

Commentary

A Children's Comfort Promise:

how can we do everything possible to prevent and treat pain in children using quality improvement strategies?

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The decade of pain control and research (2001-2010; Nelson, 2003) has long passed, and the joint statement issued by the World Health Organization (WHO) and the International Association for the Study of Pain (IASP) declared that, "the relief of pain should be a human right" (WHO, 2004). Yet, data from children's hospitals worldwide, including Canada, USA and UK reveal that pain in inpatients was common, under-recognized and undertreated (Taylor et al., 2008; Stevens et al., 2012; Twycross & Collis, 2013; Birnie et al., 2014; Friedrichsdorf et al., 2015; Shomaker et al., 2015). In addition, it appears non-ethical research studies are still approved by ethics committees, performed with children, and accepted in medical journals for publication. Bellieni and Johnston (2016) recently reviewed 45 studies published between 2013 and 2015 of trials that test new analgesic treatments for procedural pain in neonates. They found that despite international guidelines, neonates included in control groups during painful procedures did not receive analgesia in the majority of cases. As recently as 2015, a study was published describing physically restraining small children, while performing an exquisitely painful procedure, a myringotomy and tube insertion in an office of an ENT surgeon without any analgesia nor sedation (Rosenfeld et al., 2015).

Rosenfeld et al. (2015) describe in the latter study a practice in infants and children which is

actually banned for animals. For instance, in the state of Oregon the Veterinary Practice Act was amended in 2010 to include pain control as a mandatory part of veterinary practice (OAR 875-015-0030). Minimum pain management may not be omitted by the veterinarian or declined by the client. So how can it be that a dog owner is not allowed to consent to strapping a puppy to a board for a painful procedure, but in 2015 a respected medical journal published a report of a provider essentially doing that during a painful procedure to a child? (Friedrichsdorf et al., 2016).

How can we significantly improve pain treatment for children? Should quality improvement (QI) initiatives be part of our strategy? The majority of QI studies indicate that making pain management an organizational priority indeed can improve practices. However, many of the QI strategies used are time and resource intensive, and the studies to date are generally small scale with change not always being evaluated over a sustained period (Twycross & Dowden, 2010). Over the past decade it has become apparent that organizational culture is a key element that needs addressing if pain management practices are to improve. This commentary illustrates our efforts to shift culture and policy around pediatric pain management throughout a large institution.

What can be done, and how does one go about getting an institution to change policies? At our institution, a busy, free-standing children's hospital

in the upper Midwest of the United States, with 385 staffed beds (50% of them on intensive care units), the need to understand how well we were managing pain was recognized. In 2013, a prospective, cross-sectional survey and electronic medical record (EMR) review of all inpatients who received medical care on a specific day was conducted (Friedrichsdorf et al., 2015). Not surprisingly, the survey revealed the single biggest source of pain and anxiety for our patients and families was needle procedures. Needle procedures include blood draws, intravenous access, and injections (including vaccinations). More revealing was in a separate staff survey that these same procedures were also the ones with the least pain control and the lowest staff awareness and/or acknowledgement of the need for pain control.

The cross-sectional survey was key to providing data to leadership in alignment with the strategic goals of the institution, which included improving patient experience. As a result, hospital leadership decided that this was an unacceptable situation for a children's hospital and committed to an organization-wide initiative to address it. Seeking strategic support from leadership was a key strategy early on and resulted in the Chief Medical Officer (CMO) and the Chief Nursing Officer (CNO) becoming executive sponsors of a lean value stream called "Children's Comfort Promise: We will do everything possible to prevent and treat pain" (www.childrensMN.org/comfortpromise). The objective of this work, as stated in its value stream lean charter, is to: "Design, test & deploy the clinical practices and foster the culture required to eliminate all needless pain and to minimize all moderate and severe physical pain and distress associated with, anticipated, or experienced pain in patients and their families through the continuum of care." The first priority of this multi-year effort was to reduce, or even possibly eliminate, needle pain. This alone affects more than 200,000 children annually at our institution.

Current evidence (Taddio et al., 2010; Taddio et al., 2015a; Taddio et al., 2015b), supported by the Canadian Paediatric Society (www.caringforkids.cps.ca/uploads/handout_image/s/3p_babiesto1yr_e.pdf) and Immunize Canada (www.immunize.ca/en/parents/pain.aspx) and

brought forward by "Be sweet to babies" by Harrison et al. (www.cheo.on.ca/en/BeSweet2Babies) and the outstanding "It doesn't have to hurt" science-to-social media campaign from Chambers et al. (<http://itdoesnthavetohurt.ca>), strongly suggests that four modalities need to be offered for elective needle procedures to children to decrease or eliminate pain caused by needles. We decided to implement all four of them system-wide as non-negotiables: (1) Numb the skin (we chose topical anesthetic 4% lidocaine cream or needle-less lidocaine application via J-tip), (2) Sucrose or breastfeeding for infants 0-12 months, (3) Comfort positioning (swaddling, skin-to-skin, or facilitated tucking for infants, sitting upright for older children), and (4) age-appropriate distraction (www.childrensMN.org/comfortpromise).

Lean improvement systems are focused on removing waste. If waste is defined as anything that the customer (i.e. patient, parents, but also clinic staff and management) does not value, it is a logical conclusion that pain is a form of waste. This is the reasoning that led to the use of lean improvement practices to implement the clinical practices needed to improve pain management with needle procedures. Utilizing these principles (Womack & Jones, 2003; Graban, 2016) and recognizing that pain is a type of waste, a systematic improvement approach to changing hospital policy and culture was utilized, including:

1. Leadership structure (as spelled out in the lean charter for the value stream, including executive leadership sponsorship)
2. Dedicated resources (including clinical resource specialist, child life specialist, lean specialist and physician champion)
3. Hands-on, small group education (e.g. meeting with unit councils, medical assistants, phlebotomy staff, teaching at pediatric- and cardiac intensive care education days providing small-group education)
4. Process analysis and design utilizing front line staff (e.g. work groups for neonatal intensive care units, medical/surgical units, critical care, phlebotomy and ambulatory clinics all included front line staff to map out current process and opportunities for improvement)

5. Logistics assistance (e.g. help with ordering and organizing supplies and distraction materials)
6. Hands-on, small group training (including undertaking small group, hands-on training for positioning, lidocaine cream and sucrose application, as well as distraction for staff in each of the 12 primary and 14 specialty clinics, as well as for nurses at the annual competency fair, and phlebotomy staff, and emergency medical technicians)
7. Collection and reporting of process and result measurement (such as monthly audits for process measures until units achieved > 95% adherence to the non-negotiables, and tracking Picker satisfaction data for pain outcome measures)
8. Performance incentives (part of the system wide manager and physician performance improvement plans in 2016)
9. Area rounding by subject matter experts (the Comfort Promise clinical resource specialist and child life specialist round on all of the units until they hit targets [>95% adherence])

The basic tactic was to move department by department, learning from each effort, replicating where possible and developing new solutions to unique issues. The efforts overlapped but had staggered start times. Outpatient phlebotomy was the first area addressed, followed by inpatient medical-surgical units, emergency departments, neonatal units, critical care, and radiology. Currently, we are working in our 26 ambulatory clinics, following the roll-out there on July 1, 2016.

As with any systemic change, there was resistance to overcome among some individuals, but key to success was providing the resources, support and training staff required to consistently offer the 4 non-negotiables. When we could demonstrate that waiting times went down, topical anesthetics did not decrease chance of venous cannulation, and most importantly, the immediate difference it made for patients (fewer tears and calmer, cooperative children), the Comfort Promise was embraced by nearly all staff. As part of the lean process, regular audits are conducted to measure progress and identify issues early and problem solve with staff.

At the core of our process audits, we benefit from knowledge translation strategies (Zhu et al., 2012) such as audit and feedback, education materials and outreach and we utilize Plan-Do-Study-Act-(PDSA)-Repeat cycles. Now that all units are rolled out, bonuses are tied to success and for individuals who do not adhere to the new standard it will become a performance issue.

This structured initiative was successful both due to leadership support (including a letter signed by the Children's Minnesota Chief Executive Officer (CEO), Chief Operating Officer (COO), CNO and CMO pointing out that that we offer the non-negotiables to all our patients, including topical anesthesia for term infants and older and that we at Children's will not hold down children for elective needle procedures anymore and many individuals at many clinical and non-clinical levels who embraced the Comfort Promise during the roll out. Key lessons were to have a framework for implementation; education and guidelines alone were not sufficient. A major strategy was "You have to make the new way easier than the old way", and the only way to do that was to engage frontline staff. Key to success was that Children's Minnesota put resources behind the change initiative, including a full-time clinical resource nurse (D.E.), a full-time child-life specialist and half-time lean consultant (C.W.).

Because change does not happen by command but rather happens by influence (Grenny et al., 2013), the main aim of the Comfort Promise team was to establish trust and ensure engagement of the frontline staff, in order to build a culture that would foster and sustain meaningful change. Surprises in the process included that objections by some individuals occurred very late in the process, which required additional time and leadership interventions to be reconciled. We also underestimated the time it takes to implement lasting changes, with our initial roll-out (two outpatient laboratories) in late 2013 taking the longest – 10 months until we reached 95% adherence to the non-negotiables.

Other important successes include that following our intervention the Minnesota Department of Human Services added 4% lidocaine cream as reimbursable by the public insurance

Medicaid/Medicare and Picker pain satisfaction data increased significantly following the system wide roll-out in first quarter of 2015. But a culture shift takes a long breath: Although usually more than 80% of the children were offered or received the 4 non-negotiables in nearly all areas within two month of roll-out, it took 12 months until early 2016, until the first inpatient unit (newborn intensive care, NICU) consistently applied all (and not just some) of the four modalities for more than 95% of needle procedures.

The hospital marketing department was involved early in the process and supported a re-naming of our initial “No Needless Pain” value stream, which wording our Children’s Youth Advisory Council (<https://vimeo.com/128990829>) of 9-18-year-olds disliked, into language that could be branded, resulting in the “Children’s Comfort Promise: We Promise to Do Everything Possible to Prevent and Treat Pain”. This achieved our goal of consistent messaging to staff and families. Thanks to a grant from The Mayday Fund, we will be able to roll out the Comfort Promise strategies for needle pain in 2 Canadian (Montréal, Toronto) and 2 US (Atlanta, Kansas City) children’s hospitals in 2016-2017, thus expanding the reach of our efforts.

Pediatric pain management for hospitalized children or in children undergoing painful procedures, including vaccinations in the ambulatory setting, clearly shows room for

improvement. Our results, and those of other institutions worldwide, seem to demonstrate that quality improvement strategies coupled with knowledge translation strategies might be an important set of instruments in our toolbox to improve pediatric pain treatment and prevention (Zhu et al., 2012; Stevens et al., 2014). Analgesic treatment is mandatory for children when they undergo painful procedures and no avoidable suffering is acceptable nowadays, even for so-called minor interventions (Children’s Hospitals Australasia, 2010; Bellieni & Johnston, 2016).

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