The Importance of Doing Dual Diligence

Jeffrey R. Alberts, PhD

Indiana University, NFI Science Committee, Associate Editor for Science

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Target Article: Maryam Fatollahzade, Soroor Parvizy, Mandana Kashaki, Hamid Haghani & Mona Alinejad-Naeini (2020) The effect of gentle human touch during endotracheal suctioning on procedural pain response in preterm infant admitted to neonatal intensive care units: a randomized controlled crossover study, *The Journal of Maternal-Fetal & Neonatal Medicine*.

Little is ordinary about an ordinary day in a NICU. Without a break, 24/7, technological and biomedical wizardry is combined with expert applications of other, "low-tech" tools and "no-tech" methods. Together, it works: Babies born as early as 23- or 24-weeks survive and thrive. Miraculous outcome is almost ordinary. How do these miracles happen?

Let's start with one element in the miracle-making formula: The element is human touch. No technology needed. Our target article, a recent study by Fatollahzade[1] was designed to ask whether an intervention termed Gentle Human Touch (GHT) would reduce pain during the suctioning procedure commonly needed to keep open the airways of premature infants equipped with an endotracheal tube.

34 preterm infants (born at 27-34wks) comprised the study population. Cleverly, this research team utilized the on-going care regime as a testbed, knowing that the suctioning procedure, vital to breathing support of the intubated neonate is potentially painful. Their "crossover" design refers to an efficient and statistically powerful approach in which each baby is tested with and without the experimental intervention. Order was counterbalanced, meaning half the babies received the GHT intervention during suctioning on the first trial and routine treatment (no intervention) during the next need-based suctioning. The other babies also experienced both conditions, but in the reverse order.

The GHT intervention was administered to infants positioned prone in a gently flexed posture. The researcher cupped one hand around the infant's head while cupping the other hand around the infant's bottom. GHT was provided for the duration of the suctioning procedure. Using the Premature Infant Pain Profile (PIPP) protocol, a 15-sec-long pre-suction baseline assessment was made, followed by a 30-sec-long post-suctioning assessment. The PIPP yields a numerical score of infant pain in three ranges (mild to severe). It is considered well-validated and is used widely in research.[2]

The results were impressive. With standard care, 85% of the infants showed moderate pain responses to the suctioning procedure. GHT reduced the occurrence of moderate pain responses to 65%. Severe pain responses were manifested in about 9% of the control trials and GHT reduced these to about 3%. Such results are a first step toward adding Gentle Human Touch to the list of non-pharmacological methods of pain management in the NICU. Many of us are aware of the powers of skin-to-skin contact (Kangaroo Maternal Care[3,4]) as well as the efficacy of holding[5], facilitated tucking,[6-8] nursing,[9] non-nutritive sucking,[10] and oral sucrose,[11,12] each a method for pain mitigation, and more. Our target article is a new contribution. It builds on past knowledge of GHT and touch; it newly addresses the procedural pain of suctioning; and it expands the range of PIPP for assessment. There is more to learn about the scope, the magnitude, and unexplored outcomes of using GHT.

Though preliminary in several ways, Fatollahzade et al.[1] is an elegant study, particularly when viewed in the light of basic biomedical ethics. Importantly, they noted that GHT is safe. It did no harm. By explicitly registering that no harm to the baby came from the procedure, they formally recognized a vital dimension of their method. In other words, they addressed the familiar dictum, *Primum non nocere*, or 'First, do no harm'.

But, it is not enough to deem something as ethically-sound because risk is minimal. There is an ethical imperative to examine whether procedure actually "does good"?[13] In fact, Fatollahzade and her colleagues reported that GHT reduced pain responses. Gentle Human Touch during suctioning provided actual, active benefit.

Stay with me now: "Not to harm", in the language of ethics is *non-maleficence* [mə-'le-fə-sən(t)s]. The principle of non-maleficence is alive and well throughout medical ethics. After all, Premum non nocere. Infants cared for in the NICU deserve pledges of non-maleficence. All our patients do. But, again, it is not enough simply to avoid doing harm. In addition, ethical practices demand that we promote and do good. "To do good" in the language of ethics is *beneficence* [bə-'ne-fə-sən(t)s]. A beautiful word for a beautiful principle.

Whereas non-maleficence is mainly a prohibition against harm, beneficence has at least three forms, each of which we should examine as part of our awareness of doing good. As such, beneficence includes (a.) doing good, (b.) preventing harm, and (c.) removing harm.

In the NICU we can say the coin of the realm is ethical treatment of each baby. There are two sides to this coin: non-maleficence and beneficence. As two sides of the same coin, they are inseparable. So, as we hold this coin in our hand, we must continually turn it and examine each side. Such diligence is due to both sides. For this reason, I favor the label of *dual diligence*, stipulating the obligation to honor both principles – beneficence and non-maleficence.

Illustrative examples of non-maleficence without beneficence abound. Look no further than the previous issue of the *Developmental Observer*![14] Dr. Ita Litmanovitz, a neonatologist and NIDCAP Trainer, contributed a thoughtful and expert Commentary to the Science Desk column. Ita examined a technological *tour de force* report,[15] in which extremely prematurely born neonates were monitored for their first 72 hours with a combination of cerebral regional oxygen saturation ($CrSO_2$) via Near Infrared Spectroscopy (NIRS), amplitude-integrated EEG (aEEG), functional echocardiography (ECHO), further supported by head ultrasounds. The authors concluded that such multimodal monitoring "is feasible, safe, and well tolerated by extremely prematurely born infants in the first 72 h after birth". True, yes, but remember dual diligence!

Dr. Litmanovitz's commentary guides us through a set of critical considerations of the ocean of data that were collected -- without harming the newborns' skin or increasing adverse events. Despite the investigators' rationale, the multimodal measures did not prevent IVH or reduce adverse outcomes. More serious, however, was that to make these measurements, there was an obligatory, 72-hr separation of infant and mother!

It is well-documented that such separations can have both immediate and long-term negative effects both on the baby and mother. Dr. Litmanovitz cited of the costs of losing early postnatal mother-infant contact, while seeking some still-elusive benefits of predicting a hemorrhagic event. Awareness and attendance to dual diligence – recognizing and documenting both non-maleficence and beneficence can provide the clarity we need to realize ethical care.

Dual diligence is not only fully compatible with NIDCAP practice, it is embedded within it.

In caregiving, in formulating treatment protocols, and in evaluating research, it is imperative for us to examine both avoiding harm and doing good. Doing dual diligence is a foundation of ethically-guided practice.

NICU miracles of successful development arise from a combination of high-tech, low-tech and no-tech. We do not know how they combine into success, but we do know that they are all involved, and I bet that it is not via simple addition of separate factors. Each modality supports the other. High-tech medical wizardry is crucial. So is parental love and human touch.

Remember always that an *ordinary* day in a NICU is made of the extra-ordinary. *Ordinarie* in Old French, for *rule* or *ordinance*, as in rules that prescribe forms of action, gave us the English word ordinary. Think of the protocols you follow that make an ordinary day. In this way, everything you do makes miracles almost ordinary. Look for and see the duality of non-maleficence and beneficence present in a simple protocol. In developmental care, they are the core of the miraculous.

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