# Developmental versus Conventional Care: A Comparison of Clinical Outcomes for Very Low Birth Weight Infants

Bonnie Stevens, Patricia Petryshen, John Hawkins, Barry Smith, and Pamela Taylor

L'objectif de la présente recherche était de décrire le profil clinique des nouveaux-nés dont le poids à la naissance était extrêmement faible alors qu'on leur prodiguait des soins standardisés ou des soins individualisés en fonction du développement durant leur hospitalisation, et de déterminer si les interventions individualisés en fonction du développement ont été appropriées. Une étude (par phase décalé) auprès de 124 prématurés a montré que, même s'il n'existe pas de différence importante pour ce qui concerne les résultats cliniques individuels, les soins individualisés en fonction du développement ont eu à la longue un effet significatif sur la stabilité physiologique de l'enfant. Tous les nourrissons à qui on prodiguait des interventions individualisés en fonction du développement ont bénéficié, avec fréquence variable, de soins individualisés en fonction du développement.

The purpose of this research was to describe the clinical profile of very low birth weight (VLBW) infants receiving conventional versus developmental care during their hospitalization and to determine the appropriateness of developmental-care interventions. A phase-lag study with 124 preterm infants indicated that although there were no significant differences in individual clinical outcomes, developmental care had a significant effect on the physiologic stability of the infant over time. Developmental interventions were used for all infants receiving the developmental-care intervention, with varying frequency.

Enormous financial and technological resources have been allocated for neonatal intensive care, resulting in a dramatic improvement in mortality and morbidity for the very low birth weight (VLBW) infant. This improvement, however, has been tempered by the emergence of subtle long-term developmental delays in learning, academic achievement, visual-motor integration, and language performance, and in behav-

Bonnie Stevens, R.N., Ph.D., is Associate Professor in the Faculty of Nursing at the University of Toronto. Patricia Petryshen, R.N., Ph.D., is Vice-President and Chief Nursing Officer, and John Hawkins, M.A., is Director, Nursing Informatics, at St. Michael's Hospital, Toronto. Barry Smith, M.D., F.R.C.P., is Dean of the Faculty of Medicine at Queen's University, Kingston, Ontario. Pamela Taylor, R.N., M.Sc.N., is a Clinical Nurse Specialist in Plano, Texas.

ioural difficulties (Hack et al., 1994; Ornstein, Ohlsson, Edmonds, & Asztalos, 1991). These delays may be the result of intrauterine insult prior to the onset of labour (Low, Robertson, & Simpson, 1989; Low, Simpson, & Ramsey, 1992) or the result of the extrauterine environment. Recent documentation indicates that there is a 50% incidence of cognitive dysfunction at school age among neurologically intact VLBW survivors. Careful attention to the nature and quality of care of the VLBW infant in the neonatal intensive-care unit (NICU) can optimize the quality of survival and positive developmental outcomes (Hack et al., 1991).

An individualized, developmentally sensitive approach to neonatal care was proposed more than a decade ago to enhance clinical outcomes and the developmental potential of VLBW infants and their families (Als, 1984). Investigators have reported that VLBW infants who received developmental care demonstrated improved clinical and developmental outcomes (Als et al., 1986; Als et al., 1994; Becker, Grunwald, Moorman, & Stuhr, 1991, 1993; Buehler, Als, Duffy, McAnulty, & Liederman, 1995; Fleisher et al., 1995). However, a number of methodologic issues have been raised (Garland, 1995; Lacy, 1995; Ohlsson, 1995; Saigal & Streiner, 1995). In addition, the physiologic stability of the NICU infant and the appropriateness of developmental-care interventions have not been thoroughly investigated. The purpose of this research was (a) to compare clinical outcomes (including severity of illness) of VLBW infants receiving conventional versus developmental care during the NICU stay, and (b) to determine the appropriateness of developmental-care interventions.

## Theoretical Framework

Als's (1982) Synactive Theory of Development incorporates ethological and behavioural theory and physiologic principles to develop a framework for understanding medical and behavioural outcomes. The infant is viewed as a dynamic organism that continually strives for equilibrium and is in constant interaction with the environment. The developmental approach to care envisions infants as active participants in their own developmental trajectories, supported by the ongoing co-regulation process of infant and parent development. For preterm infants who are unexpectedly removed from the intrauterine environment and its complex co-regulatory mechanisms, it is extremely important that NICU care is supportive of the realignment and co-regulation of the newborn and his family.

## Literature Review

Developmental care is an individualized-care approach that uses systematic behavioural observations (Newborn Individualized Developmental Care and Assessment Program – Als, 1986, 1992) and a formal evaluation of infant behaviour (Assessment of Fullterm and Preterm Infants' Behaviour – Als, Lester, Tronick, & Brazelton, 1982; Als, Duffy, & McAnulty, 1988). The results of these observations and evaluations provide the basis for an individualized plan of care to support the infant, which involves (a) structuring the physical environment to reduce light and noise levels; (b) minimal handling, clustering of care, time-out, and use of a pacifier; (c) bundling, nesting, and containment; and (d) flexion of infant extremities, hand-to-mouth, and prone/side positioning (Als, 1984, 1992).

The evidence supporting positive clinical outcomes associated with developmental care for VLBW infants has been steadily accumulating (Als et al., 1986; Als et al., 1994; Becker et al., 1991, 1993; Buehler et al., 1995; Fleisher et al., 1995). In phase-lag studies (Als et al., 1986; Becker et al., 1991, 1993) and a randomized controlled trial (Als et al., 1994), VLBW infants who received developmental care demonstrated more optimal respiratory and feeding status, lower levels of morbidity, shorter hospital stay, and improved behavioural organization. In Als's most recent study (Als et al., 1994), infants followed up to nine months who had received developmental care showed improved neurodevelopmental outcomes over those who had not. Buehler et al. (1995) also report that preterm infants who received developmental care showed behavioural and electrophysiologic performances comparable to fullterm infants at two weeks after the expected due date, whereas infants in a control group performed significantly less well. Fleisher et al. (1995) report more organized performance in motor-system function, state regulation, interactive capabilities, and ability to self-regulate at 42 weeks postconceptual age.

Although the differences between infants receiving developmental care and those receiving conventional care on reported clinical outcomes and costs are impressive, the research often suffers from methodologic inadequacies. The studies have been criticized for their sample size, sample selection bias, complexity of observations, method of allocation concealment, over-generalization of results, and for using a large number of dependent variables, with inappropriate analyses (Garland, 1995; Lacy, 1995; Lacy & Ohlsson, 1993; Ohlsson, 1995; Saigal & Streiner, 1995).

In the first study by Als et al. (1986), only 16 of the 43 infants eligible for the study were included. The Becker et al. (1991, 1993) study included 21 control and 24 study infants. Studies by Fleisher et al. (1995) and Buehler et al. (1995) had no more than 12 infants per experimental or control group. These small numbers may have allowed the introduction of unknown biases and limited generalization of the results. In the Als et al. (1986) and Becker et al. (1991, 1993) studies, the inclusion criteria favoured the experimental group according to infant gestational age, mean birth weight, and mean Apgar scores. Only a few studies were conducted following the widespread use of surfactant, and therefore the results may not be generalizable to present-day NICUs. Several studies used complex data-collection measures without the benefit of multivariate analyses or adjustment for multiple comparisons.

Many studies employed phase-lag designs that precluded blinding or adequate concealment of the treatment groups. Despite claims regarding large cost savings, there is little detail on the calculation of direct hospital charges or indirect costs to hospitals, to other health-care institutions where infants are transferred, or to families.

None of the published studies adequately addresses physiologic stability of VLBW infants or the appropriateness of developmental-care interventions. Severity of illness as a consequence of NICU is often directly related to the functional status of preterm infants as measured by physiologic stability and the potential for comorbidity and/or complications (Petryshen & Stevens, 1995). Physiologic stability is also a useful measurement for providing classifications for evaluating the degree of physiologic stress in preterm infants (Richardson, Gray, McCormick, Workman, & Goldman, 1993). Data on physiologic stability could reflect the amelioration of stress for infants receiving both developmental and conventional NICU care and, as such, could be considered an indicator of quality of life in this population.

Based on these inadequacies, the American Academy of Pediatrics Committee on the Fetus and Newborn was challenged to evaluate the developmentally sensitive approach to care and make recommendations regarding the appropriateness of its use in the NICU (Merenstein, 1994). The Canadian Pediatric Society Committee on the Fetus and Newborn has also taken on this challenge (Abbott Laboratories, 1994).

#### Methods

## Setting and Sample

The study was conducted at Toronto's Mount Sinai Hospital (MSH), a university-affiliated teaching hospital with a 50-bed Level 11 and Level 111 NICU where the care-delivery model is primary nursing. Of the 130 infants admitted to the study over an 18-month period, 65 received conventional care and 65 received developmental care. Infants were eligible to participate in the study if they were between 750 and 1,500 grams at birth, an appropriate weight for gestational age at birth (as determined by an antenatal ultrasound and Dubowitz assessment), and free of chromosomal and/or other major genetic anomalies and/or congenital infections. In the case of multiple births, the first-born infant was entered into the study.

## Sample-Size Estimation

The sample-size estimate was consistent with that reported in other developmental-care research conducted by Als et al. (1986) and Becker et al. (1991, 1993). Oxygen saturation, rate of weight gain, and length of stay were used to estimate the effect size (alpha .05, with 80% power). For the three outcome variables, the most conservative sample-size requirement was for the variable oxygen saturation, whereby a sample size of 63 subjects per group was required to detect a significant difference at the 5% level (Kramer, 1988). As a very low level of refusal was anticipated, 65 subjects per group were entered into the study.

## Data-Collection Procedure

A comparative (phase-lag) study design was used to compare clinical outcomes of infants receiving conventional versus developmental care. A clinical trial randomizing infants to conventional versus developmental care was not feasible, because the NICU environment employs an open concept. Conventional care would be contaminated with nurses implementing the developmental-care interventions. Ethics approval for this study was obtained from the Research Ethics Board. Eligible infants were identified by the clinical nurse specialist, the study was explained to the parents, and the parents were asked to give their written consent. Data on clinical outcomes and the frequency and type of developmental-care interventions were collected by the research nurse within the first 72 hours of the infant's birth, as well as on days 7, 14, 21, 28, and 35 of the hospital stay. Clinical and demographic information was abstracted from the infant's medical record.

Data were collected for the infants in the conventional-care group during an eight-month period prior to the implementation of developmental care. Developmental care was implemented and a three-month integration period was left before data collection was resumed. Data for the developmental-care group were collected during a five-month period eight months after developmental care had been implemented.

# Conventional-Care and Developmental-Care Groups

Conventional care in this setting involved primary nursing by experienced neonatal nurses, standardized care plans, and unadjusted lighting and noise levels. Nurses did not receive any developmental-care training prior to or during data collection. Developmental care involved experienced neonatal nurses trained in developmental care, individualized patient-care plans, developmental-care interventions (such as bundling, positioning, and containment), and decreased lighting and noise levels. All nurses on the unit received a three-day orientation to developmental care and six nurses were trained and certified as developmental-care specialists. Repeated in-service education was offered to nurses and physicians. Reduced lighting levels were achieved by using isolette covers and dimming overhead lights. Reduced noise levels were achieved by lowering the volume of the overhead paging system and substituting flashing lights for the ringing in the fire-alarm system. These changes were implemented following discussions with external consultants.

It is possible that the conventional-care group was contaminated by the use of developmental-care interventions (such as bundling, positioning, and containment) on the part of experienced nurses who had read or heard about developmental care. However, the impact was thought to be minimal considering the individualized care plans and additional developmental-care interventions such as lighting and noise reductions, time-out, clustering of care, and increased interactions with families. No attempt had been made, prior to this study, to introduce developmental care into the NICU or to formally educate nurses in this approach to care.

#### Measures

The *Physiologic Stability Index (PSI)* (Georgieff, Mills, & Bhatt, 1989) was used to assess the level of physiologic instability in critically ill infants. By quantifying physiologic instability, the PSI sub-scores provided an overall assessment of the severity of the infant's illness. The

original PSI, developed to assess severity of illness in critically ill pediatric patients, consisted of 34 variables from seven physiologic systems, including cardiovascular, respiratory, and neurological (Yeh, Pollack, Ruttimann, Holbrook, & Fields, 1984). The degree of abnormality (during the previous 24 hours) of each variable (i.e., heart rate, respiratory rate, blood pressure) was assigned a score from 0 to 5 reflecting the clinical importance of the derangements. Content validity was established by using the clinical judgement of pediatric intensivists to score the abnormality of the observed measurements. Criterion validity was determined by comparing the PSI with the Clinical Classification System (Civetta, 1973) and the Therapeutic Intervention Scoring System (Cullen, Civetta, Briggs, & Ferrara, 1974; Keene & Cullen, 1983). Construct validity was demonstrated by comparing PSI scores with hospital mortality rates and between diverse groups. There were no reports on the measure's reliability. The original PSI (Yeh et al.) was modified by Georgieff et al. to reflect neonatal physiology. In re-establishing criterion and construct validity for the modified 26-item measure, the PSI scores correlated significantly with the Therapeutic Intervention Scoring System (TISS) (Cullen et al.; Keene & Cullen) (r=.75, p<.001) and Nursing Utilization Management Intervention System classifications (r = .62, p < .001). The modified form of the PSI for premature infants was pretested and then used in this study.

The NICU Daily Patient Record, a standard form from the study setting, was used to record information on the number of days on oxygen and on the ventilator and growth measures (weight and head circumference). Data on the incidence and frequency of developmental-care interventions were also recorded by the developmental-care specialist or the bedside nurse. This record was kept at the bedside of each infant in the study.

# Data Reduction and Management

All data were recorded directly on the data-collection measures and stored in a locked drawer in the office of the research nurse. Confidentiality was maintained through the use of numerical codes. A master list of study codes and names of participating infants was stored in the office of one of the co-principal investigators. The master list was destroyed at the end of the study, but the coded data were kept and could be retrieved through the medical records department for future analyses, if so desired. All data were entered on the SPSS:PC software program by a trained data-entry clerk, and summary scores were computed for each outcome variable, including the PSI.

## Results

Data were analyzed using (a) descriptive statistics to describe the study sample, distribution of the data, and frequency of developmental-care interventions, and (b) parametric statistics (unpaired *t*-tests and logistical regression) to detect significant differences between the groups and to determine the effect of the study intervention over time.

## Descriptive Characteristics of the Groups

A total of 130 infants (65 per group) were entered into the study. There were no refusals. Of the 130 infants, 4/65 infants in the conventional-care group and 2/65 infants in the developmental-care group died prior to day 3 of life, leaving 61 and 63 infants, respectively, in the conventional-care and developmental-care groups for the analyses.

Mean gestational age at birth for the conventional-care group was 28.43 weeks (SD 2.28), for the developmental-care group 28.56 weeks (SD 1.73). Mean birth weight for the conventional-care group was 1,078 grams (SD 224), for the developmental-care group 1,140 grams (SD 202). Mean head circumference at birth for the conventional-care group was 26.07 cm (SD 1.88), for the developmental-care group 26.58 cm (SD 1.72). There were no significant differences between the two groups for gestational age at birth (t= -0.36, p<.73), birth weight (t= -0.62, p<.11), or birth head circumference (t= -1.50, p<.14).

# Incidence and Frequency of Developmental-Care Interventions

The developmental-care interventions were summarized for each infant at the end of each week of life (days 7, 14, 21, 28, and 35), to gain an understanding about which interventions were used most frequently during hospitalization. Interventions were summarized into three categories: caregiving (minimal handling, clustering of care, time-out, use of pacifier); containment (bundling, nesting, containment with hands); and positioning (flexion, hand-to-mouth positioning, prone- and side-lying, foot and side rolls). The percentage of infants in the developmental-care group who received each intervention as recorded daily on the NICU Daily Record at 7, 14, 21, 28, and 35 days is reported in Table 1.

During caregiving, all developmental-care interventions described by Als were used. Minimal handling and clustering of care were most

evident in the earlier weeks of hospitalization. Time-out from being handled and use of a pacifier as a developmental intervention were used throughout hospitalization. Approximately 50% of the infants were given a pacifier during their first 35 days of life. Bundling and containment were used substantially; nesting was used less often. Flexion of the infant's extremities and positioning of hand to mouth was an important developmental approach. Infants were often placed in the prone/side position, with occasional use of foot and side rolls.

	Page 1		Day		
	7	14	21	28	35
Developmental-Care Interventions	(n = 63)	(n = 56)	(n = 50)	(n = 44)	(n = 39)
Caregiving					
Minimal handling	44%	20%	8%	7%	13%
Clustering of care	33%	20%	18%	11%	13%
Time-out	29%	34%	28%	36%	21%
Pacifier	44%	50%	56%	48%	51%
Containment					
Bundling	41%	55%	44%	55%	41%
Nesting	24%	21%	16%	18%	5%
With hands	67%	61%	50%	50%	31%
Positioning					
Flexion	73%	71%	54%	57%	41%
Hand to mouth	25%	30%	22%	20%	23%
Prone & side lying	68%	70%	68%	64%	26%
Foot & side rolls	17%	21%	26%	23%	5%

## Comparison of Clinical Outcomes between Groups

Physiologic Instability Index (PSI) (Georgieff et al., 1989) scores were calculated weekly to assess the level of physiologic instability in critically ill infants. There were no significant differences using multiple comparisons (*t*-tests for independent groups) between the conventional-care and developmental-care groups in PSI scores at admission and days 7, 14, 21, 28, and 35. However, lower mean PSI scores were

found in the developmental-care group at all points except day 35 (Table 2). The overall effect of group and time on PSI was examined using repeated measures analysis of variance (RMANOVA). However, there was insufficient power, due to the declining sample size as infants were discharged or transferred prior to day 35, to detect any significant effects with this analysis.

	Gr	roup		
Day	Conventional Care	Developmental Care	t	р
Admission				
M	17.25	16.21	0.78	.44
SD	(7.07)	(7.81)		
n	61	63		
Day 7				
M	13.82	12.03	1.25	.22
SD	(7.60)	(8.29)		
n	61	63		
Day 14				
M	13.32	11.09	1.52	.13
SD	(7.95)	(7.54)		
n	56	56		
Day 21				
M	12.43	11.74	0.43	.67
SD	(8.05)	(8.02)		
n	51	50		
Day 28				
M	12.14	9.68	1.42	.16
SD	(7.92)	(8.24)		
n	44	44		
Day 35				
M	9.49	10.00	-0.30	.77
SD	(7.66)	(7.61)		
n	39	39		

While there were no significant effects of treatment group on PSI scores, any potential benefits of developmental care, as evidenced by the overall pattern of means on days 7 through 28, may have been obscured by the relatively high degree of variability in PSI scores within each group. Subsequent exploratory analyses revealed that the distribution of PSI scores was bimodal, suggesting that infants might be better classified as high or low in physiologic stability. The PSI scores were recoded as a dichotomous variable, and the data for days 7 through 28 were re-analyzed using logistic regression. Infants who received a PSI score of 10 or less were classified as stable, while those who received a PSI score of 11 or greater were classified as unstable. This 10-11 split represents the point at which there was a clear break in this distribution, rather than an arbitrary mid-point median. As shown in Table 3, logistic regression analysis revealed a significant effect of treatment day on PSI and also a significant effect of group, such that infants who received development care were more likely to be classified as high in physiologic stability (lower PSI scores) during each week of their hospitalization as compared with infants who received conventional care.

Variable	b	se	Wald	df	Р	$\chi^2$	df
Step One:						002100000000	
Main Effects Model						8.97	2
Constant	0.707	0.331	4.559	1	.033		
Group	-0.433	0.197	4.859	1	.028		
Time	-0.182	0.089	4.559	1	.033		
Step Two:							
Interaction Model						0.15	1
Constant	0.821	0.447	3.381	1	.067		
Group	-0.662	0.628	1.111	1	.292		
Time	-0.216	0.126	2.938	1	.087		
Group* Time	0.068	0.178	0.148	1	.701		

Table 4 M	Table 4         Mean Scores on Growth Measures by Conventional/Developmental-Care Group and Day of Hospitalization	win intensation of						
		Weight (gr)	0			Head Circumference (cm)	erence (cn	(e)
	Group	Ь			G	Group		
Day	Conventional Care	Developmental Care	. 44	d	Conventional Care	Developmental Care	+-	d
Day 7 M SD	1008.61 (233.32) 61	1050.32 (218.53) 63	-1.03	.31	26.07 (2.04) 54	26.82 (1.67) 55	-2.10	.04
Day 14 M SD	1102.81 (250.59) 57	1136.95 (223.65) 56	-0.76	.45	26.85 (2.11) 54	27.29 (1.71) 52	-1.18	.25
Day 21 M SD	1165.70 (265.02) 50	1220.40 (252.69) 50	-1.06	.30	27.49 (1.99) 45	27.82 (1.77) 47	-0.84	.41
Day 28 M SD	1244.89 (277.27) 44	1319.55 (295.62) 44	-1.22	.23	28.06 (2.05) 40	28.66 (1.99) 41	-1.33	.19
Day 35 M SD	1338.03 (291.89) 38	1429.87 (318.29) 39	-1.32	.20	28.34 (2.15) 38	29.57 (1.91) 39	-2.42	.02

Four clinical outcomes (number of days on oxygen, number of days on the ventilator, weight, head circumference) were compared in the two groups. The mean number of days on oxygen in the conventional-care group was 10.21 (SD 12.88), in the developmental-care group, 7.38 (SD 10.50). The mean number of days on the ventilator in the conventional-care group was 14.51 (SD 13.34), in the developmental-care group, 12.77 (SD 14.09). There were no significant differences between the two groups of infants in number of days on oxygen (t = 1.33, p < 1.9) or on the ventilator (t = 0.70, p < 1.9). There was no difference in weight gain between the groups at any data-collection point. However, infants in the developmental-care group displayed a significantly greater head circumference one week after birth (t = -2.10, p < .04) and at the end of the study, on day 10.00 (Table 4).

## Discussion

Health professionals in NICUs throughout North America are advocating widespread implementation of developmental care in response to promising reports of its effectiveness. Although there are reported improvements in clinical outcomes, such as days on the ventilator, days on oxygen, and length of stay in the NICU, there has been little research into whether developmental care improves the infant's growth, quality of life, and physiologic stability. There is also a paucity of research on the appropriateness of implementing these interventions for VLBW infants during their hospital stay.

No differences in the clinical outcomes of weight gain, days on the ventilator, or days on oxygen were found in this study. This finding is inconsistent with the published results of several other studies, which report fewer days on the ventilator and on oxygen and tolerance of full breast or bottle feeding. The inconsistency in findings may be due to methodologic inadequacies in the other studies, as discussed in the literature review.

The phase-lag design in the early Als study (1986), the Becker study (1991, 1993), and the present study is also problematic in that there is no control for historical extraneous variables in the settings, which may account for the reported differences between the two groups. For example, because current economic restraints demand shorter hospital stays, it is not possible to compare length of stay in the present study. Length of stay is also problematic in that it is highly susceptible to the discharge practices of physicians, the space needs of the unit, and the discharge and transfer policies of the unit. The RCT design is also problematic when randomization of developmental care takes place within

the same clinical setting as conventional care. Contamination between groups is impossible to control in circumstances of environmental interventions and shared caregivers. In order to determine the effect of developmental care on the infant, randomization of similar NICU settings must be carried out. Even then, the sites must be matched to allow for reasonable comparison. In light of the difficulty (and expense) of this design, the clinical profile of the infant at birth and throughout the study allows for statistical control of likely extraneous effects.

In this study, there was a significant difference in severity of illness when infants were classified on the PSI as stable or unstable. It is conceptually feasible that severity of illness takes into account the individual differences in clinical outcomes reported in other studies, even though they were not evident as individual clinical outcomes in this study. These results suggest that developmental care is effective, and, most importantly, that it is effective in improving the physiologic stability or quality of life of the infant. When these differences are translated into caregiver time and NICU costs, substantial benefits may be realized. An analysis of costs was beyond the scope of this paper but is addressed elsewhere (Petryshen, Stevens, Hawkins, & Stewart, submitted).

Finally, this study provides some evidence about the most frequently used developmental-care interventions for VLBW infants in their trajectory through the NICU. Although all interventions were used throughout an infant's hospitalization, there was a pattern to how particular interventions were employed. Because nurses who developed the care plans for these infants had been NIDCAP trained, it was assumed that interventions were proposed and implemented based on observation of and response to infant cues. Those interventions that supported the integrity of infant boundaries (nesting, flexion, containment), maintained infant state equilibrium (minimal handling, clustering of care), and promoted infant coping (containment with hands, pacifier) were most frequently implemented in the first weeks of the infant's stay in the NICU. Although nurses continued to implement these interventions throughout the infant's stay in the NICU, the frequency of the interventions decreased over time as they became less appropriate. Other interventions (time-out, pacifier, bundling) were implemented consistently and may have provided comfort, security, and a sense of equilibrium to the vulnerable VLBW infant in a chaotic environment.

#### Conclusions

Developmental care had a positive effect on the physiologic stability and one growth outcome (head circumference) of the VLBW infants in this study. This effect is conceptually consistent with the improvement in individual clinical outcomes reported in the literature. Developmental care had no effect on other individual clinical outcomes (e.g., days on the ventilator, days on oxygen, weight gain) in this study. The frequent use of developmental-care interventions by nurses caring for VLBW infants within the NICU setting supports the appropriateness of this individualized type of care.

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Correspondence should be addressed to Bonnie Stevens, R.N., Ph.D., 50 St. George Street, Toronto, Ontario M5S 1A1, Canada.

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