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Surfactant Use for Premature Infants with Respiratory Distress Syndrome in Three New York City Hospitals: Discordance of Practice from a Community Clinician Consensus Standard

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Abstract

Objectives—To assess concordance with a locally developed standard of care for premature infants with respiratory distress syndrome (RDS) for whom the standard recommends surfactant treatment within two hours of birth, and to examine the association between clinical, demographic, and hospital characteristics with discordance from the standard.

Study Design—Retrospective cohort study of 773 infants weighing ≤ 1750 grams born in any of three New York City hospitals between 1999 and 2002.

Results—227 of the 773 infants (29%) met criteria for treatment according to the standard. Of these, 37% received surfactant by two hours. By four hours, 70% of infants who met the standard received surfactant. White infants were more likely to receive surfactant by 4 hours (85%) than African American (61%) or Latino infants (67%). Multivariable logistic regression revealed significant odds ratios predicting discordance from the relaxed criteria (4 hours) for: African American race (4.10, 95% CI 1.30–13.00), 100 grams of birth weight (OR of 1.22, 95% CI 1.10–1.34), and hospital of birth.

Conclusion—Many infants with RDS failed to receive surfactant replacement therapy at 2 and 4 hours after birth. African Americans and those born larger were less likely to receive surfactant. If these data can be generalized, there is a large opportunity to reduce infant morbidity from RDS and to reduce racial/ethnic disparities in birth outcomes by increasing the rate and speed with which surfactant is delivered to these infants.

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Keywords

preterm infants; quality of care; racial disparities; surfactant; RDS

Introduction

Surfactant therapy prevents the development of respiratory distress syndrome (RDS) in many premature infants and shortens the course of RDS in others.[1–3] Although universal (prophylactic) treatment of at risk infants immediately after birth appears to confer the greatest benefit at a population level, the need to deliver endotracheal (ET) intubation and respiration in order to administer surfactant has given some clinicians pause. This concern arises because optimal respiratory management of the individual child who is not in severe distress would be nasal continuous positive airways pressure (nasal CPAP) rather than mechanical ventilation via an ET tube.[4,5] Selective treatment of children who develop RDS can be effective in reducing morbidity and mortality from RDS, especially if treatments begins within two hours of birth.[6] In general, preterm infants who do not receive prophylactic surfactant and who develop signs of RDS, should receive surfactant as soon as possible.[1]

The Vermont Oxford Network, a leading voluntary network of neonatal intensive care providers, has found that despite the overwhelming evidence supporting surfactant use, there were significant practice variations in both the use and timing of surfactant: approximately 80% of very low birth weight infants between 23 and 29 weeks of gestation born in the year 2000 received surfactant.[7]

To date, most studies of the use of surfactant have focused upon its prophylactic use (where clinical disagreements remain) rather than upon its use in response to signs and symptoms of RDS, for which its use is undisputedly important.[1,6] This study seeks to fill that gap. This study also used a community-focused design by bringing together clinicians at three hospitals to develop a *consensus community* standard to define and identify RDS for the audits that we describe below. The objectives of this study were to: 1) develop a local community definition for RDS appropriate for use in these three hospitals; 2) determine the proportion of RDS infants in these hospitals who receive surfactant; 3) determine characteristics of the infants (including race and ethnicity) and the delivery (such as time of day) that are associated with the failure to provide indicated surfactant therapy to infants demonstrating RDS.

Methods

Development of the Community Consensus Standard

We utilized community partnered methods[8] to bring together stakeholders from three institutions to develop a local community standard for our chart audits. In this case, the community was the group of clinicians who practice at the three hospitals. In the summer of 2001, we convened a panel of local experts – neonatologists, pediatricians, maternal fetal medicine specialists, and obstetricians – from the three hospitals included in this study to

develop a consensus definition of RDS that the experts agreed was sufficient to indicate the need for surfactant therapy. Chairs of Obstetrics and Pediatrics at each of the three institutions nominated and helped us to recruit thought leaders among their community of physicians to participate in the panel.

Our community-focused approach had the potential advantages of creating local buy-in of practitioners and of allowing us to supplement the evidence from efficacy and effectiveness studies with clinical wisdom of experts who care for the actual patients whose care we were auditing. The inclusion of practitioners from each of the hospitals assured that the panel could integrate a variety of perspectives from three distinct practice environments. In fact the participating hospitals had evolved very different practices regarding the ventilatory management of infants with RDS: this caused us to shift our goal for the standard from developing an operational definition of RDS to developing a standard that distinguished those children whose RDS is of sufficient severity that it ought to initiate surfactant therapy. The study team developed a synthesis of the literature for the participating experts. The review was based upon an electronic literature search using terms related to perinatal quality of care and also included relevant references from those articles. Search terms emphasized the postnatal use of surfactant, the natural history of respiratory distress syndrome, and the efficacy and effectiveness of surfactant in preterm infants with signs of respiratory distress syndrome, which were shared with our expert group. Based upon the literature review, the team drafted preliminary recommendations for the guidelines, which were then modified by the experts based on the synthesis and discussion among the experts. The standard was approved by consensus.

The panel recommended that surfactant (either natural or synthetic) be administered within two hours of birth to all premature infants with signs of respiratory distress syndrome (RDS), defined as: 1) chest radiographs consistent with RDS, requirement for mechanical ventilation with FIO2 ≥50%, 2) chest radiographs consistent with RDS, requirement for mechanical ventilation with FIO2≥30–49 and are worsening, or 3) evidence of RDS on chest radiograph, need for nasal continuous airways pressure with FIO2 ≥50%, and have two pCO2 measurements >55 (absent another respiratory or mechanical diagnoses, such as pneumothorax or diaphragmatic hernia, that offered an alternative explanation for the respiratory distress). The panel agreed further that in the absence of a chest x-ray, surfactant should be used within two hours if the clinical picture suggested RDS in a premature infant with no identifiable mechanical (e.g. poorly placed ET tube) cause of distress. The panel recommended that we assess surfactant use at two time points: two hours after birth and four hours after birth.

Patient Population

We identified all infants who weighed less than or equal to 1750 grams at birth between January 1, 1999 and December 31, 2002 at three institutions serving patients in New York City using hospital administrative databases. One hospital was a major urban tertiary care academic medical center and the other two hospitals were community hospitals. All three hospitals were Level 3 nurseries or a Regional Perinatal Center (the highest level designation in New York State). Although all three served diverse patient populations, they

differed both in terms of their organizational structures and their philosophies and aggressiveness in terms of their respiratory management. The Institutional Review Boards of all three hospitals approved this study.

Data Collection

We developed a computerized medical chart abstraction tool that incorporated the panel's definitions for RDS and organized the collection of detailed clinical characteristics sufficient to identify the presence or absence of RDS. We trained medical chart abstractors, and conducted a retrospective medical chart audit for all 773 infants to collect both clinical and socio-demographic variables. In addition to those clinical features needed to identify RDS, we abstracted information about the delivery, identified the presence of respiratory conditions (e.g., pneumonia, pneumothorax, pulmonary effusion, pulmonary interstitial emphysema) that might provide alternate explanations from RDS for the infant's clinical distress, and detailed information on timing, dosages, and route of administration of medications. We noted the hospital of birth and linked each audit to data regarding that hospital's characteristics.

Data Analysis

All statistical analyses were done using PC SAS version 9.1 (SAS Institute Inc., Cary, NC). Bivariate analyses used Chi Square, Fisher exact tests, t tests or Spearman rho as appropriate to assess the association of infant characteristics, delivery characteristics, infant complications, and hospital characteristics with underuse of surfactant. Independent variables that were statistically significant *($p<.05$)* or clinically important were included in multivariable analyses. As gestational age and birth weight were highly correlated, we included only birth weight in 100-gram increments in the multivariable models. Multivariable logistic regression models assessed the independent association of infant demographics, delivery factors, and hospital characteristics with underuse of surfactant. The final models included insurance as a dichotomous variable (private insurance versus all other types of insurance) as Medicaid, Medicaid Managed Care, self-pay, other were very similar. Results did not differ when insurance was entered as a four-level variable in the multivariable models. Exchanging gestational age for birth weight did not substantively change the results.

Results

Our sample included 773 infants (95.1%) out of the 813 infants identified who weighed ≤ 1750 grams, excluding only the three infants (0.4%) who were transferred before four hours and 37 (4.5%) whose medical records did not include all of the data elements included in our analysis. Hospital 1 accounted for 13% of the infant sample, Hospital 2 accounted for 20% of the sample, and Hospital 3 accounted for 67% of the sample. Of our infant sample, 25% were White, 34% were African American, 31% were Latino, and 10% were of other race/ethnicity. Forty-three percent had Medicaid, the mean birth weight was 1199 grams (standard deviation of 397 grams), mean gestational age was 29.3 weeks (standard deviation of 3.7), and the median 5-minute Apgar score was 7.0 (interquartile range of 3). (Table 1) Of the 773 infants, 227 infants (29.4%) developed signs of respiratory distress syndrome as

defined by the local community standard within the first two hours of life and 264 infants (34.2%) developed signs of RDS within the first four hours of life. Among the 227 infants who developed RDS, 38% were African American, 21% were white, 33% were Latino and 7% were other racial/ethnic groups, which was not significantly different than the overall racial/ethnic breakdown of the infant sample.

Thirty-seven percent of the 227 infants with signs of respiratory distress syndrome at two hours of age received surfactant within two hours of birth (Table 2). Bivariate analyses revealed higher rates of treatment were associated with lower birth weight, lower 5-minute Apgar, insurance, hospital of birth, weekend birth, and time of birth. By four hours of age, 71% of the infants with signs of RDS within 2 hours of life had received surfactant.

In the multivariable model predicting discordance from the recommendation to deliver surfactant at two hours of age, increasing birth weight was associated with failure to receive surfactant whereas being born at night was associated with lower odds. Hospital of birth remained significant in the multivariable model (Table 3).

Audits of care at the four hour time point found that 70% (186/264) of low birth weight infants who had shown signs of RDS by that time had received surfactant. Eighty-five percent of white, 80% of other, 67% of Latino, and 61% of African American infants with RDS had received surfactant within 4 hours of life. Variation across the hospitals remained significant at four hours, as did birth weight. (Table 4). The multivariable model predicting failure to use surfactant for children with community-defined RDS by four hours old, identified 100 grams of birth weight (OR=1.22, 95% CI 1.10–1.34), African American race (4.10, 1.30–12.99), and hospital of birth as factors associated with increased odds of failure to treat (Table 5).

Of the 78 infants who had signs of respiratory distress syndrome by 4 hours of birth but had not received surfactant, 30 received surfactant during their hospital stay. Of the remaining 48 infants who had signs of respiratory distress but never received surfactant during their hospital stay, four were White, 30 were African American, one was Latino, and 13 were from other racial/ethnic categories. In other words, by discharge, 6% of whites, 33% of African Americans, and 1% of Latino children who had signs of RDS within 4 hours of life had not received surfactant by discharge *(p<.001)*.

Discussion

Care deviated from that recommended by the consensus of a group of clinicians who practiced in the three hospitals that we studied. This standard called for the use of surfactant within two hours for those children who met the criteria for significant RDS. This was particularly important because one of the hospitals had a preference for use of nasal CPAP rather than mechanical ventilation and endotracheal intubation; endotracheal intubation is the preferred means of delivery for surfactant. We had hoped that by employing a definition that identified more severely affected infants, we would demonstrate similarly high rates of surfactant use across the hospitals, with limited hospital to hospital variation. Unfortunately, care for many of these infants deviated from the community standard: 63% and 30% of

infants had not received surfactant therapy by 2 hours and 4 hours post delivery respectively, and hospital to hospital variation was evident. Larger babies were less likely to receive surfactant than smaller ones, keeping in mind that all the infants in the study were less than or equal to 1750 grams. We found that African American infants were less likely than white infants to receive surfactant by four hours of age. This is concerning because surfactant use improves infant outcomes in infants with signs of RDS, regardless of race or ethnicity.

We incorporated the perspectives of local practitioners from several relevant specialties to develop a consensus standard for the use of surfactant, which assured that the recommendations would be applicable to the local patient population. Because one of our hospitals was reluctant to intubate infants unless absolutely necessary, our standard restricted the eligible population to those with more significant disease. Hence this is the population that is most likely to benefit from surfactant therapy. In other words, the prophylactic use of surfactant may leave room for clinical judgment to identify children for whom the risk of treatment may exceed the benefit; it is less likely that such extenuating circumstances represent a meaningful fraction of the infants in our study.

Our findings that practice varies by race/ethnicity extends to treatment findings from the Vermont Oxford Network study that found White preterm infants more likely to receive prophylactic surfactant than Nonwhite infants.[7] More than a decade ago, as surfactant therapy was still diffusing into practice, such disparities were not found.[9] The association of insufficient or delayed therapy with poorer outcomes for African Americans is consistent with current hypotheses.[10] Our findings of racial/ethnic disparities in this potentially life-saving treatment highlight the critical need to understand, improve, and deliver high quality care to all. The inadequate delivery of surfactant to 63% of infants within 2 hours of delivery and the failure to deliver surfactant at all to infants within 4 hours emphasizes why we need to re-design health care such that delivery of treatment such as surfactant is a function of clinical characteristics and of the health care delivery system and less dependent upon the individuals who are functioning within it.

The Institute of Medicine[11] has identified both equity and timeliness as key attributes of quality care. This study utilized a local community standard to identify the failure to provide timely treatment in infants for whom it was indicated. We found both delay and underuse of surfactant in our cohort. Our finding that care varied between hospitals is consistent with previous work looking at processes and outcomes related to delivery[12] and neonatal intensive care.[13], [14] Our findings support previous evidence that preterm infants at higher gestational age are less likely to receive indicated surfactant.[7] This finding would be expected if clinicians systematically over-estimate the gestational age or lung maturity of larger infants compared to smaller ones and thus withhold or delay surfactant. We note that nighttime births were associated with increased use of surfactant in the first 2 hours and that by 4 hours, this trend was no longer evident. We are unable to say if this reflects differences in quality of the staff, culture of practice between day and night, or fewer competing priorities at night compared to day. In either case, study of differences between practices at night and during the day may prove fruitful by identifying favorable practices within institutions.

As with any review of medical chart data, errors occur with collection of data and clinical information may be missing. However, we trained medical chart abstractors and used an automated electronic tool in order to reduce the likelihood of errors in collecting the data. Our study design is not sufficient to make statements regarding causality. Given the unambiguous efficacy of early treatment of RDS with surfactant, our findings of frequent delay or failure to provide surfactant therapy in children with demonstrable RDS may represent only the tip of the iceberg regarding avoiding preventable complications of RDS. Our results suggest opportunities to develop process and system changes to increase the use of surfactant in institutions and by clinicians.[15]

Three diverse New York City area hospitals with differing organizational characteristics and clinical practice styles jointly were able to develop practical standards for studying the under-use of surfactant in low birth weight infants with signs consistent with RDS. We found significant discordance from those recommendations: substantial delays in surfactant use for a majority of infants, and racial disparities regarding who receives surfactant at all. Any lingering controversies regarding the prophylactic use of surfactant should not be allowed to obscure the importance of surfactant to treat infants with RDS, for whom early treatment is an imperative. Hospitals that treat premature infants should be responsible to audit their use of surfactant for these sick infants and be accountable to improve their treatment rates accordingly. Efforts to incorporate measures of surfactant use by accrediting and regulatory agencies should be considered. Although our data suggest that racial disparities exist, the goal should extend beyond reducing disparities: any death or misadventure of an untreated premature infant with RDS should be regarded as preventable and therefore unacceptable.

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Table 1

Characteristics of Infant Sample (N=773)

Infant Characteristics	Infant Sample (N=773)
Mean birth weight ± s.d. (grams)	1199 ± 397
Mean gestational age ± s.d. (weeks)	29.3 ± 3.7
Median 5 min. Apgar (interquartile range)	7 (3)
Gender	
Male	384 (50%)
Female	389 (50%)
Race/ethnicity	
White	190 (25%)
Black	266 (34%)
Latino	241 (31%)
Other	76 (10%)
Insurance	
Medicaid/Medicaid HMO	332 (43%)
Private Insurance	279 (36%)
Self-pay	118 (15%)
Other	44 (6%)
Delivery Type*	
Vaginal Delivery	169 (22%)
C-section	308 (40%)
Hospital	
Hospital #1	100 (13%)
Hospital #2	158 (20%)
Hospital #3	515 (67%)
Weekend Birth	
Yes	214 (28%)
No	559 (72%)
Nighttime Birth	
Yes	259 (34%)
No	514 (66%)

*A data processing error corrupted the coding of delivery type, resulting in data missing for 296 births.

Table 2

Association between Infant and Delivery Characteristics and Use of Surfactant by two hours of age (N=227)

Infant Characteristics	Infants with signs of RDS	Failure to Treat	Received Surfactant	P
Eligible Sample	227	143 (60%)	84 (37%)	
Mean birth weight ± s.d.(grams)	949 ± 329	1007 ± 342	851 ± 282	**0.0005**
Median 5 min. Apgar (interquartile range)	7 (3)	7 (3)	7 (2)	**.0001**
Gender				0.308
Male	117	70 (60%)	47 (40%)	
Female	110	73 (66%)	37 (34%)	
Race/ethnicity				**0.008**
White	47	34 (72%)	13 (28%)	
Black	87	59 (68%)	28 (32%)	
Latino	76	35 (46%)	41 (54%)	
Other	17	15 (88%)	2 (12%)	
Insurance				**0.04**
Medicaid/Medicaid HMO	106	67 (63%)	39 (37%)	
Private Insurance	67	49 (73%)	18 (27%)	
Self-pay	36	20 (56%)	16 (44%)	
Other	18	7 (39%)	11 (61%)	
Delivery Type*				0.62
Vaginal Delivery	45	29 (64%)	16 (36%)	
C-section	90	54 (60%)	36 (40%)	
Hospital				**.0025**
Hospital #1	38	27 (71%)	11 (29%)	
Hospital #2	57	25 (44%)	32 (56%)	
Hospital #3	132	91 (69%)	41 (31%)	
Weekend Birth				**.0342**
Yes	75	40 (53%)	35 (47%)	
No	152	103 (68%)	49 (32%)	
Nighttime Birth				**.0040**
Yes	81	41 (51%)	40 (49%)	
No	146	102 (70%)	44 (30%)	

*A data processing error corrupted the coding of delivery type, resulting in data missing for 92 births.

Table 3

Multivariable Logistic Regression for Failure to Receive Surfactant within 2 hours of birth

Characteristics	Underuse of Surfactant (2hr)		
	Adjusted Odds Ratio	95% Confidence Interval	P
Black	1.15	(0.35–3.76)	NS
Latino	0.33	(0.10–1.12)	NS
Other	4.43	(0.78–25.32)	NS
Private insurance vs. Medicaid/self-pay/other	0.84	(0.30–2.36)	NS
Birth weight *	**1.29**	**(1.15–1.45)**	**<.0001**
5-minute Apgar	1.07	(0.92–1.25)	NS
Hospital #1	1.17	(0.45–3.03)	NS
Hospital #2	**0.36**	**(0.15–0.87)**	**0.02**
Weekend birth	0.71	(0.37–1.36)	NS
Nighttime birth	**0.41**	**(0.21–0.79)**	**0.008**

* Birth weight in 100-gram increments

Table 4

Association between Infant Characteristics and Underuse of Surfactant (w/in 4 hours)

Infant Characteristics	Infants with signs of RDS	Failure to Treat	Received Surfactant	P
Eligible Sample	264	78 (30%)	186 (70%)	
Mean birth weight ± s.d.(grams)	986 ± 340	1094 ± 360	942 ± 322	**.0015**
Median 5 min. Apgar (interquartile range) s.d.	7 (3)	7 (2)	7 (3)	**.0001**
Gender				0.407
Male	139	38 (27%)	101 (73%)	
Female	125	40 (32%)	85 (68%)	
Race/ethnicity				**0.0042**
White	65	9 (14%)	56 (86%)	
Black	92	36 (39%)	56 (61%)	
Latino	87	29 (33%)	58 (67%)	
Other	20	4 (20%)	16 (80%)	
Insurance				**0.03**
Medicaid/Medicaid HMO	117	40 (34%)	77 (66%)	
Private Insurance	86	15 (17%)	71 (83%)	
Self Pay	41	15 (37%)	26 (63%)	
Other	20	8 (40%)	12 (60%)	
Delivery*				0.45
Vaginal Delivery	54	18 (33%)	36 (67%)	
C-section	105	29 (28%)	76 (72%)	
Hospital				**.0003**
Hospital #1	39	22 (56%)	17 (44%)	
Hospital #2	61	17 (28%)	44 (72%)	
Hospital #3	164	39 (24%)	125 (76%)	
Weekend Birth				.60
Yes	84	23 (27%)	61 (73%)	
No	180	55 (31%)	125 (69%)	
Nighttime Birth				.11
Yes	90	21 (23%)	69 (77%)	
No	174	57 (33%)	117 (67%)	

*A data processing error corrupted the coding of delivery type, resulting in data missing for 105 births.

Table 5

Multivariable Logistic Regression for Risk of Underuse of Surfactant within 4 hours of births

Characteristics	Underuse of Surfactant (4hr)		
	Adjusted Odds Ratio	95% Confidence Interval	p
Black	**4.10**	**(1.30–12.99)**	**.016**
Latino	2.64	(0.85–8.17)	NS
Other	2.16	(0.48–9.81)	NS
Private Insurance vs. Medicaid/self-pay/other	0.58	(0.22–1.50)	NS
Birth weight *	**1.22**	**(1.10–1.34)**	**<.0001**
5-minute Apgar	1.14	(0.97–1.34)	NS
Hospital #1	**2.80**	**(1.16–6.74)**	**.02**
Hospital #2	0.62	(0.28–1.39)	NS
Weekend birth	1.06	(0.55–2.04)	NS
Nighttime birth	0.65	(0.33–1.26)	NS

* Birth weight in 100-gram increments