Chapter 8 What is the Role of Prenatal Care in Reducing Racial and Ethnic Disparities in Pregnancy Outcomes?

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After a comprehensive review of the literature on the value of prenatal care, the committee concluded that the overwhelming weight of the evidence is that prenatal care reduces low birthweight. This finding is strong enough to support a broad, national commitment to ensuring that all pregnant women in the United States, especially those at medical or socioeconomic risk, receive high-quality prenatal care.

Institute of Medicine (IOM), Preventing Low Birthweight (1985b, pp. 18-19)

According to the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG), comprehensive prenatal care "involves a coordinated approach to medical care and psychosocial support that optimally begins before conception and extends throughout the antepartum period" (AAP/ACOG, 2007, p. 83). It consists of a series of clinical visits and ancillary services designed to promote the health and well-being of the mother, fetus, and family. Its three major components, as defined by the US Public Health Service Expert Panel on the Content of Prenatal Care [US Department of Health and Human Services (USDHHS), 1989] include: (1) early and continuing risk assessment; (2) health promotion; and, (3) medical and psychosocial interventions and follow-up.

Prenatal care has been offered to pregnant women in the U.S. for nearly 100 years, beginning with Mrs. William Lowell Putnam making home visits to pregnant women registered at the Boston Lying-In Hospital in 1909 (Alexander & Kotelchuck, 2001). Maternal morbidity and mortality, particularly related to complications of preeclampsia and eclampsia, were among the earliest targets of prenatal care. During the 1900s, support grew for the hypothesis that prenatal care could reduce the risk of infant mortality from LBW and preterm birth. In 1915, J. Withridge Williams of the Johns Hopkins Hospital, in championing the potential benefits of prenatal care, asserted that "prenatal care and instruction offer great possibilities for the diminution in the number of deaths [due to prematurity]" (p. 99). In 1947, Eastman described a marked reduction in risk for low birthweight among mothers who received "adequate care" (3+ visits, p. 347).

Several studies (Eisner, Brazie, Pratt, & Hexter, 1979; Greenberg, 1983; Taffel, 1978) published in the 1970s and early 1980s found a significant association between no prenatal care and the incidence of LBW, although none of these studies controlled for possible gestational age bias. In 1973,

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Kessner, Singer, Kalk, and Schlesinger demonstrated a systematic relationship between categories of adequate prenatal care utilization and LBW, developing the first prenatal care index. When Gortmaker reanalyzed the same data in 1979 using a modified Kessner Index, he found that the percentage of LBW births decreased with increasing adequacy of prenatal care use and that the relationship between prenatal care and infant mortality was attributed to the impact of prenatal care on LBW. Citing these and several other studies, the 1985 IOM report, *Preventing Low Birthweight*, concluded that the "overwhelming weight of the evidence is that prenatal care reduces low birthweight" (IOM, 1985b, p. 18).

Soon thereafter, in the mid- and late 1980s, the U.S. Congress enacted a series of legislative initiatives that incrementally expanded Medicaid eligibility to low-income pregnant women and children, independent of their welfare status (Hill, 1992). Many states followed by further expanding Medicaid eligibility and streamlining the process of enrollment into prenatal care. Arguments for expanding access to prenatal care were buttressed by cost-effectiveness analyses (IOM, 1985a) that suggested savings could be achieved by reducing LBW, although the cost-savings may have been overstated (Huntington & Connell, 1994). In 1986, the US Public Health Service assembled an expert panel to assess the content of prenatal care, which published its landmark report in 1989 (USDHHS, 1989). Following the report, several states expended considerable effort to enhance the content of prenatal care, motivated in part by the expectation that increases in early initiation and adequate utilization of high-quality prenatal care would lower the risk of LBW and, as a result, reduce infant mortality rates.

Partly as a result of these national and state policies, the use of early and adequate prenatal care has increased substantially over the past decade (Kogan et al., 1998; Martin et al., 2002, 2007). This increase, however, has not led to a significant decline in LBW and preterm births, as shown in Table 8.1.

While changes in maternal demographics, increases in multiple gestation, and advances in medical technology may have contributed to the rise in LBW (Alexander & Slay, 2002), some have begun to question the effectiveness of prenatal care in preventing LBW. As early as 1962, Schwartz suggested that gestational age may well be confounding the association between LBW and the trimester in which prenatal care began or the number of prenatal care visits. Terris and Glasser concluded from their life table analysis in 1974 that "early birth prevents the initiation of prenatal care instead of vice versa" (p. 870). Although the Kessner Index adjusts for gestational age at delivery, it fails to accurately reflect AAP-ACOG recommendations regarding the number of visits for "adequate" care, resulting in residual gestational age bias. Indeed, when other indices (Alexander & Kotelchuck, 1996; Kotelchuck, 1994) that better account for gestational age bias are used, the incremental relationship between less adequate use of prenatal care and LBW traditionally observed when using the Kessner Index disappears (Alexander & Kotelchuck, 2001).

Another important limitation of most observational studies examining the effectiveness of prenatal care has been their failure to adequately control for critical confounders and selection bias (Lu, Tache, Alexander, Kotelchuck, & Halfon, 2003). Women who seek prenatal care early may differ from those who seek prenatal care late or not at all. Similarly, women who attend all of their prenatal appointments may differ in many ways from those who miss most of their prenatal visits. Women who seek prenatal care early and attend all their prenatal appointments may be more likely to engage in other advantageous health-care-seeking and health-promoting behaviors, including planning their pregnancies, obtaining preconception and interconception care, maintaining a healthy diet, and abstaining from the use of tobacco, alcohol, and other drugs. They may also command more resources that promote good health before and during pregnancy. Because these advantageous behaviors and resources may contribute to reducing their risk of LBW deliveries, the adequacy of their prenatal care utilization could be conceptualized as a proxy indicator for a myriad of health-enhancing maternal behaviors and resources, rather than having a direct cause-effect relationship with LBW.

Randomization can help avoid some of the problems associated with potential confounding and selection bias. For ethical considerations, no study has examined the effectiveness of prenatal care

Vear									
Vear	First trimester prenate	er prenatal care (%)		Low birth weight (%)	eight (%)		Preterm births (%)	IS (%)	
TCal	All races	Non-Hispanic white	Non-Hispanic black	All races	Non-Hispanic white	Non-Hispanic black	All races	Non-Hispanic white	Non-Hispanic black
1990	75.8	83.3	61.0	7.0	5.6	13.3	10.6	8.5	18.9
1991	76.2	83.7	61.9	7.1	5.7	13.6	10.8	8.7	19.0
1992	T.T.	84.9	64.0	7.1	5.7	13.4	10.7	8.7	18.5
1993	78.9	85.6	66.1	7.2	5.9	13.4	11.0	9.1	18.6
1994	80.2	86.5	68.3	7.3	6.1	13.3	11.0	9.3	18.2
1995	81.3	87.1	70.6	7.3	6.2	13.2	11.0	9.4	17.8
1996	81.9	87.4	71.5	7.4	6.4	13.1	11.0	9.5	17.5
1997	82.5	87.9	72.3	7.5	6.5	13.1	11.4	9.6	17.6
1998	82.8	87.9	73.3	7.6	6.6	13.2	11.6	10.2	17.6
1999	83.2	88.4	74.1	7.6	6.6	13.2	11.8	10.5	17.6
2000	83.2	88.6	74.3	7.6	6.6	13.1	11.6	10.4	17.4
2001	83.3	88.6	74.5	<i>T.T</i>	6.8	13.1	11.9	10.8	17.6
2002	83.7	88.7	75.3	7.8	6.9	13.4	12.1	11.0	17.7
2003	84.0	89.1	76.2	7.9	7.0	13.6	12.3	11.3	17.8
2004	84.2	89.0	76.3	8.1	7.2	13.7	12.5	11.5	17.9
2005	83.9	88.7	76.5	8.2	7.3	14.0	12.7	11.7	18.4
Source: Mi Reports, 56 Martin, J. / 1–101. Hys Martin, J. / 1–116. Hya	Source: Martin, J. A., Hamilton, F <i>Reports, 56</i> (6), 1–103. Hyattsville Martin, J. A., Hamilton, B. E., Sui 1–101. Hyattsville, MD: National Martin, J. A., Hamilton, B. E., Sut 1–116. Hvattsville, MD: National	milton, B. E., Sutt yattsville, MD: Na 3. E., Sutton, P. D. National Center foi 3. E., Sutton, P. D., Vational Center foi	Source: Martin, J. A., Hamilton, B. E., Sutton, P. D., Ventura, S. J., Menacka <i>Reports</i> , 56(6), 1–103. Hyattsville, MD: National Center for Health Statistics Martin, J. A., Hamilton, B. E., Sutton, P. D., Ventura, S. J., Menacker, F., Kiu 1–101. Hyattsville, MD: National Center for Health Statistics Martin, J. A., Hamilton, B. E., Sutton, P. D., Ventura, S. J., Menacker, F., Mur Martin, J. A., Hamilton, B. E., Sutton, P. D., Ventura, S. J., Menacker, F., Mur 1–116. Hyattsville, MD: National Center for Health Statistics	, S. J., Menack Health Statistics fenacker, F., Ki macker, F., Mu	er, F, Kirmeyer, S s rmeyer, S. (2006). nson, M. L. (2005)	, et al. (2007). B Births: Final data Births: Final data	irths: Final dat a for 2004. <i>Nat</i> a for 2003. <i>Nat</i>	Source: Martin, J. A., Hamilton, B. E., Sutton, P. D., Ventura, S. J., Menacker, F., Kirmeyer, S., et al. (2007). Births: Final data for 2005. <i>National Vital Statistics Reports</i> , 56(6), 1–103. Hyattsville, MD: National Center for Health Statistics Martin, J. A., Hamilton. B. E., Sutton, P. D., Ventura, S. J., Menacker, F., Kirmeyer, S. (2006). Births: Final data for 2004. <i>National Vital Statistics Reports</i> , 55(1), 1–101. Hyattsville, MD: National Center for Health Statistics Martin, J. A., Hamilton, B. E., Sutton, P. D., Ventura, S. J., Menacker, F., Kirmeyer, S. (2006). Births: Final data for 2004. <i>National Vital Statistics Reports</i> , 55(1), 1–101. Hyattsville, MD: National Center for Health Statistics Martin, J. A., Hamilton, B. E., Sutton, P. D., Ventura, S. J., Menacker, F., Munson, M. L. (2005). Births: Final data for 2003. <i>National Vital Statistics Reports</i> , 54(2), 1–116. Hyattsville. MD: National Vital Statistics	ıl Vital Statistics s Reports, 55(1), s Reports, 54(2),

by randomizing pregnant women to receiving prenatal care vs. no prenatal care. Several studies have randomized pregnant women to more vs. fewer visits and found no significant difference in birth outcomes (Villar, Carroli, Khan-Neelofur, Piaggio, & Gülmezoglu, 2002). A number of studies have randomized pregnant women to receiving standard vs. enhanced prenatal care with added components, such as preterm birth education. A systematic review by Fiscella in 1995 failed to demonstrate the effectiveness of these enhanced prenatal care programs in preventing preterm birth or LBW.

Both the 1995 Fiscella review and an additional 1995 review (Alexander & Korenbrot) raised other concerns regarding the validity of the evidence used to support the effectiveness of prenatal care. Citing problems with inconsistent results, insufficient adjustment for prematurity bias, and inadequate control for the effect of critical confounders and potential selection bias in earlier studies, Fiscella concluded that "current evidence does not satisfy the criteria necessary to establish that prenatal care definitely improves birth outcomes" (1995, p. 475). Alexander and Korenbrot (1995) also concluded from their systematic review that "[t]here is little done during the standard prenatal care visit that could be expected to reduce low birth weight" (p. 113), although they found prenatal care to have a positive effect on LBW at term. In a more recent review of the *content* of prenatal care in 2003, Lu et al. concluded that neither preterm birth nor intrauterine growth restriction (IUGR) – the twin constituents of LBW – can be effectively prevented by prenatal care in its present form.

Thus two decades following the 1985 IOM report, the effectiveness of prenatal care in preventing LBW remains a subject of great controversy. Furthermore, the claim that increasing access to and utilization of prenatal care can help reduce racial-ethnic disparities in LBW and related outcomes has yet to be validated. The primary aim of this chapter is to review the evidence of the effectiveness of prenatal care in preventing LBW, with an emphasis on its effectiveness in reducing racial-ethnic disparities in LBW.

Methods

Independent literature searches were conducted by two co-authors (HH and ST) to gather evidence on the effectiveness of prenatal care in preventing LBW. Since Fiscella (1995) had previously conducted an excellent systematic review of the literature between 1966 and 1994, we focused our review on studies published between January 1995 and August 2006. Studies were retrieved during July–August 2006 from PubMed and MDConsult using the search terms "prenatal care," "prenatal care adequacy," "prenatal care utilization," "enhanced prenatal care," "randomized," "low birth weight," and "preterm birth." In a second search, the references of retrieved articles were hand-searched for relevant studies (i.e., the snowball technique). No search software was used, no efforts were made to identify unpublished studies, and no contacts were made with the authors.

The intervention was defined broadly as prenatal care utilization; we did not review evidence of the effectiveness of any specific components of prenatal care. The studies fell into two broad categories: utilization studies and enhanced studies. Utilization studies are typically cohort or case-control (observational) studies aimed to establish whether adequate prenatal care is associated with better outcomes than inadequate care. Enhanced care studies as defined in this chapter are randomized controlled trials designed to determine if enhanced prenatal care provided to women at high risk produces better pregnancy outcomes than standard prenatal care. We excluded a third category of studies which use ecological designs to examine whether a change in availability of prenatal care affects population birth outcome statistics because such studies while producing results at the population level do not allow conclusions at the individual level. We focused on LBW, defined as birthweight of less than 2,500 g, or related outcomes including: preterm delivery (PTD, delivery before 37 completed weeks' gestation), intrauterine growth restriction (IUGR, defined as birthweight below the tenth percentile in most studies), small-forgestational age (SGA), very LBW (VLBW, birthweight less than 1,500 g), and very PTD (VPTD, delivery before 32 completed weeks' gestation). These birth outcomes were included in the review because they are related to LBW. Specifically, PTD and IUGR, two outcomes with overlapping but also divergent pathways, are two causes of LBW. Although the pathway for SGA is undefined in most studies, IUGR is one of several causes of SGA. VLBW and VPTD are subsets of LBW and PTD, respectively. Lastly, studies that treated birthweight and/or gestational age as continuous outcomes were also included.

Specific inclusion and exclusion criteria were established prior to the literature searches, modeled after the criteria used in the 1995 Fiscella study. Utilization studies were included if they statistically adjusted for potential confounders and used an adjustment factor for prenatal visits relative to gestational age (e.g., the Kessner Index, the Kotelchuck Index, R-Gindex, or a comparable factor) (Alexander & Kotelchuck, 1996; Kessner et al., 1973; Kotelchuck, 1994). Studies not primarily designed to assess the effects of prenatal care were included if they met all the aforementioned criteria. Studies were excluded if prenatal care was treated as a categorical variable (presence vs. absence of prenatal care). Enhanced care studies were included if the subjects were randomly assigned to either standard or enhanced prenatal care. Randomized controlled trials were excluded if there was evidence of contamination of treatment and control groups. Studies were excluded if LBW or a related outcome (VLBW, PTD, VPTD, IUGR, SGA) was not reported as a study outcome. Studies were also excluded if they were published solely in a foreign language or conducted outside of the U.S., since the experiences of racial-ethnic groups in the U.S. may differ from those of the same racial-ethnic groups living outside of the U.S. We searched all included studies for data related to racial-ethnic disparities in LBW.

Results

Our search identified 31 studies published between January 1995 and August 2006 that examined the basic relationship between prenatal care and LBW. Seven studies met both our inclusion and exclusion criteria: two utilization studies (Collins, Herman, & David, 1997; Krueger & Scholl, 2000) and five enhanced care studies (Brooten et al., 2001; Kitzman et al., 1997; Klerman et al., 2001; Little, Saul, Testa, & Gaziano, 2002; Moore et al., 1998). In Table 8.2, the utilization studies from this review have been added to those from the Fiscella review (Gortmaker, 1979; Kogan, Alexander, Kotelchuck, & Nagey, 1994; Malloy, Kao, & Lee, 1992; Murray & Bernfield, 1988; Mustard & Roos, 1994; Parker, McFarlane, & Soeken, 1994; Quick, Greenlick, & Roghmann, 1981; Raine, Powell, & Krohn, 1994; Scholl, Miller, Salmon, Cofsky, & Shearer, 1987; Schramm, 1992; Shiono, Kebanoff, Graubard, Berendes, & Rhoads, 1986; Showstack, Budetti, & Minkler, 1984; Terris & Glasser, 1974; Tyson et al., 1990). In Table 8.3, the enhanced care studies from this review have been added to those from the Fiscella review (Bryce, Stanley, & Garner, 1991; Collaborative Group on Preterm Birth Prevention, 1993; Goldenberg et al., 1990; Graham, Frank, Zyzanski, Kitson, & Reeb, 1992; Heins, Nance, McCathy, & Efird, 1990; Main, Gabbe, Richardson, & Strong, 1985; Main, Richardson, Hadley, & Gabbe, 1989; McLaughlin et al., 1992; Olds, Henderson, Tatelbaum, & Chamberlain, 1986; Spencer, Thomas, & Morris, 1989; Villar et al., 1992).

Table 8.4 lists all the excluded studies (Armson, Dodds, Haliburton, Cervin, & Rinaldo, 2003; Barnet, Duggan, & Devoe, 2003; Barros, Tavares, & Rodrigues, 1996; Binstock & Wolde-Tsadik, 1995; Blanchette, 1995; Boss & Timbrook, 2001; Dyson et al., 1998; Edwards et al., 1995; Gómez-Olmedo, Delgado-Rodriguez, Bueno-Cavanillas, Molina-Font, & Gálvez-Vargas, 1996; Helfand & Zimmer-Gembeck, 1997; Herman et al., 1996; Homan & Korenbrot, 1998; Hueston, 1995;

Table 8.2 Observations	Observational studies on the effect of pre-	of prenatal care on birth outcomes				
- - -	Populations studied/	Adjustment for potential		Key findings related to intervention	Address	Findings support the intervention? For which
Authors (year)	sample size	contounders	Outcome measures	effectiveness	disparities	populations?
Terris and Glasser (1974) ^a	NYC, 1991, black birth certificates/34,949	Age, parity, married, hospital, infant sex	% LBW vs. NBW	NS, 9.6 vs. 11.0% ^b	Yes	No Blacks
Gortmaker (1979) ^a	NYC, 1968, birth certificates/90,339	Age, education, parity, married, medical or	Odds ratio	0.71° (White), 0.56° (Black)	Yes	Yes
	~	OB risk, hospital	LBW	NS, 0.94 ^b (White), 0.83 ^c		Whites, Blacks
			Neonatal mortality	(Black) (Protective OR calculated by chapter authors)		
Quick et al. (1981) ^a	Portland, OR, 1973, white birth and death certificates/23,264	Age, education, HMO provider, birth order, married, medical risk	Improvement in mean birth weight	160 g ^c	No	Yes Whites
Showstack et al. (1984) ^a	CA, 1978, birth certificates/18,470	Age, race, education, multiple gestation, medical risk, hospital	Improvement in mean birth weight	207 g ^d	No	Yes
Shiono et al. (1986) ^a	Kaiser Birth Defects Study, 1974– 1977/29,415	Age, race, education, married, employed, infant sex, parity, OB history, smoking, alcohol	Improvement in mean birth weight	29 g ^c	No	Yes
Scholl et al. (1987) ^a	Adolescent Program	Age, race, parity, insurance,	Odds ratio		No	No (LBW)
	data 1983–1984/757	medical risk, alcohol, smoking	LBW	NS, 1.35 ^b (0.41–4.44) 0.34 ^e (0.15–0.73)		Yes (PTB)
			Preterm delivery			
Murray and Bernfield	CA, 1978, birth	Age, education	Odds ratio	0.29 ^d (Black), 0.62 ^d	Yes	Yes
$(1988)^{2}$	certificates/31,000	A and another advantations	LBW Odds motio	(white)	N.C.	Whites, Blacks
Iyson et al. (1990)	HOSPILAL DALA	Age, race, education,	Odds rano		INO	[NO
	1977–1980/28,838	married, education, multiple gestation,	Short gestation	NS ^b for any cohort 0.80 ^c , 38 weeks cohort		
		OB history	SGA Stillbirth	0.67°, 42 weeks cohort 0.68°, 34 weeks cohort 0.23°, 42 weeks cohort		
			Infant death			
Schramm (1992) ^a	Birth certificates, Medicaid claims data 1988/12.023	Age, race, education, birth order, married, smoking	Relative risk LBW VI RW	0.63° 0.66°	No	Yes
			VLDW	00:0		

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Yes Yes	No	Yes	No Whites	LBW declines w/ increasing PNC, but PNC does not eliminate disparities in LBW (continued)
No No	No	No	No	Yes
Reduced only among term infants ^f 0.48° (0.39–0.59)	NS, 1.1 ^b (0.9–1.1)	58 86 1	NS, 0.77 ^b (0.5–1.11)	 4.8 (3.4–3.8) (Black vs. Mexican American) 2.0 (1.5–2.7) (Black vs. White) 3.8 (2.5–5.9) (Black vs. Mexican American) 2.5 (1.8–3.5) (Black vs. White)
% Mortality (stillbirth or infant death) Odds ratio LBW	Relative risk LBW	Improvement in mean birth weight	Relative risk LBW	Odds ratio LBW, with inadequate PNC LBW, with adequate PNC
Birth or death certificates, Age, race, education, parity, 1980–1984/374,244 multiple gestation National Maternal and Age, race, parity, married, Infant Health Survey, employed, income, site 0988/9,394 of care, OB history, hypertension, smoking, received recommended advice	Age, married, education, parity, OB history, weight gain, interpregnancy interval, battering, infection, bleeding in first or second trimester, anemia, smoking, alcohol and drug use	Age, married, income, parity, native, OB history, smoking, prenatal education, pregnancy complication	Age, married, prior LBW birth, prior miscarriage, smoking, interprevnancy interval	Ethnicity, income
Birth or death certificates, 1980–1984/374,244 National Maternal and Infant Health Survey, 1988/9,394	Medical record retrospective review, 1990–1993/1,203	Winnipeg hospital records 1987– 1988/12,646	WA, white women with two births, 1984– 1990/3,334	Chicago, IL, Birth files, 1982–1983/81,427
Malloy et al. (1992) ^a Kogan et al. (1994) ^a	Parker et al. (1994) ^a	Mustard and Roos (1994) ^a	Raine et al. (1994) ^a	Collins et al. (1997)

	Populations studied/	Adjustment for potential		Key findings related to intervention	Address	Findings support the intervention? For which
Authors (year)	sample size	confounders	Outcome measures	effectiveness	disparities	populations?
Krueger and Scholl (2000)	NJ, Camden Study, 1985–1995/1,771	Krueger and SchollNJ, Camden Study, (2000)Age, parity, ethnicity, pregravid body massOdds Ratio (intermediate/ adequate vs. adequate vs. index, inadequate adequate vs. index, inadequate gestation, cigarettesOdds Ratio (intermediate/ intermediate/ 1.46° (1.00-2.12) (Kessner, 1973) (Kessner, 1973) 2.10 (1.58-2.81) 	Odds Ratio (intermediate/ adequate vs. inadequate) LBW Preterm delivery	1.46 ^b (1.00–2.12) (Kessner, 1973) 1.14 ^b (0.80–1.62) (Kotelchuck, 1994) 2.80 (2.07–3.78) (Kessner, 1973) 2.10 (1.58–2.81) (Kotelchuck, 1994)	No	Yes, for PTD delivery

LBW low birth weight; NBW normal birth weight; NS not significant; OB obstetric; SGA small for gestational age; HMO health maintenance organization; BMI body mass index; WIC women, infant, and children; PNC prenatal care; PTD preterm delivery

^a Studies included in Fiscella (1995)

Risk ratios for inadequate care have been inverted to risk rates for adequate care to facilitate comparison:

 $^{b}p > 0.05$

 ${}^{\circ}_{p} < 0.01$ ${}^{d}_{p} < 0.001$ ${}^{\circ}_{p} < 0.05$ ${}^{f}_{p} < 0.001$

Table 8.2 (continued)

Table 8.3 Rande	Table 8.3 Randomized controlled trials of enhanced prenatal care (studies are listed within enhancement type)	ced prenatal care (studies are l	sted within enhanceme	int type)		
Primary author	Sample description (group sizes)	Intervention	Outcome measure	Results	Caveats/biases	Supports intervention? For which populations?
Main (1985) ^a	Black, high risk (treatment: 64, control: 68)	Preterm birth prevention: weekly/biweekly visits and cervical examinations, education, hot line	Mean birth weight Mean GA % Preterm births	NS NS NS	Inadequate sample size	No
Main (1989) ^a	Indigent, black, high risk (treatment: 198, control: 178)	Preterm birth prevention, weekly or biweekly visits and cervical exams, education	Mean GA Mean birth weight % Preterm births	NS NS NS	90% Power to detect 50% reduction in preterm delivery	No
Goldenberg (1990) ^a	Predominantly black, indigent, high risk, (treatment: 474, control: 463)	Preterm birth prevention, weekly visits and cervical exams, educatior	% Preterm births % LBW	NS NS	Trend toward worse outcomes among treatment group	No
Collaborative Group (1993) ^a	Predominantly black, high risk (multicenter) (treatment: 1,200, control: 1,195)	Preterm birth prevention, weekly or biweekly visits, cervical exams, education	% Preterm births % LBW % VLBW	NS NS NS	Investigators disagreed about reasons for negative results	No
Heins (1990) ^a	High risk (treatment: 667, control 679)	Comprehensive care assessment and case management, weekly visits, education, follow up	% LBW	NS	90% Power to detect 38% reduction in LBW	No
McLaughlin (1992)ª	Indigent, less than 28 weeks' gestation (treatment: 217, control 211)	Comprehensive care, multidisciplinary team approach, education, psychosocial support, follow up	% LBW	NS	Possible benefit for primiparous women (p < 0.05); higher dropout rate in control group (13 vs. 8%)	No
Klerman (2001)	African-American, high risk (treatment: 318, control: 301)	Comprehensive care, multidisciplinary team, psychosocial support, education, smoking cessation, additional appointments	Mean birth weight Mean GA IUGR % Preterm birth	NS NS NS NS	Positive trends for intervention in outcome variables; Small sample size; Exclusion of women with high risk medical conditions	Ŷ

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	Sample description (group					Supports intervention?
Primary author	sizes)	Intervention	Outcome measure	Results	Caveats/biases	For which populations?
Moore (1998)	African-American, white or "other" ethnicity, high risk	Telephone intervention by registered nurses	Mean weight Mean GA & I RW	NS NS NS	1,573 women excluded because they could	Total sample showed no treatment effect on
	white, control: 556 AA, 159 white)		% Preterm	SN	not be contacted by telephone	outconnes. orreatest statistical significance in subgroup of AA women age 19 and older
Little (2002)	Predominantly African- American, Hispanic, high risk (treatment: 61, control: 50)	Telephonic nursing care and education	Mean gestation age Mean birthweight	NS SS SS	Small sample size	No significant difference in mean gestational age. Increased mean birth weight in treatment group
Olds (1986) ^a	White, high risk (treatment: 189, control: 165)	Home visitation by trained nurses	% LBW % Preterm births Mean birth weight	NS NS NS		Potential reduction in LBW and preterm birth in women ages 14–16
Spencer (1989) ^a	British, high risk (treatment: 271, control: 633)	Home visitation by trained lay workers	% LBW % Preterm birth % SGA	NS NS NS	Failed to analyze results by intention to treat	No
Bryce (1991) ^a	Australian, high risk (treatment: Home visitation by 983, trained midwive control: 987) and telephone c	: Home visitation by trained midwives and telephone calls	% Preterm birth	SN	Analyzed by intention to treat	No overall effect of social support. Significant reduction in preterm birth in higher social class. Potential benefit for women with multiple gestations or prior preterm birth
Graham (1992)ª	Black, high risk (treatment: 87, control: 58)	Home visitation byblack paraprofessionals	% LBW	NS	Inadequate sample size, failed to analyze results by intention to treat	No

No	No Other beneficial effects noted, but did not reduce LBW or preterm birth	Treatment statistically significant for twin pregnancies for both PTD and LBW. Mean birth weight was greater in treatment group in preterm infant	BW very low birth weight
80% Power to detect 6% reduction in LBW	High risk medical conditions excluded	Small sample size	A small for gestational age; VL
NS NS	NS NS NS NS NS NS	NS NS NS SS S	nal age; SG
% LBW % Preterm births	Mean birth weight Mean GA % LBW % IUGR % Preterm births	<i>Preterm infant:</i> Mean GA Mean birth weight <i>Term infant:</i> Mean GA Mean birth weight <i>Twin infants:</i> No. preterm Mean GA Mean birth weight	th weight; GA gestatio
Home visitation by trained social workers	Home visitation by trained nurses	Home visitation by trained nurses, telephone outreach, postpartum visits	ificant, $p > 0.05$; LBW low bir
Latin American, high risk (mulitcenter) (treatment: 1.115. control: 1.120)	African-American, Iow income (treatment: 458, control: 681)	Predominantly African- American, high risk (treatment: 85 women, 95 infants, control: 88 women, 100 infants)	"Studies included in Fiscella (1995) NS not statistically significant; SS statistically significant, p > 0.05; LBW low birth weight; GA gestational age; SGA small for gestational age; VLBW very low birth weight
Villar (1992) ^a	Kitzman (1997)	Brooten (2001)	^a Studies included <i>NS</i> not statisticall

Hueston, Gilbert, Davis, & Sturgill, 2003; Ickovics et al., 2003; Jackson et al., 2003; Laditka, Laditka, Mastanduno, Lauria, & Foster, 2005; Lazariu-Bauer, Stratton, Pruzek, & Woelfel, 2004; McDuffie, Beck, Bischoff, Cross, & Orleans, 1996; Mvula & Miller, 1998; Partridge & Holman, 2005; Perkocha, Novotny, Bradley, & Swanson, 1995; Quinlivan & Evans, 2004; Reichman & Teitler, 2005; Sánchez-Nuncio, Pérez-Toga, Pérez-Rodriguez, & Vázquez-Nava, 2005; Tasnim, Mahmud, & Arif, 2005; Taylor, Alexander, & Hepworth, 2005; Vintzileos, Ananth, Smulian, & Scorza, 2003; Vintzileos, Ananth, Smulian, Scorza, & Knuppel, 2002; Visintainer et al., 2000; Zotti & Zahner, 1995) and rationale for exclusion. Table 8.5 presents quality ratings for the seven reviewed studies based on the Quality Checklist for RCTs and Observational Studies of Treatment Studies (see Chap. 2). Below we summarize the design and findings of each of the seven included studies.

Utilization Studies

Our search identified two prenatal care utilization studies (Collins, Herman, & David, 1997; Krueger & Scholl, 2000) that fit our inclusion/exclusion criteria since the last major review by Fiscella (1995). The characteristics and outcomes of the two included utilization studies are summarized in Table 8.2.

Collins et al. (1997) conducted a retrospective cohort study using 1982–1983 Chicago birth files to examine the relationship between prenatal care utilization, maternal ethnicity, and LBW. Of the 81,427 singleton birth files, 54% were African-American, 13% Mexican-American, and 34% white. Income data were obtained by linking birth files to census tract information. Prenatal care utilization was classified using the Kotelchuck Adequacy of Prenatal Care Utilization Index. The study found that adequacy of prenatal care utilization varied by race and place of residence. The African-American birthweight disadvantage persisted even among infants born to mothers in moderateincome areas (median family annual income of \$20,001-\$30,000) who received adequate and adequate-plus prenatal care. Similarly, although race-specific term (gestational age >37 weeks) LBW rates declined as prenatal care usage rose, the position of African-Americans relative to Mexican-Americans and whites was essentially unchanged. For example, among mothers with inadequate prenatal care residing in low-income areas, African-Americans had a 4.8 (95% CI 3.4, 3.8) times greater risk of LBW than Mexican-Americans and a 2.0 (95% CI 1.5, 2.7) times greater risk than whites. Among mothers with adequate prenatal care residing in low-income areas, African-Americans had a 3.8 (95% CI 2.5, 5.9) times greater risk of LBW than whites and a 2.5 (95% CI 1.8–3.5) times greater risk than Mexican-Americans. The authors concluded that maternal race or some factor closely related to it affects pregnancy outcome regardless of the adequacy of prenatal care utilization.

Krueger and Scholl (2000) conducted a retrospective cohort study in Camden, New Jersey to examine the association between prenatal care utilization and preterm birth. The study analyzed data from 1,771 pregnant women enrolled in a study of maternal growth among young gravidas. The study population included approximately 58% African-American, 33% Hispanic and 9% white women. Women were excluded from the study if they had serious medical complications. Prenatal care utilization was classified using both the Kessner and the Kotelchuck indices. PTD was measured using both the last menstrual period and the obstetric estimate for length of gestation. Logistic regression was used to control for potential confounding variables including black ethnicity, maternal age, pregravid body mass index, parity, inadequate weight gain for length of gestation, smoking, and previous delivery of low birth weight or preterm infant. The analysis compared women receiving inadequate care to women receiving adequate or intermediate care, instead of comparing each prenatal care utilization level separately. The study found that women who received inadequate care were at greater risk of having a PTD. The association between prenatal care

Authors (year)	Study design	Rationale for exclusion
Edwards et al. (1995)	Retrospective cohort	Enhanced care study, but not randomized.
Perkocha et al. (1995)	Retrospective cohort	Enhanced care study, but not randomized. Compared two enhanced prenatal care programs (CPSP and CTAPPP).
Binstock and Wolde-Tsadik (1995)	Randomized control trial	Failed to use Kotelchuck, Kessner or comparable index: Counted number of visits.
Hueston (1995)	Retrospective cohort	Failed to use Kotelchuck, Kessner or comparable index. Compares prenatal care in urban and rural settings.
Zotti and Zahner (1995)	Retrospective cross-sectional study	Enhanced care study, but not randomized.
Blanchette (1995)	Retrospective cohort	Enhanced care study, but not randomized. Compared two different settings (private vs. public).
Gómez-Olmedo et al. (1996)	Case-control	Conducted outside of US
Barros et al. (1996)	Retrospective cohort	Conducted outside of US
McDuffie et al. (1996)	Randomized control trial	Failed to use Kotelchuck, Kessner or comparable index: Counted number of visits.
Hormon at al. (1006)	Patrospactive schort	
Herman et al. (1996) Helfand and Zimmer- Gembeck (1997)	Retrospective cohort Retrospective cohort	Enhanced care study, but not randomized. Examined specific component of prenatal care.
Homan and Korenbrot (1998)	Retrospective cohort	Enhanced care study, but not randomized.
Dyson et al. (1998)	Randomized control trial	Compared different types of enhanced care.
Mvula and Miller (1998)	Prospective cohort	Enhanced care study, but not randomized.
Visintainer et al. (2000)	Prospective cohort	Enhanced care study, but not randomized.
Boss and Timbrook (2001)	Retrospective cohort	Examined continuity of care rather than utilization of care.
Vintzileos et al. (2002)	Retrospective cohort	Failed to use Kotelchuck, Kessner or comparable index: Treated PNC as a dichotomous variable
		(presence vs. absence of PNC).
Vintzileos et al. (2003)	Cohort	Failed to use Kotelchuck, Kessner or comparable index: Treated PNC as a dichotomous variable (presence vs. absence of PNC).
Jackson et al. (2003)	Cohort	Enhanced care study, but not randomized. Did not measure birth outcomes of interest
Ickovics et al. (2003)	Prospective matched cohort	Enhanced care study, but not randomized.
Barnet et al. (2003)	Retrospective cohort	Enhanced PNC study, but not randomized. Compared PNC in different settings (school vs. hospital based).
Hueston et al. (2003)	Retrospective cross-sectional study	Failed to use Kotelchuck, Kessner or comparable index: Analyzed by trimester of PNC initiation.
Armson et al. (2003)	Case-control	Enhanced PNC study, but not randomized. Study conducted outside the US.
Quinlivan and Evans (2004)	Prospective cohort	Enhanced PNC study, but not randomized. Conducted outside of the US.

 Table 8.4
 Excluded studies and rationale for exclusion

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(continued)

Table 8.4 (continued)

Authors (year)	Study design	Rationale for exclusion
Lazariu-Bauer et al. (2004)	Retrospective cohort	Comparison of early vs. late PNC initiation.
Partridge and Holman (2005)	Retrospective cohort	Failed to use Kotelchuck, Kessner or comparable index:
		Counted number of visits.
Taylor et al. (2005)	Retrospective cohort (cluster analysis)	Failed to use Kotelchuck, Kessner or comparable index:
		Treated PNC as a dichotomous variable (presence vs. absence of PNC).
Tasnim et al. (2005)	Prospective cohort	Failed to use Kotelchuck, Kessner or comparable index:
		Counted number of visits.
		Conducted outside US.
Reichman and Teitler (2005)	Retrospective cohort	Failed to use Kotelchuck, Kessner or comparable index:
		Analyzed by trimester of PNC initiation.
Sánchez-Nuncio et al.	Case-control	Article in Spanish.
(2005)		Conducted outside US.
Laditka et al. (2005)	Retrospective cohort	Failed to report on primary outcome
		measures (LBW + preterm birth).

PNC prenatal care; *LBW* low birth weight; *CPSP* Comprehensive Perinatal Services Program; *CTAPPP* Comprehensive Teenage Pregnancy and Parenting Program

Primary author (year)	Study design	Reporting (max. 13)	External validity (max. 4)	Internal validity – bias (max. 7)	Internal validity – confounding (max. 6)	Power (max. 2)	Total quality score (max. 32)
Utilization studies							
Collins (1997)	Case-control	11	4	6	4	0	25
Krueger (2000)	Cohort	11	3	7	4	0	25
Enhanced studies							
Kitzman (1997)	RCT	12	3	6	6	2	29
Moore (1998)	RCT	12	3	6	5	1	27
Klerman (2001)	RCT	11	3	5	6	1	26
Brooten (2001)	RCT	10	4	5	6	0	25
Little (2002)	RCT	12	3	4	5	0	24

 Table 8.5
 Quality rating of PNC utilization and enhanced care studies included in this review

utilization and LBW was not statistically significant. The study did not examine how these associations might vary by race and ethnicity.

Enhanced Care Studies

Our search identified five randomized controlled trials of enhanced prenatal care (Brooten et al., 2001; Kitzman et al., 1997; Klerman et al., 2001; Little et al., 2002; Moore et al., 1998), since the last major review by Fiscella (1995) that met our inclusion/exclusion criteria. The characteristics and outcomes of the five included enhanced care studies are summarized in Table 8.3.

Kitzman et al. (1997) conducted a randomized controlled trial in Memphis, Tennessee to test the effect of nurse prenatal and infant home visits by nurses on birth and child health outcomes. The study enrolled 1,139 primarily African-American (92%) women who were at less than 29 weeks' gestation, had no previous live births, and met at least two sociodemographic risk characteristics (unmarried, <12 years of education, unemployed). Women with high-risk medical conditions were excluded. With computer-generated random assignment, women were randomized to an intervention group (n = 458) and a control group (n = 681). Intervention assignment was concealed from both study participants and intervention staff until recruitment was complete. Neither study participants nor those measuring main outcomes were blinded. In the control group, women received standard prenatal care plus free taxi transportation for prenatal appointments. In the treatment group, women received standard prenatal care, free transportation, and intensive nurse home visits. Nurses made an average of seven (range 0-18) home visits during pregnancy and followed a detailed visit-by-visit protocol to help women improve health related behavior. They helped women complete 24-h diet histories and track the weight gained over the course of the pregnancy in order to assess nutritional status. Nurses assessed cigarette smoking, alcohol, or illicit drug use and facilitated reduction in substance use through behavioral analysis. They also taught women how to identify the signs and symptoms of pregnancy complications, with particular attention to urinary tract infections, sexually transmitted diseases, and hypertensive disorders.

There were no significant differences in LBW, mean birthweight, preterm birth, mean gestational age, and intrauterine growth restriction between the intervention and control group. The incidence of LBW was 15% in the intervention group and 14% in the control group. The only birth outcome that differed between the two groups was the incidence of pregnancy-induced hypertension (13% vs. 20%; p = 0.009). While the intervention did not reduce LBW or related birth outcomes, it was found to reduce the number of subsequent pregnancies, close-spaced births, the use of welfare, negative beliefs about child-rearing, and criminal behavior among low-income unmarried mothers for up to 15 years after the birth of their first child (Olds et al., 1997, 1998). The study did not compare intervention effects by race and ethnicity.

Moore et al. (1998) conducted a randomized controlled trial in Winston-Salem, North Carolina to test the effect of a nursing telephone intervention on LBW and preterm births among low-income pregnant women. A total of 1,554 women receiving prenatal care in a public clinic who met study criteria were assigned randomly to intervention and control groups using a computer-generated randomization table, with a final analysis sample size of 1,433. Another 1,573 eligible women were not included in the study because they either refused or could not be contacted by telephone; their characteristics were not reported, raising questions about the generalizability of the study. Women in the intervention group received telephone calls from three registered nurses. Three calls were attempted weekly from 24 weeks' through 37 weeks' gestation, but only half of the calls (approximately 1.5 per week) were completed. Although no formal script was followed, each telephone call addressed three major areas: assessment of health status (perception of uterine contractions and other pregnancy changes, color of urine as an assessment of hydration, number of meals eaten, number of cigarettes smoked, alcohol and drug use, and ingestion of a prenatal vitamin capsule on the previous day); recommendations based on assessment; and, discussion of any additional issues important to the mother. Clinical personnel, including physicians, residents, and nurses, were blinded to group assignment during the study period. The nurse collecting data on the main outcomes was also blinded to group assignment.

LBW rates were 10.9% in the intervention group and 14.0% in the control group (RR 0.75; 95% CI 0.55, 1.03). Preterm birth rates were 9.7% in the intervention group and 11.0% in the control group (RR 0.87; 95% CI 0.62, 1.22). Neither main study analysis reached statistical significance. However, differences in the rates of LBW and preterm birth bordered on statistical significance for African-American women. A closer examination found the intervention to be

effective for a subgroup of African-American women aged 19 years and older. In this subgroup, LBW rates were 11.4% in the intervention group and 17.3% in the control group (RR 0.66; 95% CI 0.46, 0.94) and preterm birth rates were 8.7% in the intervention group and 15.4% in the control group (RR 0.56; 95% CI 0.38, 0.84). The authors attributed the intervention effect to enhanced education and support for a subgroup of women (African-American women aged 19 years and older) who often do not receive the same level of family and community support afforded to younger pregnant teens.

Klerman et al. (2001) conducted a randomized controlled trial in Jefferson County, Alabama, to test the effect of augmented prenatal care among high-risk African-American women on pregnancy outcomes as well as patients' knowledge of risks, satisfaction with care, and behavior. A total of 619 women (n = 318 in augmented care, n = 301 in regular care) were enrolled in the study. Nearly 8% of eligible women refused participation. The women enrolled were African-American, aged 16 years or older, and eligible for Medicaid. They had scored 10 or higher on a risk assessment scale but had no major medical complications. Augmented care was provided by a multidisciplinary team including an obstetrician, trained nurse practitioners, social workers, and behavioral medicine specialists and included educationally oriented peer groups, additional appointments, extended time with clinicians, and other supports. The control group received standard prenatal care from the county health department or the university's obstetric department. On-site child-care was provided, evening hours were available, and transportation was provided. Structured postpartum interviews were administered by interviewers blinded to the treatment group. Data were also gathered from clinic records, special forms prepared for the study, and a computerized database on Medicaid patients. Blinding of data collectors was not reported.

There were no significant differences in LBW, VLBW, mean birthweight, preterm birth, mean gestational age, IUGR, or any measured pregnancy outcomes between groups. LBW rates were 12.5% in the intervention group and 11.2% in the control group (p = 0.60). Both groups had lower than predicted rates of LBW. Preterm birth rates were 10.6% in the intervention group and 14.0% in the control group (p = 0.22). The authors concluded that high-quality augmented prenatal care that emphasized education, health promotion, and social support significantly increased women's satisfaction, knowledge of risk conditions, and perceived mastery in their lives; however, it did not reduce LBW.

Brooten et al. (2001) conducted a randomized controlled trial in Philadelphia, Pennsylvania to test the effect of prenatal nurse home visits on maternal and child health outcomes. A sample of 173 women (and 194 infants) with high-risk pregnancies (gestational or pregestational diabetes mellitus, chronic hypertension, preterm labor, or high risk of preterm labor) were enrolled in the study, of which approximately 94% (162 of 173) were African-American. The subjects were randomly assigned to the intervention group (85 women and 94 infants) or the control group (88 women and 100 infants) using a table of random numbers. Intervention assignment was concealed from both study participants and intervention staff until recruitment was complete. Women in the control group received standard prenatal care. Women in the intervention group received half of their prenatal care in their homes, in addition to education, counseling, telephone outreach, daily telephone availability, and a postpartum home visit. Blinding was not described in the paper.

LBW rates were 34% in the intervention group and 36% in the control group (RR = 0.95; 95% CI 0.65, 1.40). Preterm birth rates were 31% in the intervention group and 41% in the control group (RR = 0.76; 95% CI 0.1, 1.11). Neither main study analysis reached statistical significance. Mean birthweight among preterm infants was approximately 300 g greater in the intervention group (2,263.5 g ±711.0) compared to the control group (1,960 g ±748) (p < 0.05). Mean birthweight among term infants and mean gestational age did not differ significantly between the two groups. A large intervention effect was found among twins gestations; 4 of 18 twin gestations in

the intervention group (22%) and 16 of 24 twin gestations in the control group (67%) delivered preterm (p < 0.05). Mean birthweight was approximately 320 g greater and mean gestational age was 2.6 weeks greater among twin gestations in the intervention group compared to the control group. The intervention group also had fewer fetal/infant deaths among all infants (2 vs. 9; p < 0.01). Finally, the study reported preventing more than 750 total hospital days and saving \$2,496,145 in hospital costs.

Little et al. (2002) conducted a randomized controlled trial in Minneapolis, Minnesuta to test the effects of telephonic nursing care on birth outcomes (mean gestational age and mean birth weight) and clinical resource utilization among low-income high-risk pregnant women. A total of 111 high-risk pregnant women who obtained prenatal care from two large obstetric clinics were enrolled in the study and randomly assigned to the case management group or the control group. Randomization was conducted by the study administrative assistant. No blinding by clinical personnel or data collectors was described. There were no significant differences between treatment and control groups; however, the treatment group had a larger proportion of patients with anemia, obesity, symptoms of preterm labor, and undiagnosed vaginal bleeding in pregnancy. The control group had a larger number of patients who reported problems with substance abuse. Another 64 women eligible for the study were eliminated because they could not be contacted, had a miscarriage, or refused to participate. Compared with participants, non-participants were more likely to be multiparous, single and white with less than a college-level education.

Nurse case managers contacted women in the intervention group every 7–14 days to assess their pregnancy status and offer support and teaching related to their pregnancy and diagnoses. The treatment group participants were encouraged to maintain good prenatal care and educated in the signs and symptoms of preterm labor, the importance of hydration, and the self-monitoring of fetal movement. Nurse case managers contacted the patients' health care providers as appropriate. A final contact was made after delivery to obtain delivery information and complete the postpartum mother/infant assessment. The control group completed the initial pregnancy risk screening and the postpartum mother/infant assessment.

A multiple analysis of variance with covariates was performed to examine the effect of the nursing telephone care on birth weight and gestational age, controlling for maternal obesity, maternal age, NICU admission, study group (treatment vs. control), gestational age at referral and number of preterm births. There was no effect of the intervention on preterm births; the mean gestational age at delivery was not significantly different between groups. After controlling for confounders, the study found a positive correlation between telephonic nurse case management and mean birthweight. Subgroup analysis by age and race-ethnicity was not performed due to small sample size.

Taken together, these studies overall found equivocal effects of enhanced prenatal care on LBW or preterm birth rates. However, some benefits in specific subgroups [e.g., for twin gestations in Brooten et al. (2001) or African-American women aged 19 years and older in Moore et al. (1998)] were noted.

Discussion

Consistent with the last major review, our review does not support the conclusion of the 1985 IOM report that "the overwhelming weight of the evidence is that prenatal care reduces low birthweight" (IOM, 1985b, pp. 18–19). Our review also suggests that prenatal care as currently delivered or in an enhanced form of the type discussed here is not effective in reducing racial-ethnic disparities in LBW.

Utilization Studies

Collins et al. (1997) found that race-specific term (gestational age >37 weeks) LBW rates declined as prenatal care usage rose. However, since the study only stratified on residential income within raceethnic strata, it may not have adequately controlled for critical confounders and potential selection bias. Moreover, the study found that increased prenatal care utilization did not reduce disparities in the occurrence of LBW for blacks relative to whites and Hispanics. Krueger and Scholl (2000) did not find a significant association between prenatal care utilization and LBW; however, they did find inad-equate prenatal care to be associated with increased risk for preterm birth. Their study controlled for a number of potential confounders, but several methodological limitations, including recruitment, exclusions, and combining categories of prenatal care utilization, raise concerns about the external and internal validity of the findings. Importantly, they did not examine the interaction between race/ethnicity and prenatal care utilization with respect to LBW or preterm birth.

Our review does not change the conclusion made in the last major review. Fiscella (1995) reviewed 14 observational studies on the association between prenatal care utilization and birth outcomes. Of the eight observational studies reporting LBW as an outcome, four found a significant benefit from prenatal care, while four did not. Although two studies found adequate prenatal care to be associated with greater reduction in the odds of LBW among African-American than among whites, Fiscella was critical of these studies for their failure to adequately control for potential confounding. He also raised concerns that while the Kessner, Kotelchuck, and similar indices were designed to minimize gestational age bias, they do not eliminate this bias altogether. Using Bradford-Hills criteria for evaluating evidence of a causal relationship, he concluded that the current evidence did not satisfy such criteria. We do not find evidence from the two included studies published subsequent to his review sufficiently strong to reverse this conclusion.

Enhanced Care Studies

None of the five randomized controlled trials was able to demonstrate a main effect of enhanced prenatal care in preventing LBW, though some studies suggested there may be specific subgroups that might benefit from enhanced prenatal care or that outcomes such as mean birthweight may be affected. The interventions included telephone calls, nurse home visits, and comprehensive prenatal care. Our findings are consistent with those of previous reviews. Fiscella (1995) reviewed 11 randomized controlled trials published between 1966 and 1994; none of the trials of enhanced care in his review showed positive main effects. Hueston, Knox, Eilers, Pauwels, and Lonsdorf (1995) also reviewed six randomized controlled trials of preterm birth prevention educational programs among high-risk women; using meta-analytic techniques, no significant benefits were found for preterm birth education programs in preventing neonatal death, LBW, or preterm birth. Hodnett and Fredericks (2003) conducted a Cochrane review of social support during pregnancy. Sixteen trials involving 13,651 women at-risk for preterm birth or LBW were included. Interventions included emotional or instrumental support, provided by professional or trained lay person, in-home or in clinical settings. Programs offering additional social support for at-risk pregnant women were not associated with improvements in any perinatal outcomes, including LBW and preterm birth. To date, available evidence does not support the effectiveness of enhanced prenatal care, in the forms of telephone calls, home visits, preterm birth education, comprehensive care, or social support, in preventing LBW and preterm birth for most populations although other benefits may be evident.

Racial-Ethnic Disparities in Birth Outcomes

A primary aim of this review is to examine the effectiveness of prenatal care in reducing racial-ethnic disparities in LBW and related birth outcomes. Of the two included utilization studies, only Collins et al. (1997) examined the association between prenatal care utilization and LBW by race-ethnicity. Collins et al. found that although race-specific term LBW rates declined as prenatal care usage rose, the position of African-Americans relative to Mexican-Americans and whites was essentially unchanged, raising serious doubts as to whether increasing access to and utilization of prenatal care in its current form can help reduce racial-ethnic disparities in LBW and related outcomes.

With respect to the randomized controlled trials of enhanced prenatal care, three studies enrolled predominantly African-American women. Kitzman et al. (1997) and Klerman et al. (2001) recruited sociodemographically at-risk African-American women, whereas Brooten et al. (2001) recruited medically at-risk African-American women. Since none of these three trials found a main effect of enhanced prenatal care on LBW and related outcomes, whether enhanced prenatal care (i.e., nurse home visits or comprehensive care model) can reduce racial-ethnic disparities in LBW and preterm birth remains questionable. Moore et al. (1998) found an intervention effect in a subgroup of African-American women 19 years and older. In this subgroup, a nursing intervention by telephone call reduced LBW rates by 34% and preterm birth rates by 44%. While these results appear promising, methodological concerns have been raised including the method of random allocation and the high rate of loss-to-follow-up. Furthermore, it remains unclear why the program succeeded when other trials involving more intensive nursing interventions failed. The authors argued that the program provided education and support to a subgroup with the greatest unmet needs for education and support, but offered no data to support this claim, such as a change in knowledge or perceived support pre- and postintervention. Thus presently there is no conclusive evidence that enhanced prenatal care can reduce racial-ethnic disparities in LBW and related birth outcomes.

The Challenges of Studying the Effectiveness of Prenatal Care

The inconclusiveness of the evidence reviewed in this chapter reflects in part the challenges of studying the effectiveness of prenatal care. As discussed earlier, there are three major types of studies on the effectiveness of prenatal care: ecological studies, utilization studies and enhanced care studies. Ecological studies correlate prenatal care utilization to birth outcomes *at a population level*. For example, the study might show that following expansion of Medicaid eligibility in a state, there was an increase in the proportion of women who started prenatal care in the first trimester concomitant to a decline in LBW rate in the state. However, one cannot tell from population-level data correlating a rise in prenatal care utilization to a decline in LBW rate whether prenatal care is associated with favorable outcomes at the individual level.

The major challenge to the validity of utilization studies is the potential for selection bias. There are at least four different types of selection bias (Bell & Zimmerman, 2003). *Favorable selection* (low risk/high use) results when healthy women at low risk for poor outcomes are more likely to receive early and adequate prenatal care; such selection may overestimate the measured effects of prenatal care on birth outcomes. *Adverse selection* (high risk/high use) results when women at high risk for adverse outcomes are more likely to seek early and intensive prenatal care because of a preexisting medical condition, prior experience or family history; such selection (high risk/low use) results when women at risk for adverse outcomes are more likely to receive inadequate or no prenatal care because of life circumstances such as homelessness, substance abuse or intimate partner

violence; such selection may overestimate prenatal care efficacy. Finally, *confidence selection* (low risk/low use) results when healthy women at low risk for adverse outcomes are less likely to use prenatal care because their general health or prior experience leads them to believe that they will have a healthy birth outcome with or without care; such selection may underestimate the measured effects of prenatal care on birth outcomes. It is possible that all four types of selection bias, operating in different directions, may be in play in most utilization studies.

Randomized controlled trials are typically considered the gold standard of study designs; however, randomizing women to receiving prenatal care vs. no prenatal care is neither feasible nor ethical. Enhanced care studies address a different question; instead of evaluating the effectiveness of prenatal care, these studies evaluate the effectiveness of added components of care such as health education or home visitation. Unfortunately, none of the 16 randomized controlled trials [11 reviewed by Fiscella, 1995 (Table 8.3) and five additional RCTs reviewed in this chapter] found a main effect of these added components on birth outcomes. Furthermore, in a review of psychosocial interventions to prevent LBW, Lu, Lu, and Schetter (2005) concluded that most such interventions were not driven by theory, did not have effective risk screening, did not match intervention to risk, and did not test process variables. Thus it is difficult to determine from these studies whether the failure of enhanced care in preventing LBW is due to ineffective interventions, poor study design, or both.

Most importantly, the effectiveness of prenatal care may well depend on how prenatal care is defined. In most studies, prenatal care is defined as a series of clinical visits based on a schedule recommended by ACOG and AAP (2007): "Generally, a woman with an uncomplicated pregnancy is examined every 4 weeks for the first 28 weeks of pregnancy, every 2-3 weeks until 36 weeks of gestation, and weekly thereafter" (p. 100). This schedule, which has been used to define the adequacy of prenatal care, was designed largely for early detection of preeclampsia and other pregnancy complications rather than for prevention of LBW or preterm birth. It is, therefore, not surprising that the adequacy of prenatal care is not definitively associated with LBW or preterm birth. In most utilization studies, only the timing and quantity of prenatal visits is considered; few studies have evaluated birth outcomes in relation to the content, quality, and mode of delivery of prenatal care. The effectiveness of prenatal care may also depend on the outcomes being studied. Prenatal care may not have been shown to be effective in preventing LBW for the index pregnancy, but little is known about its impact on a subsequent pregnancy or its long-term impact on the health and behaviors of the mother, child, and family. For example, less than adequate prenatal care has been associated with significantly fewer well-child visits and incomplete immunizations (Kogan, Alexander, Jack, & Allen, 1998). We caution against over-interpretation of our findings as a rejection of the importance of prenatal care; rather, our findings merely demonstrated the inconclusiveness of the evidence for its effectiveness in preventing LBW and potentially reducing disparities in LBW.

Rethinking Prenatal Care

More than two decades following the IOM report, the effectiveness of prenatal care for preventing LBW or reducing racial-ethnic disparities in LBW remains unproven. We suggest that some rethinking about the *content*, *timing*, and *context* of prenatal care is needed.

The Content of Prenatal Care. As several reviews had previously concluded, prenatal care in its present form is unlikely to reduce LBW because it does not address the underlying causes of LBW (Alexander & Kotelchuck, 2001; Lu et al., 2003). Recent advances in biomedical and social-behavioral research have improved our understanding of the etiologic mechanisms leading to LBW. Could the *content* of prenatal care be redesigned to address more effectively the underlying causes of LBW? For example, while the multiple pathways leading to PTD have not been clearly

elucidated, a growing body of evidence implicates: (1) activation of the maternal or fetal hypothalamic-pituitary-adrenal axis; (2) decidual-chorioamniotic or systemic inflammation; (3) decidual hemorrhage (i.e., abruption); and, (4) pathological distention of the uterus in the pathogenesis of PTD (Lockwood, 2003). Similarly, recent advances in research are beginning to elucidate some of the complex pathophysiological processes leading to IUGR, including the interaction between immunology and human placental implantation, the control and function of growth factors such as insulin-like growth factor and its binding proteins, and vasoactive agents such as prostacy-clin, thromboxane A₂, endothelin-1, and nitric oxide, and genetic mutations.

Given these known pathways to preterm birth and IUGR, it is perhaps not surprising that prenatal care in its present form is ineffective in preventing LBW. The content of prenatal care, as recommended by current AAP-ACOG guidelines, was not designed to address these underlying mechanisms of LBW. For example, it is quite unlikely that checking blood pressure and urine protein, designed for early detection of preeclampsia, does anything to reverse premature activation of the maternal or fetal hypothalamic-pituitary-adrenal axis or decidual-chorioamniotic or systemic inflammation. Measuring fundal height, designed to screen for IUGR, has high interobserver variance and poor predictive values. Moreover, available interventions, such as bedrest or antenatal testing, may do little to improve placental blood flow that has been compromised by thromboses, atheroses, and other placental pathologies that may have resulted from aberrant placentation in early pregnancy (Lu et al., 2003). The challenge of rethinking the content of prenatal care to address racial-ethnic disparities in LBW is even more daunting because the underlying causes of the disparities are less well understood. Given known pathways to preterm birth and IUGR, chronic stress, inflammation and nutrition probably are major contributors to the disparities; yet presently these three concerns are poorly addressed by prenatal care. To prevent LBW and reduce disparities, there needs to be some rethinking about the content of prenatal care so that it can better address the underlying causes of LBW.

The Timing of Prenatal Care. Could the timing of prenatal care be improved to address more effectively the underlying causes of LBW? Many of the pathophysiologic processes leading to PTD or IUGR may have their onset early in pregnancy. For example, an infection potentially responsible for PTD may already be present in the urogenital tract in early pregnancy or even before conception (Goldenberg, Hauth, & Andrews, 2000). If it is not cleared by midgestation, preterm labor, or preterm premature rupture of membranes (PPROM) may ensue. Screening for and treating bacterial vaginosis with antibiotics in midgestation, weeks or perhaps even months after its onset, or giving antibiotics after preterm labor is already in progress, may prove to be ineffective in preventing preterm birth. Perhaps this explains the disappointing results of the antibiotic trials in pregnancy (King & Flenady, 2002). Even if the infection is treated, it may be too late to arrest the immuneinflammatory processes that have long been initiated. Similarly, the "uteroplacental insufficiency" responsible for IUGR may be traced to abnormal trophoblastic invasion during implantation early in pregnancy (Khong, De Wolf, Robertson, & Brosens, 1986). Implantation, in turn, is regulated by immunologic mechanisms involving predominantly decidual natural killer cells, which secrete certain cytokines to stimulate growth, differentiation, and migration of trophoblasts (Loke & King, 1997). Immunologic dysregulation of implantation could lead the pregnancy, shortly after conception, down the pathophysiogic pathway toward IUGR which may be difficult for prenatal care to reverse. The timing of these events underscores the potential contributions of preconception and interconception care to preventing LBW. While current research has focused primarily on its benefit in preventing congenital anomalies through dietary control of pregestational diabetes mellitus or hyperphenylalaninemia or nutrition supplementation (e.g., folic acid) (Korenbrot, Steinberg, Bender, & Newberry, 2002), future research needs to investigate the effectiveness of preconception interventions in preventing PTD or IUGR, and that of interconception care in preventing their recurrence (Johnson et al., 2006). Given significant racial-ethnic disparities in healthcare access for women before and between pregnancies, increasing access to preconception and interconception

care may hold greater promise for reducing racial-ethnic disparities in LBW than prenatal care has demonstrated.

But even preconceptional care may do too little too late for preventing LBW or reducing disparities in LBW. Lu and Halfon (2003) recently proposed using a life-course perspective to reexamine racial-ethnic disparities in birth outcomes. Vulnerability to PTD or IUGR may be traced to not only risk factors before and during pregnancy, but to experiences and exposures that occur early in life and accumulate throughout the life course of the woman. A growing body of research on life course health development has suggested that the functional capacity of many organ systems begins in-utero and continues to develop over the life course. A woman's reproductive capacity is no exception. Early life experiences become embedded into her reproductive biology and may influence her future potential to conceive and carry a healthy pregnancy to term. For example, it has been shown that maternal stress is associated with higher stress reactivity in her offspring that persists well into adulthood (Hertzman, 1999; Seckl, 1998; Wadhwa, 1998), which may be related to feedback resistance as a result of decreased expression of glucocorticoid receptors in the brain during critical period of neuroendocrine development (Meaney, Aitken, Sharma, Viau, & Sarrieau, 1989). Early life exposures to stress hormones during critical periods of immune maturation may also alter immune function, leading to increased susceptibility to infectious or inflammatory diseases over the life course (Coe, 1999). Hypothetically, maternal stress could thus prime the neuroendocrine axes and immune system of her developing fetus with stress hormones, leading to higher stress reactivity and immune-inflammatory dysregulation that could increase her female offspring's vulnerability to PTD or IUGR later on in life (Lu & Halfon, 2003). This might help explain the observed intergenerational clustering of preterm birth and LBW (Emanuel, 1997).

Beyond early life, cumulative exposures to chronic stress results in wear and tear, what Bruce McEwen refers to as "allostatic load," on the body's adaptive systems (1998). Studies have found in animals and humans subjected to chronic and repeated stress, elevated basal cortisol levels and exaggerated ACTH and cortisol responses to natural or experimental stressors (Kristenson et al., 1998; Sapolsky, 1995; Sapolsky, Krey, & McEwen, 1984). This HPA hyperactivity may reflect the inability of a worn-out HPA axis for self-regulation, possibly due to the loss of feedback inhibition via down-regulation of glucocorticoid receptors in the brain (Sapolsky; Sapolsky et al.). Similarly, chronically elevated levels of cortisol may also lead to not only relative immune suppression, but also immune-inflammatory dysregulation due to the loss of several possible mechanisms by which accommodation to chronic and repeated stress over the life-course may lead to increased vulnerability to PTD and IUGR during pregnancy. Evidence supporting the cumulative pathway mechanism comes from research on the weathering hypothesis (Geronimus, 1996).

From a life-course perspective, it is perhaps not surprising that the effectiveness of prenatal care for preventing LBW or reducing racial-ethnic disparities in LBW has not been conclusively demonstrated. To expect prenatal care, in less than 9 months, to reverse the impacts of early life programming and cumulative allostatic load on a woman's reproductive health may be expecting too much of prenatal care. Even preconceptional care may do too little too late if it is provided in a single visit shortly before a planned pregnancy, rather than as an integral part of women's health care continuum for all women of reproductive age. Ultimately, preventing LBW will take a fundamental reconceptualization of prenatal care as part of a longitudinally integrated strategy that promotes optimal development of women's reproductive health not only during pregnancy, but over their entire life course.

The Context of Prenatal Care. Could the context of prenatal care be expanded to address more effectively the multilevel, multiple determinants of racial-ethnic disparities in LBW? Presently, prenatal care is still delivered primarily through the obstetrical visit, with links to public health ancillary services such as WIC services or social support services for low-income women (Alexander &

Kotelchuck, 2001). These clinical and ancillary services, while necessary, are hardly sufficient to address the multiple causes of LBW. For example, Collins et al. (1998) found a two to threefold increase in the risk of VLBW births (most of which were preterm) among African-American women who rated their neighborhoods unfavorably in terms of police protection, protection of property, personal safety, friendliness, delivery of municipal services, cleanliness, quietness, and schools. A more recent case-control study (Collins et al., 2000) found that among low-income African-American women in Chicago, the adjusted odds of giving birth to a VLBW infant was 3.3 times greater among women who reported having experienced racial discrimination than among those who did not. A greater African-American-white gap in infant mortality has also been found in cities that are more segregated (LaVeist, 1993; Polednak, 1996). A growing body of literature also links air and water pollution to preterm birth and IUGR (Sram, Binkova, Dejmek, & Bobak, 2005). In many disadvantaged communities, there are more liquor stores than grocery stores, and more fast food restaurants than healthy restaurants. It has been shown that the typical cost of food is approximately 15–20% higher in poor neighborhoods, while the quality of food available is poorer (Emmons, 2000). For individuals growing up and living in those communities, the relative unavailability of healthy, nutritious food may pattern a lifelong habit of making unhealthy food choices that becomes difficult to change during pregnancy. Currently, little is done during the standard prenatal visit, or through its public health ancillary services, to address neighborhood factors, racial discrimination and residential segregation, air and water pollution, unavailability of healthy food choices, or other contextual determinants of LBW.

Health care providers and public health professionals are not exempt from addressing causes of health disparities outside of the clinical domain (Hogan, Njorge, Durant, & Ferre, 2001). They may not be able to solve all the problems, but it is imperative that they reach out to those who could. These may include the partner, family, and peers who could provide the pregnant woman with consistent daily support between prenatal visits. These may also include leaders of business, community or faith-based organizations who could reinforce health promotion messages outside of clinical settings. Prenatal care should not cease once the pregnant woman walks out of her doctor's office; it should continue at home, at work, in neighborhood parks and grocery stores, and in every aspect of her everyday life.

What is needed is a contextually integrated model of prenatal care. Risk assessment, health promotion, and medical and psychosocial interventions need to address causes of LBW not only at the individual level, but also at the interpersonal, institutional, community, and policy levels. A contextually integrated model of prenatal care will require cross-sectoral collaboration; health care providers and public health professionals need to engage other Maternal and Child Health (MCH) and non-MCH service providers, as well as leaders from business, civic, and faith-based sectors, in a collaborative effort to prevent LBW. It will take building stronger and healthier communities that promote not only healthy pregnancy, but the life-course health development of women and families. This will require investments in infrastructure, such as affordable and decent housing, safe neighborhood, accessible parks and recreation, clean air and water, and competent health care. These investments ought to be decided with full community participation. A contextually integrated model of PNC will also require social investments, with the goal of reducing cumulative allostatic load over the life-course of women. This requires policymakers to pay attention to issues that disproportionately impact on women's lives, such as domestic violence and child care. Men (especially fathers) play an important role, positive or negative, in the lives of women and children, and yet they are often treated as an afterthought in MCH. Current policies provide little support, and in some cases great disincentives, for male involvement in pregnancy and parenting, leaving women to bear greater burdens of childbearing and childrearing (Lu et al., 2007). The impact of social legislation (e.g., maternity leave policies, laws prohibiting employment discrimination, or safeguards for work safety and working conditions) on pregnancy and parenting also merits greater attention. Public policies and social movements to combat racism and gender inequality may be one of the most effective components of

prenatal care. As Alexander and Korenbrot observe, the "ultimate success of prenatal care in reducing current low birth weight percentages in the United States may hinge on the development of a much broader and more unified conception of prenatal care than currently prevails" (1995, p. 114).

Conclusion

Our review should not be interpreted as a rejection of prenatal care, which may benefit pregnancy outcomes other than LBW, such as reduced maternal, fetal, and infant morbidities and mortality, or improved maternal health status and parenting behaviors (e.g., well-baby care or vaccinations) (Grimes, 1994; Kogan et al., 1998). From a life-course perspective, the benefits of prenatal care may accrue over the maternal life course, from one pregnancy to the next or even across generations, rather than in immediate birth outcomes. Our specific aims were to review the evidence of effective-ness of prenatal care for preventing LBW or reducing racial-ethnic disparities in LBW in the current pregnancy, and to catalyze some rethinking about its content, timing, and delivery. We conclude that preventing LBW and reducing racial-ethnic disparities will take much more than prenatal care in its present form; it will require a fundamental reconceptualization of prenatal care as part of longitudinally and contextually integrated strategy to promote optimal development of women's reproductive health not only during pregnancy, but over the life course.

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