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# A Pulse for Progress – Examining the Efficacy of Best Nursing Developmental Care Practices for Children with Congenital Heart Disease at Risk for Developmental Delay in the PCICU: A Prospective Quasi-Experimental Cohort Study

Jasmyn Jansen
*Dominican University of California*

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# A Pulse for Progress – Examining the Efficacy of Best Nursing Developmental Care Practices for Children with Congenital Heart Disease at Risk for Developmental Delay in the PCICU: A Prospective Quasi-Experimental Cohort Study

Jasmyn Jansen

Nursing Department, Dominican University of California

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Professor Noyce, MSN, AGPCNP-BC, RN, WCC

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## Abstract

Emerging advances in pediatric cardiovascular surgery have significantly decreased the mortality rates in infants born with critical congenital heart disease (CHD), in turn, leading to increasing prevalence in adolescence and adulthood. At the same time, developmental delays (DD) are on the rise among children with CHD. Recent research suggests that prolonged exposure to the pediatric cardiac intensive care unit (PCICU), with its environmental stressors, negatively implicates neurodevelopment raising the question, and risk, of DD. In January 2023, the American Heart Association (AHA) issued a scientific advisory calling hospitals to implement developmental care practices for hospitalized infants and young children with complex CHD. Recent exploratory research confirms clinicians' acceptability of a developmental care bundle known as the Cardiac Inpatient Neurodevelopmental Care Optimization (CINCO) program. However, there is limited evidence regarding its efficacy to prevent DD. In order to address this evidence gap, this paper proposes a prospective quasi-experimental cohort study aiming to answer the following research question: What is the efficacy of CINCO, in addition to appropriate medical/nursing orders and modifications to the ICU environment, in minimizing DD among children with CHD? By measuring child performance on various age-appropriate tasks using the Denver Developmental Screening Test-2 (DDST-2) at different timepoints (i.e., hospital admission, at 2 weeks length of stay (LOS), at 1 month LOS, upon discharge, and 2 weeks post-discharge) and comparing the results between children who received care that included CINCO with children who received care without CINCO, the efficacy of CINCO is evaluated. The odds ratio is used to express the treatment effect of CINCO. Chi-square tests will be employed for hypothesis testing.

## Acknowledgements

*Haiku: An Homage to My Thesis*

*Beating hearts and busy stressors*

*In the midst of the fast-paced ICUs, children fight to be healthier*

*Advocate for best care practices for them to live long, happy lives*

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## Introduction

### Background

Significant advances in pediatric surgical, interventional, and pharmacological treatments over the past half-century have changed the prognosis of congenital heart disease (CHD) from a death sentence to a chronic condition. In the United States of America, 85% of this patient population is surviving into adolescence, and beyond (Moodie, 2011). CHD encompasses problems or defects with the heart's structure, including but not limited to conditions such as atrial septal defect, Tetralogy of Fallot, and tricuspid atresia (Mayo Clinic, 2023). The Center for Disease Control reports that 50% of those with CHD are more likely to receive special education services compared to children without such birth defects (CDC, 2023). As these CHD patients live longer lives, it is critical to consider how early life exposures, particularly of the pediatric cardiac intensive care unit (PCICU), impact their development. In fact, the experiences of sound, light, touch, temperature, parent presence, and caregiving in the intensive care unit have long-term impact on cognitive function, executive functioning, and neurobehavior. The frequent activation of the stress response systems leads to reductions of frontal and parietal brain volumes, reduced white matter maturation, and epigenetic changes. In turn, these neurodevelopmental alterations lead to developmental delays (DDs), lower educational achievement, and diminished quality of life (Lisanti et al., 2023). Notably, approximately 10% of children with mild CHD and more than 50% of children with critical CHD have a developmental delay or disability (Smith et al., 2023). Developmental delays refer to a child's failure to attain developmental milestones, encapsulating gross and fine motor skills, speech and language, cognitive and performance, social, psychological, and sexual functioning and activities of daily living (ADL) compared to peers of the same population. Delays can be isolated (involving a single domain), multiple (involving two or more domains), or global (affecting most developmental areas) (Khan et al., 2023).

**Problem Statement**

As more and more children with CHD are living into adulthood, it is imperative to optimize their quality of life (QoL), and thus, reduce their risk of DDs. The noxious stimuli of the PCICU can exacerbate the risk of DD. Up to 50% of hospitalized infants can become hypothermic during invasive procedures or operations, with cardiac interventions placing them at an increased risk. Further, they experience sleep disruptions, with a sleep duration of less than 30 minutes for a majority of infants. In addition, many are woken up over 100 times over a 4-day period, impacting brain development as synapse formation and memory facilitation occur during sleep. The excessive light of the intensive care unit is related to alterations in rest and sleep patterns, with evidence suggesting infants are regularly exposed to light intensity more than twice the recommended levels. The high noise levels of the PCICU further have been associated with physiologic instability and increased oxygen consumption. Noise levels of >80-90 dB in the CICU have been demonstrated while the maximum recommended by the American Association of Pediatrics is 45 dB (Ryan et al., 2019). This goes to show that there is a pressing need to implement universal developmental care practices to modify PCICU environments so as to curb DDs among children with CHD.

Once hospital leadership becomes cognizant of the many ways their PCICU environment can adversely influence the neurodevelopment of its young and vulnerable patients, they can begin to consider improvement programs. The Cardiac Inpatient Neurodevelopmental Care Optimization (CINCO) program is a developmental care bundle designed for use in the ICU and has the potential to reduce the severity of DD among very young hospitalized children with CHD (Wolfe et al., 2023).

**Purpose Statement**

Given a lack of evidence of alternative developmental care practices to reduce the risk of DDs among children with CHD in the PCICU, the risk of DDs can continue to persist, severely impacting their

future quality of life (QoL). It is imperative to evaluate the efficacy of developmental care practices in order to optimize care for children with CHD in the PCICU. Given the comprehensiveness of the CINCO program and demonstrated feasibility in earlier research (Wolfe et al., 2023), it is pertinent to evaluate the efficacy of CINCO added to appropriate medical/nursing orders and modification in the PCICU.

**Research Question**

What is the efficacy of CINCO added to appropriate medical/nursing orders and modifications to the PCICU environment in minimizing DD among children with CHD?

**Hypothesis**

The implementation of the CINCO program, a developmental care bundle, reduces DD among children with CHD.

## Literature Review

**Introduction**

This literature critique explores the relationship between CHD and DDs, while also investigating contemporary developmental care practices that can be implemented in the PCICU. The articles discussed here were found by searching Google Scholar, PubMed, and the Dominican University of California CINAHL database. The database search terms were as follows: congenital heart defects; congenital heart disease; developmental care; developmental care practices; neurodevelopment; neurodevelopmental deficits; neonatal intensive care unit; pediatric cardiac intensive care unit; pediatric intensive care unit; pediatric population.

Initially, over 100+ articles were identified with the literature search. For this literature review, six of the most relevant articles were selected based on the following criteria: peer-reviewed, published within the last decade, primary study rather than a systematic review, and provide relevant information for the topic of interest with substantial evidence. The selected articles are presented according to

themes identified: a) neurodevelopmental delay; b) developmental care practices; and c) lack of universal developmental care.

**Neurodevelopmental Delay**

Vagha et al. (2023) studied 6 month old infants to 6 year olds with CHD confirmed by two-dimensional (2D) echocardiography, and utilized the Denver Developmental Screening Test 2 (DDST-2) to evaluate their neurodevelopmental outcomes, both acyanotic and cyanotic CHD patients. This cross sectional study asserts the demand for interventions to curb the risk of DD in children with CHD. Utilizing the DDST-2, the researchers evaluated each child's progress in four distinct categories: personal-social, fine motor-adaptive, language, and gross motor. The researchers concluded that the most substantial DD was found in the gross motor domain, followed by the fine motor domain, and the least impact noted in the social domain. These outcomes are confirmed by the developmental quotient. The developmental quotient refers to a child's performance on a standard set of tasks compared with a normative sample of children the same age (Vagha et al., 2023). Using the developmental quotient as a secondary data analysis method strengthens this study's DDST-2 results as well as the comparative analysis of similar studies. However, relying solely on DDST-2 as the primary assessment tool is a limitation. The article does not consider a comparative analysis of various developmental screening methods in identifying these neurodevelopmental delays. Instead, Vagha et al., 2023 only did a comparative analysis of studies which yielded similar results to the results presented in this study. Furthermore, this study's population size and age group are also drawbacks. A wider age range and larger sample size would have enabled assessment of various DDs across more childhood stages (Vagha et al., 2023).

Wehrle et al. (2022) conducted a prospective, single-center longitudinal study involving 155 children with CHD, and 251 children very premature at birth (VPT). They found that children with CHD had milder intellectual impairments (17.4% vs 22.1%) as well as more severe motor and behavioral

issues than VPT children. Additionally, the children with CHD also had worse global motor abilities and dynamic balance. The researchers in this study utilized independent t-tests, $X^2$ tests, and equivalence testing to analyze the IQ, motor abilities, behavior, and therapy usage between the two participant groups. Major findings were: (a) mild ($70 \leq IQ < 85$) and severe intellectual impairments ($IQ < 70$) occurred in 17.4% and 4.5% respectively in children with CHD compared to 22.1% and 5.5% in VPT children; (b) motor and behavioral functions were more impaired in CHD (57.0% and 15.3% respectively) compared to the motor and behavioral functions of VPT children (37.8% and 11.5% respectively); and (c) global motor abilities (d= -0.26) and dynamic balance (d= -0.62) were more impaired in CHD than in VPT children. The researchers also reported lower therapy usage among children with CHD compared to children with VPT (23.4% vs 40.3% with a P=<.001) (Wehrle et al., 2022). This demonstrates not only how DD significantly impacts academic performance, but also the need to educate healthcare staff about these DDs so that they can be curbed, especially as these children approach adolescence and adulthood. The study's strengths include its longitudinal approach, multiple IQ measures, and equivalence testing to prevent any ecological fallacies. However, the study took place in a single center and, therefore, does not fully represent the patient population. The authors did not mention whether there was any standardized neurodevelopmental care at this center (Wehrle et al., 2022).

Oster et al. (2017) utilized a retrospective cohort design to explore the relationship between CHD severity and academic outcomes. Data came from North Carolina's Birth Defects Monitoring Program, involving educational records and birth certificates. The research team used a logistic regression to analyze the relationship of academic outcomes considering factors such as maternal education, race, pre-K enrollment, and gestational age. The study's authors concluded that, compared to children without CHD, those with CHD had 24% increased odds of not meeting standards in either reading or math (95% confidence interval, 1.12-1.37). Further, 44.6% of children with CHD did not meet the standard in reading and/or math compared with 37.5% without CHD. This can be illustrated with

pediatric critical CHD patients having an adjusted odds ratio of 1.46 when measuring their probability of receiving services compared to children with noncritical CHD (95% confidence interval, 1.15-1.86) (Oster et al., 2017). The key strengths of this study include the use of logistic regression; dichotomized achievement scores; comparative analysis of modeling outcomes of interest with children with and without additional non cardiac defects vs children without any structural birth defects; and, being the largest of its kind to study educational outcomes in children with CHD by linking 3 databases in North Carolina to address important knowledge gaps. In using a logistic regression, the study's authors account for confounding variables. By dichotomizing achievement scores, the researchers confirm objective assessment of academic achievement. Modeling outcomes for patients with CHD against children with and without additional defects compared to healthy children strengthens the final results as the study's authors accounted for a control group and placebo. The endeavor to link state-wide databases to address this research question sets a precedent for future similar studies to be conducted. Limitations, however minimal, are its focus on North Carolina and its state educational records and birth defects registry. The research design and methodology employed in this study are credible, ensuring it is conceivable to replicate using the educational records and birth defects registries of individual states. Such an endeavor would offer an extensive, and valuable, perspective on the correlation between CHD severity and academic outcomes throughout the entire United States (Oster et al., 2017).

**Developmental Care Practices**

LaRonde et al. (2022) examines current developmental care practices across intensive care units in the United States of America, specifically the use of individualized family-centered developmental care (IFDC) for infants younger than 6 months with CHD. IFDC is considered the current standard of care for premature/medically fragile newborns and their families in intensive care units (ICUs). The study's researchers distributed electronic surveys to one nurse per participating intensive care unit center. These surveys evaluated four classifications of each ICU: demographics, nursing practice, interdisciplinary

practice, and parent support. Descriptive statistics summarized the results based on three clinical scenarios of varying patient acuity by using the $X^2$ test as well as an analysis of the differences in IFDC practices and IFDC-related education. The researchers found that among the intensive care units that participated in this study, only 29% reported they had a neurodevelopmental team, 72% did not follow IFDC guidelines, and 67% documented IFDC practices. They also concluded that IFDC practice was associated with IFDC-related nursing education. Given these results, it is evident that there is a lack of implementation of IFDC even though it is considered standard of practice in ICU settings. This study identifies a fundamental developmental care practice that aims to reduce the risk of DDs, an essential constituent of nursing care of children with congenital heart disease, especially in efforts to improve quality of life (QoL) for this pediatric population. This study gains credibility for its implementation of its electronic survey among three clinical scenarios of varying patient acuity as it validates the likelihood of IFDC in practice, especially as respondents were asked to report the frequency IFDC interventions would be performed in each scenario. On the other hand, the utilized study method of an electronic survey designed using the Likert scale which could be interpreted as subjective given that respondents were asked to rate their 'perceived' competence with and frequency of participation in core IFDC nursing practices. This potential subjectivity is a limitation of this study, as well as the response rate of 66%, only 25 centers. Subsequently, the population is not entirely representative of the true population of all intensive care units across the country and their current implementation of IFDC practices. Furthermore, the fact that participating centers were asked to identify only one nurse working in the pediatric ICU setting to complete the survey further limits the generalizability that this study could hold. To be considered of greater value, increasing the participation of nurses will provide insight into the current scope of IFDC nursing practice. Given that the researchers discovered that IFDC nursing practice varies greatly, future studies can examine the impacts of a universal implementation of IFDC. Thus, this study

may be considered a seminal article in understanding the relationship between IFDC and DD risk for children with CHD (LaRonde et al., 2022).

Wolfe et al. (2023) evaluated the feasibility of the implementation of an interdisciplinary inpatient neurodevelopmental care program, CINCO, to neurodevelopmental care across the continuum of hospitalizations for patients with CHD utilizing three plan-do-study-act models and a prospective, single-site quality improvement interventional study. This CINCO program encompasses nursing/medical orders for developmental care practices, developmental kits for patients, bedside developmental plans, caregiver education and support, developmental care rounds, and a specialized volunteer program. The researchers analyzed the program's efficacy by analyzing data from the electronic health record of patients ranging from newborn to 2 years olds for 7 days utilizing a statistical process control chart, and a pairwise comparison of utilization to evaluate any changes that may occur with implementation of CINCO over time. To account for possible confounding variables, such as patient sociodemographic or medical characteristics and history of extracorporeal membrane oxygenation, the researchers employed exploratory multivariable analyses. The study's authors concluded that the utilization of CINCO increased dramatically over time, particularly the implementation for medical/nursing order sets and caregiver handouts. This study expanded current knowledge of developmental care practices, developed a possible intervention, and evaluated the intervention's implementation in practice. Such a developmental care bundle is imperative to consider for best nursing care practice in efforts to alleviate the risk of DDs among children with CHD. This study's strengths lie in its all-encompassing, systematic, integrated, universal approach to providing neurodevelopmental care in the cardiac ICU. The study highlights how CINCO can be a potential model in various PCICUs across the United States. However, the findings may not be generalizable to other PCICUs as the study was conducted at a single site, Children's Hospital Colorado, for only 18 months, and coincided with the COVID-19 pandemic as well. Regarding limitations, specific environmental and care-based interventions, such as the Newborn Individualized

Developmental Care Assessment Program (NIDCAP)-informed care and noise/light reduction, were not addressed and may have been confounders (not accounted for by the exploratory multivariable analyses conducted). The study's authors do acknowledge the need for further research on how to best study the impact of CINCO (Wolfe et al., 2023).

**Lack of Universality of Developmental Care Practices**

Sood et al. (2016) implemented a 47-item online survey of developmental care practices sent to 35 PCICUs. Staff knowledgeable about developmental care practices in the CICU completed this survey in order to characterize current developmental care practices in North American PCICUs. Results indicated that 89% PCICUs have targeted efforts to encourage developmental care. Additionally, 50% and 43% PCICUs reported having a developmental care committee and holding developmental rounds, respectively. This study reinforced the notion that there is a lack of universality of developmental care practices which is imperative in curbing the effects of DDs on children with CHD, but also reducing health inequities. This study is the first of its kind to examine current developmental care practices across North American PCICUs. Even with an 80% response rate as a strength of this study, the participation of only 28 PCICUs is not a true representation of all PCICUs, preventing these results from being entirely generalizable. Survey responses could have differed depending on the respondent's role and general perspectives with developmental care in the PCICU. Survey domains that were evaluated encapsulate hospital information, developmental education/rounding, environmental adaptations, implementation of infant care (positioning, restraints, and sedation), infant holding, and developmental support for preschool and school-aged children with the majority of questions being multiple-choice, and fifteen items open-ended response. Based on these survey domains, it is imperative to be cognizant of how the knowledge regarding current environmental adaptations, infant care, and developmental care among PCICUs will be incomplete or lacking among respondents with an ignorance, or minimal awareness, of developmental care. Overall, this article highlights a critical study of current developmental care

practices, reiterating the pertinence of developmental care bundle standards of practice to ensure equity and equality for all children with congenital heart disease at risk for DDs. At this time, this research has not inspired changes for practitioners to implement more comprehensive developmental care in PCICUs across the United States of America (Sood et al., 2016).

**Conclusion**

Overall, these articles emphasize a strong association between CHD and DD, underscore ongoing efforts to mitigate PCICU stressors, and discuss the practicality of implementing IFDC and CINCO. As this research links PCICU stressors and prolonged admissions with delayed neurocognitive development, specifically poor gross and fine motor skill deficits, in children with CHD, it also illuminates current issues and opportunities for future research. Despite the recent call for action by the American Heart Association (AHA) imploring hospitals to implement developmental care practices for hospitalized infants and young children with complex CHD, the literature exposes significant, and critical, developmental care practice voids and inconsistencies. While there are developmental care practices in place, along with the provision of an extensive scientific advisory from the AHA, there remains significant gaps and inconsistencies in developmental care practices across the United States of America. Universality of developmental care practices is imperative to curb the effects of DDs on children with CHD. As these studies have demonstrated, they provide significant progress for equitable, standard developmental care practices. The two developmental care practices that hold promise are IFDC and CINCO, whereas CINCO is most comprehensive as this bundle encompasses developmental care nursing/medical order sets and caregiver handouts as well as a hospital volunteer program to assist in the delivery of age-appropriate developmental care delivery. A developmental care bundle is crucial to consider in best nursing care practices in efforts to alleviate the risk of DDs among children with CHD. Further research must be conducted to evaluate this developmental care bundle's long-term effects on reducing risk of DDs by studying children with CHD over time and subsequently, staff acceptance among PCICU staff.

## Research Proposal

### Research Question

What is the efficacy of CINCO added to appropriate medical/nursing orders and modifications to the PCICU environment in minimizing DD among children with CHD?

### Rationale

As the literature highlights, there remain significant voids in consistency of developmental care practices across the United States of America, despite the substantial evidence linking the risk of DDs with CHD, the implications of these DDs for academic performance, and current developmental care interventions. The CINCO program, a comprehensive developmental care bundle, was well accepted at a children's hospital in Colorado. This CINCO program holds promise as a comprehensive standard for developmental care among PCICUs across the United States of America.

### Theoretical Framework

The proposed research aims to evaluate the long-term impact of the CINCO developmental care bundle on alleviating the risk of DDs. In this context, nursing theories like Jean Watson's Theory of Human Caring and Callista Roy's Adaptation Model provide valuable guidance. Watson reinforces the importance of the nurse-patient relationship and the nurse's role of caring in this healing process (Watson Caring Science Institute, 2023). The nurse practices compassion with their patients, honors patient's needs and values, is present with their patients, problem solves, provides caring patient education, modifies the environment by minimizing sounds and reducing light exposure for example, and maintains patients' dignity at all times. By following the CINCO program and applying Watson's theory, nurses aid in creating a calming, nurturing PCICU environment that promotes healthy neurodevelopment. This mitigates the risk of DD,  and enhances the QoL for children with CHD. By creating a nurturing environment through the implementation of nursing/medical order sets according

to CINCO, patients' mental health can improve which is vital for their recovery. This will subsequently be measured utilizing the DDST-2 in minimizing DDs. Callista Roy's Adaptation Model perceives individuals as flexible, reinforcing their ability to adapt to changes in health and environment (*Nursing Theory*, 2020). Roy explains how patients are in constant interaction with their environment, adapting as a function of the stimuli they are exposed to. Callista Roy's model applies to the proposed study as the efficacy of CINCO is evaluated through modifications to the PCICU environment and medical/nursing order sets. Patients adapt to their hospital setting as they become accustomed to the sounds, lights, etc of the PCICU. Modifying the PCICU by using CINCO, e.g. lowering the volume of infusion pumps, dimming lights and closing blinds, clustering care and many more, promotes positive developmental outcomes. To evaluate the efficacy of CINCO in the context of Callista Roy's Adaptation Model and foster positive developmental outcomes, the DDST-2 will be utilized to assess DDs. Both of these nursing theories provide a relevant framework for this research by considering the impacts of the modifiable care environment of children with CHD, and the impact that CINCO has on the quality of life for these children.

**Primary Research Aim**

This research intends to address the short implications of a PCICU team adhering to the CINCO developmental care bundle on the occurrence of DDs in children with CHD as assessed by the DDST-2.

**Ethical Considerations**

Prior to the initiation of the study, an application will be sent to the Dominican University of California review board and Institutional Review Board (IRB) for approval. Through the entirety of the data collection process, the infant's and children's wellbeing and safety is prioritized. All participants' parents and/or caregivers will confirm consent per an Informed Consent form, detailing the study's procedures, the CINCO program, and any possible risks or benefits. Participants will be informed of their voluntary participation, and can withdraw at any point during the study without any consequences. A

$20 Starbucks gift card will be awarded to participant's families who complete the study. The study will also maintain the participants' rights to confidentiality and privacy by anonymizing participants' information. The CINCO interventions will be implemented by PCICU nurses trained and certified in this program and will monitor the participants throughout the study ensuring their comfort and safety. If at any phase of the study the child demonstrates signs and symptoms of distress, the intervention will be modified or ceased. This study will be supervised in adherence with relevant ethical standards and guidelines while prioritizing the ethical management and wellbeing of all participants involved.

**Research Method**

***Study Population and Sample Size***

Inclusion criteria are children diagnosed with cyanotic and acyanotic CHD, age 0-6 years, admitted to a Northern California PCICU with a hospitalization of >1 week, DD risk, and history of cardiopulmonary resuscitation efforts or heart transplantation or cardiac surgery or mechanical support. Exclusion criteria involve non-critical CHD, and children older than age six. All participants will be recruited on a rolling basis meeting the inclusion criteria upon admission to the selected Northern California PCICUs. Power analysis determined a sample size of n=116 with 58 participants per group, considering a two-tailed test, 5% significance level (α), effect size of 25%, and a power of 80%.

***Study Design and Methodology***

A quasi-experimental study design will be utilized to evaluate CINCO's effect on DDST-2 scores for this pediatric population. Given the nature of CINCO, it is not logistically feasible to assign (all elements of) CINCO in a randomized fashion to individuals within a hospital. As such, the treatment group where CINCO is provided consists of eligible patients admitted to one Northern California PCICU, and the control group consists of eligible patients admitted to another Northern California PCICU where patients receive care *without* the implementation of CINCO. Inclusion criteria for the Northern California PCICUs encompass: at least 6-10 ICU beds, at least two computers for documentation, a central hemodynamic

display monitor, bassinets with overhead radiant warmers for neonates and infants, a lead intensivist (potentially a pediatric cardiologist), and an in-house physician and nursing staff (Balachandran, 2010). To minimize the risk of confounding, the two selected PCICUs should have similar resources available and a catchment area with a similar distribution of demographic characteristics. CINCO is implemented, and monitored, by the PCICU nurses.

***Data Collection***

The PCICU nurses will use the DDST-2 to assess the performance of participating CHD patients on various age-appropriate tasks to determine the presence of DD. This assessment will be conducted for participants upon admission, at 2 weeks, at 1 month, and 2 weeks post-discharge. Length of stay (LOS) will be analyzed later relative to DDST-2 results. PCICU nurses will be trained in the 31-step administration of the DDST-2 prior to their use. A developmental quotient will account for DDST-2 score differences between the control and intervention groups. Patient characteristics that will be collected involve: type of congenital heart defect, type of DD, age, ethnic and racial background, and type of previous cardiac intervention whether that be surgery or CPR.

***Data Analysis***

The odds ratio will be used to express the efficacy of CINCO based on the proportion of CHD patients with DD according to the DDST-2 in the intervention group and control group at different follow-up time points. The chi-square test will be used for hypothesis testing. A p-value of $<0.05$ indicates a statistically significant difference in the occurrence of DD between the intervention and control group. A power calculation determined a sample size of 58 participants per group, considering a two-tailed test, 5% significance level ($\alpha$), effect size of 25%, and a power of 80%. If there are differences between intervention and control groups regarding the distribution of type of congenital heart defect, type of DD, age, ethnic and racial background, and type of previous cardiac intervention whether that be surgery or CP, statistical adjustment may be required.

**Limitations**

There are several limitations to the proposed study. This study has a non-randomized design which means there is a risk of confounding if there are differences between the two groups other than the implementation of CINCO. Randomization of pediatric patients admitted to a hospital is not feasible because elements of CINCO are provided at the PCICU level, rather than the patient level. One could randomize different PCICUs to CINCO implementation, but this requires many PCICUs, and such a study is not feasible in the planned time frame from a logistics perspective. An alternative quasi-experimental design would be the following: The first 50% of the planned sample size of eligible CHD patients admitted to a PCICU to receive care *without* the implementation of CINCO (the control group), and the subsequent 50% of the planned sample size of eligible patients admitted to these PCICUs to receive care *with* implementation of CINCO (the intervention group). With such a design, between-hospital differences that may confound the observed effect of CINCO on DD will be avoided. However, such a study would take longer to perform than available for study completion. If the average LOS is about 1 month and patients get admitted on a rolling basis, completion of the follow-up of the control group would take 1 month plus the time it takes to enroll the 58 patients to ensure all of those patients are discharged before implementing CINCO in that hospital and creating the intervention group. Assuming that enrollment and completion of the treatment group would take the same time as the control group, one can imagine that the study cannot be completed within the allocated time. As such, we opted for the design presented above. To minimize the risk of confounding due to differences in the two hospitals that define the intervention and control groups, these two hospitals must be as similar as possible, especially in terms of resources. Although we may opt to statistically adjust for confounding factors, the limited sample size may provide challenges to this thoroughly. Another limitation of only having two matched hospitals is that findings may not be generalizable to hospitals in a different setting or with varying levels of resources or different populations. Similarly, only including PCICUs in the Bay area

means that findings may not be generalizable across the US. Finally, the short-term nature of the study may not be entirely generalizable to the long-term impacts of CINCO among children with CHD as they progress throughout childhood, adolescence, and adulthood. Despite these limitations, the proposed study should give meaningful insight in the efficacy of CINCO.

## Conclusion

While there have been numerous pediatric cardiac advances, CHD remains a prominent diagnosis among the pediatric population. Recent research provides substantial evidence of a link between CHD and the risk for DDs. The implications of these DDs for academic performance and QoL has also been corroborated by the literature. Within the PCICU, environmental stressors compound the risk for DDs for these infants and children. There are current developmental care practices that aim to minimize the development of DDs among patients. However, the risk for DDs among children with CHD continue to persist, impacting their academic performance and QoL. Two emerging developmental care practices are the IFDC and CINCO models, yet, CINCO is more comprehensive compared to IFDC. Even so, there remain significant gaps and inconsistencies in standards for developmental care practice across PCICUs throughout North America. The CINCO program shows promise as a standard developmental care model for all PCICUs across the US. This research underscores the benefit of practicing appropriate, evidence-based developmental care in both the PCICU with pediatric patients with CHD as well as any ICU setting where a CHD patient is hospitalized. Through the implementation of evidence-based developmental care in these hospital settings, the reduced environmental stressors improve the patients' neurodevelopment. With a lower risk rate for DDs, academic outcomes improve and ultimately, QoL is positively reinforced. The proposed study aims to build upon the current evidence-based developmental care practices, and enhance best nursing care practices in the PCICU for patients with CHD. By examining the relationship between the CINCO program, a comprehensive developmental care bundle, and the reduction of DDs based on DDST-2 scores, the proposed research will evaluate the

efficacy of this program. The results of this study will pose either a strong argument for the implementation of CINCO as a standard for developmental care in ICU settings, or not. This study can set a precedent for conversations surrounding the nation-wide adoption of this program. Research that intends to universally implement CINCO should involve the CDC, JCAHO, AAP, AHA, and AACN.

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# Appendices

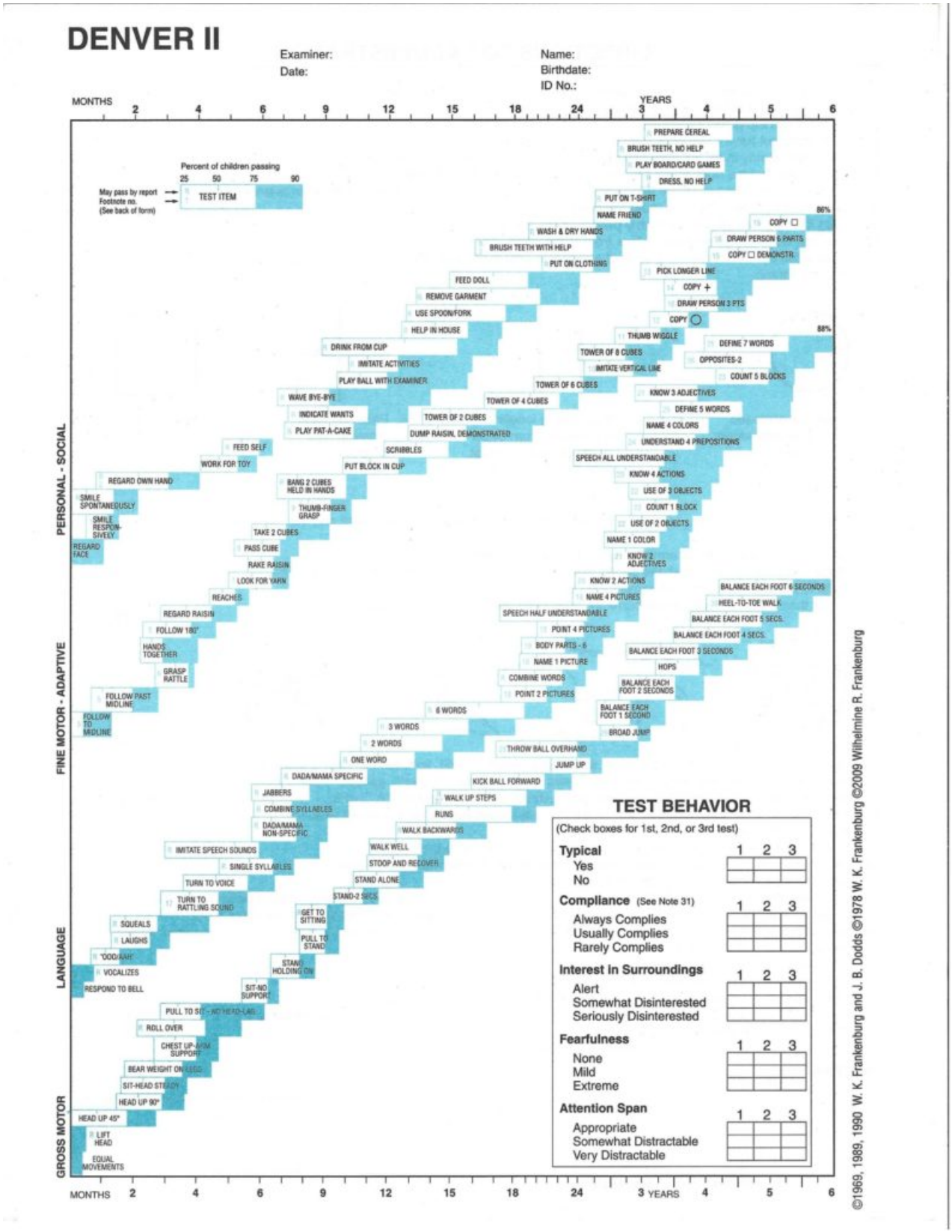
## Appendix A: Literature Review Table

**A Pulse for Progress – Examining the Efficacy of Best Nursing Developmental Care Practices for Children with Congenital Heart Disease at Risk for Developmental Delay in the PCICU: A Quasi-Experimental Retrospective Cohort Study**

**Your name: Jasmyn Jansen** **Date: 9.13.23**

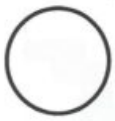
| Authors/Citation | Purpose/Objective of Study | Population of interest, sample size | Study Design | Study Methods | Major Finding(s) | Strengths | Limitations |
|---|---|---|---|---|---|---|---|
| Vagka, K., et. al, 2023 https://doi.org/10.7759/cureus.33373 | Undertaken given the paucity of studies on the developmental status in children with CHD in central India, evaluate and compare prevalence of neurodevelopmental delay in individuals with different CHD diagnosis. | Population of interest: pediatric population with CHD. Sample size: 82 children with CHD, children aged six months to six years. | Prospective, cross sectional study. | Denver Developmental Screening Test assesses neurodevelopment. | Greatest DD in gross motor domain, least affected in social domain. Cyanotic CHD patients are more susceptible to DD than children with acyanotic CHD due to hypoxia. | Developmental quotient as a secondary assessment tool. Comparative analysis of similar studies. | Sole utilization of the DDST-2 as a neurodevelopmental assessment tool. Population size minimal, not wide enough of an age group. |
| Wehrle, PhD et. al, 2022 https://doi.org/10.1016/j.peds.2022.05.047 | To describe the similarities & differences in the neurodevelopmental outcome of children with CHD undergoing cardiopulmonary bypass surgery compared with children born very premature (VPT) at school entry. | Population of interest: children with CHD undergoing cardiopulmonary bypass surgery. Sample size: 155 children with CHD, 251 children VPT. | Prospective, single-center, longitudinal study. | Independent t-tests, $X^2$ tests, equivalence testing. | Significant motor and behavioral impairments compared to VPT children. Poorer global motor abilities and dynamic balance compared to VPT children. Therapy usage is less frequent among children with CHD. | Longitudinal study, multiple IQ measures, and equivalence testing. | Single center, no mention of standardized neurodevelopmental care |
| Oster, M., et. al, 2017 https://doi.org/10.1161/CIRCOUTCOMES.116.003074 | Determine the association of CHD with academic outcomes and compare outcomes according to severity of CHD. | Population of interest: children with CHD Sample size: 5624 with CHD born between 1998-2003, 10832 w/o structural birth defects. | Population based retrospective cohort study. | Logistic regression, case analysis, odds ratio. | Children with CHD, both cyanotic and acyanotic, have poor academic performance, particularly in reading and math standardized tests at the end of 3rd grade. Children with non-critical CHD may benefit from better recognition and treatment of potential neurocognitive deficits. | Use of logistic regression, dichotomized achievement scores, comparative analysis of modeling outcomes of interest with children with and without additional non cardiac defects vs children without any structural birth defects, and being the largest of its kind to study educational outcomes in children with CHD. | Focus on North Carolina only. |
| LaRonde, MSN, RN, CCRN, et.al, 2022 https://doi.org/10.4037/ajcc2022124 | Determine state of individualized family centered developmental care (IFDC) for infants with CHD in the ICU. | Population of interest: ICU centers with infants with CHD. Sample size: 25 ICU centers. | Quasi-experimental cohort study. | Electronic survey of 55 multiple choice questions. Descriptive statistics with $X^2$ tests, and SPSS statistical package for stratified analysis. | 72% don't have IFDC guidelines, 63% incorporated IFDC, 67% documented IFDC practices, 29% have a neurodevelopmental team; nurse education r/t IFDC increased usage. | Implementation of its electronic survey among three clinical scenarios of varying patient acuity. | Subjective Likert scale, 66% response rate, only 1 nurse respondent per center. |
| Wolfe, PhD, ABPP-CN, et. al, 2023 https://doi.org/10.1017/S1047951123000562. | Acceptability of the Cardiac Inpatient Neurodevelopmental Care Optimization program, as a method to address modifiable factors of the ICU. | Population of interest: children with CHD at risk for DD Sample size: 619 children over 18 months 0-2 years old. | Prospective, single-site quality improvement interventional study | Statistical process control chart, pairwise comparison of utilization, exploratory bivariate analyses. | Feasibility demonstrated through increasing implementation rates over time. | All-encompassing, systematic, integrated, universal approach for developmental care practices. | Single site thus, not generalizable. NIDCAP-informed care and noise/light reduction not addressed and could have been confounders. Need for further research to understand impacts of CINCO. |
| Sood, PhD, et.al, 2016 https://doi.org/10.1097/ANC.0000000000000264 | Characterize current developmental care practices in North American CICUs. | Population of interest: North American CICUs. Sample size: 28 CICUs. | Cross sectional, descriptive study. | 47 item electronic survey. Descriptive statistics. | 89% report efforts to promote developmental care, 50% and 43% have a developmental care committee and hold developmental rounds, respectively. 86% provide darkness for sleep, 71% provide indirect lighting, 43% provide low levels of sound, 43% provide TV restrictions, 21% have designated quiet times. 82% cluster care, 86% promote self soothing during procedures, and 46% have formal holding policies. | First of its kind, 80% response rate. | Not entirely generalizable, respondents' level of knowledge influencing results. |

## Appendix B: Denver Developmental Screening Test-2



## DIRECTIONS FOR ADMINISTRATION

1. Try to get child to smile by smiling, talking or waving. Do not touch him/her.
2. Child must stare at hand several seconds.
3. Parent may help guide toothbrush and put toothpaste on brush.
4. Child does not have to be able to tie shoes or button/zip in the back.
5. Move yarn slowly in an arc from one side to the other, about 8" above child's face.
6. Pass if child grasps rattle when it is touched to the backs or tips of fingers.
7. Pass if child tries to see where yarn went. Yarn should be dropped quickly from sight from tester's hand without arm movement.
8. Child must transfer cube from hand to hand without help of body, mouth, or table.
9. Pass if child picks up raisin with any part of thumb and finger.
10. Line can vary only 30 degrees or less from tester's line.
11. Make a fist with thumb pointing upward and wiggle only the thumb. Pass if child imitates and does not move any fingers other than the thumb.



12. Pass any enclosed form. Fail continuous round motions.

13. Which line is longer? (Not bigger.) Turn paper upside down and repeat. (pass 3 of 3 or 5 of 6)

14. Pass any lines crossing near midpoint.

15. Have child copy first. If failed, demonstrate.

When giving items 12, 14, and 15, do not name the forms. Do not demonstrate 12 and 14.

16. When scoring, each pair (2 arms, 2 legs, etc.) counts as one part.
17. Place one cube in cup and shake gently near child's ear, but out of sight. Repeat for other ear.
18. Point to picture and have child name it. (No credit is given for sounds only.)
    If less than 4 pictures are named correctly, have child point to picture as each is named by tester.

19. Using doll, tell child: Show me the nose, eyes, ears, mouth, hands, feet, tummy, hair. Pass 6 of 8.
20. Using pictures, ask child: Which one flies?...says meow?...talks?...barks?...gallops? Pass 2 of 5, 4 of 5.
21. Ask child: What do you do when you are cold?...tired?...hungry? Pass 2 of 3, 3 of 3.
22. Ask child: What do you do with a cup? What is a chair used for? What is a pencil used for?
    Action words must be included in answers.
23. Pass if child correctly places and says how many blocks are on paper. (1,5).
24. Tell child: Put block **on** table; **under** table; **in front of** me, **behind** me. Pass 4 of 4.
    (Do not help child by pointing, moving head or eyes.)
25. Ask child: What is a ball?...lake?...desk?...house?...banana?...curtain?...fence?...ceiling? Pass if defined in terms of use, shape, what it is made of, or general category (such as banana is fruit, not just yellow). Pass 5 of 8, 7 of 8.
26. Ask child: If a horse is big, a mouse is ___? If fire is hot, ice is ___? If the sun shines during the day, the moon shines during the ___? Pass 2 of 3.
27. Child may use wall or rail only, not person. May not crawl.
28. Child must throw ball overhand 3 feet to within arm's reach of tester.
29. Child must perform standing broad jump over width of test sheet (8 1/2 inches).
30. Tell child to walk forward, → heel within 1 inch of toe. Tester may demonstrate.
    Child must walk 4 consecutive steps.
31. In the second year, half of normal children are non-compliant.

**OBSERVATIONS:**