

Consistency of Maternal Telephone Administration of the Asthma Control Test Using Postpartum Recall Compared to Repeated Measures during Pregnancy

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Abstract:

Background: Suboptimal asthma control during pregnancy may impact perinatal outcomes.

U.S. guidelines recommend questionnaires to assess asthma control including the Asthma Control Test (ACT). It is unknown in a research setting to what extent recall differs by the time between symptom occurrence and the administration of the questionnaire.

Methods: Between 2009 - 2014, 196 pregnant asthmatic women were recruited by the Organization of Teratology Information Specialists (OTIS) MotherToBaby Pregnancy Studies. Participants were administered the ACT at enrollment, gestational weeks 20 and 32, and shortly after delivery. The same women were also administered the ACT retrospectively at approximately six months postpartum.

Results: The Pearson correlation coefficients between the in-pregnancy and retrospective continuous ACT scores for the 1st, 2nd and 3rd trimesters were: 0.67 (95% CI: 0.58, 0.74), 0.61 (0.52, 0.70) and 0.65 (0.56, 0.72), respectively. When dichotomized into well-controlled asthma (ACT score ≥ 20) versus otherwise, the chi-square test for all three trimesters resulted in p-values < 0.0001 . Cohen's Kappa statistics for the same dichotomized scores were 0.51, 0.45 and 0.40 for each trimester respectively. There was no evidence that adverse outcome of pregnancy (recall bias) influenced postpartum responses.

Conclusions: The retrospectively recalled ACT score obtained postpartum was substantially different compared to in-pregnancy administration of the same questionnaire which could reflect test-retest variability as well as attenuation of recall. Documentation of the magnitude

and direction of these differences could be useful in interpretation of the impact of asthma control when the ACT is used in retrospective case-control studies for pregnancy outcomes.

Keywords: Asthma Control Test, telephone-based questionnaire, asthma, pregnancy

Introduction

In the United States (U.S.), approximately 9% of pregnant women have asthma during pregnancy.¹ Asthma is associated with an increased risk for a number of adverse perinatal outcomes including preeclampsia, preterm birth, low birth weight and small for gestational age infants.² In addition, several studies have demonstrated that the severity of asthma or the degree of asthma symptom control contributes in a dose-response manner to the risk for adverse pregnancy outcomes.^{3, 4}

The National Asthma Education and Prevention Program (NAEPP) recommends using validated questionnaires to assess asthma control including the Asthma Control Test (ACT).⁵ The ACT is a simple, patient-based questionnaire that measures asthma control and was first described in the literature in 2004.⁶ It is comprised of five questions regarding frequency of asthma symptoms, asthma impact on functioning and rescue medication use during the past four weeks. Scores range from 5 (poor control) to 25 (complete control). A score of 20 or higher reflects well-controlled asthma, whereas a score of 15 or less reflects asthma that is very poorly controlled.⁷ Recently the telephone administered ACT was validated as a tool for the clinical management of pregnant women with asthma and for use in observational and interventional studies of asthma during pregnancy.⁸

Research studies on adverse pregnancy outcomes can employ prospective cohort study designs in which measures of disease symptom control can be collected during the pregnancy.

However, studies of rare outcomes such as specific birth defects often require a retrospective case-control design in order to achieve adequate statistical power.⁹ For such case-control studies in asthmatic women, assessment of asthma control in pregnancy may be accomplished by retrospective questionnaires. In order to better interpret the contribution of asthma control to adverse pregnancy outcomes across studies in the literature, there is a need to compare the results of the ACT administered during pregnancy to the ACT administered retrospectively after the conclusion of the pregnancy. The purpose of the current study was to determine the agreement between the ACT measures collected within pregnancy and the same measures collected postpartum in order to achieve a better understanding of the consistency of the ACT when administered in each time frame. A second objective was to determine whether the correspondence between retrospective and within pregnancy measures differed if the pregnancy ended with an adverse outcome.

Methods

Recruitment and study participants

The pregnant women included in this analysis were part of a parent study of women recruited between November 2009 and July 2014 by the Organization of Teratology Information Specialists (OTIS) MotherToBaby Collaborative Research Group, as part of the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS).^{10,11} The overall purpose of the parent study was to compare risk (or safety) for birth defects and other adverse outcomes of pregnancy associated with asthma medications used by women in the U.S. or

Canada. The main study used a prospective observational design. Pregnant women who resided in the U.S. or Canada and who had a current diagnosis of asthma were eligible to participate. The inclusion criteria also required enrollment prior to 20 completed weeks of gestation, and no prior knowledge of prenatal diagnosis of a major congenital anomaly. Participants' report of asthma was confirmed by medical record review. The study was approved by the Institutional Review Board of University of California, San Diego.

Data collection

Trained interviewers collected data from participants through telephone calls at up to four time points during and shortly after the completion of pregnancy, as illustrated in Figure 1 and described in detail below. Data were collected on demographics, health and pregnancy history, medication exposures, and pregnancy outcome (i.e., live birth, preterm birth, small for gestational age infant and infant with a major birth defect). At each interview, the five questions from the ACT were also administered (Appendix 1). Additionally, interviewers posed the same ACT questions retrospectively at about six months postpartum, asking women to reflect about their asthma control during each trimester of the pregnancy (Appendix 2).

1. Intake-1. At the enrollment interview which was conducted between the date of conception

and 19 completed weeks of gestation, each woman was asked to respond to the ACT questions regarding asthma control during the previous 4 weeks of pregnancy.

2. Intake-2. If a woman was enrolled between 12 and 20 weeks of gestation, in addition to the

Intake-1 ACT reflecting the previous 4 weeks, each woman was asked to respond to the Intake-2 ACT questions regarding her asthma control during weeks 4 to 8 of gestation.

3. Week 20. At approximately 20 weeks of gestation, women were asked to respond to the

ACT questions reflecting the previous 4 weeks of pregnancy.

4. Week 32. At approximately 32 weeks of gestation, women were asked to respond to the

ACT questions reflecting the previous 4 weeks of pregnancy.

5. Outcome. Shortly after delivery, women were asked to respond to the ACT questions reflecting the last 4 weeks of pregnancy.

6. 6 Months Postpartum. At approximately 6 months after delivery, women were asked to

respond to three sets of ACT questions, each reflecting their recall of asthma control in each of the three trimesters of pregnancy.

Statistical analysis

We used the following algorithm to select the most appropriate ACT questionnaire time period in pregnancy to represent each trimester for comparison to the retrospective data.

1. First Trimester. If a woman enrolled in the study before week 12 of gestation, Intake-1 data were used. If a woman enrolled in the study after week 12 of gestation, Intake-2 data were used.
2. Second Trimester. Week 20 data were used. In the case of enrollment at approximately gestational weeks 18 or 19, when no Week 20 interview was conducted, Intake-1 data were used.
3. Third Trimester. Week 32 data were used. In the case of a pregnancy that ended before week 32 of gestation, outcome data were used.

For each trimester, the Pearson correlation coefficients and their 95% confidence intervals (CI) between the in-pregnancy and the retrospective ACT scores were computed for the continuous ACT scores by trimester. The ACT scores were also cross-tabulated according to categories of poorly controlled (5-15), moderately controlled (16-19), and well controlled (20-25).⁸ These were further dichotomized into two categories of <20 or not, and compared between in-pregnancy and retrospective reports, and chi-square tests were performed for these contingency tables. Concordance between in-pregnancy and retrospective report was computed as the proportion of pairs of in-pregnancy and retrospective responses belonging to the same categories of asthma symptom control, out of the total number of pairs. To further examine level of agreement, Cohen's (weighted) Kappas for the categorical ACT measures in pregnancy vs. retrospectively by trimester were computed using the R package 'irr'. Finally, women were categorized into three summary asthma control groups reflecting ACT scores throughout pregnancy:

1. ACT score between 5-15 during any trimester (poorly controlled)
2. ACT score between 20-25 during all three trimesters (well controlled)
3. Otherwise (moderately controlled)

Scatter plots were generated reflecting these overall categories to examine the relationship between the in-pregnancy and retrospective ACT scores. These analyses were repeated for

the subset of pregnancies that ended with an infant with a major birth defect, an infant small for gestational age, or preterm birth was compared to those ending with a normal outcome.

Results

Between November 2009 and July 2014, a total of 196 asthmatic women with live born infants had completed both the in-pregnancy and the retrospective ACT questionnaires. Of these, one woman gave birth at 32 weeks' gestation, and was not administered the retrospective ACT questionnaire for the third trimester. There were five women missing the first- trimester in-pregnancy ACT score, and 9 women missing the second trimester in-pregnancy ACT score.

The mean gestational age at enrollment was 12.5 weeks. The average maternal age was 32.4 years old. Most cohort members were non-Hispanic white and had relatively high socioeconomic status (Table 1). Approximately 14.8% of the women used an oral corticosteroid at least once during pregnancy. As shown in Table 2, mean ACT scores for all three trimesters were similar for in-pregnancy vs. retrospective assessments. The Pearson correlation coefficients between the in- pregnancy and retrospective ACT scores for the three trimesters were: 0.67 (95% CI 0.58, 0.74), 0.61(95% CI 0.52, 0.70) and 0.65 (95% CI 0.56, 0.72), respectively.

As shown in Table 3, ACT scores categorized as poor, moderate or well-controlled differed significantly in each trimester for the in-pregnancy and retrospective reports. Cohen's weighted Kappas for this categorical measure of ACT scores were 0.39, 0.40 and 0.28 for the 1st, 2nd and 3rd trimesters, respectively. When the ACT scores were dichotomized into <20

(not well controlled) versus otherwise, the Cohen's Kappas were 0.51, 0.45 and 0.40 for the 1st, 2nd and 3rd trimester, respectively. The concordance rates for the dichotomized levels of asthma control during the 1st, 2nd and 3rd trimesters were 80.7%, 78.6% and 79.0%, respectively. The chi-square test for dichotomized categories during all three trimester had p-values < 0.0001.

Figure 2 shows scatter plots of the in-pregnancy versus retrospectively collected ACT data during each of the trimesters, with women categorized into overall poorly, moderately or well-controlled throughout pregnancy. Retrospectively reported ACT scores were generally higher (reflecting better control) than in-pregnancy scores among those who had more poorly controlled asthma as reported in pregnancy in each trimester. In contrast, retrospectively reported ACT scores tended to be lower (reflecting worse control) than in-pregnancy scores for those with better controlled asthma as reported in pregnancy in each trimester. Both these trends translated to an attenuating effect for the six-month postpartum recall. When the analysis was restricted to the subset of those mothers who had any adverse outcome (preterm birth, small for gestational age infant or infant with a major malformation), the results did not materially differ (data not shown).

Discussion

In this cohort of pregnant women with relatively well-controlled asthma, we compared the retrospectively administered ACT at six months postpartum against the same questionnaire administered within pregnancy during each trimester of pregnancy. We found significant differences in the maternal reports across the two time periods, and found only

moderate levels of inter-rater reliability using Cohens Kappa. While we found attenuation of reports of symptom control in the postpartum reports, reassuringly, we did not find that these differences were biased by adverse outcome.

The ACT is a validated instrument in wide use for ascertaining asthma control, and its validated look-back period is four weeks. When the instrument is used outside of this time period, it cannot be expected to perform in the same manner. Thus, it is perhaps no surprise that the in-pregnancy and retrospective results are not in close agreement. Regression to the mean, or attenuation of the responses as seen here, would be the most likely occurrence. Additionally, it should be noted that no rating scale of this nature is perfectly reproducible. The test-retest reliability of the ACT was reported to be 0.77 and on this basis, the test was deemed reliable.¹² When dichotomized into well controlled or not, the concordance rates between in-pregnancy and retrospective recall were in the vicinity of 80% which is consistent with the test-retest reliability of the instrument.

The ACT was designed to be a clinical screening tool with a cutoff of 20, denoting well-controlled asthma and has been validated in research settings using those same cutoffs. It was not designed as a tool where the continuous measurement should be taken precisely, and thus it is not surprising that we did not find the correlation between the two sets of continuous scores to be high. However, we did note systematic attenuation of the retrospectively reported scores (Figure 2) compared to the in-pregnancy responses. Regardless of the reasons underlying this variability, this information can be useful when the ACT score is utilized in retrospective studies of asthma in pregnancy. These differing distributions need to be taken into account, and for such future purposes we provide in

Appendix 3 the regression outputs including error variances, with the in-pregnancy ACT score as the independent variable, and the retrospective score as the dependent variable. This could be useful in comparing data from prospective and retrospective study designs, and in support of application of methods to address issues.¹³

This study has its limitations. The cohort was primarily comprised of women who were white women of relatively high socioeconomic status and women who had relatively well-controlled asthma. The results may have limited generalizability in pregnant women with less well-controlled asthma, in non-white women or in women of lower socioeconomic status.

We had no biological measure of asthma severity or symptom control such as a peak flow measure. However, previous data have suggested that the ACT is a reasonable measure of asthma symptom control and that ACT scores do correlate with pregnancy outcomes.

Both retrospective and prospective study designs are of value in evaluating the safety of medication use in pregnant asthmatics. Given the contribution of asthma control to pregnancy outcomes, in studies of medication safety, assessment of asthma control during pregnancy is essential in both designs. When the ACT is used for this purpose, the timing of assessment of asthma control is an important consideration.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Appendix 1. AMPSS Asthma Exacerbation and Control Questionnaire- *Impairment Questions*

Pregnancy ID #	GA at enrollment =		20 wk	32 wk	Outcome
	Intake #1:	Intake #2:			
		*Ask intake # 2 questions for 4-8 weeks gestation-- give MOB			
In the past 4 weeks, how much of the	5. None of the time	5. None of the time	5. None of the time	5. None of the time	5. None of the time 4. A little of the
During the past 4 weeks, how often	5. Not at all 4. Once or	5. Not at all 4. Once or	5. Not at all 4. Once or	5. Not at all 4. Once or	5. Not at all 4. Once or twice a
During the past 4 weeks, how often did your asthma	5. Not at all 4. Once or twice	5. Not at all 4. Once or twice	5. Not at all 4. Once or twice	5. Not at all 4. Once or twice	5. Not at all 4. Once or twice 3. Once a week
During the past 4 weeks, how often have you used your	5. Not at all 4. Once or twice	5. Not at all 4. Once or twice	5. Not at all 4. Once or twice	5. Not at all 4. Once or twice	5. Not at all 4. Once or twice 3. 2 to 3 times per

	5.	5. Completely	5.	5.	5. Completely
How would you rate	Completely	controlled	Completely	Completely	controlled
your asthma control	controlled	4. Well-	controlled	controlled	4. Well-controlled
Date of call					
Interviewer					
DE date					
DE initials					
Validation date /					

* Regardless of MOB's response, have her choose one of the standard responses.

Appendix 2. AMPSS Asthma 6-Month Post-Partum Call

Pregnancy ID #	1st On average during	2nd On average during	3rd On average during
How much of the time did your asthma keep	5. None of the time 4. A little of the time	5. None of the time 4. A little of the time	5. None of the time 4. A little of the time
How often did you	5. Not at all 4. Less than once a month	5. Not at all 4. Less than once a month	5. Not at all 4. Less than once a month
How often did your asthma symptoms (wheezing, coughing	5. Less than once a month 4. 1-2 nights per	5. Less than once a month 4. 1-2 nights per	5. Less than once a month 4. 1-2 nights per
How often did you use your rescue inhaler or	5. Less than once per month 4. Once or twice a	5. Less than once per month 4. Once or twice a	5. Less than once per month 4. Once or twice a
How would you rate	5. Completely controlled 4. Well-controlled	5. Completely controlled 4. Well-controlled	5. Completely controlled 4. Well-controlled
Date of call			
Interviewer			
DE date			
DE initials			
Validated by			
Validation date			

Appendix 3. Regression Model Outputs

Trimester 1 Linear Regression Model Output

Call:

```
lm(formula = tot.1st ~ intake.tot, data = asthma_df)
```

Residuals:

	Min	1Q	Median	3Q	Max
	-10.4652	-1.4652	0.8643	1.7011	8.8643

Coefficients:

	Estimate	Std. Error	t value	Pr(> t)	(Intercept)
	7.13982		1.15085	6.204	3.4e-09 ***
intake.tot	0.66632	0.05413	12.310	< 2e-16	***

Signif. codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 2.939 on 189 degrees of freedom (5 observations deleted due to missingness)

Multiple R-squared: 0.445, Adjusted R-squared: 0.4421 F-statistic: 151.5 on 1 and 189 DF, p-value: < 2.2e-16

Trimester 2 Linear Regression Model Output

Call:

```
lm(formula = tot.2nd ~ tot20, data = asthma_df)
```

Residuals:

	Min	1Q	Median	3Q	Max
	-11.2524	-1.5438	0.4562	1.4562	8.0390

Coefficients:

	Estimate	Std. Error	t value	Pr(> t)	(Intercept)
	7.08673		1.33520	5.308	3.16e-07 ***
tot20	0.65828	0.06211	10.599	< 2e-16	***

Signif. codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 3.064 on 185 degrees of freedom (9
observations deleted due to missingness)

Multiple R-squared: 0.3778, Adjusted R-squared: 0.3744 F-
statistic: 112.3 on 1 and 185 DF, p-value: < 2.2e-16

Trimester 3 Linear Regression Model Output

Call:

lm(formula = tot.3rd ~ tot32, data = asthma_df)

Residuals:

Min	1Q	Median	3Q	Max
-15.2483	-1.2483	0.7517	1.7517	4.6852

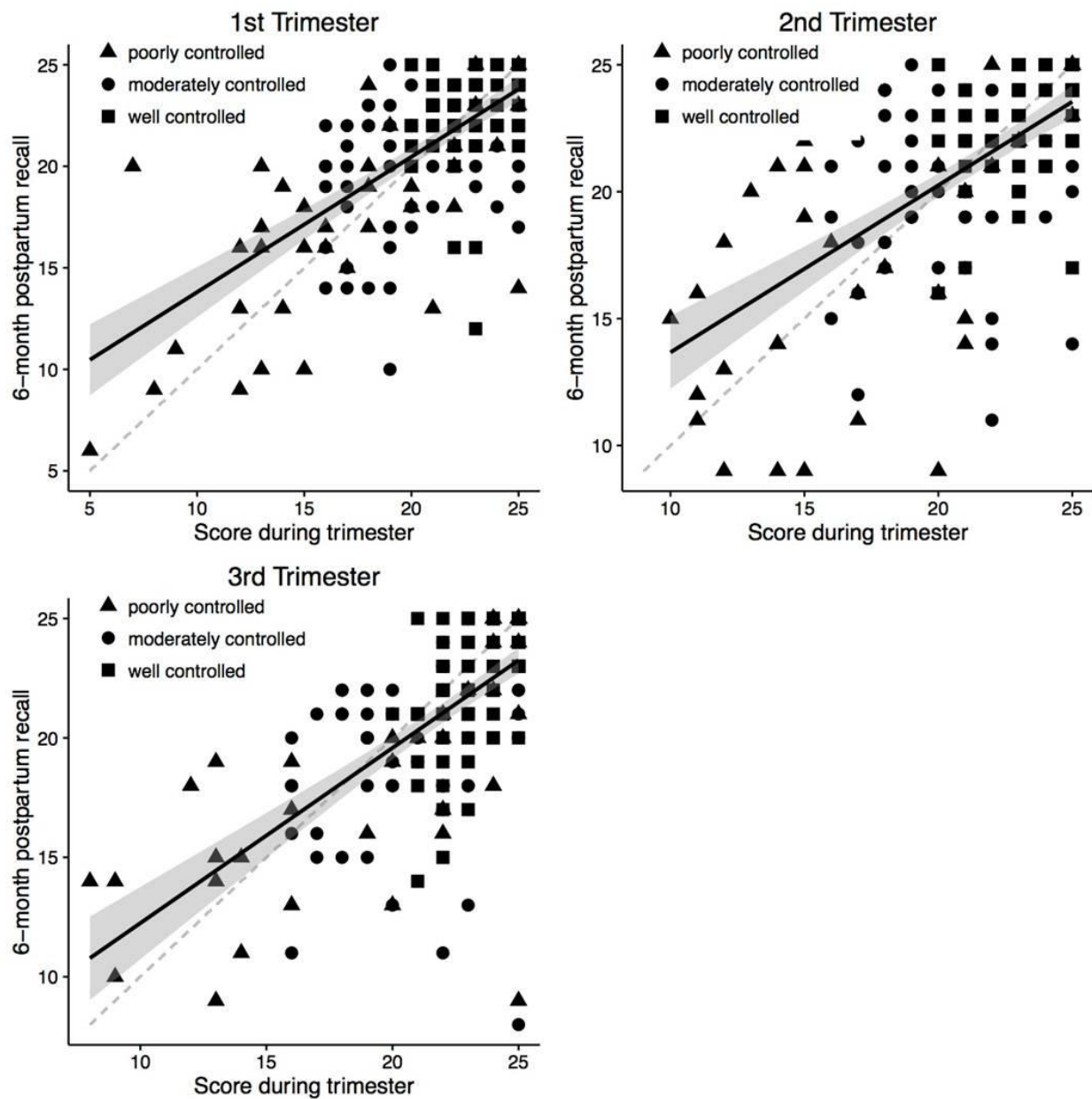
Coefficients:

	Estimate	Std. Error	t value	Pr(> t)	(Intercept)
	4.91393		1.36631	3.596	0.00041 ***
tot32	0.73338	0.06123	11.978	< 2e-16	***

Signif. codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 2.953 on 193 degrees of freedom (1
 observation deleted due to missingness)

Multiple R-squared: 0.4264, Adjusted R-squared: 0.4234 F-
 statistic: 143.5 on 1 and 193 DF, p-value: < 2.2e-16



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Table 1. Maternal characteristics.		
Characteristics		All Women (N=196)
Gestational Week at Enrollment, mean (standard deviation)		12.5 (4.3)
Age, mean (standard deviation)		32.4 (5.4)
Race, n (%)		
White		180 (91.8)
Black		5 (2.6)
Asian/Pacific Islander		10 (5.1)
Indian/Native American		1 (0.5)
Other		0
Ethnicity		
Non-Hispanic		183 (93.4)
Hispanic		13 (6.6)
Socioeconomic Status†, n (%)		
1		81 (41.3)
2		75 (38.3)
3		26 (13.3)
4		10 (5.1)
5		4 (2.0)
Nulliparous, n (%)		120 (61.2)
Multifetal gestation, n (%)		
Singleton		189 (96.4)
Twin		7 (3.6)

Body Mass Index, n (%)	
<25	97 (49.5)
25-29.9	60 (30.6)
≥30	39 (19.9)
Any Smoking During Pregnancy, n (%)	14 (7.1)
Asthma Medication Use During Pregnancy [‡] , n (%)	
None Observed	18 (9.2)
Short-Acting Beta2-Agonists	158 (80.6)
Inhaled Corticosteroids	125 (63.8)
Long-Acting Beta2-Agonists	88 (44.9)
Leukotriene Receptor Antagonists	35 (17.9)
Oral Corticosteroids	29 (14.8)
Short- or Long-Acting Anticholinergics	6 (3.1)
Inhaled Asthma Medication Not Otherwise Specified	3 (1.5)
[†] Calculated using Hollingshead categories based on maternal and paternal education and occupation; 1, highest; 5, lowest.	
[‡] Women may be classified in multiple exposure groups due to the use of combination products and the use of multiple medications during pregnancy.	

Table 2. Summary of in-pregnancy and retrospective continuous ACT scores

	In-Pregnancy Mean (SD)	Retrospective Mean (SD)	Pearson Correlation (95% CI)
1 st trimester	20.9 (3.9)	21.1 (3.9)	0.67 (0.58, 0.74)
2 nd trimester	21.2 (3.6)	21.1 (3.8)	0.61 (0.52, 0.70)
3 rd trimester	21.9 (3.5)	21.1 (3.9)	0.65 (0.56, 0.73)

Table 3. Summary of categorical ACT scores

	In-Pregnancy		Retrospective		P-value
		Poor (5-15)	Moderate (16-19)	Well (20-25)	
1 st trimester	Poor	8 (4.2%)	6 (3.1%)	4 (2.1%)	
	Moderate	7 (3.7%)	12 (6.3%)	18 (9.4%)	< 0.0001
	Well	3 (1.6%)	12 (6.3%)	121 (63.4%)	
2 nd trimester	Poor	9 (4.8%)	3 (1.6%)	5 (2.7%)	
	Moderate	3 (1.6%)	14 (7.5%)	15 (8.0%)	< 0.0001
	Well	7 (3.7%)	13 (7.0%)	118 (63.1%)	
3 rd trimester	Poor	8 (4.1%)	2 (1.0%)	0 (0%)	
	Moderate	5 (2.6%)	8 (4.1%)	12 (6.2%)	< 0.0001
	Well	8 (4.1%)	21 (10.8%)	131 (67.2%)	

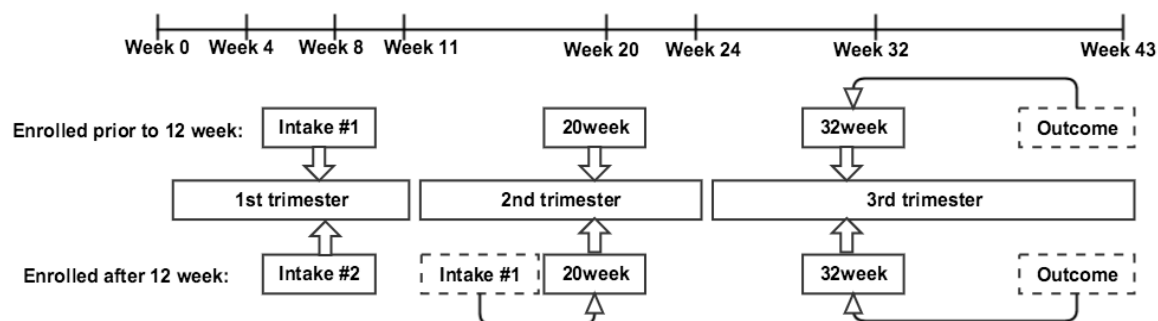


Figure Legends

Figure 1. Schema of data collection.

Figure 2. Scatter plots of in-pregnancy versus retrospectively collected ACT data for each trimester.