



## Differential Effects of the Single-Family Room Neonatal Intensive Care Unit on 18- to 24-Month Bayley Scores of Preterm Infants

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**Objectives** To determine the effects of human milk and social/environmental disparities on developmental outcomes of infants born preterm cared for in a single-family room (SFR) neonatal intensive care unit (NICU).

**Study design** Outcomes were compared between infants weighing  $\leq 1250$  g cared for in an open-bay NICU (1/2007-8/2009) ( $n = 394$ ) and an SFR NICU (1/2010-12/2011) ( $n = 297$ ). Human milk provision at 1 week, 4 weeks and discharge, and 4 week volume (mL/kg/day) were analyzed. At 18-24 months of age, the Bayley III was administered. Group differences were evaluated and multiple linear regression analyses were run.

**Results** Infants cared for in the SFR NICU had higher Bayley III cognitive and language scores, higher rates of human milk provision at 1 and 4 weeks, and higher human milk volume at 4 weeks. In adjusted regression models, the SFR NICU was associated with a 2.55-point increase in Bayley cognitive scores and 3.70-point increase in language scores. Every 10 mL/kg/day increase of human milk at 4 weeks was independently associated with increases in Bayley cognitive, language, and motor scores (0.29, 0.34, and 0.24, respectively). Medicaid was associated with decreased cognitive ( $-4.11$ ) and language ( $-3.26$ ) scores, and low maternal education and non-white race with decreased language scores ( $-4.7$  and  $-5.8$ , respectively). Separate models by insurance status suggest there are differential benefits from SFR NICU and human milk between infants with Medicaid and private insurance.

**Conclusions** Infants born preterm cared for in the SFR NICU have higher Bayley language and cognitive scores and receive more human milk. Independent effects on outcomes were derived from SFR NICU, provision of human milk, and social and environmental factors. (*J Pediatr* 2017;185:42-8).

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A number of studies have reported neonatal benefits for infants born preterm cared for in a single-family room (SFR) neonatal intensive care unit (NICU). Benefits reported include reduction in mortality, sepsis, and duration of hospitalization; fewer apneas; more optimal provision of human milk; and shorter interval to full enteral feeds.<sup>1-4</sup> In addition, there is greater parent satisfaction with the more private environment.<sup>5</sup> Several investigators have shown that improved family-centered care is associated with improved neonatal medical outcomes and more optimal neonatal neurobehavioral outcomes.<sup>6-8</sup> A report from our SFR NICU identified increased family-centered care, developmental support, and enhanced maternal involvement were associated with improved developmental outcomes at 18 months of age.<sup>9</sup> Maternal involvement is a reflection of the NICU learning environment of the infant. Mothers living in poverty and who are more poorly educated have more barriers impacting on visiting their infants in the NICU and more disparities impacting on long-term developmental outcomes.<sup>10-13</sup> In a *Eunice Kennedy Shriver* National Institute of Child Health and Human Development study, mothers of preterm infants who provided human milk for their infants in the NICU were more educated and twice as likely to have private insurance.<sup>14</sup> Infants born preterm who receive human milk are also reported to be at decreased risk of sepsis and necrotizing enterocolitis (NEC),<sup>15-20</sup> which are major predictors of adverse neurodevelopmental outcomes, and human milk has been shown to be associated independently with improved neurodevelopmental outcomes.<sup>14,17,21-23</sup> A report of more mature infants born preterm (median gestations of 31-32 weeks) showed that mothers in a SFR nursery had more sustained high-grade lactation and their infants were more likely to be discharged on human milk.<sup>1</sup>

The rationale for this report is that mothers and infants within a SFR NICU have greater opportunities for family-centered care, privacy, one-on-one interaction, and skin-to-skin contact, resulting in greater rates of pumping human milk, success with breast feeding, and provision of human milk. It was also proposed that environmental disparities, including Medicaid insurance as a marker of poverty and low maternal education, would impact on developmental outcomes.

IVH	Intraventricular hemorrhage
NEC	Necrotizing enterocolitis
NICU	Neonatal intensive care unit
SFR	Single-family room

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The authors declare no conflicts of interest.

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<http://dx.doi.org/10.1016/j.jpeds.2017.01.056>

The objective of this study was to determine the association of a SFR NICU on human milk provision and postdischarge developmental outcomes for inborn infants born preterm and weighing <1250 g. The primary outcome was the 18- to 24-month developmental outcomes. Secondary outcomes were human milk provision and neonatal outcomes. It was hypothesized that (1) infants born preterm and cared for in the SFR environment will have better cognitive, language, and motor outcomes at 18-24 months corrected age compared with infants cared for in the open-bay NICU; (2) infants in the SFR environment will receive more human milk, and human milk will be associated with better developmental outcomes, fewer episodes of sepsis and or NEC, and shorter duration of hospitalization; and (3) low maternal education and Medicaid insurance will be associated with developmental outcomes.

## Methods

Survival rates, neonatal outcomes, and postdischarge outcomes were compared for all in-born live births  $\leq 1250$  g for 2 time periods that include the old open-bay NICU (1/1/2007-8/31/2009) and the new SFR NICU (1/1/2010-12/31/2011). A 4-month hiatus between the study periods was chosen to eliminate overlap of care between the 2 nurseries.

Derivation of the study sample of infants who weighed  $\leq 1250$  g is shown in **Figure 1** (available at [www.jpeds.com](http://www.jpeds.com)). This birth weight category was chosen because this preterm group is considered high risk and is standardly followed in our follow-up program. Survival rates of 81% and 82% for live births were similar during the 2 time periods. Follow-up rates were 86% for the open-bay and 77% for the new SFR NICU. The study was approved by the Women & Infants Hospital Institutional Review Board. Participation in follow-up clinic is standard of care and voluntary, and informed consent was waived. Maternal and neonatal data were collected prospectively from the hospital electronic medical record database. Neonatal data included survival, neonatal characteristics, and major morbidities including intraventricular hemorrhage (IVH) 3-4, cystic periventricular leukomalacia based on reported ultrasound examination, bronchopulmonary dysplasia (defined as treatment with supplemental oxygen at 36 weeks postmenstrual age), late-onset sepsis (defined as culture positive sepsis >72 hours of age), and NEC (defined as modified Bell classification stage IIA or higher). Provision of any human milk during the NICU stay and provision of human milk at discharge are components of the clinic database for infants weighing <1250 g. Human milk was fortified during both study periods with Similac powder human milk fortifier. For infants born at an extremely low birth weight ( $\leq 1000$  g), an extensive nutrition database that contains prospectively collected data, including 24-hour intake for days 1, 4, 7, and weeks 2, 3, 4, 5, and 6, and 36 weeks postmenstrual age or at discharge is maintained by the NICU dietician. For infants weighing 1001-1250 g, the nutrition database provided any human milk at 1 week and 4 weeks and volume (mL/kg/day) at 4 weeks of age. Feeding protocols were similar during both study periods and all mothers were provided with a pump and encouraged to start pumping

on day 1 and to increase to 8-10 times per day. Donor milk was not provided. Lactation support services were increased from 0 hours in the open bay NICU to 16 hours in the SFR NICU as of January 1, 2010.

Postdischarge maternal and child data, interventions, growth (World Health Organization Growth Standards), and neurodevelopmental outcomes are collected prospectively in the clinical program. The follow-up evaluation consists of a standard neurologic assessment based on Amiel-Tison<sup>24</sup> and a comprehensive developmental assessment. Hearing status postdischarge was obtained by parental history. A history of eye examinations and procedures since initial discharge was obtained and a standard eye examination was completed. Blindness was defined as bilateral corrected vision of <20/200. Development was assessed with the Bayley Scales of Infant and Toddler Development III.<sup>25</sup> The test has a mean of 100 and SD of 15. Bayley III cognitive composite scores, language composite scores, motor composite scores, and subscores of fine and gross motor skills and receptive and expressive communication are part of the database.

## Statistical Analyses

Primary outcomes were Bayley III scores at 18-24 months corrected age. Secondary outcomes were rates of human milk provision, NEC  $\geq$  stage IIA, proven late-onset sepsis, and duration of hospitalization. Our total study cohort seen in follow-up included 435 infants. A power analysis was performed to estimate the minimum detectable difference in Bayley scores at 80% power and an alpha of  $P = .05$ , using our available sample sizes for each group. The minimum detectable difference was 4.2 points, or approximately 0.28 SDs. Group differences were evaluated with  $\chi^2$  analyses for categorical variables and  $t$  tests or Wilcoxon tests for continuous variables. Variables significantly different between NICUs in bivariate analyses were tested in regression models. Logistic regression was used to determine the associations of predictors (NICU type and human milk) on rates of sepsis and or NEC and negative binomial regression was used to analyze days of hospitalization. Linear regression analyses were run to evaluate the independent associations of nursery type (open-bay and SFR NICU), human milk at discharge, and volume of human milk at 4 weeks on Bayley III scores. Additional predictor variables included Medicaid insurance, non-white race and high school education or less as markers of socioeconomic status risk and days in the NICU and number of major neonatal morbidities (late-onset sepsis, bronchopulmonary dysplasia, IVH 3-4, periventricular leukomalacia, NEC  $\geq$  Bell stage II) as markers of illness severity and immaturity. After significant effects of Medicaid were identified in the primary model, separate regressions were run for infants with Medicaid and infants with private insurance.

## Results

Maternal characteristics by study group are shown in **Table I**. There were 394 live births of infants weighing  $\leq 1250$  g in time 1 (open-bay NICU) and 257 in time 2 (SFR NICU). There was

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