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Obstacles to Optimal Antenatal Corticosteroid Administration to Eligible Patients

Kara M. Rood, M.D.,
Lynda G. Ugwu, Ph.D.,
William A. Grobman, M.D., M.B.A.,
Jennifer L. Bailit, M.D., M.P.H.,
Ronald J. Wapner, M.D.,
Michael W. Varner, M.D.,
John M. Thorp Jr., M.D.,
Steve N. Caritis, M.D.,
Alan T. N. Tita, M.D., Ph.D.,
George R. Saade, M.D.,
Dwight J. Rouse, M.D.,
Sean C. Blackwell, M.D.,
Jorge E. Tolosa, M.D., M.S.C.E.,

Eunice Kennedy Shriver* National Institute of Child Health and Human Development Maternal-Fetal Medicine Units (MFMU) Network

Departments of Obstetrics and Gynecology of The Ohio State University, Columbus, OH (K.M.R.); Northwestern University, Chicago, IL (W.A.G.); MetroHealth Medical Center-Case Western Reserve University, Cleveland, OH (J.L.B.); Columbia University, New York, NY (R.J.W.); University of Utah Health Sciences Center, Salt Lake City, UT (M.W.V.); University of North Carolina at Chapel Hill, Chapel Hill, NC (J.M.T.); University of Pittsburgh, Pittsburgh, PA (S.N.C.); University of Alabama at Birmingham, Birmingham, AL (A.T.N.T.); University of Texas Medical Branch, Galveston, TX (G.R.S.); Brown University, Providence, RI (D.J.R.); University of Texas Health Science Center at Houston, McGovern Medical School-Children's Memorial Hermann Hospital, Houston, TX (S.C.B.); Oregon Health & Science University, Portland, OR (J.E.T.); and the George Washington University Biostatistics Center, Washington, DC (L.U.)

Abstract

Address for correspondence: Kara M. Rood, MD, The Ohio State University, Department of Obstetrics and Gynecology, , Columbus, Ohio 43210 (kara.rood@osumc.edu).

*See Appendix for a list of other members of the NICHD MFMU Network

CONFLICT OF INTERESTS

The authors have no conflicts to declare.

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Background—Administration of antenatal corticosteroids (ANCS) is recommended for individuals expected to deliver between 24 and 34 weeks of gestation. Properly timed administration of ANCS achieves maximal benefit. However, more than 50% of individuals receive ANCS outside the recommended window.

Objective—To examine maternal and hospital factors associated with suboptimal receipt of ANCS among individuals who deliver between 24–34 weeks gestation.

Study Design—Secondary analysis of the Assessment of Perinatal Excellence (APEX), an observational study of births to 115,502 individuals at 25 hospitals in the US from March 2008–February 2011. Data from 3123 individuals who gave birth to a non-anomalous live-born infant between $24^{0/7}$ to $34^{0/7}$ weeks gestation, had prenatal records available at delivery, and data available on the timing of ANCS use were included in this analysis. Eligible individuals' ANCS status was categorized as optimal (full course completed >24 hours after ANCS but not >7 days before birth) or suboptimal (none, too late, or too early). Maternal and hospital-level variables were compared using optimal as the referent group. Hierarchical multinomial logistic regression models, with site as a random effect, were used to identify maternal and hospital-level characteristics associated with optimal ANCS use.

Results—Overall, 83.6% (2612/3123) of eligible individuals received any treatment: 1216 (38.9%) optimal and 1907 (61.1%) suboptimal. Within suboptimal group495 (15.9%) received ANCS too late, 901 (28.9%) too early and 511 (16.4%) did not receive any ANCS. Optimal ANCS varied depending on indication for hospital admission ($p<0.001$). Individuals who were admitted with intent to deliver were less likely to receive optimal ANCS while individuals admitted for hypertensive diseases of pregnancy were most likely to receive optimal ANCS (10% vs 35%**).** The median gestational age of individuals who received optimal ANCS was 31.0 weeks.

Adjusting for hospital factors, hospitals with electronic medical records and who receive transfers had fewer eligible individuals who did not receive ANCS. ANCS administration and timing varied substantially by hospital; optimal frequencies ranged from 9.1 to 51.3%, and none frequencies from 6.1% to 61.8%. When evaluating variation by hospital site, models with maternal and hospital factors, did not explain any of the variation in ANCS use.

Conclusions—Optimal ANCS use varied by maternal and hospital factors and by hospital site, indicating opportunities for improvement.

Keywords

antenatal corticosteroids; preterm birth; preterm delivery

Administration of at least a single course of antenatal corticosteroids (ANCS) is recommended for pregnant individuals between $24^{0/7}$ weeks and $33^{6/7}$ weeks of gestation who are at risk of preterm delivery within 7 days.[1,2,3] Treatment is widely accepted as beneficial for the short- and long-term health of the infant.[4,5,6] Although seemingly straightforward, optimal ANCS treatment of individuals who deliver preterm has been difficult to achieve in practice. This is largely because of difficulty in identifying individuals who will deliver within the ideal treatment interval.[7,8,9,10] Ideal administration of ANCS is considered to have occurred if it is at least 24 hours after two ANCS

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injections (each 24 hours apart) but no more than 7 days before birth.[11,12] Variation in rates of ANCS administration to eligible individuals among hospitals suggests that there may be opportunities to improve the proportion of eligible individuals who receive any ANCS. However, there has been little investigation about the factors associated with timing of ANCS.[13,14,15] Therefore, we sought to identify factors associated with optimal administration of ANCS.

MATERIALS AND METHODS

This is a secondary analysis of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network Assessment of Perinatal Excellence (APEX) observational study. This study was intended to develop quality measures for intrapartum obstetrical care and contains detailed information on births to 115,502 women at 25 hospitals in the US from March 2008– February 2011. Itwas approved by the institutional review board at each participating institution under a waiver of informed consent.

The current study is a secondary analysis of data from individuals who gave birth to a live-born infant without anomalies between $24^{0/7}$ to $34^{0/7}$ weeks gestation, who had prenatal records available at delivery to verify gestational age, and had data available on the timing of ANCS relative to the time of delivery. We categorized ANCS administration as optimal - defined as a full course of either betamethasone 12 mg by intramuscular injection given twice over more than 24 hours, or dexamethasone 6 mg by intramuscular injection given 4 times over more than 24 hours, within 7 days before birth) and suboptimal which includes too late (a partial course, defined as 1 injection of betamethasone or less than 4 injections of dexamethasone), too early (a full course completed more than 7 days before birth) and none (defined as no administration of either betamethasone or dexamethasone before delivery)

Individuals who met the criteria for each category of ANCS administration were identified and the frequencies were determined. Frequencies of optimal use were compared with suboptimal ANCS categories (Ttoo late, too early and none) using the Wilcoxon rank-sum test for continuous variables and Chi-Square and Fisher exact tests for categorical variables.

The analyses intended to identify barriers to optimal treatment; we related these categories to maternal and hospital-level variables. Included maternal and hospital-level variables were identified as factors that may affect timing of ANCS administration based on review of existing literature.

Maternal demographic factors include private insurance, nulliparous, singleton gestation, history of prior preterm birth (delivered ≤37 weeks, before this current pregnancy) and prenatal care provider (generalist, midwife, or nurse practitioner; maternal-fetal medicine (MFM) specialist or MFM co-management; family practitioner or none). Maternal antepartum factors include reason for admission to hospital: delivery (the patient was admitted to the hospital with the intent to deliver), confirmed / suspected preterm labor (includes patients with a short cervix and advanced cervical effacement), preterm premature rupture of membranes, hypertensive diseases of pregnancy (includes preeclampsia and

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gestational hypertension) and other (includes oligohydramnios, vaginal bleeding/abruption, intrauterine growth restriction, diabetic problems, non-reassuring fetal status, cystitis/pyelonephritis, deep vein thrombosis, injury/trauma, asthma exacerbation or seizures). Gestational age at time of receipt of ANCS and latency (days) from administration of ANCS and delivery were also included. Hospital factors included use of electronic medical records (EMR), receives transfers and differences in care team availability that included in-house MFM specialist, in-house attending 24/7 coverage and presence of OBGYN residents on labor floor.

We performed hierarchical multinomial logistic regression modeling with hospital as a random effect to identify factors associated with ANCS treatment using optimal ANCS as the referent. Maternal and hospital variables with a p-value < 0.10 in bivariable analyses were included in the models and were retained in the model if p-values were less than 0.05. We first fitted the intercept-only model and then fitted models with hospital factors. Lastly maternal factors were added to the model. Odds ratios and 95% confidence intervals were estimated for maternal-level and hospital-level variables. Using the methods of Synnes et al[16], for each level of ANCS, we compared the standard error of the estimate of the random effect in the intercept only model with estimates in each hierarchical model. The percent change represents the amount of variation across hospitals explained by the model. Imputation for missing data was not performed. Analyses were conducted using SAS software (SAS Institute, Cary, NC).

RESULTS

Of the 115,502 individuals in the APEX population, 4,194 had a non-anomalous livebirth delivery at or after $24^{0/7}$ weeks but before $34^{0/7}$ weeks of gestation, those with incomplete or missing data were excluded (Figure 1).Thus, a total of 3123 eligible individuals were included in the analysis. Of these, ANCS were given to 2612 of the eligible individuals (83.6%). 1216 (38.9%) were treated within the optimal group and 1907 (61.1%) were in suboptimal group, with 495 (15.9%) too late, 901 (28.9%) too early and 511 (16.4%) did not receive any ANCS (none). Maternal, antepartum and hospital characteristics according to receipt and timing of ANCS are presented in Tables 1 and 2. Frequency of ANCS administration was significantly higher in individuals with singleton gestation. Rates of optimal and suboptimal ANCS administration were similar between individuals who had private insurance and those with history of prior preterm birth (Table 1). Optimal ANCS varied depending on reason for hospital admission. Individuals who were admitted for delivery were less likely to receive optimal ANCS (10%). Whereas, individuals admitted for hypertensive diseases of pregnancy were more likely to receive optimal ANCS (35%)(Table 2). Receipt of optimal ANCS was more common in hospitals with EMR and that receive patient transfers (Table 2).

In multinomial logistic regression models (Table 3) adjusting for hospital factors only, hospitals with EMRs had significantly reduced odds of no ANCS (none) (aOR 0.50 95%CI 0.34–0.75). Hospitals that accept transfer patients had significantly decreased odds of not giving ANCS (none) (aOR 0.25 95%CI 0.18–0.35) and for administrating ANCS too early (aOR 0.60 95%CI 0.49–0.74).

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Adjusting for maternal and hospital factors, hospitals with EMRs continued to have significant decreased odds of no ANCS (aOR 0.50 95%CI 0.34–0.75) but no difference in too early or too late ANCS administration.

Patients admitted for hypertensive disorders of pregnancy had significantly decreased adjusted odds for suboptimal ANCS groups compared to optimal ANCS [too late aOR 0.51 95%CI 0.34–0.77); too early aOR 0.35 95%CI 0.25–0.48); none aOR 0.42 95%CI 0.27–0.65)].

Treatment varied substantially by hospital (Figure 2); optimal frequencies ranged from 9.0 to 51.3%, and none frequencies from 6.1% to 61.8%. Frequencies of too late administration ranged from 7.1% to 33.3% and too early ranged from 8.3% to 51.9%. Hospital factors explained 20% of the variation across sites for no ANCS use, (Table 4 models with hospital factors only). However, when evaluating variation by hospital site, models with maternal and hospital factors did not explain any of the variation in ANCS use.

DISCUSSION

Factors related to patterns of ANCS use at hospitals in this study are similar to previous reports showing that more than 80% of eligible individuals receive at least one dose of ANCS before a preterm birth. Furthermore, fewer than 40% deliver within the optimal timeframe after ANCS administration to produce optimal benefit.[17] The principal barrier to well-timed treatment is difficulty in identifying when individuals will deliver.[18, 19] We did not identify unexpected differences in demographics, prenatal care providers, or maternal indication for early birth. ANCS were most often administered at the appropriate time to individuals admitted for hypertensive disease of pregnancy. This is not surprising, as this is a condition where delivery is often not acutely required permitting time for optimal ANCS administration.[20] Individuals who were admitted for intent to deliver, were less likely to receive any ANCS and if they did receive ANCS it was often a partial course, given the short time interval from admission to delivery.

Our data showed substantial variation in use and timing of ANCS administration across sites to a degree that was unexpected. Hospitals with EMR and those that accept patient transfers were less likely to miss opportunity to initiate ANCS.. These differences may be explained by differences between larger academic and smaller rural hospitals. Given variations in smaller hospitals' preparedness for neonatal resuscitation of preterm infants, individuals presenting with concern for preterm delivery are often quickly referred to higher level of obstetric care hospitals. Focus on expeditious transfer to higher level of care hospitals may decrease observation time and limit ability to gather additional information to aid in decision to initiate ANCS. This scenario may contribute to administrating ANCS too early or not at all. Given limitations of this data set we are unable to determine if all of the referring hospitals had ANCS administration protocols or routinely call accepting provider at referring hospital to discuss need for initiation of ANCS course prior to transfer. This is an area for future investigation and possible area to focus on to improve optimally timed administration of ANCS.

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It is important to acknowledge that almost one quarter of individuals in the none group were managed expectantly with ruptured membranes at 32 weeks of gestation or more. During the time of APEX data collection, from March 2008– February 2011, the National Institutes of Health recommended administration of corticosteroids before 34 weeks' gestation. However, there may have been some reluctance to use ANCS between 32 and 34 weeks, given prior controversy as to whether the benefit outweighed risk of neonatal or maternal infection at that gestational age range.[21] This underscores the variation in practice that can continue to exist despite clear consensus recommendations from professional organizations. Also, during the time of data collection, the current recommendations and guidelines for single repeat course, rescue course and use of late-preterm ANCS had not been established.[1] This current practice may result in more individuals falling into the too late and too early categories, placing more emphasis on need to identify factors for optimal first course of ANCS administration.

The inverse relation between rates of optimal and none might suggest that policies or customs that emphasized administration of ANCS were in place at these sites. This was not confirmed by the limited information gathered in APEX, nor in a provider-specific secondary analysis of APEX data that included an independent assessment of hospital cultures. Bousleiman et al., found a high level of expressed support for ANCS use in MFMU Network hospitals that were unrelated to the climates of innovation measured at the same hospitals.[22]

The principal barrier to improvement in use of ANCS is the absence of a reliable test for imminent preterm birth.[23,24] Thehospital site variation reported in this study demonstrates opportunities to apply quality improvement measures to this problem. Kaplan et al., reported findings from an intensive review of hospital and quality improvement personnel involved in all phases of administration of antenatal steroids at six Ohio hospitals participating in a state-wide effort to increase use of ANCS.[25] Reliable use was related to six factors: presence of a high reliability culture of safety; adoption of processes that promote high reliability; timely and efficient ANCS administration processes; involvement of multiple disciplines; awareness of evidence supporting use of ANCS; and broad recognition of the benefits of ANCS.[24]

Chandrasekaran et al., identified tangible opportunities that included decreasing the time interval from patient evaluation to ANCS administration and standardizing outpatient follow-up evaluation for patients who were discharged with symptoms of preterm labor to improve optimal ANCS adminstration.[17] Achieving appropriate and timely administration of ANCS is an ongoing challenge. Developing ANCS administration protocols that provide a more standardized approach for evaluation and timing of ANCS would be helpful in improving the percent of preterm births that receive ANCS. However we must acknowledge that this practice could also lead to an increase in overutilization of ANCS and those receiving ANCS too early.

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Appendix

In addition to the authors, other members of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network are as follows:

The Ohio State University, Columbus, OH – C. Latimer, L. Guzzo (St. Ann's), F. Johnson, L. Gerwig (St. Ann's), S. Fyffe, D. Loux (St. Ann's), S. Frantz, D. Cline, S. Wylie, J. Iams

Columbia University, New York, NY – M. Talucci, M. Zylfijaj, Z. Reid (Drexel U.), R. Leed (Drexel U.), J. Benson (Christiana H.), S. Forester (Christiana H.), C. Kitto (Christiana H.), S. Davis (St. Peter's UH.), M. Falk (St. Peter's UH.), C. Perez (St. Peter's UH)

University of Utah Health Sciences Center, Salt Lake City, UT – K. Hill, A. Sowles, J. Postma (LDS Hospital), S. Alexander (LDS Hospital), G. Andersen (LDS Hospital), V. Scott (McKay-Dee), V. Morby (McKay-Dee), K. Jolley (UVRMC), J. Miller (UVRMC), B. Berg (UVRMC)

University of North Carolina at Chapel Hill, Chapel Hill, NC – K. Dorman, J. Mitchell, E. Kaluta, K. Clark (WakeMed), K. Spicer (WakeMed), S. Timlin (Rex), K. Wilson (Rex)

University of Texas Southwestern Medical Center, Dallas, TX – L. Moseley, K. Leveno, M. Santillan, J. Price, K. Buentipo, V. Bludau, T. Thomas, L. Fay, C. Melton, J. Kingsbery, R. Benezue

University of Pittsburgh, Pittsburgh, PA – H. Simhan, M. Bickus, D. Fischer, T. Kamon (deceased), D. DeAngelis

MetroHealth Medical Center-Case Western Reserve University, Cleveland, OH – B. Mercer, C. Milluzzi, W. Dalton, T. Dotson, P. McDonald, C. Brezine, A. McGrail

University of Alabama at Birmingham, Birmingham, AL – M. Wallace, A. Northen, J. Grant, C. Colquitt, D. Rouse, W. Andrews

Northwestern University, Chicago, IL – G. Mallett, M. Ramos-Brinson, A. Roy, L. Stein, P. Campbell, C. Collins, N. Jackson, M. Dinsmoor (NorthShore University HealthSystem), J. Senka (NorthShore University HealthSystem), K. Paychek (NorthShore University HealthSystem), A. Peaceman

University of Texas Medical Branch, Galveston, TX – J. Moss, A. Salazar, A. Acosta, G. Hankins

Wayne State University, Detroit, MI – N. Hauff, Y. Sorokin, L. Palmer, P. Lockhart, D. Driscoll, L. Wynn, C. Sudz, D. Dengate, C. Girard, S. Field

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Brown University, Providence, RI – P. Breault, F. Smith, N. Annunziata, D. Allard, J. Silva, M. Gamage, J. Hunt, J. Tillinghast, N. Corcoran, M. Jimenez

The University of Texas Health Science Center at Houston, McGovern Medical School-Children's Memorial Hermann Hospital, Houston, TX– F. Ortiz, P. Givens, B. Rech, C. Moran, M. Hutchinson, Z. Spears, C. Carreno, B. Heaps, G. Zamora

Oregon Health & Science University, Portland, OR – J. Seguin, M. Rincon, J. Snyder, C. Farrar, E. Lairson, C. Bonino, W. Smith (Kaiser Permanente), K. Beach (Kaiser Permanente), S. Van Dyke (Kaiser Permanente), S. Butcher (Kaiser Permanente)

The George Washington University Biostatistics Center, Washington, D.C. – E. Thom, M. Rice, Y. Zhao, P. McGee, V. Momirova, R. Palugod, B. Reamer, M. Larsen

Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, MD – C. Spong, S. Tolivaisa

MFMU Network Steering Committee Chair (*Medical University of South Carolina, Charleston, SC*) – J. P. VanDorsten, M.

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Key Points-

- Majority of individuals who deliver between 24–34 weeks gestation do not receive properly timed antenatal corticosteroids
- Optimal use of antenatal corticosteroids varies by maternal and hospital factors and hospital site.
- Significant variation in hospitals sites regarding optimally timed administration of antenatal corticosteroids, indicate opportunities for improvement.

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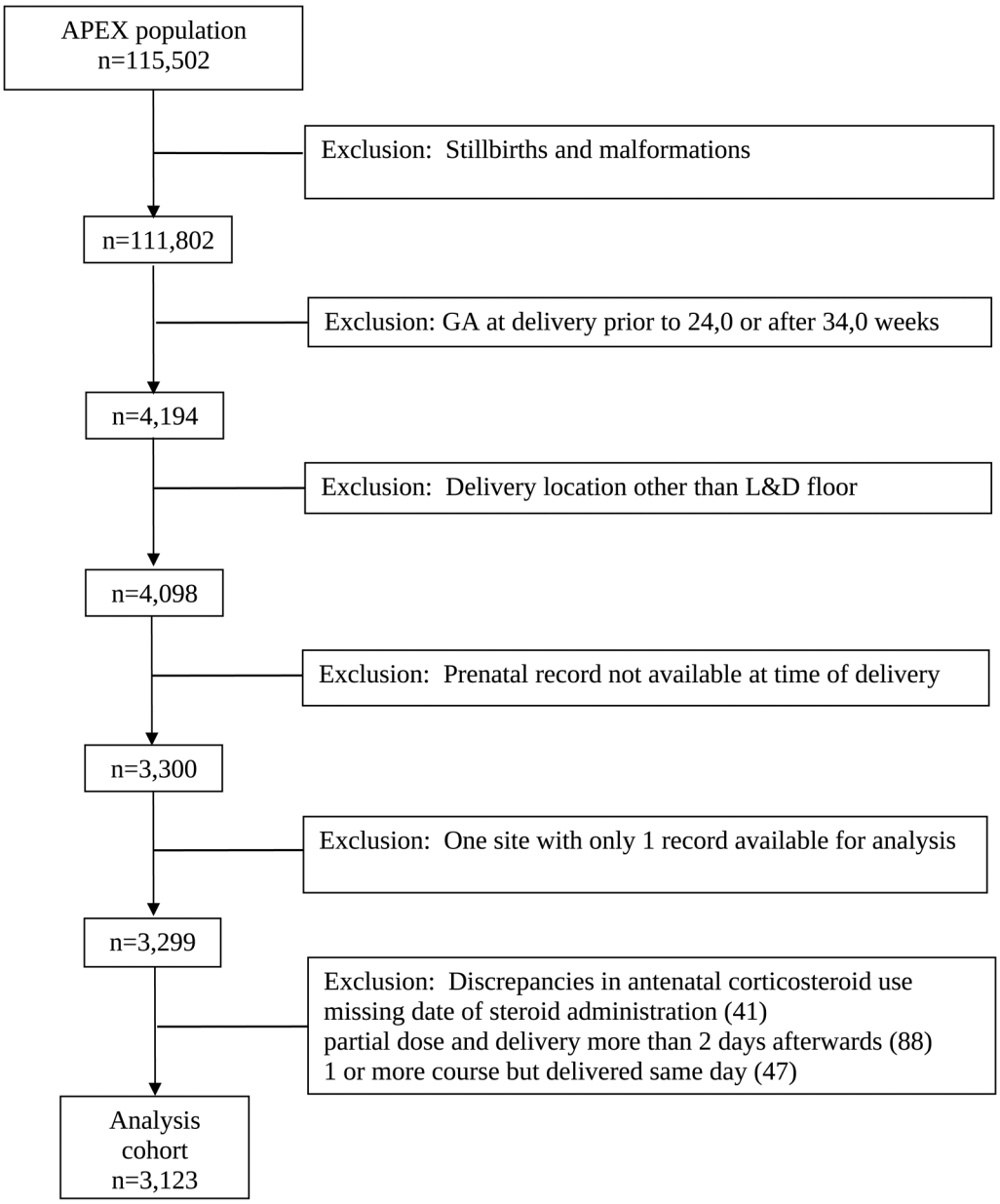

Figure 1.
Flow Diagram

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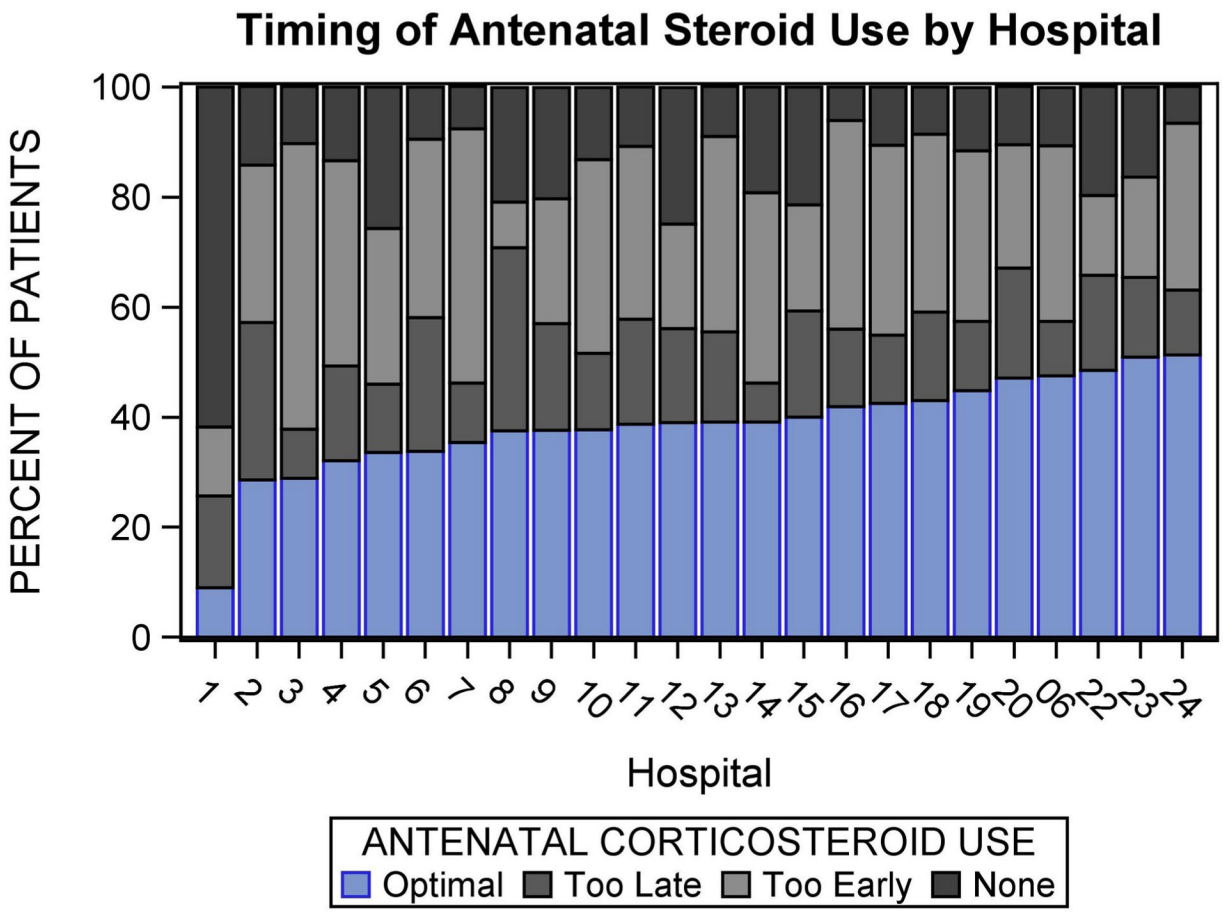

Figure 2.
Frequencies of ANCS administration by hospital site

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Table 1.

Demographics of the study population stratified by timing of antenatal corticosteroid administration

	Optimal N=1216 38.9%	**Too Late N=495 15.9%**	**Too Early N=901 28.9%**	**None N=511 16.4%**	**p***
Characteristic					
Age, *years*					0.11
Median	28	28	29	27	
Interquartile range	[22–33]	[23–33]	[24–33]	[23–33]	
Private insurance	495 (41.0)	204 (41.5)	418 (46.8)	162 (31.8)	0.83
Nulliparous	564 (46.4)	231 (46.7)	395 (43.8)	196 (38.4)	0.07
Singleton Gestation	1071 (88.1)	424 (85.7)	668 (74.1)	444 (86.9)	<0.001
Prior preterm birth	286 (23.5)	118 (23.8)	253 (28.1)	121 (23.7)	0.15
Antenatal care provider					0.38
Generalist/Midwife/NP	964 (79.4)	404 (82.5)	663 (73.8)	414 (81.0)	
MFM/Co-managed with MFM	198 (16.3)	61 (12.5)	203 (22.6)	81 (15.9)	
Family practitioner/None	52 (4.3)	25 (5.1)	33 (3.7)	16 (3.1)	

*Optimal vs. all other categories combined. Based on X^2 test or Fisher exact test for categorical variables and Wilcoxon rank-sum test for continuous variables.

Data presented as median [Interquartile range] or n (%).

Number missing private insurance (20), prior preterm birth (1), antenatal care provider (9)

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Table 2.

Antepartum and hospital characteristics

	Optimal N=1216 38.9%	Too Late N=495 15.9%	Too Early N=901 28.9%	None N=511 16.4%	p*
Antepartum Characteristic					
Primary reason for hospital admission					<0.001
Delivery	123 (10.1)	124 (25.1)	116 (12.9)	226 (44.2)	
Confirmed/suspected PTL	235 (19.3)	133 (26.9)	206 (22.9)	78 (15.3)	
Preterm PROM	294 (24.2)	106 (21.4)	311 (34.5)	79 (15.5)	
Hypertensive disorders of Pregnancy	422 (34.7)	80 (16.2)	128 (14.2)	73 (14.3)	
Other	142 (11.7)	52 (10.5)	140 (15.5)	55 (10.8)	
GA at ANCS, *weeks*					<0.001
Median	31.0	31.6	27.3		
Interquartile range	[28.3–32.6]	[29.0–33.0]	[25.0–29.7]		
ANCS to delivery, *days*					<0.001
Median	3	0	19		
Interquartile range	2–4	0–1	12–31.0		
Hospital Characteristics					
Patient transferred to hospital	404 (33.2)	145 (29.3)	200 (22.2)	53 (10.4)	<0.001
EMR use	1140 (93.8)	454 (91.7)	851 (94.5)	420 (82.2)	0.001
MFM available in-house	1146 (94.2)	460 (92.9)	863 (95.8)	467 (91.4)	0.66
In-house attending 24/7	1138 (93.6)	463 (93.5)	833 (92.5)	487 (95.3)	0.92
OB/GYN resident on L&D	1190 (98.4)	478 (96.8)	890 (98.9)	500 (98.2)	0.58

*Optimal vs. all other categories combined. Based on X^2 test or Fisher exact test for categorical variables and Wilcoxon rank-sum test for continuous variables.

Data presented as median [Interquartile range] or n (%).

PTL: preterm labor, PROM: premature rupture of membranes, GA: gestational age, ANCS: antenatal corticosteroid; EMR: electronic medical record, MFM: Maternal Fetal Medicine

Number missing OB/GYN resident on L&D (11)

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Table 3.

Hierarchical multinomial logistic regression models of ANCS treatment, with site as a random effect

	Optimal	Too Late	Too Early	None
Hospital factors				
EMR use, OR (95%CI)	Referent	0.80 (0.53–1.23)	0.95 (0.64–1.41)	**0.50 (0.34–0.75)**
Transfer, OR (95%CI)	Referent	0.83 (0.66–1.06)	**0.60 (0.49–0.74)**	**0.25 (0.18–0.35)**
Hospital and patient factors				
EMR use, OR (95%CI)	Referent	0.83 (0.54–1.28)	1.01 (0.68–1.52)	**0.54 (0.35–0.82)**
Transfer, OR (95%CI)	Referent	0.86 (0.67–1.10)	**0.65 (0.53–0.81)**	**0.28 (0.20–0.40)**
Nulliparous, OR (95%CI)	Referent	1.08 (0.84–1.39)	1.12 (0.90–1.39)	**0.73 (0.56–0.96)**
Singleton gestation, OR (95%CI)	Referent	0.88 (0.64–1.20)	0.44 (0.34–0.56)	1.10 (0.77–1.56)
History preterm birth, OR (95%CI)	Referent	1.05 (0.78–1.42)	1.46 (1.14–1.87)	0.73 (0.53–1.00)
Reason for hospital admission				
Delivery	Referent	**2.79 (1.85–4.21)**	1.06 (0.74–1.51)	**6.61 (4.37–10.0)**
PTL/pPROM	Referent	1.23 (0.86–1.76)	1.06 (0.81–1.39)	0.76 (0.52–1.12)
Hypertensive disorders of pregnancy	Referent	**0.51 (0.34–0.77)**	**0.35 (0.25–0.48)**	**0.42 (0.27–0.65)**
Other		Referent	Referent	Referent

PTL preterm labor, pPROM preterm premature rupture of membranes

Data presented as adjusted odds ratio with (95% CI)

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Table 4.

Hospital site variation (σ) in hierarchical regression models of ANCS treatment

Model	Optimal	Too Late	Too Early	None
Intercept only Estimate (SE)	Referent	0.10 (0.05)	0.13 (0.05)	0.44 (0.15)
Hospital factors Estimate (SE), % difference in SE *	Referent	0.09 (0.05), 0%	0.12 (0.05), 0%	0.33 (0.12), 20%
Hospital and patient factors Estimate (SE), % difference in SE *	Referent	0.11 (0.06), --	0.10 (0.05), 0%	0.54 (0.18), --

SE standard error

* compared with the standard error for the intercept only model