth weight baby when compared to adolescents without a community health worker (Heins, Nance, & Ferguson, 1987; Julnes, Konefal, Pindur, & Kim, 1994; Rogers, et al., 1996). Culturally targeted community health worker interventions for pregnant Hispanic/Latina women have also proven effective in increasing access to prenatal care, linking women to appropriate health services, increasing social support, and education (Bray & Edwards, 1994; Mahon, McFarlane, & Golden, 1991; McFarlane & Wiist, 1997).

Community health workers are also a cost-effective approach to promoting continuity of care, coordination, and improving quality of care. Training costs are relatively low when compared to other health care professionals and many community health worker interventions rely on volunteers (Giblin, 1989). Costly health care procedures can be avoided by this primary and preventive care approach of getting underserved high risk pregnant adolescents into adequate early prenatal care, providing health education, and improving the patient-provider communication. Approximately $40 billion per year from the federal government is spent on support to families beginning with an adolescent birth. These high costs associated with adolescent pregnancy can be reduced with early intervention programs for underserved adolescents and their children (Nguyen, et al., 2003).

The use of community health workers as a strategy to improve birth outcomes, initiate early prenatal care, and increase access to health service is a strategy that has improved the health of mothers and children in a variety of settings. Culturally sensitive community health worker interventions have had positive effects on the psychological and physical health of pregnant women. Pregnant women are also more likely to respond to someone with characteristics and cultural backgrounds similar to themselves (Persily, 2003). Lack of access to care combined with other risk factors put rural pregnant adolescents at risk for delivering a preterm infant, low-birth-weight infant, having obstetrical complications during pregnancy, and medical risks for the child (Nguyen, et al., 2003). Risk factors combined with social, cultural, and economic disparities contribute to individuals not seeking prenatal care and other preventive services (Persily, 2003). Community health workers will be essential in empowering adolescent pregnant girls in realizing their health care needs and finding solutions that address their social, cultural, health, and economic needs.

Currently, Gila County has a Health Start program in place to assist pregnant women in accessing necessary services through visitations and classes. These women are followed from pregnancy until two
years postpartum and are educated on fetal growth/development, prenatal nutrition, infant growth/development, car seat use, and child safety. The Health Start program does not provide transportation for these women to their appointments, nor does it provide childcare. Home visits are made if the family does not have transportation to meet the community health worker at the Gila County Health Department. The Health Start program is not targeted towards any specific racial/ethnic group or pregnant adolescents.

3 Design & Methods

3.1 Overall Study Design

This study will be quasi-experimental dual-arm study, with a regression-discontinuity design arm and a regression point displacement design arm. Building upon the existing Healthy Start program in Gila County, the proposed program will engage in the following activities: facilitate focus groups and conduct key informant interviews with key stakeholders to gain greater understanding of the barriers to prenatal care at the local level; foster relationships with service providers to enhance patient care; train CHWs; provide outreach to pregnant, Hispanic/Latina adolescents; assist patients identify health providers; assist patients apply for insurance, if needed; offer transportation to and from prenatal appointments; accompany patients to medical appointments; provide support groups with an educational component; refer to appropriate services as needed.

The regression-discontinuity design arm (Table 2) will be constructed from pregnant, Hispanic/Latina adolescents in Gila County according to inclusion/exclusion criteria below (page 14, section 3.5.3). Adolescents will be given a pre-test at enrollment, which will direct assignment into either an intervention group or comparison group based upon behavior risk score. The intervention group will received the aforementioned enhanced services in addition to the standard Healthy Start services, whereas the control group will only receive Healthy Start services. The cutoff behavior risk score will be developed from retrospective Gila County birth certificate analysis with prospective distributional validation prior to group assignment. Study participants will be enrolled on a rolling basis until 10 months prior to the end of the study. Post-tests will be administered 1 month after delivery. Regression analysis to compare the two groups will be performed according to the criteria below (page 16, section 3.6).

<table>
<thead>
<tr>
<th>Table 2. Regression-Discontinuity Design Model</th>
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<tbody>
<tr>
<td>Intervention</td>
</tr>
<tr>
<td>Control</td>
</tr>
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</table>

The regression point displacement design arm (Table 3) will compare the pre- and post-intervention birth outcome data from the Gila County source cohort to other Arizona county source cohorts, and the pre-intervention Gila County source cohort, where all source cohorts meet the inclusion/exclusion criteria below (page 14, section 3.5.3). Regression analysis to compare the cohorts will be performed according to the criteria below (page 16, section 3.6).
3.1.1 Design Rationale
Rolling study entry permits adolescents to participate at any time during their pregnancy, and further permits future pregnant adolescents to enter, rather than merely having a cross-sectional enrollment. Although the regression-discontinuity design requires a larger sample size than that of most true experimental designs, it proffers ethical superiority, whereby the most at-risk adolescents are enrolled in the intervention group without significant diminishment of internal validity.

The small number of adolescent pregnancies in Gila County limits additional design layering. Although pre-test may not influence behavioral adherence thereby mitigating testing threat to internal validity, assessment of pre-test influences via hybridization of a Solomon Four-Group design is not feasible due to the low number of adolescent pregnancies. Further, implementing a second cutoff score with additional mid-range randomized intervention and control groups would require a much larger sample size as well.

Use of the entire Gila County source cohort in the regression point displacement design arm, rather than just the intervention group, provides a more realistic assessment of actual outcomes in comparison to other counties. This approach accounts for study enrollment, attrition, and non-enrollment among all pregnant, Hispanic/Latina adolescents.

3.1.2 Setting & Participants
Gila county is located in the central part of Arizona and covers 4,796 square miles (Arizona Department of Commerce, 2010). The population is 57,361 and approximately 21% of the population is between the ages 0-14 years and 11% are between the ages of 15-24 years (Arizona Department of Commerce, 2010). Hispanics make up approximately 17% of the population (Arizona Department of Commerce, 2010). Globe and Payson are the two most populous cities/towns in Gila County with copper mining being the major industry still in this area (Arizona Department of Commerce, 2010). Our target population for this intervention will be pregnant Hispanic/Latina adolescents aged 19 years and younger who reside in Gila County, Arizona. The sample size will be determined using Arizona Department of Public Health data (Bureau of Public Health Statistics, 2010). In 2009, there were 158 pregnancies among females 19 years of age or younger; 34 births were among Hispanic adolescents (Bureau of Public Health Statistics, 2010). Using data from the Arizona Department of Public Health, we expect to enroll at least 27 teenagers (80% of all pregnant Hispanic adolescents) into the program.

3.1.3 Personnel
This program will recruit community members for participation on a community advisory board (CAB), which will guide recruitment, retention, monitoring, and evaluation activities. According to Strauss, et al. (2001), “[h]aving a CAB provides a context for researchers and community members to discuss the
intent, risks, benefits, and implications of research projects in culturally sensitive terms” (p. 1942). The importance of community acceptance and sponsorship of this program cannot be stressed enough, especially given the strong socio-cultural influences and perceptions of adolescent pregnancy.

3.2 Formative Frameworks

3.2.1 Conceptual Framework
These barriers to prenatal care access are influenced by a variety of upstream factors addressed above in Background & Rationale (page 5, section 2). Of note Quelopana, Champion, and Salazar (2009) categorize barriers to prenatal care access as psychological or personal, where the most prevalent were personal barriers, which include money and health insurance status. These barriers exist within socio-cultural, structural, systemic, political, and environmental contexts. These relationships are further explored below.

3.2.2 Theoretical Framework
The Health Belief Model guides program development though consideration of influences on decision-making. The assumption is that health seeking behavior will occur only when the following conditions are met, as quoted from Glanz, Rimer, & National Cancer Institute (2005):

- “Believe they are susceptible to the condition (perceived susceptibility)
- Believe the condition has serious consequences (perceived severity)
- Believe taking action would reduce their susceptibility to the condition or its severity (perceived benefits)
- Believe costs of taking action (perceived barriers) are outweighed by the benefits
- Are exposed to factors that prompt action (e.g., a television ad or a reminder from one’s physician to get a mammogram) (cue to action)
- Are confident in their ability to successfully perform an action (self-efficacy)” (p. 13)

These embodied contextual perceptions both influence and are influenced by the environment. However, broad-scale environmental alteration is not a primary purpose of this intervention. Thus, the Health Belief Model is particularly valuable for directing focus on internal factors.

3.2.3 Synthesized Frameworks
Figure 1 (below) illustrates the conceptual framework and specific aims interwoven with the Health Belief Model in a time-framed sequence. The important relationships between these influences are depicted by associative arrows, and can be embodied, socio-cultural, or environmental; they ultimately determine the presence and degree health seeking behavior. The horizontal axis is categorized into time-framed influences, with corresponding applications of the specific aims. For example, Formative Research - Specific Aim 1 (Section 3.3) includes both qualitative and quantitative evaluation of the barriers, which may be externally or internally derived. Of note, the primary intervention not only directly influences the pathway to seeking prenatal care, but also works upstream through various other relationships (dotted arrows) through continuing interaction with CHWs, peers, and providers. Ideally, program participants will begin to alter their perceptions leading to prenatal care as a result.
3.3 Formative Research - Specific Aim 1
To assess baseline prenatal care utilization and describe access barriers using qualitative (key informant interviews) and quantitative (retrospective analysis) methods in order to establish local needs prior to intervention design and deployment.

Despite the fact that the Gila County Health Department’s Health Start Program has provided pre-natal education classes and home visits for 18 years, Gila County has the highest rate of low birth weight infants in the State. Furthermore, relative to other Arizona counties, women in Gila County displayed high rates of risky behaviors while pregnant. In the formative stage of the project, baseline data such as early prenatal utilization rates, infant health outcomes, and the degree of high-risk behavior among the target population will be assessed using archival data sources. Once the quantitative data has been reviewed, the first step in the formative phase will be to establish personal relationships with representatives from the community. Prior to conducting formal interviews, informal meetings will be held with representatives from the Gila County Health Department, practicing physicians and local
officials in order to explain the program and address any questions or concerns. These initial contacts will be useful in building support and recruiting the appropriate individuals needed for participation in the qualitative data collection effort. Qualitative methods, including focus groups and key informant interviews, will be used to gain insight into cultural and environment factors that serve as barriers to accessing early prenatal care in Gila County.

### 3.3.1 Quantitative Methods
County specific data including infant birth weight, gestational age, the rate of prenatal care utilized in the first trimester, tobacco use during pregnancy and alcohol use during pregnancy is available through the ADHS Vital Statistics database. Collected retrospectively, this data will provide an overview as to the severity of the problem in Gila County relative to the State. Health indicators specific to the target population (Hispanic adolescents) will be obtained through Gila County Health Records.

### 3.3.2 Qualitative Methods
To gain a better understanding of the cultural and environment factors associated with underutilization of early prenatal care among Hispanic adolescents in Gila County, focus groups and key informant interviews will be conducted. While barriers to prenatal care among adolescents and Hispanics have been identified in the literature, key informant interviews and focus groups will add a local and cultural perspective to the issue in Gila County. Information obtained from the qualitative analysis will be used to enhance the community health workers’ (CHW’s) training. CHW’s hired to work with the program participants will be required to under 4 hours of additional training. Information derived from the literature and the formative research will be synthesized and compiled into a training.

#### 3.3.2.1 Key Informant Interviews
Interviews with key stake holders and community members will be conducted. Each semi-structured interview will last approximately 2 hours. Topics addressed will include: factors associated with the low rate of early prenatal care utilization, social norms associated with adolescent pregnancy and other culturally and locally relevant information that will be useful in tailoring an intervention protocol. Identified key stakeholders include:

- Pregnant and parenting Hispanic adolescents,
- The Coordinator of the Health Start program in Gila County,
- Community Health Workers currently working on the Health Start program,
- OB/GYN’s practicing in Gila County, and
- Parents/guardians of pregnant and parenting Hispanic adolescents.

#### 3.3.2.2 Focus Groups
There will be a total of ten focus groups conducted. Five of the focus groups will be comprised of pregnant and parenting adolescents and the other five focus groups will be comprised of professionals representing key sectors of the community. An hour will be allotted for each focus group, and refreshments will be served. Focus groups will be conducted in locations that are sufficiently large and bright, as well as easy to access. This is especially important in a rural county.

#### 3.3.2.2.1 Focus Groups with Parent and Pregnant Adolescents
Pregnant and parenting adolescents will be recruited from the Gila County Health Department, schools, physician’s offices, Planned Parenthood clinics and day care centers. Flyers in English and Spanish will be
posted to aid in the recruitment effort. The flyers will outline the purpose of the focus group, the time, the location and state that there will be refreshments available as well as the opportunity to win a $50.00 gift certificate to Babies R Us.com. Focus group participants will be required to register with the Program Coordinator.

Each focus group will have no more than 6 participants. At least two program representatives will facilitate the meeting (one facilitator and one note taker). All participating facilitators will be trained in focus group methodology. Prior to the meeting, consent forms will be completed and confidentiality will be assured. The facilitator will review the protocol with the participants at the beginning of each session. An hour will be allotted for each session, including time set aside for refreshments and the raffle.

3.3.2.2 Focus Groups with Professionals
Individuals representing the health care field will be identified during the initial meeting stage and encouraged to attend the focus groups. These individuals will be encouraged to identify other professionals who will then be invited to participate. The feasibility of this “snow ball” sampling method will be ascertained prior to formalizing the focus groups. If needed, professional participants will be recruited via flyers and other means of communication, such as organizational newsletters and Public Service Announcements (PSA’s).

The professional focus groups will be run similarly to the adolescent focus groups with the exception of the raffle. Consent forms will be collected and the protocol will be reviewed. Effort will be made to conduct professional focus groups at the work place, provided an adequate meeting space exists. To encourage participation, focus groups will be held before work or during the lunch hour.

3.3.2.3 Qualitative Data Analysis
Information derived from the focus groups and key informant interviews will be used to provide a culturally and age appropriate perspective to the experience of adolescent pregnancy. All interviews and focus groups will be transcribed for content analysis with NVivo 11 (Bazeley, 2007). Re-occurring themes and factors associated with barriers to early prenatal care among Hispanic/Latina adolescents in Gila County will be identified and coded. This information, along with barriers identified in the research literature, will be consolidated into a training manual. The mixed-method integration of qualitative and quantitative findings provides for community-derived support and verification of otherwise faceless statistical data.

3.4 Community Priorities - Specific Aim 2
To establish community-derived priorities and develop culturally-competent interventional strategies for integration into community health worker training and program design.

Once the formative research has been completed, the data will be analyzed and the main findings will be documented. Barriers identified through key informant interviews and focus groups will be documented. A recruited community advisory board will provide guidance for 4 hour training curriculum to be completed by the CHW’s hired to work with the program participants. A training manual along with learning materials in English and Spanish will be created for the CHW training. Pre and post-test
3.5 Intervention - Specific Aim 3

To implement a community health worker-driven intervention in order to increase prenatal care utilization and promote healthy maternal behaviors among pregnant, Hispanic/Latina adolescents during the course of the intervention.

3.5.1 Recruitment and Enrollment of Participants

Teenagers will be recruited through various methods that have shown to be effective in other studies (Meister, et al., 1992; Rogers, et al., 1996). The community health workers will actively recruit pregnant teenagers through community education and outreach activities. For instance, the community health workers will make presentations to health providers, social service organizations, clinics, schools, churches and other organizations that provide services to teenagers. The community health workers will distribute brochures during presentations and street outreach. Participants will also be recruited through announcements on the radio, posters in stores, visits to WIC groups and friend-to-friend referrals (Meister, et al., 1992). Referrals into the program can come from WIC, prenatal clinics, human services agencies, schools, churches, physicians, and teenagers already in the program (Rogers, et al., 1996).

3.5.2 Institutional Review Board and Informed Consent

Approval for this project will be obtained from the institutional review board of the University of Arizona. Parental consent and assent (children under the age of 18) will be obtained for all of those who are eligible to participate in this intervention. The parental consent and assent forms will specify the purpose of the intervention, benefits to participating in the intervention, risks involved in participating in the intervention, and services offered in the program. The documents will be available in both English and Spanish. The Spanish forms will be back translated into English to ensure that it is accurate. A handwritten signature will be required to participate in the intervention. For individuals who are illiterate, the consent forms will be read to them and a thumb print will be required.

3.5.3 Inclusion/Exclusion Criteria

Participants are eligible for the intervention if they are pregnant, a Hispanic/Latina adolescent aged 19 years and younger, and reside in Gila County, Arizona. Adolescents who are having their first, repeat, or any other subsequent pregnancy are eligible for participation. Teenagers can enter the program at any point during their pregnancy, but will be encouraged to enroll early. Individuals will be excluded if they do not meet any of the eligibility requirements and if parental consent and assent is not obtained.

3.5.4 Incentives

Once enrolled, teenagers will be encouraged to attend all prenatal care appointments. Upon completion of all scheduled appointments, a $100 gift card to BabiesRUs will be provided as a reward for completion. This gift card will be provided to all participants who complete all scheduled appointments.
Since this intervention involves teenage mothers, many of these girls will not have access to full time jobs, are still in high school, or have just completed high school. This $100 gift card will aid these teenagers in purchasing necessary materials for their new infant which is minimal compared to the cost of raising a child. According to a survey by BabyCenter, the cost of raising a baby during the first year of life was approximately $10,000 (Olsen, 2007). New mothers must purchase diapers, baby clothing, car seats, strollers, cribs, formula, bottles, and many other items. Providing incentives will also decrease attrition which will enable researchers to accurately evaluate the program.

3.5.5 Home Visits
Home visits will provide an opportunity for the pregnant teenagers to realize the importance of prenatal care. Community health workers will provide education on the need for early and regular prenatal care, reduction of risk taking behavior, such as, alcohol use, cigarette use, and other substance use. Community health workers will also provide social support to the teenagers and will be a source of information and encouragement during this emotional time in a pregnant teenager’s life. During these visits, the community health workers can assess the teenager’s needs, help them navigate through the health and social services system, and refer them to appropriate services. Each visit will be structured with specific goals and objectives based on the individual’s needs.

Once participants are enrolled, community health workers will make weekly visits to the teenagers for the first four weeks and then every other week until delivery. After the birth of the child, community health workers will make weekly visits to the teenagers for up to six weeks postpartum. After six weeks postpartum, visits will be made at least once a month, or more based on a risk assessment performed by the team (Persily, 2003) until six months. The home visitation schedule will help the teenager continue recommended prenatal and postpartum well-baby visits (Mannheim & Zieve, 2010).

3.5.6 Transportation and Accompaniment to Visits
Transportation has been cited as a main reason why women do not access prenatal care (McClanahan, 1992; Mikhail & Curry, 1999; Quelopana, et al., 2009; Zaid, et al., 1996). To facilitate the use of prenatal care and support services, community health workers will provide transportation to necessary medical appointments, and other community and health services. Assisting teenagers to needed appointments will help bridge relationships between providers, the community health worker, and the teenager.

3.5.7 Provider Meetings
To ensure the needs of the teenager are being met, monthly meetings will be scheduled where community health workers, clinicians, and other health providers can gather to provide feedback and have informal discussions on the intervention. These meetings will generate ideas on how the program can be improved to meet the needs of the teenagers and providers. On selected dates, in-service trainings will be provided on cultural sensitivity which will help make the teenagers feel more comfortable around providers, thus eliminating another barrier to accessing prenatal care (McClanahan, 1992; Mikhail & Curry, 1999; Quelopana, et al., 2009; Zaid, et al., 1996).

3.5.8 Support Groups
Quarterly meetings will be scheduled for all participants who are currently in the program or who have recently completed the program to come together, share stories, and encourage one another. In these support groups, friendships can be made and pregnant teenagers can learn from each other on what to
expect once the child is born, provide one another with pregnancy advice and tips to make the pregnancy a positive experience for the mother and child.

3.6 Data Management & Analysis
Community health workers will be trained on how to document outputs from program activities. Log books will be used to document the number of home visits made, transportation provided, prenatal visits attended by the teenager, support groups attended by the teenager, and the number of provider and clinicians that attend the monthly meetings. Data collected will be kept confidential and will be locked in a cabinet at the Gila County Health Department; electronic data will be protected using multiple layers of security, including 128-bit database encryption. Only researchers at the University of Arizona who are assigned to this project will have access to the data.

Prior to analysis, all identifiable data will be separated from study observations and kept in a separated secure database, linked only by observation number. Qualitative data will be analyzed using NVivo 9. Quantitative data will be analyzed using SPSS 18. Regression-discontinuity and regression point displacement analyses will be performed with guidance and consultation from experienced a biostatistician.

4 Monitoring & Evaluation - Specific Aim 4

To assess intervention effectiveness by comparing pre-, mid-, and post-intervention longitudinal data.

A mixed method approach (quantitative and qualitative) will be used to monitor and evaluate the inputs, processes, outcomes and impact of the program.

4.1 Inputs & Input Evaluation

Program inputs include funding, personnel, office space, equipment and supplies. Personnel will be comprised of the research team, the CHW’s, consultants and the project coordinator. Every program item purchased (lap tops, office supplies) or service utilized (printing, graphic design work) will be recorded in a log and stored along with the original receipts. The software program Microsoft Project will be used to maintain electronic records. Periodic monitoring of program inputs will occur at regular intervals to ensure that the program is remaining true to the proposed budget.

4.2 Processes & Process Evaluation

Process data will be collected qualitatively through the use of focus groups. On a yearly basis, two focus groups will be conducted: one comprised of professional partners and one comprised of program participants. Qualitative data will be collected in an effort to measure participants’ and partners’ satisfaction with various components of the program. This feedback will be used to modify the program, if needed.
4.3 Outcomes & Outcome Evaluation
Outcome measures include increases in prenatal care initiation, increases in the number of mothers who participate in an adequate number of prenatal visits, increases in achieving optimal weight gain among the mothers, increases in the number of mothers who breast feed and decreases in alcohol use among pregnant adolescents. Statistical methods that will be used to analyze the data related to the outcome measures are discussed in the Data Management & Analysis section (3.6).

4.4 Impact
This program proposes to improve birth outcomes among Hispanic/Latina adolescents in Gila County. The following indicators have been selected: infant birth weight and gestational age. Hospital birth records will be used collect this information.

4.5 Logframe Matrix
Logframes help provide a structured approach to priority setting as well aid in planning, implementing and evaluating projects (Jackson, 1997). Logframe Matrices are used to link project goals and objectives to the inputs, processes and outputs needed to implement the program. Table 4. Logframe Matrix, below, summarizes the activity design. Program objectives are displayed vertically and are depicted hierarchically: Goal → Outputs → Activities. The ways in which progress against each objective is assessed is displayed horizontally. External factors that might influence the achievement of objectives, assumptions and risks, are listed in the last column.
<table>
<thead>
<tr>
<th>Narrative Summary</th>
<th>Objectively Verifiable Indicators</th>
<th>Means of Verification</th>
<th>Risks and Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Goal:</strong></td>
<td>Rate of low birth weight infants (≤2500 grams), premature births (&lt;37 weeks) and infant mortality</td>
<td>Gila County Birth Records</td>
<td>Targeted, culturally sensitive intervention will improve birth outcomes among target population</td>
</tr>
<tr>
<td><strong>Purpose:</strong></td>
<td>The number of Hispanic/Latina adolescents who enroll in early prenatal care and complete adequate number of visits</td>
<td>Patient Medical Records</td>
<td>The proposed activities will remove barriers to access prenatal care among target population</td>
</tr>
<tr>
<td><strong>Outputs:</strong></td>
<td>Number of adolescents who gain the recommended weight gain</td>
<td>Patient Medical Records</td>
<td>That targeted education and support will result in a decrease in risk behaviors resulting in positive health outcomes</td>
</tr>
<tr>
<td></td>
<td>The rate of participants who report alcohol use while pregnant</td>
<td>Pre/posttest surveys assessing substance use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The rate and duration of breast feeding practices among program participants</td>
<td>Surveys assessing breast feeding practices</td>
<td></td>
</tr>
</tbody>
</table>
### Narrative Summary

<table>
<thead>
<tr>
<th>Objectively Verifiable Indicators</th>
<th>Means of Verification</th>
<th>Risks and Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Activities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1 Assess baseline prenatal care utilization</td>
<td>Rate of prenatal care utilization among target population in Gila County</td>
<td>Bureau of Public Health Statistics</td>
</tr>
<tr>
<td>1.2 Assess access barriers</td>
<td>Number of focus groups conducted with pregnant and parenting adolescents</td>
<td>Focus group transcripts, Sign-in sheets</td>
</tr>
<tr>
<td></td>
<td>Number of focus groups conducted comprised of professionals</td>
<td>Focus group transcripts, Sign-in sheets</td>
</tr>
<tr>
<td></td>
<td>Number of key informant interviews</td>
<td>Interview notes</td>
</tr>
<tr>
<td>2.1 Develop culturally competent intervention strategies</td>
<td>With information obtained from Activity 1.2, trainings will be delivered to Community Health workers assigned to the program</td>
<td>Pre/post-tests</td>
</tr>
<tr>
<td>Narrative Summary</td>
<td>Objectively Verifiable Indicators</td>
<td>Means of Verification</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>3.1 Implement intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recruit program participants</td>
<td>Number of recruitment materials disseminated</td>
<td>Log Reports</td>
</tr>
<tr>
<td>Provide transportation to pregnancy related appointments</td>
<td>Number of times transportation was provided to program participants</td>
<td>Log Reports</td>
</tr>
<tr>
<td>Deliver in-service trainings to health care professionals</td>
<td>Number of in-service trainings provided</td>
<td>Sign-in sheets</td>
</tr>
<tr>
<td>Provide education and to program participants</td>
<td>Number of educational topics covered for each home visits</td>
<td>Log Reports</td>
</tr>
<tr>
<td>Facilitate support groups for program participants</td>
<td>Number of support groups session; Number of attendees</td>
<td>Log Reports; Sign-in Sheets</td>
</tr>
<tr>
<td>Provide home visitation</td>
<td>Number of home visits</td>
<td>Log Reports</td>
</tr>
<tr>
<td>Offer supervision of participants’ children during medical appts.</td>
<td>Number of times CHW watched participants’ children during prenatal visits</td>
<td>Log Reports</td>
</tr>
<tr>
<td>Refer program participants to available services</td>
<td>Number of referrals provided</td>
<td>Log Reports</td>
</tr>
<tr>
<td>Narrative Summary</td>
<td>Objectively Verifiable Indicators</td>
<td>Means of Verification</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>4.1 Assess intervention effectiveness</td>
<td>Increase first-trimester prenatal care initiation by 50%</td>
<td>Medical Records</td>
</tr>
<tr>
<td></td>
<td>Increase the number of mothers who participate in an adequate number of prenatal care visits by 50%</td>
<td>Medical Records</td>
</tr>
<tr>
<td></td>
<td>Increase achievement of proper weight gain by 50%</td>
<td>Medical Records</td>
</tr>
<tr>
<td></td>
<td>Decrease alcohol use by 50%</td>
<td>Pre/post-test substance use assessment surveys</td>
</tr>
<tr>
<td></td>
<td>Decrease the incidence of premature births to adolescent mothers by 50%</td>
<td>Medical Records</td>
</tr>
<tr>
<td></td>
<td>Increase breast-feeding within the neonatal period by 50%</td>
<td>Surveys assessing breastfeeding practices</td>
</tr>
<tr>
<td></td>
<td>Achieve a 80% satisfaction rating</td>
<td>Satisfaction Questionnaire</td>
</tr>
</tbody>
</table>
5 Program Logistics

5.1 Organizational Capacity

In 1982, Arizona began experiencing a steady increase in the rate of women receiving inadequate or no prenatal care, and in 1984 the Rural Health Office of the University of Arizona College of Medicine in the Department of Family and Community Medicine developed community health worker programs to address gaps in the health care infrastructure in Arizona (Bureau of Women's and Children's Health, 2010). One of the earliest programs, “Un Comienzo Sano/A Health Beginning” was established to deliver prenatal and perinatal care particularly among rural and minority populations. In 1992, the Health Start Program was established in Arizona, administered by the Arizona Department of Health Services (ADHS) Office of Women's and Children's Health. Health Start is a neighborhood outreach program that helps high-risk pregnant women obtain early and consistent prenatal care and, for their children, timely immunizations (Bureau of Women’s and Children’s Health, 2010).

From July 1993 through June 1994, there were over 1,000 pregnant women served in seven neighborhood/community locations throughout Arizona. During this time period, follow up for infants to age two and their siblings was initiated through funding provided by a three year grant from the National Association for the Education of Young Children. In 1994, the passage of the Arizona Children and Families Stability Act formalized and expanded several early intervention programs for Arizona’s high-risk children and families, including the Health Start Program.

In May 1999, the Health Start Program was funded by the State Legislature’s general funds until June 2004 and was expanded to cover postpartum women. In August 1999, eight Health Start sites were implemented which served 1312 prenatal women, 9 postpartum women, 202 non-pregnant women, and 599 children. Health Start increased to fifteen sites in July 2000, and served 3057 pregnant women, 68 postpartum women, 367 non-pregnant women, and 1147 children. In 2005, the program issued another Request for Proposal and funded 16 programs for 5 years until June 2010. In 2009, there were 2,319 unduplicated clients served and 13,922 visits provided.

Using community health workers who reflect the ethnic, cultural and socioeconomic makeup of the neighborhoods they serve, the Health Start Program connects pregnant/postpartum women with community resources that provide prenatal and related infant/child services. The families are followed for two years after the birth of the child to assist with identification of a "medical home" for each family member and to encourage immunizations for all children in the family. The community health workers also provide education on normal child development and parenting skills, and may serve as a referral source in the identification of children with special needs. According to Health Start, it recruits community health workers from within the targeted communities because it feels that they are most knowledgeable of the local customs, problems, cultures and service system. By utilizing neighborhood or community health workers, the program works to assure that the program respects the differences in culture, family structure, personal and family resources which are found in the different communities throughout the state, while addressing the needs of women, children and their families based on the unique characteristics of the community in which they live. By making the program sensitive and responsive to local concerns, Health Start attempts to promote collaborative efforts within the
community to improve the health of women, children and their families (Bureau of Women’s and Children’s Health, 2010).

In order to be eligible to enroll in Health Start, individuals must meet the following criteria:

At risk women who reside in the Health Start targeted service area program sites, and who may be pregnant, or just had a baby, have an initial contact with a community health worker. Community health workers through a variety of sources identify these women. A potential client learns about the program from the community health worker, or through other sources. The community health worker verbally explains the program and determines if the potential clients: 1) resides in the targeted service area; 2) is pregnant; 3) is postpartum with a child under age two; 4) has one or more medical and social prenatal/postpartum risk factors. Community health worker offers enrollment to the woman if criteria is met. If enrollment is accepted, the woman fills out the Intent to Participate form, signs the form and the community health worker completes the Health Start Enrollment form. (Bureau of Women’s and Children’s Health, 2010)

Collaboration between this program and the established Health Start will be beneficial because of the different areas of focus and additional services provided. Although both initiatives target pregnant women, this program specifically focuses on adolescent Latinas, an area that Health Start has not placed most of its resources on due to continual barriers in recruitment. Although there is a Health Start program and office in Gila County, more specifically Globe, Arizona, it does not provide transportation services, retention incentives, support groups, referrals, patient accompaniment, nor events like this program will. The success and strengths from the outcomes of this program can then be used to expand the services of Health Start as well as argue for increased funding from State revenue.
### 5.2 Budget

Table 5. Program Budget; Period: 06/01/2011 - 05/31/2013

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Role</th>
<th>Annual Salary</th>
<th>Project FTE</th>
<th>Cal. Months</th>
<th>Requested Salary</th>
<th>ERE</th>
<th>Total Salary</th>
<th>Total Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. X</td>
<td>Principal Investigator</td>
<td>135,994</td>
<td>0.25</td>
<td>3.00</td>
<td>33,999</td>
<td>9,656</td>
<td>43,654</td>
<td>2</td>
</tr>
<tr>
<td>Dr. Y</td>
<td>Co-Principal Investigator</td>
<td>135,994</td>
<td>0.25</td>
<td>3.00</td>
<td>33,999</td>
<td>9,656</td>
<td>43,654</td>
<td>2</td>
</tr>
<tr>
<td>TBH</td>
<td>Doctoral Student</td>
<td>30,720</td>
<td>1.00</td>
<td>12.00</td>
<td>30,720</td>
<td>13,087</td>
<td>43,808</td>
<td>2</td>
</tr>
<tr>
<td>TBH</td>
<td>Program Coordinator</td>
<td>30,720</td>
<td>1.00</td>
<td>12.00</td>
<td>30,720</td>
<td>3,133</td>
<td>33,853</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>333,428</td>
<td>2.50</td>
<td>30.00</td>
<td>129,437</td>
<td>35,531</td>
<td>164,969</td>
<td>2</td>
</tr>
<tr>
<td>Subtotal Personnel</td>
<td></td>
<td>$329,939</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Reimbursments**

- Promotora Travel to and from site, clinical transportation, etc: $42,000, 2 years
- Travel from university to Gila County: $300 a month, $3,600, 2 years

Total Reimbursments: $84,000

**Supplies**

- Office Supplies @ $75 a month: $900, 2 years
- Food for events and meetings @ $100 a month: $900, 2 years

Total Supplies: $1,800

Total Other Costs: $21,000

**Subject Incentives**

- Promotoras: 35 total participants, $200 cash, 7,000, 2 years
- Participants: 35 total participants, $100 gift cards, 3,500, 2 years

Total Subject Incentives: $21,000

**Total Direct Costs**: $439,139

**Indirect Costs**

- IDC Base: MTDC: $439,139
- UA Indirect Cost @ 51.5% off campus: 24 months, $414,620

Total Budget: $853,759
The Principal Investigator will be the main person in charge of the program, its implementation, monitoring, evaluation, and eventual publication. The Co-Principal Investigator will assist the Principal Investigator in similar duties involving implementation, monitoring, evaluation, and analysis of the program and will also act as second in command. The doctoral student will mediate between the Principal Investigator, Co-Principal Investigator, Program Coordinator, and promotoras, as well as develop their own research interest within the realm of the project as part of his/her doctoral thesis. The Program Coordinator will be responsible for coordinating the program among the promotoras, those enrolled in the program, and Health Start. The Program Coordinator is also responsible for all administrative duties and reporting to the Principal and Co-Principal Investigator. The promotoras will not receive salaries per se but rather incentives for each participant enrolled in the program. It was determined that the number of pregnant adolescent Hispanics in Gila County in 2008 was 35. We will give each promotora $200 a year per successfully enrolled participant as an incentive to pursue and recruit unwilling pregnant Hispanic adolescents.

There shall also be incentives for those successfully recruited in the program. Rather than appearing that the program is encouraging young girls to get pregnant in order to receive benefits from the program, enrolled participants will receive $100 gift cards to Babies-R-Us after each year that they are enrolled in the program. This ensures that only those that are serious in promoting the health of their babies are rewarded and they are rewarded with products that will benefit the baby. The justification for this incentive is noted above in Incentives (page 14, section 3.5.4).

Since the program is similar to Health Start, we plan to share some of their resources and would like to equally contribute. Therefore, budget projections for office materials such as paper and equal share of rent have been allocated for. In order to accommodate for travel expenses and other expenses, promotoras will be allotted $50 a month for each enrolled adolescent. Promotoras will have to show receipts and justification for reimbursements to receive any portion of the $50.

5.3 Reporting - Specific Aim 5

To recommend statewide, regionally-based goals for increasing prenatal care utilization.

Reporting, or publishing, will begin during the second quarter of the last year of funding for the study. The Principal Investigator along with the Co-Principal Investigator and the doctoral student will work on publishing their findings in peer reviewed journals, presenting in conferences, publishing in proceedings, getting media coverage, and working with State leaders. Stakeholder meetings will also be conducted to report on the findings and disseminate information. Executive summaries and fact sheets will be developed and distributed on the successes and limitations of the program for community leaders, advocates, and State legislators in order to promote the expansion of the program and Health Start throughout the state and elsewhere.

5.4 Sustainability

The design and success of this program relies heavily upon community involvement and ownership. This lends an assurance of project sustainability through community prioritization. The overall conceptual and theoretical foundations guide evidence integration in a viable manner. Although the project grant
period lasts only two years, much of the initial groundwork, training, development, and piloting will be completed on the front end. This means that continuation of this project beyond this trial period will be significantly less costly. While the project is mainly preventive in terms of adverse birth outcomes from both mother and child, there are also behavioral secondary and tertiary preventive implications, with health behavior modification. These individual-level changes, along with a continued presence in the community will engender long-term cultural changes, and ideally, produce measurable impacts. The project is strengthened not only through community engagement, but also by building upon existing delivery frameworks. In this case, the well established Health Start program is being expanded to address deficits in utilization. As mentioned above, results from the study will be disseminated to all stakeholders in the community, as well as county and state health delivery systems. The results from this study will help guide future interventions not only in this community, but throughout the state. Buy-in beyond the community relies upon reporting, however given the high costs of poor maternal and child birth outcomes, the cost-effectiveness will likely facilitate additional funding and sponsorships into the foreseeable future.

6 Conclusion & Limitations

In the context of Gila County Arizona being ranked highest in the state for teen pregnancy rate and the overwhelming amount of evidence supporting the fact that prenatal care is essential for neonatal health outcomes, we believe that the program we propose is important. Among the anticipated outcomes of our project are:

- Reduce pregnancy related morbidity and mortality by 50% in each (preterm birth; fetal and infant deaths; maternal death);
- Increase pregnant adolescents who initiate prenatal care before the second trimester by 50%; utilize postpartum maternal care by 50%; utilize at birth and follow up new born screenings by 50%;
- Increase maternal healthy behaviors by 50% in each (supine position, alcohol, tobacco, drug abstinence, breast feeding, childbirth class; optimal weight gain; pregnancy intervals; folic acid supplementation;
- Increase pregnant adolescents whom maintain health coverage for themselves and their children from pregnancy through 1-year after delivery by 50%.

- Dissemination of results will ensure replication of good practices in other parts of Arizona, the country and elsewhere.

There are inevitable limitations to every study. Identified limitations to this intervention include the following:

- With a tough immigration law in the state, it may affect our participant recruitment. Although legal status or citizenship status is not a prerequisite for enrollment in the
program, those with an unfavorable status or of parents with an unfavorable status may be hesitant to participate.

- Since the program is targeting pregnant adolescent Latinas, there may be a cultural generational gap between the promotoras and program participants. Although promotoras reflect the ethnic, cultural and socioeconomic makeup of the neighborhoods they serve and they are most knowledgeable of the local customs, problems, cultures and service systems, generational gaps can be limiting as program participants find it difficult to relate to or trust promotoras older than them.

- Normal daily activities of adolescents such as school work and relationships can be inhibiting factors. Adolescents may see prenatal care as a lower priority in the realm of all the other occurrences in their life that they may not make time for aspects of the program.

The Hispanic population is growing rapidly in Arizona and Gila County is no exception. There is a need for programs that are tailored to this population that addresses the whole family let alone improve adolescent health. Working collaboratively with community health workers or promotoras, churches, schools, community leaders, and state run programs will help ensure participation and individual behavior change in the promotion of prenatal care. This unique collaboration will improve adolescent health, prenatal care, and ultimately healthier babies and Hispanic populations. Finally, in spite of the sometimes difficult cultural circumstances in the Latino/Hispanic community in Gila County and in Arizona, we are confident that it is feasible for us to execute this endeavor.
7 Appendices

7.1 Consent Form

THE UNIVERSITY OF ARIZONA HUMAN SUBJECTS PROTECTION PROGRAM
INFORMED CONSENT FORM

Project Title: Improving birth outcomes among pregnant, Hispanic/Latina adolescents in Gila County, Arizona

You are being invited to take part in a research study being conducted by The University of Arizona and asked to read this form so that you know about this research study. The information in this form is provided to help you decide whether or not to take part. If you decide to take part in the study, you will be asked to sign this consent form. If you decide you do not want to participate, there will be no penalty to you, and you will not lose any benefit you normally would have.

- The purpose of this project is to improve birth outcomes among pregnant, Hispanic/Latina adolescents in Gila County, Arizona.
- You are being asked to participate in this project because you live in Gila County Arizona; you are pregnant; Hispanic/Latina; under the age of 19.
- A total of 35 participants will be recruited for this project.
- If you choose to participate, you will partake in regular prenatal checkups, pre and post assessments, and neonatal check ups all with the help of promotoras.
- The things that you will be doing have no more risk than you would come across in everyday life.
- There is considerable direct benefit to you by being in this study. Partaking in regular check ups both pre and post partum will improve the life of your child as well as yours.
- Aside from your time, there are no costs for taking part in the study. You will paid with a $100 Babies-R-Us gift card for each year you are in the program for as long as the program lasts.
- Information about you will be stored in locked file cabinet; computer files protected with a password. This consent form will be filed in an official area.
- Information about you will be kept confidential to the extent permitted or required by law. People who have access to your information include the Principal Investigator and research study personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP) and entities such as the University of Arizona Human Subjects Protection Program may access your records to make sure the study is being run correctly and that information is collected properly. The agency that funds this study and the institutions where study procedures are being performed (The University of Arizona and the Arizona Department of Health Services) may also see your information. However, any information that is sent to them will be coded with a number so that they cannot tell who you are. Representatives from these entities can see information that has your name on it if they come to the study site to view records. If
there are any reports about this study, your name will not be in them.

- You can call the Principal Investigator to tell him/her about a concern or complaint about this research study. The Principal Investigator can be called at (520) 626-XXXX. You may also contact the Program Coordinator, at (520) XXX-XXXX or your promotor.

- For questions about your rights as a research subject; or if you have questions, complaints, or concerns about the research and cannot reach the Principal Investigator or want to talk to someone other than the Investigator, you may call the University of Arizona Human Subjects Protection Program office at (520) 626-6721 or visit their website at http://orcr.vpr.arizona.edu/irb/contact

- You have the choice whether or not to be in this research study. You may decide to not begin or to stop the program at any time.

- Any new information discovered about the project will be provided to you.

**STATEMENT OF CONSENT:**

I agree to be in this project and know that I am not giving up any legal rights by signing this form. The procedures, risks, and benefits have been explained to me, and my questions have been answered. I know that new information about this research study will be provided to me as it is available and that the researcher will tell me if I must be removed from the study. I can ask more questions if I want, and I can still receive medical care if I stop participating in this study. A copy of this entire, signed consent form will be given to me.

___________________________________  __________________________________
Subject's Signature  Date

___________________________________  __________________________________
Parent or Legal Guardian Signature  Date

**INVESTIGATOR'S AFFIDAVIT:**

Either I have or my agent has carefully explained to the subject the nature of the above project. I hereby certify that to the best of my knowledge the person who signed this consent form was informed of the nature, demands, benefits, and risks involved in his/her participation.

___________________________________  __________________________________
Signature of Presenter  Date

___________________________________  __________________________________
Signature of Investigator  Date
7.2 Sample Surveys

Participant ID Number________________

Behavioral Health Survey
Pre-test

The first set of questions assesses your opinion as to the importance of some issues. Please put an “X” in the box next to each statement.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Not Important</th>
<th>Somewhat Important</th>
<th>Not Sure</th>
<th>Very Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seeing a health professional when someone <em>first</em> finds out they’re pregnant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seeing a health professional throughout the <em>entire</em> pregnancy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quitting smoking if you’re pregnant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not drinking alcohol if you’re pregnant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eating healthy food if you’re pregnant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning about how to take care of a new baby</td>
<td></td>
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<tr>
<td>Having help taking care of a new baby</td>
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</tr>
</tbody>
</table>

Now, we’re going to ask you about how you feel about performing some tasks. Please put an “X” in the box next to each statement.

<table>
<thead>
<tr>
<th>Task</th>
<th>Disagree</th>
<th>Somewhat Agree</th>
<th>Not Sure</th>
<th>Strongly Agree</th>
</tr>
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<tbody>
<tr>
<td>I feel confident that I can get to my doctor’s appointments</td>
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</tbody>
</table>
Now, we're going to ask you about how you feel about some behaviors. Please put an “X” in the box next to each statement.

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Disagree</th>
<th>Somewhat Agree</th>
<th>Not Sure</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women who don’t get medical care when they’re pregnant are more likely</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>to have an unhealthy baby</td>
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<td></td>
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<tr>
<td>Drinking a lot of alcohol while pregnant can harm the baby</td>
<td></td>
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<tr>
<td>Gaining too much or too little weight while pregnant can result lead to</td>
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<td></td>
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<tr>
<td>health problems for the mom and the baby</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Almost done! Now, we’d just like to ask a few questions about some of your behaviors.

Since joining our program on how many occasions (if any) have you:

<table>
<thead>
<tr>
<th>occasions</th>
<th>0</th>
<th>1-2</th>
<th>3-5</th>
<th>6-9</th>
<th>10-19</th>
<th>20-39</th>
<th>40+</th>
</tr>
</thead>
<tbody>
<tr>
<td>had alcoholic beverages (beer,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wine or hard liquor) to drink?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>used marijuana?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>used cocaine?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>used methamphetamines (meth,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>crystal meth)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>used prescription pain relievers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(such as Vicodin Oxycontin,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percodet or Codeine)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Thank you
Behavioral Health Survey
Post-test

The first set of questions assesses your opinion as to the importance of some issues. Please put an “X” in the box next to each statement.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Not Important</th>
<th>Somewhat Important</th>
<th>Not Sure</th>
<th>Very Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seeing a health professional when someone <em>first</em> finds out they’re pregnant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seeing a health professional throughout the <em>entire</em> pregnancy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quitting smoking if you’re pregnant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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</tr>
</tbody>
</table>

Did you enjoy being a part of this program?  

Yes  

No

What did you like **best** apart the program?

________________________________________________________________________________

What did you like **least** about the program?

________________________________________________________________________________

Additional Comments:

________________________________________________________________________________

Thank you
7.3 Protection of Human Subjects.

7.3.1 Risks to the Subjects

7.3.1.1 Human Subjects Involvement and Characteristics
The purpose of this study is to reduce infant morbidity and mortality in Gila County, Arizona among Hispanic/Latina adolescent’s ages 19 years and under. To accomplish this aim we will use a community health worker model to improve access to prenatal care, increase care utilization, and promote healthy behaviors among pregnant teenagers. In order to design the implementation, formative research will be conducted in our specific aim 1 and community derived priorities will be developed in our specific aim 2. In specific aim 1, we will conduct baseline assessments on utilization and confirm access barrier estimations that were derived from retrospective data analysis. We will conduct focus groups and key informant interviews to assess barriers to prenatal care and factors associated with low prenatal care utilization. Social and cultural norms will be documented and will be used in designing a culturally competent intervention. Barriers identified from the formative analysis will be used in specific aim 2 to develop a culturally competent intervention. This study protocol will be submitted to the University of Arizona Institutional Review Board for approval. All researchers involved with the study will undergo IRB training and will be informed of the purpose and components of the intervention. Parental consent and assent will be obtained from all participants and their parents prior to enrollment. The intervention will be culturally appropriate for the Hispanic/Latina population and will protect their confidentiality. Key personnel involved with this study have taken the Collaborative Institutional Training Initiative (CITI) certification through the University of Arizona (https://www.citiprogram.org/Default.asp?).

Specific Aim 3 involves implementing the community health worker intervention in Gila County, Arizona. Community health workers will provide home visitations, transportation to prenatal appointments, meet with health care providers, and childcare. This intervention will also offer support groups to pregnant and parenting teenagers. To measure the effectiveness of the intervention validated questionnaires will be used to assess health outcomes and medical records will be reviewed. As mentioned for specific aim 1 and 2, all measurement tools will be reviewed by the University of Arizona Institutional Review Board for approval. All participants must give assent and have parental consent prior to participation in the intervention. Individuals who decide to participate in the intervention will be reminded that they may withdraw at any time and will be made aware of their rights not to answer any of the interview questions.

Participants in this study will be pregnant Hispanic/Latina adolescents aged 19 years and younger who reside in Gila County, Arizona. According to the Arizona Public Health Department, teenage pregnancy rates were higher in Gila County and pregnant women in general had riskier behavior (Bureau of Public Health Statistics, 2009a, 2009b).

7.3.1.2 Sources of Material
Materials used in research will include surveys on alcohol use and drug use. Health assessments will be collected on other risky behavior, breastfeeding, prenatal care utilization, and birth outcomes. Transcripts of the focus group discussions will be documented.
7.3.1.3 Potential Risks
There is no more than minimal risk to participating in this study. Although steps have been taken to minimize risk, possible risks may occur. For instance, risks may develop involving disclosure of sexual partners of the adolescent girls. State laws require mandatory reporting of statutory rape, and community health workers working with adolescent females may encounter ethical issues if the adolescent is dating an individual of an older age. According to Findholt and Robrecht (2002), “researchers have an ethical obligation to obtain study participants’ informed consent to release information to authorities, they may also have a legal obligation to report certain information even without informed consent.” Participants must know that confidentiality cannot always be assured (Findholt & Robrecht, 2002). It is essential that researchers inform potential participants that confidentiality cannot be assured under these circumstances (Findholt & Robrecht, 2002). All participants will be assigned a unique identification number that will be used in the baseline and follow-up assessment. The identity of the participants in the intervention will remain confidential except to community health workers, study investigators, and other teenage participants who will meet one another during support groups. All other participants will be asked to maintain the privacy of other group members attending support groups.

The intervention will be explained, along with the risks and benefits of participation. Adolescents will be informed that participation is completely voluntary and that they may leave the intervention at any time and that none of the services they receive will be affected if they decide to decline the intervention or withdraw from the intervention. The physical risks involved will not exceed those that might occur at regular prenatal care appointments. Psychological or social risks may occur from being a pregnant teenager in general, but not from the intervention. Parental consent will also be obtained from each of the adolescent’s parents.

7.3.2 Adequacy of Protection Against Risks

7.3.2.1 Recruitment and Informed Consent
Recruitment will be conducted throughout various community settings. The community health workers will actively recruit pregnant teenagers through community education and outreach activities. The parental consent and assent forms will specify the purpose of the intervention, benefits to participating in the intervention, risks involved in participating in the intervention, and services offered in the program. The documents will be available in both English and Spanish. Only one parent needs to provide parental consent. Those interested in participating in the intervention will be asked to explain the intervention components to make sure they understand what the intervention entails. Questions and concerns will be addressed to all participants. For participants who are illiterate, the assent and parental consent document will be read by the community health worker. Once the participant and parent understand the intervention, a signature or thumb print will be obtained from those who are interested in being a part of the intervention.

7.3.2.2 Protection Against Risk
Proper care will be taken to ensure that participants are protected from risks. Actively involving community leaders and health care providers in the formative process will assist in making the teenagers feel more comfortable and facilitate their continual attendance to their prenatal care appointments. The surveys used to assess health behavior will be labeled with a unique identification
number assigned to each participant. The list of the unique identification numbers and the actual study participants will be secured in separate location. Each will be stored in locked drawers, in a locked room where individuals have limited access. Individuals who participant in focus groups will be given pseudonyms from any transcribed notes or audio-recordings. All participants must check whether or not they agree to have the focus groups audio-recorded on the informed consent and assent documents. Electronic data will be kept in an encrypted password protected computer that only select researchers will have access.

7.3.3 Potential Benefits of the Proposed Research to the Subjects and Others
Participants will be educated on the importance of healthy behaviors and prenatal care when pregnant. This intervention is also culturally targeted towards Hispanic/Latina adolescents. Targeting Hispanic adolescents is justified because this group has been cited as having higher rates of teenage pregnancy and are at higher risk of receiving no prenatal care (Kaufmann et al., 1998). Research involving adolescents is often difficult and this intervention allows researchers to improve birth outcomes among a high risk group. This intervention will identify barriers to accessing prenatal care and remove those barriers to improve birth outcomes and maternal health outcomes. The benefits gained from this study outweigh the potential risks.

7.3.4 Importance of the Knowledge to be Gained
With the high rate of teenage pregnancy in the United States, and the low uptake of prenatal care among Hispanic/Latina, it is important that barriers to prenatal care are identified and removed. If this intervention is effective, it can be piloted in other communities with a high prevalence of teenage pregnancy. Components of the program could be modified to become culturally appropriate for other racial/ethnic groups in settings throughout the United States. The findings from this intervention will be translated into policy and practice.

7.3.5 Inclusion of Women and Minorities:
Participants in this study will include pregnant, Hispanic/Latina adolescents aged 19 years and younger who reside in Gila County, Arizona. The community health workers will be women.

7.3.6 Inclusion of Children:
Pregnant teenagers who are 19 years of age or younger are eligible to participate in the intervention. Assent will be obtained from each participant along with parental consent from one parent/legal guardian.

7.3.7 Data and Safety Monitoring Plan:
Adverse events will be immediately reported to the principal investigator via cell phone. Study investigators and community health workers will complete the adverse events form and send it to individuals on the safety committee. The principal investigator will be available to discuss adverse events to community health workers and other research staff. The principal investigator will inform the University of Arizona Institutional Review Board of any adverse events within 48 hours or receiving the report.
7.3.8 Data Sharing Plan:
Data from this intervention will be stored in locked file cabinets and electronically. Any items that could identify participants from the data will be removed, along with any items that could lead to the deductive disclosure of any participants’ identities. We plan to publish the results from this intervention and will consider all requests for data sharing by other researchers working with community health worker interventions to improve prenatal care utilization among pregnant women and teenagers. The requests for data sharing will be decided by members of the steering committee. If an agreement for data-sharing is made, applicants will only have access to the non-identifiable data and the principal investigator would want a copy of all published research results from the data.
8 References


