

## ORIGINAL ARTICLE

# Substance abuse treatment linked with prenatal visits improves perinatal outcomes: a new standard

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**Objective:** To evaluate the impact of Early Start, an obstetric clinic-based prenatal substance abuse treatment program, on perinatal outcomes.

**Study Design:** Subjects were 49 985 women who completed Prenatal Substance Abuse Screening Questionnaires at obstetric clinics between 1 January 1999 and 30 June 2003, had urine toxicology screening tests and either live births or intrauterine fetal demises (IUFDs). Four groups were compared: women screened/assessed positive and treated by Early Start ('SAT',  $n = 2073$ ); women screened/assessed positive without treatment ('SA',  $n = 1203$ ); women screened positive only ('S',  $n = 156$ ); controls who screened negative ( $n = 46 553$ ). Ten neonatal and maternal outcomes were studied.

**Result:** SAT women had either similar or slightly higher rates than the control women on most outcomes but significantly lower rates than S women. SA women generally had intermediate rates to the SAT and S groups. In multivariate analysis, the S group had significantly worse outcomes than the SAT group: preterm delivery (odds ratio (OR) = 2.1, 1.3 to 3.2), placental abruption (OR = 6.8, 3.0 to 15.5) and IUFID (OR = 16.2, 6.0 to 43.8).

**Conclusion:** Substance abuse treatment integrated with prenatal visits was associated with a positive effect on maternal and newborn health. *Journal of Perinatology* advance online publication, 26 June 2008; doi:10.1038/jp.2008.70

**Keywords:** prenatal substance abuse; program evaluation; prenatal care; pregnancy complications; neonatal outcomes; maternal outcomes

## Introduction

Substance abuse during pregnancy continues to be a serious problem in the US with considerable adverse effects for women and their babies.<sup>1–8</sup> Healthy People 2010 states a national goal of increasing the proportion of pregnant women who achieve

complete abstinence from alcohol to 94%, with 100% abstinence from illicit drugs.<sup>9</sup> Although these goals are necessary given the association of alcohol and drugs to adverse outcomes, they have been difficult to attain. A coordinated program is required to provide access to care for this group of marginalized women. Kaiser Permanente Northern California (KPNC) has a well-established coordinated prenatal substance abuse treatment program called Early Start as part of the comprehensive prenatal care program.

Early Start provides state-of-the-art and effective care for substance abuse, exceeding the 2004 American College of Obstetricians and Gynecologists (ACOG) Committee on Ethics Opinion<sup>10</sup> recommendations to use universal screening questions, brief intervention and referral to treatment within the Department of Obstetrics and Gynecology (Ob/Gyn) to provide patients and their families with comprehensive medical care throughout pregnancy. The program began as a pilot in 1990 and was implemented in KPNC over a period of years. As of 2008 it is operational in nearly all 40 outpatient obstetric clinics, screening almost 40 000 women annually, and is considered the standard of care. Early Start has three key components: (1) placing a licensed substance abuse expert, the Early Start Specialist, in the department of Ob/Gyn, whose appointments for assessment and treatment are linked to the patients' prenatal care appointments, (2) universally screening all women for drugs and alcohol by questionnaire and, with signed consent, by urine toxicology testing and (3) educating all providers and patients about the effects of drugs, alcohol and cigarette use in pregnancy.

Potential Early Start patients are identified based on (1) response to the universal self-administered prenatal substance abuse screening questionnaire completed at the first prenatal appointment; (2) clinician referral; (3) self-referral and/or (4) positive urine toxicology screen results on the universal toxicology screening test. Women who are identified as having some risk for alcohol, tobacco or other drug use during pregnancy are then immediately referred to the Early Start Specialist, a licensed clinical social worker or marriage and family therapist, who conducts an in-depth psychosocial assessment with the patient. At the time of the assessment, all women receive education regarding stopping

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substance usage in pregnancy and the women who were assessed positive also receive a brief intervention session. Early Start is designed to diagnose all levels of substance abuse problems. Women who meet the diagnosis of chemical dependency or substance abuse based on Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)<sup>11</sup> criteria receive education, interventions and a comprehensive follow-up care plan, which includes linked follow-up visits with routine prenatal care appointments and may also include subsequent toxicology screening. Additionally, patients who do not meet the criteria for a DSM-IV diagnosis but had a pattern of use prior to pregnancy that increases their risk of use throughout pregnancy are also offered counseling with the Early Start Specialist at subsequent prenatal visits. A variety of counseling techniques are used, including motivational therapy, cognitive/behavioral therapy and psychodynamic therapy. It is important to note that the screening and identification process does not always result in all at-risk patients receiving Early Start treatment. Despite the fact that the design of Early Start eliminates many of the traditional barriers to care by having the Early Start Specialist in the Department of Ob/Gyn, some patients do not participate in Early Start due to factors such as entering prenatal care late, scheduling and transportation problems, motivation, issues of fear and potential stigmatization. We have described Early Start, including the screening questionnaire, in greater detail elsewhere.<sup>12</sup>

Initial research on Early Start demonstrated that pregnant women who were screened positive, assessed and treated for substance abuse problems by Early Start had neonatal outcome rates for assisted ventilation, preterm delivery and low birth weight similar to control women, and significantly lower than substance abusers who were screened positive only or screened positive and assessed but not treated.<sup>13</sup>

The purpose of this study, which looked over a longer time period and at maternal outcomes not included in the original study, was to provide a more comprehensive evaluation of Early Start on maternal and neonatal outcomes to support this becoming the standard of care for all prenatal clinics and establish the program as a gold standard for replication.

## Methods

This study was a retrospective cohort study. The setting was KPNC, a multispecialty group model managed care organization with integrated information and care delivery systems. The study sites were 21 KPNC outpatient obstetric clinics where Early Start was in operation during the study period and the Northern California Kaiser Foundation hospitals with labor and delivery facilities that serve those clinics.

The study cohort included 49 985 female KPNC members who completed Early Start Prenatal Substance Abuse Screening Questionnaires between 1 January 1999 and 30 June 2003. Study

eligibility required that the pregnant women have at least one urine toxicology screening test during the pregnancy, answer a screening questionnaire about drug, alcohol and cigarette use, and receive her prenatal care at KPNC. Only the first pregnancy for each woman that resulted in a live birth or intrauterine fetal demise (IUFD) was included in the cohort. Multiple gestations were excluded.

Fetal/neonatal outcomes analyzed were IUFD, neonatal-assisted ventilation (intermittent mandatory or nasal continuous airway pressure), low birth weight (<2500 g), preterm delivery (<37 completed weeks of gestation), neonatal intensive care unit (NICU) admission, infant rehospitalization within 30 days of discharge from birth hospitalization and infant Emergency Department visits within 180 days of discharge from the birth hospitalization. Maternal outcomes analyzed were cesarean delivery, preterm labor and placental abruption.

KPNC's information systems employ a common medical record number and a clinical data repository, permitting multiple database linkages across facilities and comprehensive follow-up on a population basis.<sup>14,15</sup> Early Start maintains its own database, which links (1) responses to the Prenatal Substance Abuse Screening Questionnaire, (2) patient assessment results as recorded by the Early Start Specialist and (3) follow-up visit summary data. Adverse neonatal and maternal outcomes were obtained from inpatient visit data and a research database, the Neonatal Minimum Data Set (NMDS). Professional medical record analysts verify all outcomes through a medical record review prior to entering data in the NMDS. A separate oversight quality review process is in place for accuracy.<sup>16</sup> These systems also have several security components to ensure that access to confidential information (for example, urine toxicology screen results) is limited to authorized individuals. The data sources were linked to develop a comprehensive database for analysis.<sup>14–17</sup>

During the study period, KPNC used universal urine toxicology screening tests as part of the initial standard labs of prenatal care along with the self-assessment questionnaire as measures of substance abuse. All pregnant patients were asked to consent in writing to have urine toxicology testing performed at the first prenatal visit (referred to as the 'universal test') and during pregnancy as needed based on treatment recommendations of the Early Start Specialist and the Obstetrician. These tests screen for nine substances of abuse: alcohol, amphetamines, barbiturates, benzodiazepines, cocaine, methamphetamines, opiates, (phencyclidine, angel dust) PCP and THC (marijuana).

We defined four study groups:

Group 1, 'Screened, assessed and treated' (SAT) ( $n = 2073$ ), consisted of women who were screened positive (by questionnaire with or without positive toxicology), assessed and diagnosed as chemically dependent, substance abusing or at-risk for alcohol and/or substance use by an Early Start Specialist and had at least 1 follow-up Early Start appointment.

Group 2, 'Screened and assessed' (SA) ( $n = 1203$ ), consisted of women who were screened positive (by questionnaire with or without positive toxicology), assessed and diagnosed as chemically dependent, substance abusing or at-risk for alcohol and/or substance use by an Early Start Specialist but who did not have any subsequent Early Start follow-up appointments.

Group 3, 'Screened only' (S) ( $n = 156$ ), consisted of pregnant women who were identified as substance abusers based on a positive urine toxicology screening test (with or without positive screening questionnaires) but were never assessed or treated in Early Start.

Group 4, 'Controls' (C) ( $n = 46\,553$ ), were women with no evidence of substance abuse during pregnancy, defined as a negative screening questionnaire and a negative universal toxicology test. There was otherwise no difference in the prenatal care program for the four groups.

We compared the four study groups on demographic variables, substance abuse risk factors and the rates of the neonatal and maternal outcomes. We used Fisher's exact tests adjusted for multiple comparisons using the MULTEST procedure in SAS for categorical variables, and used analysis of variance with the Tukey method of adjustment for multiple comparisons for continuous variables. Separate logistic regression models were used to estimate the odds ratios (ORs) for each outcome, comparing each of the controls, SA and S groups to the SAT group. Models were controlled for maternal age, ethnicity and the number of prenatal visits during the pregnancy adjusted for the number of week gestation at delivery (by dividing the number of prenatal visits by the number of weeks gestation at delivery). A propensity score analysis was also conducted.

This study was approved by the KPNC Institutional Review Board for the Protection of Human Subjects.

## Results

Table 1 provides demographic comparisons of maternal and neonatal factors for the four study groups. The control group was significantly less likely to be under 19 years of age and more likely to be over 35 years. The control group was significantly more likely to be married, of higher education and have a greater annual income than the other groups. The control group was also significantly more likely to be Asian and less likely to be Black than the other groups and more likely to be Hispanic than the SAT and S groups. Both the SAT and control groups were significantly more likely to enter prenatal care at <13 weeks; however, the median amount of prenatal care was not different in the four groups. As such, once a patient entered prenatal care the amount of care that she received was not related to whether she agreed to the Early Start intervention or not. Moreover, the median week that the S and SA groups entered prenatal care was 10.0 and 9.3 weeks, respectively.

Table 2 provides comparisons of the SAT, SA and S groups on substance use risk factors, based on responses to the Early Start screening questionnaire. For multiple risk factors (methamphetamine use before pregnancy, and smoking and THC use before and since pregnancy, alcohol use before pregnancy), the SAT group rate was statistically significantly higher than the S group rate (all  $P$ -values <0.03). For all risk factors considered, the SAT and SA groups had higher rates than the S group with two exceptions: (1) methamphetamine use weekly/daily since pregnancy, which was equivalent in the SAT and S groups and highest in the SA group and (2) heroin use was highest in the S group both before and since pregnancy.

Analysis of toxicology screens revealed that the average numbers of toxicology screens in the pregnancy were as follows: 6.7 (SAT), 4.8 (SA), 4.4 (S) and 1.0 (control). Although 11.1% of the SAT women and 6.5% of the SA women had at least one positive toxicology screen during pregnancy, only 2.7% of the SAT women and 1.8% of the SA women had more than one positive toxicology screen. By definition, all women in the S group had at least one positive toxicology screen and 17.3% had more than one.

The unadjusted rates of the outcomes by study group are shown in Table 3. We found consistent patterns in the results for neonatal-assisted ventilation, low birth weight, preterm delivery, preterm labor, placental abruption and IUD. For these outcomes, the S group had higher rates than the SAT group, while the SA group had intermediate rates. The SAT women had either similar or slightly higher rates than the control women but significantly lower rates than the S group on most outcomes studied. The rates for the S group on the maternal outcomes of placental abruption and IUD were significantly higher than the rates for the SAT and control group, while the SAT and SA rates showed no significant difference from each other for these outcomes. We conducted multivariate logistic regression analyses on the outcomes, comparing the control, SA and S groups to the SAT group (Table 4). The final models included maternal age, ethnicity and the number of prenatal visits during the pregnancy adjusted for the number of weeks gestation at delivery; late-to-prenatal care and other potential risk factors were not significant confounders and were omitted from the final models. All but two ORs (low birth weight and NICU admission) comparing the controls to the SAT group were not significantly less than 1.0. All the ORs with the exception of two (cesarean section and infant emergency department visits) comparing the S group to the SAT group were elevated, particularly for placental abruption (OR = 6.8) and intrauterine fetal demise (OR = 16.2). The propensity score analysis did not change the results.

## Discussion

Despite information received by the general public on the adverse effects of substance abuse in pregnancy, there is still significant

**Table 1** Demographic characteristics by study group

Characteristics	Study group (%)			
	Screened positive, assessed and treated (SAT) (n = 2073)	Screened positive and assessed (SA) (n = 1203)	Screened positive only (S) (n = 156)	Controls (C) (n = 46 553)
<i>Maternal characteristics</i>				
Age (%)				
< 19 years	16.3 <sup>a</sup>	13.4 <sup>a</sup>	10.3 <sup>a</sup>	4.2
> 35 years	7.2 <sup>a</sup>	7.7 <sup>a</sup>	10.9	12.6
Mean (standard deviation (s.d.))	24.9 (6.3) <sup>a,b</sup>	25.4 (6.3) <sup>a,b</sup>	26.9 (6.8) <sup>a</sup>	28.7 (5.8)
Race (%)				
White	31.6 <sup>a,c</sup>	36.9 <sup>a,b</sup>	23.1	25.0
Black	26.5 <sup>a,c</sup>	20.1 <sup>a</sup>	31.4 <sup>a,c</sup>	7.7
Hispanic	12.3 <sup>a</sup>	14.3 <sup>a</sup>	19.2	27.2
Asian	4.8 <sup>a</sup>	5.2 <sup>a</sup>	6.4 <sup>a</sup>	23.2
Other	21.0 <sup>a</sup>	19.6 <sup>a</sup>	17.3	14.0
Missing	3.9	3.9	2.6	2.9
Marital status (% married)	42.8 <sup>a,c</sup>	49.4 <sup>a</sup>	48.1 <sup>a</sup>	78.1
Education (% ≤ high school)	48.0 <sup>a,c</sup>	42.5 <sup>a</sup>	53.6 <sup>a</sup>	31.5
Annual income (% < \$25 000)	41.9 <sup>a,c</sup>	33.8 <sup>a</sup>	46.2 <sup>a,c</sup>	19.1
Late (> 13 weeks) to prenatal care (%)	22.2 <sup>b,c</sup>	26.0 <sup>a</sup>	31.4 <sup>a</sup>	18.5
Median amount of prenatal care <sup>d</sup> (interquartile range)	0.28 (0.23–0.33) <sup>a,b,c</sup>	0.26 (0.21–0.32) <sup>a,b</sup>	0.25 (0.15–0.32)	0.26 (0.21–0.31)
<i>Neonatal characteristics</i>				
Gestational age at delivery (%)				
33–36 weeks	6.4	7.0	9.7	5.4
< 33 weeks	1.7 <sup>b</sup>	2.7 <sup>a,b</sup>	7.7 <sup>a</sup>	1.4
> 36 weeks	91.9 <sup>b</sup>	90.3 <sup>a,b</sup>	82.6 <sup>a</sup>	93.2
Mean birth weight (grams) (s.d.)	3352 (605) <sup>a,c</sup>	3356 (623) <sup>a</sup>	3182 (724) <sup>a</sup>	3419 (569)

<sup>a</sup>*P* < 0.05 vs C.<sup>b</sup>*P* < 0.05 vs S.<sup>c</sup>*P* < 0.05 vs SA.<sup>d</sup>Number of prenatal visits during pregnancy divided by the number of weeks gestation at delivery.

substance abuse among pregnant women in the US.<sup>18</sup> This is the largest Health Maintenance Organization (HMO) study, with 49 985 patients over 4.5 years, that examines both neonatal and maternal outcomes of a comprehensive, coordinated intervention program for substance abuse during prenatal care.

As with the previous Early Start study<sup>11</sup> there were significantly lower rates of neonatal-assisted ventilation, preterm delivery (< 37 weeks gestation) and low birth weight (< 2500 g) in the SAT group compared to the S group with intermediate rates for the SA group. These outcomes are important to examine as they are independent of hospital policy or provider bias, which might explain the findings regarding NICU admissions (Table 3). Many hospitals during the study period still had policies leading to neonatal NICU

admissions if the mother reported any drug or alcohol use at any time in the pregnancy.

The rate of infant rehospitalization within 30 days from discharge from the birth hospitalization was significantly lower in the SA group than the control group. Since there were no other significant differences among the study groups, we conclude that the low SA rate might be a chance finding warranting further analysis.

Substance abuse also impacts maternal outcomes. Women in the SAT group had higher rates of cocaine, methamphetamine and cigarette, use which are substances associated with placental abruption and IUFD (Table 2). Placental abruption has a large impact on both maternal and neonatal morbidity. As seen in Table 3, the SAT rates were the same as the controls with a rate

**Table 2** Substance use risk factors by study group

Characteristics	Study group (%)		
	Screened positive, assessed and treated (SAT) (n = 2073)	Screened positive and assessed (SA) (n = 1203)	Screened positive only (S) (n = 156)
<i>Weekly/daily since pregnancy</i>			
Alcohol	6.6	7.2	4.5
Methamphetamine	1.3	1.7	1.3
THC (marijuana)	14.7 <sup>a,b</sup>	8.9	5.1
Cocaine	0.7 <sup>a</sup>	0.1	0.0
Heroin	0.3 <sup>a</sup>	0.0 <sup>b</sup>	1.3
Smoked cigarettes	26.6 <sup>a,b</sup>	22.1	16.7
<i>Weekly/daily before pregnancy</i>			
Alcohol	33.1 <sup>b</sup>	33.9 <sup>b</sup>	17.3
Methamphetamine	5.7 <sup>b</sup>	4.6	1.3
THC (marijuana)	34.0 <sup>a,b</sup>	28.0 <sup>b</sup>	12.2
Cocaine	1.5	0.8	0.6
Heroin	0.5	0.2	1.3
Smoked cigarettes	54.1 <sup>a,b</sup>	47.7 <sup>b</sup>	30.1

<sup>a</sup>P < 0.05 vs SA.

<sup>b</sup>P < 0.05 vs S.

**Table 3** Unadjusted rates of neonatal and maternal outcomes according to study group

Outcomes	Study group unadjusted rate (%)			
	Screened positive, assessed and treated (SAT)	Screened positive and assessed (SA)	Screened positive only (S)	Controls (screened negative)
Neonatal-assisted ventilation	3.2	4.2 <sup>a</sup>	6.9 <sup>b</sup>	2.2 <sup>c</sup>
Low birth weight <2500 g	6.5	7.7 <sup>a</sup>	12.4 <sup>a,c</sup>	4.7 <sup>c</sup>
Preterm delivery <37 weeks	8.1	9.7 <sup>a,d</sup>	17.4 <sup>a,c</sup>	6.8
Neonatal intensive care unit admission	16.4	15.3 <sup>a</sup>	21.4 <sup>a</sup>	10.3 <sup>e</sup>
Infant rehospitalization <sup>f</sup>	2.5	1.5 <sup>b</sup>	3.5	3.3
Infant emergency department visit <sup>g</sup>	9.5	8.8	8.3	7.5 <sup>c</sup>
Placental abruption	0.9	1.1 <sup>d</sup>	6.5 <sup>a,e</sup>	0.9
Preterm labor	9.6	11.3 <sup>a,d</sup>	19.5 <sup>a,e</sup>	7.3 <sup>e</sup>
Cesarean section	17.2	17.7	12.3	17.8
Intrauterine fetal demise	0.5	0.8 <sup>h</sup>	7.1 <sup>a,e</sup>	0.6

<sup>a</sup>P < 0.0001 vs C.

<sup>b</sup>0.001 ≤ P < 0.05 vs C.

<sup>c</sup>0.001 ≤ P < 0.05 vs SAT.

<sup>d</sup>0.001 ≤ P < 0.05 vs S.

<sup>e</sup>P < 0.0001 vs SAT.

<sup>f</sup>Within 30 days of discharge from birth hospitalization.

<sup>g</sup>Within 180 days of discharge from birth hospitalization.

<sup>h</sup>P < 0.0001 vs S.

of 0.9%, which is consistent with other studies.<sup>18</sup> Tables 3 and 4 demonstrate that the S group had a significantly higher rate of abruption at 6.5% (OR 6.8, 95% CI 3.0 to 15.5). Multiple known

risk factors exist for placental abruption, including previous placental abruption, trauma, hypertension, premature rupture of membranes, multiple gestation, uterine anomalies, inherited

**Table 4** Adjusted odds ratios for neonatal and maternal outcomes by study group

Outcome	Study group			
	Odds ratios <sup>a</sup> (95% CI)			
	Screened positive, assessed and treated (SAT) (reference)	Screened positive and assessed (SA)	Screened positive only (S)	Controls (screened negative)
Neonatal-assisted ventilation	1.0	1.4 (1.0–2.0)	2.2 (1.1–4.4)	0.8 (0.6–1.0)
Low birth weight <2500 g	1.0	1.2 (0.9–1.6)	1.8 (1.1–3.1)	0.7 (0.6–0.9)
Preterm delivery <37 weeks	1.0	1.2 (0.9–1.5)	2.1 (1.3–3.2)	0.8 (0.7–1.0)
Neonatal intensive care unit admission	1.0	1.0 (0.8–1.2)	1.4 (0.9–2.1)	0.6 (0.6–0.7)
Infant rehospitalization <sup>b</sup>	1.0	0.6 (0.4–1.0)	1.4 (0.6–3.6)	1.2 (0.9–1.6)
Infant emergency department visit <sup>c</sup>	1.0	1.0 (0.8–1.3)	0.9 (0.5–1.7)	0.9 (0.8–1.0)
Placental abruption	1.0	1.3 (0.6–2.6)	6.8 (3.0–15.5)	1.1 (0.7–1.7)
Preterm labor	1.0	1.3 (1.0–1.6)	2.3 (1.5–3.5)	0.8 (0.7–1.0)
Cesarean delivery	1.0	1.1 (0.9–1.3)	0.7 (0.4–1.1)	1.0 (0.9–1.1)
Intrauterine fetal demise	1.0	2.0 (0.7–5.5)	16.2 (6.0–43.8)	1.5 (0.7–3.3)

<sup>a</sup>Estimated from logistic regressions, controlled for maternal age, ethnicity and prenatal care.

<sup>b</sup>Within 30 days of discharge from birth hospitalization.

<sup>c</sup>Within 180 days of discharge from birth hospitalization.

thrombophilia, uterine leiomyoma, increased parity and substance abuse including cigarette use. However, there is no other single intervention reported in the literature to impact the rate of placental abruption as dramatically as found in this study. For IUID, baseline rates for the control and SAT groups were not significantly different at 0.6 and 0.5%, respectively. These rates are consistent with national averages reported by the Centers for Disease Control and Prevention.<sup>19</sup> As seen in Tables 3 and 4, the only group with statistically increased rates compared to controls was the S group at 7.1% (OR 16.2, 95% CI 6.0 to 43.8). The emotional impact of IUID is enormous. The reductions that we have reported as a result of Early Start intervention not only have great implications for the health of mothers and neonates, but also for the entire family unit. These are dramatic decreases in morbidity and mortality secondary to providing a comprehensive care program to stop the use of drugs and alcohol in pregnancy.

This study additionally considers severity of use among the groups. If the severity of use among women in the S group was higher than the other groups, there would be questions about its subsequent effect on increased negative outcomes. Consistently, the group with the most severe substance use patterns reported was the SAT group (Table 2) with the highest percentage of subjects reporting methamphetamine, cocaine, THC or cigarette use weekly/daily before pregnancy as well as the highest rates of use since pregnancy of THC, cocaine and cigarettes. Women in the S group, despite not partaking in Early Start, were still having toxicology screens ordered by their OB providers during their prenatal care.

A factor that may contribute to the better outcomes of the SAT group is that women who initially have higher risk may be more

acutely aware of the real risks of their substance abuse, possibly due to having already experienced negative consequences and/or pressure from loved ones, employers, etc. Therefore they may be more motivated to return for care. Women who admit to use might be more motivated to stay clean in pregnancy. However, they will only get better if they receive appropriate support that they can access without the barriers of travel, discrimination, stigmatization or fears of criminal investigation. Early Start provides this support.

One limitation of this study is that it is a retrospective evaluation of a current treatment program in an HMO setting and was not designed as a research study, so there is no randomization to the study groups. However, a propensity score analysis was conducted to eliminate possible confounding that could result from this lack of randomization. The results of this analysis were the same as the original analysis.

Other limitations to the study are that we did not exclude medical co-morbidities such as diabetes, hypertension, psychiatric illness or uterine anomalies. However, we would not expect to see differential rates of these potential confounders among the four study groups.

There are a number of variables as mentioned in the introduction that would account for the 156 women (S group) who were never assessed or treated in Early Start. Despite the fact that the S group was not seen by Early Start, the obstetric providers continue to identify and counsel all women to stop using and continue to refer them to Early Start and other treatment programs consistent with ACOG guidelines. Moreover, the S group represents only 5% of the total number of women who qualify for intervention services. Early Start clearly provides a service that is easily accessible to most of the women in need.

It is time for our nation to look at the issue of substance abuse in pregnancy with a non-judgmental, coordinated, effective intervention that all pregnant women can easily access. ACOG supports universal screening of all women for substance abuse in pregnancy, as well as a mechanism for referral and treatment.<sup>10</sup> Because every pregnant woman who enters prenatal care at KPNC is screened for substance use through a universal screening questionnaire and urine toxicology, the question of bias in identification of patients is removed. The emotional and fiscal costs of neonates on ventilators and of mothers experiencing placental abruption or an IUFD are exponentially large for the US population. Early Start has demonstrated a marked, statistically significant reduction to these negative and costly outcomes. In addition, KPNC internal business case cost analysis for Early Start resulted in a 30% return on investment, which is congruent with ACOG's Committee Opinion no. 294 which states "Treatment is both more effective and less expensive than restrictive policies, and it results in a mean net saving of \$4644 in medical expenses per mother/infant pair."<sup>10</sup> Prior to Early Start, women identified with substance abuse problems were counseled to stop using and referred to programs outside the Ob/Gyn department. They generally did not keep the appointments. The ready availability of the Early Start Specialist, who specializes in both pregnancy as well as substance abuse treatment and maintains a practice in the Women's Health Clinic, affords women easy access to the program by removing both the physical and emotional barriers that can be overwhelming during pregnancy.

The coordination of care between mental health and obstetric professionals enhances the service delivery model for addressing substance abuse in pregnancy. Early Start's replicable model of integrating substance abuse treatment with prenatal care is cost-effective and significantly decreases negative birth outcomes as well as maternal morbidity. The women and babies served by Early Start are healthier; therefore, the impact of the program reaches beyond them to also positively influence the health and well-being of the community at large, and consequently must also be considered from a public health perspective. The results of this study reflect the importance of widespread implementation of this model of care as a national standard.

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