IMPLEMENTATION MATTERS: ETHICAL RESPONSIBILITIES OF PEDIATRIC PAIN RESEARCHERS IN CHANGING CLINICAL PRACTICE

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Over the past 30 years, pediatric pain research has shattered the long-held belief that infants do not experience pain (Anand & Hickey, 1987). Furthermore, we have taken great strides in understanding pain mechanisms, developing effective pain assessment tools, (Stinson, Kavanagh, Yamada, Gill, & Stevens, 2006; von Baeyer & Spagrud, 2007), pain management interventions (both pharmacological and non-pharmacological), (e.g., Uman, Chambers, McGrath, & Kisely, 2008) and understanding contextual influences on pain experience (Craig, Lilley, & Gilbert 1996; Craig & Pillai Riddell, 2003). As time has passed, our role as pediatric pain researchers has evolved to where we are the experts in understanding, assessing, and managing pain in children. Clinicians, research ethics boards, and the general public are increasingly turning to us for expertise and guidance. Consequently, this begs the question: Whose responsibility is it to ensure that optimal pain management is being implemented?

The starting point of such a discussion requires a definition of "optimal care." To do so, we juxtapose it with both "standard care" and "substandard care," two terms that can be more easily agreed upon. For our purposes, standard care is defined as the pain assessment and management guidelines outlined by policy at a particular care setting, such as a hospital. Conversely, substandard care is defined as care that falls below that threshold and is typically considered to be unacceptable and unethical. However, in many cases, standard care is also suboptimal, falling short of those recommendations put forth by pain societies based on empirical evidence contributed by pediatric pain researchers (e.g., International Association for the Study of Pain, American Pain Society, Canadian Pain Society, etc.). The gray area falls in the differing practices and recommended guidelines found locally, nationally, and internationally.

Arguably, the randomized-controlled trial is the "gold standard" for determining the most effective, efficient, and ultimately, best tools for assessing and treating pain in children. Before such a study is undertaken, the phenomenon in question must be understood. There are still many areas of pediatric pain that remain poorly understood and one of the best ways to understand these phenomena requires direct observation of the current reality. However, is it ethical to conduct naturalistic observational studies of painful procedures when we, as pain researchers, know that children are receiving suboptimal care? This ethical dilemma is further complicated when suboptimal care is the institution's standard of care. In this scenario, the researcher reaches a crossroad where intervening would effectively destroy the integrity of the scientific research, while choosing not to intervene, goes against our ultimate research purpose to reduce the pain and suffering of children. We cannot hang our hat on the utilitarian argument that our research benefits the greatest number of people while individual children in our studies continue to suffer (Kopelman, 2000). Furthermore, are we condoning suboptimal practices that we observe by choosing not to intervene?

Clinical equipoise is a standard upon which the ethical appropriateness of clinical trials is judged. Clinical equipoise requires credible uncertainty in the expert medical community regarding a preferred treatment for a particular condition, that is, no arm of the trial is considered better than another. Uncertainty on the part of the individual researcher is not necessary or sufficient (Freedman, 1987). We would also argue that clinical equipoise should be judged by uncertainty in the research medical community, in this case other pediatric pain researchers. As our knowledge base in pediatric pain research continues to grow, true clinical equipoise is arguably becoming less common. This has effectively resulted in debate over the ethical use of placebo groups in pediatric research (Anderson & Cranswick, 2005). According to the Declaration of Helsinki (2008), the use of a placebo group is acceptable if: a) no current proven treatment exists (i.e., clinical equipoise); or b) where, for compelling and scientifically sound methodological reasons, the use of a placebo group is necessary to determine the efficacy or safety of an intervention and the patient will not be subject to any risk of serious or irreversible harm. However, the use of a placebo group may be justified if standard practice includes the absence of pain treatment (Anand et al., 2006).

In observational studies, researchers may observe practice, albeit standard care within the institution, that they know to be suboptimal. One can draw parallels between studies that lack clinical equipoise and the aforementioned observational investigations, whereby researchers are aware that children are not receiving evidence-based pain management interventions. Comparison to historical placebo groups and inferiority trials present two alternatives to the traditional randomized controlled trial, admittedly both with scientific limitations. However, the alternatives are less clear for pediatric pain researchers who conduct observational studies within the context of standard care that is suboptimal (e.g., no pain management), specifically when clinical equipoise exists within the medical community. Whereas the ethical principle of non-malfeasance requires that children are not harmed during their research participation, there is also a need to document the deleterious effects of unacceptable standards across care settings. After all, this is the necessary prerequisite to changing practice and effective knowledge transfer.

As researchers, much of our work resides at the forefront of the field exploring new understandings and approaches to pediatric pain. When considering our role in disseminating findings, we must be cautious in using research that has not sufficiently undergone repeated investigations as justification to create guidelines and change policy. A fine balance must be drawn between expert consensus in the field and novel effective treatment approaches. This end is expedited through the execution of well-designed and rigorous scientific research, which often involves direct observation of varying standards of care across institutions.

Ultimately, our research informs pain management guidelines, however clinical practice is prone to lag behind research. Are we achieving our overarching goal of reducing pain if we stop short of ensuring change in clinical standard care? Are we following up after studies are conducted to pass on the knowledge we have gained in our research? Effecting change in our local care setting is not sufficiently facilitated through the dissemination of research at scientific conferences and academic journals. Perhaps our responsibility has evolved to include increased time spent on knowledge translation research and activities that effectively engage multiple organizational stakeholders beyond the individual front line clinician (e.g., supervisors, policy makers, patients)

(Scott-Findlay & Estabrooks, 2006). Indeed, a growing body of important research has been taken up with this intent (e.g., the Translating Research on Pain in Children (TROPIC) study led by Dr. Bonnie Stevens), but as a whole we have a long way to go. Given that most of us have not been trained as advocates or policy makers, these efforts in knowledge translation do not necessarily come easily. Regardless, it is our responsibility to embrace this evolved role as pediatric pain experts and share our knowledge in a way that can most effectively result in the reduced pain and suffering of children.

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