

UNDER-DELIVERY OF ANALGESIC ASSOCIATED WITH INTRAVENOUS PATIENT-CONTROLLED ANALGESIA (IV PCA) INFUSION PUMPS: FINDINGS FROM THE FDA MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE (MAUDE) DATABASE

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ABSTRACT

Purpose: Previous research documents patient adverse events arising from inadvertent over-delivery of analgesic associated with intravenous patient-controlled analgesia (IV PCA) infusion pumps. However, little is known about inadvertent under-delivery of analgesic associated with these devices. We sought to systematically examine under-delivery of IV PCA-administered analgesic, using a large, publicly available database of adverse events involving medical devices: the US Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database.

Methods: We extracted all IV PCA-related MAUDE records from January 2002 through December 2003 to identify documented IV PCA-related reports. We reviewed these to identify cases of IV PCA analgesic under-delivery occurring during patient use. Key phrases included: "patient pressed the pump dose button, but did not receive any pain medication," "the pump was reportedly not responding to the patient's efforts in pushing the button to call for pain medication," "pump non-delivered during patient use," and "pump continued to appear to deliver the medication but the bag was not emptying." We classified reported causes of under-delivery documented within MAUDE reports as: possible operator errors (eg, errors in programming made by the healthcare professional responsible for programming the pump), possible device-related events (eg, device malfunctions), and indeterminate events (causes unspecified).

Results: Among 2,009 IV PCA-related MAUDE reports documented during this 2-year index period, there were 89 (4.4%) pertaining to under-delivery of analgesic. Reports of analgesic under-delivery were classified as follows: 51 (57%) possible device-related events, 7 (8%) possible operator errors, and 31 (35%) indeterminate events. The 51 possible device-related events were attributed to: 11 (22%) battery, software, or display malfunctions; 10 (20%) failed alarms; 8 (16%) defective pendants; 6 (12%) silent shut-downs; 6 (12%) faulty syringe injectors; and 10 (20%) unspecified device-related problems. Among the 7 possible operator errors, 3 (43%) were attributed to improper loading of the analgesic, 2 (29%) occurred when the tube clamp was not removed, 1 (14%) was a programming error, and 1 (14%) occurred when a staff member turned off the device's occlusion alarm because it was perceived to be a "nuisance." There were 31 cases (35%) in which patients reportedly received no analgesic for a prolonged period of time; these were discovered upon shift change or hospital discharge. The duration of time without any analgesic was specifically recorded in 15 cases; among these, patients received no analgesic for the following lengths of time (mean, 26 h; median, 20 h): 7 patients, 1 to 12 h; 3 patients, 13 to 24 h, 3 patients, 25 to 48 h, and 2 patients, 49 to 72 h.

Conclusions: Over 4% of IV PCA-related MAUDE reports documented under-delivery of analgesic. The majority were reportedly attributable to possible device-related events. Among reports in which duration without any analgesic was recorded, patients received no analgesic for an average of 26 hours. Because the FDA mandates facility and manufacturer reports for only those events that result in patient death or medical intervention, our findings may not fully represent the extent of IV PCA-related under-treatment. Given recent assertions that patients have the right to appropriate assessment and management of pain (JCAHO Standard RI 1.2.8, 2000), reporting agencies may wish to reexamine mandatory reporting requirements to include under-delivery of analgesic.

BACKGROUND

- Patients commonly receive intravenous patient-controlled analgesia (IV PCA) in the postoperative setting for the management of acute, moderate-to-severe pain
- Case reports have documented the occurrence of serious injuries, and sometimes deaths, resulting from problems associated with IV PCA infusion pumps^{1,2}
 - During a 2-year index period (1/1/02 to 12/31/03), 165 IV PCA-related adverse events were documented in the MAUDE database
- Little is known, however, about the inadvertent under-delivery of analgesic by IV PCA devices

PURPOSE

- The purpose of the current study was to conduct a systematic examination of the under-delivery of IV PCA-administered analgesic using the US FDA's MAUDE database

METHODS

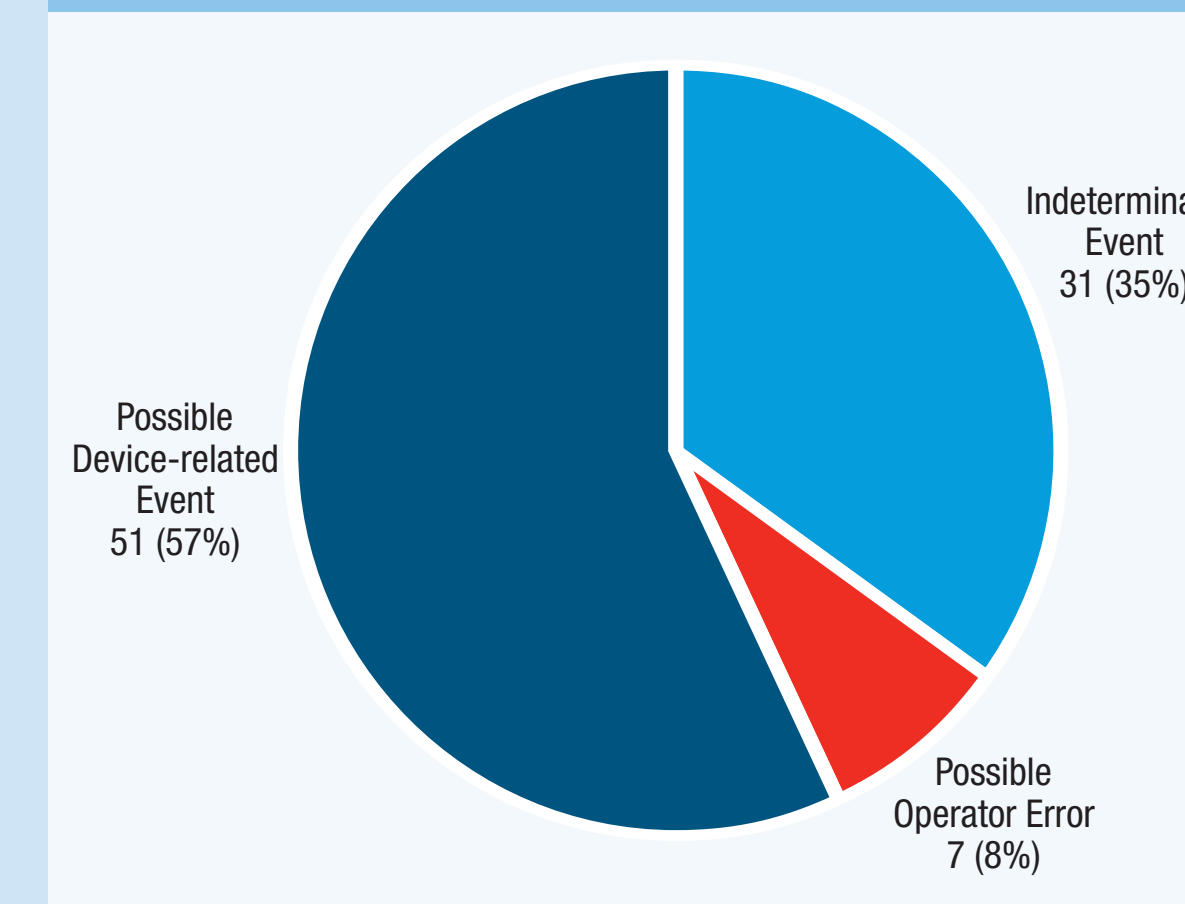
- All records pertaining to IV PCA (FDA product code "MEA") for the period 1/1/02 to 12/31/03 were downloaded from the MAUDE database into Microsoft Access format (Figure 1)
- Narrative text describing potential causes of each event, provided by the reporting facility or the manufacturer, were classified per Leavitt, 2004³ (Figure 2)
- Cases of analgesic under-delivery by IV PCA devices were identified by phrases in the narrative text of each report that included such phrases as: "patient pressed the pump dose button, but did not receive any pain medication," "the pump was reportedly not responding to the patient's efforts in pushing the button to call for pain medication," "pump non-delivered during patient use," and "pump continued to appear to deliver the medication but the bag was not emptying"

RESULTS

- A total of 2,009 IV PCA-related MAUDE reports were documented during the 2-year index period, 89 (4.4%) of which pertained to inadvertent under-delivery of analgesic

- Cases of analgesic under-delivery were classified as possible operator errors (eg, errors in programming made by the healthcare professional responsible for programming the pump), possible device-related events (eg, device malfunctions), or indeterminate events (causes unspecified) (Figure 3)

Figure 3. Reported causes of under-delivery of analgesic per documented narrative text (n = 89).



- Possible device-related events (n = 51) were classified into 6 categories according to the reported cause of under-delivery of medication (Figure 4)

- Possible operator errors (n = 7) were classified into 4 categories according to the reported cause of under-delivery of medication (Figure 5)

Figure 4. Possible device-related events (n = 51).

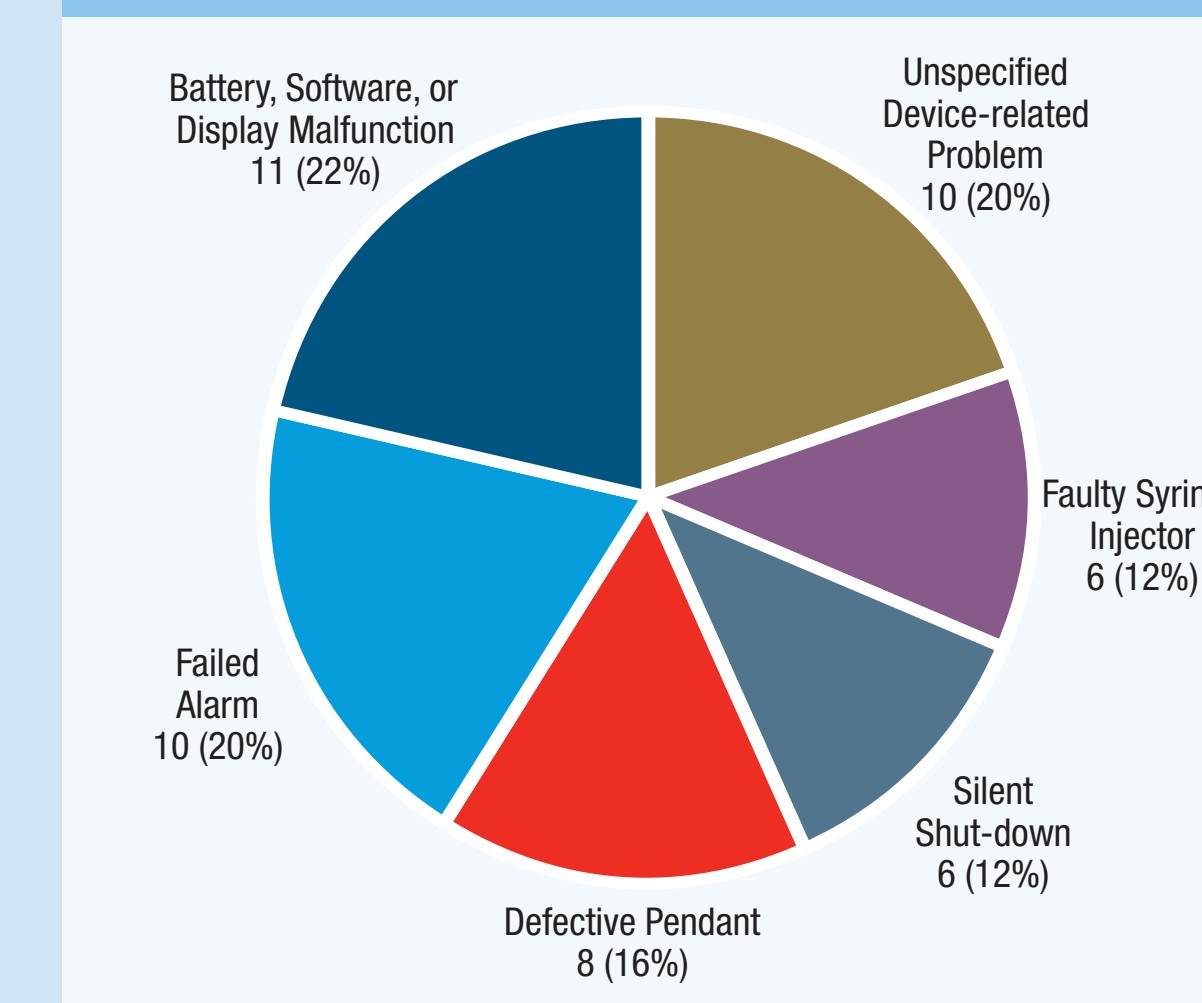


Figure 5. Possible operator errors (n = 7).

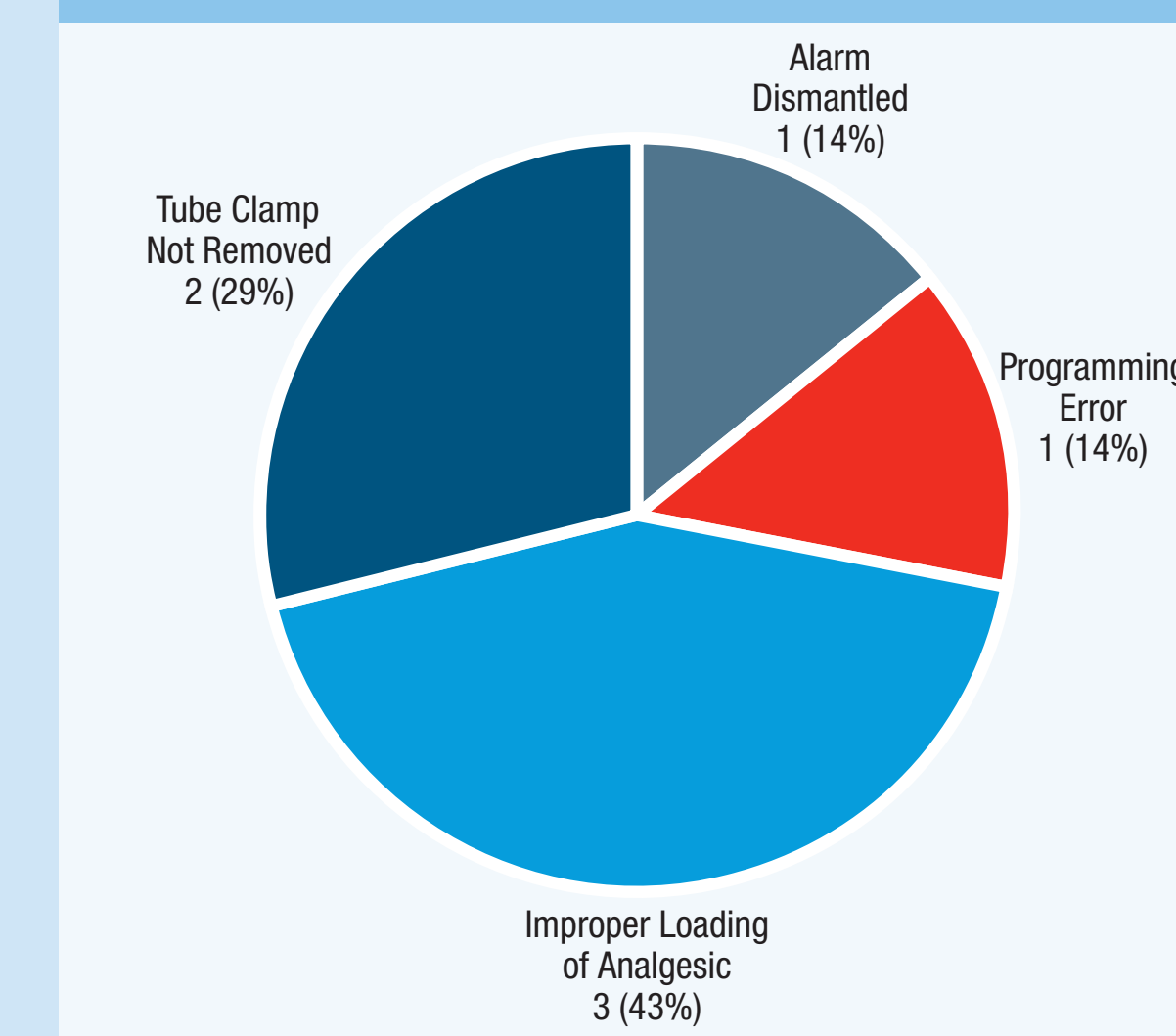


Figure 2. Classification of text information regarding event cause.

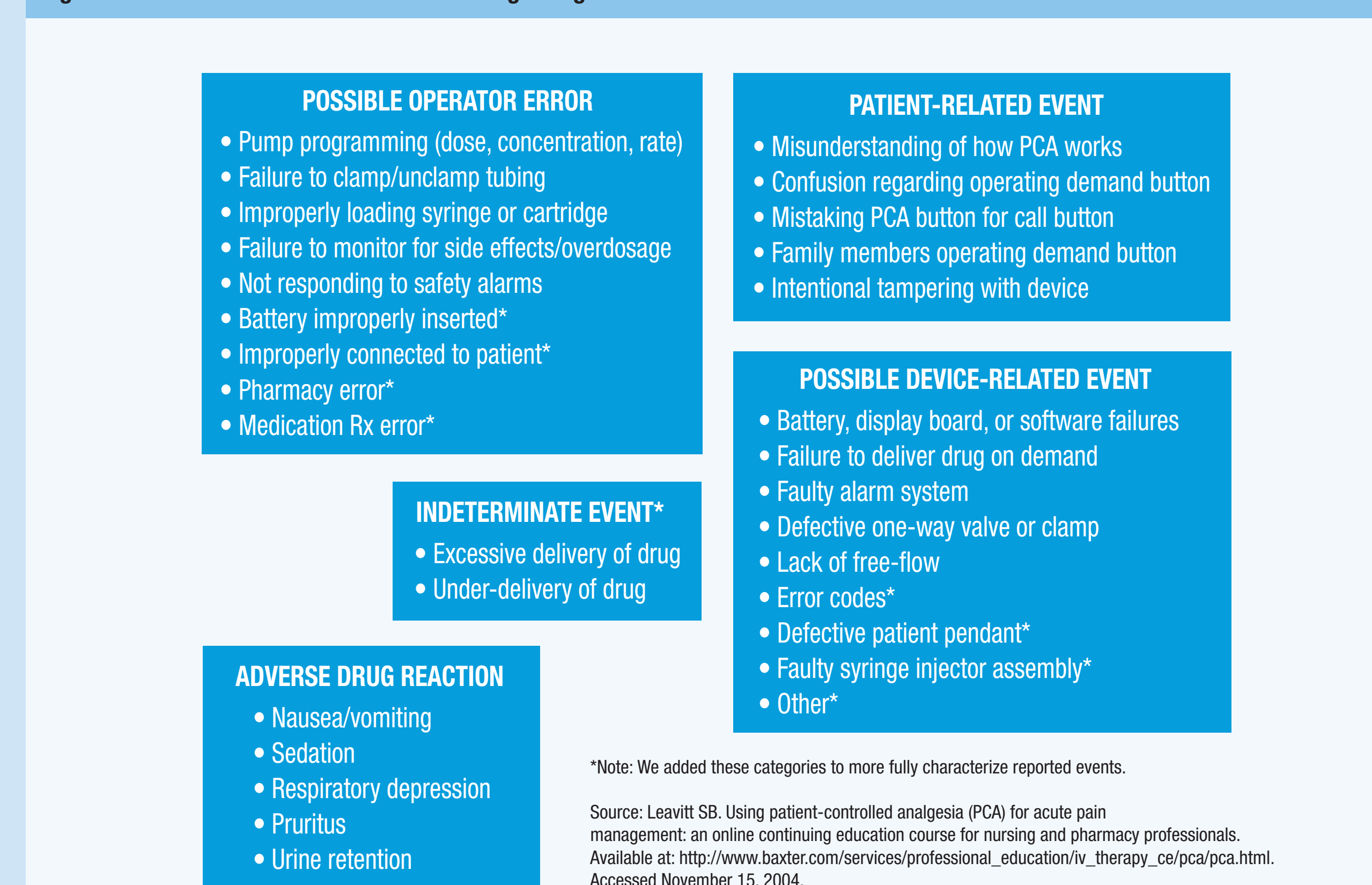
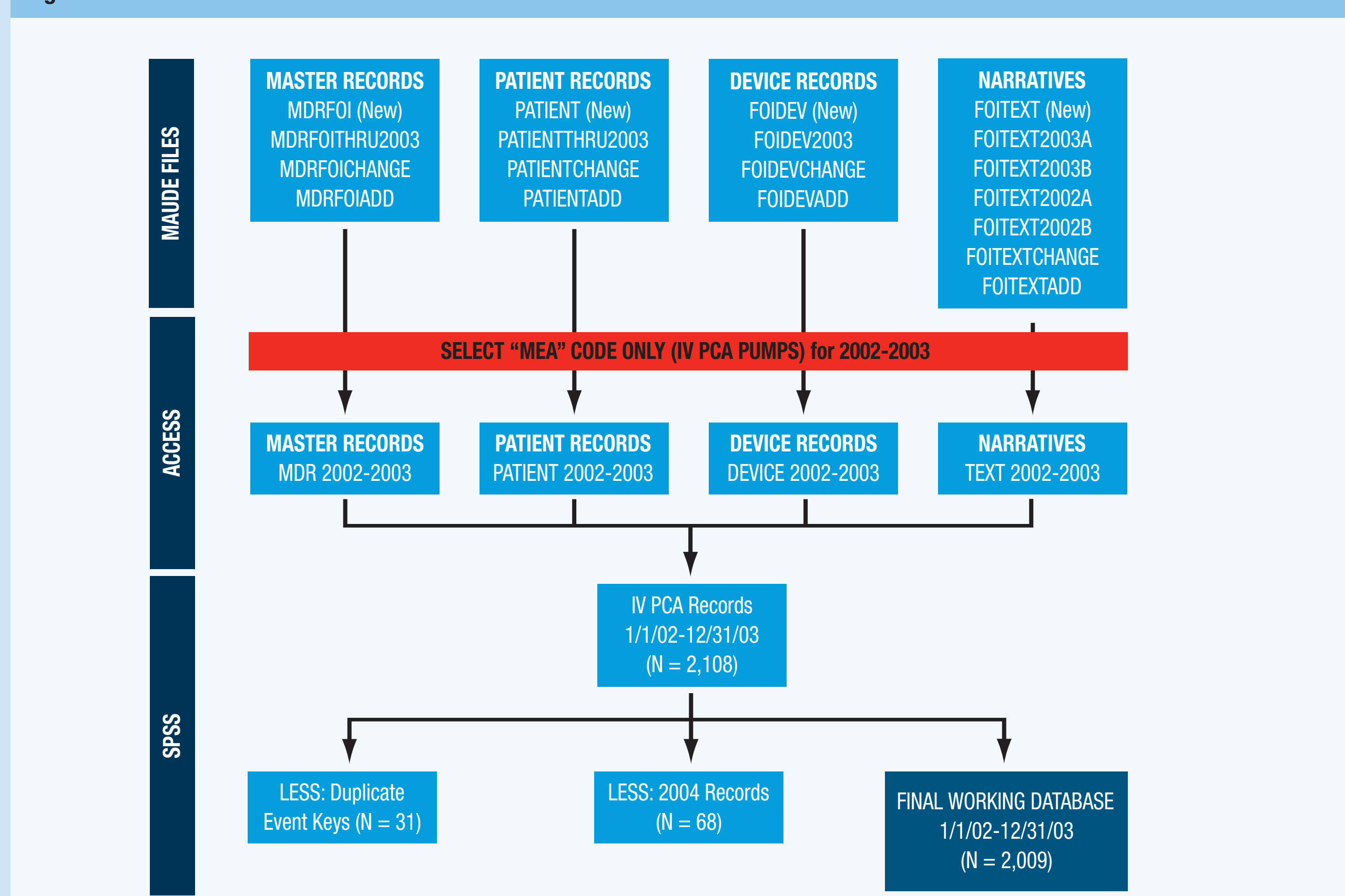


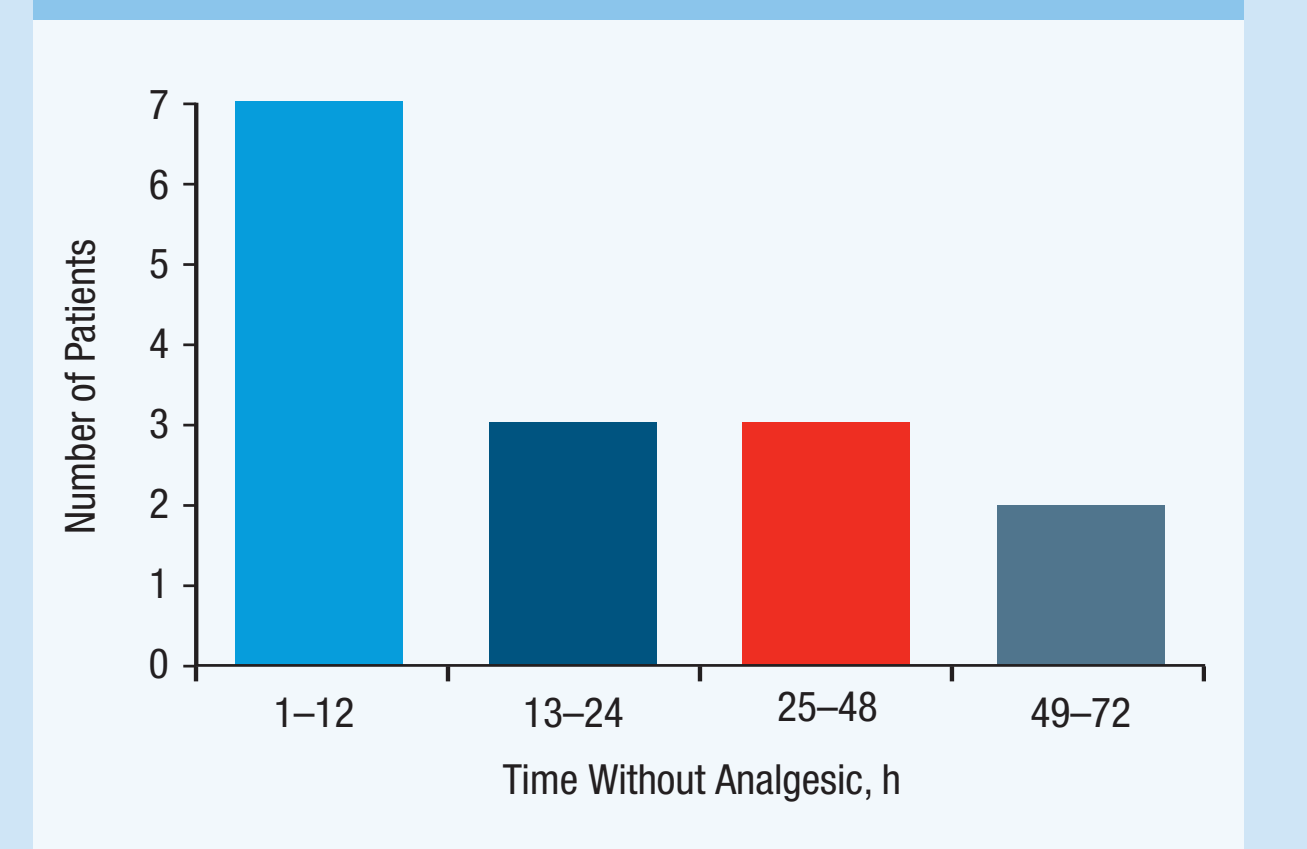
Figure 1. Extraction of MAUDE data.



- There were no cases of under-delivery of analgesic reportedly attributable to patient-related events (ie, patient tampering or family member operating the demand button) or adverse drug reactions

- The time during which patients received no analgesic was reported in 15 cases (Figure 6)

Figure 6. Amount of time during which patients received no analgesic (n = 15).



CONCLUSIONS

- Over 4% of IV PCA-related MAUDE reports documented under-delivery of analgesic, the majority (57%) of which were attributable to possible device-related events
- Because reports are mandated only for those events that result in patient death or medical intervention, our findings may not fully represent the extent of under-treated pain that may result from IV PCA-related problems
- Reporting agencies may wish to revise mandatory reporting requirements to include all incidents of analgesic under-delivery
- In conclusion, reports documented by the FDA suggest that many patients receiving postoperative analgesia via IV PCA may not be adequately treated for their pain

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