A Paradigm Shift to Balance Safety and Quality in Pediatric Pain Management

abstract

OBJECTIVE: Undertreating pain and inappropriate use of opioids are potentially harmful to patients. We created a reliable process to discuss the pain plan preoperatively, hypothesizing that it will enhance the safety of opioid administration while improving the quality of pain management.

METHODS: A multidisciplinary group was convened for a 3-day workshop where a reliable method for preoperative discussion of the pain plan was created for patients having ambulatory hernia repair. Four targets were defined: (1) pain management is discussed by the provider; (2) a pain plan is accurately documented in the electronic medical record; (3) parents perceive that pain is adequately discussed; and (4) behavioral indicators demonstrate the pain plan is effective. The goal was 100% compliance with targets at 60 days. A standard pain regimen was created. Data collection included chart review and a postoperative phone call. Patients were separated into 30-day postimplementation cohorts for evaluation of their hernia. Analysis was descriptive.

RESULTS: A total of 235 patients had hernia repair. Discussion and documentation of pain occurred in 73% at 60 days (n = 15). Providers entered orders for postoperative pain in 80% at 240 days after implementation. Parents reported that pain was adequately discussed and treated between 87% and 100% of the time.

CONCLUSIONS: Balancing the potential harm from undertreating pain and inappropriate use of opioids requires an evidence-based, multidisciplinary family-centered approach. The development and implementation of a reliable method for the management and treatment of pain reduces variability allowing for delivery of safe and quality care.

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Pain and its associated suffering are harmful. Consequences of untreated and undertreated pain in children range from the short-term impact on hormonal and metabolic stability, impaired respiration, and slower recovery to the long-term changes in nervous system development and functioning. Inappropriate use of opioid analgesics is also harmful. Ethical practice demands careful consideration of the risks and benefits of pain interventions versus those of untreated pain.

Perhaps this balance is most important in an ambulatory surgery setting, where postoperative pain is likely to ensue, yet monitoring and other safeguards are absent. The American Academy of Pediatrics and American Pain Society joint policy stated that planning for pain management in children should take place before the operative procedures.

LOCAL PROBLEM
There was a sentinel event at our institution involving a patient with developmental issues undergoing dental surgery in the ambulatory setting. In the moments before discharge, it became evident that the typical methods of providing oral opioid medication were not suitable for this patient, and an improper dose and formulation of opioid analgesics was prescribed. The patient died as a result of the administration of this medication, raising awareness of the risk and the opportunity for systems change throughout surgical programs. An in-depth root cause analysis identified a failure in the processes of ordering and dispensing. The cascade of events began with the failure to plan preoperatively with the patient and family regarding postoperative pain management.

INTENDED IMPROVEMENT
The specific aim was to implement a process for holding a conversation to partner with parents and patients as early in the process as possible, defining and prescribing the analgesic protocol and assuring clear and consistent communication through discharge and follow-up after the surgery. As described by advocates for institutional change regarding pain management, it is essential to have support from the highest levels of administration to implement stable change. Although the initial impetus for this work arose from the sentinel event and focused on medication safety, this was also seen as an opportunity to improve the quality of postoperative pain care as well.

STUDY QUESTIONS
The primary study question was whether a reliable method to ensure preoperative discussions regarding postoperative pain management is an effective strategy to increase medication safety around the prescription of opioids. Secondary goals focused on the quality of postoperative pain management. Specifically, this included (1) parental understanding of the plan of care for pain and (2) the clinical impact of an evidence-based postoperative analgesic regimen as measured by objective behavioral observations.

METHODS
Ethical Issues
We were obligated to pursue changes because both poorly treated pain and unsafe prescribing practices pose potential harm to the patients. There were no additional elements of risk posed to our patients by the intervention. The authors had no vested interest in implementing these changes, with the exception of advocating optimal pain management in the ambulatory surgical setting. This study was approved by the institutional review board (13971).

Setting
The root cause analysis of the sentinel event led to direct observations in the surgery clinics, operating room, and surgical recovery areas. These observations revealed the lack of a reliable method for discussing the nature and treatment of postoperative pain in the ambulatory setting.

Planning the Intervention
Our institution adopted continuous performance improvement (CPI), based on the Toyota Production System, a change management philosophy over a decade ago. CPI methodology has successfully applied process improvement to facilitate long-term iterative change to efficiently and safely care for our patients.

The scope of this work was narrowly defined so that a reliable process could be identified, instituted, assessed, and then replicated for other types of surgery across all specialties. Our general surgery program had experience with CPI, with local leadership ready to implement a process. Inguinal and umbilical hernia repairs were the most common ambulatory procedure in general surgery and became the focus of this intervention.

Preintervention data were gathered through medical record reviews and process walks. Process walks were used to capture the current state of the process by observing the actual process in the clinical environment and the individuals doing the work. The generated observational data provided an evaluation of the stability of the process and information flow. For this project, 2 distinct 2-hour process walks were conducted, tracing patients’ and families’ experiences in a preoperative appointment to the day of surgery to the postoperative phone call in both otolaryngology and general surgery clinics. Observations of surgeons in...
the ambulatory clinic indicated that postoperative pain was discussed 29% of the time (21 observations). These observations indicated no reliable method for discussing the nature and treatment of postoperative pain in the ambulatory setting. In addition, the following barriers were observed: (1) no responsibility or accountability for the discussion of pain, (2) variation at the provider level for the assessment and management of pain, (3) patient concerns about pain were often minimized or dismissed, and (4) excessive waste in the current process in the form of waiting, system complexity, and processing. Analysis of prescription records for the period of Apr 2009 to Mar 2010 indicated variability between and within surgeons for analgesic medications prescribed to treat postoperative pain in children undergoing ambulatory hernia repair (Fig 1A).

On the basis of these data, 4 process targets were defined: (1) pain management is discussed by the provider; (2) a pain plan is accurately documented in the electronic medical record; (3) parent perception that pain is adequately discussed; and (4) psychometrically sound behavioral indicators show that the pain management plan was effective. All 4 targets had goals of 80% compliance at 30 days and 100% by 60 days.

**Design Event**

Two process owners, with faculty/staff-paired accountability consisting of a surgeon (JRA) and a clinic nurse (SLS), performed a planning the process workshop. The planning team consisted of a CPI consultant and 4 principal sponsors (chief operating officer, medical director, clinical nurse specialist in pain medicine [LMP], and the director of pain medicine [GAW]). This group convened with a management guidance team, consisting of operational leaders in areas involved in the process whose purpose was to provide

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**FIGURE 1**

A, Prescription for analgesic medication before implementation of a standard process. Circles represent medications prescribed. The size of the circle represents the relative number of prescriptions written (larger circles represent more prescriptions for the analgesic medication). B, Prescription for analgesic medication after implementation of a standard process. Circles represent medications prescribed. The size of the circle represents the relative number of prescriptions written (larger circles represent more prescriptions for the analgesic medication). ACE, acetaminophen; HYD, hydrocodone; IBU, ibuprofen; OXY, oxycodone; PER, Percocet; TC, acetaminophen with codeine.
oversight and governance to the project and eliminate barriers preventing completion of the work. Critical steps in the planning phase included collection of current-state data for the process, mapping the current state of the process, scoping the process, identifying process development team members, and defining targets for the process. A rapid design workshop was conducted during a 3-day period in June 2010. The process development team included a pediatric surgeon, a clinic nurse, 2 parents, a medical assistant, an outpatient pharmacist, an anesthesiologist from the hospital pain consultation service, nurse practitioners from general and plastic surgery, and a recovery room nurse. The team mapped the current and ideal states of the process, and subgroups developed detailed processes for each step in the ideal state map. A report-out session with the management guidance team and sponsors was held to elicit feedback and discuss barriers to implementation. The team developed implementation and audit plans. The implementation plan included a set of tools and materials to hardwire the process, including pamphlets, posters, a documentation tool, and writing of prescriptions for pain medication in clinic.

Process
The process begins when the family calls to schedule an appointment in the surgery clinic for a child with a hernia. The schedulers cue parents to ask their providers about pain at the initial appointment. On arrival to the clinic, the medical assistant provides written materials to the family about pain management. A poster in the examination room provides information about pain, including setting expectations, and suggests questions parents may ask providers about pain. The surgeon and the clinic nurse visit with the patient and family together.

The physician evaluates the patient, confirms the diagnosis, discusses the etiology and repair of hernias, and then discusses postoperative pain management. The nurse documents the pain plan on a standardized computerized template. The surgeon enters prescriptions for analgesic medications into the electronic medical record.

On the day of surgery, all parties access the same pain plan documentation in the electronic medical record and provide consistent information to patients and families. Preoperatively, the surgeon reviews the pain plan with the parent and signs printed copies of the prescription. Prescriptions are immediately forwarded to the pharmacy, enabling parents to pick up the medications while their child is in surgery. Children received an open hernia repair. Administration of local or regional anesthesia was variably performed and not recorded. Postoperatively, the surgeon and recovery nurse independently review the analgesic regimen and complications with the parent, confirming parents’ comprehension of the plan.

As per our divisional standard, a general surgery clinic nurse telephones families on postoperative day 5 with a checklist of questions focusing on the patient’s overall well-being; diet; number of days and doses of ibuprofen, acetaminophen, and oxycodone; and medication side effects. The questions were not validated, and clarification was provided if the parent did not understand the question. If the phone is not answered, a message is left, and a second call is placed 24 to 72 hours after the initial call.

Standard Pain Regimen
Although reaching consensus on an analgesic regimen was out of the scope of the process development team, it was identified as parallel work. The surgical division saw changing the process of prescription writing as an opportunity to introduce a standard approach to postoperative pain management. The analgesic regimen was defined by using evidence and supplemented with collaborative decision-making by the surgery and pain medicine programs.

The analgesic regimen consisted of alternating around the clock oral acetaminophen and ibuprofen for 24 hours, reduced to as needed thereafter. Adequate pain control was assessed during the postoperative phone call by using the Parent’s Postoperative Pain Measure (PPPM), a behavioral pain measure validated in the postoperative setting. In this 15-item scale, scores ≥6 constitute clinically significant pain, which served as a trigger for parents to administer oxycodone in addition to acetaminophen and ibuprofen. The PPPM has been used extensively in children 2 to 12 years of age across a number of different surgical procedures.

Planning the Study of the Intervention
Discussion and documentation of the pain plan was verified by reviewing the patient’s electronic medical record. During the postoperative phone call, parents were asked if the pain plan was discussed adequately, and the child’s PPPM score was recorded. Parents were also asked about medication side effects. Compliance with administration of the analgesic regimen was also assessed. Data were recorded into a database (Excel; Microsoft, Redmond, WA) and reviewed by the process owners quarterly. For longitudinal comparison, patients were placed into separate postimplementation 30-day cohorts (30, 60, 90, 120, 150, 180, 210, and 240 days) based on when they first presented to the clinic for evaluation of their hernia. The study design is quasi-experimental in nature because there has been no random assignment of participants and
specified outcomes are not being compared before and after intervention. The CPI methodology measures iterative change over time, interventions are designed and implemented, and results are examined on a regular basis.

**Methods of Evaluation**

The Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials used an evidence-based approach followed by a consensus of experts to recommend specific strategies to assess acute pain, adverse events, and symptoms. In line with those recommendations, the PPPM was chosen to assess acute pain intensity and its impact on function. The process outcomes were measured directly, indexed by compliance to guidelines. These outcomes included a discussion of pain at the preoperative visit, documentation of that discussion, and generation of a pain plan. Patient and family satisfaction with that discussion was also ascertained in the postoperative telephone call through a scripted question: “was the pain plan clearly communicated to you?”

**Pharmacy records were used to show the analgesic prescribing habits of each surgeon for patients undergoing ambulatory hernia repair procedures.**

**Analysis**

Because of the quasi-experimental nature of this study and the lack of baseline data on some key indices (eg, pain scores, parental satisfaction with preoperative pain discussion), this analysis was descriptive in nature. Initial areas of interest for the process emphasize compliance, with a target of 100% compliance by all providers 60 days after the event.

**RESULTS**

**Initiation of Postoperative Pain Management Plans**

Discussion and documentation of pain occurred in 80% of visits at 30 days \((n = 20)\), dropped to a low of 65% at 210 days \((n = 23)\), and rebounded to 73% at 240 days \((n = 15)\). At 30 days, 60% of the time, providers entered orders for postoperative pain medications during the preoperative visit, increasing to 80% at 240 days after implementation. After implementation, parents reported that pain was adequately discussed between 87% and 100% of the time over the 8-month study period (Fig 2).

**Adherence to Pain Regimen**

Baseline data indicated variability in medication prescribed for treating pain in children undergoing ambulatory hernia repair (Fig 1A). This variability diminished on review at 240 days after implementation, although 2 providers did not conform to the agreed on regimen (Fig 1B). Oxycodone was prescribed for breakthrough pain in 110 of 161 (68%) patients 1 year who were eligible to receive oxycodone. Parents of 65 of 110 patients prescribed oxycodone were reached by telephone, of which 27 patients (41%) were administered the opioid. Nausea occurred in 2 patients (2%) and constipation in 5 patients (5%).

**Patient Outcomes for Pain Management**

Pain, as defined by a score of ≤6 of 15, was adequately controlled in all patients whose parents were contacted by telephone \((n = 113)\). Data from postoperative phone calls also indicated that there were no adverse events or other unexpected concerns about the pain treatment regimen.

**Missing Data**

Over the 240-day period after implementation, 235 children underwent ambulatory procedures to repair inguinal or umbilical hernias. Data on documentation of discussions of postoperative pain management during the preoperative visit were obtained on 182 patients. It is unknown if a discussion occurred in the 53 patients without documentation. The call placed 5 days after the procedure was successful in reaching the family for 113 patients. Data on side effects
were obtained in 93 of 182 (51%) patients.

DISCUSSION
The overall goal of this work is to partner with patients and families to provide safe and effective postoperative pain treatment of children undergoing surgical procedures. The scope was to design a reliable method for postoperative pain after inguinal and umbilical hernia repairs in the ambulatory setting. This method may be replicated to other surgical procedures. Several key points were recognized for the care of our patients and families.

First, safe and effective postoperative pain management requires planning, forethought, and partnership with patients and families. Processes implemented must clearly define each individual’s responsibility to discuss pain preoperatively and to implement a plan for pain management. The process must engage physicians and staff to embrace patients’ and families’ concerns, providing sufficient information and tools to facilitate successful implementation of the pain plan at home, including education about administration of pain medication, how to identify and treat pain, and the side effects that may be experienced. Reliable methods reduce variation at the provider level for the assessment and management of pain, which optimizes safety and effectiveness. The goal is to isolate variation to patient-specific factors. Simplifying and standardizing the process reduces waste in the system, ultimately improving outcomes. Second, parents have a validated tool to assess functional status related to postoperative pain at home (PPPM), enabling decision-making about analgesic administration. Third, an around-the-clock analgesic regimen is in place for the first 24 hours, alternating acetaminophen and ibuprofen, followed by as needed dosing for subsequent days. This regimen is intended to preempt exacerbations in pain, thereby facilitating more rapid recovery. An opioid analgesic, oxycodone, is given for situations in which pain levels break through the baseline, as indicated by scores on the PPPM. Follow-up calls 5 days postoperatively indicated high levels of parent satisfaction with this process, excellent pain management for the children, and no serious adverse events.

Pain is one of the most significant elements of value to patients and families. Often, pain is undertreated in children, and there is potential for medication errors. Many assume hernias are not painful procedures, yet we found that >40% of patients required an opioid to manage postoperative pain. A balance needs to be created so children’s pain may be prevented and treated, a quality parameter, juxtaposed with attention to safety. We sought to minimize not only the potential harm of high-risk medications but also the potential harm of poorly treated pain. Initial assessment demonstrated a diffusion of responsibility and no reliable method for managing postoperative pain, increasing the risks for unsafe practice and inadequate pain treatment. We believe the reliable method created through CPI efforts makes the right thing to do easy, leading to stable and enduring behavior change.

Relation to Other Evidence
Many papers have focused on efforts to change the culture of pain in health care organizations. The Wisconsin Cancer Pain Initiative offered guidelines for institutional change in the assessment and management of pain. Two of the impacts were (1) pain recognized as a fifth vital sign and (2) changes in the Joint Commission on Accreditation of Healthcare Organizations clinical standards reflecting the documentation of adequate assessment and treatment of pain. It is clear from previous efforts that broad-based change is difficult to invoke. Recognizing these challenges, a novel idea was espoused to push institutions to better address postoperative pain. A basic premise is that untreated or poorly treated pain poses risk of harm. The occurrence of preventable or treatable pain may be deemed a serious adverse event and managed accordingly.

Limitations
We identified a number of limitations. First, families are contacted on postoperative day 5. If the child is reported to have pain at the time of the call, the PPPM is administered. This missed opportunity to gather precise data on the previous days’ experiences, which may be mitigated by the use of pain diaries or electronic data capture to improve information collected related to the patient’s pain. Second, only 8 of the 10 general surgeons routinely followed the evidence-based protocol for postoperative pain treatment. Despite agreement, reasons for nonadherence are not documented, nor is an escalation protocol in place to ensure accountability. As a result, we were not able to achieve our targets. Third, the PPPM is not validated and of limited utility for children <1 year of age. Fourth, oxycodone is only prescribed to children >1 year because of safety concerns by the prescribing surgeons. Thus, we have little data on the pain experience of our youngest patients. Fifth, we were only able to reach 62% of patients’ families by phone, which may bias our results because these available families may represent a distinct group.

Interpretation
One of the hallmarks of CPI methodology is incremental change. The design event to address postoperative pain related to hernia repair in the ambulatory
setting led to many positive changes, including that children’s pain was addressed effectively and safely. The limitations described above are recognized, and potential remediation is to be pursued. However, the steps invoked to date have already shown tremendous promise.

CONCLUSIONS
With preoperative planning and individualized care, the sentinel event inspiring this work may have been prevented. Poorly treating children’s postoperative pain presents risk of harm. Failing to attend to critical details of high-risk medication management, such as opioids, presents risk of harm. Balancing the two requires evidence-based, family-centered care, involving the participation of the providers, family, and patient. By using CPI techniques, development and implementation of a reliable method for the management and treatment of pain reduces variability, allowing for delivery of safe and quality care. Such improvement efforts are iterative and require a long-term view to ensure ultimate success. This project offered a significant initial step in this process.

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