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Using the pain principle to provide a new approach to invasive treatments and end-of-life care

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End-of-life issues involving small babies are particularly challenging for doctors, particularly pediatricians as there are complex issues involved, including long-term disabilities (1) and the parents' wishes (1). Evaluations can be based on statistical risks (2) and case-by-case issues. Some authors (3) suggest that intensive care can be withheld when consciousness is compromised, but that raises questions about what level of consciousness equates to a baby being completely compromised (4). Other authors have questioned whether suspending therapies when the baby is not at their end-of-life is ethically right. Concerns have also been expressed that there is a risk that babies lives are undervalued, in comparison with older patients, because their life support is removed more easily than when adults have a similar prognosis (5). Moreover, some think that the vital treatment that babies receive cannot be deliberately stopped, even in the absence of signs of consciousness, for example on the basis that life is sacred; the Child Abuse Amendments of 1984 introduced legislation was strongly protective of the rights and interests of disabled children in the USA and left little room for non-treatment decisions based on their quality of life or on the parents' interests.

Most doctors use the best interest principle for difficult cases, namely putting themselves in their patients' shoes and deciding on their behalf. The problem with this is that doctors hold individual views and often disagree about what is actually in the best interest of a baby.

Those who advocate therapies and those who want them withheld both say that they have the baby's best interests at heart. Diekema has expressed the need for a criterion that is more robust than the best interest principle, namely the harm principle (6), which is based on avoiding harm rather than promoting the babies' best interests. However this principle faces the same issues as the best interest principle: what is harm and who can define it? Physical harm exists, but moral, existential and economic types of harm are also possible. Some clinicians also think that the harm threshold necessary to withdraw therapies can be extended to cases of blindness, paralysis or any physical or mental handicap. However, this approach

has been challenged as being disrespectful and stigmatising towards people with disabilities (7).

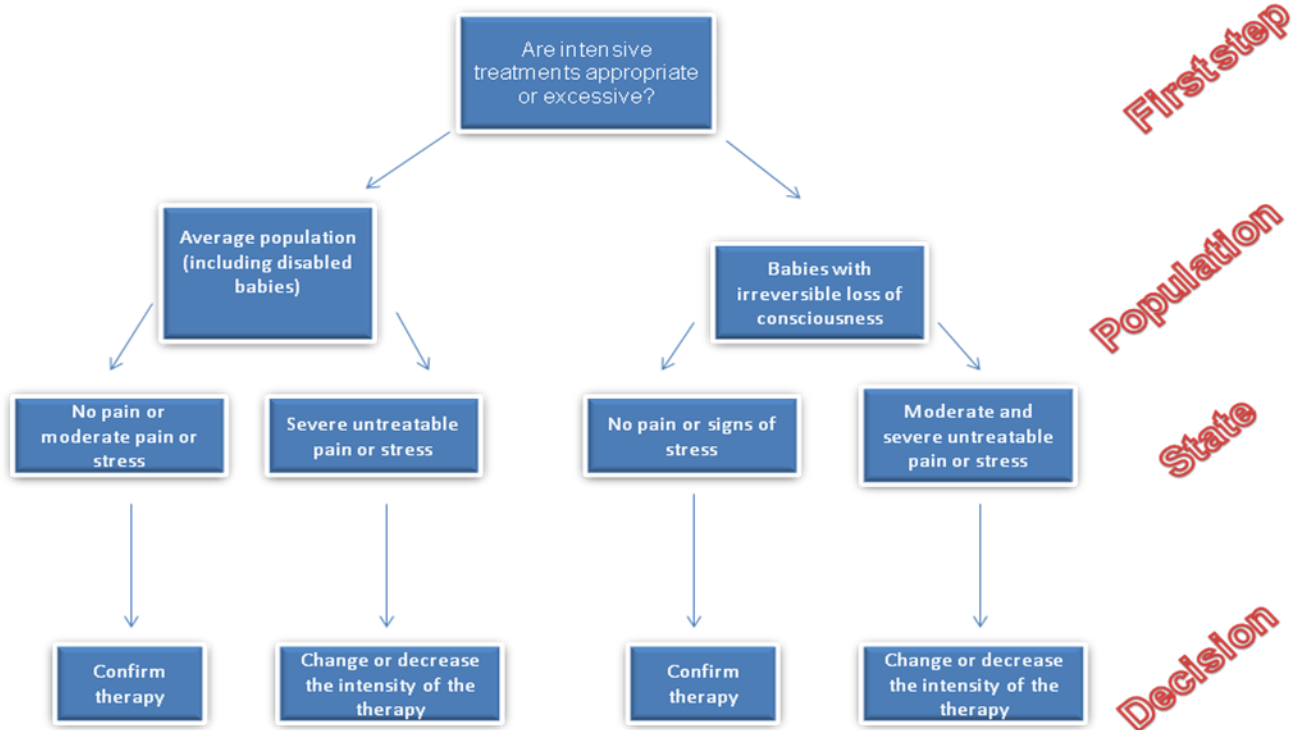
An easy and robust parameter is needed to decide when an invasive treatment is excessive and this needs to have the lowest possible margin of error. One option is to consider what we call the pain principle as a reliable marker for this decision, namely the presence of pain or stress. Pain and stress are objective markers, because they can be measured. We can acknowledge if babies are really feeling these undesirable sensations, using direct observation, asking the patient when possible, or with subjective or multifactorial algometric scales. We can also score pain and stress by measuring the production of acute-stress hormones (8), measuring skin impedance, which is a sign of alterations in the autonomic nervous system due to pain or stress (9), or looking for pain-related electroencephalogram changes (10). Good tools for pain assessment in non-verbal patients are available and have been validated, but they are scarcely used and some are hard to use. In addition, a lot of effort is needed to apply and refine them in end-of-life settings. Some authors have also determined the threshold that separates severe from mild pain, using some of the aforementioned tools, and these findings need to be refined by scientific societies. We recognise that pain and stress are two different feelings and distinct phenomena, but we have considered them as a single entity in this paper as they can be measured using the same markers.

Thus, we propose using the pain principle to assess whether an invasive treatment is to be carried out. It can be so summarised as follows: medical procedures should be measured and then withdrawn or reduced to a lower intensity level when measurable pain or stress are excessive and untreatable. Two examples of this reduction are: removing a peritoneal dialysis set, when it can no longer be tolerated, or moving from endotracheal invasive ventilation to mask ventilation.. So, the main concern in end-of-life care shifts from dealing with death to

dealing with pain and the main goal becomes relieving pain. A collateral effect of this is that it can reduce the patients' life expectancy, but this will be an unwanted consequence of our attempt to shield the baby from pain, rather than a deliberate choice.

In Figure 1, we propose an algorithm for the pain principle. We have considered that a moderate amount of stress or pain can be accepted in the general population, including disabled babies, if it leads to advantages for the patient in the future. However, any level of stress is unacceptable in babies with irreversible loss of consciousness and social interaction and any invasive treatments should be reduced in intensity, or made less invasive, at the first sign of pain or stress. Of course, all efforts should be made to minimise and overcome pain before saying that pain or stress are too severe and international guidelines on this are essential. We also feel that brain damage should be diagnosed based on solid evidence, such as an electroencephalogram or a magnetic resonance imaging scan, and not just on a statistical or probabilistic basis, namely just gestational age (2). The pain principle is not a substantial alternative to the best interest principle, but it is a pragmatic way of applying it. Importantly, the pain principle does not recommend that clinicians arbitrarily remove vital treatments, but it does suggest their progressive removal, or a decrease in intensity, allowing the use of palliative care, when they become excessively burdensome to the patient.

Figure 1: The pain principle algorithm



Legend:

A distinction is made for babies with irreversible loss of consciousness and the rest of the population, because in the former group, no level of stress or pain is acceptable.

REFERENCES

1. Streiner DL, Saigal S, Burrows E, Stoskopf B, Rosenbaum P Attitudes of parents and health care professionals toward active treatment of extremely premature infants. *Pediatrics*. 2001; 108:152-7.
2. Janvier A, Barrington KJ, Aziz K, Bancalari E, Batton D, Bellieni C et al. CPS position statement for prenatal counselling before a premature birth: Simple rules for complicated decisions. *Paediatr Child Health*. 2014;19:22-4
3. Lagercrantz H. Observations on the case of Charlie Gard. *Arch Dis Child*. 2018;103:409-410.
4. Aleman B, Merker B. Consciousness without cortex: a hydranencephaly family survey. *Acta Paediatr*. 2014;103:1057-65
5. Haward M, Mercurio M, Janvier A. Perpetuating Biases and Injustice Toward Preterm Infants. *Am J Bioeth*. 2017;17:27-29
6. Diekema DS. Parental refusals of medical treatment: the harm principle as threshold for state intervention. *Theor Med Bioeth*. 2004;25:243-64
7. Golden M, Zoanni T. Killing us softly: the dangers of legalizing assisted suicide. *Disabil Health J*. 2010;3:16-30
8. Okamura H, Kinoshita M, Saitsu H, Kanda H, Iwata S, Maeno Y et al. Noninvasive surrogate markers for plasma cortisol in newborn infants: utility of urine and saliva samples and caution for venipuncture blood samples. *J Clin Endocrinol Metab*. 2014;99:E2020-4.
9. Scaramuzzo RT, Faraoni M, Polica E, Pagani V, Vagli E, Boldrini A. Skin conductance variations compared to ABC scale for pain evaluation in newborns. *J Matern Fetal Neonatal Med*. 2013;26:1399-403

10. Klarer N, Rickenbacher H, Kasser S, Depoorter A, Wellmann S. Electrophysiological Measurement of Noxious-evoked Brain Activity in Neonates Using a Flat-tip Probe Coupled to Electroencephalography. *J Vis Exp.* 2017 29;(129).