

# Translating Neurodevelopmental Care Policies Into Practice: The Experience of Neonatal ICUs in France—The EPIPAGE-2 Cohort Study

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**Objectives:** To describe the implementation of neurodevelopmental care for newborn preterm infants in neonatal ICUs in France in 2011, analyze changes since 2004, and investigate factors associated with practice.

**Design:** Prospective national cohort study of all births before 32 weeks of gestation.

**Setting:** Twenty-five French regions.

**Participants:** All neonatal ICUs ( $n = 66$ ); neonates surviving at discharge ( $n = 3,005$ ).

**Interventions:** None.

**Measurements and Main Results:** Neurodevelopmental care policies and practices were assessed by structured questionnaires. Proportions of neonates initiating kangaroo care during the first week of life and those whose mothers expressed breast milk were measured as neurodevelopmental care practices. Multilevel logistic regression analyses were used to investigate relationships between kangaroo care or breast-feeding practices and

unit policies, taking into account potential confounders. Free visiting policies, bed availability for parents, and kangaroo care encouragement significantly improved between 2004 and 2011 but with large variabilities between units. Kangaroo care initiation varied from 39% for neonates in the most restrictive units to 68% in less restrictive ones ( $p < 0.001$ ). Individual factors associated with kangaroo care initiation were gestational age (odds ratio, 5.79; 95% CI, 4.49–7.48 for babies born at 27–31 wk compared with babies born at 23–26 wk) and, to a lesser extent, single pregnancy, birthweight above the 10th centile, and mother's employment before pregnancy. At unit level, policies and training in neurodevelopmental care significantly influenced kangaroo care initiation (odds ratio, 3.5; 95% CI, 1.8–7.0 for Newborn Individualized Developmental Care and Assessment Program implementation compared with no training). Breast milk expression by mothers was greater in units with full-time availability professionals trained for breast-feeding support (60% vs 73%;  $p < 0.0001$ ).

**Conclusions:** Dissemination of neurodevelopmental practices occurred between 2004 and 2011, but large variabilities between units persist. Practices increased in units with supportive policies. Specific neurodevelopmental care training with multifaceted interventions strengthened the implementation of policies. (*Pediatr Crit Care Med* 2016; 17:957–967)

**Key Words:** breast-feeding; cohort study; kangaroo care; neurodevelopmental care; neonatal intensive care; preterm neonate

Preterm birth is associated with high rates of cognitive and behavioral difficulties that usually become apparent at school age and can significantly affect the child's learning and social abilities (1, 2). Long-term morbidities are related to the increased frequency of depression, posttraumatic stress, and attachment disorders that have been described in parents (3–5). Neurodevelopmental care has the potential to support the brain development of preterm babies during hospital stay and to enhance parental competencies and well being (6–9). The concept encompasses a wide range of environmental and behavioral strategies, including protection of infant sleep, pain management, skin-to-skin (kangaroo) care (KC), feeding support with breast-feeding (BF) encouragement, reduction of environmental stressors, and integration of parents in their child's care (10).

Neurodevelopmental care is advocated by parents' associations (11), but uptake varies widely around the world. Implementation remains difficult (12, 13) especially for nurses who often feel challenged ethically and may experience moral distress (14). Most neonatal units incorporate specific aspects of neurodevelopmental care, such as reduction of noise or protection against direct light, whereas some implement complex programs, such as Newborn Individualized Developmental Care and Assessment Program (NIDCAP) (15), which aims to integrate all aspects of neurodevelopmental care based on the neurobehavioral readiness of the individual baby in a family-centered approach. The role of such programs to support implementation is vigorously debated. They are embedded in the complexity theory, which identifies the multilayered reality of healthcare and the relationships between

macrostructures and microlevel behavior of a system (16). In practice, it requires understanding of the interactions between professionals, neonates, and parents in the organization of care (17). Factors influencing the implementation of neurodevelopmental care in neonatal clinical practice are poorly understood, and evidence-based strategies for accomplishing changes are needed. The most comprehensive area-based studies carried out so far have been based on professional reports of policies and showed large variation between and within countries (18, 19). It is not known, however, to what extent reported policies were associated with clinical care of individual patients.

The EPIPAGE-2 cohort study was designed to survey neonatal unit policies and measure survival and morbidity after very preterm birth in 2011 in France and to explore variations in clinical practice (20). Neurodevelopmental care data were specifically recorded both at unit and patient levels, thus providing unique opportunities to explore relationships between policies and practices. This article aims first to describe neonatal ICU (NICU) policies regarding several measures of neurodevelopmental care in France in 2011 and to gauge change by comparing them with the 2004 data collected in the same units by the European Science Foundation (ESFs) survey (18, 19). KC and BF have high levels of evidence (21–24); they were examined for individual infants with intention to highlight strategies to prioritize for improving care at the national level.

## MATERIALS AND METHODS

### Population

EPIPAGE-2 is a national, prospective population-based study of very preterm neonates, with planned follow-up of survivors up to 12 years old (20). Data for all births occurring between 22 and 31 completed weeks of gestational age (GA) during the EPIPAGE-2 inclusion period were collected prospectively in 25 participating French regions. All level III NICUs in these areas ( $n = 66$ ) participated in the study. Among the 3,963 neonates born alive, 3,274 survived to discharge. Neurodevelopmental care provision was analyzed for infants admitted to NICUs during the first week of life and surviving to discharge ( $n = 3,005$ ).

### Data Sources

We used structured questionnaires to collect information at NICU level (policies) and for each infant (practices). The NICU questionnaire, completed by a senior pediatrician, collected general information, such as affiliation with a university teaching hospital and number of very preterm neonates admitted per year. Data were also collected on several neurodevelopmental care measures (for details, see **ESM-1**, Supplemental Digital Content 1, <http://links.lww.com/PCC/A283>). Missing data were obtained by telephone before analysis. The response rate was 100%. Information about neurodevelopmental care training was cross-checked with the declaration of French trainers.

The neonatal questionnaire provided data on the age of the baby at the first KC, feeding support defined as swaddling and/or sucking and/or KC during a feed, breast milk expression by the mother defined as BF initiation, and protection against light and noise.

## Data Analysis

We first described the characteristics of the 66 level III NICUs and their neurodevelopmental care policies. We analyzed the evolution of neurodevelopmental care policies between 2004 and 2011 by comparing information available from NICUs that participated in both the ESFs and EPIPAGE-2 ( $n = 43$ ). We then described neurodevelopmental care practices at the infant level. The main outcome measures were KC and BF initiation during the first week of life assessed as binary variables (yes/no), and we correlated them with KC and BF policies. We used available variables in the NICU questionnaires to calculate aggregated indices, based on existing guidelines (25, 26), reflecting the extent of KC or BF supportive policies. We classified units into three groups for these two indicators, with group 1 having the lowest level of implementation and group 3 aiming for the highest level (**supplemental file**, Supplemental Digital Content 1, <http://links.lww.com/PCC/A283>). We then carried out multilevel multiple logistic analysis to investigate the association between NICUs characteristics and infant outcomes, taking into account the hierarchical nature of the database with infants (level 1) nested within NICUs (level 2).

Variables considered as potential confounders at infant level were GA, single or multiple pregnancies, birthweight below 10th centile, and maternal nationality, education, and employment before pregnancy. Maternal education and employment before pregnancy were highly correlated within each other, so we entered only maternal employment, with less than 5% missing values, in the final regression models. At unit level, variables of interest were KC or BF policies and training in neurodevelopmental care.

We first estimated a random intercept model without any predictor variables (model 1) to obtain the baseline unit-level variance ( $\text{var}^{(1)}$ ). In model 2, we included infant characteristics to investigate the association of infant-level variables with KC and BF initiation and to estimate the residual unit-level variation after adjustment for infant-level variables ( $\text{var}^{(2)}$ ). We used the proportional change in variance ( $\text{PCV} = [\text{var}^{(1)} - \text{var}^{(2)}] / \text{var}^{(1)}$ ) to assess the extent to which units' differences in KC and BF initiation may be explained by differences in the distribution of infant-level characteristics across units. In model 3, we added unit characteristics after adjustment for infant-level variables to investigate the association of policies and training with KC and BF initiation and calculated the PCV between model 1 and model 3 ( $\text{PCV} = [\text{var}^{(1)} - \text{var}^{(3)}] / \text{var}^{(1)}$ ). As a sensitivity analysis, we used multiple ( $n = 12$ ) imputations by chained equations to impute missing data. Multiple imputation models included all baseline variables and outcomes. Estimates were combined across imputed data sets using Rubin rules.

Analyses were performed using SAS version 9.3 (SAS, Cary, NC); the SAS GLIMMIX and the multiple imputation procedures were used for multilevel logistic modeling and imputations. Chi-square test, McNemar test for pairwise comparison, and Fisher exact test were used as appropriate.  $p$  value less than 0.05 was considered statistically significant.

## Ethics

Recruitment and data collection for the EPIPAGE-2 study occurred only after families had received information and agreed to participate. Data for this study were extracted from the national database. Ethics approval was obtained from appropriate French ethics committees (20).

## RESULTS

### Neurodevelopmental Care Policies and Changes Since 2004

**Table 1** shows characteristics and policies of the 66 level III NICUs in 2011. Most NICUs (91%) admitted over 50 neonates born less than 32 weeks of GA per year. Unlimited parental access over 24 hours was allowed in 89%. However, only seven of 66 NICUs (11%) simultaneously offered beds, bathrooms, and facilities for meals inside the unit. KC was offered routinely to mothers in 64% and to fathers in 53% of units. A professional dedicated to BF was available in 88% of the units, but in 39 of 58 cases, he/she had no formal training in human lactation. Overall, 40 NICUs (61%) were in KC group 3, whereas this was true for only seven units (11%) for BF. Neurodevelopmental care training programs were reported as NIDCAP (15), sensory-motor program (27), and introductory course. The 2-day introductory course was delivered by NIDCAP professionals in 13 of 18 units and was attended by a substantial number of professionals from the team. Forty-four percent of units had not implemented any neurodevelopmental care training program.

**Table 2** shows changes between 2004 and 2011 in the 43 NICUs participating to both the ESFs and EPIPAGE-2. The number of units allowing visits over 24 hours, having a bed for parents inside units and routinely encouraging KC, significantly increased. The use of standardized neurobehavioral assessment decreased; in 2004, this was used in 21 units (49%) compared with 12 (28%) in 2011.

### Neurodevelopmental Care Practices During the First Week of Life

Neurodevelopmental care practices were analyzed for infants born at 23–26 and 27–31 weeks of GA (**Table 3**). KC initiation was reported for 61% of the neonates, with important differences by the GA group; BF initiation was consistent (62%) across both GA groups. Less than 10% of neonates were exposed to the breast, and 39% had parents involved in feeding support. Protection against direct light was common, and around one third of the babies were hospitalized in a single room.

### Factors Associated With KC and BF Initiation

**KC Initiation.** The proportions of neonates initiating KC (**Fig. 1**) in the three groups reflecting unit level KC implementation were 39% (95% CI, 32–43) in group 1, 55% (95% CI, 51–57), in group 2, and 68% (95% CI, 64–69) in group 3 ( $p < 0.001$ ). **Table 4** shows the multilevel regression analysis, which was carried out on 2,636 completed cases. Compared with neonates included in the analysis, those excluded because of missing data were younger ( $p = 0.02$ ), required

**TABLE 1. Characteristics and Neurodevelopmental Care Policies of French Level III Neonatal ICUs in 2011**

Characteristics of the NICUs, Neurodevelopmental Care Policies, and Implementation of KC	Level III NICUs (n = 66)
	n (%)
Characteristics of the NICUs	
In a teaching hospital	37 (56)
No. of units admitting more than 50 very preterm neonates/yr	60 (91)
Neurodevelopmental care policies	
Visiting policies	
Free parental visiting over 24 hr	59 (89)
Facilities for parents	
Beds inside units for parents	26 (39)
Beds outside the units for parents	32 (48)
A room for parents to talk and relax	48 (73)
A bathroom with shower for parents	26 (39)
Facilities for parents to heat food and/or make drinks	30 (45)
Implementation of KC	
Mother encouraged to use KC	
No/on request	2 (3)
Often	22 (33)
Routinely	42 (64)
Father encouraged to use KC	
No/on request	9 (14)
Often	22 (33)
Routinely	35 (53)
Minimum duration of KC	
0.25–2 h	43 (65)
No limit	23 (35)
Maximum duration of KC	
1–3 hr	12 (18)
No limit	54 (82)
KC group	
Group 1	6 (9)
Group 2	20 (30)
Group 3	40 (61)

(Continued)

**TABLE 1. (Continued). Characteristics and Neurodevelopmental Care Policies of French Level III Neonatal ICUs in 2011**

Characteristics of the NICUs, Neurodevelopmental Care Policies, and Implementation of KC	Level III NICUs (n = 66)
	n (%)
Breast-feeding support	
Professional available to support breast-feeding	58 (88)
If yes, with formal training	39 (67)
Part-time available for breast-feeding support	22 (38)
Full-time available for breast-feeding support	10 (17)
Breast-feeding group	
Group 1	21 (32)
Group 2	38 (58)
Group 3	7 (11)
Neurodevelopmental care implementation	
Use of a neurobehavior scale	15 (23)
Training program	
Newborn Individualized Developmental Care and Assessment Program implementation (achieved or in progress)	11 (17)
Sensory-motor program	8 (12)
Introductory course	18 (27)
None	29 (44)

KC = kangaroo care, NICU = neonatal ICU.

Notes: kangaroo care (KC) group 1: KC allowed only on request for the mother and/or the father, with restrictions on minimal and maximal durations; group 2: KC allowed often or routinely for the mother, upon request for father, with restriction on minimal duration; and group 3: KC encouraged often or routinely for mothers and fathers without any limitation on duration. Breast-feeding (BF) group 1: units with or without a reference professional for BF but without any professional trained in human lactation; group 2: units with a reference professional for BF trained in human lactation and sometimes available for BF support; and group 3: units with a trained professional in human lactation, full-time available for BF support.

less mechanical ventilation ( $p = 0.002$ ), and were more often admitted to KC group 1 and 2 units ( $p < 0.001$ ) or units without any neurodevelopmental care training ( $p = 0.03$ ).

Variance in proportion of KC initiation across units was statistically significant (model 1; unit-level variance,  $\text{var}^{(1)} = 1.07$ ;  $p < 0.001$ ). Differences in infants' characteristics across units could not explain unit-level variations in KC initiation that remained significant and slightly increased after adjustment for patient-level variables (model 2). GA was the main factor associated with KC initiation (odds ratio [OR], 5.8; 95% CI, 4.5–7.5 for neonates born at 27–31 weeks of GA compared with neonates



**TABLE 2. Evolution of Neurodevelopmental Care Policies for French Level III Neonatal ICUs Between 2004 and 2011**

Characteristics of the Units and Neurodevelopmental Care Policies	2004 (n = 43)	2011 (n = 43)	p <sup>a</sup>
Characteristics of the units			
In a teaching hospital	26 (60)	26 (60)	
No. of very low birth weight admitted/yr, median (range)	109 (50–300)	128 (30–392)	
Neurodevelopmental care policies			
Visiting policy features			
Allowed for both parents over 24 hr	29 (67)	38 (88)	0.03
Allowed for both parents over 24 hr and visit duration unlimited	28 (65)	38 (88)	0.02
Allowed for both parents over 24 hr, visit duration unlimited and visits allowed during medical rounds	22 (51)	34 (79)	0.01
Facilities for parents			
Beds inside the units	7 (17)	20 (47)	< 0.01
Beds outside the units	22 (51)	23 (53)	0.83
Room to talk and relax	25 (58)	31 (72)	0.11
Bathroom with shower	10 (24)	17 (40)	0.16
Facilities to heat food and/or make drinks	17 (40)	21 (49)	0.32
KC for parents			
Mother routinely encouraged for KC	14 (35)	28 (65)	< 0.01
Father routinely encouraged for KC	8 (20)	25 (58)	< 0.01
Conditions preventing KC			
Continuous positive airway pressure	13 (32)	0 (0)	
Mechanical ventilation	12 (30)	7 (16)	0.13
Use of a neurobehavioral scale	21 (49)	12 (28)	0.04

KC = kangaroo care.

<sup>a</sup>McNemar test for pairwise comparison.

Data are presented as n (%) unless indicated.

born at 23–26 weeks of GA) and, to a lesser extent, type of pregnancy, intrauterine growth, and maternal employment. The inclusion of unit variables (model 3) reduced the variance ( $\text{var}^{(3)} = 0.64$ ;  $p < 0.001$ ). Unit-level variables explained 40% of unit-level variation in KC initiation across units. After adjustment for infant-level factors, unit policies and training were significantly associated with KC initiation (OR, 3.3; 95% CI, 1.5–7.4 for KC group 3 compared with group 1 and OR, 3.5; 95% CI, 1.8–7.0 for NIDCAP training compared with no training).

**BF Initiation.** The proportion of neonates whose mothers started to express milk was higher in the group of units with higher level of BF policies (group 3) ( $p < 0.001$ ) (Fig. 1).

The multilevel regression analysis (2,635 completed cases) is reported in **Table 5**. No difference between neonates included and excluded from the analysis was observed. As the rate of BF initiation was similar in BF group 1 and 2 units, data for these 2 groups were aggregated and compared with group 3 data.

Variation in proportion of BF initiation across units was statistically significant. Adjustment for patient-level variables (model 2) slightly increased this variance. Maternal employment before pregnancy was the main factor associated with BF initiation (OR, 1.3; 95% CI, 1.1–1.6). Inclusion of unit-level variables (model 3) slightly reduced the variance in BF initiation across units. After adjustment for infant-level factors, group 3 units were significantly associated with BF initiation (OR, 1.8; 95% CI, 1.0–3.2).

For both models, results using multiple imputations were consistent with those from complete case analyses (data not shown).

## DISCUSSION

This study is the first to investigate dissemination of neurodevelopmental care at country level and the impact of structured programs on this dissemination. In this large population-based French sample, we found that almost 90% of NICUs allowed unlimited parental presence and over half routinely offered KC

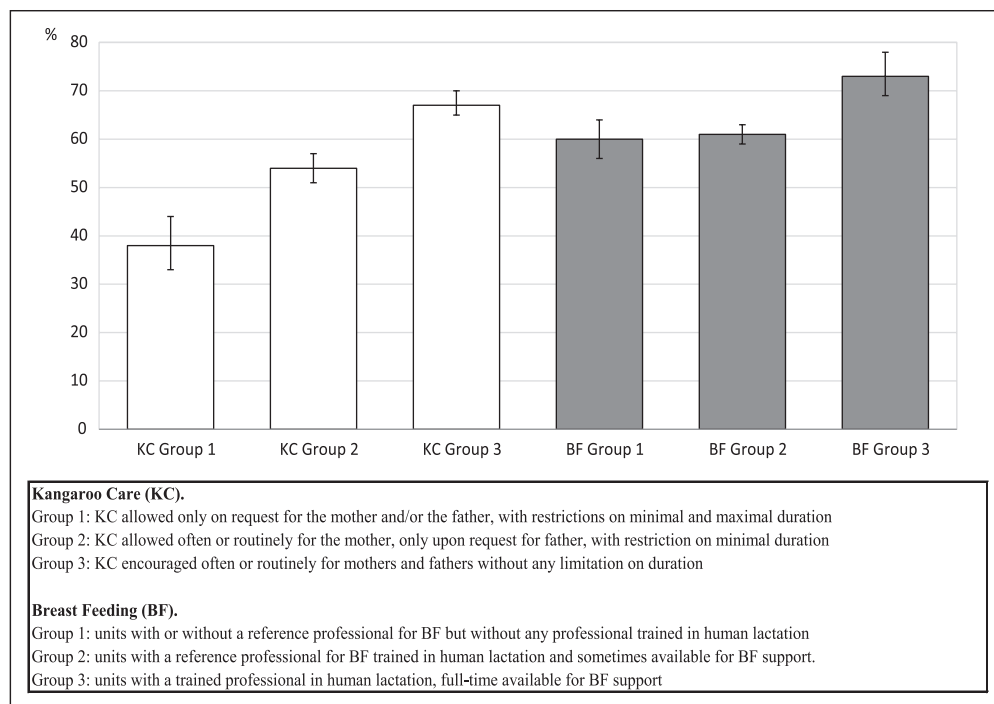
**TABLE 3. Neurodevelopmental Care Practices During the First Week of Life by Gestational Age for Neonates Admitted to French Level III Neonatal ICUs in 2011**

Characteristics of the Neonates and Neurodevelopmental Care Practices	Total (n = 3,005)	23- to 26-Wk of GA, n = 545	27- to 31-Wk of GA, n = 2,460	p <sup>a</sup>
Characteristics of the neonates				
GA, mean (SD)	28.8 (1.8)	25.5 (0.7)	29.4 (1.4)	< 0.01
Weight, mean (SD)	1,206.1 (337.4)	813.3 (133.8)	1,270.8 (318.1)	< 0.01
Neurodevelopmental care practices				
KC during the first week of life				
Yes	1,694 (61)	159 (32)	1,535 (66)	< 0.01
Days 1–3	776 (47)	49 (32)	727 (48)	< 0.01
Days 4–7	891 (53)	105 (68)	786 (52)	
Missing	27	5	22	
No	1,143 (39)	344 (68)	799 (34)	< 0.01
Main causes				
Policy of the unit or nursing staff unavailable	181 (18)	42 (13)	139 (20)	< 0.01
Parents unavailable or anxious	252 (26)	41 (13)	211 (30)	
Infant unstable	575 (55)	235 (74)	340 (49)	
Other	4 (0)	1 (0)	3 (0)	
Missing	132	25	107	
Missing	168	42	126	
Breast-feeding				
No. infants whose mothers initiated breast-feeding	1,769 (62)	317 (62)	1,452 (62)	0.86
Missing	164	33	131	
No. infants exposed to the breast	209 (8)	7 (1)	202 (9)	< 0.01
Missing	132	17	115	
Feeding support				
Involvement of parents in feeding support for the infant	1,050 (39)	113 (23)	937 (42)	< 0.01
Missing	255	50	205	
Promotion of a healing environment				
Protection against direct light				
No	75 (3)	14 (3)	61 (3)	< 0.01
Irregular/intermittent	731 (26)	99 (19)	632 (27)	
Regular/permanent	2,064 (72)	402 (78)	1,662 (71)	
Missing	135	30	105	
Hospitalization in single rooms or wards				
Room with ≥ 4 children	937 (34)	173 (36)	764 (33)	0.38
Room with 2 or 3 children	923 (33)	149 (31)	774 (34)	
Single room or KC unit	914 (33)	165 (34)	749 (33)	
Missing	231	58	173	

GA = gestational age, KC = kangaroo care.

Data are presented as n (weighted %) unless indicated. Percentages were weighted to take into account the different recruitment periods.

<sup>a</sup>χ<sup>2</sup> test for categorical variables and Student *t* test for continuous variables.



**Figure 1.** Proportion of kangaroo care (KC) and breast-feeding (BF) initiation among the neonates admitted in the three groups of units defined according to their policies.

to both parents. Policies that support parents increased significantly between 2004 and 2011, and importantly, units with more evidence-based KC or BF policies were significantly more likely to apply these interventions. In addition, structured programs, such as NIDCAP, seemed to enhance KC and, to a lesser extent, BF initiation.

Areas explored have ethical and legal support or have received a high level of evidence. Not separating neonates and parents has been advocated internationally (28–30) and in several national recommendations, including France (31). KC is highly recommended even in high-income environments (25). Breast milk has many proven benefits for preterm newborns (23, 24). However, difficulties in translating research findings and recommendations into clinical practice are well known (32), and many studies point out the underutilization of appropriate research-based knowledge in clinical practice (33). In our study, large variabilities between units were observed with gaps between policies and opportunities for implementation. Open access visiting policies were nearly universal, but facilities for parents were lacking. KC was widespread but with frequent restrictions. Professional support for BF was available in most units, but one third of these professionals did not receive any formal training in human lactation. Although policies had positively evolved since 2004, they were still less developed than those described in countries with the highest uptake in 2004, such as Denmark, Sweden, and the United Kingdom for parental access or Denmark, Sweden, and the Netherlands for KC (18, 19). It is generally stated that it takes an average of 17 years for research evidence to reach widespread clinical practice (34), and the evolution described in our study can be considered as positive. On the other hand, a better understanding of factors that facilitate the translation of research into

practice is necessary. Public policies and funding, together with stakeholder groups, have effectively promoted family-centered and neurodevelopmental care program at national levels (35, 36), and countries that showed greater implementation of neurodevelopmental care in 2004, compared with France, are also described as having strong national policies or adequate governmental funding (11). In comparing the 2004 and 2011 French data, areas of improvement were mainly those that require strong supportive leadership in the NICUs rather than additional resources and clinical-administrative partnerships. However, all aspects of neurodevelopmental care are embedded in complex healthcare systems (16) where change is dependent on macro- and microlevel orga-

nization. For example, multifaceted interventions are needed to implement KC, even in countries with many facilitators, such as Sweden (14, 38). In our cohort, initiation of KC was associated with maternal and neonatal characteristics, but a substantial part of the variance among units was explained by unit policies and training. Higher levels of supportive policies were associated with greater KC initiation, but specific neurodevelopmental care training aiming to support KC (15) strengthened the implementation. Guidelines do not implement themselves (39), and our results support this assumption; policies increased KC uptake, but structured training based on NIDCAP theory strengthened the impact of policies. However, we do not know if the “dose” of KC received by the infants in those units was influenced by training. Units with training in the sensory-motor development program (27) were less likely to initiate KC during the first week of life. The two programs have different theoretical frameworks with the NIDCAP, emphasizing relationship-based care with guidance for system change (9, 15), whereas the sensory-motor program is more task focused.

Not surprisingly, BF policies were more strongly associated with BF initiation than neurodevelopmental care training, which uses newborn neurobehavioral observation to facilitate transition from tube to oral feeds (39). BF initiation requires knowledge of the physiology of human lactation, and units with trained professionals in lactation may have higher competencies to support early breast milk expression.

The lack of shared knowledge on newborn neurobehavioral observation might hold back the dissemination of beneficial practices. A U.K. survey indicated that having staff trained in newborn observation positively affected developmental care uptake in units (40). In our cohort, less than 30% of units used

**TABLE 4. Multilevel Logistic Regression Analysis of Infant and Unit Factors Associated With Kangaroo Care Initiation During the First Week of Life in French Level III Neonatal ICUs in 2011**

Fixed and Random Effects in the Multilevel Logistic Regression Analysis	Model 1 (Empty Model) (n = 2,636)	Model 2 (Infant Characteristics) (n = 2,636)			Model 3 (Infant and Unit Factors) (n = 2,636)		
		OR	95% CI	p	OR	95% CI	p
Fixed effects							
Infant characteristics							
Gestational age, wk							
23–26		1		< 0.01	1		< 0.01
27–31		5.8	4.5–7.5		5.9	4.5–7.6	
Pregnancy							
Single		1.7	1.4–2.0	< 0.01	1.7	1.4–2.0	< 0.01
Multiple		1			1		
Small-for-gestational age							
No		1.3	1.1–1.6	< 0.01	1.3	1.1–1.6	< 0.01
Yes		1			1		
Mother employed before pregnancy							
Yes		1.8	1.5–2.2	< 0.01	1.8	1.5–2.2	< 0.01
No		1			1		
Unit factors							
Neurodevelopmental care training							
Newborn Individualized Developmental Care and Assessment Program					3.5	1.8–7.0	< 0.01
Sensory-motor program					0.6	0.3–1.2	
Introductory course					2.7	1.5–4.7	
No training					1		
Kangaroo care policies							
Group 1					1		0.02
Group 2					2.3	1.0–5.4	
Group 3					3.3	1.5–7.4	
Random effect							
p		< 0.01		< 0.01		< 0.01	
Variance for neonatal units		1.0757		1.2063		0.6440	
SD		0.238		0.2668		0.1647	
Proportional change in variance <sup>a</sup>				–0.12		0.40	

OR = odds ratio.

<sup>a</sup>Proportional change in variance by the new model compared with the empty model.

Notes: kangaroo care (KC) group 1: KC allowed only on request for the mother and/or the father, with restrictions on minimal and maximal durations; group 2: KC allowed often or routinely for the mother, upon request for father, with restriction on minimal duration; and group 3: KC encouraged often or routinely for mothers and fathers without any limitation on duration.

a scale to assess newborn neurobehavior. Surprisingly, this number decreased between 2004 and 2011, possibly because the practice is time consuming and neuroimaging has increased (41, 42).

The French situation is not unique in Europe. A gap between North and South has been described for neurodevelopmental care implementation and more generally for parental role in NICUs,



**TABLE 5. Multilevel Logistic Regression Analysis of Infant and Unit Factors Associated With Breast-Feeding Initiation in French Level III Neonatal ICUs in 2011**

Fixed and Random Effects in the Multilevel Logistic Regression Analysis	Model 1 (Empty Model) (n = 2,635)	Model 2 (Patient Characteristics) (n = 2,635)			Model 3 (Patient and unit Factors) (n = 2,635)		
		OR	95% CI	p	OR	95% CI	p
Fixed effects							
Individual characteristics							
Gestational age, wk							
23–26		1		0.70	1		0.65
27–31		1.0	0.8–1.3		1.0	0.8–1.3	
Type of pregnancy							
Simple		1.0	0.8–1.2	0.95	1.0	0.8–1.2	0.93
Multiple		1			1		
Birthweight below 10th centile							
No		1.2	1.0–1.4	0.04	1.2	1.0–1.4	0.04
Yes		1			1		
Mother employed before pregnancy							
Yes		1.4	1.1–1.6	< 0.01	1.3	1.1–1.6	< 0.01
No		1			1		
Unit factors							
Developmental care training							
Newborn Individualized Developmental Care and Assessment Program					1.5	0.9–2.4	0.07
Sensory-motor course					0.8	0.4–1.3	
Introductory course					1.5	1.0–2.2	
No training					1		
BF policies							
BF group 1–2					1		0.03
BF group 3					1.8	1.0–3.2	
Random effect							
p	< 0.01			< 0.01			< 0.01
Variance of neonatal units	0.3684			0.3845			0.3412
SE	0.09337			0.09667			0.09031
Proportional change in variance <sup>a</sup>				–0.09			0.04

BF = breast-feeding, OR = odds ratio.

<sup>a</sup>Proportional change of variance by the new model compared with the empty model.

Notes: breast-feeding (BF) group 1: units with or without a reference professional for breast-feeding but without any professional trained in human lactation; group 2: units with a reference professional for breast-feeding trained in human lactation and sometimes available for breast-feeding support; and group 3: units with a trained professional in human lactation, full-time available for breast-feeding support.

suggesting social and cultural differences (18, 19). However, a study in Spain highlighted how structured programs based on the NIDCAP framework can bridge this gap, with staff perceptions

after training becoming similar to those described in Northern Europe (43). Several models designed to improve neonatal neurodevelopmental care have been published, all of which incorporate

neurobehavioral observations of neonates are shared with parents (15, 44–46), and some of them have investigated the impact on outcome (47, 48). However, they were evaluated in a research context, and no data are available on their dissemination at national level. The number of neurodevelopmental care programs available in France was limited, but we were able to investigate modes of training, based on different strategies for implementation.

This study has limitations. Although KC and BF initiation are two core neurodevelopmental measures, they do not cover a full range of neurodevelopmental care practices. However, both have large developmentally supportive effects, promoting parental participation and attachment, as well as physiologic stability, preservation of sleep, and analgesia (21, 22, 26). It might have been interesting to study the “dose” of KC received by each infant, as well as BF at discharge, but practices during the first week of life were more easily explored at population level, and dose is usually related to early initiation (49). The observational design of the study allowed us to establish potential associations rather than causal factors. NIDCAP seemed to enhance early KC initiation and, to a lesser extent, BF initiation, but we were not able to describe the level of implementation in each unit, and variability among units could also be explained by patient or unit characteristics, such as nurse-to-patient ratio, that we did not control for. Finally, data for 12% of the neonates were missing and excluded from final analysis. Their exclusion might have altered the strength of associations, but this was not observed after multiple imputations.

The strengths of the study are substantial. Data were recorded at population level, with a high rate of completeness for NICU questionnaires. The large sample size assures representativeness and power of the study. Questions in the ESFs and the French survey were worded exactly the same, facilitating the comparison between the two studies. Availability of unit policies and parallel data at the level of individual babies allowed us to investigate the impact of policies on clinical care, taking into account maternal and infant characteristics. The significant associations that were found between policies and practices suggest that these data could help to define national guidelines and realistic goals to improve neonatal services.

## CONCLUSIONS

In Europe, neurodevelopmental care implementation is advocated by parent associations. It has been increasingly recognized that context is a critical element in the successful implementation of evidence into practice. Unit policies seem essential for neurodevelopmental care implementation, but conceptual models to guide clinical care seem to affect practices and strengthen policies. This study contributes to a better understanding of factors that effectively spread the implementation of neurodevelopmental care measures and factors that need to be explored for a wider range of strategies and in different cultural backgrounds.

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## REFERENCES

1. Milligan DW: Outcomes of children born very preterm in Europe. *Arch Dis Child Fetal Neonatal Ed* 2010; 95:F234–F240
2. Wolke D, Baumann N, Strauss V, et al: Bullying of preterm children and emotional problems at school age: Cross-culturally invariant effects. *J Pediatr* 2015; 166:1417–1422
3. Forcada-Guex M, Borghini A, Pierrehumbert B, et al: Prematurity, maternal posttraumatic stress and consequences on the mother-infant relationship. *Early Hum Dev* 2011; 87:21–26
4. Korja R, Latva R, Lehtonen L: The effects of preterm birth on mother-infant interaction and attachment during the infant's first two years. *Acta Obstet Gynecol Scand* 2012; 91:164–173
5. Cacciani L, Di Lallo D, Piga S, et al: Interaction of child disability and stressful life events in predicting maternal psychological health. Results of an area-based study of very preterm infants at two years corrected age. *Res Dev Disabil* 2013; 34:3433–3441

6. Als H, Duffy FH, McAnulty GB, et al: Early experience alters brain function and structure. *Pediatrics* 2004; 113:846–857
7. Melnyk BM, Crean HF, Feinstein NF, et al: Maternal anxiety and depression after a premature infant's discharge from the neonatal intensive care unit: Explanatory effects of the creating opportunities for parent empowerment program. *Nurs Res* 2008; 57:383–394
8. Montirosso R, Provenzi L, Calciolari G, et al; NEO-ACQUA Study Group: Measuring maternal stress and perceived support in 25 Italian NICUs. *Acta Paediatr* 2012; 101:136–142
9. Westrup B: Family-centered developmentally supportive care. *NeoReviews* 2014; 15:e325–e35
10. Coughlin M, Gibbins S, Hoath S: Core measures for developmentally supportive care in neonatal intensive care units: Theory, precedence and practice. *J Adv Nurs* 2009; 65:2239–2248
11. EFCNI - European Foundation for the Care of Newborn Infants: EFCNI White Paper. Available at: <http://www.efcni.org/index.php?id=1890>. Accessed July 26, 2016
12. Jobe AH: A risk of sensory deprivation in the neonatal intensive care unit. *J Pediatr* 2014; 164:1265–1267
13. Gibbins S, Hoath SB, Coughlin M, et al: The universe of developmental care: A new conceptual model for application in the neonatal intensive care unit. *Adv Neonatal Care* 2008; 8:141–147
14. Wallin L, Rudberg A, Gunningberg L: Staff experiences in implementing guidelines for Kangaroo mother care—a qualitative study. *Int J Nurs Stud* 2005; 42:61–73
15. Als H, McAnulty GB: The Newborn Individualized Developmental Care and Assessment Program (NIDCAP) with Kangaroo Mother Care (KMC): Comprehensive care for preterm infants. *Curr Womens Health Rev* 2011; 7:288–301
16. Chandler J, Rycroft-Malone J, Hawkes C, et al: Application of simplified complexity theory concepts for healthcare social systems to explain the implementation of evidence into practice. *J Adv Nurs* 2016; 72:461–480
17. Franck LS, Oulton K, Bruce E: Parental involvement in neonatal pain management: An empirical and conceptual update. *J Nurs Scholarsh* 2012; 44:45–54
18. Greisen G, Mirante N, Haumont D, et al; ESF Network: Parents, siblings and grandparents in the neonatal intensive care unit. A survey of policies in eight European countries. *Acta Paediatr* 2009; 98:1744–1750
19. Pallás-Alonso CR, Losacco V, Maraschini A, et al; European Science Foundation Network: Parental involvement and Kangaroo care in European neonatal intensive care units: A policy survey in eight countries. *Pediatr Crit Care Med* 2012; 13:568–577
20. Ancel PY, Goffinet F; EPIPAGE 2 Writing Group: EPIPAGE 2: A preterm birth cohort in France in 2011. *BMC Pediatr* 2014; 14:97
21. Conde-Agudelo A, Diaz-Rossello JL: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants. *Cochrane Database Syst Rev* 2014; 4:CD002771
22. Johnston C, Campbell-Yeo M, Fernandes A, et al: Skin-to-skin care for procedural pain in neonates. *Cochrane Database Syst Rev* 2014; 1:CD008435
23. Gartner LM, Morton J, Lawrence RA, et al: Breastfeeding and the use of human milk. *Pediatrics* 2005; 115:2:496–506
24. Moro GE, Arslanoglu S, Bertino E, et al: XII. Human milk in feeding premature infants: Consensus statement. *J Pediatr Gastroenterol Nutr* 2015; 61(Suppl 1):S16–S19
25. Nyqvist KH, Anderson GC, Bergman N, et al: Towards universal Kangaroo mother care: Recommendations and report from the first European conference and seventh International Workshop on Kangaroo Mother Care. *Acta Paediatr* 2010; 99:820–826
26. Nyqvist KH, Häggkvist AP, Hansen MN, et al: Expansion of the ten steps to successful breastfeeding into neonatal intensive care: Expert group recommendations for three guiding principles. *J Hum Lact* 2012; 28:289–296
27. Martinet M, Borradori Tolsa C, Rossi Jelidi M, et al: [Development and assessment of a sensory-motor scale for the neonate: A clinical tool at the bedside]. *Arch Pediatr* 2013; 20:137–145
28. UNICEF - Convention on the Rights of the Child [Internet]: Convention on the Rights of the Child. Available at: <http://www.unicef.org/crc/>. Accessed January 2016
29. Giannini A, Garrouste-Orgeas M, Latour JM: What's new in ICU visiting policies: Can we continue to keep the doors closed? *Intensive Care Med* 2014; 40:730–733
30. Flacking R, Lehtonen L, Thomson G, et al; Separation and Closeness Experiences in the Neonatal Environment (SCENE) Group: Closeness and separation in neonatal intensive care. *Acta Paediatr* 2012; 101:1032–1037
31. Bulletin Officiel No 2004-52: Circulaire No 83-24 du 1er Août 1983 relative à l'hospitalisation des enfants. Available at: <http://www.sante.gouv.fr/fichiers/bo/2004/04-52/a0523394.htm>. Accessed July 26, 2016
32. Rycroft-Malone J: Implementing evidence-based practice in the reality of clinical practice. *Worldviews Evid Based Nurs* 2012; 9:1
33. Eccles MP, Armstrong D, Baker R, et al: An implementation research agenda. *Implement Sci* 2009; 4:18
34. Morris ZS, Wooding S, Grant J: The answer is 17 years, what is the question: Understanding time lags in translational research. *J R Soc Med* 2011; 104:510–520
35. Bedford Russell AR, Passant M, Kitt H: Engaging children and parents in service design and delivery. *Arch Dis Child* 2014; 99:1158–1162
36. Staniszewska S, Thomas V, Seers K: Patient and public involvement in the implementation of evidence into practice. *Evid Based Nurs* 2013; 16:97
37. Vesel L, Bergh AM, Kerber KJ, et al; KMC Research Acceleration Group: Kangaroo mother care: A multi-country analysis of health system bottlenecks and potential solutions. *BMC Pregnancy Childbirth* 2015; 15(Suppl 2):S5
38. Boivin A, Currie K, Fervers B, et al; G-I-N PUBLIC: Patient and public involvement in clinical guidelines: International experiences and future perspectives. *Qual Saf Health Care* 2010; 19:e22
39. Browne JV, Ross ES: Eating as a neurodevelopmental process for high-risk newborns. *Clin Perinatol* 2011; 38:731–743
40. Hamilton KE, Redshaw ME: Developmental care in the UK: A developing initiative. *Acta Paediatr* 2009; 98:1738–1743
41. Brown N, Spittle A: Neurobehavioral evaluation in the preterm and term infant. *Curr Pediatr Rev* 2014; 10:65–72
42. Pierrat V: Computer-based analysis of general movements reveals stereotypes predicting cerebral palsy. *Dev Med Child Neurol* 2014; 56:922–923
43. Mosqueda-Peña R, Lora-Pablos D, Pavón-Muñoz A, et al: Impact of a developmental care training course on the knowledge and satisfaction of health care professionals in neonatal units: A multicenter study. *Pediatr Neonatol* 2015; 89:37–33
44. Welch MG, Hofer MA, Brunelli SA, et al; Family Nurture Intervention (FNI) Trial Group: Family nurture intervention (FNI): Methods and treatment protocol of a randomized controlled trial in the NICU. *BMC Pediatr* 2012; 12:14
45. Milgrom J, Newnham C, Anderson PJ, et al: Early sensitivity training for parents of preterm infants: Impact on the developing brain. *Pediatr Res* 2010; 67:330–335
46. Melnyk BM, Feinstein NF, Alpert-Gillis L, et al: Reducing premature infants' length of stay and improving parents' mental health outcomes with the Creating Opportunities for Parent Empowerment (COPE) neonatal intensive care unit program: A randomized, controlled trial. *Pediatrics* 2006; 118:e1414–e1427
47. Als H, Duffy FH, McAnulty G, et al: NIDCAP improves brain function and structure in preterm infants with severe intrauterine growth restriction. *J Perinatol* 2012; 32:797–803
48. Newnham CA, Inder TE, Milgrom J: Measuring preterm cumulative stressors within the NICU: The Neonatal Infant Stressor Scale. *Early Hum Dev* 2009; 85:549–555
49. Beake S, Pellowe C, Dykes F, et al: A systematic review of structured compared with non-structured breastfeeding programmes to support the initiation and duration of exclusive and any breastfeeding in acute and primary health care settings. *Matern Child Nutr* 2012; 8:141–161