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Commentary

Reducing opioid medication errors:

Taming the dark side of the Force

"Yes, a Jedi's strength flows from the Force. But beware of the dark side."

-Yoda to Luke Skywalker (Star Wars Episode V: The Empire Strikes Back, 20th Century Fox, Lucasfilms, 1980)

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In 1999, the Joint Commission on Accreditation of Health Care Organizations (now the Joint Commission) introduced accreditation standards that address the assessment and management of pain in hospitals and other health care settings. These standards "acknowledge that patients have a right to effective pain management, and require that the presence of pain be routinely assessed for all patients" (Joint Commission, 2009, p. 7).

According to the Joint Commission, ineffective pain management contributes to patient dissatisfaction, slower recoveries from painful procedures, and higher healthcare costs. Following the Joint Commission's lead, healthcare providers have significantly improved their pain management processes.

However, a dark side to pain management exists. With improved awareness of patient pain, more doses of pain medications, especially opioids, are prescribed. Not surprisingly, more adverse drug events (ADE) related to pain management occur. Vila et al. (2005) found more than a two-fold increase in opioid over-sedations after implementation of a patient pain management program in a population of adult cancer patients.

In pediatric patients, ADEs are "common, costly, and occasionally life-threatening" (Sharek et al., 2008, p. e861). In a study of 960 inpatients at 12 United States children's hospitals, Takata et al. (2008) found a mean rate of 11.1 ADE per 100 admissions. More than 20% of these events were preventable although few were life-threatening. In an earlier study, however, Kaushal et al. (2001) found that 7% of pediatric ADEs were fatal or life-threatening. In the United States, these data extrapolate to over 160,000 preventable adverse events, more than 11,000 preventable life-threatening events or deaths, and a cost of over $750 million per year (Sharek et al., 2008). The "dark side" of pain management is powerful and we must be diligent in our efforts to reduce the physical, social and financial harm that result from these ADEs while at the same time ensuring pain relief.

To this end, we conducted a quality improvement collaborative involving 14 children's hospitals (Sharek et al., 2008). The group, a subset of the 43 member Child Health Corporation of America (CHCA; Shawnee Mission, Kansas), studied the effect of a combination of evidence-based interventions on opioid-related ADEs in hospitalized pediatric patients. We focused on opioid medications because they are high risk (Institute for Safe Medication Practices, 2008), high priority (Institute for Healthcare Improvement, 2008), commonly administered to hospitalized children, and account for more than a third of pediatric ADEs (Takata et al., 2008). The goal of the collaborative was to achieve a 50% reduction in ADEs related to opioid medications. The collaborative did not address the risk of error related to inadequate treatment of patient pain.

Prior to the initiation of the collaborative, an expert panel convened to develop a "pediatric-

specific 'change package' of evidence-based practices" (Sharek et al., 2008, p. e862). The change package[1] was organized into four broad categories: (1) opioid use, (2) medication systems, (3) medication reconciliation, and (4) culture of safety. Participating teams were invited to review the change package and to implement those elements that were likely to achieve the collaborative's goal. However, certain elements were mandatory for all participants. These elements included: (1) reducing automated dispensing device overrides, (2) developing opioid weaning protocols, (3) implementing corollary orders for laxative or stool softeners, and (4) developing a comprehensive medication reconciliation process. Optional change recommendations included: (1) use of protocols or pre-printed orders for specific processes (e.g. post-operative pain management, use of non-opioid analgesics, monitoring over-sedation, and patient controlled analgesia [PCA]); (2) standardizing epidural infusions, (3) implementing computer medication error alerts, (4) use of pre-printed drug dosing charts, and (5) standardized infusion pumps for PCA and epidural drips.

The collaborative process followed the Institute for Healthcare Improvement (IHI) model (IHI, 2003; Resar et al., 2003). This model included three quality improvement learning sessions, monthly conference calls, an electronic discussion group, readily available content and quality experts, and monthly data reporting. Data were collected by each team using a trigger tool methodology designed by IHI for opioid ADE detection (Resar et al., 2003), and modified for pediatric patients (Sharek et al., 2006; Takata et al., 2008). The eight triggers used to identify opioid-related ADEs included: (1) use of antiemetics, (2) use of naloxone, (3) over-sedation, lethargy, or falls, (4) abrupt cessation of opioids, (5) administration of laxatives or enemas, (6) administration of diphenhydramine, (7) intubation and respiratory arrest, and (8) use of a combination of three or more opioids. The trigger tool methodology required each team to review 20 randomly selected inpatient medical records each month. All records were those of patients who had received opioid therapy. Each medical record was reviewed for any of the 8 triggers. Associated ADEs were identified; the harm and potential preventability of the ADEs were assessed. Additionally, teams collected information on opioid doses obtained from automatic medication dispensing devices without proper pharmacist order verification (override). (See Sharek et al., 2008 for further methodological details.)

A baseline ADE rate was determined from December 2004 through March 2005 for each participating institution. Data were then collected monthly through March 2006 as change package elements were implemented. Results were reported transparently and unblinded. Participants openly shared their successes and their failures. Barriers to success were discussed during the conference calls and participants collaborated to find solutions. The entire collaborative process was coordinated centrally by CHCA staff. They received monthly reports from participating teams and prepared formal reports that were returned to each hospital's chief executive officer and senior team leaders.

The primary outcome measure for the collaborative was opioid-associated ADE rates either expressed per 1000 opioid doses or 1000 opioid patient days. Each team could choose how they wished to report their data. Secondary measures included rates of constipation, and percentage of opioids dispensed from automated devices via an override. The change from baseline ADE rate was determined for each participating team and for the collaborative overall. The baseline rates were 41.0 opioid-related ADEs per 1000 doses (n = 10 sites) and 164.9 opioid-related ADEs per 1000 opioid days (n = 3 sites). Baseline constipation rates were 14.1 events per 1000 opioid doses (n = 10 sites) and 36.1 events per 1000 opioid days (n = 3). (One team declined to release their data for publication.)

The collaborative reduced opioid-related ADEs by 67%. Median rates of constipation decreased 69%, and median override rates decreased from 10.2% at baseline to 5.9% in the post-implementation period. The authors estimate that over 14,500 potential opioid ADEs were averted during the year-long collaborative.

The most effective element of the change package probably varied by participating site. Each site began with different elements of the change package already implemented at the beginning of

the collaborative. However, considering the impact of the collaborative on the incidence of constipation, the implementation of the corollary order for stool softener may have been noteworthy. At Nationwide Children's Hospital (Columbus, Ohio), the standard computerized order-set for patient-controlled analgesia (PCA) included the option of prophylactic stool softeners. However, few practitioners made use of this option. Following a small "test-of-change" to evaluate the impact of an opt-out approach, the order-set was modified. Subsequently, the stool softeners were automatically included as part of the order-set for PCA. The practitioner could choose to remove this therapy if they desired. Most did not.

Other approaches to reducing medication errors in pediatric inpatients include computerized prescriber order entry systems, intravenous infusion safety systems (Smart pumps), and bar-coding systems (Bates, 2007). Some of the participating sites in our collaborative utilize one or more of these technology-driven approaches. However, they are expensive and they may promote technology errors of their own.

Another approach to reduce ADEs is the availability of a unit-based clinical pharmacist (Kaushal et al., 2008). These authors found a significant reduction of medication errors in a pediatric critical care unit that utilized a full-time clinical pharmacist. This benefit was not noted on general care pediatric units that utilized part-time clinical pharmacists. Several of the participants in our collaborative utilize full-time clinical pharmacists in the intensive care units. However, the exact number of institutions that employ unit-based clinical pharmacists is not known.

The paper by Sharek et al. (2008) is the first report of a pediatric medication safety collaborative that demonstrates a significant reduction in opioid-related ADEs. We attribute the success of this collaborative to three key components. First, CHCA provided a performance improvement infrastructure that facilitated the work of the various teams. The CHCA staff prepared a collaborative instruction manual that clarified the various processes. They communicated regularly with the teams via the electronic discussion group and the monthly telephone calls. The CHCA staff along with quality experts from IHI facilitated the three collaborative learning sessions. CHCA established an on-line repository to which participating teams could submit their monthly data. CHCA staff then reviewed the data and prepared reports showing individual team progress and progress of all participating sites collectively. These "Senior Leader Reports" included CHCA assessment and site self-assessment progress scores; annotated run charts of all site data; and annotated run charts of key measures across all sites with written explanation of the overall collaborative progress.

Second, transparency in the reporting of data was vital. Knowledge of benchmark performance data was highly motivating. Transparency is a major power that can drive improvement and change (Reinertsen et al., 2008). Third, each team made a public commitment to complete their work on time. The CHCA staff proved to be gentle taskmasters who held the teams accountable with regular reports to the hospitals' CEOs. Thus, to tame the "dark side" of pain management, we need a performance improvement infrastructure, a mindset of transparency, and a sense of accountability in our work.

As noted by Hicks et al. (2008), all methods of pain control have limitations and are associated with adverse events. If hospitalized children experience an estimated 160,000 preventable ADEs per year and a third of the ADEs are opioid-related, how many of the over 50,000 opioid-related ADEs could be averted if all hospitals providing care to children in North America implemented the collaborative's change package?

Endnote

[1] The change package is available at: www.chca.com/mm/misc/Change%20Package%20ADE-Narcotics.xls.

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