

kept an appropriate distance from politicians and the pharmaceutical industry, or was directly accountable to the public.⁵ With the publication of this paper, we might further question whether NICE was delivering the goods.

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Collaborative quality improvement to promote evidence based surfactant for preterm infants: a cluster randomised trial

Jeffrey D Horbar, Joseph H Carpenter, Jeffrey Buzas, Roger F Soll, Gautham Suresh, Michael B Bracken, Laura C Leviton, Paul E Plsek, John C Sinclair

Vermont Oxford Network, 33 Kilburn Street, Burlington, VT 05401, USA

Jeffrey D Horbar
chief executive and scientific officer

Joseph H Carpenter
director of technical operations

Roger F Soll
director of clinical trials

University of Vermont, Burlington, VT

Jeffrey Buzas
associate professor of mathematics and statistics

Medical University of South Carolina, Charleston, SC, USA

Gautham Suresh
assistant professor of paediatrics

Center for Perinatal, Pediatric and Environmental Epidemiology, Yale University, New Haven, CT, USA

Michael B Bracken
professor of epidemiology

Robert Wood Johnson Foundation, Princeton, NJ, USA

Laura C Leviton
senior program officer

Paul E Plsek and Associates, Atlanta, GA, USA

Paul E Plsek
quality improvement consultant

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Abstract

Objective To test a multifaceted collaborative quality improvement intervention designed to promote evidence based surfactant treatment for preterm infants of 23-29 weeks' gestation.

Design Cluster randomised controlled trial

Setting and participants 114 neonatal intensive care units (which treated 6039 infants of 23-29 weeks gestation born in 2001).

Main outcome measures Process of care measures: proportion of infants receiving first surfactant in the delivery room, proportion receiving first surfactant more than two hours after birth, and median time from birth to first dose of surfactant. Clinical outcomes: death before discharge home, and pneumothorax.

Intervention Multifaceted collaborative quality improvement advice including audit and feedback, evidence reviews, an interactive training workshop, and ongoing faculty support via conference calls and email.

Results Compared with those in control hospitals, infants in intervention hospitals were more likely to receive surfactant in the delivery room (adjusted odds ratio 5.38 (95% confidence interval 2.84 to 10.20)), were less likely to receive the first dose more than two hours after birth (adjusted odds ratio 0.35 (0.24 to 0.53)), and received the first dose of surfactant sooner after birth (median of 21 minutes *v* 78 minutes, $P < 0.001$). The intervention effect on timing of surfactant was larger for infants born in the participating hospitals than for infants transferred to a participating hospital after birth. There were no significant differences in mortality or pneumothorax.

Conclusion A multifaceted intervention including audit and feedback, evidence reviews, quality improvement training, and follow up support changed the behaviour of health professionals and promoted evidence based practice.

Introduction

Health services continue to show major gaps between routine practice and what the research evidence

suggests is optimal patient care.¹ In neonatology, systematic reviews indicate that prophylactic surfactant treatment of high risk preterm infants reduces risk of death and pneumothorax by 40%, and that earlier treatment is more effective than later treatment.²⁻³ Despite this evidence, few such infants routinely receive prophylactic surfactant treatment, and many infants, particularly those born at outlying hospitals, receive delayed treatment.⁴

Various strategies for promoting behaviour change and evidence based practice have been proposed.⁵⁻⁸ Experience from the Vermont Oxford Network suggests that multidisciplinary collaborative quality improvement based on four key "habits" (change, evidence based practice, systems thinking, and collaborative learning) modifies practice in neonatal intensive care units, improves clinical outcomes, and reduces costs.⁹⁻¹⁰

We therefore conducted a cluster randomised controlled trial to test whether teams in neonatal intensive care units exposed to a multifaceted collaborative quality improvement intervention based on the four key habits would administer the first dose of surfactant sooner after birth, and achieve improved patient outcomes for preterm infants of 23-29 weeks' gestation.

Methods

Eligibility, enrolment, and randomisation

Of the 300 North American hospitals in the Vermont Oxford Network (see bmj.com),¹¹ 178 were eligible to enter the trial and 114 enrolled. A secure computer program assigned enrolled hospitals to one of two study arms using a completely randomised design.

Components of the multifaceted intervention

Audit and feedback—In July 2000 intervention hospitals received confidential, individualised feedback from the Vermont Oxford Network including site-specific



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Participants in the Vermont Oxford Network, and details of the intervention workshop appear on bmj.com

Table 1 Median (interquartile range) characteristics of infants treated in 114 hospitals that participated in trial of quality improvement intervention for surfactant treatment of preterm infants, in the assessment year, 2001*

	All infants		Infants born at participating hospitals		Infants transferred to participating hospital after birth	
	Intervention hospitals (n=57)	Control hospitals (n=57)	Intervention hospitals (n=57)	Control hospitals (n=57)	Intervention hospitals (n=57)	Control hospitals (n=57)
No of infants treated per neonatal unit	45 (35-75)	40 (25-68)	40 (33-64)	36 (22-56)	6 (3-12)	5 (2-12)
Birth weight (mean grams)	942 (902-968)	925 (896-973)	937 (902-963)	920 (889-960)	963 (890-1063)	989 (907-1085)
Gestational age (mean weeks)	27 (26-27)	27 (26-27)	27 (26-27)	27 (26-27)	27 (26-27)	27 (26-27)
Female (%)	47 (41-51)	45 (41-51)	47 (41-51)	47 (42-53)	50 (33-63)	40 (25-50)
Maternal ethnicity (%):						
Black	24 (8-40)	29 (11-50)	26 (9-40)	29 (11-50)	13 (0-50)	15 (0-68)
Hispanic	6 (2-17)	6 (3-28)	6 (2-15)	7 (2-30)	0 (0-20)	0 (0-16)
White	57 (43-70)	44 (24-68)	59 (43-72)	44 (25-68)	50 (25-86)	50 (8-92)
Asian	1 (0-4)	0 (0-3)	1 (0-4)	0 (0-3)	0 (0-0)	0 (0-0)
Other	0 (0-3)	0 (0-4)	0 (0-2)	0 (0-2)	0 (0-0)	0 (0-0)
Small for gestational age (%)	10 (6-12)	9 (7-13)	11 (6-13)	10 (7-13)	0 (0-2)	0 (0-5)
Multiple birth (%)	26 (20-35)	24 (16-31)	27 (21-33)	25 (17-33)	0 (0-24)	0 (0-20)
Given antenatal corticosteroids (%)	77 (68-85)	77 (68-86)	83 (73-89)	84 (75-91)	33 (20-50)	40 (19-65)
Delivered by caesarean section (%)	62 (54-70)	58 (49-63)	61 (54-71)	59 (50-64)	50 (23-71)	50 (29-60)
Apgar score ≤ 3 at 1 minute (%)	32 (25-39)	30 (24-36)	32 (24-39)	29 (21-38)	38 (25-50)	32 (17-50)

*Characteristics reported by study arm and birth location for clusters. Each hospital is considered a cluster.

information and peer comparisons related to the administration and timing of surfactant, and delivery room practice for infants of 23-29 weeks' gestation born in 1998 and 1999.

Workshop—Intervention hospitals were invited to attend a workshop (see bmj.com). Of the 57 teams invited, 56 attended (53 physicians, 46 nurses, and 21 respiratory therapists). The workshop included didactic sessions, facilitated site team exercises, and multi-institutional group exercises designed to promote four key "habits" (change, evidence based practice, systems thinking, and collaborative learning).^{9, 12}

Ongoing support—Collaboration among intervention arm teams was fostered through quarterly conference calls and an email discussion list.

Control hospitals received centre-specific, confidential reports routinely prepared for members of the Vermont Oxford Network.

Outcome measures

Primary outcome measures consisted of process of care measures (surfactant treatment in the delivery room, first surfactant treatment more than two hours after birth (among those receiving surfactant), and time after birth when first surfactant dose was administered) and infant outcome measures (death before discharge from hospital, and pneumothorax).

Statistical methods

We assessed outcomes for infants born in 2001 with gestational ages of 23 weeks to 29 weeks, with birth weights of 401 to 1500 g, and without major birth defects. We pre-specified conducting primary analyses among all infants, and separately among infants born in the participating hospitals (inborn) and among infants transferred to a participating hospital after birth (outborn).

Our analyses were on an intention to treat basis. We adjusted analyses for infant covariates (gestational age, birth location, ethnicity) and hospital covariates (type of neonatal intensive care unit, teaching status, and annual volume of infant patients) (see bmj.com for more details).

Results

Baseline comparability

The hospitals in the two study arms were generally similar in types of neonatal intensive care unit, teaching status, and annual volume of preterm infant admissions, although more of the neonatal intensive care units in the control arm were type A (restricted assisted ventilation or no major surgery available).

The characteristics of the infants were comparable except the proportion of white infants which was higher at intervention hospitals (table 1).

Primary outcomes

Delivery room surfactant treatment was significantly higher in the intervention than in the control arm for all infants, for the infants born at participating hospitals (inborn), and for those transferred to participating hospitals after birth (outborn) (table 2). First surfactant treatment more than two hours after birth was significantly lower in the intervention than in the control arm. Infants in the intervention arm received surfactant significantly sooner after birth than did infants in the control arm (median 21 minutes (interquartile range 10-128) *v* 78 minutes (29-410), adjusted hazard ratio 1.57 (95% confidence interval 1.42 to 2.07)). For inborn infants, median times were 18 minutes and 75 minutes in the intervention and control arms (adjusted hazard ratio 1.83 (1.50 to 2.23)); for outborn infants, the median times were 74 and 103 minutes (adjusted hazard ratio 1.30 (1.00 to 1.69)). When restricted to infants who received surfactant, the median times to first dose for all infants were 15 and 52.5 minutes in the intervention and control arms (adjusted hazard ratio 1.75 (1.47 to 2.09)).

There were no significant differences in mortality or pneumothorax. There was a trend towards decreased pneumothorax for outborn infants in the intervention arm (adjusted odds ratio 0.58 (0.33 to 1.03)).

There were significant interactions between treatment arm and location of birth for surfactant administration in the delivery room ($P < 0.003$) and for first surfactant treatment more than two hours after birth

Department of Pediatrics, McMaster University, Hamilton, Ontario, Canada

John C Sinclair
professor emeritus

Correspondence to:
J D Horbar
horbar@vtxoxford.org

Table 2 Dichotomous primary study outcomes for 114 hospitals that participated in trial of quality improvement intervention for surfactant treatment of preterm infants, in the assessment year, 2001.* Values are percentages unless stated otherwise

	Intervention hospitals (n=57)	Control hospitals (n=57)	Odds ratios (95% CI)	
			Unadjusted	Adjusted†
Surfactant given in delivery room:				
All infants	54.7	18.2	5.41 (3.30 to 8.87)	5.38 (2.84 to 10.20)
Inborn infants‡	58.0	18.4	6.15 (3.62 to 10.43)	6.16 (3.03 to 12.54)
Outborn infants‡	26.9	17.2	1.77 (1.01 to 3.11)	1.99 (1.12 to 3.53)
First dose of surfactant given after 2 hours:				
All infants	9.4	24.9	0.31 (0.21 to 0.45)	0.35 (0.24 to 0.53)
Inborn infants‡	7.4	23.4	0.26 (0.17 to 0.40)	0.29 (0.18 to 0.47)
Outborn infants‡	26.4	36.0	0.64 (0.40 to 1.00)	0.57 (0.37 to 0.89)
Infant mortality:				
All infants	17.8	18.2	0.97 (0.81 to 1.16)	1.01 (0.79 to 1.30)
Inborn infants‡	17.5	17.7	0.99 (0.82 to 1.19)	1.08 (0.83 to 1.42)
Outborn infants‡	20.2	20.3	0.99 (0.68 to 1.45)	0.74 (0.52 to 1.06)
Infant pneumothorax:				
All infants	6.6	7.4	0.89 (0.68 to 1.17)	0.89 (0.67 to 1.18)
Inborn infants‡	6.6	7.2	0.92 (0.69 to 1.22)	0.92 (0.68 to 1.25)
Outborn infants‡	6.2	9.1	0.66 (0.39 to 1.13)	0.58 (0.33 to 1.03)

*Outcomes reported by study arm and birth location for clusters. Each hospital is considered a cluster.

†Covariates in adjusted model include gestational age, maternal ethnicity (black, Hispanic, white, or other), teaching hospital (yes or no), type of neonatal intensive care unit (A, B, or C), and average annual volume of very low birthweight infants.

‡Inborn infants are those born in the participating hospitals. Outborn infants are those born at another hospital and transferred to a participating hospital after birth.

($P < 0.001$) resulting from larger effect sizes for inborn infants than for outborn infants (table 2). There was a significant interaction between treatment arm and gestation for first surfactant treatment more than two hours after birth among inborn infants ($P = 0.01$) due to changes in the size, but not the direction, of the effect across gestational age. The differences between treatment arms for this measure were greatest at 25 weeks and smallest at 29 weeks.

The intraclass correlation coefficients were 0.31 for surfactant administration in the delivery room, 0.09 for first surfactant treatment more than two hours after birth, 0.25 for time to first surfactant dose, and 0.01 for both mortality and pneumothorax.

Changes in 2000 and 2001

We saw persistent reductions in the median time of the first surfactant dose and in interhospital variability for intervention hospitals starting in the last quarter of 2000, after the workshop (figure).

Discussion

The multifaceted intervention tested in this trial produced significant improvement in the timing of surfactant use for very low birthweight infants in neonatal intensive care units. The improvements were greater for infants born at the participating hospitals (inborn) than for those transferred after birth (outborn) (unsurprising given delays between birth and transfer and the involvement of non-study teams in providing delivery room care and initial stabilisation for outborn infants).

Comparison with other studies

Systematic reviews suggest that audit and feedback,⁵ interactive workshops,⁶ and multidisciplinary collaboration⁷ can modify professional practice and improve patient outcomes. A systematic review of 117 studies assessing implementation of practice guidelines, including 46 cluster randomised trials of multifaceted

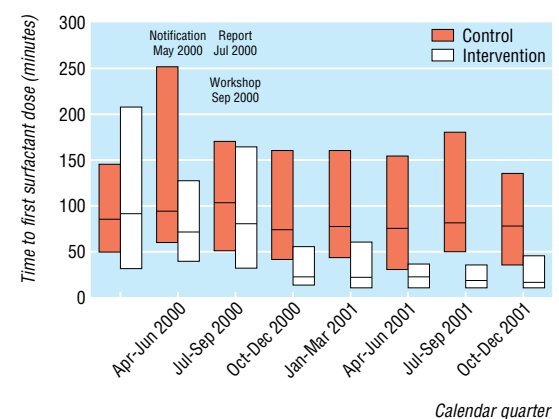
interventions, showed small to modest improvements in the processes of patient care.⁸ Eight studies that evaluated combinations of educational materials, educational meetings, and audit and feedback showed a median 3% improvement in target outcome (range 2.6% to 9.0%). The 37% increase we observed in delivery room surfactant treatment is large in comparison.

Patient outcomes

On the basis of results from systematic reviews,^{2,3} we expected that if our intervention resulted in earlier surfactant treatment it would also lead to reductions in death and pneumothorax. However, we observed no significant reductions in either death or pneumothorax. There are several possible explanations. Firstly, our wide confidence intervals for death and pneumothorax are compatible with the effects observed in the systematic reviews. Secondly, our trial was not designed to test the efficacy of prophylactic or early surfactant treatment, since infants were not randomly assigned to these treatment options. Thirdly, our study may have had insufficient power to detect an effect on mortality. Although we had 80% power to detect a 4% difference in mortality, a difference this large would have required a 60% increase in surfactant administration in the delivery room and a relative risk for death of 0.6. Such a relative risk of death, although based on the systematic reviews, may have been too large an expected effect: antenatal corticosteroid therapy, which reduces the risk of death of preterm infants, has increased and time after birth to first dose of surfactant has decreased since the original trials were performed.^{4,13} These changes may reduce the additional benefit expected from prophylactic surfactant.

Limitations of this study

Our study was not designed to determine the effects of individual components of the multifaceted intervention, or its cost. Although only 114 of the 178 eligible hospitals enrolled in the study, enrolled and non-enrolled hospitals had similar characteristics, and our findings are probably generalisable to other neonatal intensive care units. However, we cannot predict the generalisability of our findings to other clinical settings



Median (interquartile range) time after birth at which first dose of surfactant was administered to preterm infants in neonatal intensive care units by calendar quarter. Units in intervention group were notified of their status in May 2000, were given individualised feedback in July 2000, and were invited to a quality improvement workshop in September 2000

What is already known on this topic

The quality improvement collaborative is a promising intervention to encourage evidence based practices and has been used in a variety of healthcare settings

What this study adds

A multifaceted collaborative quality improvement intervention based on four key habits was used to promote evidence based surfactant therapy for preterm infants

It produced significant changes in the timing of surfactant use and a 37% increase in surfactant treatment in the delivery room

It did not result in significant changes in mortality or pneumothorax, however, but the study's power to detect these changes may have been low

involving different target practices and evidence, and we cannot predict whether a different workshop faculty would achieve similar results. Our trial is unlikely to suffer from the problems reported in a recent review of cluster trials since randomisation was secure and blinded, and there was no attrition of clusters.¹⁴

Conclusion

A multifaceted collaborative improvement intervention—including audit and feedback, evidence reviews, quality improvement training based on four key habits, and follow up support—changed the behaviour of neonatologists and promoted evidence based practice.

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Competing interests: JDH is chief executive and scientific officer, RFS is a director, and JHC is an employee of the Vermont Oxford Network. JB received funding for research from the Ver-

mont Oxford Network. RFS has acted as a consultant and spoken at meetings sponsored by various manufacturers of surfactant products, including Ross Laboratory Division of Abbott Laboratories and Chiesi Pharmaceuticals. RFS has also received grant funding from Ross Laboratories to conduct research regarding surfactant therapy. PEP has served as a paid consultant to the Vermont Oxford Network and other clients who sponsor improvement collaboratives. GS has served as a paid consultant to Dey Laboratories, a manufacturer of surfactant.

Ethical approval: The study was approved by the University of Vermont Institutional Review Board.

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A memorable patient

A fishy tale

As part of my GP vocational training, I was working in the accident and emergency department when I met Mr A. He described an evolving rash on his right hand and arm, but was otherwise well. It had started after he had cleaned out his fish tank two weeks before. He first noticed some small nodules under the skin of his forearm. These continued to grow, up to 2 cm in diameter, and the overlying skin became discoloured. Further smaller nodules could be felt but not seen.

I had no idea what this could be, and, with a packed waiting room, I was in no mood to go pouring through textbooks. At this point, I recalled all the hours I had spent learning about consultation models in my GP training. The first step should be to ascertain patients' reason for attending, their understanding of the problem, and their expectations for this consultation.

"What do you think it could be?" I tentatively asked the patient, not expecting much help.

"Fish TB," he replied. He went on to tell me that he knew all about this from reading magazines on aquarium keeping over the years. *Mycobacterium marinum* is one of 80 environmental or

"non-tuberculous" mycobacteria. It is found in water and most often affects swimmers and aquarium keepers, entering the body through breaks in the skin. Similar lesions are seen with the fungal infection sporotrichosis.

Mr A was referred to the dermatology department, where a biopsy confirmed that his diagnosis was correct. After a course of minocycline, he made a full recovery.

In accident and emergency, consulting with patients is very "doctor oriented." The cubicles are set out for our convenience, the questions we ask are often closed, and there is always the pressure to make a diagnosis, dispense the treatment, and discharge the patient from the department as quickly as possible. Meeting Mr A was a useful reminder to me that we can often learn as much from our patients' ideas and beliefs about their health as we can from our textbooks and investigations. Even in accident and emergency those GP consultation models could be useful.

Ceris Watson *senior house officer, Wrexham Maelor Hospital, Wrexham*