OBSTETRICS

Reduction in elective delivery at <39 weeks of gestation: comparative effectiveness of 3 approaches to change and the impact on neonatal intensive care admission and stillbirth

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OBJECTIVE: No studies exist that have examined the effectiveness of different approaches to a reduction in elective early term deliveries or the effect of such policies on newborn intensive care admissions and stillbirth rates.

STUDY DESIGN: We conducted a retrospective cohort study of prospectively collected data and examined outcomes in 27 hospitals before and after implementation of 1 of 3 strategies for the reduction of elective early term deliveries.

RESULTS: Elective early term delivery was reduced from 9.6-4.3% of deliveries, and the rate of term neonatal intensive care admissions fell by 16%. We observed no increase in still births. The greatest improvement was seen when elective deliveries at <39 weeks were not allowed by hospital personnel.

CONCLUSION: Physician education and the adoption of policies backed only by peer review are less effective than "hard stop" hospital policies to prevent this practice. A 5% rate of elective early term delivery would be reasonable as a national quality benchmark.

Key words: elective delivery, patient safety, practice change

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The practice of elective delivery at <39 weeks of gestation is common in the United States and may account for 10-15% of all deliveries, despite longstanding recommendations by the American College of Obstetricians and Gynecologists against this practice.[1-4] Recent publications have demonstrated that this practice is associated with significant newborn morbidity and increased rates of primary cesarean delivery.[1-3,5] This issue is of sufficient importance to warrant recent inclusion as a national perinatal quality benchmark both by the National Quality Forum and the Joint Commission.[6,7] Although the morbidity that is associated with this practice is widely recognized, there has also been speculation about the potential for an increase in term stillbirths were this practice to be reduced significantly.[8]

We sought to investigate the comparative effectiveness of 3 types of policies that were directed toward the reduction of elective delivery at <39 weeks of gestation in a large, national hospital system and the effects of such policies on both neonatal intensive care admissions and stillbirths. To our knowledge, this approach has not been used previously and may have wider applicability to the examination of change in physician practice patterns beyond the question of elective early term delivery.

Materials and Methods

In the summer of 2007, 27 pilot facilities of the Hospital Corporation of America in 14 states were chosen for an investigation into the frequency of elective delivery at <39 weeks of gestation and the impact of this practice on neonatal outcomes. Facilities were chosen for geographic and demographic representation of our larger system that is responsible for the delivery of approximately 220,000 babies annually in 21 states.[9] Thirteen facilities had annual delivery volumes of <2000; 9 facilities had delivery volumes of 2000-4000, and 5 facilities had delivery volumes of >4000. This system has been shown previously to be roughly representative of the United States as a whole.[10-12] During a 3-month period, data were collected from >17,000 deliveries.

Based on the observed morbidity that is associated with this early term delivery, we then instituted efforts to reduce its frequency throughout our system. After a period of physician and nursing education that included the provision of published practice guidelines and our own internal data, medical staffs at all hospitals were informed of our intent to restrict this practice on the basis of patient safety considerations. However, medical staffs were allowed to choose 1 of 3 approaches to reduction of this practice: (1) a "hard stop" approach that involved the adoption of a policy that

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TABLE 1
Elective deliveries at <39 weeks of gestation and newborn intensive care admission

Variable	2007	2009	*P* value
Deliveries, n	17,794	17,221	NA
Deliveries ≥37 wk, n	14,995	14,863	NA
Planned + elective deliveries at 37.0-38.6 wk, n	6562	4349	< .001[a]
Elective deliveries at 37.0-38.6 wk, n (%)	1712 (9.6)	746 (4.3)	< .001[a]
Group 1: 7 hospitals, n/N (%)	320/3886 (8.2)	65/3818 (1.7)	.007[b]
Group 2: 9 hospitals, n/N (%)	403/4797 (8.4)	155/4646 (3.3)	< .025[b]
Group 3: 11 hospitals, n/N (%)	989/9111 (10.9)	526/8757 (6.0)	.135[b]
Neonatal intensive care unit admissions at ≥37 wk, n (%)	1328 (8.9)	1119 (7.5)	< .001[a]

For gestational age, days are expressed as decimals; elective deliveries are expressed as percent of total deliveries. *NA*, not applicable.

[a] χ^2 with Yates correlation correction; [b] 2-way analysis of variance.

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TABLE 2
Change in elective early term deliveries by facility

Facility	2007	2009
Group 1		
1	12.3	5.8
2	8.6	1.2
3	3.6	0.7
4	44.7	4.1
5	3.2	0
6	22.3	0.7
7	8.8	0.3
Group 2		
8	22.2	5.7
9	5.6	7.1
10	13.9	8.5
11	5.9	0
12	7.9	5.8
13	9.0	3.8
14	9.6	3.8
15	5.8	0.9
16	4.4	2.0
Group 3		
17	1.4	2.7
18	10.4	4.7
19	5.8	0.6
20	2.9	1.4
21	12.7	4.8
22	14.0	7.2
23	2.4	1.3
24	4.2	5.6
25	18.9	8.5
26	26.7	8.0
27	16.7	20.5

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would prohibit purely elective inductions and primary and repeat cesarean deliveries at <39 weeks of gestation. This policy would be enforced by hospital staff members who were empowered to refuse to schedule any such deliveries. Questionable "indications" would be handled in the standard manner by accessing chain of command. (2) A "soft stop" approach that would include adoption of a similar policy to that described earlier. In contrast to the "hard stop" approach, compliance would be left up to individual physicians, and elective deliveries at <39 weeks of gestation would be allowed if ordered by the attending physician. However, all such cases would be referred to the local peer review committee for evaluation and potential action. (3) An "education only" approach that would involve the provision of available literature to attending physicians and both internal and professional association recommendations against this practice, which was also provided with the first 2 approaches. However, no formal policy prohibiting this practice would be adopted by the medical staff.

Data regarding physician compliance and neonatal outcomes were collected exactly 2 years later (2009) during the same 3 months of the year (May, June, July) and compared with the baseline data from these same 27 facilities in 2007. Analysis of identical facilities during identical months of the year within a 2-year period was necessary to minimize confounding effects of changes in patient or provider population or of scheduling concerns. Because of a concern regarding potential development of "creative" indications by staff physicians, we tracked rates of each type of planned delivery (elective and indicated) during these 2 time periods as an internal control. A *planned delivery* was defined as 1 in which the mother delivered after entering the labor and delivery suite not in labor and with intact membranes. An *elective delivery* was defined as a planned delivery without a recognizable medical or obstetric indication for delivery by either the attending physician or the nurse who collected the data.[1] This included inductions and primary and repeat cesarean deliveries. Gestational age was assigned based on the best estimate of the attending clinician according to both menstrual history and prenatal sonography.[1,2] For the overall reduction in rates of elective early term delivery and newborn intensive care unit admissions, the unit of analysis was the individual delivery.

For the comparison of departmental policy, facility rates were used as the unit of analysis. Statistical analysis for the overall performance and neonatal outcome data was performed with the χ^2 test with Yates correlation correction. One-way analysis of variance and Friedman repeated measures analysis of variance on ranks with all pairwise multiple comparison procedures (Student-Newman-Keuls method) and 2-way analysis of variance with multiple comparisons vs control group (Holm-Sidak method) were used to compare sequential performance differences in the 3 study groups. Significance was set at a probability value of .05. This was a quality improvement project that used deidentified data for analysis. Exemption from institutional review board review was obtained based on 45CFR46.101(b)[2] and 46.102(f) and 45CFR164.514(a)-(c) of the Health Insurance Portability and Accountability Act. However, institutional review board approval had been obtained for the control data publication.

RESULTS

During the 3 study months in 2009, 17,221 deliveries occurred in these 27 facilities, compared with 17,794 deliveries during the same months of 2007. The rate of elective delivery between 37 and 39 weeks of gestation fell from 9.6% of all deliveries in 2007 to 4.3% of deliveries in 2009 ($P < .001$; relative risk [RR], 0.45; 95% confidence interval [CI], 0.41–0.49; Table 1) The rate of elective and indicated planned deliveries also fell significantly during this interval (36.9-25.3%; $P < .001$; RR, 0.69; 95% CI, 0.66–0.71).

Performance improvement by type of policy adopted and the effect of such changes on term newborn intensive care unit admission rates are detailed in Tables 1 and 2 and Figures 1 and 2. There were no differences in the initial (2007) rates of elective early term delivery among the 3 groups ($P = .52$) Both groups 1 and 2 demonstrated a significant decline in the rate of elective early term delivery over the study period; group 1 experienced twice as great a reduction as group 2 (Table 1). Although a decline was also seen in group 3, this change did not reach statistical significance.

Table 2 shows the individual facility rate of change by group. Facilities with initially high rates of elective early term delivery were found within each group. However, only groups 2 and 3 included facilities with no improvement over the study period. Additional demographic differences between groups were minor. As seen in Table 1, a greater number of larger hospitals were represented in group 3 (no policy adopted), although all groups contained facilities with deliv-

FIGURE 1
Reduction in elective delivery by group, 2007-2009

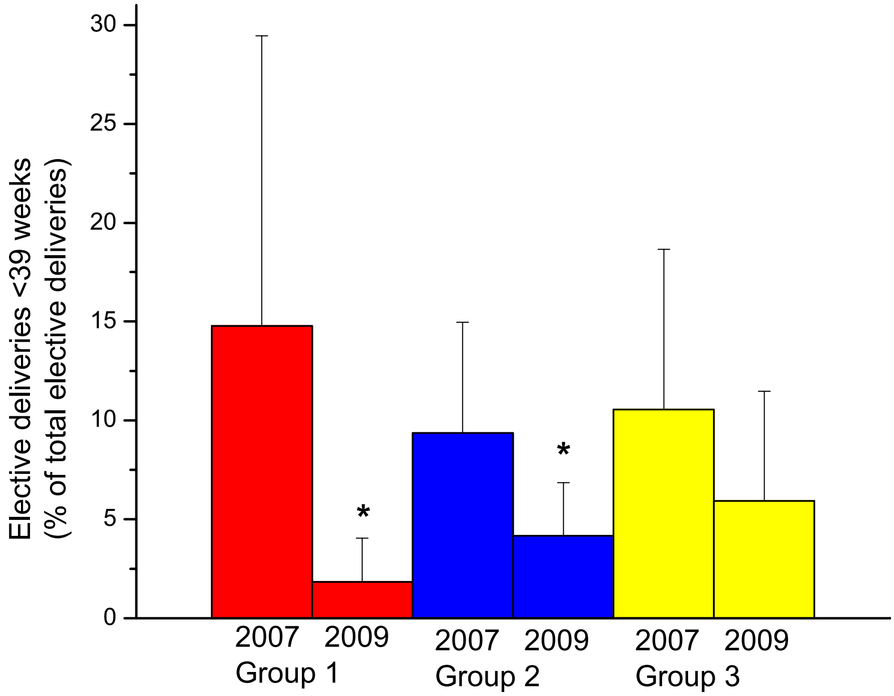

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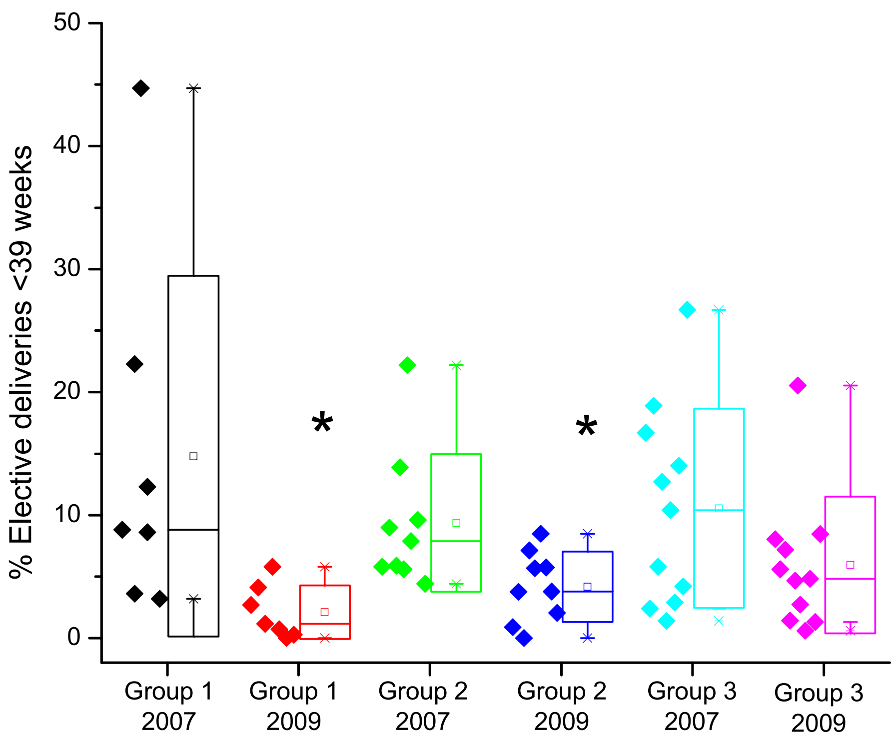
FIGURE 2
Box and whisker plot shows variability among facilities by group



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ery volumes in both the highest and lowest volume groups described in the "Materials and Methods" section. All study groups included facilities from geographically diverse states.

For all study facilities during this time frame, the rate of term newborn intensive care unit admission fell from 8.9-7.5% ($P < .001$; RR, 0.85; 95% CI, 0.79–0.92; Table 1). There was no change in the rate of system-wide stillbirth during this time frame (2007: 1522 stillbirths/222,084 births [0.69%]; 2009: 1497 stillbirths/211,467 births [0.71%]; $P = .38$; RR, 1.3; 95% CI, 0.96–1.11).

COMMENT

National interest in the practice of elective term delivery at <39 weeks of gestation was spurred by documentation of significant short- and long-term morbidity that was associated with near-term (34- to 37-week) deliveries and a realization of the absence of evidence for a biologic threshold at 37 weeks of gestation, which is the traditional definition of *term*.[13-15] Subsequent investigations revealed significant morbidity that is associated with both 37- to 38-week and 38- to 39-week elective deliveries, compared with those deliveries that occurred at >39 weeks of gestation.[1-3,16] This finding pertains to elective induction of labor and elective primary or repeat cesarean delivery. Recent data suggest that such morbidity is seen even when lung maturity has been documented before delivery.[3] Further, some studies suggest a contribution of elective induction to the rising cesarean delivery rate.[1,5] Such data have led the Joint Commission to adopt elective early term delivery as a national quality metric beginning in 2010.[7]

Previous success in lowering rates of early elective induction has been reported.[17,18] However, our data are unique both in the size and diversity of the population studied and in the inclusion of an ideal reference group of patients who delivered at the same facilities during the same months of the year before the initiation of efforts to change practice. In addition, the physicians involved were neither employed by the hospital nor a part of a closed insurance panel. Although we lacked these 2 powerful tools for encouraging physician compliance that was available in other settings, our results are more widely generalizable to practice in the United States where clinical policy changes must be approved by independent medical staffs. Thus, from the hospital standpoint, education, leadership, and recommended policy are the only tools that are available to change these deeply ingrained but flawed practice patterns.

Perhaps of greatest advantage of this study was our ability to compare the relative efficacy of various approaches to physician behavior change, which are observations that have potential ramifications beyond the specific issue of reducing elective deliveries at <39 weeks of gestation.

Under these circumstances, we were encouraged by a 55% reduction in elective early term delivery rate that was achieved in 2 years (9.6-4.3%,) in facilities of the nation's largest healthcare delivery system in which individual medical staffs were free to choose their approach to quality improvement. Given the myriad of indications for admission of a term infant to a special care unit, the fact that a modest change in this single practice resulted in a 16% decline in overall term newborn intensive care unit admissions is testament to the magnitude of the morbidity that is incurred by the practice of elective early term delivery in the United States today.

Concern has been raised regarding the potential effects on stillbirths of delaying elective delivery until 39 weeks of gestation.[8] In light of such concerns, our finding of no statistical increase in the rate of stillbirth that is associated with implementation of this policy is important and merits further discussion. Delivery at any gestational age for any reason whatsoever absolutely eliminates the possibility of subsequent stillbirth; the earlier the delivery, the greater will be the observed effect. Thus, it is certain that, with a sufficiently large denominator, reduction of elective deliveries at <39 weeks of gestation would be associated with an increased rate of stillbirth compared, for example, with a cohort of infants who were delivered at 38 weeks of gestation. Uniform delivery at 28 weeks of gestation would yield an even more impressive reduction in stillbirths. In such an analysis, 3 considerations appear germane. First, our inability to demonstrate any statistically significant increase in stillbirths in a population of almost one-quarter million births suggests that the number of actual stillbirths that potentially are associated with this policy is very small. Second, any objection to the implementation of such a policy based on concern for stillbirths is only logically consistent if accompanied by advocacy of uniform delivery at <39 weeks of gestation. Otherwise, the benefit of such objections would accrue only to those women whose physicians violate current practice guidelines.[4] Finally, an appropriately conducted randomized clinical trial in a very large population potentially could define the cost, in terms of both dollars and morbidity of each stillbirth avoided by uniform delivery at <39 weeks of gestation. However, such a trial is not only logistically unrealistic, but also the data would be of no value in the absence of universal agreement on the relative value of large amounts of iatrogenic morbidity vs the prevention of a small number of deaths. Under these circumstances, we believe it appropriate to invoke *primum non nocere* and advocate avoidance of a practice associated with well-documented iatrogenic morbidity in the complete absence of contrary data.[1-7,15-20]

A comparison of the 3 approaches to practice change that is outlined in Table 1 and Figures 1 and 2 is instructive. All facilities began with similar rates of elective delivery at <39 weeks of gestation. Groups 1 (formal policy enforced by hospital staff) and 2 (formal policy not enforced by hospital staff, but with automatic peer review of exceptions) both demonstrated significant decreases in this practice, with the greatest improvement seen in group 1. On the other hand, medical staffs eschewing any form of formal practice oversight (group 3: education only) achieved a much smaller, nonsignificant decrease in elective early term deliveries, despite the longstanding recommendations of the American College of Obstetricians and Gynecologists against this practice. These data suggest a correlation between quality of care and physician willingness to accept practice standardization and oversight, in accordance with observations from the Institute of Medicine.[19,20]

Unfortunately, our data document the relative ineffectiveness of education alone in changing the practice of many obstetricians and demonstrate how far the specialty has to go in embracing the concept of evidence-based (as opposed to anecdotal experience-based) practice. It is also disheartening that self-oversight (peer review) appears to be of limited value in this regard, compared with outside oversight (hospital enforcement.) (Tables 1 and 2; Figures 1 and 2). The relative ineffectiveness of physician peer review is a phenomenon previously noted by us and others.[9,21]

Approximately 5% of babies in the United States are born in a facility of the Hospital Corporation of America. An extrapolation of our data to the entire US population reveals the staggering medical and economic impact of the practice of elective early term delivery. We have shown previously that those infants who were delivered electively between 37 and 39 weeks of gestation who are admitted to newborn intensive care units have an average length of stay in such units of 4.5 days.[1] A calculation that involved the number of admissions that were avoided in our system with a reduction in the rate of elective early term delivery to 4.3% and the observation that a rate of 1.7% is achievable with a "hard stop" approach suggests that one-half million newborn intensive care unit days could be avoided in the US population were a national rate of 1.7% to be achieved; the cost savings would approach $1 billion annually.

Nonrandomization of facilities might be viewed as a limitation of this study. However, the achievement of voluntary randomization (and actual practice compliance) of independent medical staffs with an issue as emotional as the elimination of elective early term deliveries would not be possible. Further, because this study deals with decision-making and the clinical consequences of these decisions, artificial randomization would impact negatively the degree to which our results would be generalizable to real-life medical staff situations. In addition one cannot discount a potential Hawthorne effect on the absolute rates of compliance with departmental policies. However, the relative changes that were seen in the 3 groups would not be effected markedly, because comparison was made with the same facilities that were undergoing the same scrutiny with respect to compliance with a decades-old standard of care during the 2007 control period. Moreover, given the recent addition of this metric as a quality indicator by the National Quality Forum, Joint Commission, and Leapfrog, an ongoing Hawthorne effect is now an integral part of this issue for all facilities in the United States, which makes such an effect on our data a strength rather than a weakness.

Elective early term delivery may be reduced to a level of ≤2% by the use of a "hard stop" policy described earlier. Correcting patient misconceptions regarding the safety of early term births will also play an important role in practice change.[22] Current definitions of "elective" used by organizations such as the National Quality Forum and Joint Commission rely on the absence of indications that are defined by a diagnosis-related group code. Because some valid indications for such practice exist but do not have a specific diagnosis-related group code (for example, a history of a precipitous delivery in a woman with a dilated cervix at 38 weeks of gestation who lives remote from the hospital), no facility would be expected to reduce the rate of such "elective" deliveries to zero. However, a review of the variability seen in Figure 2 would suggest that achievement of a rate of such deliveries at <5% would be realistic for use as a national quality benchmark. Our data also suggest that, as a general rule, a hard stop approach to elective early term delivery with hospital oversight will be needed to achieve the type of change that is mandated by the practice of evidence-based medicine. ■

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