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Perinatal legislative policies and health outcomes

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ABSTRACT

Perinatal epidemiology examines the variation and determinants of pregnancy outcomes from a maternal and neonatal perspective. However, improving public and population health also requires the translation of this evidence base into substantive public policies. Assessing the impact of such public policies requires sufficient data to include potential confounding factors in the analysis, such as coexisting medical conditions and socioeconomic status, and appropriate statistical and epidemiological techniques. This review will explore policies addressing three areas of perinatal medicine—elective deliveries prior to 39 weeks' gestation; perinatal regionalization; and mandatory paid maternity leave policies—to illustrate the challenges when assessing the impact of specific policies at the patient and population level. Data support the use of these policies to improve perinatal health, but with weaker and less certain effect sizes when compared to the initial patient-level studies. Improved data collection and epidemiological techniques will allow for improved assessment of these policies and the identification of potential areas of improvement when translating patient-level studies into public policies.

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Perinatal epidemiology examines the variation and determinants of pregnancy outcomes, both from a maternal and neonatal perspective. Improving public and population health requires the translation of this epidemiological data into public policies that impact perinatal population health. For clinical practice, such translation may occur through the development of hospital protocols, legislation, or changes in how perinatal care is financed. Assessing the impact of such policies requires sufficient data to include potential confounding factors in the study, such as coexisting medical conditions and socioeconomic status, along with the appropriate statistical and epidemiological techniques.

This review will explore the impact of policies addressing three areas of perinatal medicine to highlight these issues. These areas cover perinatal medicine from delivery through the postpartum period: elective deliveries prior to 39 weeks' gestation; perinatal regionalization; and mandatory paid maternity leave policies. For each policy area, we will examine the available epidemiological evidence to support the development of these specific policy areas; the impact of the particular policies; and limitations to this evidence base, especially as it pertains to selection bias and confounding by indication, unmeasured confounding, and the inability to identify subpopulations for whom the policy may have a different effect than the remainder of the population.

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Elective deliveries prior to 39 weeks' gestation, or early elective delivery (EED)

Elective deliveries prior to 39 weeks' gestation are associated with an increased risk of adverse maternal and neonatal outcomes, especially for elective Cesarean section. This evidence resulted in a 2013 policy from the American College of Obstetricians and Gynecologists to discourage EED.¹ As a result, hospitals and states have enacted policies to reduce or eliminate deliveries prior to 39 weeks. Such policies include educational initiatives by quality improvement collaboratives to discourage such deliveries; so-called "hard-stop" policies that prevent such practice within a hospital or, for some states, all hospitals within a state; and a reduction or elimination in physician payment for EED by an insurer, typically a state Medicaid agency. This section will describe the increasing rates of EED in the US since 2000, the epidemiological studies examining the association between EED and adverse maternal and neonatal outcomes, and the impact of hospital and state policies on both the rates of EED and various adverse outcomes of pregnancy.

Epidemiology of EED

EED have increased in the United States over the past 2 decades. One study from a multistate dataset of hospital discharge records linked to birth certificates found an 86% increase in EED from 1995 to 2009, with the EED rate peaking in 2006 at a 103% increase in rates compared to 1995.² Such increases occurred even in the face of decreasing rates of early-term deliveries in the United States from 2005 (31.8% of all deliveries) to 2011 (28.5% of all deliveries). Such rates vary between states³ and between hospitals.⁴

Outcomes of EED

Patient-level epidemiological studies generally show significant increase in adverse outcomes with EED, with early elective Cesarean section providing greater adverse outcomes for women and infants compared to early elective induction. Overall, the risk of adverse outcomes associated with EED is greater for the newborn compared to the mother.

Neonatal outcomes of EED

Numerous studies have identified a statistically significant increased risk of respiratory distress, need for admission to the NICU, and feeding difficulties in infants delivered by early elective Cesarean section. Compared to spontaneously born infants, the risk ratio for infants delivered by early elective Cesarean section developing a composite "adverse outcome" measure varies from 1.5 (95% CI: 1.3–1.7) in 38-week infants in the NICHD Neonatal Research Network⁵ to 2.74 (95% CI: 1.79–4.21) in Australian infants <39 weeks' gestation at birth.⁶ Similar results have been reported from other US studies.^{7–9} Other outcomes such as ventilation use (OR = 4.51, 95% CI: 3.24–6.28) and perinatal asphyxia (OR = 4.91, 95% CI: 2.85–8.44) have been associated with early elective Cesarean section compared to spontaneous delivery.¹⁰

The outcomes of infants delivered via early elective induction have been more varied. A study of 125 facilities in Florida found no increased odds of neonatal respiratory morbidity, sepsis or admission to the NICU for infants delivered by early elective induction compared to infants delivered spontaneously at 39–40 weeks' GA.⁷ A Scottish population study from 1981 to 2007 found decreased odds of mortality for infants delivered via elective induction compared to expectant management after stratifying by gestational age. However, NICU admission was increased at each gestational-age week.¹¹ Similar reductions in neonatal adverse outcomes with early elective induction were seen in consortium of 19 US hospitals,^{10,12} although a single center study also found an increased risk of NICU admission for infants delivered via elective induction.⁹ As discussed in an ensuing section, all of these studies of EED suffer from challenges to identifying the appropriate control population, specifically including infants who could deliver at 37 or 38 weeks but who subsequently deliver later in their pregnancy, also known as the "fetus-at-risk" control population.

Maternal outcomes of EED

There are fewer studies of the outcome of mothers undergoing EED. Much of the data center on the morbidity associated with a Cesarean section, particularly one that is not indicated. Women undergoing early elective Cesarean section have a higher risk of a prolonged postpartum hospital stay¹³ without changes in the rates of such outcomes as hysterectomy, uterine rupture or atony, blood transfusion, or thromboembolic complications. One other study found higher rates of hysterectomy with both elective inductions (OR = 3.21, 95% CI: 1.08–9.54) and early elective Cesarean section (OR = 6.57, 95% CI: 1.78–24.3).¹⁰ Similar to studies of neonatal outcomes, there have been few studies that examine maternal outcomes after early elective inductions, with one study showing an association between early elective induction and lower infection rates.¹²

Impact of EED policies

Published data examine both the effect of hospital-level plans, primarily "hard-stop" policies to prevent EED, and state-level initiatives to reduce EED through either a state-wide quality collaborative or Medicaid payment reform that denies payment to providers for EED. These studies found a reduction in the number of EED after introduction of each of these policies. However, there has been conflicting evidence concerning the association of these policies with either undesired secondary effects of these policies, such as increased rates of stillbirths, or reductions in rates of other adverse outcomes, such as neonatal respiratory morbidity and admission to the NICU.

Hospital-level studies

Numerous studies show a decrease in EED when hospitals undertake interventions to reduce such deliveries. These interventions fall into three general categories: "hard-stop" policies that prohibit purely elective inductions and Cesarean sections before 39 weeks' gestation; "soft stop" approaches, where EED would be allowed if ordered by an attending

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