Outbreaks of Infections Associated With Drug Diversion by US Health Care Personnel

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Abstract

Objective: To summarize available information about outbreaks of infections stemming from drug diversion in US health care settings and describe recommended protocols and public health actions.

Patients and Methods: We reviewed records at the Centers for Disease Control and Prevention related to outbreaks of infections from drug diversion by health care personnel in US health care settings from January 1, 2000, through December 31, 2013. Searches of the medical literature published during the same period were also conducted using PubMed. Information compiled included health care setting(s), infection type(s), specialty of the implicated health care professional, implicated medication(s), mechanism(s) of diversion, number of infected patients, number of patients with potential exposure to blood-borne pathogens, and resolution of the investigation.

Results: We identified 6 outbreaks over a 10-year period beginning in 2004; all occurred in hospital settings. Implicated health care professionals included 3 technicians and 3 nurses, one of whom was a nurse anesthetist. The mechanism by which infections were spread was tampering with injectable controlled substances. Two outbreaks involved tampering with opioids administered via patient-controlled analgesia pumps and resulted in gram-negative bacteremia in 34 patients. The remaining 4 outbreaks involved tampering with syringes or vials containing fentanyl; hepatitis C virus infection was transmitted to 84 patients. In each of these outbreaks, the implicated health care professional was infected with hepatitis C virus and served as the source; nearly 30,000 patients were potentially exposed to blood-borne pathogens and targeted for notification advising testing.

Conclusion: These outbreaks revealed gaps in prevention, detection, and response to drug diversion in US health care facilities. Drug diversion is best prevented by health care facilities having strong narcotics security measures and active monitoring systems. Appropriate response includes assessment of harm to patients, consultation with public health officials when tampering with injectable medication is suspected, and prompt reporting to enforcement agencies.

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In May 2012, the New Hampshire Department of Health and Human Services began investigating a cluster of hepatitis C virus (HCV) infections at a single hospital. This investigation uncovered a large HCV outbreak spanning several years, involving more than a dozen hospitals, and impacting thousands of patients in 8 states. This outbreak was caused by an HCV-infected traveling radiology technician who, in August 2013, had admitted to having been addicted to narcotics and diverting medications such as fentanyl from patients. The mechanism of diversion used by the technician involved a form of tampering that exposed patients to his blood. This outbreak has resulted in multiple lawsuits involving the staffing agencies and institutions that employed the technician. This multistate outbreak and others like it have revealed multiple gaps in prevention, detection, and response to drug diversion in US health care facilities. The National Association of Drug Diversion Investigators defines drug diversion as any criminal act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient. This can include the outright theft of the drugs, or it can take the form of a variety of deceptions such as doctor shopping, forged prescriptions, counterfeit drugs, and international smuggling. Diversion by health care personnel represents one facet of drug diversion that is gaining recognition as a ubiquitous and poorly controlled patient safety risk. Mechanisms

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of diversion by health care personnel can include documentation of a medication dose that was not actually administered to the patient but saved for use by the health care professional, theft by scavenging of wasted medication (e.g., removal of residual medication from used syringes), and theft by tampering (e.g., removal of medication from a medication container or syringe and replacement with saline or other similar-appearing solution that may be administered to patients). Patient safety is compromised whenever diversion by health care personnel occurs. Harms can include patients not obtaining adequate pain management, exposure to substandard care from an impaired health care professional, and exposure to life-threatening infections. However, when diversion is suspected or identified, the potential for patient harm may be overlooked.

In light of the multistate outbreak of HCV infections identified in New Hampshire and the gaps it highlighted, we reviewed reported outbreaks of infections resulting from drug diversion by health care personnel in US health care settings. In this article, we offer a summary of available information about the types of infections, drugs, mechanisms of diversion, and health care personnel that have been associated with outbreaks stemming from this activity. We conclude with a summary of recommended standard protocols and public health actions that should be considered when diversion by health care personnel is suspected or identified.

PATIENTS AND METHODS
The Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC) frequently assists health departments and institutions with investigations of outbreaks involving health care exposures, including drug diversion. We reviewed our internal records and CDC-authored reports related to US outbreaks from drug diversion by health care personnel for the 14-year period extending from January 1, 2000, through December 31, 2013. A PubMed search was conducted for outbreak investigations occurring during the same time period using combinations of key words including outbreak, diversion, and narcotics. We also examined reference lists from selected publications seeking to identify additional outbreaks meeting our inclusion criteria.

For the purposes of this review, an outbreak was defined as a health care–associated infection occurring in 2 or more patients in whom disease transmission likely resulted from drug diversion by health care personnel in a US health care facility. We excluded outbreaks occurring prior to January 1, 2000, outbreaks occurring in health care settings outside the United States, as well as reports of drug diversion in which no resulting patients' infections were documented.

We compiled the following information for each outbreak identified: year investigated, state(s), health care setting(s), specialty of the implicated health care professional, implicated medication(s), infection type(s), number of patients with documented or suspected infection, mechanism(s) of diversion, and resolution of the investigation. We relied on case definitions developed by investigators for each specific outbreak when enumerating the number of infected patients. Typically, case definitions were based on results of laboratory testing and temporal associations between health care exposures and symptom or infection onset among affected patients.

Patient notification, with recommendations for blood-borne pathogen testing, is often performed when health care–associated viral hepatitis transmission risks are identified. For outbreaks of HCV infection, we compiled information about the number of facilities performing notification and the number of potentially exposed patients, using information from media reports and other sources that were available online or in our files.

RESULTS
We identified 6 outbreaks of infections that resulted from drug diversion by health care personnel in US health care settings in the past 10 years. Two outbreaks resulted in gram-negative bacteremia in 34 patients; the remaining 4 outbreaks resulted in HCV infection in 84 patients. All of the outbreaks occurred in one or more hospitals; these facilities were located in 8 states. Tampering with injectable controlled substances was documented or suspected in all of the outbreaks; fentanyl was diverted in at least 4 of these events.

Implicated health care professionals included 3 technicians and 3 nurses (including 1 certified registered nurse anesthetist [CRNA]); 2 of the health care professionals were
women.\textsuperscript{10,11} Four of the health care professionals were documented to be infected with HCV. Of the remaining 2 health care professionals, 1 was tested in the midst of the outbreak and did not have hepatitis B virus, HCV, or human immunodeficiency virus\textsuperscript{12}, blood-borne pathogen testing was either not performed or not reported for the other health care professional.\textsuperscript{10}

**Summary of Bacterial Outbreaks**

**Illinois Hospital, 2006.** From January 1 through July 15, 2006, 9 medical-surgical patients at an Illinois hospital had development of *Achromobacter xylosoxidans* bacteremia.\textsuperscript{10} All of the infected patients received morphine via a patient-controlled analgesia pump (PCA) before bacteremia developed. Having a PCA pump cartridge started by one nurse was statistically significantly associated with becoming a case-patient. This nurse was the only nurse on the unit who worked during the period from hospital admission to before fever onset for all 9 cases. Investigators hypothesized that the nurse may have substituted contaminated water for the morphine or used contaminated needles or syringes to extract the morphine from cartridges. The nurse resigned from the hospital upon being informed of the association with *A. xylosoxidans* bacteremia. The state licensing board was informed, but no disciplinary action was taken.

**Minnesota Hospital, 2011.** Gram-negative bacteremia developed in 25 surgical patients at a Minnesota hospital between October 2010 and March 2011.\textsuperscript{12,13} The predominant pathogens identified in blood cultures from infected patients were *Klebsiella oxytoca* and *Ochrobactrum anthropi*. The 6 infected patients initially identified all received hydromorphone via a PCA. The identification of the same bacteria in 2 patients’ blood and 2 hydromorphone bags in use by these patients led to concerns about possible drug diversion as the source of the outbreak. A review of automated dispensing logs identified a nurse who had an access rate several times greater than that of any other staff during the outbreak period. This nurse admitted to tampering with narcotic bags from locked narcotic boxes. The nurse reported peeling back the foil covering on the tops of bags containing drugs such as hydromorphone, withdrawing narcotic with a syringe, and then placing displaced liquid with saline solution, and returning the bags to the lock box. *O. anthropi* was found in a saline bottle collected from the nurse’s desk. The nurse was removed from practice and, in 2012, pled guilty to obtaining a controlled substance by fraud and was sentenced to 2 years in prison.

**Summary of HCV Outbreaks**

**Texas Hospital, 2004.** Between July and October 2004, 16 surgical patients at a Texas hospital had development of HCV infection (CDC, unpublished data, 2004).\textsuperscript{14-16} All 16 patients had received care from an HCV-infected CRNA. The 2 index patients were detected in September 2004 when acute HCV infection was diagnosed following surgical procedures on consecutive days in August 2004. The infected CRNA was identified early in the investigation as a result of health care personnel testing that targeted surgical staff who had cared for the first 5 infected patients identified. The CRNA denied having engaged in diversion activities but was suspended from clinical care duties and was offered treatment for HCV infection. The CRNA left Texas and went on to practice in other states. In 2009, the CRNA admitted to diverting fentanyl by a variety of methods. One of those methods involved removing portions of fentanyl from vials that were designated for an impending patient procedure; a syringe was used to transfer this fentanyl to a vial kept for personal use, which was likely contaminated with the CRNA’s blood. Reportedly, the remainder of the fentanyl in the patient’s vials was then administered to patients using the same syringe that was used to make the transfer. This mechanism of transmission by indirect syringe reuse, involving accessing contaminated vials or containers, has been well documented in other viral hepatitis outbreaks associated with health care and injection drug use.\textsuperscript{17,18} Epidemiological and laboratory evidence indicated that the CRNA became infected, sequentially, with 2 different strains of HCV from chronically infected patients and subsequently transmitted them to susceptible patients. The CRNA pled guilty to aggravated assault and possession of a controlled substance by fraud and, in 2009, was sentenced to 41 months in prison.

**Florida Hospital, 2008.** Five interventional radiology patients at a Florida hospital had
The development of HCV infection.\textsuperscript{19,20} The 3 initially detected patients were identified between January 2007 and December 2008; none were identified because of symptomatic infection. Rather, 2 were organ transplant patients identified through routine screening conducted as part of facility protocols, and 1 was identified through evaluation of an unexplained increase in liver enzymes. All had previously negative HCV RNA test results. Through molecular analysis, the HCV isolates from the patients were found to be genetically related, further supporting the likelihood of health care-associated transmission. Record review of these 3 patients revealed that all had received fentanyl in the interventional radiology unit of the hospital. Twenty-one employees assigned to the interventional radiology area were recorded as being at work when these patients received fentanyl and submitted blood specimens for testing. A radiology technician was found to be infected with an HCV strain that was genetically related to the patient isolates. The technician reported the following methods of diversion: (1) removing syringes containing residual fentanyl from used sharps containers and (2) self-administering fentanyl from a syringe that had been filled in anticipation of patient care, refilling the syringe with saline, and returning the syringe to the patient care area. The technician pled guilty to tampering with a consumer product resulting in death, tampering with a consumer product resulting in serious bodily injury, and stealing fentanyl by deception and, in 2012, was sentenced to 30 years in prison.

\textbf{Colorado Hospital, 2009:} Hepatitis C virus infection developed in 18 surgical patients at a Colorado hospital (Colorado Department of Public Health and Environment [CDPHE], unpublished data, 2010).\textsuperscript{19} Two cases of acute HCV infection were initially reported to the health department in April 2009. Both patients denied traditional risk factors for HCV infection but had undergone surgical procedures at the same hospital during their exposure period and shared a common HCV genotype. An HCV-infected surgical technician, who had recently been terminated for suspicion of narcotics diversion, was identified early in the investigation as a possible source of the infections. Following termination from the hospital, the technician had gained employment at an ambulatory surgical center. The technician reported removing predrawn syringes of fentanyl from unattended anesthesia carts, self-injecting the fentanyl, refilling the syringes with saline, and returning the syringes to the cart. The technician pled guilty to tampering with a consumer product and obtaining a controlled substance by deception and, in 2010, was sentenced to 30 years in prison.

\textbf{New Hampshire, Kansas, and Maryland Hospitals, 2012:} Forty-five cardiac catheterization/interventional radiology patients from 4 hospitals in 3 states had development of HCV infection.\textsuperscript{12,21} An HCV-infected traveling radiology technician was part of a cluster of HCV-infected patients reported to the health department by a single New Hampshire hospital in May 2012. The technician was suspected as the source of the outbreak on the basis of factors including review of work schedule and key card access, reports of behavior concerning for drug abuse, suspected duration of the outbreak, and results of molecular testing. The technician eventually admitted to stealing syringes filled with narcotics, self-injecting, refilling them with saline, and placing them back into the procedure area. This act had been repeated at multiple hospitals over several years. The technician pled guilty to tampering with a consumer product and obtaining controlled substances by fraud and, in 2013, was sentenced to 39 years in prison.

\textbf{Patient Notification and Blood-borne Pathogen Testing:} Patient notification and blood-borne pathogen testing was described for the 4 HCV outbreaks.\textsuperscript{19,22-25} (CDC, unpublished data, 2004, 2013; CDPHE, unpublished data, 2010) (Table 1). These activities supported case-finding efforts as part of the public health investigations. In each of these instances, additional cases of documented HCV transmission, reflected in the total case counts described previously, were identified. In total, nearly 30,000 patients were determined to have been potentially exposed and were targeted for notifications advising blood-borne pathogen testing. Of note, the number notified may have been less than the number potentially exposed: for example, patients who had died in the interval.
between the potential exposure and patient notification were not always included in the actual notifications. In 3 of the outbreaks, because of concerns about previous or ongoing diversion activities, patient notification expanded beyond the facility where the outbreak was detected to include other facilities where the implicated health care professional had worked or was working (CDC, unpublished data, 2004, 2013; CDPHE, unpublished data, 2010).1,22–25

**DISCUSSION**

Over the past 10 years, outbreak investigations have documented more than 100 infections and nearly 30,000 potentially exposed patients stemming from drug diversion in US health care facilities. The frequency with which these events have been detected appears to have increased; using similar methods, we identified 3 additional US outbreaks of this type in the previous 20 years.26–28 For HCV, drug diversion has emerged as the leading cause of health care transmission between infected health care professionals and patients.29 All of the outbreaks described herein involved diversion of injectable controlled substances, with contamination and infections resulting from some form of tampering by the implicated health care professional. A variety of health care professionals were implicated in these outbreaks; 3 of the 6 were employed as technicians who lacked authorized primary access to the diverted medication. In most of these events, diversion was not suspected or identified by the affected facilities until many patients had become infected. In several cases, implicated health care professionals were able to gain subsequent employment at other health care facilities, despite evidence or concerns about diversion. As a result, thousands of additional patients were placed at risk.

These outbreaks highlight gaps in the prevention, detection, and response to drug diversion in US health care facilities. Under Title 21, CFR Section 1301.71(a), the Drug Enforcement Administration (DEA) “requires that all registrants provide effective controls and procedures to guard against theft and diversion of controlled substances.”30 In their Conditions

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**TABLE 1. Summary of Patient Notification Efforts for Outbreaks of HCV Infection Associated With Diversion of Narcotics by HCV-Infected Health Care Personnel**

<table>
<thead>
<tr>
<th>Year investigated</th>
<th>State(s) that notified patients</th>
<th>Time period for potential exposure</th>
<th>No. of health care facilities that notified patients</th>
<th>No. of potentially exposed patients</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>Texas, District of Columbia</td>
<td>2004-2006</td>
<td>3: Hospital where the outbreak was initially identified; hospital where the CRNA worked at the same time as the outbreak hospital; and hospital where the CRNA worked after the outbreak hospital was initially identified</td>
<td>1497: 1135 patients at the outbreak hospital and 362 patients at the 2 additional hospitals</td>
<td>CDC, unpublished data, 2004</td>
</tr>
<tr>
<td>2008</td>
<td>Florida</td>
<td>2004-2010</td>
<td>1: Hospital where the outbreak was initially identified</td>
<td>6132</td>
<td>19</td>
</tr>
<tr>
<td>2009</td>
<td>Colorado, New York</td>
<td>2007-2009</td>
<td>3: Hospital where the outbreak was initially identified; ASC where the surgical technician worked after the outbreak hospital; and hospital where the technician worked before the outbreak hospital was initially identified</td>
<td>8770: 4718 patients at the outbreak hospital; 1222 patients at the ASC, and approximately 2800 patients at the additional hospital</td>
<td>22, Colorado Department of Public Health and Environment, unpublished data, 2010</td>
</tr>
<tr>
<td>2012</td>
<td>Arizona, Georgia, Kansas, Maryland, Michigan, New Hampshire, New York, Pennsylvania</td>
<td>2005-2012</td>
<td>16: Hospital where the outbreak was initially identified and 15 hospitals where the radiology technician worked before the outbreak hospital was initially identified</td>
<td>&gt;12,000 patients; 4719 patients at the outbreak hospital and more than 7,500 patients from the 15 additional hospitals</td>
<td>1,23,25, CDC unpublished data, 2013</td>
</tr>
</tbody>
</table>

1ASC = ambulatory surgical center; CRNA = certified registered nurse anesthetist; HCV = hepatitis C virus.
2Exact number of patients notified at all 15 hospitals not available.
of Participation for hospitals, the Centers for Medicare and Medicaid Services requires that "drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area."31 Injectable schedule II drugs, primarily fentanyl, were implicated in all of the outbreaks included in this review. In 3 of the outbreaks, technicians were able to access syringes of fentanyl that had been prepared and left unlocked in an operating room or procedure area in anticipation of a patient's procedure. In these instances, health care personnel may have believed these fentanyl syringes did not need to be kept in a locked container while they were outside their immediate possession, perhaps because they considered the area itself to be secure (ie, access restricted to health care personnel). However, in this period of time, the addicted technicians were able to remove the syringes and replace them with decoy syringes (eg, syringes they had previously used and filled with another clear solution such as saline or water). Of note, unseal injection practices involving various forms of syringe reuse represent a well-documented mechanism of blood-borne pathogen transmission in US health care settings.17

In addition to adhering to the basic Centers for Medicare and Medicaid Services and DEA controlled substance security requirements, strategies founded on technological advances hold promise in prevention and early detection of diversion. These include tamper-resistant and tamper-evident syringes, automated dispensing cabinets with security features that allow for control and tracking of drug distribution, algorithmic auditing of pharmacy and other dispensing records, and testing to verify the identity or concentration of wasted drugs (ie, unused drugs that are returned to pharmacy or discarded by health care personnel). Several of the outbreaks involved syringe substitutions; tamper-resistant or tamper-evident syringes may have prevented this type of deception (ie, passing off syringes that had been used for self-injection as unused fentanyl syringes). Of course, simple actions like preparing medications as close as possible to the time of administration and properly labeling predrawn syringes to include patient name can also make it more challenging for health care personnel to tamper with or swap predrawn syringes. During investigation of the Minnesota outbreak, review of access records from an automated medication dispensing system identified a nurse who had an access rate several times greater than that of other staff.12 Routine review of access records as a component of diversion prevention programs, absent an identified outbreak, may help detect diversion and prevent further harm.
Health care facilities need sound policies and systems to address suspected or confirmed diversion activity, in addition to systems addressing primary prevention (Table 2). Although appropriate personnel actions and treatment referrals are important considerations when responding to diversion events, patient harm and risk mitigation should also be prioritized. To prevent further risk to patients at the facility, initial steps include removing the implicated health care professional from the clinical environment and revoking any previously authorized access to controlled substances pending further investigation. In addition, the facility should ascertain the specific types of medications diverted and the mechanisms of diversion used by the health care professional. If injectable medications were diverted and tampering is suspected, it is highly recommended that the health care facility pursue blood-borne pathogen testing of the implicated health care professional. The need for patient notification is best assessed in consultation with the local or state health department and guided by information gathered about mechanisms of diversion (eg, was tampering involved?) and results of the implicated health care professional’s blood-borne pathogen testing. In addition, other forms of disclosure or reparations may be warranted (eg, to ensure that patients and their insurance companies were not improperly billed for medications that were never administered).

Early engagement of state and federal regulatory bodies (eg, DEA, Federal Bureau of Narcotics, Food and Drug Administration Office of Criminal Investigations, pharmacy and licensing boards), as well as local law enforcement, is also critical. Such reporting may facilitate better tracking and identification (eg, via preemployment background checks) of health care personnel who have diverted, with protection of “downstream” facilities. Current systems such as the National Practitioner Data Bank may require enhancements to better address oversight of all health care personnel (including technicians or other categories not holding controlled substances registrations) and the timeliness of action taken to investigate or manage reported concerns. The multi-state outbreak of HCV infections identified in New Hampshire is the most recent example of a health care professional being able to repeatedly gain employment, even after diversion had been strongly suspected or documented by previous employers. The New Hampshire hospital has filed suit against the staffing agencies that employed the implicated technician, alleging that their “actions, including failing to report [the technician] for improper conduct, enabled him to secure employment in [New Hampshire].” Facilities will benefit from ensuring that they are aware of state and federal reporting requirements when diversion is identified (eg, requirement to notify the DEA Field Division Office in their area, in writing, of the “theft or significant loss of any controlled substance” within 1 business day of the discovery of such loss or theft) and protections offered (immunity statutes) regarding disclosure of adverse information to prospective employers.

The outbreaks summarized in this article are likely an underestimate of the burden of infections resulting from diversion in health care settings. We did not include outbreaks occurring outside the United States that may have been associated with diversion. Further, linking health care–associated infections to drug diversion, which itself may be difficult to detect, can be incredibly challenging. For example, most patients with HCV infection do not experience symptoms of acute disease, and infections may go undetected for years, making it difficult to identify an exposure window or likely source of their infection. For most of the HCV outbreaks reported herein, confirmed case definitions relied on advanced molecular testing demonstrating genetic relatedness between the virus of the implicated health care professional and infected patients. However, many patients had died or had evidence of resolved infection at the time the outbreak was detected and patient notification was performed. Thus, additional patients may have been part of the outbreak but were not included as confirmed cases.

In addition to underestimating the burden of infections resulting from diversion, this summary also does not adequately reflect the frequency of diversion by health care personnel or other harms resulting from this activity. There are no reliable national estimates of the prevalence of drug diversion activities by health care personnel in the United States. However, one useful data point comes from a recent study that examined substance abuse disorders among anesthesia residents; the prevalence rate...
was nearly 1%, with fentanyl and other intravenous opioids accounting for 57% of reports.\textsuperscript{45} From a state perspective, a task force in Minnesota identified 345 events of theft or loss of controlled substances reported to the DEA during 2005-2011.\textsuperscript{46} These numbers only reflected the events that were actually identified and reported, thus representing a lower bound estimate. Nonetheless, 39% of the Minnesota events involved intravenous or intramuscular medications; depending on the methods used to divert, some may have posed risks similar to those in the reported outbreaks.

The outbreaks summarized herein illustrate some of the devastating and wide-reaching impacts of drug diversion in US health care settings. Health care facilities should ensure that patients safely receive medications as prescribed. This effort includes having systems in place to prevent drug diversion as well as developing protocols for early detection and appropriate response if, despite safeguards, diversion does occur. Appropriate response includes assessment of potential for patient harm, including consultation with public health officials when diversion involving tampering with injectable controlled substances is suspected. Prompt reporting to enforcement agencies and applicable licensure/credentialing bodies should be pursued when any form of diversion is identified to help mitigate risks including exposure to potential liability for subsequent actions by the implicated health care professional. Actions by state licensing boards and other legal mechanisms may be required to prevent health care professionals with a history of drug diversion from perpetrating similar acts elsewhere.

CONCLUSION
Outbreaks of HCV and other infections have highlighted the need for system-wide improvements to address the problem of drug diversion in the health care community. Basic patient safety depends on effective, reliable safeguards to maintain the security of injectable medication in any health care setting.

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Abbreviations and Acronyms: CDC = Centers for Disease Control and Prevention; CDPH = Colorado Department of Public Health and Environment; CRNA = certified registered nurse anesthetist; DEA = Drug Enforcement Administration; HCV = hepatitis C virus; PCA = patient-controlled analgesia pump

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