

# Adverse events involving intravenous patient-controlled analgesia

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Opioids are among the top five high-alert medications, indicating that they have a particularly high risk of causing patient harm, including serious injury and death.<sup>1</sup> Most hospitalized patients currently receive medications, including opioids, intravenously,<sup>2</sup> and infusion pumps are used to deliver most i.v. continuous infusion and intermittent medications in the United States.<sup>3</sup> Errors that occur during the delivery of medication are a frequent cause of preventable adverse drug events (ADEs), which are defined as “injuries resulting from medical intervention related to a drug,”<sup>4</sup> and those that involve high-alert medications are of particular concern. Intravenous patient-controlled analgesia (PCA) pumps, which deliver preprogrammed doses of opioid in response to patient activation (depressing a button), mitigate some of the dangers associated with continuous infusion of analgesia and empower patients with control of their pain management.<sup>5</sup> Although i.v. PCA represents a well-accepted and satisfactory

**Purpose.** This article systematically characterizes aspects of all Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) reports associated with i.v. patient-controlled analgesia (PCA) postoperative use during a two-year index period.

**Methods.** Intravenous PCA represents a well-accepted and satisfactory means of acute pain treatment; case reports and large case series have described the occurrence of i.v. PCA-related adverse drug events (ADEs). MAUDE data files were downloaded, and all records pertaining to i.v. PCA devices were extracted for the two-year period from January 1, 2002, through December 31, 2003. Medical device events were categorized by their reported cause, including patient-related event, device safety event, operator error, and adverse reactions to opioids. Because there was not sufficient information to grade the certainty of each reported cause, all reported causes were graded “possible,” except for device safety events that were confirmed on inspection by the manufacturer.

**Results.** There were 2009 individual i.v. PCA-related MAUDE medical device events reported during the two-year period. Of these events, 1590 (79.1%) were classified as possible device safety events, 131 (6.5%) as possible operator error, 25 (1.2%) as possible adverse reactions to opioids, 12 (0.6%) as possible patient-related events, and 235 (11.7%) as indeterminate.

**Conclusion.** Manufacturer-confirmed device malfunction was a major cause of reported ADE with i.v. PCA infusion pumps while operator errors were more likely to be associated with more serious adverse outcomes than device safety problems. To reduce the incidence of these problems, potential vulnerabilities in the design and manufacture of i.v. PCA pumps must be identified and addressed.

**Index terms:** Devices; Drugs, adverse reactions; Errors, medication; Food and Drug Administration (U.S.); Opiates; Patient-controlled analgesia; Reports

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means of acute pain treatment,<sup>6,7</sup> individual case reports<sup>8-21</sup> and larger case series<sup>8,22,23</sup> have described the

occurrence of i.v. PCA-related ADEs resulting from operator error, patient error, or device malfunction.

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Despite concerns generated by reports of ADEs involving i.v. PCA pumps, few studies to date have sought to describe the likely causes of these events; those few studies that have examined reports of i.v. PCA-related ADEs have generally concluded that operator error was the major cause of these events and that device malfunctions were relatively rare.<sup>8,24</sup> For example, an analysis of medical device reports to the Food and Drug Administration (FDA) Centers for Devices and Radiological Health from 1984 to 1989 found that 67% of problems associated with PCA pumps were attributable to operator error and that a small (unspecified) proportion was due to device malfunctions.<sup>24</sup> To our knowledge, this early analysis of reports in FDA's publicly available medical device reporting (MDR) Manufacturer and User Facility Device Experience (MAUDE) database represents the only attempt to characterize adverse events related to i.v. PCA pumps as reported from a wide range of health care facilities in the United States.

Several factors contributed to the need to conduct an updated analysis of the MAUDE database for events involving i.v. PCA devices. First, the analysis by Callan<sup>24</sup> was conducted before the MDR system was expanded to include mandatory reporting by user facilities. Beginning in 1984, device manufacturers and distributors were required to report incidents involving "device malfunctions and serious injuries or deaths" to FDA.<sup>25</sup> In 1989, a General Accounting Office study found that less than 1% of medical device problems occurring in hospitals were reported to FDA.<sup>26</sup> This spurred an expansion of the regulations in 1990 to include mandatory reporting by user facilities (e.g., hospitals) to FDA when information reasonably suggests a medical device caused or contributed to a patient's death or serious injury (health care professionals and consumers may voluntarily report events using the

MedWatch system).<sup>27</sup> Second, many new i.v. PCA devices have been introduced to the market since the Callan paper was published 17 years ago. Third, this early analysis failed to describe the methods used to classify possible causes of events reported to FDA and did not indicate whether suspected causes of events were confirmed by manufacturers.

The purpose of this article is to systematically characterize aspects of all MAUDE reports associated with i.v. PCA postoperative use during a recent two-year index period. In addition, this analysis seeks to shed light on the most frequently reported causes of i.v. PCA-related events that result in serious patient harm.

## Methods

MAUDE data are available in text file format. Publicly available information includes characteristics of each report, such as reporter (health care facility, distributor, or manufacturer) and date report was received by FDA; deidentified patient data including patient outcomes (such as disability or death); device information, including whether the device was returned to the manufacturer for further evaluation; and narrative text information in which the reporter and manufacturer may provide descriptions of the events, possible or confirmed causes, patient outcomes, and results of subsequent manufacturer device testing. MAUDE data files were downloaded into Microsoft Access, and all records pertaining to i.v. PCA devices (FDA product code "MEA") were extracted for the two-year period from January 1, 2002, through December 31, 2003. Data were then exported into SPSS, version 13.0 (SPSS Inc., Chicago, IL) to facilitate analysis.

Patient harm was defined as an unintended and unwanted outcome that negatively affects a patient's health to the extent that treatment is required or permanent damage results. Because a causal link between a medical device event and

patient harm could not always be conclusively established, we did not use the term "adverse event" (harm in a patient administered a drug but not necessarily caused by a drug<sup>28</sup>) or "adverse medical device event" (any patient harm caused by device-related medical or surgical management rather than the patient's illness<sup>29</sup>) but did describe the frequency and type of patient harm (e.g., respiratory distress, oversedation) associated with medical device events. A medical device event was defined as actual or potential patient harm associated with the use of a medical device.

On the basis of a classification system developed by Leavitt,<sup>30</sup> medical device events were categorized by their reported cause (per narrative text provided within each report), including patient-related event (e.g., intentional tampering with the device), device safety event (e.g., device malfunction such as software or battery failure), operator error (e.g., pump programming error), and adverse reactions to opioids (e.g., nausea, sedation) (appendix). As there was not sufficient information to grade the certainty of each reported cause, we conservatively graded all reported causes as "possible," with the exception of device safety events that were confirmed on subsequent inspection by the manufacturer; in these cases, we classified causality for the medical device event as "confirmed." Although other taxonomies have been developed, such as the National Coordinating Council for Medication Error Reporting and Prevention, these do not encompass the wide array of potential causes of events, such as patient tampering or device malfunctions that have been specifically associated with i.v. PCA pumps. We added a category, "indeterminate," to indicate events that could not be categorized as possible patient-related, device safety, or operator error events due to insufficient information provided in the report. An adverse reaction to opioids was

defined as harm “directly caused by a drug at normal doses.”<sup>28</sup>

## Results

There were 2009 individual i.v. PCA-related MAUDE medical device events reported from January 1, 2002, through December 31, 2003. Of these events, 1590 (79.1%) were classified as possible device safety events, 131 (6.5%) as possible operator error, 25 (1.2%) as possible adverse reactions to opioids, 12 (0.6%) as possible patient-related events, and 235 (11.7%) as indeterminate. Three reports (0.1%) were not applicable because they involved home use of i.v. PCA for chronic pain, and 13 (0.6%) were clearly unrelated to i.v. PCA (e.g., a patient dying from a traumatic injury while coincidentally receiving analgesia from an i.v. PCA device).

**Possible device safety events.** As shown in Table 1, of the 1590 events possibly related to device safety, over three quarters (76.4%) were associated with suspected switch ( $n = 516$ ); motor ( $n = 488$ ); or battery, display board, or software ( $n = 214$ ) defects. Three quarters ( $n = 1191$ ) of devices associated with suspected device safety events were sent to the manufacturer for further inspection; the manufacturer confirmed that device defects were likely to have caused the device safety events in 86.6% ( $n = 1032$ ) of devices that were inspected by the manufacturer. Among all device safety events, 0.5% ( $n = 8$ ) were reported to have caused patient harm (4 required naloxone, 2 resulted in the patient receiving no analgesic, 1 adverse event was unspecified, and 1 injury occurred when the pump battery fell on a patient).

**Possible operator error.** Among the 131 events reportedly attributable to operator error, the majority (80.9%) involved errors in pump programming (Table 1). There were 65 devices returned to the manufacturer for further inspection; of these, 61.5% ( $n = 40$ ) were confirmed as likely operator errors, 23% ( $n = 15$ ) were not confirmed to be operator

errors, 3% ( $n = 2$ ) remained under continued investigation by the manufacturer, and 12% ( $n = 8$ ) were judged as indeterminate because programming data had been erased or overwritten. Patient harm occurred in 63 (48.1%) cases, including 6 (5%) patient deaths.

**Possible adverse reactions to opioids.** There were 25 reports of possible adverse reactions to opioids, in which the dose and method of opioid administration were reportedly appropriate. The majority (58.3%) of cases involved morphine, 12.5% involved hydromorphone, 16.8% involved various other analgesics (citalopram with meperidine, meperidine, fentanyl, morphine with ketorolac), and 12.5% involved unspecified medications (not shown). The most common adverse reactions were respiratory depression (40%), sedation (28%), and death (16%) (Table 2). Of these 25 events, 2 resulted in the device being sent to the manufacturer for inspection; the manufacturer confirmed that both events were likely attributable adverse reactions to opioids.

**Possible patient-related events.** As shown in Table 1, there were 12 reports of possible patient-related events. Of these, 8 were suspected intentional patient tampering, and 4 were attributed by the reporter to family members operating the demand button. Of the 8 suspected cases of intentional patient tampering, 3 were sent to the manufacturer for further testing; of these 3, 1 was confirmed by the manufacturer to show evidence of intentional tampering. Among the 12 reported possible patient-related events, there were 4 (33%) classified as having caused patient harm; all were associated with likely patient tampering, and all required naloxone administration.

**Indeterminate events.** There were 235 events classified as indeterminate due to insufficient information in the report narrative (Table 1). Of these, 70.2% referred to overdosing of analgesia, 24.3% referred to under-

delivery of analgesia, and 5.5% were unspecified (e.g., report stated that an “inaccurate” analgesic amount was delivered). In 1 case, the device was returned to the manufacturer for further testing; this device delivered an unrequested bolus dose during inspection. There were 51 documented cases of patient harm (21.7%), including 7 deaths (3.0%).

## Discussion

It has become increasingly clear that the majority of ADEs are preventable<sup>31</sup> and that these events substantially contribute to patient morbidity, mortality, and increased health care costs.<sup>16,32-36</sup> Progressively more complex medical devices, such as i.v. PCA pumps, are now routinely used in postoperative care and may contribute to preventable adverse events due to design flaws, device failure, and misuse. Because i.v. delivery of opioid analgesics carries a high risk of potential patient injury, special attention to problems associated with these devices is warranted. An Institute of Medicine committee has recommended that all adverse events resulting in serious injury or death be evaluated to assess whether improvements in the delivery of care can be made to reduce the likelihood of similar events occurring in the future. Errors that do not result in harm also represent an important opportunity to identify system improvements that have the potential to prevent adverse events.<sup>32</sup> Although many states mandate that user facilities report serious adverse events, these data are rarely available to the public.<sup>16</sup> The MAUDE database constitutes a unique and underused resource for researchers interested in understanding the nature of serious adverse events involving medical devices.

We identified 2009 i.v. PCA-related reports filed with FDA during a recent two-year index period, the majority of which could be classified as possibly preventable. Device safety events (e.g., device malfunctions) were the suspected causes of nearly

Table 1. Frequency of Reported Events by Possible Causes, Results of Manufacturer Testing, and Adverse Patient Outcomes

Reported Event and Possible Cause	No. (%) Events Reported	No. Devices Sent to Manufacturer for Testing	No. (%) Possible Causes Confirmed by Manufacturer	Adverse Patient Outcomes	
				No. (%) Reported	Description
<b>Device safety</b>					
Defective reed switch	516 (32.5)	437	409 (93.6)	0	...
Defective motor	488 (30.7)	428	384 (89.7)	1 (0.2)	Required opioid antagonist (n = 1)
Battery, display board, software problem	214 (13.5)	129	84 (65.1)	2 (0.9)	Unspecified (n = 1), battery fell on patient (n = 1)
Defective support assembly	114 (7.2)	96	80 (83.3)	0	...
Faulty alarm system	48 (3.0)	29	22 (75.9)	0	...
Failure to deliver drug on demand	38 (2.4)	1	0	1 (2.6)	No analgesic delivered (n = 1)
Defective patient pendant	29 (1.8)	20	19 (95.0)	2 (6.9)	Required opioid antagonist (n = 2)
Defective mechanism board	23 (1.4)	12	4 (33.3)	0	...
Defective or loose switch and/or alarm	19 (1.2)	19	14 (73.7)	0	...
Faulty syringe injector assembly	6 (0.4)	1	1 (100.0)	1 (16.7)	Required opioid antagonist (n = 1)
Other	95 (6.0)	19	15 (78.9)	1 (1.1)	No analgesic delivered (n = 1)
<b>Total</b>	<b>1590 (100.0)</b>	<b>1191</b>	<b>1032 (86.6)</b>	<b>8 (0.5)</b>	
<b>Operator error</b>					
Patient-controlled analgesia pump programming error	106 (80.9)	58	39 (67.2)	54 (50.9)	Death (n = 3), required opioid antagonist (n = 38), respiratory arrest (n = 1), sedation (n = 5), unspecified (n = 4), respiratory depression (n = 3)
<b>Failure to clamp or unclamp tubing</b>					
Pharmacy error	6 (4.6)	2	0	1 (16.7)	Required opioid antagonist (n = 1)
Improperly connected to patient	4 (3.1)	1	0	4 (66.7)	Death (n = 1), required opioid antagonist (n = 1), respiratory arrest (n = 2)
Improperly loading syringe or cartridge	4 (3.1)	0	0	2 (50.0)	Sedation (n = 1), required opioid antagonist (n = 1)
Medication prescription error	3 (2.3)	0	0	0	...
Battery improperly inserted	2 (1.5)	2	1	2 (66.7)	Death (n = 2)
<b>Total</b>	<b>131 (100.0)</b>	<b>65</b>	<b>40 (61.5)</b>	<b>63 (48.1)</b>	...
<b>Patient related</b>					
Intentional tampering with device	8 (66.7)	3	1 (33.3)	4 (50.0)	Required opioid antagonist (n = 4)
Family members operating demand button	4 (33.3)	3	0	0	...
<b>Total</b>	<b>12 (100.0)</b>	<b>6</b>	<b>1 (16.7)</b>	<b>4 (33.3)</b>	
<b>Indeterminate</b>					
Inaccurate amount of drug delivered	13 (5.5)	2	0	3 (23.1)	Blood backed up in catheter (n = 1); catheter broke off in patient (n = 1); required opioid antagonist (n = 1)

Table 1 (continued)

Reported Event and Possible Cause	No. (%) Events Reported	No. Devices Sent to Manufacturer for Testing	No. (%) Possible Causes Confirmed by Manufacturer	Adverse Patient Outcomes	
				No. (%) Reported	Description
Overdelivery of drug	165 (70.2)	57	1 (1.8)	48 (29.1)	Coma (n = 1), death (n = 7), dizziness (n = 1), required opioid antagonist (n = 31), respiratory arrest (n = 1), death (n = 2), sedation (n = 1), unspecified (n = 4)
Underdelivery of drug	57 (24.3)	22	0	0	...
Total	235 (100.0)	81	1 (1.2)	51 (21.7)	

80% of events reported to FDA. Given that published accounts of i.v. PCA problems have historically focused on operator error and patient tampering,<sup>8,9,24</sup> we were surprised to find that nearly two thirds (64.9%) of suspected device malfunctions were duplicated and confirmed on inspection by the manufacturer. Of those device malfunctions that were not confirmed, about half are under continued evaluation by the manufacturer and nearly one quarter were never received by the manufacturer. Only 159 suspected device malfunctions (representing 10% of the total events in this category) were conclusively cleared of defects upon manufacturer inspection.

Although operator errors were less frequent than device malfunctions, these events were associated with the most severe consequences, including six deaths, two occurrences of respiratory arrest, and 50 cases in which naloxone was administered. In contrast, device safety events were associated with no deaths or instances of respiratory arrest or depression and with only four occurrences of naloxone administration. This seems to suggest that operator errors were more likely than device malfunctions to result in the overdelivery of drugs, which is the most dangerous consequence of an i.v. PCA-related event.

Consistent with other reports, we found that most operator errors (80%) occurred during device programming. Given that i.v. PCA device setup is extremely complex and each PCA pump uses a different user interface which must be learned by the operator, there are numerous opportunities for operator error during pump programming.<sup>37</sup> Overdose may paradoxically occur when an inaccurately low concentration is set (e.g., 0.1 mg/mL of morphine rather than a 1-mg/mL concentration) because the device may automatically divide the desired unit dose by the concentration.<sup>18</sup> Consequently, the patient would receive a 10-fold higher dose than intended. Other errors

may occur when device default settings, which are not universally programmed by the factory, vary within or across models, manufacturers, or health care facilities.

Current efforts to apply human factors engineering principles to understand how operators may err in interacting with the i.v. PCA pump may lead to improvements in the design of these devices.<sup>37</sup> One such improvement has been the development of “smart” infusion pumps, which have built-in software that checks programmed doses against preset limits associated with a specific drug and clinical location and alerts providers when programmed doses exceed safe limits.<sup>38,39</sup> In one study, use of two smart infusion pumps over an eight-month period in one health care facility averted 99 programming errors; 20 of these errors involved administering doses more than 10 times the dosing limit.<sup>39</sup> However, another recent study found that only 1 of 389 i.v. infusion pump errors would have been prevented with a “smart” infusion pump as most errors occurred in the process of receiving, reconciling, and documenting orders rather than in pump programming.<sup>38</sup> Given the diversity of errors that can occur with i.v. PCA pumps, it is unlikely that any single intervention can address the latent systemic failures that increase the likelihood of such errors.<sup>38</sup>

The i.v. PCA events captured by MAUDE represent only a subset of all i.v. PCA events that occur each year in U.S. health care facilities. Per federal reporting guidelines, events involving serious injury or death in which a medical device may have been a contributing or causal factor, as well as suspected device malfunctions that have the potential to cause serious injury, must be reported to FDA.<sup>25,27</sup> Events related to user errors must be reported under the law since the design of the medical device may have contributed to these errors.<sup>27</sup> In addition to the mandatory reporting

Table 2.  
Adverse Reaction to Opioids

Possible Adverse Reaction to Opioids	No. (%) Reported	No. Device Sent to and Tested by Manufacturer	Possible Cause Confirmed by Manufacturer		
			No.	% of Tested	% of Total
Sedation	7 (28)	1	1	100	14
Death	4 (16)	1	1	100	25
Blurred vision	1 (4)	0	0	...	...
Seizure	1 (4)	0	0	...	...
Loss of consciousness	1 (4)	0	0	...	...
Respiratory arrest	1 (4)	0	0	...	...
Respiratory depression	10 (40)	0	0	...	...
Total	25 (100)	2	2	100	8

rules, user facilities are encouraged to voluntarily report suspected medical device malfunctions that did not result in serious injury to FDA.<sup>27</sup> Intravenous PCA events that do not fall under the FDA mandatory reporting rules may be reported through any number of voluntary incident reporting systems including FDA's MedWatch; the United States Pharmacopeia's (USP's) MEDMARX, an anonymous, subscription-based program that has accrued the largest number of medication errors of any nongovernmental database in the United States<sup>40</sup>; and USP's Medication Error Reporting (MER) program, a voluntary incident reporting system accessible to all health care providers in the United States. In the years 1998–2003, a total of 5377 medication errors reported using the MEDMARX and MER systems were related to i.v. PCA use.<sup>41</sup> Of these events, 7.9% were considered harmful, compared with a 2% harm rate among all medication errors<sup>41</sup> and a 3–5% harm rate for all i.v.-related medication errors reported through MEDMARX.<sup>42</sup> Thus, it appears that the risk of harm increases two to four times when PCA pumps are used,<sup>41</sup> confirming the high risk of danger associated with these devices.

From 2000 to 2003, 24,157 i.v.-related medication errors were reported using the MEDMARX system<sup>42</sup> while just 2,009 events were reported to the FDA MAUDE database during this same time period. Whereas most

events captured by the MAUDE database were device related, the majority of events in the MEDMARX database were provider related; 89% of errors captured by MEDMARX were caused by performance deficits, procedure or protocol deviations, and inaccurate or omitted transcription.<sup>42</sup> This is not surprising since human error is estimated to cause about 80% of all adverse events.<sup>43,44</sup>

It is difficult to conclusively determine an incidence rate for i.v. PCA-related events because of different reporting systems, the problem of event underreporting, and the absence of a base rate of i.v. PCA device use. The total number of events captured by the MAUDE reporting system likely underestimates the true number of potentially serious events involving i.v. PCA pumps as all incident reporting systems are limited by underreporting.<sup>45-48</sup> Indeed, researchers estimate that only 1.2–7.7% of actual adverse events are ever reported,<sup>49-52</sup> suggesting that the true rate of i.v. PCA-related events that occurred during our two-year index period ranged from 13,948 (1,074 divided by 7.7%) to 89,500 (1,074 divided by 1.2%). Adverse events that do not result in patient harm or do not reach the patient are most apt to be underreported as they may be viewed as unimportant by providers,<sup>53,54</sup> yet these types of events (often referred to as “near misses”) probably occur with much greater frequency than do events that cause patient harm

and could be a rich source of data to be mined to identify vulnerabilities in i.v. PCA use. Other significant barriers to incident reporting are uncertainty about which events should be reported, fear of being blamed and judged incompetent, and fear of implicating others for reporting medical errors.<sup>55</sup>

The study had limitations. First, with the exception of those events that were examined by the manufacturer and where causality was confirmed, reported problem types and their attributions are not substantiated. The quality of information provided in each event report was highly variable and prevented definitive conclusions about causality in many cases, which is why we apply the term “possible cause” in describing reported events. Second, our findings do not reflect the vast use by which patients safely receive i.v. PCA analgesia for postsurgical acute pain each year. Unfortunately, there is no way to accurately estimate the denominator of i.v. PCA use to estimate the incidence of errors involving i.v. PCA pumps. Third, the analysis was based on reports generated through a mandatory reporting system. Currently, 93% of adverse events involving medical devices reported to FDA come from industry, 1% from importers, 3% from health care institutions (mandated), and the remaining from voluntary reports (<1% from physicians).<sup>56</sup> The kinds of incidents reported via

mandatory reporting systems may be qualitatively different from those that are identified through other methods (e.g., examination of claims data, voluntary incident reporting systems, chart review) and thus may represent only a particular subset of all adverse events. Finally, we note that the MAUDE database may not contain all reports submitted to FDA for the period investigated, as there may be a significant lag between receipt and entry of reports into the database.

Notwithstanding these limitations, to our knowledge this is the first study to comprehensively examine FDA reports of i.v. PCA-related problems since event reporting became required by both industry and health care facilities. The frequency of device malfunctions is troubling and warrants more in-depth study to determine aspects of device design and manufacturing that might increase the vulnerability of these devices. A number of recommendations have been proposed to reduce i.v. PCA medication errors, whether caused by human error or device malfunction, including routinely scheduled testing of all i.v. PCA devices by trained hospital staff before the devices are released for patient use; staff, family, and patient education regarding the safe and appropriate use of i.v. PCA devices; institution of double checks following initial pump setup and following changes in regimen, dosing, or drug; standardizing all pump default settings across manufacturers, brands, and facilities; and conducting routine checks on pump reservoir levels to monitor “reasonableness” of remaining drug available.

It is clear that i.v. PCA pumps are inherently complex devices that may be especially susceptible to both operator error and device malfunction. Continued in-depth study of adverse events involving these devices can help identify innovations in device design and testing to reduce the occurrence of preventable adverse events.

### Conclusion

Manufacturer-confirmed device malfunction was a major cause of reported ADEs with i.v. PCA infusion pumps while operator errors were more likely to be associated with more serious adverse outcomes than device safety problems. To reduce the incidence of these problems, potential vulnerabilities in the design and manufacture of i.v. PCA pumps must be identified and addressed.

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**Appendix—Definition of terms**

<u>Term</u>	<u>Definition</u>
Device safety event	A medical device event primarily attributed to a defective device; for example <sup>30</sup> : <ul style="list-style-type: none"> <li>• Defective battery, display board, software, or microprocessor</li> <li>• Defective reed switch</li> <li>• Failure to deliver drug on demand</li> <li>• Faulty alarm system</li> <li>• Defective one-way valve or clamp</li> <li>• Lack of free-flow protection</li> <li>• Defective motor</li> <li>• Defective support assembly</li> <li>• Defective patient pendant</li> <li>• Defective mechanism board</li> <li>• Defective loose 5-mL switch</li> <li>• Faulty syringe injector assembly</li> <li>• Other</li> </ul>
Patient-related event	A medical device event primarily caused by a patient or family member, such as <sup>30</sup> <ul style="list-style-type: none"> <li>• Misunderstanding how patient-controlled analgesia (PCA) works</li> <li>• Confusion regarding operating demand button</li> <li>• Mistaking PCA button for call button</li> <li>• Family members operating demand button</li> <li>• Intentional tampering with device</li> </ul>
Operator error	A medical device event primarily caused by error of the person operating the device <sup>30</sup> : <ul style="list-style-type: none"> <li>• PCA pump programming error</li> <li>• Failure to clamp or unclamp tubing</li> <li>• Improperly loading syringe or cartridge</li> <li>• Not monitoring for adverse effects and overdose</li> <li>• Battery improperly inserted</li> <li>• Improperly connected to patient</li> <li>• Pharmacy error</li> <li>• Medication prescription error</li> <li>• Not responding to safety alarms</li> </ul>
Indeterminate	A medical device event without adequate information to determine likely cause. Potential outcomes are <ul style="list-style-type: none"> <li>• Excessive delivery of drug</li> <li>• Underdelivery of drug</li> <li>• Unspecified amount of drug delivered</li> </ul>