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Developing a Measure of Prenatal Case Management Dosage

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Abstract Recently, federal funding was designated through the Patient Protection and Affordable Care Act giving states the opportunity to expand their prenatal case management programs (PCM) through home visitation. Studies evaluating the effect of PCM on birth outcomes have shown little or no positive results. One suggested reason for these findings is a lack of attention in the assessment of dosage. The objective of this study is to demonstrate the use of measuring PCM dosage when assessing pregnancy outcomes. A birth cohort (N = 4,582) encompassing Medicaid-insured Iowa residents enrolled in PCM who gave birth to a singleton from October 2005 to December 2006 was constructed from linked Iowa birth, Medicaid Claims, and Women's Health Information Systems datasets. Data was used to create a dosage measure capturing the duration of enrollment, amount of time spent with a case manager, and breadth of interventions. Bivariate analysis and logistic regression were used to assess the relationship between PCM dosage and the birth outcomes. Dosage was significantly associated with LBW ($X^2 = 31.1$, $P < 0.001$) and PTB ($X^2 = 56.2$, $P < 0.001$). After adjustment for potential confounders, the likelihood of LBW and PTB were aOR: 0.47 (95% CI: 0.36–0.63) and aOR: 0.60 (95% CI: 0.44–0.82) for women with medium dosage (compared to low dosage), respectively. For women with high PCM dosage the likelihood of LBW and PTB was aOR 0.40 (95% CI: 0.31–0.51) and aOR = 0.62 (95% CI: 0.48–0.81), respectively. This study showed that PCM dosage was significantly associated with lower odds of an adverse pregnancy outcome occurring.

Keywords Prenatal case management · Dosage · Birth outcomes · Home visiting · Program evaluation

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Introduction

The Patient Protection and Affordable Care Act (ACA), P.L. 111–148, contains a title devoted to home visitation for high risk pregnant women and early parenting mothers [1]. Implementation of the ACA includes federal funding and provides states who currently have prenatal case management (PCM) through home visitation the opportunity to improve and/or expand their programs to communities deemed "at risk" through needs assessment [1]. With this recent national support, it is now more important than ever for health professionals to unravel and understand the complex relationship between the dose of PCM and perinatal and child health outcomes that programs target.

PCM is defined as a community-based health related service offered to medically and/or socially vulnerable high-risk pregnant women to improve outcomes related to maternal and infant health [2]. Great variability exists in the risk characteristics of pregnant women with a corresponding variation in their health related needs. PCM is designed to be a collaborative process between the case manager and the client, working together to develop a tailored care plan to address the client's identified needs and health risks [3, 4]. Delivering both single and multiple interventions should result in achieving "specific objectives" for a PCM program [5].

While randomized control trials and observational studies examining the effect of PCM on high-risk pregnant

women have shown positive effects in outcomes related to mental health, substance use, employment, parenting skills, and educational attainment for mothers [6–10] studies have shown little or no significant effects in reducing adverse pregnancy outcomes [11]. The inconclusive research findings on the relationship between PCM and birth outcomes may be due to methodological issues that plague this research.

One methodological issue is the measurement of the dose of PCM interventions received by pregnant women. Studies evaluating the effectiveness of PCM on pregnancy outcomes, such as low birth weight (LBW) and preterm birth (PTB) have only assessed the effect of PCM programs as an overall entity. These studies have not measured the intensity of interventions [2, 6, 8, 10, 12]. The lack of attention to measuring dosage of interventions provided may be one reason why published literature on PCM shows mixed results for pregnancy outcomes. However, it is possible to conceptualize and measure dosage of interventions provided through PCM.

Background

During a case management encounter, a case manager performs an assortment of distinct, specific interventions "that may be delivered simultaneously, individually, or in sequence, within the discretion of the individual case manager's judgment" [13]. The complex process of delivering interventions and its impact on maternal and infant health outcomes has not been adequately explored [14]. For example, a literature review revealed that PCM programs appear to vary in types of interventions offered [10]. PCM includes one or more of the following interventions: assessment, teaching, counseling or support, referral, clinical services, assistance with tangibles, and monitoring [2, 13, 15]. Evaluations of PCM effectiveness must account for variations across programs in the use of different interventions to address the same pregnancy outcome.

Just as with medication trials, when assessing PCM program effectiveness the dosage of the interventions provided ought to be considered in order to determine whether "what was prescribed actually was delivered and whether desired outcomes were achieved as a result of the interventions" [13]. The dosage of interventions provided through a program is different from the dose of a medication which is used only after undergoing clinical testing [13]. Accordingly, the dosage of PCM interventions is characterized by the amount of contact time, duration of enrollment, and breadth of interventions (Table 1).

The ideal measure of PCM dosage involves all three dimensions of time, duration and breadth [5, 6, 13, 16]. However, most studies measure the receipt of PCM interventions as a dichotomous variable: participation versus no participation [8, 17–24]. Measuring dosage as a dichotomous variable fails to describe the amount of effort expended toward optimizing outcomes for each woman. Using a dichotomous measure may also contribute to the possibility of Type II error because it does not capture the variability of dosage both across PCM programs and within a program [13]. If Type II error is present, results may indicate that participation in PCM had no effect on client outcomes when it actually might have. Having a variable that captures dosage is necessary in order to assess the actual effectiveness of PCM.

The little evidence available suggests that variability exists across PCM programs in intervention dosage. For example, a review of 42 PCM studies [10] found that frequency of visits ranged from weekly to monthly and duration of enrollment ranged from the prenatal period to the child's second or third birthday. Literature reviews [6, 10] have also found that PCM programs vary in their deadline for onset- the week of gestation in which a woman was enrolled. Onset was found to range from the first trimester to the 30th week of gestation. Differences in onset limit the dosage dimensions of duration and possibly

Table 1 Conceptual and operational definitions for PCM dosage dimensions

Dosage dimensions	Conceptual definition	Operational definition
Duration of enrollment	The length of time a woman is enrolled in the PCM program, beginning with the date of the enrollment visit and ending with the time the targeted outcome occurs or with the woman dropping out of the program	Number of weeks between the 1st PCM visit and the date of infant's birth (or the date of discharge from program)
Breadth of interventions	The variety of types (e.g., risk assessment, health education, care coordination, etc.) of interventions provided by case managers to women in the PCM program	Number of intervention types received by the woman while enrolled in PCM
Amount of contact time	The amount of time (hrs, min, visits) spent with the case manager during interventions conducted throughout the course of enrollment in PCM	The total number of hours of time billed to Medicaid for health education or care coordination visits

frequency. Variations in the amount of time that a pregnant woman receives PCM interventions before the birth of the baby is important and may contribute to the limited amount of evidence linking the usage of PCM programs to improved pregnancy outcomes.

The purposes of this paper are to: (1) develop a single measure of program dosage that captures amount of contact time, duration of enrollment, and breadth of interventions received; and (2) demonstrate its usefulness when applied to a PCM program.

Methods

Iowa's PCM Program

Iowa is a predominately rural state, with a population of approximately 3 million people (52.4 people per square mile) [25]. In Iowa, Medicaid-insured and low income pregnant women are eligible for PCM. Throughout the state, PCM is provided by 24 Maternal Health Services (MHS) agencies which serve Iowa's 99 counties. The agencies are funded by the Iowa Department of Public Health and the Iowa Department of Human Services, and are monitored by the Bureau of Family Health. To be eligible for Medicaid-reimbursement for case management interventions provided, each MHS agency is required to have a physician, registered nurse, licensed dietician, and a person with at least a bachelor's degree in social work, counseling, sociology, or psychology on staff [26].

Interventions provided by MHS agencies include risk assessment, care coordination, health education, nutrition education, and psychosocial services. The Iowa Department of Public Health requires that MHS agencies provide Medicaid-eligible pregnant women seeking services a prenatal risk assessment using the Iowa Department of Human Services' Medicaid Prenatal Risk Assessment tool. Based upon the Medicaid Prenatal Risk Assessment women are categorized as either low risk or high risk. A score of 10 or higher on the risk assessment tool qualifies a pregnant woman as high risk. Women who are classified as low risk are eligible to receive care coordination and health education. High risk women are eligible to receive intense care coordination, intense health education, nutritional services, psychosocial services, and postpartum home visit.

Study Population and Procedures

A retrospective birth cohort study used Iowa birth certificate data from October 2005 to December 2006, 2005–2006 Medicaid Claims, and 2005–2006 risk assessment data captured in Iowa's Women's Health Information System (WHIS). Medicaid Claims and birth certificate data were linked a priori by the Iowa Department of Public Health. Ninety percent of WHIS risk assessment data was probabilistically linked by the authors to the Medicaid Claims-birth certificate data using maternal date of birth; and maternal first, last, and maiden name. After conducting the linkage, the birth cohort consisted of 19,280 Medicaid births.

Using indicators on the birth certificate, women were excluded from the dataset if their race was not White or Black (4.3%), and plurality >1 (2.8%) for proposes of homogeneity. To help reduce the impact of gestational age (GA) misclassification and underreporting, GA was estimated on the date of last menstrual period (LMP). If the LMP derived gestation differed by more than 2 weeks from the clinical estimate of gestation, or was missing, then the clinical estimate of gestation was used instead. Records with GA <22 weeks or >42 weeks (0.5%) were excluded. Records were also deleted if the birth weight < 400 g (0.4%). Women with a Medicaid Claims file, but no WHIS risk assessment file (2.2%) were also excluded given that dates used to determine PCM enrollment were only present within the WHIS risk assessment file. After exclusions there were 16,500 Medicaid births. Of those Medicaid births, 28.1% had a WHIS risk assessment file, yielding a sample size of 4,639 women. Fifty-seven women with WHIS risk assessment files were subsequently excluded from the analysis since they had no recorded interventions. The final sample size for this study included 4,582 women. This study was approved by the University of Illinois at Chicago, Office for the Protection of Research Subjects and the Iowa Department of Public Health.

Calculating PCM Dosage

The goal in developing a measure of PCM dosage was to provide a composite measure that can be used by state and local health departments, researchers, and program evaluators to monitor the performance of PCM in relationship to pregnancy outcomes. Dosage was conceptualized as having three dimensions: duration, breadth, and contact time. *Duration* of enrollment was defined as the length of time a woman was enrolled in PCM. For PCM, duration began with the PCM onset visit (first visit) and concluded with the infant's birth date or the PCM discharge date, whichever occurred first. PCM onset was the date of the initial risk assessment, given that risk assessment should occur prior to any other intervention. Approximately, 2% of the women enrolled in PCM had no initial risk assessment; hence the date their WHIS risk assessment file was opened was used as a proxy for when contact started between the woman and the case manager. The distribution of duration was examined and women were categorized as having 0-none, 1-low (1–12 weeks), 2-medium (13–27 weeks), or

3-high (≥28 weeks). Category cutoffs were chosen to correspond with the number of weeks in a trimester.

Breadth of interventions is the number of intervention types received while enrolled. In PCM, the following interventions were captured in the datasets: (1) Medicaid Prenatal Risk Assessment (WHIS risk assessment data); (2) Care coordination (Medicaid Claims data); and (3) Health education (Medicaid Claims data). No other types of interventions were captured in Medicaid Claims or WHIS risk assessment data, therefore, breadth ranged from 1 to 3.

Contact time is the amount of time a provider (i.e., the case manager) spent with a woman delivering the interventions. Contact time was measured as the total amount of hours billed to Medicaid for either health education or care coordination visits. Visits were billed in 15 min increments for health education and 30 min increments for care coordination. Billed visits were summed in order to calculate the total amount of contact time. Time spent with a case manager during the initial risk assessment was not included since risk assessments were not billed in time increments. Based on the distribution, the amount of contact time was categorized as 0-none, 1-low (0.1–1 h), 2-medium (1.1–3.25 h), and 3-high (≥3.25 h).

PCM dosage was calculated as the average score of the three 3 dimensions:

$$PCMdosage = \left(\frac{duration + breadth + amount}{3}\right)$$

To increase interpretability, PCM dosage was categorized into 3 groups: low (0.1–1.4), medium (1.5–2.4), and high (2.5–3.0) based on the distribution of scores. Individual domains of PCM dosage were given equal weights (of 1) since this is the simplest and most transparent weighting method and can easily be reproduced by other researchers and program evaluators. Equal weighting was also performed because the relationship between each domain and pregnancy outcome has not been fully established in research literature to indicate order of importance.

Dependent Variables

The dependent variables were low birth weight (LBW) and preterm birth (PTB). Using data from the birth certificate LBW was defined as birth weight < 2,500 g; PTB was defined as GA <37 weeks.

Potential Confounding Variables

Maternal characteristics hypothesized to affect the association between PCM dosage and the pregnancy outcomes of LBW and PTB were chosen as potential confounders. Demographic and medical characteristics were selected a priori based on previously published literature and biologic plausibility [27–30]. Demographic variables available on the birth certificate and included in the analysis were maternal education (<high school, high school, >high school), marital status (married/unmarried), Hispanic ethnicity (yes/no), maternal race (black or white), maternal age (<18 years, 18–34 years, ≥35 years), and rural/urban residency. Maternal city of residence at the time of birth was categorized into four groups: central city, metropolitan statistical area (MSA), rural adjacent to an urban area, and rural not adjacent to an urban area.

For each pregnancy outcome, a dichotomous variable indicating the presence of relevant maternal medical condition recorded on the birth certificate was created [22]. Maternal medical conditions relevant for LBW were the presence of the following: diabetes, anemia, cardiac disease, lung disease, chronic hypertension, and renal disease, pregnancy associated hypertension, eclampsia, uterine bleeding, hydramnios, oligohydramnios, and incompetent cervix. Similarly for PTB, relevant maternal medical conditions were those for LBW plus the presence of premature rupture of membrane, placenta previa, abruption placenta, and other excessive intrapartum bleeding [27–30].

Other maternal characteristics as potential confounders included in the analysis were parity (nulliparous, primiparous, 2, ≥3 live births), smoking during pregnancy (yes/no), previous PTB (primiparous, multiparous with previous PTB, and multiparous no previous PTB), and adequacy of prenatal care (PNC) entry [27–30]. Adequacy of PNC entry was defined as inadequate (>6 months), intermediate (5–6 months), adequate (3–4 months), and adequate plus (1–2 months) [31].

All potential confounding variables were assessed for missing values. No single variable exhibited more than 2% missing. Data were not missing at random; therefore expectation–maximization (EM) algorithm was used to impute missing values based on EM estimates [32].

Statistical Analysis

Statistical analysis was conducted using SAS version 9.2. To examine the distribution of dosage for each maternal characteristic, bivariate analyses were conducted using ANOVA and chi-square tests. Since PCM dosage had more than two categories multinomial logistic regression with generalized logit model was used to model dosage as a function of the maternal characteristics that may indicate risk status for an adverse pregnancy outcome.

Next, the distribution of PCM dosage was examined for each pregnancy outcome using bivariate analyses. To assess the association between PCM dosage and the pregnancy outcomes, crude and adjusted odds ratios (ORs) and 95% confidence intervals were calculated using binomial logistic regression. Binomial logistic regression also was

used to assess the association of PCM dosage, duration, breadth, and amount, with each pregnancy outcome. To address overt selection bias and confounding maternal characteristics were included as covariates in each of the regression models.

Results

This study encompassed 4,582 Medicaid recipients who received PCM in Iowa from October 2005 through December 2006. Approximately, 9% of PCM participants' pregnancies ended in PTB and 6.6% in LBW. Overall, the sample consisted of young, single, non-Hispanic, White women receiving Medicaid (Table 2). Approximately, two-thirds of participants had at least a high school education and 42.6% resided in a rural area. The majority (90.2%) of women entered into PNC during the first 4 months of pregnancy. A relatively large percentage (27.8%) of the PCM participants, compared to the US national average of 18.1% [33], reported smoking during their current pregnancy. Descriptive statistics for maternal characteristics by PCM dosage category are displayed in Table 3. The distribution of PCM dosage was only significantly different by maternal age, rural/urban residency, Hispanic ethnicity, and entry into PNC.

Descriptive statistics for PCM dosage and its dimensions are displayed in Table 2. Among the 4,582 Medicaid women enrolled in PCM, nearly half (48.1%) had a medium duration of enrollment (13–27 weeks). A little more than a third (36.7%) of the PCM participants were enrolled for at least 28 weeks (high duration). The majority (86.5%) of women enrolled in PCM before their third trimester, with 49% entering during the first 3 months of pregnancy. When looking at amount of contact time, 62% of participants had no recorded contact time with respect to care coordination or health education. Only 11.5% of the 4,582 women enrolled in PCM, spent more than 3.25 h (high) with a case manager. With respect to breadth of interventions, a vast majority of participants had at least one intervention while enrolled in PCM. Almost all of the women (99.5%) had an initial risk assessment, 35% had health education and 27% had care coordination.

When looking at the dose of PCM, the average rank across the three dimensions, 58.8% of participants were classified as having medium to high PCM dosage. Bivariate analysis using chi-square tests showed dosage to be significantly associated with both LBW ($X^2 = 31.1$, $P < 0.001$) and PTB ($X^2 = 56.2$, $P < 0.001$).

Multivariable logistic regression was used to further examine the relationship between PCM dosage and each pregnancy outcome (Table 4). After adjustment for potential confounders, dosage remained significantly associated with both LBW and PTB. A LBW event was 50% less likely to occur among women with medium dosage when compared to women with low dosage (aOR = 0.47, 95% CI: 0.36–0.63) and 40% (aOR = 0.60, 95% CI: 0.44–0.82) less likely to arise when comparing women who received high to low dosage. With respect to PTB, women who received medium and high doses of PCM were 60% (aOR = 0.40, 95% CI: 0.31–0.51) and 38% (aOR = 0.62 (95% CI: 0.48–0.81) less likely to have a PTB infant then women who received a low dose of PCM, respectively. Maternal medical conditions, parity, and smoking during pregnancy also were significantly associated with both pregnancy outcomes in the multivariate logistic regression models examining dosage (data provided on request).

To further understand the relationship of the PCM dosage measure and each pregnancy outcome, the likelihood of having an adverse pregnancy outcome was regressed on each dimension of dosage (Table 3). High duration of enrollment (aOR = 0.32 (95% CI: 0.22–0.47), early PCM onset (aOR = 0.37 (95% CI: 0.26–0.52), and high amounts of contact time (aOR = 0.58 (95% CI: 0.37–0.89) were significantly associated with lower rates of LBW. Maternal medical conditions, parity, and smoking during pregnancy were significantly also associated with PTB in the multivariate logistic regression model examining dosage (data provided on request).

For PTB, both the duration of enrollment and PCM onset were significantly associated with the likelihood of having an adverse event. The aOR for high duration of enrollment was 0.19 (95% CI: 0.13–0.27); while the aORs for entry into PCM during the first and second trimester were 0.27 (95% CI: 0.20–0.3 and 0.75 (95% CI: 0.58–0.98), respectively. No significant association was found between the presence of health education, care coordination, or breadth of interventions with either pregnancy outcome.

Discussion

To our knowledge this is the first study to develop a population measure of PCM dosage and subsequently investigate the relationship between PCM dosage and birth outcomes. The likelihood of having a LBW or a PTB was reduced the most for women who received a high dosage of PCM, with a slightly lower reduction in likelihood for women who received medium dosage. These results suggest that information on PCM dosage may be essential to unraveling the inconsistent findings across studies that have examined the relation between PCM and pregnancy outcomes [6, 10]. The conceptual definition of dosage used in

Table 2 Descriptive statistics of maternal characteristics and PCM dosage by pregnancy outcome for Iowa's medicaid insured women who participated in PCM

Maternal characteristics	Total (n = 4,582) No. (%)	LBW (n = 303) No. (%)	*P*-value[1]	PTB (n = 425) No. (%)	*P*-value[2]
Age (year), mean (sd)	23.4 (5.1)	22.9 (4.8)	0.10	23.3 (5.1)	0.71
Education					
<High school	1,544 (33.7)	109 (36.0)	0.68	157 (36.9)	0.30
High school	1,845 (40.3)	117 (38.6)		166 (39.1)	
>High school	1,193 (26.0)	77 (25.4)		102 (24.0)	
Unmarried	3,129 (68.3)	227 (74.9)	0.01	301 (70.2)	0.24
Hispanic	877 (19.1)	45 (14.9)	0.05	74 (17.4)	0.34
Race					
Black	255 (5.6)	20 (6.6)	0.42	24 (5.7)	0.94
White	4,327 (94.4)	285 (93.4)		406 (94.4)	
Rural/urban residency					
Central city	1,736 (38.0)	108 (35.6)	0.62	152 (35.8)	0.74
MSA	896 (19.6)	57 (19.6)		82 (19.3)	
Rural adjacent urban	779 (17.0)	51 (16.8)		75 (17.7)	
Rural not adjacent urban	1,171 (25.6)	87 (28.7)		116 (27.3)	
Parity					
Nulliparous	2,364 (51.6)	180 (59.4)	<.01	215 (50.6)	0.28
Primiparous	1,097 (23.9)	68 (22.4)		99 (23.3)	
2	690 (15.1)	24 (7.9)		60 (14.1)	
≥3	431 (9.4)	31 (10.2)		51 (12.0)	
Smoking	1,273 (27.8)	110 (36.3)	<.001	143 (33.7)	<0.01
Medical conditions		95 (31.2)	<.001	129 (30.4)	<0.001
Adequacy of PNC entry					
Inadequate (>6 months)	122 (2.7)	11(3.6)	0.44	18 (4.2)	<0.01
Intermediate (5–6 months)	332 (7.2)	22 (7.3)		32 (7.5)	
Adequate (3–4 months)	1,914 (41.8)	116 (38.3)		145 (34.1)	
Adequate plus (1–2 months)	2,214 (48.3)	154 (50.8)		230 (54.1)	
PCM dosage					
Low	1,843 (40.2)	168 (55.5)	<.001	239 (56.2)	<.001
Medium	1,722 (37.6)	77 (25.4)		97 (22.8)	
High	1,017 (21.2)	58 (19.1)		89 (20.9)	
Duration of enrollment			<.001		<.001
Low (1–12 weeks)	698 (15.2)	68 (22.4)		105 (24.7)	
Medium (13–27 weeks)	2,204 (48.1)	183 (60.4)		267 (62.8)	
High (≥28 weeks)	1,680 (36.7)	52 (17.1)		53 (12.5)	
Amount of contact (hours)					
None (0)	2,816 (61.5)	197 (65.0)	0.25	269 (63.3)	0.47
Low (0.1–1)	635 (13.8)	40 (13.2)		50 (11.8)	
Medium (1.1–3.25)	595 (13.0)	41 (13.5)		60 (14.1)	
High (≥3.26)	536 (11.7)	25 (8.3)		46 (10.8)	
Breadth of interventions					
Low [1]	2,832 (61.8)	197 (65.0)	0.36	269 (63.3)	0.13
Medium [2]	677 (14.8)	37 (12.2)		49 (11.5)	
High [3]	1,073 (23.4)	69 (22.8)		107 (25.2)	
PCM onset					
1st Trimester	2,239 (48.9)	89 (29.4)	<.001	107 (25.2)	<.001
2nd Trimester	1,721 (37.6)	148 (48.8)		218 (51.3)	

Table 2 continued

Maternal characteristics	Total (n = 4,582) No. (%)	LBW (n = 303) No. (%)	*P*-value[1]	PTB (n = 425) No. (%)	*P*-value[2]
3rd Trimester	622 (13.6)	66 (21.8)		100 (23.5)	
Risk assessment	4,558 (99.5)	303 (100)	0.19	425 (100)	0.11
Health education	1,594 (34.8)	95 (31.4)	0.23	143 (33.7)	0.60
Care coordination	1,253 (27.4)	80 (26.4)	0.70	120 (28.2)	0.67

[1] Chi-square test comparing LBW to Non-LBW

[2] Chi-square test comparing PTB to Non-PTB

Table 3 Descriptive statistics of maternal characteristics and PCM dosage for Iowa's medicaid insured women who participated in PCM

Maternal characteristics	High (n = 1,017) %	Medium (n = 1,722) %	Low (n = 1,843) %	*P*-value[a] %
Age				
<18 years	6.6	5.8	8.1	.04
18–34 years	88.9	90.4	88.4	
>34 years	4.5	3.9	3.4	
Education				
<High school	34.8	32.6	34.1	0.79
High school	39.6	41.0	39.9	
>High school	25.6	26.4	25.9	
Unmarried	69.6	66.6	69.1	0.14
Hispanic	21.8	17.1	19.7	0.01
Race				
Black	6.0	5.6	5.3	0.75
White	94.0	94.4	94.7	
Rural/urban residency				
Central city	43.0	40.5	32.6	<.001
MSA	19.1	22.4	17.2	
Rural adjacent urban	16.2	15.0	19.3	
Rural not adjacent urban	21.7	22.0	31.0	
Parity				
Nulliparous	53.2	50.2	52.3	0.49
Primiparous	23.6	24.6	23.6	
2	14.8	16.0	14.3	
≥3	8.5	9.2	10.1	
Smoking	27.2	28.1	27.8	0.90
Medical conditions for LBW	18.8	16.1	17.4	0.21
Medical conditions for PTB	23.5	20.2	21.8	
Adequacy of PNC Entry				
Inadequate (>6 months)	1.5	2.0	3.9	<.001
Intermediate (5–6 months)	4.0	5.2	11.0	
Adequate (3–4 months)	40.0	42.0	42.5	
Adequate plus (1–2 months)	54.5	50.8	42.7	

[a] Chi-square test comparing high, medium, and low Dosage

this study was influenced by the data available, which limited our ability to capture women's full level of engagement. While examining participation in the context of after school programs, Roth et al. [34] identified five dimensions of participation which have relevance to dosage of community health programs, including PCM. The dimensions were: (1) intensity -frequency of attendance, (2) duration- years of attendance, (3) total participation-

Table 4 Multivariate logistic regression analysis of the relationship between prenatal case management (PCM) dosage and pregnancy outcomes among Iowa PCM participants

Model	Independent variables (n = 4,582)	Low birth weight aOR (95%CI)[a]	Preterm birth aOR (95%CI)[a]
Model 1	PCM Dosage		
	Low	Reference	Reference
	Medium	**0.47 (0.36–0.63)**	**0.40 (0.31–0.51)**
	High	**0.60 (0.44–0.82)**	**0.61 (0.47–0.80)**
Model 2	Duration of enrollment		
	Low (1–12 weeks)	Reference	Reference
	Medium (13–27 weeks)	0.89 (0.66–1.20)	0.81 (0.63–1.04)
	High (≥28 weeks)	**0.32 (0.22–0.46)**	**0.19 (0.13–0.27)**
Model 3	Amount of contact (hours)		
	None (0)	Reference	Reference
	Low (0.1–1)	0.90 (0.63–1.29)	0.81 (0.59–1.12)
	Medium (1.1–3.25)	1.01 (0.71–1.44)	1.09 (0.81–1.47)
	High (≥3.26)	**0.58 (0.39–0.92)**	0.78 (0.56–1.09)
Model 4	Breadth of interventions		
	Low [1]	Reference	Reference
	Medium [2]	0.78 (0.54–1.12)	**0.72 (0.52–0.99)**
	High [3]	0.90 (0.68–1.20)	1.02 (0.80–1.30)
Model 5	PCM onset		
	1st Trimester	**0.36 (0.26–0.51)**	**0.27 (0.20–0.37)**
	2nd Trimester	0.81 (0.60–1.11)	**0.76 (0.58–0.99)**
	3rd Trimester	Reference	Reference
Model 6	Health education	0.84 (0.65–1.08)	0.92 (0.74–1.14)
Model 7	Care coordination	0.93 (0.71–1.21)	1.02 (0.81–1.28)

Results given in bold are statistically significant

[a] The following confounding variables were included in each multivariate logistic regression model: maternal smoking, maternal age, maternal education, marital status, Hispanic ethnicity, maternal race, maternal medical conditions, and parity

frequency divided by duration, (4) breadth of types of activities/interventions, and (5) engagement or effort on the part of the students. The engagement or effort dimension would be essential to include in future definitions of dosage.

Most administrative datasets have no indicators of the level of interest pregnant women have in receiving PCM. A vicious cycle can occur in which a disinterested or unengaged woman acts in ways that lowers the frequency and length of case manager visits. A receptivity dimension of dosage would be important for uptake of the educational or care coordination interventions, leading to their contribution to improved birth outcomes. Gathering data on participants' level of interest and active participation is not easy, yet this information may be a missing link in understanding the reasons why the PCM interventions of health education and care coordination were not associated with the likelihood of an adverse pregnancy event occurring.

As resources in agencies become tighter, PCM providers may systematically reduce the outreach to enroll women and provide a wide breadth of interventions. One set of clinical trials of home visiting for pregnant women found that the number of visits was associated with better maternal outcomes [7, 35, 36]. Even in those venerable studies, no comparisons were made of randomized dosage of home visiting. In short, the "gold standard" of PCM dosage has not been definitively established, nor has a minimum threshold for dosage been set. Our findings suggest that a minimum threshold does exist and ought to be quantified for the distinct sub-groups who receive PCM.

The ACA title regarding home visiting for pregnant and early parenting mothers requires evaluation of PCM programs. The requirement for a rigorous evaluation gives this research immediate policy relevance at the state and federal levels. The most obvious implication is the need to have state and federal databases include data elements which capture more detailed information on what was done as interventions during the home visit. Currently, the administrative data only captures three out of the eight possible interventions known to be provided within PCM [4]. Without much effort, case managers could note the breadth of interventions provided during a PCM visit. At minimum, the measure of PCM dosage presented here can be used as a standard measure of intervention for comparing implementation of programs within or across states.

Research Implications

The receipt of health education or care coordination was not associated with a reduced likelihood of having a LBW

or PTB infant. Although no significant association was found, it does not mean neither intervention should be offered. These interventions may be associated with other more intermediate and proximal outcome (e.g., prenatal care utilization) that affect LBW and PTB [10, 37]. A theoretical base must be developed which establishes the hypothesized mechanisms by which the interventions, separately and synergistically, might influence each key maternal and birth outcome [11]. Basing future studies on a sound theoretical base has the advantage of better guiding the design of prospective studies.

Very little research has explored the concept of engagement in the area of PCM. One such study examining engagement in PCM among 125 women found that these women enrolled in PCM for greatly varied reasons [38], such as for job training referrals, social support, prenatal nutritional and health information, education on how to take care of a baby postpartum, and transportation to doctors appointments. More research needs to be conducted in order to understand the mechanisms that promote or inhibit early engagement by women who are referred to PCM.

It is tempting to call for randomized trials which would tease out the relationships between different levels of dosage and different birth outcomes. The caveats to such a call would be whether such studies are ethical or even feasible. Unlike a medication or medical treatment which can be studied for efficacy, PCM as a community-based program which is comprised of a set of individually tailored interventions is not amenable to efficacy trials. These caveats do not preclude the need for more carefully monitored implementation studies [11] with refined and conceptually developed sets of variables about the PCM participants, the case managers, and the program protocols.

Practice Implications

Given that PCM dosage is important, greater efforts need to be devoted to enrolling women early in their pregnancy in order for women have time to receive sufficient breadth of interventions and contact time with case managers before the birth. Health professionals also need to ensure that PCM participants stay engaged with PCM throughout their pregnancy. This suggestion is based on the finding that PCM participants with high amounts of contact time were less likely to have a LWB infant compared to PCM participants who had no recorded time for both health education and care coordination.

Study Limitations

Although this study employed rigorous methods, limitations should be acknowledged. Some limitations stem from using secondary data. The Medicaid Claims and WHIS risk assessment only contained data on interventions billable to Medicaid or that were required by the state to be reported. Any time spent between a woman and case manager which was not billed was not captured. This may have resulted in an underestimation of breadth of interventions and the amount of time spent with a case manager, possibly resulting in non-differential misclassification of the exposure. Data quality and registration completeness are concerns when using vital record data [39]. Both medical and pregnancy complications may also be underreported on birth certificates. Data linkage across three sources (Medicaid Claims, birth certificates, and WHIS risk assessment database) could have contributed to loss of women in the sample, and especially the loss of women with low dosage PCM.

The generalizability of the study findings is limited to Iowa PCM participants with WHIS risk assessment files. Nonetheless, the sample size and representativeness of the women with Medicaid Claims files suggests that the findings may be generalizable to Medicaid-insured pregnant women.

Although this study controlled for potential confounders, hidden selection bias from unobserved and non-measured characteristics may still be present. A wider range of factors might have influenced the dosage level than were detectable in the available data. For example, no data were available on characteristics of the case manager which might have affected the woman's receptivity to interventions offered. Similarly, no data were available on program site specific protocols which might have influenced the case manager's efforts to engage and retain the women in PCM.

Conclusion

PCM programs have been providing services intended to improve the pregnancy outcomes of socially and/or medically high risk women. Medicaid-insured women enrolled who entered Iowa's PCM program during their first trimester were approximately two-thirds less likely to have a LBW or PTB infant. For PTB, women who entered PCM during their second trimester still had a significant advantage over women who entered PCM during their third trimester. Understanding how the dose of PCM is associated with improved pregnancy outcomes is important for enabling PCM program providers to exhibit the value of the interventions that are packaged within the program [40, 41].

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