Gravens By Design: Infant and Family-Centered Developmental Care Standards, Competencies and Best Practices—What is the Evidence?

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> ***"In considering how implementation of EBP has evolved over time, the integration of a more targeted and organized approach to the best research, clinical expertise and the family's individual values and circumstances, as well as the clinical practices where the health professional works are considerations in setting evidence based standards for care (3)."***

Developmental and family-centered care has emerged over the past several decades and is now seen as essential for the clinical care of babies and families. As in any emerging clinical approach, evidence accumulates with varying degrees of scientific rigor. The Infant and Family-Centered Developmental Care (IFCDC) interprofessional consensus panel has, over the past five years, been committed to providing the best evidence regarding developmental care practices for intensive care (1). As a result, the panel has reviewed, evaluated, and documented evidence leading to developing standards and competencies for babies and their families in intensive care.

A recognized definition of evidence-based practice (EBP) by Sackett is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research (2). In considering how the implementation of EBP has evolved, the integration of a more targeted and organized approach to the best research, clinical expertise, and the family's individual values and circumstances, as well as the clinical practices where the health professional works are considerations in setting evidence-based standards for care (3). Traditional medical models, emphasizing experience, clinical judgment, and rationale from pathophysiology, utilized research but in a less organized and systematic fashion (4). Evidence is examined in an organized fashion for the level of evidence leading to a strength of recommendation when combined with clinical judgment. Evidence should be reviewed regularly to update treatment recommendations regardless of the strength of recommendation.

Several structured approaches to evaluating available evidence exist, but for application to the population of preterm and/or medically fragile babies and their families in intensive care, the Interprofessional panel chose Melnyk's Scale (5), which scores intervention studies by the level of evidence according to study design and provides a Critical Appraisal Guide to understand the quality of the studies further. Evidence in Melnyk's Scale was then used to grade the strength of recommendation ranging on an A to D continuum consistent with the Oxford Centre for Evidence-Based Medicine. The committee continues to examine evidence and schedule regular updates.

The first level of evidence possible in Melnyk's model demonstrates a reduction in bias for selection of participants, observer expectations, procedural changes between groups, measurement bias, and recall bias. Additionally, these studies have a large enough sample size to increase the confidence that the result is accurate and not due to chance or innate variability in outcomes. The first level involves proper randomizing participants with care providers and observers blinded to the intervention. Strong representative measures are planned and collected prospectively. Many studies in intensive care that examine pharmacological effects fall into the randomized, double-blinded category. In this type of study, preparatory research also estimates the number of participants needed to achieve significance through power analysis. Treatments based on these studies are labeled as having Grade A strength of recommendation(6).

At the other end of the evidence are studies of rare diseases for which the best evidence may be a few descriptive case studies that are the best evidence available to us. This evidence is combined with clinical judgment inside a clinical setting and working with family/patient preference to produce a care plan. A limitation of this research is the low number of patients and a lack of randomization. However, reviewing a few cases and how care decisions are made in those instances provide insight into how to care for the infant in front of the provider. Treatments based on this research have a Level C strength of recommendation.

Most clinical intervention research falls in between those two approaches. The evidence in many of the "in between" studies comes from cohort studies, crossover studies, case-control studies, and cross-sectional studies. We have accepted observational studies that are compelling, such as loud noise causing physiologic instability in preterm infants (7, 8). Higher-level cohort studies have deepened our understanding of the details of the effect of the acoustic environment. Action-based interventions are challenging to assure "masked" observers and difficult to randomize in a truly clinical environment. The family and the nurse are usually not blind to the intervention, which may change how they assess the infant. Parents and staff in a non-intervention group may also be influenced by observing the interventions and change their behavior, causing a drift in the comparison group. Proper randomization may be flawed if, for example, a developmental intervention is performed on one wing of a unit and standard care is on the other wing. If the intervention changes the length of stay, beds may be available in one condition and not the other, and the participant may not be randomly assigned. Additionally, many available developmental care research study designs include a number of "individualized" and multimodal approaches. Even with these limitations, good quality studies from these levels allow us to have Level B strength of recommendation.

EBP requires a methodical examination of the best evidence available to support the development of recommendations for best practice. Research and clinical experience in developmental care are emerging, so is whether there is sufficient quality in the available studies to inform clinical decision-making and setting standards. Documenting what constitutes evidence-based practice (EBP) in IFCDC is important as it provides the most effective and appropriate clinical care available and does so in the context of the patient's/family's preferences, cultural values, and traditions.

The IFCDC consensus panel, recognizing the need for standardization of practices yet sensitivity to baby and family needs, explored the currently available evidence using a stringent model that incorporates scientific studies and documented clinical judgment. The consensus panel took on the challenge of critically appraising evidence long before developing the standards and best practices. The panel first established "pillars" consisting of assumptions that take into consideration the baby as a communicator and interactor with their primary caregivers, the baby's and family's individualized developmental needs, neuroprotection of the developing brain, relationship-based infant mental health, and the family contexts all provide the context for evidence-based developmental care in intensive care units. Six domains of current care practices attributed to developmental and family-centered care exhibited enough research and clinical experience to demonstrate merit for inclusion in the standards. Those justifiable domains of evidence include Systems Thinking, Positioning and Touch, Sleep and Arousal, Skin to Skin Contact with Intimate Family Members, Managing Pain and Stress for Newborns and Intimate Family Members and Feeding, Eating and Nutrition Delivery. Three aspects of appraisal of each domain included whether the studies were trustworthy or valid, whether the results were clinically useful and applicable in the clinical setting.

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The interprofessional panel carefully evaluated the evidence for each domain and assigned a level of evidence, resulting in the recommended standards, competencies, and best practice guidelines for IFCDC. The levels of evidence, practical application, and appropriate references are found for each domain at https://nicudesign.nd.edu/nicu-care-standards/. As more studies on the current domain areas are published and reviewed by the panel, revisions will be added. As evidence for other areas attributable to IFCDC become available, they will also be added to the current standards.

All clinical decision-making should be based on available evidence and clinical judgment, including those regarding developmental care. Based on the IFCDC consensus panel's structured review of available research and published clinical practice articles, they developed standards for practice. As the body of research studies evolves and expands, and as clinical experience informs practice, expanding the standards and best practices will ultimately benefit babies and families in intensive care.

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