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Challenges in conducting prospective research of developmentally directed care in surgical neonates: A case study

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ABSTRACT

Background: Evaluation is fundamental to evidence-based practice. Due to practical constraints inherent in real-world clinical environments, however, innovations in clinical practice are often implemented without rigorous research. We set out to evaluate the effectiveness of developmentally directed care in surgical neonates using a randomised controlled trial with a Newborn Individualized Care and Assessment Program (NIDCAP) intervention.
Aim: The aim of this paper is to inform future studies by sharing lessons learnt in conducting prospective research of a practice-intervention in a critical care setting.
Method: Three intervention components were used to assess implementation: number of NIDCAP observations; infant allocation to project nurses, and consistency of care. Barriers to implementation were identified through discussions with nurses who had key roles.
Results: Insufficient episodes of NIDCAP observation and infant allocation to project nurses, and lack of consistency of care indicated that the intervention had not been successfully implemented. Barriers to implementation (fast 'turnover' of patients, unpredictable changes in medical status, staff/skill shortages, and inconsistent care) were attributed to the competing demands between service provision and research in a busy critical care context.
Conclusions: The findings regarding barriers to successful implementation of NIDCAP in this case study are relevant to any critical care setting where complex interventions are under consideration, as similar challenges are plausible across a range of clinical contexts. Adopting a critical methodologically-informed approach to appraise implementation and evaluate complex interventions is essential.

1. Introduction

As survival rates improve following advances in newborn care and surgical techniques, attention is increasingly focussed on the developmental outcomes of survivors and the impact of infant health problems on families. The developmental problems of preterm and very low-birthweight infants and the difficulties faced by their parents are well-documented [1,2]. Increasingly, similar developmental problems are being documented in infants with major cardiac defects requiring neonatal surgery [3]. Less is known about infants with non-cardiac defects requiring neonatal surgery, however, developmental and behavioural problems have been reported [4,5]. Long-term concerns have extended beyond organ system functioning to include adverse academic and psychosocial sequelae (e.g., [6]), and clinicians are seeking innovative practices within the neonatal intensive care unit (NICU) that may improve outcomes for these infants and their families.

One such intervention is the practice of developmentally supportive care introduced in the 1980s as a model of care aimed at minimising the adverse effects of the NICU environment on high-risk infants [7,8]. However, despite a growing body of evidence for developmental care practices, implementation has varied among institutions and widespread adoption has not been achieved [9]. One particular model of developmentally directed care, the Newborn Individualized Developmental Care and Assessment Program (NIDCAP), has been found to improve the medical outcomes of preterm and very low birthweight infants (e.g., [10–12]). However, there are also reports that challenge these findings, with some authors citing small sample sizes and lack of long-term outcomes as methodological concerns ([13], see [14] for meta-analysis).

This paper describes the difficulties encountered in conducting a randomised controlled trial (RCT) to evaluate a NIDCAP intervention of developmentally directed care in newborns who require surgery for

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major birth defects (hereafter referred to as surgical neonates). In particular, the barriers to ensuring the consistency and fidelity in practice that are essential to NIDCAP-directed care are discussed.

As far as we are aware, there have been no previously reported studies evaluating individualised, developmentally directed, family-centred care in a surgical neonatal context. First, we present a brief overview of the traditional model and the NIDCAP model of NICU care. Next, we briefly outline why a comprehensive program of developmentally directed care may improve the quality of caregiving in a surgical neonatal context and how it can be delivered using the NIDCAP approach. We then report on the current study and the contextual factors that challenged implementation of the NIDCAP intervention in our clinical setting. Finally, we discuss issues related to evaluating innovative complex interventions, like NIDCAP, across different delivery settings and make recommendations for future practice-based intervention research in the clinical care context. In particular, we raise methodological concerns pertaining to the conduct of 'gold-standard' prospective research and the validity of program evaluation studies that, as far as we are aware, have not been previously discussed in the developmental care literature.

2. Changing practice in the NICU

The NICU is a highly technical, crisis-oriented environment aimed at ensuring the survival of sick newborn infants. The physical environment — characterised by constant, intense levels of light, noise, activity and stress — and clinical efficiency that constitute "normal functioning" in the NICU is often alien and disturbing to anyone unfamiliar with the environment, especially parents and families [15,16]. The disruption to normal parenting may have adverse effects on parent–infant relationships and child developmental outcomes (e.g., [17,18]).

Over the past twenty years, there has been a transformation in care practices in the NICU. Traditional NICU nursing practice is based on the medical model — attention is focussed on the infant's medical needs and is embedded in the context of institutional requirements [19]. In contrast, NIDCAP-directed practice is based on a developmental approach — attention is focussed on the unique needs of the individual infant and is embedded in the relationship between the baby, the parents and the health care professional [8,20]. Individualised developmentally supportive practice, while still addressing the infant's illness and desired medical outcomes, involves a change from routine protocol-based care to care that is sensitively contingent upon the infant's cues. Key aspects of these two models are summarized in Table 1.

Table 1
Changing practice in the NICU: traditional NICU practice versus NIDCAP-directed practice.
Source: adapted from Browne 2001(unpublished work).

	Traditional NICU practice (protocol-based care)	NIDCAP-directed practice (relationship-based care)
Model of care	Medical pathology	Infant development
Focus	Technology and ritual	Person and process
Orientation	Task-orientated: "doing to" the infant (invasive)	Relationship-orientated: engaging with the infant (sensitive responsiveness)
Timing of care	Driven by staff schedules	Responding to infant rhythms (sleep–wake cycles)
Caregiving procedures	Dictated by institutional protocols and routines	Contingent upon infant signals: pacing and modifying procedures to suit infant's cues
Primary caregivers	Staff-centred care: nursing staff with proficiency as medical technicians	Family-centred care: parents with skills for sensitive engagement with their infant
Immediate environment	Highly technical, specialised function as medical emergency centre	Adapted to provide comfort, quiet, and support for infant and family

3. The Newborn Individualized Developmental Care and Assessment Program

NIDCAP is based on the premise that newborn infants have adaptive developmental behaviours and the ability to communicate their needs through behavioural signals [7]. In premature and sick infants, however, the neurological maturity and integrity underlying the capacity for behavioural organisation and self-regulation are compromised. Further, the often excessive and/or invasive stimuli in the highly technological environment of the NICU place extra physiological demands on these biologically compromised infants, with possible detrimental effects on infant growth and development (e.g., [21]).

Essentially, NIDCAP is a relationship-based intervention program of sensitive engagement with the infant aimed at improving parent–infant interactions and promoting optimal outcomes for the infant and family. Parents are encouraged as caregivers and helped to respond appropriately to their infant's cues. Care providers use individualised care plans to support the infant's particular physiological vulnerabilities and developmental needs during the provision of care and medical interventions [10]. These care plans are based on individualised infant assessments performed by NIDCAP trained professionals.

The NIDCAP approach uses a systematic method for infant behaviour observation. The Naturalistic Observation of Newborn Behavior for Preterm and Fullterm infants (NONB) [22] is an intensive procedure involving detailed documentation of changes in the infant's autonomic, motor, state, attention/interaction and self-regulation systems in response to environmental stimuli [23]. It is recommended that infants on a NIDCAP program receive regular observations during their hospital admission [23–25].

NIDCAP training is a rigorous process of professional and personal development, involving certification of reliability in observation and interpretation of infant behaviour, preparation of care plans, and ability to engage parents and other care providers with this information [23,24,26,27].

4. Developmentally directed care of high-risk newborns in the surgical NICU: why and how?

Children who undergo life-saving surgery for major birth defects in the newborn period share similarities with other groups of infants at biological risk, in particular, early hospitalisation, severe illness, and biological compromise. Further, because these factors impact adversely on parent–child interactions, children with major birth defects are similarly at risk for the parenting difficulties associated with prematurity. Psychological distress (e.g., [28–30]) and parent–child interaction [31] problems have been associated with parenting children who require neonatal surgery for major birth defects.

Although disease and surgical factors contribute significantly to the variance in many short-term clinical outcomes, socioeconomic and psychosocial factors are also important contributors to variability in longer-term outcomes (e.g., [6,32,33]). The quality of mother–child interaction as a mediating variable between biological risk factors and later developmental outcomes has been demonstrated in other biological risk groups (e.g., [34,35]). While there are relatively few such studies in surgical neonates, some findings indicate a link between parent factors and child developmental outcomes following newborn surgery for birth defects [36–38].

Consequently, we were interested in optimizing developmental sequelae for children who undergo surgery in the neonatal period