

# A hospital-wide initiative to eliminate or reduce needle pain in children using lean methodology

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## Abstract

**Introduction:** Pain remains common, underrecognized, and undertreated in children's hospitals and pediatric clinics. Over 200,000 patients experience needle pain annually in our institution, caused by blood draws, intravenous access, vaccinations, and injections on all inpatient units, emergency departments, outpatient laboratories, and ambulatory clinics.

**Objectives:** We implemented a hospital-based, system-wide initiative called the "Children's Comfort Promise," and created a new standard of care for needle procedures that required staff to consistently offer 4 strategies: (1) topical anesthetics, (2) sucrose or breastfeeding for infants 0 to 12 months, (3) comfort positioning (including swaddling, skin-to-skin, or facilitated tucking for infants; sitting upright for children), and (4) age-appropriate distraction.

**Methods:** The protocol was established system-wide in one of the largest children's hospitals in the United States using a staggered implementation approach over a 3-year period to allow for unit-specific customization and facilitation of knowledge transfer from one unit to another. All departments were required to offer all 4 strategies with appropriate education at least 95% of the time.

**Results:** Comparison of baseline audits with continuous postimplementation audits revealed that wait times for services decreased, patient satisfaction increased, and staff concerns about implementation were allayed (eg, concerns about wait times and success rates of venipuncture after topical anesthesia).

**Conclusion:** This is the first report of a successful system-wide protocol implementation to reduce or eliminate needle pain, including pain from vaccinations, in a children's hospital across all inpatient units, emergency departments, outpatient laboratories, and ambulatory clinics through consistent use of topical anesthesia, sucrose/breastfeeding, positioning, and distraction.

**Keywords:** Pediatric pain, Quality improvement, Lean, Needle pain, Vaccination, Procedural pain, Sucrose, Breastfeeding, Topical anesthesia, Lidocaine 4% cream, Positioning, Distraction

## 1. Introduction

According to the 2010 Declaration of Montreal, access to pain management is a fundamental human right and it is a human

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rights violation not to treat pain.<sup>30</sup> Data from children's hospitals in North America and Europe reveal that pain is common, underrecognized, and undertreated.<sup>5,19,52,55,65,68,73</sup> Needle procedures performed in childhood are a substantial source of distress. Vaccinations are the most commonly performed needle procedure in children, and pain is a common reason for vaccine hesitancy.<sup>15,35,59</sup> It is estimated that up to 25% of adults have a fear of needles, with most fears developing in childhood.<sup>24,26</sup> Untreated needle pain can have long-term consequences including needle phobia, preprocedural anxiety, hyperalgesia, and avoidance of health care, resulting in increased morbidity and mortality.<sup>57,58</sup>

The 2016 American Academy of Pediatrics guidelines for procedural pain in neonates concluded that newborns, especially premature infants, experience unnecessary pain during routine procedures.<sup>74</sup> Infants admitted to neonatal intensive care units (NICUs) experienced more than ten painful procedures per day, of which the overwhelming majority were performed without analgesia.<sup>10,47</sup> Critically ill infants may experience up to 480 painful procedures during their NICU stay.<sup>3,31</sup> Exposure to severe pain without adequate pain management has negative long-term consequences, including increased morbidity (eg, intraventricular hemorrhage) and mortality.<sup>1,60</sup> Exposure to pain in premature

infants is associated with higher pain self-ratings during venipuncture by school age<sup>71</sup> and poorer cognition and motor function.<sup>23</sup>

Children's Hospitals and Clinics of Minnesota is one of the largest freestanding pediatric health care systems in the United States, with 429 staffed beds on 2 campuses (50% of which are neonatal beds), 5 intensive care units, 2 emergency departments (EDs), and 26 primary and specialty clinics, providing care through more than 14,600 inpatient admissions, 25,800 surgical cases, 8700 home visits, and more than 96,400 ED and 447,000 clinic visits every year.<sup>2</sup>

Despite the evidence supporting pediatric pain management for needle procedures,<sup>9,29,57,62,64</sup> few strategies were used and offered for children in daily practice as identified through patient, family, and staff surveys. In 2013, a prospective, single-day, cross-sectional survey and electronic medical record review of all inpatients who received medical care at our institution were conducted to estimate how well we were managing pain.<sup>19</sup> The survey revealed that the single greatest source of pain and anxiety for our patients and families was needle procedures, such as blood draws, intravenous access, and injections. Staff surveys conducted that same year gave low priority to pain experienced during needle procedures, demonstrating a significant institution-wide gap in practice.

This report describes the implementation of a system-wide, multiyear quality improvement (QI) process to reduce needle pain using Lean methodology.<sup>21,46</sup> The process is entitled "Children's Comfort Promise: We will do everything possible to prevent and treat pain."<sup>14</sup>

## 2. Methods

### 2.1. Early institutional planning

To assess the current state of staff attitudes and beliefs about organizational pain management at Children's Minnesota, an online survey was administered in 2013. Results (unpublished) revealed that most responding clinical staff members were "completely satisfied" with our pain management efforts at the time, and either felt needles "were not very painful," or felt the best we could do was "to be fast and accurate." However, a cross-sectional patient survey conducted the same year revealed that the worst pain reported by patients was caused by needle procedures,<sup>19</sup> highlighting the gap between staff perceptions and patient experience. Findings from the 2 surveys were presented to hospital leadership, and addressing needle pain was found to be aligned with the institution's strategic goal of improving patient experiences. Hospital leadership agreed that needle pain practices were unacceptable, and pledged commitment to support an organization-wide initiative to improve pain management practices.

Children's Minnesota used a QI approach based on The Toyota Production System (also known as Lean), with a dedicated Lean department already in existence at the time. Lean improvement systems focus on removing "waste" from work processes through observation and analysis of the current state, including front-line staff, to design a future state that effectively meets the needs of the customer.<sup>21,44,75</sup> If waste is defined as anything that the "customer" (ie, patients, families, and clinical staff) does not value, it can be reasonably assumed that pain itself is a form of waste. This was the underlying rationale for using the organization's existing Lean-driven improvement strategy to improve pain management with respect to needle procedures. This project was declared as QI by Children's Institutional Review Board.

When a QI effort spans multiple areas of authority (eg, units, departments) and requires extensive coordination, a Lean methodology structure known as a "Value Stream" is frequently used. A value stream is a method for analyzing the current state and designing a future state that takes a service from its beginning (eg, clinician order of blood draw in an ambulatory clinic) through to the customer (eg, a child undergoes blood draw in outpatient laboratory). In this case, the "No Needless Pain Value Stream" was chartered, which involved identification of multidisciplinary core team members, leadership sponsors, scope, objectives, and metrics. A nurse (D.E.) was assigned as the Value Stream manager, supported by a Lean coach (C.W.) and physician sponsor (S.J.F.).<sup>21,75</sup> Seeking strategic support from leadership early on (combining top-down and bottom-up approaches)<sup>28</sup> was a key strategy, resulting in executive sponsorship from the Chief Medical Officer and the Chief Nursing Officer. The Lean Value Stream was then branded as the "Children's Comfort Promise."<sup>14</sup> The objective of this work, as stated in the charter, was to: "*Design, test, and 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 by patients and their families through the continuum of care.*"<sup>18</sup> The first priority of this multiyear effort was to reduce or eliminate needle pain using evidence-based best practice.

### 2.2. The 4 evidence-based best practices for reducing needle pain in children

Current evidence,<sup>57,62,64</sup> supported by guidelines from the Canadian Paediatric Society,<sup>9,29</sup> HELPinKids,<sup>27,41,42,61</sup> and recently brought forward by science-to-social media campaigns ("Be Sweet to Baby"<sup>12</sup> and "It Doesn't Have to Hurt"<sup>11</sup>), strongly suggests that 4 bundled modalities should be offered for elective needle procedures to reduce or eliminate pain experienced by children. After reviewing the evidence, the core Lean Value Stream team decided to require staff to consistently offer all 4 strategies institution-wide. As directed by Lean methodology, members of the core team performed initial observations to anticipate potential barriers to offering the strategies, and brainstorm possible solutions (**Table 1**). Children and their parents/legal guardians had the option of declining any or all strategies, which included the following<sup>14</sup>:

- (1) "Numb the skin" (for children of 36-week corrected gestational age and older). We chose to use 4% lidocaine cream<sup>63</sup> or needle-less lidocaine application using a J-tip (sterile, single-use, disposable injector that uses pressurized gas to propel medication through the skin)<sup>38,39</sup> as topical anesthetics.
- (2) Sucrose<sup>20,54</sup> or breastfeeding<sup>51</sup> for infants 0 to 12 months.
- (3) Comfort positioning. Restraining children for procedures is never supportive, and creates a negative experience.<sup>33</sup> For infants, we use swaddling, warmth, skin-to-skin contact, or facilitated tucking. For children 6 months and older, we offer sitting upright, with parents holding them on their laps or sitting nearby.
- (4) Age-appropriate distraction,<sup>70</sup> such as toys, books, blowing bubbles or pinwheels, stress balls, and using apps, videos, or games on electronic devices.

These 4 strategies were offered by front-line staff who were trained by the Value Stream manager and Lean coach. Training was accomplished using multiple modalities including a "train-the-trainer" approach, web-based training, educational videos and classes, lectures, and rounding. Strategies were presented

**Table 1**  
**Examples of barriers to implementation of comfort promise strategies by strategy.**

Strategy	Problem or barrier	Starting state	Solution
Topical anesthesia (numbing cream)	Phlebotomists cannot administer the cream	Due to state regulations, phlebotomist cannot place or administer any medications, even over-the-counter (OTC) medication	Stocked cream in outpatient pharmacies; created patient family education materials; made medical assistants (MAs) available
	No order set for nursing staff	Nurse needed to locate physician or nurse practitioner to sign order for every patient	Added to all admission order sets as conditional order; nurse can activate
	Vasoconstriction	Nurses and phlebotomists feared that 4% lidocaine cream would make venous access more difficult due to vasoconstriction	Reviewed literature and trialed with laboratory. Planned to reduce any vasoconstriction with tapping and warm packs; however, not a single case of vasoconstriction occurred.
	Insurance coverage	4% lidocaine is an OTC medication not reimbursed by Medicaid/Medicare	Worked with advocacy; as a result, Minnesota Department of Human Services (DHS) added it to the formulary as a covered medication
	Tegaderm removal occasionally painful	Only covering available	Stocked plastic wrap and foam tape as first choice covering
	Took too much time for clinics to apply/wait	30-minute wait for a quick injection; staff did not believe it was effective for IMs or worth placing	Reviewed research and mapped out process with clinic staff; built into patient flow process and allowed families to choose
	Orders were placed too late in clinic visits	Providers were not placing orders for laboratories or immunizations until later in the visit; too late to place the cream	A protocol was implemented to allow MAs to place the cream at the time of rooming for immunization visits
	No protocol to place in emergency departments (EDs)	Topical anesthesia required placement at time of rooming to allow for effective timing	Electronic medical record (EMR) order was added to cover for possible IV placement or laboratory draw
	Topical anesthesia cream was not available at point of need in EDs	Cream required placement at rooming for effective timing, but cream was stored in central medication room	Cream was placed in locked bedside carts in each patient room for faster nurse access.
Sucrose	Clinical education added too much time to rooming process	Most parents were not aware of 4% lidocaine or its analgesic properties	Created education sheet to be given at time of registration; reviewed at time of rooming
	Unavailable at point of need	Sucrose still stored in medication rooms	Moved sucrose to all bedside carts in all patient rooms
	Inconsistent administration	Many misperceptions about dosing and time to effect	Education and mentoring
Positioning	Lack of availability	In clinics, it was only stocked with circumcision kits	Stocked in all clinics for all needle procedures
	Concern about accidental needle sticks	Many staff were trained to immobilize and restrain children flat on their back and "pin" arms and legs	Hands-on training for upright positioning, partnering with parents
	Belief that parents should not help with positioning	Many staff believed parents would not know how to hold their children in comfort positions	Parents were easily trained with cueing. Created positioning guides and booklets using photo shoot conducted with real patients and families
Distraction	There was no way to position children upright for IV placement in ED	Without bedside table, only firm surface was the bed; most children were laid flat.	Provided bolsters for positioning and options for alternative positioning
	Supplies unavailable	Units had scattered, inconsistent supply of distraction tools, often relying on donations or unit council funds	Created supply toolkit for every unit, including toy cleaning supplies
	Restocking/reordering was difficult	Unit staff bought their own supplies from various vendors	Centralized supply ordering through materials management; so bubbles, pinwheels, stress balls, spinners, etc. were ordered and stocked by one department.
General	Few options for teenagers and older children	Staff often believed teenagers did not require distraction	Created age-appropriate distraction booklets and electronic device application lists.
	Offering bundle of 4 modalities is time-consuming	Recommended nurses in the neonatal units partner with phlebotomists for all laboratory draws to provide comfort, due to fragility of patients.	Undertook time studies, which demonstrated that times were shorter when nurses were present in the room for laboratory draws rather than trying to comfort the babies after the phlebotomist left
	Family wait times would be increased	Laboratory concerned about increased wait times due to offering service bundle.	Tracked wait times before, during, and after implementation showed reduction in wait times.

IM, intramuscular administration; IV, intravenous.

as a bundle, with patients and families deciding what works best for them. A deferral process for children with severe needle phobia included referral to child life, psychology, and/or offering our nurse-administered nitrous gas (N<sub>2</sub>O) program to treat pain and anxiety caused by needles.<sup>17,37,77</sup>

### 2.3. Comfort promise implementation process

The first department to implement the new standard of care for needle procedures was the outpatient laboratory (2 locations) in early 2014, followed by 5 inpatient medical-surgical units, later that year. In 2015, both EDs, 4 neonatal areas (including 2 NICUs), 3 critical care

units (2 Pediatric Intensive Care Units [PICUs], and a cardiovascular intensive care unit), 2 short-stay units, radiology, and the outpatient surgery program were implemented, and all 26 ambulatory (12 primary and 14 specialty) clinics completed implementation in 2016.

The laboratories were chosen as the pilot site because a small number of staff impact a large number of children, performing over 30,000 needle procedures per year. Lean improvement methodology prescribes direct observation of the process by front-line staff, in the normal environment. By watching the procedure repeatedly at both sites (“going to gemba”<sup>40</sup>) and hearing feedback from patients and families, the planning group identified both barriers and opportunities for improvement. See **Figure 1** for the process map with initial gaps identified before implementing the Children’s Comfort Promise for needle pain. Time and resource barriers were identified as primary concerns in the laboratories. To address these concerns, didactic and experiential skills-based education was offered to the laboratory staff. Resources were defined, space was revised, and a logistics plan (eg, having a standardized location for supply storage and access) was established. Ongoing mentoring and adjustments were made based on the Plan–Do–Study–Act (PDSA) model of QI, involving cycles of continuous process improvement repeated through planning (plan), implementation (do), observation (study), and making adjustments and fine-tuning the process (act) until it performs seamlessly within the established workflow and structure.<sup>36</sup>

After successful implementation in the laboratory setting, QI efforts were expanded to all areas of the organization over a period of 24 months using baseline audit reviews, observations, and findings from the pilot to guide the Lean process. All leadership sponsors and staff members were invited to informational meetings, where the team members from the unit presented their plan for implementing the new standard. Once implementation had occurred, the PDSA cycle was engaged using results from the process audits, led by core team members.

**2.4. Process and outcome measures**

The process and outcome measures collected can be seen in **Table 2** and included: patient and self-administered nurse audits to determine compliance with offering bundled services; 2 patient satisfaction questions administered through National Research Corporation (NRC)/Picker about patient/parent satisfaction with pain management to gauge improvement in patient pain experience as perceived by parents<sup>7,25,45</sup>; safety learning reports (SLRs) to measure any reduction in adverse effects; and patient wait times. Process measures were collected in all areas, tracking both baseline and postimplementation data for all 4 strategies, so that problems or barriers could be identified and resolved early on. Although it was necessary to use multiple methods to collect baseline and postimplementation data, care was taken to ensure that the data remained comparable through consistency of questions. An organization-wide target for offering the bundled services was set at 95%. The target was set high with the intent of establishing the protocol as the new standard of care for the organization.

The frequency of needle procedures was gathered for each clinical area before QI implementation and minimum audit targets were set at 10% per month for process measure audits. Audit questions were administered to patients (if verbal and attending kindergarten or higher) or parents using a paper or verbal survey. Audits were brief and consisted of questions about: (1) the type of needle procedure they underwent, (2) whether or not the 4 strategies were offered, and (3) whether or not they found each of them helpful when used. Audits were scored as 100% only if all 4 strategies were offered or approved exceptions existed (eg, age criteria for sucrose).

Audits were performed by patient care managers or supervisors as part of their normal rounding each day, and interpreters were used for families who were not English-proficient. Attempts were made to visit all rooms, but interviews were only completed if patients

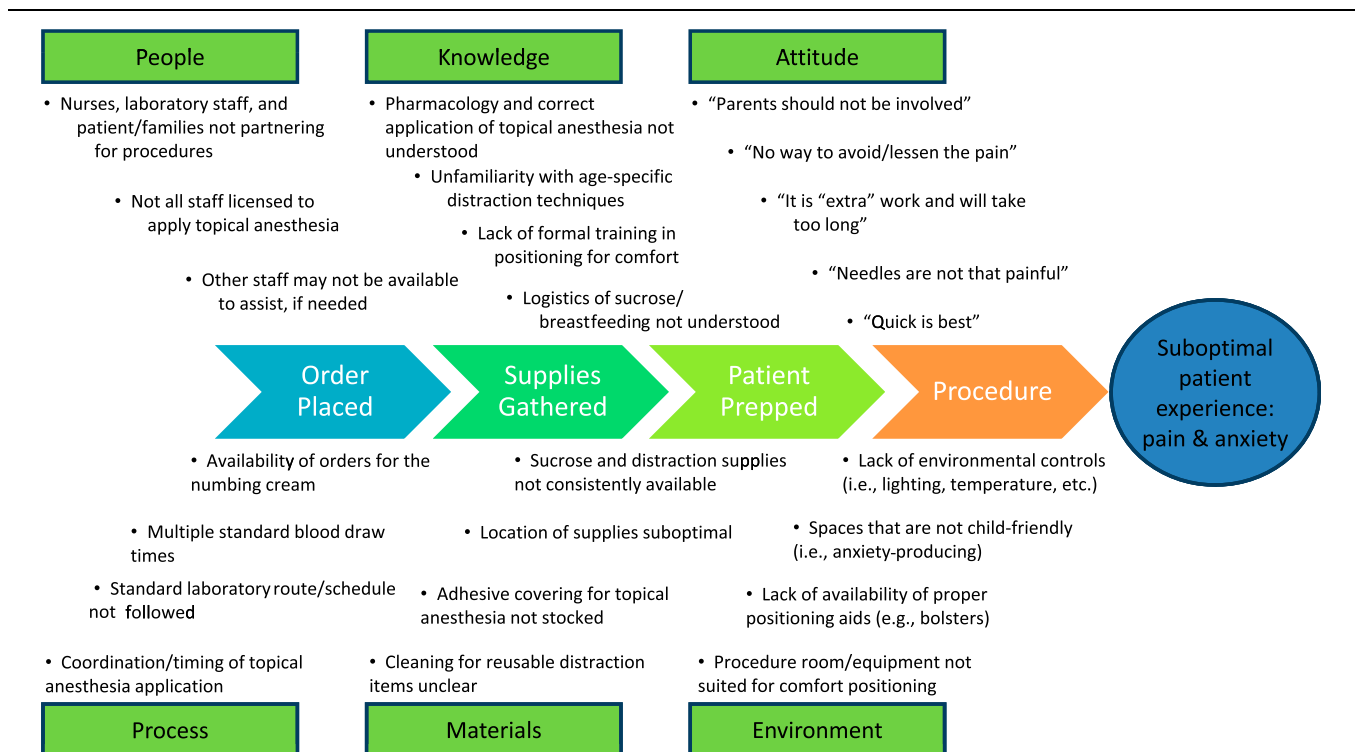


Figure 1. Fishbone Quality Improvement Process diagram.

**Table 2****Quality improvement measures and associated outcomes.**

Quality improvement goals	Measurement strategies	Details
Consistently offer the 4 best practices (bundle) for needle procedures	Monthly process audits of percentage change in staff offering bundled/individual practices by unit (eg, NICU).	Monthly baseline needle procedure volumes established by unit Minimum of 10% of unit volumes audited monthly by nurses 4 questions asking patient/family if each strategy was offered Nurse self-audits in critical care units Questions embedded in electronic medical record for ambulatory clinics
Improve patient satisfaction scores for pain by >1%/y	NRC/Picker paper survey was mailed to all families who received hospital care during QI period, per usual process. Results were tabulated quarterly.	2 questions were used to assess patient/parent satisfaction with pain: Staff did everything they could to help with pain Child's pain was well controlled Percentage of "always" responses were computed and tracked by question
Decrease SLR* adverse effects reporting for needle procedures.	Ongoing monitoring of institution-wide SLR system.	Anonymous electronic reporting was available 24/7 for all hospital staff SLRs were monitored for: Heel stick adverse events Inadvertent needle sticks Failed vascular access New concerns related to best practice strategies
Avoid increased patient wait times with the introduction of the new process.	Wait times were a preexisting outcome measure tracked in both outpatient laboratories	Times were recorded in an electronic collection system from the time the patient checked in at the front desk until draw logged in system. Wait times were routinely monitored for change Decreased wait times were achieved within 5 months of implementation and sustained over time
Avoid increased nurse time in neonatal areas with the introduction of the new process.	Nurse time and procedure time was tracked by core team members from the phlebotomists entering the room, until: 1. Sample was sent 2. Infant was back to baseline	Times were noted when: Phlebotomist entered the room Sample was sent Nurse entered the room Infant was back to baseline Collection times and nurse times were calculated Process discontinued after 2 collection periods due to compelling time-saving findings.

\* SLR = safety learning report (see text).

NICU, neonatal intensive care unit; NRC, National Research Corporation; QI, quality improvement.

had undergone a needle procedure in the past 24 hours. In the outpatient laboratory, a core team member performed audits 2 days per week, approaching all patients and families as they left the laboratory, until 20 surveys had been obtained per day. This audit method required modifications in the neonatal units and other critical care areas because many patients were nonverbal and parents were not present during procedures. On these units, nurses completed a written self-audit, recording type of procedure, which of the 4 strategies were offered, and noting reasons for any strategy not being offered. Approved exceptions were incorporated into the audits, including corrected gestational age and location of the needle stick. All units' audit compliance rates were monitored to ensure an adequate sampling on an ongoing basis, and results were entered and analyzed using Microsoft Excel software.

We tracked 2 NRC/Picker questions addressing patient/parent satisfaction with pain management during their encounter: *How often did hospital staff do everything they could to help your child with his/her pain?* and *How often was your child's pain well controlled?* (1 = Never to 4 = Always). We continued to track these scores throughout the Comfort Promise initiative, focusing on improvement in the percentage of patients and families who reported "Always" to both questions.

The electronic SLR system allows staff to report anonymously if any issues regarding patient care and/or safety were observed. For example, the neonatal areas had a number of

SLRs each month around adverse events with heel sticks and hoped to decrease those events with the addition of improved comfort measures. Recorded time stamps were monitored at baseline and for several months after implementation in the outpatient laboratory to track wait time (noting time from patient check-in to sample logged). The NICUs also had concerns about nursing time, expressing concern about the time from initiation of the procedure (ie, laboratory staff scanning their ID band) to the baby returning to baseline (ie, not crying), and need for the nurse to be present throughout. Core team members conducted time studies in the laboratory and NICUs before and after implementation to address this concern.

## 2.5. Analysis plan

Microsoft Excel was used for all analyses. The percentage change in offering individual and bundled services (y/n) was computed using MS Excel as the percentage of all patients included in the patient or nurse self-administered audit periods who indicated "yes" to being offered/offering the bundled services. Monthly percentages were computed by unit for baseline, implementation, and maintenance periods. Electronic patient satisfaction scores were extracted from quarterly NRC/Picker reports for the 2 pain management satisfaction



questions (see above). The percentage of patients and families who replied “always” to both questions (ie, they were very satisfied) was computed and tracked quarterly.

Electronic SLRs were reviewed on a monthly basis and the frequency and content of reports were reviewed by the Comfort Promise team quarterly. Patient wait times from check-in to laboratory draw were extracted from the laboratory collection system and descriptive statistics were run to determine the average wait times in minutes before and after Comfort Promise implementation. Nursing time in the NICU was recorded in Microsoft Excel by unit for 3 collection periods before implementation.

### 3. Results

The percentage of staff offering bundled services increased during the implementation period, patient and parent satisfaction with pain management improved quarterly per NRC/Picker scores, SLRs decreased, and patient wait times and nursing time decreased.

#### 3.1. Percentage change in offering bundled services

**Table 3** shows how major areas of the hospital reported consistency in offering the Comfort Promise bundled services at baseline compared with current. All areas have shown improvements to date, and some areas are continuing to refine or maintain the processes that are unique to their areas (**Table 3**). **Figure 2** shows an example of how the Minneapolis campus NICU, considered a representative neonatal unit, progressed over time in offering each of the 4 bundled services. Small gains in the initial 3 months were usual as complete dissemination of new practices to hundreds of nurses per unit took time. All units saw improvement in consistently offering all 4 strategies, with the greatest gains in administering topical anesthetics. Although baseline use of sucrose and positioning varied widely by unit, distraction techniques had been offered routinely by all units before the Value Stream, resulting in only small improvements for this modality.

Initial results consistently demonstrated that patients who used the bundled strategies found them to be “very helpful”; so, this question was omitted from the surveys after the 1st

year. In addition, very few patients declined any of the strategies in the inpatient setting, when education was given. Audits served a dual purpose, as education was provided in the moment if misperceptions were identified in the interview process or families had additional questions. In the outpatient setting, the numbing cream was the strategy declined most often, with the 30-minute wait time being cited as the main reason.

#### 3.2. Patient satisfaction

National Research Corporation/Picker patient satisfaction scores<sup>45</sup> increased from the point of implementation, and quarterly gains in satisfaction scores have been reported across all hospital units since inception of the Comfort Promise. Although scores historically show some variability from quarter to quarter (typically lower scores in third and fourth quarter), year over year comparisons by quarter saw consistent improvement. After a staggered system-wide rollout starting in 2014, the percentage of families surveyed who said hospital staff “always did everything they could to help with pain” increased from 78.3% to 85.3% (**Fig. 3**). Families who felt their “child’s pain was always well controlled” rose from 59.6% to 72.1% (**Fig. 4**). Before implementation of the Comfort Promise, pain satisfaction scores had typically increased by 1% per year over the previous 10 years.

#### 3.3. Safety learning reports and patient wait times

There was a significant reduction in electronic SLRs filed about heel sticks after implementation of the Children’s Comfort Promise, procedure and nursing time decreased, and average patient wait times decreased. During observations, it was noted that nurses and phlebotomists rarely collaborated during laboratory draws, and babies experienced distress throughout the procedure as evidenced by crying, kicking, increased heart rate, oxygen desaturations, and heel bruising. Nurses raised concerns that our recommendations to be present for all laboratory draws to provide comfort to the infants during the procedure would be too time-consuming. However, time studies were undertaken and were discontinued after only 2 collection periods after implementation because there was compelling evidence that comforting babies after procedure was more time-

**Table 3**  
Percentage of audits indicating best practices were offered by hospital unit, before and after comfort promise implementation.

Department/unit (N units)	Ambulatory phlebotomy (2)		Medical/surgical (4)		Neonatal (4)		Critical care (3)		Ambulatory clinics primary (12)	
	January 14, 2014		July 1, 2014		January 1, 2015		May 1, 2015		July 1, 2016	
Implementation date	Baseline (n = 52)	October 2014 (n = 64)	Baseline (n = 38)	December 2016* (n = 40)	Baseline (n = 121)	December 2016 (n = 206)	Baseline (n = 35)	December 2016* (n = 50)	Baseline (n = 202)	December 2016* (n = 19,949)†
Numbing %	0	56‡	0	85	0	98	0	94	0	60
Sucrose or breastfeeding %	0	100	10	83	36	98	25	81	0	90
Comfort positioning %	28	100	39	75	21	99	20	100	62	60
Distraction %	44	95	62	75	28	96	60	100	59	60

Some clinical areas were not included in this table due to low procedural frequency in their patient population (ambulatory specialty clinics, radiology, short stay, perioperative sites, and one overflow med/surg unit), or inconsistent or insufficient audit volumes (EDs).

\* These units have not yet reached their target goals and are still collecting audit data.

† Baseline audits were conducted manually. They are now embedded in EMR and pulled 100% monthly.

‡ Note that phlebotomists are not allowed to apply topical anesthesia.

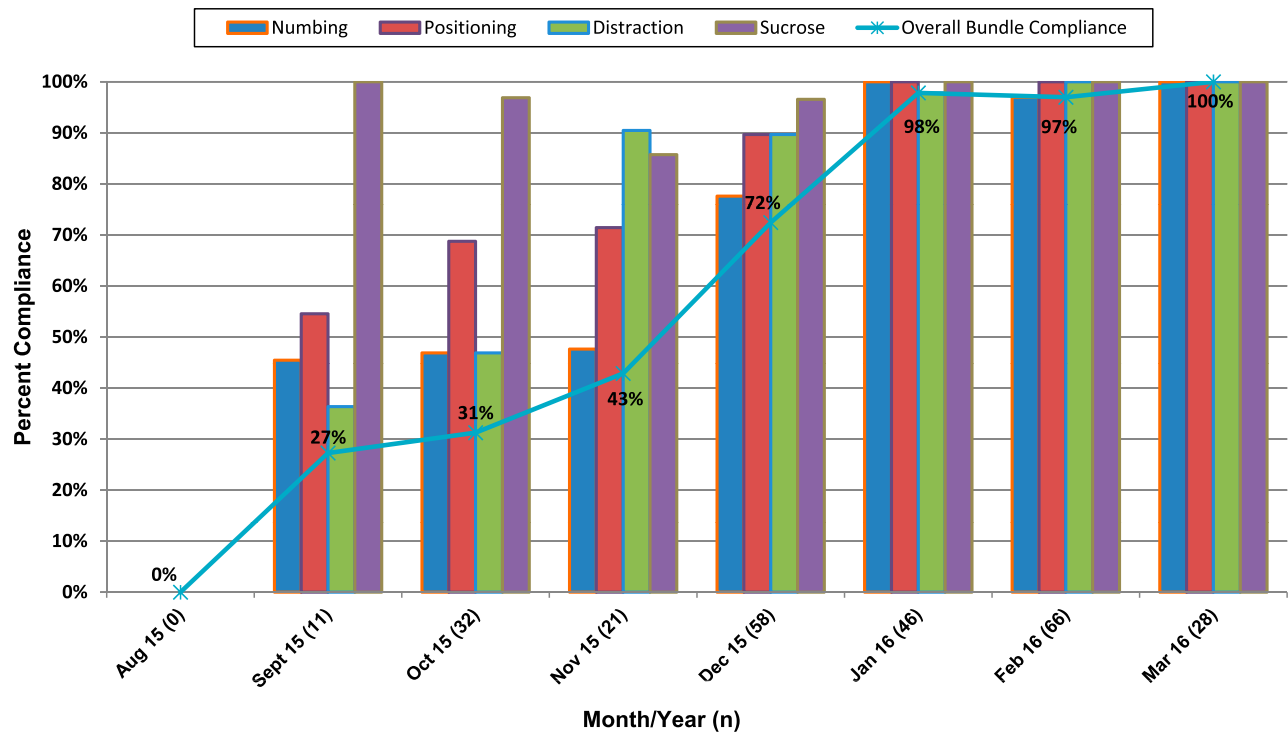


Figure 2. Neonatal intensive care unit compliance by bundle and each of the 4 best practices.

consuming than time spent when involved in the procedure. Safety learning reports for complications with heel sticks decreased by 50% since implementation of the Comfort Promise measures, with most infants now sleeping through their laboratory draws. Time duration to undertake the needle procedures was not lengthened by implementation of the Comfort Promise. For instance, in the neonatal areas, nurses spent 40% less time in the room, and the total procedure time was decreased by 60%, whereas in the outpatient laboratory, wait and procedure times were reduced by 20% from 20 minutes to 16 minutes in 6 months and sustained over time.

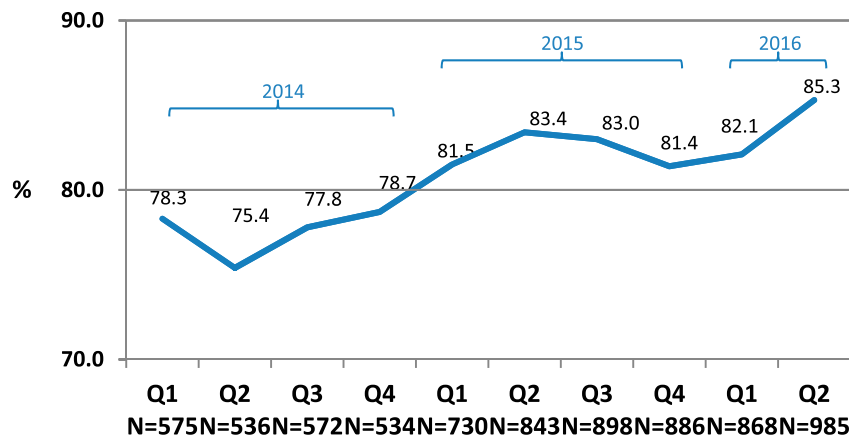
#### 4. Discussion

This is the first report of a successful system-wide implementation of a protocol to reduce or eliminate needle pain, including pain from vaccinations, in a children's hospital for all inpatient units, EDs, outpatient laboratories, and ambulatory clinics by offering a bundle of topical anesthesia, sucrose/breastfeeding, positioning, and distraction. An estimated 200,000 children now benefit annually from the Comfort Promise initiative to reduce and eliminate pain caused by elective blood draws, intravenous access, and injections. Wait times decreased and patient satisfaction increased between 2014 and 2016.

Organizational culture has been identified as key to changing pain management practices.<sup>6,8,32,67</sup> Published studies indicate that making pain management an organizational priority can improve practices. Quality improvement pain studies to date are promising,<sup>49</sup> although generally small scale with change not always being evaluated over a sustained period.<sup>16,36,43,53,69</sup> This structured initiative was successful both due to staff and leadership support, which included a letter signed by the Children's Minnesota Chief Executive Officer, Chief Operating Officer, Chief Nursing Officer, and Chief Medical Officer stating that, as an institution, we will offer the bundled services, including

topical anesthesia, to all patients and that we will not hold children down for elective needle procedures. The decision of the organization to supply 4% lidocaine in all service areas (removing the burden for families) was critical to the success of the process. This was achieved through early efforts to work with the Minnesota Department of Human Services to secure reimbursement for 4% lidocaine as an essential over-the-counter pain medication. Approval was secured in April 2014. Despite its availability, the 30-minute wait time for the cream was still a deterrent to its use but concerns were reduced after time studies that showed a decrease in wait times and time needed to address adverse reactions to blood draws. Work has been ongoing in the ambulatory setting to educate families about placing cream properly before their visit and to further improvements in workflow to accommodate early placement of the cream.

A framework for implementation was essential because education and policy alone are often insufficient.<sup>69</sup> Supporting and encouraging multidisciplinary staff members who created processes and embraced the Comfort Promise was important, as was putting institutional resources behind the change initiative. This included mobilizing a full-time clinical resource team (nurse, child life, and lean staff member) supported by a physician champion. Because change happens through influence rather than by command,<sup>22</sup> the main aim of the Comfort Promise team was to establish trust and ensure engagement of the front-line staff, to build a culture that would foster and sustain meaningful change across roles and responsibilities.<sup>72</sup> Culture shift takes time and patience. Although over 75% of the children were offered or received the bundled services in nearly all areas within 2 months of rollout, it took 9 months for the first inpatient unit to consistently offer all 4 best practice strategies for 95% of needle procedures. This was a relatively short period, considering the fact that it took our institution 4 years to increase adherence to hand-washing policies from 50% to over 94%.



\*Response options for National Research Corporation (NRC) Picker Scores were Never, Sometimes, Usually, and Always. This figure shows the percentage of children and families who selected “Always.”

Figure 3. Percentage of families surveyed who said hospital staff always did everything they could to help with pain (2014–2016).

The rollout of the “Comfort Promise” was associated with increases in patient satisfaction (Figs. 3 and 4). Although we cannot demonstrate causation, there were no other pain-directed, system-wide initiatives implemented in the period. Reasons for a temporary decrease in Q4 2015 may include regression to the mean, expected statistical variation, or uncontrolled covariates (such as possible longer waits in the ED and/or decreased staff willingness to offer the bundled modalities during a busy winter 2015/2016 season).

Resistance toward implementation at the individual staff and unit level presented challenges during the rollout process. We found that the key to overcoming this resistance was providing necessary resources, support, and training to staff: “The new way had to be easier than the old way.” When we could demonstrate that wait times went down instead of up (as often anticipated by staff); that topical anesthetics did not decrease the chance of venous cannulation (there was not a single report of venous constriction impeding cannulation, confirming published data<sup>38,46</sup>); and—most importantly—that the 4 strategies provided an immediate benefit to patients (eg, fewer tears; more calm and cooperative children), the Comfort Promise was embraced by nearly all staff. The Lean Value Stream process involves regular process audits, implementation of knowledge translation strategies,<sup>76</sup> development of educational and outreach materials (see supplemental figure for an example, available at <http://links.lww.com/PR9/A24>), and utilization of PDSA cycles. After implementing the Children’s Comfort Promise for needles institution-wide, we tied leadership performance improvement bonuses to successful achievement of target goals. The new care standard was integrated into all organizational policies, the electronic medical record, and new staff orientation, making nonadherence a performance issue.

#### 4.1. Barriers

Table 1 shows examples of implementation barriers that were experienced as they relate to each of the 4 best practices. Because the Comfort Promise was implemented in different locations at different time points, barriers were more likely to be averted in locations with later implementation through careful

application of lessons learned. Acceptance of the numbing cream in ambulatory clinics by parents is an area of continued focus, with further education targeting correct application before the visit and additional workflow improvements made during the visit.

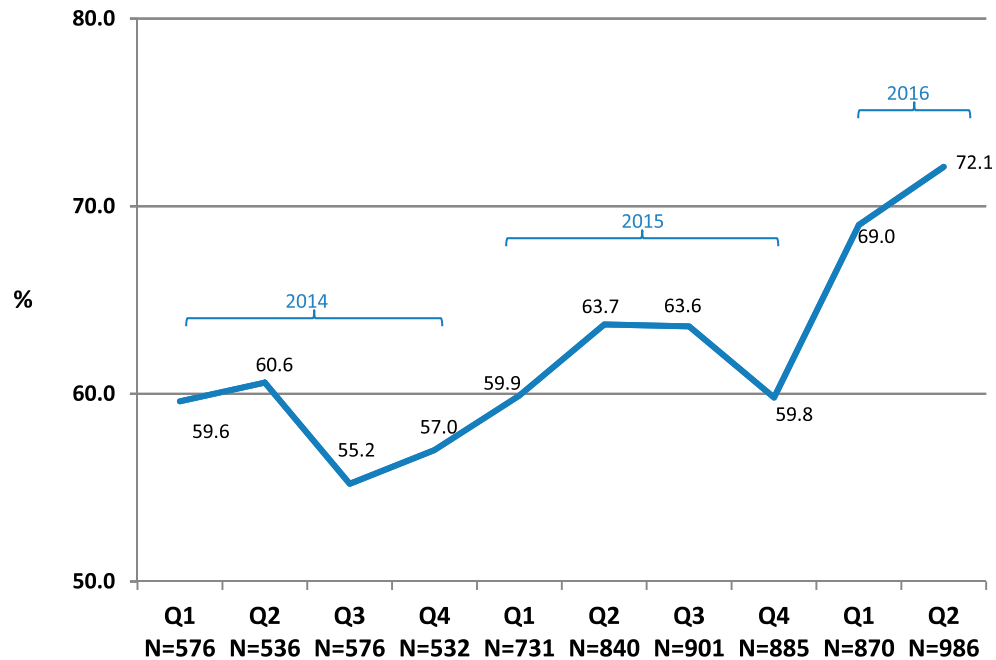
#### 4.2. Limitations

One limitation during the rollout of the Lean Value Stream was the reliance on process audits with different collection methods. This created variability and challenges in obtaining data quickly enough to provide feedback to the staff and make process adjustments. Accuracy of self-audits by nursing staff was also a limiting factor, although efforts were made to verify those results through observations by core team members and spot audits from laboratory personnel, which were closely aligned. Recent changes to the electronic medical record allow clinicians performing the needle procedure to review monthly posted audit results, with the Comfort Promise core team continuing to monitor and perform PDSA cycles in clinical areas not achieving their goals. In addition, pain satisfaction scores do not necessarily correlate with effective pain management;<sup>34</sup> however, they do correlate with perceived pain relief and participation in treatment.<sup>50</sup>

#### 4.3. Conclusion and implications

Analgesic treatment is mandatory for children undergoing painful procedures, and avoidable suffering is unacceptable, even for the so-called minor interventions.<sup>4,13</sup> Findings from this institution-wide QI project targeting pain associated with needle procedures, along with similar findings at other institutions, suggest that QI strategies coupled with knowledge translation strategies are key components of successful pediatric pain management strategies at the institutional level.<sup>56,76</sup> The Children’s Comfort Promise has become our institution’s new standard of care for needle procedures. It has drawn institution-wide, interdisciplinary attention, resulting in increased awareness of the importance of optimal pain management for all patients and families. This in turn will be an important catalyst in the development and rollout of future





\*Response options for National Research Corporation (NRC) Picker Scores were Never, Sometimes, Usually, and Always. This figure shows the percentage of children and families who selected "Always."

**Figure 4.** Percentage of families who felt their child's pain was always well controlled (2014–2016).

local and national interventions aimed at minimizing various sources of pain.

The 4 bundled modalities for needle pain prevention and treatment (ie, consistent use of topical anesthesia, sucrose/breastfeeding, positioning, and distraction) are not a proprietary aspect of our "Children's Comfort Promise: We promise to do everything to prevent and treat pain," and pediatric institutions are encouraged to replicate our process and use the bundled modalities as they see fit. Strategies from the current Comfort Promise are being taught and implemented in 2017 to 2018 at 4 children's hospitals in North America through a grant from The MAYDAY Fund, with the aim of developing and refining the process, tools, and educational materials needed to replicate these efforts throughout the pediatric community, and establishing a new standard of care for needle procedures.<sup>66</sup>

## Disclosures

None of the authors have any financial or other conflicts of interest to report.

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## Appendix A. Supplemental digital content

Supplemental digital content associated with this article can be found online at <http://links.lww.com/PR9/A24>.

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