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Association of Widespread Adoption of the 39-Week Rule With Overall Mortality Due to Stillbirth and Infant Death

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IMPORTANCE To improve neonatal morbidity, efforts have been made to reduce elective deliveries prior to 39 weeks' gestation, also known as the *39-week rule*. Prolonging pregnancies also prolongs exposure to the risk of stillbirth. The true association of a 39-week rule with mortality is unknown and studies to date have shown conflicting results.

OBJECTIVE To determine if widespread adoption of a 39-week rule, limiting elective deliveries prior to 39 weeks' gestation, is associated with an increase or decrease in overall mortality when considering both stillbirths and infant deaths.

DESIGN, SETTING, AND PARTICIPANTS This historical cohort study used birth certificate and infant death certificate data in the United States to compare years before and after the adoption of the 39-week rule. Births between 2008 and 2009 were considered to be in the preadoption period (n = 7 322 234), and those between 2011 and 2012 were considered to be in the postadoption period (n = 6 972 626). Included births were singleton, nonanomalous births between 37 0/7 weeks' and 42 6/7 weeks' gestation. Statistical analysis was performed from July 19, 2016, through June 27, 2019.

EXPOSURES The exposure of interest was the Joint Commission adoption of the 39-week rule as a quality measure.

MAIN OUTCOMES AND MEASURES The primary outcomes of interest were stillbirth and infant death.

RESULTS A total of 7 322 234 births (49.0% girls and 51.0% boys) were included in the preadoption period and 6 972 626 births (49.1% girls and 50.9% boys) were included in the postadoption period. Compared with the preadoption period, there was a decrease in the proportion of deliveries at 37 weeks (−0.06%) and 38 weeks (−2.5%) and an increase in the proportion of deliveries at 39 weeks (6.8%) and 40 weeks (0.2%) in the postadoption period ($P < .001$). The stillbirth rate increased in the postadoption cohort compared with preadoption (0.09% vs 0.10%; $P < .001$). The infant death rate decreased in the postadoption period compared with preadoption (0.21% vs 0.20%; $P < .001$). An overall mortality rate of 0.31% was calculated for the preadoption period and 0.30% for the postadoption period ($P = .06$). Additional analysis in a counterfactual model suggests that up to 34.2% of the difference in mortality could be associated with the 39-week rule.

CONCLUSIONS AND RELEVANCE Stable overall perinatal mortality rates were observed in the 2-year period immediately after adoption of the 39-week rule, despite an increase in stillbirth.

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Supplemental content

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There is expanding evidence demonstrating that neonatal morbidity and mortality is increased in the early-term period, defined as 37 0/7 weeks' to 38 6/7 weeks' gestation, compared with delivery at 39 0/7 to 40 6/7 weeks' gestation.[1-4] Given this evidence, and in response to an increasing proportion of deliveries occurring in the late preterm and early-term period,[5] systemwide quality measures and statewide perinatal collaborative efforts to reduce the number of elective deliveries before 39 weeks' gestational age (also known as the *39-week rule*) were initiated.[6-8] Based on reports of successful compliance and reduced neonatal morbidity, in 2010 a recommendation to avoid unindicated deliveries before 39 weeks' gestation became a widespread guideline endorsed by national organizations and adopted as a quality measure by the Joint Commission.[9-13]

Since that time, multiple studies examining compliance with the 39-week rule have found considerable reductions in early-term deliveries.[7,8,14-18] In clinical practice, the risk of stillbirth associated with remaining pregnant must be balanced against the risk of delivery prior to 39 weeks. With the acknowledgment that deliveries were shifting from the late preterm and early term to 39 weeks and beyond, a national discussion began to examine the possible unintended association of this policy with increasing stillbirths. Most of these investigations have found no difference in stillbirth rates,[7,8,15,18,19] but 2 have suggested an increase in stillbirth rates after the reduction in unindicated deliveries before 39 weeks.[14,17] In addition, not all studies have used infant mortality, defined as death within 1 year of a live birth, despite evidence to suggest that sudden infant death syndrome rates that occur beyond the neonatal period may be associated with gestational age at delivery.[20,21]

Given the inconsistent findings, coupled with the policy goal of reducing adverse perinatal outcomes, this study examined the rate of stillbirth and infant death before and after the 2010 widespread adoption of the 39-week rule to determine the association with overall mortality. We hypothesized that the implementation of the 39-week rule may be associated with an increase in overall stillbirths, but that overall mortality—combined infant deaths and stillbirths—is reduced.

Key Points

Question Is widespread adoption of a policy to limit elective deliveries before 39 weeks' gestational age associated with increased or decreased overall mortality when considering both stillbirth and infant death?

Findings In this historical cohort study, there was a statistically significant increase in the rate of stillbirths from 0.09% in the preadoption period to 0.10% in the postadoption period and a statistically significant decrease in the rate of infant death from 0.21% in the preadoption period to 0.20% in the postadoption period. This change resulted in an overall mortality rate of 0.31% in the preadoption period and 0.30% in the postadoption period.

Meaning Overall mortality was not increased in the period after the widespread adoption of limiting elective early-term deliveries despite an increase in stillbirth.

Methods

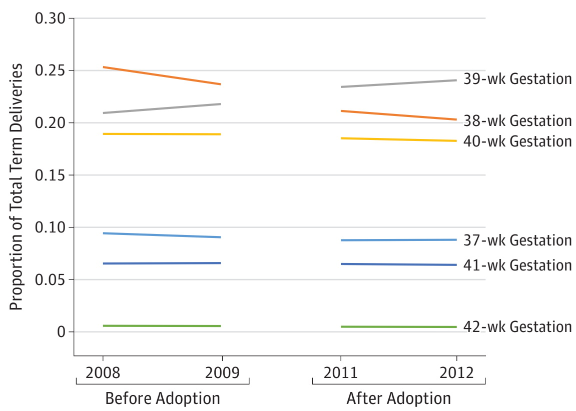
We conducted a historical cohort study using the approach of a natural experiment with the 2010 widespread adoption of the 39-week rule using National Center for Health Statistics (NCHS) birth and infant death certificate period-linked files. The exposure of interest was the Joint Commission adoption of the 39-week rule as a quality measure in 2010; as such we were interested in the years 2008, 2009, 2011, and 2012. We excluded the year 2010 as it included deliveries occurring both before and after the policy adoption. At the time of this analysis, cohort-linked data were not available for all years of interest, so period-linked data files were used. We included in our analysis the years 2008-2013 so that all infant deaths up to 365 days after birth would be included, even if they occurred in a different calendar year than the linked birth. We excluded any birth in these files occurring in 2010 and 2013, but included deaths occurring in these years if the birth occurred in the preceding year. We grouped 2008 and 2009 as the preadoption period and 2011 and 2012 as the postadoption period. We limited our analysis to the 2 years before and 2 years after 2010 to minimize confounding from significant practice changes over time other than the Joint Commission quality measure adoption. The primary outcomes of interest were stillbirth and infant death. Records with missing gestational age or fetal anomaly data were excluded from analysis. Maternal race/ethnicity was obtained from birth and death certificate data, which is self-reported. This study was exempt from formal review by the Oregon Health & Science University Institutional Review Board as the data source was publicly available and contained no identifying patient information.

Statistical analysis was performed from July 19, 2016, through June 27, 2019. We calculated the proportion of total deliveries occurring at each week of gestation using the total number of term deliveries as a denominator and compared proportions of deliveries occurring at each week in the preadoption and postadoption periods. Stillbirth was defined as fetal death prior to delivery. The rate of stillbirth was calculated among all pregnancies in each period examined and was also calculated for each gestational age week using a pregnancies at-risk life table method. The at-risk life table method estimates an incidence density as the rate of stillbirth per gestational age week and considers the time at risk that each fetus contributes, acknowledging that deliveries are distributed throughout the gestational age week in question. For our calculation, we used the number of stillbirths at a given gestational age week in the numerator and all ongoing pregnancies at the start of that gestational age week in the denominator with the exclusion of half the deliveries occurring during the gestational age week, a technique originally described by Smith.[22] This half-week correction accounts for the assumption that stillbirths are evenly distributed throughout each gestational age week in question. The rate of stillbirths and proportion of term stillbirths by week of gestation in the preadoption and postadoption periods were compared.

Table 1. Maternal Demographics

Demographic	% of Mothers: Preadoption (n = 7 322 234)	% of Mothers: Postadoption (n = 6 972 626)
Race/ethnicity		
White	53.2	53.6
Black	13.9	14.1
Hispanic or Latina	21.8	19.8
Asian	5.9	6.5
Unknown	5.2	6.1
≥35 y of Age	13.7	14.3
Nulliparous	34.4	33.7
Some college	51.7	57.6
Gestational diabetes	4.3	5.3
Gestational hypertension	3.3	3.7
Chronic hypertension	1.0	1.2
Cesarean delivery	30.2	30.2
Induction of labor	24.5	24.3

Figure 1. Distribution of Term Deliveries



Proportion of term deliveries by gestational age week. Difference in distribution, $P < .001$.

Infant death was defined as death of a live-born infant within 365 days of life; all deaths associated with a birth within the periods examined were captured even if the death occurred in the subsequent calendar year. Infant deaths were linked to birth certificate files by the NCHS in a process that includes multiple administrative steps to ensure accuracy and to minimize unlinked records.[23] The rate of infant death was calculated using live births per week of gestation as the denominator. Rates and proportions of stillbirths and infant deaths were compared in the preadoption and postadoption periods. Overall mortality (infant death plus stillbirth) was then examined by comparing the incidence of overall mortality at term in the preadoption period and the postadoption period. Microsoft Office Professional Plus 2013 (Microsoft Corp) and Stata software, version 11 (StataCorp) were used for all statistical analyses. The χ^2 test compared dichotomous outcomes and proportions. All *P* values were from 2-sided tests and results were deemed statistically significant at $P < .05$, as were 95% CIs that did not overlap 1.0.

Finally, to account for the possibility of temporal trends, we designed a counterfactual model. A counterfactual model takes into consideration unobservable risks as a source of confounding and allows for comparisons of actual (observed) and expected numbers of an outcome event.[24,25] Specifically, we identified the difference in proportion of deliveries occurring at 37, 38, and 39 weeks and compared them in the preadoption and postadoption periods. These absolute differences were then multiplied by the total number of term deliveries in the postadoption period to serve as a hypothetical cohort of women redistributed to deliver at a later gestational age in the postadoption period. We then compared delivery at 37 weeks with delivery at 39 weeks in this hypothetical cohort. We assumed that each of the 37-week deliveries occurred at 37 weeks with a live fetus and used rates of infant death and stillbirth derived from the postadoption period. If delivered at 37 weeks, the rate of infant death was applied. If delivered at 39 weeks, the rate of stillbirth at 37 and at 38 weeks was applied, as well as infant mortality at 39 weeks. This comparative approach is similar to that used to estimate a 1-week difference in mortality.[4]

The difference in mortality between these 2 strategies—the difference between delivery at 37 or 38 weeks compared with expectant management and delivery at 39 weeks—serves as an estimation of the difference in mortality that could be associated with gestational age changes alone (in other words, the expected mortality if rates of stillbirth and infant mortality per week gestational age were the same in both the preadoption and postadoption periods). We then compared this expected perinatal mortality in our hypothetical scenario with the observed mortality changes found in our population to estimate the proportion of the mortality difference that could potentially be attributed to the gestational age redistribution associated with the policy adoption.

Results

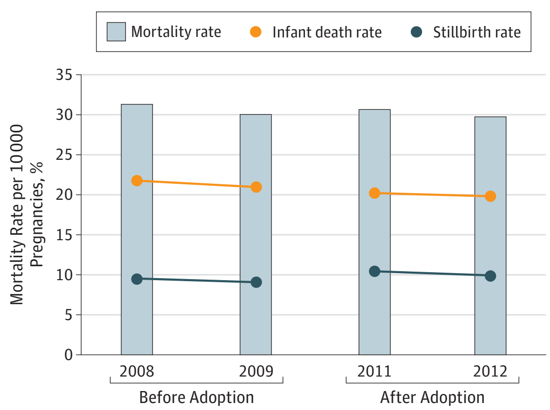
A total of 16 317 048 births were included in our data set; we excluded 1 634 886 (10.0%) for being outside of the gestational age range of interest, 43 462 (0.3%) were missing gestational age data, 214 968 (1.3%) were multiple gestations, 21 018 (0.1%) were anomalous, and 107 854 (0.7%) were missing data about the status of anomalies. Of the remaining pregnancies meeting inclusion criteria, 7 322 234 were delivered before the policy adoption and 6 972 626 were delivered after the policy adoption. Maternal characteristics are recorded in **Table 1**. There was a statistically significant difference in the distribution of deliveries at 37 weeks through 40 weeks in the preadoption period compared with the postadoption period. We observed a decrease of 0.06% at 37 weeks and a decrease of 2.5% at 38 weeks, as well as an increase of 6.8% at 39 weeks and an increase of 0.2% at 40 weeks in the postadoption period relative to the preadoption period ($P < .001$) (**Figure 1**).

When considering stillbirths, 6848 (0.09%) occurred in the preadoption cohort and 7088 (0.10%) occurred in the postadoption cohort ($P < .001$), with a difference in incidence equaling 0.81 additional stillbirths per 10 000 pregnancies. Conversely, infant deaths decreased over time, with 15 686 deaths

Table 2. Rates of Stillbirth and Infant Death by Week Gestational Age

Gestational Age	Rate (95% CI) 2008	2009	2011	2012
Stillbirth rates (per 10 000 ongoing pregnancies)				
37 wk	2.8 (2.6-3.0)	2.6 (2.4-2.8)	2.9 (2.8-3.1)	2.9 (2.7-3.0)
38 wk	3.5 (3.3-3.7)	3.4 (3.2-3.6)	3.6 (3.4-3.8)	3.5 (3.3-3.7)
39 wk	4.5 (4.2-4.7)	4.2 (3.9-4.4)	4.9 (4.7-5.2)	4.6 (4.3-4.9)
40 wk	7.1 (6.5-7.5)	6.9 (6.4-7.4)	8.1 (7.6-8.7)	7.6 (7.0-8.1)
Infant death rates (per 10 000 live births)				
37 wk	39.0 (38.4-39.7)	39.3 (38.7-40.0)	39.5 (38.8-40.1)	39.3 (38.6-40.0)
38 wk	25.1 (24.5-25.6)	24.6 (24.1-25.2)	25.0 (34.5-25.6)	24.7 (24.1-25.2)
39 wk	19.8 (19.3-20.4)	18.9 (18.4-19.4)	17.8 (17.3-18.3)	17.8 (17.2-18.3)
40 wk	16.7 (16.0-17.4)	15.9 (15.2-16.6)	14.9 (14.1-15.6)	14.4 (13.6-15.1)

Figure 2. Mortality at Term



Infant death, stillbirth, and overall mortality at term.

(0.21%) in the preadoption period and 13 981 (0.20%) in the postadoption period (P < .001), a difference of 1.37 fewer infant deaths per 10 000 pregnancies. The calculated rates of stillbirth and infant death per week of gestation by each year examined are listed in **Table 2**.

When considering overall mortality by combining infant deaths and stillbirth, 22 534 (0.31%) total deaths were observed in the preadoption period and 21 069 (0.30%) deaths were observed in the postadoption period (P = .06), although this difference was not statistically significant. The overall mortality difference was calculated as 0.56 fewer deaths per 10 000 deliveries in the postadoption period (**Figure 2**).

To account for the possibility of confounding from temporal trends in the preadoption and postadoption periods, we identified the difference in the proportion of deliveries occurring at 37, 38, and 39 weeks and compared them in the preadoption and postadoption periods. At 37 weeks, the absolute difference in proportion was 2.7% and at 38 weeks, the absolute difference was 6.6%. These absolute differences were then multiplied by the total number of term deliveries in the postadoption period to serve as a hypothetical cohort of women redistributed to deliver at a later gestational age in the postadoption period. This exercise suggested that 16 655 women (0.2%) delivered at 37 weeks and 87 180 (1.2%) delivered at 38 weeks in the preadoption period who would have delivered at a later gestational age week in the postadoption period.

To assess what association with mortality was the result of gestational age redistribution alone, we designed a counterfactual model in which these 16 655 and 87 180 women were considered pregnant with a living fetus entering the 37th week of pregnancy.[25] For this exercise, we compared delivery at 37 weeks with delivery at 39 weeks. We assumed that each of the 37-week deliveries occurred at 37 weeks with a live fetus and used rates of infant death and stillbirth derived from the postadoption period. If deliveries occurred at 37 weeks, the rate of infant death was applied. If deliveries occurred at 39 weeks, the rate of stillbirth at 37 and at 38 weeks was applied, as well as infant mortality at 39 weeks (eFigure in the Supplement). We then repeated this method, comparing delivery at 38 weeks with delivery at 39 weeks. Finally, the expected rates of stillbirth and infant death from this hypothetical model were compared with the observed rates of stillbirth and infant death in the postadoption period.

We found that a strategy of delivery at 39 weeks compared with 37 weeks resulted in 61 fewer deaths in this counterfactual cohort of 16 655 pregnant women. When comparing delivery at 38 weeks with delivery at 39 weeks, we calculated a difference of 30 fewer deaths in this hypothetical cohort of 87 180 pregnant women. Taken together, these scenarios totaled 91 fewer deaths in the postadoption period with a strategy of delivery at 39 weeks (**Table 3**). Finally, we compared these expected findings in this hypothetical cohort with our observations in the postadoption period. We found a mortality difference of 0.56 fewer deaths per 10 000 in the postadoption period, which would equal 266 fewer deaths in this population of 4 778 600 women who delivered between 37 and 39 weeks in the postadoption period. In our hypothetical model, we observed 91 fewer deaths with a perfect application of the 39-week rule, which accounts for 34.2% of the observed reduction in mortality and serves as an estimation of the true potential outcome of adoption of the 39-week rule.

Discussion

In this large historical cohort, we observed a statistically significant decrease in the proportion of deliveries at 38 weeks and a concurrent increase in the proportion of deliveries at

Table 3. Counterfactual Model Output

Characteristic	37 Weeks' Gestational Age	38 Weeks' Gestational Age	Total Hypothetical Cohort
Immediate delivery	131 Deaths	216 Deaths	347 Deaths
Delivery at 39 wk	70 Deaths	186 Deaths	256 Deaths
Net difference at 39 wk	−61 Deaths	−30 Deaths	−91 Deaths
Reduction in perinatal deaths in postadoption period			
Expected, No.	NA	NA	91
Observed, No.	NA	NA	266
Estimate of the proportion of the mortality reduction attributable to gestational age redistribution, %	NA	NA	34.2

Abbreviation: NA, not applicable.

39 weeks after the national adoption of the 39-week rule. We found a statistically significant increase in the risk for stillbirth after the adoption, although the effect was small, with a difference of 0.81 additional stillbirths per 10 000 pregnancies. In addition, we found a statistically significant decrease in infant death, with a difference of 1.37 fewer infant deaths per 10 000 live births in the postadoption period, with the greatest reduction among deliveries occurring at 39 to 40 weeks. This finding is consistent with previous reports of infant death declining nationally during the course of our study period.[26] When considering overall mortality, we did not find a statistically significant difference between the preadoption and postadoption periods.

Strengths and Limitations

The strengths of this study are in the large, diverse patient population and in comparing overall perinatal mortality as a result of adoption of the 39-week rule rather than comparing only stillbirth. Similar findings using this national data set have been published, but consider neonatal morbidity only up to 28 days after delivery, whereas this study considers all infant death up to 365 days after delivery. In a population of nonanomalous fetuses born at term, considering infant deaths is more inclusive of deaths beyond the neonatal period, including sudden infant deaths that may be associated with gestational age at delivery.[19] These findings are in agreement with other studies examining policies aimed at reducing unindicated deliveries before 39 weeks, but this is the first study, to our knowledge, to examine the outcomes of a nationwide quality measure. As with other studies examining compliance across health systems, we observed a significant redistribution in the proportion of deliveries occurring in the early-term period compared with deliveries at 39 and 40 weeks before and after adoption of the 39-week rule.

One critique of this work and other similar analyses is that the changes in mortality are owing to unknown confounding in the form of temporal changes associated with population differences, clinical practice, and administrative change. In our period examined, there are known and unknown temporal changes that add sources of confounding bias to our observed associations. First, there has been a steady decline in infant mortality in the United States during the period examined. Second, birth certificate and infant death linking through administrative work has improved steadily during the period examined, with a reduction in unlinked infant death files. These factors both offer sources of confounding associated with infant mortality, although each offers bias in opposite directions. We acknowledge that temporal changes are present and we have made efforts through a counterfactual model to minimize the outcome of such changes. Although counterfactual models do not account for all unknown confounding associated with temporal trends, policy implementation on this scale cannot be studied in a vacuum and, thus, temporal influences should be considered, but cannot be entirely accounted for. We have made efforts to estimate the true outcome of the quality measure and associated practice change. When we considered mortality changes from gestational age redistribution alone through our counterfactual model, we estimated that up to 34.2% of the mortality reduction over time could be associated with widespread adoption of the 39-week rule.

Another limitation of NCHS administrative data are that of the records that remain unlinked, as there may be a systematic bias in those that cannot be matched. The data are reviewed by NCHS prior to public release to improve linkages and a weighting process is used in the released data to account for these unlinked data; however, we cannot exclude unlinked records as a source of bias in our findings.

In addition, we lack information about the timing of fetal death and any significant delays between fetal demise and delivery, which would subject our study to misclassification bias by gestational age. Furthermore, we lack any insight into antenatal management of these patients and thus do not know if women with low-risk pregnancies were found to have features or symptoms that triggered antenatal testing. Conversely, we also lacked the ability to identify all significant maternal or fetal risk factors that warrant early-term, indicated delivery, for whom this widespread adoption may have had unintended consequences in the form of increased risk of stillbirth by inappropriately being expectantly managed to 39 weeks. Finally, we considered only perinatal mortality and not morbidity associated with this policy adoption; we recognize that this is a narrow view of the outcome to patients and health care systems from morbidity in the early-term period.

Conclusions

Despite these limitations, this work adds to the discussion of early-term deliveries by examining the outcome of a widely adopted policy shift that put into practice expectant management before 39 weeks if delivery was not indicated for maternal or fetal factors. Although the outcomes of interest were rare in both cohorts examined, the risk of stillbirth appears to be offset by a reduction in infant death at term. These findings should be interpreted with caution and we acknowledge the concern raised by any gains in infant death reductions being balanced by increased stillbirths. Additional investigations are warranted to examine the various contributions to the observed increased rates of stillbirth including the application of this policy and practice creep related to prolonging gestations at term among pregnancies with high-risk conditions warranting late preterm or early-term delivery. As the 39-week rule remains one of the perinatal quality measures examined by the Joint Commission, continued vigilance is warranted in terms of examining the full outcome of this practice change in terms of both perinatal morbidity and mortality.

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Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Pilliod, Dissanayake.
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