Opioid-related Adverse Drug Events
Do Parents Recognize the Signals?

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Objectives: Evidence of unrelieved childhood pain, adverse drug events (ADE), and deaths suggest that parents may inadequately respond to pain and opioid-related ADE signals. This study examined parents’ recognition and response to pain and ADE signals using both dynamic hypothetical scenarios and real at-home opioid decisions.

Materials and Methods: A total of 514 parents whose children required prescription opioids after discharge were surveyed. Parents made analgesic decisions for 4 hypothetical scenarios wherein the child's pain level and ADE symptoms were altered. After discharge, parents recorded their child’s real pain levels, ADEs, and their analgesic decisions. Mixed-effects logistic regression examined the influence of pain and ADE signals on parents’ opioid decisions.

Results: Pain intensity had a main effect on parents’ hypothetical and real decisions to give opioids (P ≤ 0.001). Nausea/vomiting influenced the decision to give the prescribed opioid dose (β = −1.48 [95% confidence interval (CI): −1.78, −1.19], P < 0.001) as did oversedation (β = −1.02 [95% CI: −1.30, −0.75], P < 0.001); however, parents were more likely to give the prescribed dose for oversedation than nausea/vomiting (odds ratio (OR) = 1.53 [95% CI: 1.14, 2.05], P = 0.005). Gastrointestinal effects were more likely to motivate a change in postdischarge opioid administration compared with other ADEs (OR = 4.41 [95% CI: 1.91, 10.18], P < 0.001), whereas sedation symptoms did not (OR = 0.46 [95% CI: 0.21, 1.04], P = 0.06).

Discussion: Findings demonstrated that many parents failed to withhold a prescribed opioid dose for oversedation, suggesting a lack of awareness regarding this potentially serious ADE. Strategies to improve parents’ recognition of oversedation and its potential consequences are warranted to improve opioid safety.

Key Words: opioid adverse events, pediatric pain management, analgesic decisions, parental decision making, adverse drug effects

Widespread provider efforts to reduce the prevalence of childhood pain have led to striking increases in opioid prescriptions for children and adolescents.1,2 Indeed, opioids were prescribed for a variety of pain reports during 2.3 million adolescent ambulatory visits (1 of every 9) in 2007 alone.1 Although such efforts have likely reduced pain and improved the quality of life for many children, the potential for analgesic mismanagement in the home setting is of growing concern. For instance, the high prevalence of intermittent or persistent pain (ie, 15% to 37%) suggests that analgesics may be underused for some children.3–6 In contrast, there have been worrisome increases in opioid-related adverse drug events (ADEs), unintentional poisonings, and death that expose the potentially serious consequences of mismanagement and misuse in the home.7,8 For instance, > 6000 unintentional opioid poisonings occurred in children each year from 2000 to 2009, many of which resulted in serious injury.9 In addition, in 2009 alone, 824 children and adolescents died because of unintentional opioid poisoning, mostly because of prescription agents.10 Given that these findings are based on analyses of national admission and death databases, it is difficult to discern the proportion of events related to adolescent self-use or misuse, accidental ingestion, or, rather misunderstandings regarding safe use in the home. Regardless, these data indicate critical knowledge deficits among the public regarding the safe use of opioids.

As parents likely manage most of the analgesic decisions for their children, their analgesic knowledge has critical implications for their children’s outcomes. Misunderstandings or lack of recognition of critical ADEs can potentially lead to devastating outcomes. Indeed, details from case reports of opioid-related deaths after surgery suggest that oversedation, a critical and early sign of opioid poisoning, was present but likely not attended to by parents before their child’s demise.11,12 These details are important given recent findings that half of the apnea-related deaths and neurologic injury after tonsillectomy occurred in the home setting.13,14 Furthermore, evidence suggests a great deal of parental uncertainty about how to give analgesics safely and a lack of awareness regarding common and serious ADEs.14–16

Effective and safe opioid decisions rely on appropriate detection and response to varied signs and symptoms that can occur over the course of analgesic use, including those that conflict (eg, high pain plus symptoms of ADEs). Inappropriate response to these signals can result in suboptimal pain relief or jeopardized safety. Evaluation of signal detection and response has helped explain the effectiveness of clinician decisions17,18 and may also be useful to identify gaps in parental knowledge and judgment. This prospective study, therefore, examined parents’ recognition and response to various pain and ADE signals that can occur during opioid use. We hypothesized that although
many parents would recognize and respond to situational pain and ADE signals by altering their administration of a prescribed opioid dose, they may fail to withhold the dose for signs of oversedation.

MATERIALS AND METHODS

With approval from the University of Michigan Institutional Review Board and written consent, parents/guardians were recruited prospectively in C. S. Mott Children’s Hospital. Adult parents of children (aged 3 to 17 y and thus able to self-report pain) undergoing elective, short-stay surgery requiring a prescribed opioid following hospital discharge were recruited. Mothers and fathers who understood written English and resided in the home with the child after surgery were included, whereas those whose children required chronic pain management or more than an overnight hospital stay were excluded.

First, we used a descriptive, within-subject hypothetical model of decision making to control and manipulate the situational pain and ADE signals and test the hypotheses. We surveyed mothers and fathers independently in the preoperative waiting area, after they had received routine pain management information from their child’s surgical clinician, which included a pamphlet of general analgesic use and risks (Fig. 1), as well as specific prescription information. Using vignette methodology, the survey assessed parents’ treatment decisions when faced with variable pain intensity with or without symptoms of a common but less serious ADE (ie, mild nausea/vomiting) or a serious but rare ADE (ie, oversedation). Vignettes are a standard method to study judgment and decision making so that factors of interest can be systematically varied to examine independent effects of specific factors, while eliminating the confounding effects of others.19

The survey was developed using an iterative process with expert input from pediatric pain providers and a pharmacist in the Department of Anesthesiology as well as decision researchers in the Schools of Public Health and Medicine. Various iterations of the survey were piloted in small samples of parents in our preoperative waiting area (n = 4 to 5 with each iteration, up to 30 in all) to examine face validity and feasibility. Following several revisions to wording, formatting, and structure, the final version was piloted among 10 parents who were asked to verbalize their understanding of the intent of the survey. Face validity was supported as parents readily stated the purpose/intent of the survey.

The survey provided simple instructions regarding the hypothetical opioid prescription (hydrocodone/acetaminophen) and an alternative over-the-counter nonopioid (acetaminophen) to mimic real information provided on printed prescriptions and instructions. Immediately following were 4 hypothetical scenarios wherein the pain level and the presence/absence of ADE symptoms were manipulated. We asked parents to imagine being faced with these scenarios when taking their child home after surgery. In 3 of the scenarios, the child’s pain level was held constant with a Wong-Baker Faces Pain Score (FPS) of 6 of 10, as this score is above the average level considered “treatable” by children and parents.21–23 One of these scenarios had no ADE symptoms (scenario high pain, no ADE), one described the common ADE, mild nausea/vomiting (scenario high pain, nausea/vomiting), and one described symptoms consistent with oversedation (scenario high pain, oversedation; see Fig. 2 for the complete excerpt). In the fourth scenario, the pain level was lower (ie, FPS = 4) and there were symptoms of mild nausea/vomiting (scenario low pain, nausea/vomiting). For each decision, parents were asked to choose between giving the prescribed opioid dose, a lower dose, a lower dose plus acetaminophen, acetaminophen alone, nothing, or other choice (open ended). To test the hypothesis, decisions were dichotomized as Give the prescribed opioid dose versus Lower/withhold the prescribed dose.

To elicit which primary signals parents considered during decision making, a single, open-ended question following each scenario asked them to explain why they made their choice. These reasons were categorized by 2 independent coders based on attention to the signals of interest (ie, pain or ADE signal), the prescription signals (ie, “due for dose” or “following doctor’s orders”), and other notable analgesic-related comments (eg, “don’t like narcotics”).

Next, to explore real analgesic decisions and their relationship to situational pain and ADE signals in the home setting, we asked one parent per family to record the time, type, and amount of every analgesic given to their child over the first 3 postdischarge days. They also documented their child’s FPS score before each dose, any ADE experienced, and whether and how they changed their child’s care in response. Surveys were completed and returned by mail in a prestamped envelope.

FIGURE 1. Excerpt from the University of Michigan’s General Preoperative Pain Management Instructions.
Imagine your child got Vicodin 2ml 6 hours ago and nothing else since.

S/he has been sleeping continuously, has a little snoring off and on, and wakes up only when you shake his/her shoulder.

When awakened, your child complains of pain 6 out of 10, and then falls back to sleep

How you would treat your child’s pain (X one box only):

- Give 2 mL of vicodin (prescribed dose) ONLY
- Give 1 mL vicodin (a lower dose) ONLY
- Give 1 mL vicodin (lower dose) AND Tylenol
- Give Tylenol (acetaminophen) ONLY
- Give NOTHING at this time
- Give something else (describe)

Please describe WHY you made the choice you did:

Statistical Analyses

All analyses were conducted using SPSS (version 21, IBM Corporation, New York, NY). A nonparametric analysis of variance for repeated measures (ie, the Friedman test) examined the change in analgesic decisions across scenarios. A generalized mixed-effects logistic regression model (GMLR) was used to examine the effect of the scenario pain and ADE signals on parents’ nonindependent, dichotomized decisions to Give the prescribed dose versus Lower/withhold the prescribed dose, controlling for potentially important parent and child factors (ie, parent role, education, race, child age, sex, previous surgery experience, and procedure, coded as tonsillectomy, orthopedic, or other). A random intercept for subject was included to account for the potential correlation between scenario decisions. Simple and pairwise contrasts were generated to compare differences between groups and to estimate the marginal means of the proportions who gave the prescribed opioid dose. Sequential Bonferroni was used to adjust for multiple contrasts and \( P < 0.05 \) was considered significant.

Postoperative opioids were converted into oral morphine equivalents and the percentage of the prescribed daily dose administered was calculated as “% morphine equivalents/kg/day” (to account for variations in prescriptions). A hierarchical linear regression model was used to explore factors influencing parents’ prescription opioid administration at home. Parent/child factors were entered together with important covariates (ie, nonopioid use, ADEs, child’s FPS) in the first step, and prescription instructions (around-the-clock vs. as needed or prn) at the second. In this manner, we could examine the effect of practitioner instruction on parents’ at-home opioid decisions. Regression coefficients (\( \beta \)), odds ratios (OR), and 95% confidence intervals (CI) are presented, as applicable.

RESULTS

From January to August 2013, 514 parents (from 343 families) were included in this study (described in Table 1). Fifty-one others either declined participation or returned incomplete surveys; however, these parents were similar in characteristics to participants with the exception of race (ie, 31% were nonwhite). Figure 3 depicts parents’ scenario analgesic decisions showing the change in decisions based on situational context and scenario signals. A nonparametric analysis of variance for repeated measures (ie, the Friedman test) demonstrated that parents’ decisions to give opioids varied significantly across scenarios (\( \chi^2 = 331.3; P < 0.001 \)), where the prescribed opioid dose was chosen, most often for the high pain/no ADE scenario and least often for the low pain/nausea vomiting scenario. These data show that the majority of parents changed their treatments based on the context and signals present in the situation, supporting the construct validity of the vignette methodology.

Pain Signal

When controlled for parent/child factors and the presence/absence of ADEs, the pain signal had a significant main effect on parents’ decisions to give the prescribed opioid dose versus lower/withhold it (Table 2). The estimated probability (marginal mean) of giving the prescribed opioid dose in the presence of high pain was 23% (range, 19.8% to 26.5%) compared with only 9% (range, 6.4% to 13.0%) for low pain (adjusted \( P < 0.001 \)). This finding was
likely moderated by the effect of ADEs as the estimated probability of giving the prescribed dose for the high pain scenarios in the absence of an ADE was 41.1% (95% CI: 35.7, 46.7) compared with only 16.6% (95% CI: 13.8, 19.9) when an ADE was present.

Parents’ reasons for giving the prescribed opioid dose for each of the scenarios are described in Table 3. Fifty-seven percent who chose to give the prescribed opioid dose across scenarios indicated that pain or need for relief for prevention motivated their choice. In contrast, a primary motivation for withholding the prescribed dose for the high pain, no ADE, and the low pain, nausea/vomiting scenarios was that pain was not considered bad enough. Together, these findings suggest a general attention and response to the pain intensity signal that for many parents was not bad enough to warrant administration of a prescribed opioid dose.

### ADE Signal

Despite a significant main effect of ADEs on parents’ decisions to give the prescribed opioid dose (Table 2), parents were more likely to give than lower/withhold it for the high pain/oversedation scenario than for the less risky high pain, nausea/vomiting scenario (OR = 1.53 [95% CI: 1.14, 2.05], \( P = 0.005 \)), demonstrating a lack of attention to oversedation signals. The estimated probability of choosing the prescribed dose for the high pain, oversedation scenario was 20.1% (range, 16.3 to 24.6) compared with only 14% (range, 10.8 to 17.4) for the high pain, nausea/vomiting scenario \( (P = 0.004) \).

Parents who withheld the prescribed opioid dose for the oversedation scenario were less likely to mention concern for the ADE as a motivator compared with those who did so for the nausea/vomiting scenario (Table 2; \( OR = 0.20 \) [95% CI: 0.15, 0.27], \( P < 0.001 \)). In addition, half (121 of 247) of those who acknowledged “sleepiness” during their reasoning stated that “sleep/rest is good” or that sleep meant that the child’s pain was not bad enough to treat. This finding suggests that although many parents recognized the cue of excessive sleepiness, they did not understand its potential importance.

### Postoperative Analgesic Administration

Of the eligible families, 218 (64%) returned their postoperative surveys. In addition to general prescription details (ie, drug, dose, frequency), 49 (22%) parents received a written safety instruction regarding acetaminophen use (n = 45) or to hold for sedation (n = 3). Although all prescriptions were written to be given as needed (ie, prn), 66 parents (30%) recalled being told to give the prescribed opioid around-the-clock. The total number of administered opioid doses ranged from 0 to 16 (median 6). The maximum prescribed opioid ranged from 0.07 to 0.87 oral morphine equivalents/kg/d (0.24 ± 0.08), whereas opioids administered ranged from 0 to 0.29 (0.09 ± 0.07). The average percentage of daily dose administered by parents was 37.00 ± 26.83.

One hundred seven parents (48%) reported (in an open-ended manner) that their child had ≥1 ADEs. These included, 51 (24%) with nausea/vomiting, 26 (12%) constipation, 38 (18%) excessive sleepiness or sedation, 17 (8%) dizziness, confusion, irritability, euphoria, 7 (3%) itching, and 9 (4%) with a rash or allergic reaction. Children who experienced an ADE had received significantly more opioids compared with those who did not (mean

![FIGURE 3. Description of parents’ analgesic decisions for each of the hypothetical scenarios. ADE indicates adverse drug event; NV, nausea/vomiting; OS, oversedation.](image-url)
TABLE 2. Factors Influencing the Decision to Give the Prescribed Opioid Dose (Results of the Mixed-effects Logistic Regression Model)

<table>
<thead>
<tr>
<th></th>
<th>Coefficient (95% CI)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea/vomiting (NV)</td>
<td>-1.48 (−1.78, −1.19)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>(vs. no ADE)</td>
<td></td>
<td></td>
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<tr>
<td>Oversedation (OS)</td>
<td>-1.02 (−1.30, −0.75)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>(vs. no ADE)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oversedation (vs. NV)</td>
<td>-0.04 (−0.07, −0.01)</td>
<td>0.009</td>
</tr>
<tr>
<td>High pain (vs. low pain)</td>
<td>1.08 (0.70, 1.45)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Parent role (mother vs. father)</td>
<td>0.08 (−0.17, 0.33)</td>
<td>0.519</td>
</tr>
<tr>
<td>Parent race (white vs. nonwhite)</td>
<td>0.44 (0.02, 0.87)</td>
<td>0.040</td>
</tr>
<tr>
<td>Parent education (college degree vs. less than college)</td>
<td>0.44 (−0.16, 1.03)</td>
<td>0.151</td>
</tr>
<tr>
<td>Child sex (male vs. female)</td>
<td>-0.001 (−0.29, 0.29)</td>
<td>0.996</td>
</tr>
<tr>
<td>Child age</td>
<td>0.003 (−0.03, 0.03)</td>
<td>0.866</td>
</tr>
<tr>
<td>Child previous surgery versus none</td>
<td>-0.10 (−0.33, 0.13)</td>
<td>0.407</td>
</tr>
<tr>
<td>Procedure (orthopedic vs. tonsillectomy)</td>
<td>-1.21 (−1.69, −0.74)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Procedure (other vs. tonsillectomy)</td>
<td>-1.04 (−1.50, −0.57)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Orthopedic vs. other</td>
<td>0.03 (−0.003, 0.07)</td>
<td>0.068</td>
</tr>
</tbody>
</table>

Model Statistics: $F = 20.87/df (14/2064)$, $P < 0.001$. ADE indicates adverse drug event. Significant $P$ values are shown in bold.

difference = 0.05 [95% CI: 0.02, 0.08] morphine equivalents/kg/d; $P < 0.001$. Fifty-three parents (50%) whose children had ADEs reported changing their care as a result of the effect. These changes included: giving a different analgesic (n = 40), stopping the prescribed drug (n = 17), giving the prescribed dose less often (n = 15), lowering the dose (n = 9), and other adjustments (n = 30; eg, giving drug with food). Among the subset who reported ADEs, parents were more likely to change their care for gastrointestinal effects (n = 41 [61%]) than for other ADEs (12 [28%]; OR = 4.41 [95% CI: 1.91, 10.18], $P < 0.001$). In contrast, fewer parents changed their pain management for sleepiness/sedation (n = 14 [37%]) than other ADEs (n = 39 [56%]), but this did not reach significance (OR = 0.46 [95% CI: 0.21, 1.04], $P = 0.061$). These findings show that among parents whose children experienced an ADE were more responsive to gastrointestinal effects than to sedation effects of opioids in the home setting.

The average FPS postoperatively was 5.6 ± 0.15. Pain scores associated with parents’ administration of opioids were higher than those associated with nonopioids (6.03 ± 2.27 vs. 4.93 ± 0.15; $P < 0.001$). Hierarchical linear regression demonstrated that higher average pain scores predicted greater administration of the prescribed opioid, whereas greater over-the-counter analgesic use predicted lower use (Table 4). Lastly, parents’ recall of around-the-clock instruction predicted greater use, moderating the effect of the child’s procedure.

DISCUSSION

Safe and effective health care decisions are dependent, in part, on symptom recognition (ie, signal detection) and situational awareness (ie, understanding the signals, their importance, possible implications, and how to respond appropriately).23 Safe and effective analgesic decisions for children may, therefore, be related to parents’ recognition that the pain signal warrants attention and treatment and that other concurrent symptoms (eg, ADEs) may take precedence. This study examined parents’ ability to recognize and respond to important signals, including pain intensity and the presence of common or potentially serious opioid-related ADEs (ie, nausea/vomiting and oversedation). Our findings showed that most parents changed their treatment decisions in response to situational signals. However, parents were more likely to lower/withhold the prescribed opioid dose for nausea/vomiting than for the more risky situation, oversedation, suggesting a critical knowledge gap or misunderstanding regarding the potential consequences of oversedation signals. This finding has particular implications for the safety of children who are prescribed opioids.

Previous studies have demonstrated the ability of parents to recognize their children’s pain signals and to attach meaning to these signals by acknowledging the importance of relieving pain.15,26–29 Despite this recognition, investigators have found that parents give fewer than prescribed analgesics in the presence of “clinically significant” pain.14,15 Our finding that pain intensity influenced parents’ hypothetical and real, at-home decisions to

TABLE 3. Parents’ Coded Reasons for Giving or Withholding the Prescribed Opioid Dose

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Gave Prescribed Opioid Dose (n [%])</th>
<th>Withheld Prescribed Dose (n [%])*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Physician Order/Time for Dose</td>
<td>Concern for ADE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pain Not Bad Enough or “Wait and See”</td>
</tr>
<tr>
<td></td>
<td>No Adverse Effect or Effect Not Bad</td>
<td>Don’t Like Narcotics or Prefer to Rotate</td>
</tr>
<tr>
<td>High pain, no ADE</td>
<td>136 (61)</td>
<td>4 (2)</td>
</tr>
<tr>
<td>High pain, NV</td>
<td>49 (54)</td>
<td>114 (52)</td>
</tr>
<tr>
<td>High pain, OS</td>
<td>68 (53)</td>
<td>127 (36)</td>
</tr>
<tr>
<td>Low pain, NV</td>
<td>16 (44)</td>
<td>132 (33)</td>
</tr>
</tbody>
</table>

Percentages calculated from the number of reported comments for each item, where not all parents provided reasons.

*Withheld prescribed dose group included those who chose to give the lower dose, nonopioid, or nothing.

ADE indicates adverse drug event; NV, nausea/vomiting; OS, oversedation.
TABLE 4. Summary of Hierarchical Regression Analysis Showing Predictors of Postoperative Opioid Use (ie, Percent Daily Dose Administered) (n = 166)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Unstandardized Coefficient</th>
<th>Standardized Coefficient</th>
<th>Unstandardized Coefficient</th>
<th>Standardized Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SE B</td>
<td></td>
<td>SE B</td>
<td></td>
</tr>
<tr>
<td>Parent role</td>
<td>0.47</td>
<td>7.39</td>
<td>0.004</td>
<td>1.64</td>
</tr>
<tr>
<td>Parent race</td>
<td>4.96</td>
<td>4.28</td>
<td>0.07</td>
<td>5.95</td>
</tr>
<tr>
<td>Parent education</td>
<td>-4.18</td>
<td>3.31</td>
<td>-0.08</td>
<td>-4.01</td>
</tr>
<tr>
<td>Child male</td>
<td>-2.62</td>
<td>3.35</td>
<td>-0.05</td>
<td>-2.04</td>
</tr>
<tr>
<td>Child age</td>
<td>1.37</td>
<td>0.69</td>
<td><strong>0.21</strong></td>
<td>1.29</td>
</tr>
<tr>
<td>Child procedure</td>
<td>-3.32</td>
<td>1.22</td>
<td><strong>-0.22</strong></td>
<td>-1.77</td>
</tr>
<tr>
<td>Ibuprofen (kg/d)</td>
<td>-0.56</td>
<td>0.22</td>
<td><strong>-0.17</strong></td>
<td>-0.58</td>
</tr>
<tr>
<td>Acetaminophen (kg/d)*</td>
<td>-0.65</td>
<td>0.11</td>
<td><strong>-0.37</strong></td>
<td>-0.67</td>
</tr>
<tr>
<td>Adverse drug event (ADE) at home</td>
<td>3.02</td>
<td>3.13</td>
<td>0.06</td>
<td>3.34</td>
</tr>
<tr>
<td>Average faces pain score (FPS)</td>
<td>3.34</td>
<td>0.85</td>
<td><strong>0.26</strong></td>
<td>3.29</td>
</tr>
<tr>
<td>Around-the-clock instruction</td>
<td>1.13</td>
<td>13.15</td>
<td>0.67</td>
<td>3.89</td>
</tr>
<tr>
<td>R² for change in R²</td>
<td>0.462***</td>
<td></td>
<td>0.500***</td>
<td></td>
</tr>
</tbody>
</table>

*Additional or substituted over-the-counter use of acetaminophen (ie, excluding the component of prescribed agent).

**P < 0.05.

***P < 0.001.

Significant factors are shown in bold.

give prescribed opioids provides further evidence that parents recognize and respond to pain signals. Yet, the pain signal in our hypothetical scenarios (ie, FPS = 6) was insufficient to motivate treatment with an opioid by many parents, suggesting variable interpretation of pain intensity. Other pain signals (eg, child’s function), analgesic preferences, and the presence of adverse effects may be more important motivators for parents’ analgesic use, which may help to explain our findings and those of previous investigations.

Effective parental actions depend on their ability to differentiate and prioritize potentially conflicting signals.25 Our findings demonstrated that parents were more likely to withhold the prescribed opioid dose for hypothetical scenarios where ADEs were present, even in the presence of high pain. In addition, half of the parents whose children experienced a real ADE postoperatively changed their analgesic administration in response. Nausea/vomiting was more likely than oversedation to motivate hypothetical decisions to withhold the prescribed opioid dose, and gastrointestinal effects were more likely than sleepiness/sedation to motivate changes in analgesic use postoperatively, showing a relative inattention to sedation.

Importantly, parents’ open-ended ADE descriptions were insufficient to determine the child’s depth of sedation during at-home opioid use. However, our scenario description of oversedation (ie, difficult to wake up, cannot stay awake since the last dose, snoring) indicates a level of sedation that should be attended to by withholding opioids.30 The finding that many parents chose to continue the prescribed opioid dose in the presence of these symptoms shows both a commitment to manage or prevent pain and a lack of understanding of oversedation symptoms and its potential consequences. The number of parents who remarked that, “sleep is good” in their hypothetical decision making reasoning, supports this lack of awareness. Previous studies have suggested parental uncertainty about how to give analgesics safely, and a lack of knowledge regarding common and serious ADEs.14-16,31,32 Critical knowledge deficits regarding analgesic ADEs may contribute to poor decisions that result in poor pain management or even disaster. To enhance safe opioid use, parents need to know how to recognize and distinguish potentially serious signals and what actions should be taken. Further analysis of our data will examine the influence of specific analgesic knowledge deficits on parents’ decisions.

A main influence for parents’ hypothetical and real opioid decisions, even in the presence of ADEs and oversedation, was the child’s procedure and the prescription/physician order (ie, around-the-clock vs. as needed instruction) postoperatively. These findings suggest differences in preoperative clinic instruction, particularly for those undergoing tonsillectomy, which may have influenced parents’ analgesic decisions. Indeed, around-the-clock instructions have previously been recommended for children undergoing tonsillectomy and were found to increase postoperative analgesic administration.33,34 However, this practice was also associated with a significant incidence of ADEs in these studies.33,34 This practice was recently criticized because of the high risk for potentially serious ADEs and death, particularly in tonsillectomy patients.35,36 In our sample, only 3 parents received written, but vague instruction with their prescription to hold the medicine if their child was sleeping, sedated, or too sleepy. Together, these findings emphasize the importance of prescriber instructions and the need for improved and specific safety information.

Several other findings are worthy of discussion. In these analyses, we did not demonstrate an effect of parent education on hypothetical or at-home decisions, despite previous data suggesting differences in analgesic perceptions between parents with higher or lower education.32 We did, however, find that race had an effect on hypothetical but not at-home decisions. This finding may reflect socioeconomic or cultural differences not studied, or an interaction with education that we could not detect because of the small sample of nonwhite parents. Future examination of these factors is necessary to examine potential influences on analgesic decision making. In addition, although previous studies have shown differences between mothers’ and fathers’ experimental pain thresholds for their sons and daughters that could theoretically affect their analgesic decision making,37 a similar effect for parent
role and child sex on hypothetical and real opioid decisions was not detected in this study. Potential interactions between these and other factors from our larger study warrant further exploration.

Our use of hypothetical decisions may limit the generalizability of findings, as parents may respond differently to hypothetical than real situations. However, use of scenarios facilitated signal manipulation that would have been difficult to study in the real world given the variable experiences of children and the relative rarity of oversedation. In addition, behaviors based on real and hypothetical situations have been highly correlated, and our findings were strengthened by our analyses of real decisions, which aligned with our main findings. It is possible that parents’ decisions were influenced by aspects of our survey eliciting analgesic knowledge and preference information (data not yet published), by the ordering of scenarios and the use of hypotheticals before at-home analgesic decisions. These features could have, therefore, heightened parents’ awareness, attention, and response to the pain and ADE signals. It is quite possible, therefore, that another sample may be even less attentive. Further study randomizing parents to a different order of scenarios or to receive the preoperative survey versus no survey before discharge would be necessary to examine this possibility. It is also important to note that the description of oversedation (including snoring) may have been less salient to parents of children undergoing tonsillectomy, given the prevalence of sleep disordered breathing in this group. Further investigation among this subset is warranted to determine factors influencing parents’ opioid decisions, particularly as tonsillectomy patients may be at higher risk for opioid-related ADEs. Finally, given the nature of study participants, including their level of education and racial distribution findings may not be generalizable to other settings.

CONCLUSIONS

In summary, this study is the first to our knowledge to examine the influence of common and rare but serious opioid-related ADE signals on parents’ hypothetical and real analgesic decisions. Although many parents recognized and responded to important signals presented to them, many failed to withhold a prescribed opioid dose for the child with signs of oversedation, suggesting a critical lack of awareness regarding this potentially risky ADE. Given the vital importance of opioid-related ADEs, parents may need a clearer understanding of oversedation signals and their consequences to safely and effectively manage pain postoperatively.

ACKNOWLEDGMENTS

The authors thank the following students whose efforts facilitated the efficient and accurate collection of data: Adam Eickmeyer, Lamira Ray, Tara vanVeen, and Cortney Segmen, BS; all research students and assistants in the Department of Anesthesiology, University of Michigan, Ann Arbor, MI, USA at the time of the study.

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