

PROBLEMS ASSOCIATED WITH INTRAVENOUS PATIENT-CONTROLLED ANALGESIA (IV PCA) INFUSION PUMPS: AN ANALYSIS OF THE MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE (MAUDE) DATABASE

Cheryl S. Hankin,¹ Mingliang Zhang²

¹BioMedEcon, LLC, San Jose, CA; ²Ortho-McNeil Pharmaceutical, Inc., Raritan, NJ

BACKGROUND

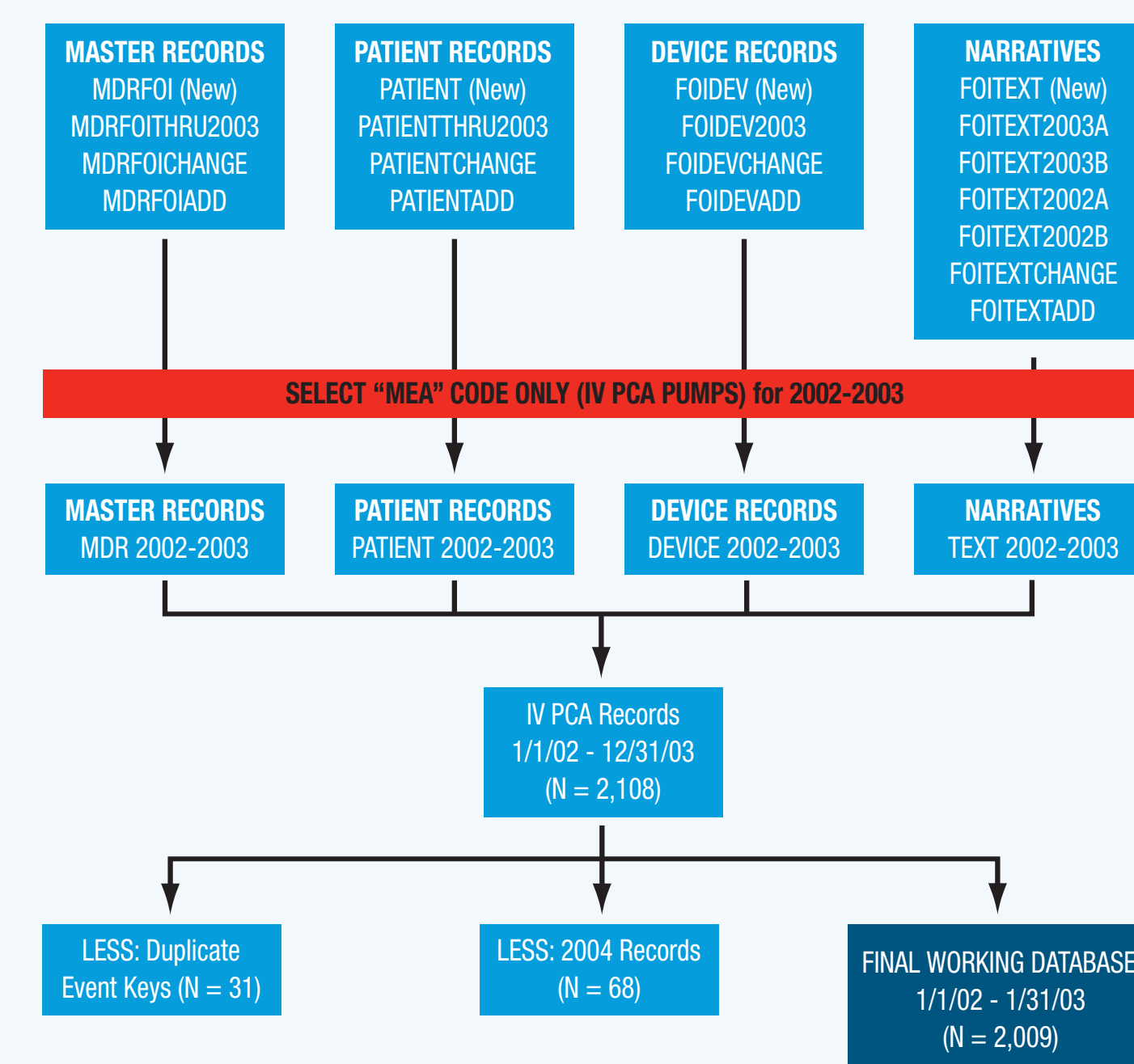
- Intravenous patient-controlled analgesia (IV PCA) infusion pumps deliver preprogrammed doses of intravenous analgesia in response to patient request. The device is commonly used in the postoperative setting to treat acute pain. Isolated case reports of IV PCA-associated problems include programming errors, patient tampering, and device malfunctions¹⁻¹⁰
- Clinicians, patients, user facilities, manufacturers, and distributors may report IV PCA-related adverse events or product problems through a variety of mechanisms. The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) provides the only government-sponsored mechanism for such reporting
- The FDA maintains a database of reports dating from 1992 within the Medical Device Reporting (MDR) Manufacturer and User Facility Device Experience (MAUDE). MAUDE data are publicly available through the FDA Web site.¹¹ Despite public availability of these data, we know of no research that comprehensively reviews MAUDE reports of IV PCA-related events. We therefore characterized reports for a 2-year period from 1/1/02 through 12/31/03

METHODS

- MAUDE data are available to the public in text files that can be downloaded into Microsoft Access format. We downloaded all records pertaining to IV PCA (FDA product code "MEA") for the period 1/1/02 through 12/31/03 into an Access database. Data were then exported into statistical software (SPSS version 13.0) for further analysis
- Publicly available MAUDE reports include information regarding event type (patient adverse event or device problem), patient outcome (eg, death, medical intervention required), and suspected drug or device involved in the event (including brand and manufacturer). Patient-specific information, such as diagnosis or demographics, is not available to the public, however
- Narrative text describing potential causes of the event provided by the reporting facility or manufacturer was abstracted and classified into 5 categories: possible operator errors (eg, pump programming errors), possible patient-related events (eg, patient tampering), possible device-related events (eg, device malfunctions), possible adverse drug reactions, and indeterminate events (unspecified causes)

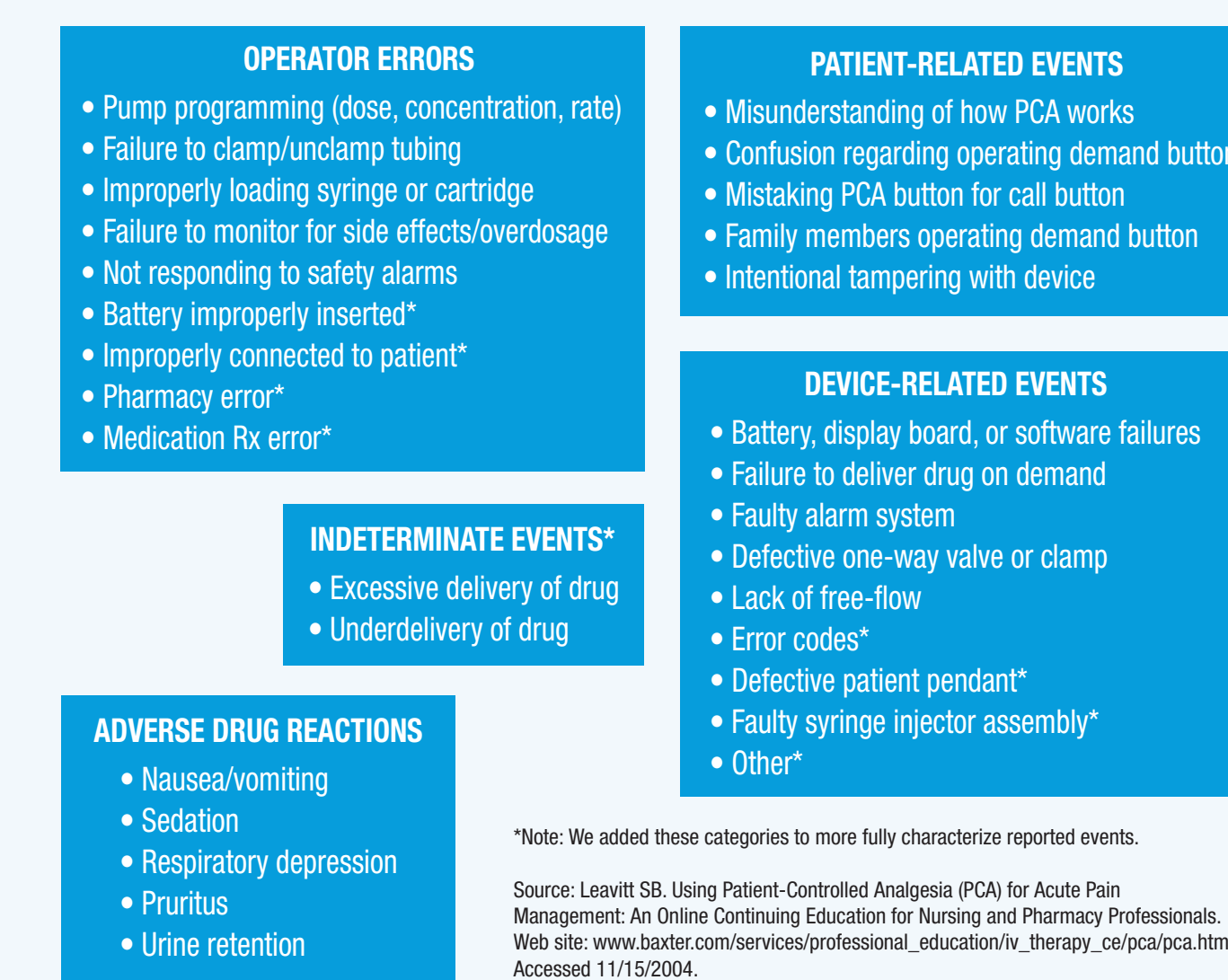
- MAUDE data were downloaded as described in Figure 1

Figure 1. Extraction of MAUDE data.



- Text information regarding event cause was abstracted and classified per Leavitt, 2004¹² (Figure 2)

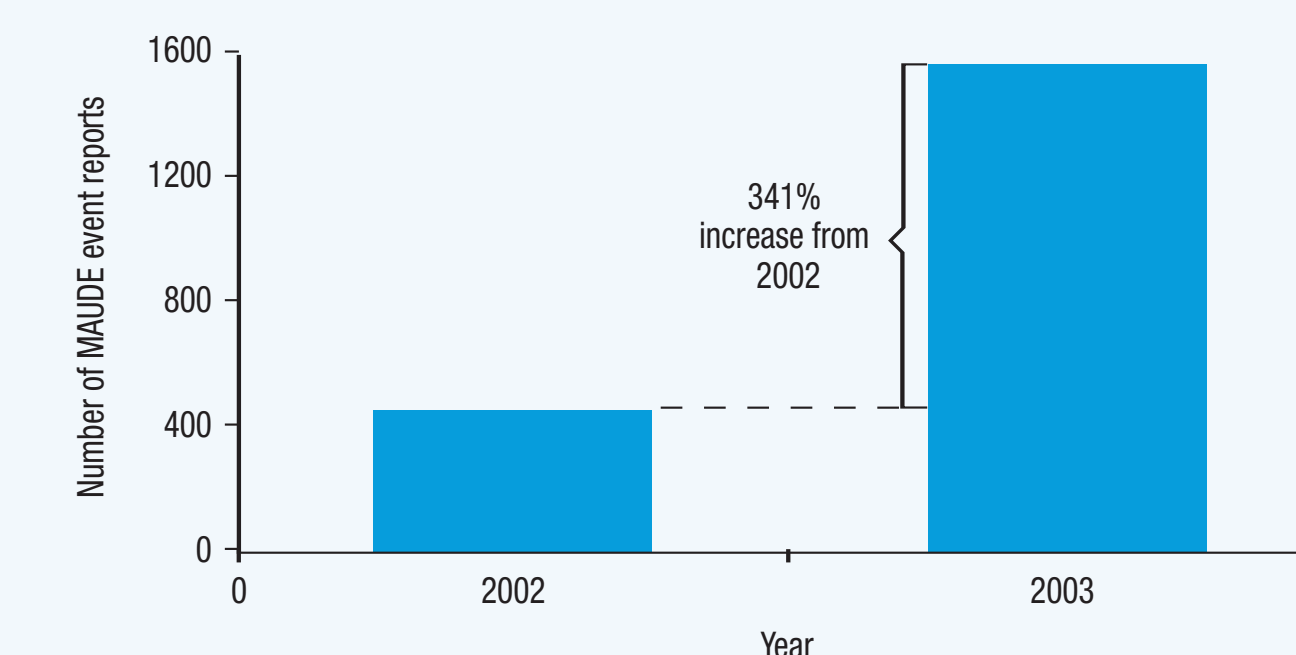
Figure 2. Classification of text information regarding event cause.¹²



RESULTS

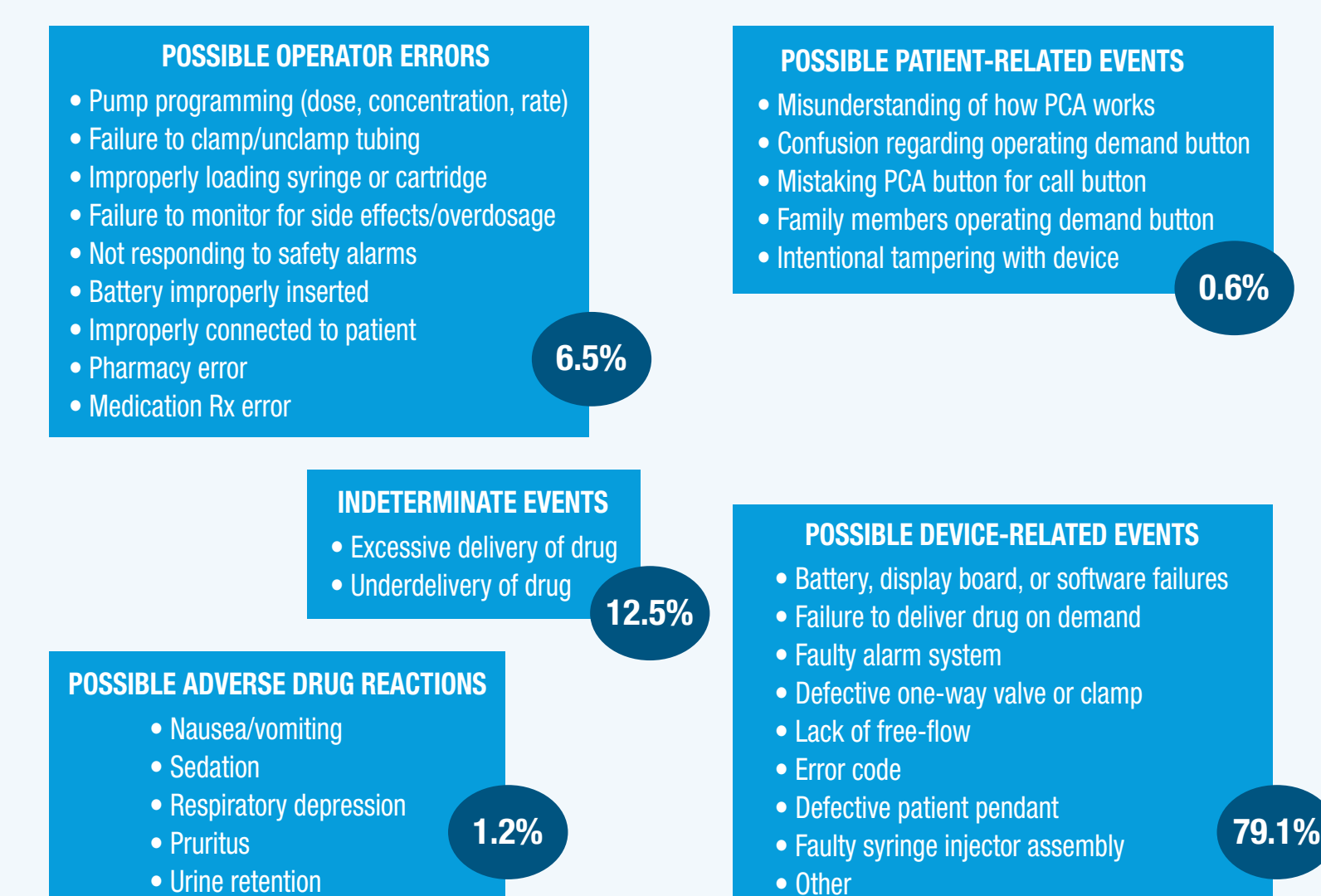
- We found 2,009 unique IV PCA-related reported events. The number of events increased from 455 in 2002 to 1,554 in 2003 (Figure 3), although the FDA instituted no corresponding changes in reporting requirements or data collection during these 2 years

Figure 3. Number of MAUDE events in 2002 and 2003.



- Among all IV PCA-related reports (N = 2,009), 79.1% (n = 1,590) were attributed to possible device-related events, 6.5% (n = 131) possible operator errors, 1.2% (n = 25) possible adverse drug reactions, 0.6% (n = 12) possible patient-related events, and 12.5% (n = 251) were indeterminate events (Figure 4). More than half (61%) of the reported possible device-related events were confirmed upon inspection by the device manufacturer

Figure 4. Frequency of reported events by possible event type 1/1/02 - 12/31/03 (N = 2,009).



LIMITATIONS

- It is difficult to know whether the frequency of events reported in the MAUDE database reflect actual occurrences of problems associated with IV PCA pumps or whether these frequencies are an underestimation, and if so, the magnitude of this underestimation
 - Researchers note that voluntary and mandatory reporting systems for adverse events typically suffer from severe underreporting.¹³ Epidemiologic studies reveal adverse event reporting rates ranging from 1.2% to 7.7% of actual reportable events.^{14,15,16,17} This may occur in response to burdensome reporting systems or concerns over liability. This may be especially relevant to operator error, where liability risk may be of greatest concern. Our findings may therefore underestimate the actual occurrence of IV PCA-related adverse events
 - In addition, we note that the increased frequency of adverse events in 2003 may be an artifact of timing of data entry; that is, events occurring at the end of 2002 may have been reported at the start of 2003

CONCLUSIONS

- A variety of IV PCA problems have been reported, with device-related problems accounting for nearly 80% of all reported events
- Although reporting bias may contribute to the high frequency of possible device-related events (ie, actual operator errors are represented as device-related events), we note that over half of possible device-related malfunctions were confirmed upon inspection by the manufacturer
- To our knowledge, this is the first study to use a large, retrospective database to examine IV PCA-related problems

References

- Finger MJ, McLeod DG. *Urology*. 1995;45:155-157.
- Owen H et al. *Anaesth Intensive Care*. 1988;16:437-447.
- White PF. *Anaesth Intensive Care*. 1989;7:63-76.
- Brown SL et al. *J Intraop Nurs*. 1997;20:311-316.
- Eade DM. *Nurs Manage*. 1997;28:38-40.
- Hicks RW et al. *J Perioper Nurs*. 2004;19:18-28.
- Ashburn MA et al. *Clin J Pain*. 1994;10:52-56.
- Notcutt WG et al. *Br J Anaesth*. 1992;69:95-97.
- Notcutt WG, Morgan RJ. *Anaesthesia*. 1990;45:401-406.
- Grover ER, Heath ML. *Anaesthesia*. 1992;47:402-404.
- United States Food and Drug Administration. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cmaude/search.cfm>.
- Leavitt SB. www.baxter.com/services/professional_education/iv_therapy_ca/pca/pca.html
- Vicente KJ et al. *Can J Anaesth*. 2003;50:328-332.
- Classen DC et al. *JAMA*. 1991;266:2847-2851.
- Cullen DJ et al. *Jt Comm J Qual Improv*. 1995;21:541-548.
- Gardner S, Flack M. www.fda.gov/cdrh/postsurv/medsun.html. Accessed Nov 18, 2004.
- Jha AK et al. *J Am Med Assoc*. 1998;280:305-314.

Supported by Ortho-McNeil Pharmaceutical, Inc.