

ORIGINAL RESEARCH

The Prevalence and Determinants of Controlled Substance Discrepancies in a Level I Trauma Hospital

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BACKGROUND: Healthcare institutions are often faced with challenges and accreditation requirements for improving treatment quality, reducing waste, and avoiding diversion of drugs, particularly controlled substances. Many automated systems have replaced manual systems but may be fraught with challenges, especially when multiple users are involved.

OBJECTIVE: To describe the characteristics of controlled substance discrepancies observed in a Level I trauma hospital for Medicare.

METHODS: Discrepancy data were captured for each user involved in a transaction for a controlled substance at the Level I trauma hospital (in Ben Taub Hospital, Houston, TX), and the information was stored in a computerized database repository. Data for the 1-year study period (from January 1 through December 31, 2013) were collected for Medicare beneficiaries, using an Excel 2013 spreadsheet, and were analyzed according to basic discrepancy characteristics and descriptive statistics.

RESULTS: During the 12-month study period, 114,000 controlled substance discrepancies were found for 100,000 Medicare patients at this Level I trauma hospital. Vending activities accounted for the majority (52.6%) of these discrepancies. Discrepancies were most likely to occur on Wednesdays, and the medications involved most frequently were combination drugs of hydrocodone and acetaminophen.

CONCLUSION: Approximately 1 (1.14) discrepancy involving a controlled substance occurred for each Medicare patient treated at the study facility. Healthcare institutions need to improve their efforts to ensure high-quality care and prevent diversion of drugs.

KEY WORDS: automated dispensation, controlled substances, discrepancies, drug diversion, Level I trauma hospital, Medicare patients

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According to the American Trauma Society, a Level I trauma center is a comprehensive tertiary-care facility capable of providing total care for every aspect of injury ranging from prevention to rehabilitation.¹ A Level I trauma hospital offers 24 hours a day, 7 days a week in-house care by surgical and medical specialties. Automated dispensing cabinets (ADCs) are popular among hospitals; numerous health centers use these cabinets for the storage and dispensation of medicines. Healthcare systems have relied on ADCs as a way to capture activities related to the dispensation of medicines, especially controlled substances.²

Historically, hospitals have grappled with the prob-

lem of drug diversion, especially with controlled substances. ADCs have helped significantly in monitoring quality-assurance data, particularly related to dispensation and diversion of controlled substances. Although periodic ADC activities have often generated discrepancy data, the degree to which hospitals are aware of these data, including any relationship to the diversion of controlled substances, is not clear.

ADCs allow for systematic monitoring of access to controlled substances, audits, and easier access to medication withdrawal and storage.² Other benefits include security of drugs and electronic capture of drug waste and expiration dates.^{3,4} A discrepancy occurs when the expected count and the actual count of a substance are not identical.^{4,5} A discrepancy may be identified during manual inventory, medication removal, the medication refill process, and other processes common in the dispensation of medication.^{4,5}

As of February 2014, Ben Taub Hospital in Houston, TX, which contains 727 beds (including swing beds), reported 210,572 inpatient days. The inpatient utilization

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KEY POINTS

- Healthcare institutions are expected to avoid diversion of drugs, especially controlled substances, through effective policies and monitoring.
- This study analyzed discrepancies related to controlled substances based on Medicare data for a Level I trauma hospital.
- Approximately 1.14 discrepancies occurred for each Medicare patient treated at the center.
- The oral combination of hydrocodone and acetaminophen (5 mg/325 mg) was most often associated with discrepancies in this study.
- As a group, intravenous agents were associated with slightly more discrepancies than oral medications.
- Vending activities accounted for the largest rate (52.6%) of discrepancies.
- More discrepancies occurred in the morning shift than in the afternoon or night shift.
- Healthcare institutions must improve efforts to prevent diversions of controlled substances.

statistics at the time the study data were analyzed (using the American Hospital Directory of the hospital⁶) by type of medical service, showing a total of 2160 Medicare patients. Medicare patients were selected for this study because (1) the statistics for this patient population were relatively consistent in the documents evaluated and (2) Ben Taub Hospital serves a disproportionately high rate of Medicare, Medicaid, and indigent patients.

This article describes the characteristics of controlled substance discrepancies found at this Level I trauma hospital among Medicare patients, with an average inpatient daily multisystem census of approximately 674.⁷ “Multisystem” refers to Ben Taub Hospital, as well as to immediate hospital affiliates, such as the psychiatric arm. “Census” refers to the average daily inpatient bed occupancy for the hospital and its immediate affiliates, such as the psychiatric hospital (which is part of Ben Taub Hospital), and is usually done on a month-to-month basis. Findings from the analysis may help to ensure proper accountability in the utilization of controlled substances.

Methods

Discrepancy data captured from the Pyxis CII Med-Station (CareFusion, San Diego, CA), the type of ADC used at Ben Taub Hospital, was recorded automatically in CareFusion Analytics reports for the year 2013 (January 1-December 31).⁶ The data contained all old (un-

resolved) and new hospitalwide cases captured by the ADC on transactions involving controlled substances (CII-CV), as classified by the Drug Enforcement Administration (DEA). Drugs that required additional controls (at that time), such as tramadol, according to the Texas State Board of Pharmacy or the Texas Department of Public Safety, were included in the study.

The discrepancies were categorized according to the type of transaction being performed when the discrepancy occurred. Transaction types included vending, cancellation, inventory, loading and unloading the controlled substance into the ADC machine (Pyxis), refill, and stock/expired return items.

Of note, the controlled substances most often associated with discrepancies were identified to examine potential relationships with diversion and to determine avenues to eliminate the discrepancies. All discrepancies in the descriptive analysis relate to the previous user activity; that is, discrepancies created by a previous Pyxis user. This assumption was made based on the hospital's policy for controlled substances.⁵ Several other characteristics were analyzed, including time of day, day of week, route of administration, and dosing types.

Time of day of previous activity. Per policy,⁵ previous activity refers to the previous user activity, which is assumed to be responsible for creating the discrepancy; the new user typically discovers the discrepancy. The time of each discrepancy was categorized by the day shift. The shifts were defined as morning shift (6:45 AM-3:15 PM), afternoon shift (3:16 PM-11:15 PM), and night shift (11:16 PM-6:44 AM). This analysis was performed to examine if any particular shift recorded an unusual prevalence of discrepancies.

Table Characteristics of Controlled Substance Discrepancies, by Type of Transaction

Type of transaction	Discrepancy found, N (%) ^a
Cancellation	323 (13.1)
Expired item	12 (0.5)
Inventory	308 (12.5)
Load/unload	22 (0.9)
Refill	277 (12.2)
Return item	173 (7.0)
Stock item	10 (0.4)
Missing information	44 (1.8)
Vending	1299 (52.6)
Total	2468

^aThe percentages exceed 100%, because of rounding.

Day of the week. Discrepancies were categorized by day of the week to compare data for the various days, to determine whether any particular day was associated with a higher rate of discrepancy, and to examine causal factors (if any) that may contribute to an increased rate of discrepancy.

Route of administration. The route of administration was also assessed to see if there was a specific dosage form (eg, oral, injection) that was more likely to be involved in controlled substance discrepancies.

Type of drugs with highest rates of discrepancy. The study reviewed the 10 substances (individual doses) associated with the highest rates of discrepancy.

Results

Among the 367,799 transactions for controlled sub-

stances during the 1-year study, 2468 discrepancies were captured, representing an annual incidence rate of 0.67% (discrepancies per transaction). Data were exported to an Excel spreadsheet (Windows, version 2013; Microsoft, Redmond, WA) to examine the epidemiology of the discrepancies.

The **Table** shows baseline characteristics of the discrepancies for the study year, grouped by the action of the previous Pyxis user (ie, the action of the person who created the discrepancy). More than half (52.6%; N = 1299) of the discrepancies occurred during a regular vending activity. “Vending activity” denotes the action of a registered user (in most cases, a nurse) who signs out a routine medication to be administered to a patient. Inventory activities accounted for 12.5% of discrepancies, just behind cancellations (13.1%).

The greatest number of discrepancies (N = 1176; 47.6%) occurred in the morning shift (**Figure 1**). The afternoon shift had nearly twice as many discrepancies as the night shift (825 vs 467, respectively). The day of the week associated with the highest rate of discrepancies was Wednesday (18.3%; N = 452; **Figure 2**).

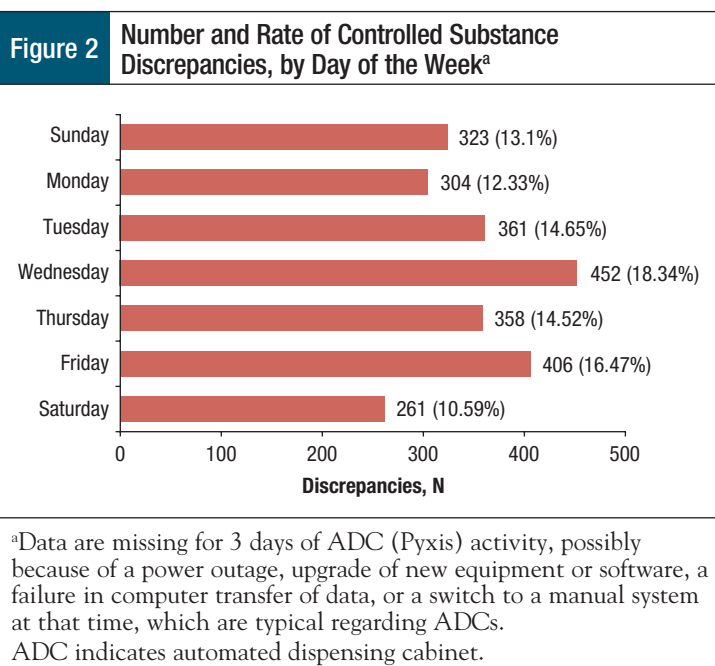
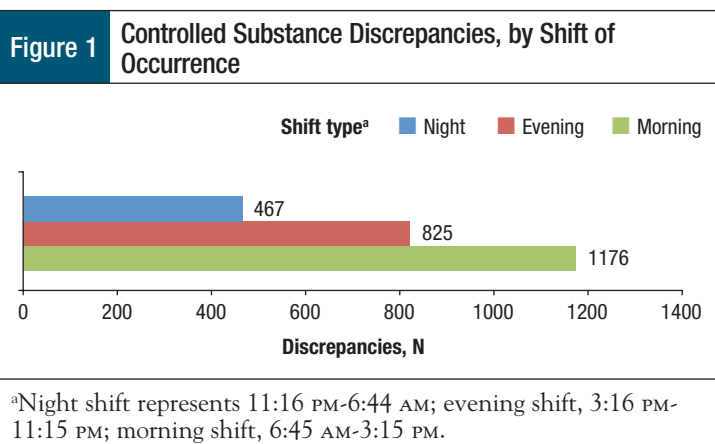
Saturday was associated with the lowest rate (10.6%; N = 261). In other words, a controlled substance discrepancy is least likely to occur on a Saturday and most likely to occur on a Wednesday (odds ratio [OR], 0.577; confidence interval [CI], 0.9-0.99). The reason for this, however, is not clear. The average discrepancy rate for weekdays was 15.3% (OR, 1.288; CI, 0.9-0.99), and the rate for weekends was 11.8% (OR, 0.778; CI, 0.9-0.99).

The 10 controlled substances with the highest rates of discrepancies are listed in **Figure 3**. The substance most often implicated was the hydrocodone plus acetaminophen combination (5 mg/325 mg), representing 370 incidents (15% of discrepancies). The combination of hydrocodone and acetaminophen, 10 mg/325 mg, was also among the top 10 controlled substances with diversions. These medications (formulations of the same drugs) represent more than 33% of the discrepancies found for the 10 top drugs on the list.

Figure 4 shows that the rate of discrepancy of controlled substances in this hospital setting was similar for intravenous (IV) and orally administered substances: 52% versus 48% (1260 vs 1186), respectively. IV formulations were slightly more likely (OR, 1.08) than oral formulations to be involved in a discrepancy. The injectable agents with the most discrepancies were morphine sulfate (4-mg and 2-mg vials), fentanyl (100-mcg injection), and midazolam (2-mL vial) (**Figure 3**).

Discussion

Inventory discrepancies arise from errors in controlled substance counting, whereas vending discrepancies arise



from errors in dispensing a controlled substance agent from the ADC. Refill-related discrepancies result from errors in refilling the ADC with the drug.

Discrepancy by Type of Activity

Because vending activity accounted for most (52.6%, N = 1299) of the discrepancies captured, it is necessary, at least from the safety standpoint, to ensure that patients are being “vended” the correct medication and strength. Therefore, clinicians must be more careful when withdrawing a controlled substance (or any other) medication from an ADC.

Discrepancy by Shift

The morning shift had more discrepancies than any other shift, accounting for 47.6% of all discrepancies. A plausible but anecdotal explanation could be that more treatment-related and dispensing activities occur during the morning shift, whereas the activities during other shifts relate more to maintenance therapies.

Discrepancy by Drug

Anecdotal and published data have suggested a link between discrepancies and drug diversion, especially in community pharmacies.^{4,8} Thus, it was not surprising that the hydrocodone plus acetaminophen, 5-mg/325-mg oral combination, a DEA schedule 2 controlled substance, was the drug (and drug strength) most often associated with discrepancies in our study, accounting for 15% (N = 370) of discrepancies. When these data are combined with the other available formulary strength of hydrocodone plus acetaminophen (10 mg/325 mg), in the same facility, the discrepancies increase by approximately 5%. Therefore, hydrocodone plus acetaminophen may be the most diverted of any scheduled controlled substance in the US health-care system setting, particularly the 5-mg/325-mg strength. Moreover, hydrocodone plus acetaminophen ranks among the most prescribed drugs in the United States.^{9,10}

This oral combination drug also has been implicated in medication-related adverse events, diversions, and abuse in the inpatient and outpatient pharmacy settings, with much higher rates of all 3 occurring in outpatient pharmacy facilities.⁸⁻¹⁰ As a matter of policy, all hospitals should define a maximum time frame between the retrieval and the administration of a controlled substance.¹¹

Discrepancy by Route of Administration

Although it may be assumed that oral medications, because of convenience, would be associated with more discrepancies than drugs administered by other routes, our study showed that, as a group, IV formulations were associated with slightly more discrepancies among controlled substances than oral agents (Figure 4). The oral combina-

Figure 3 Top 10 Drugs Involved in Controlled Substance Discrepancies During the Study, by Specific Dose

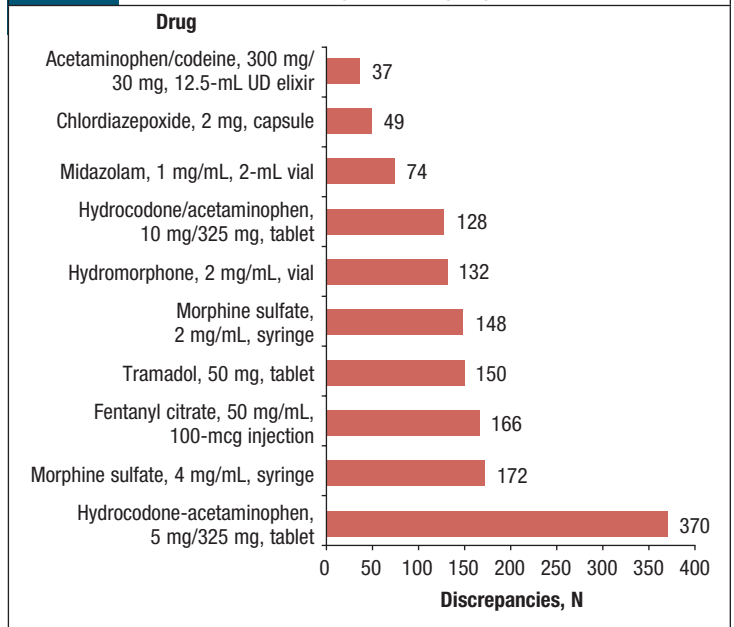
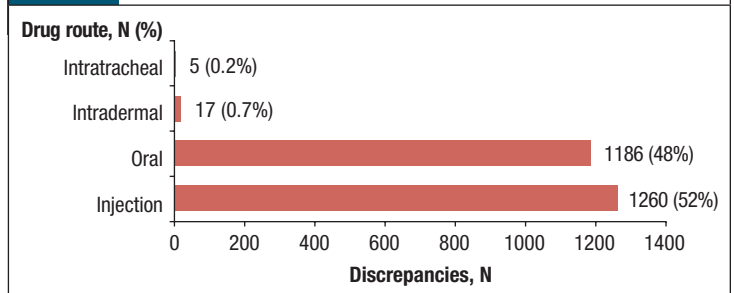


Figure 4 Controlled Substance Discrepancies, by Drug Route and Percentage



tion of hydrocodone and acetaminophen had the most discrepancies in terms of individual drugs or doses. However, when the drug discrepancies are grouped according to their routes of administration (or their dosage forms), the injected drugs (IV/subcutaneous) outnumber the oral drugs (Figure 4).

Among the injectable agents, morphine sulfate (2-mg and 4-mg syringes), fentanyl (100-mcg injection), and midazolam (2-mL vial) had the highest discrepancies (Figure 3). These agents also are the most frequently used drugs in operating rooms according to anecdotal observations at our hospital.

Our observations also showed that common sources of discrepancies for injectable controlled substances were associated with activities related to anesthesia and the operating room. The magnitude of discrepancies related to injectable formulations is a noteworthy finding of this

study. Hospital administrators should therefore pay more attention that DEA-scheduled injectable drugs are a very likely source of drug diversion rather than only orally prescribed drugs.

The utilization of controlled substances may require further measures of accountability in a hospital operating room setting. The findings of this study indicate that healthcare institutions must find better ways to ensure compliance with controlled substance policies and to minimize the risk of diversion and abuse, particularly because of safety issues surrounding the utilization of controlled substances in hospitals.

Detection and prevention of diversion may sometimes be difficult, and multiple factors are often involved. Therefore, a challenge for healthcare institutions becomes the ability to track and address this issue effectively.

Diversion has many consequences aside from medical effects, including legal, regulatory, ethical, humanistic, and practical implications.¹² Although our findings do not necessarily imply that drug discrepancies represent diversion, available publications have made connections between controlled substance diversion and ADC discrepancies.¹⁰⁻¹² Detection and prevention of diversion may sometimes be difficult, and multiple factors are often involved.¹⁰ Therefore, a challenge for healthcare institutions becomes the ability to track and address this issue effectively among healthcare professionals, while trying to achieve a balance with trust.¹³

Discrepancy by Day of the Week

It is important to note that maintaining weekly inventories for controlled substances tends to deter diversion, but such practices have also resulted in additional discrepancies.⁸ In our study, the preponderance of discrepancies on Wednesdays may in part be a factor that the drug inventories in this trauma hospital typically are conducted on Wednesdays.

Limitations

The drug inventory schedule in this trauma hospital may not be a limitation of the study, but it may represent a confounding variable, because inventory-related discrepancies also were detected in this study (Table).

IV formulations of controlled substances, such as midazolam, are frequently used in operating rooms; therefore, they might have disproportionately related to discrepancies in this study. Our data do not differentiate

between “true” discrepancies (which relate more to drug diversion) and “false” discrepancies (which relate less to diversion). Per Harris Health System’s policy,⁵ a true discrepancy is a discrepancy that has been investigated and is not related to a miscount or cannot be accounted for, whereas a false discrepancy is one that has been investigated and found as a result of a miscount or that can be accounted for. A true discrepancy may involve a discrepancy that was duly investigated and was discovered to have occurred, whereas a false discrepancy may manifest purely as a miscount.⁵ Controlled substance discrepancies are often related to drug diversion, and tracking and addressing this problem among professionals in hospital settings can be difficult, as noted earlier.

At the time of this study, tramadol was not a DEA-scheduled drug. However, most trauma centers and trauma hospitals, such as this one, had established additional safeguards for this drug, including policies aimed at preventing its diversion.

Conclusion

Based on our findings, as well as the size of the inpatient Medicare population, the estimated prevalence of total discrepancies for controlled substances is 1.14 per Medicare patient. This means that for every Medicare patient in this trauma hospital, there were at least 1.14 controlled substance discrepancies. In addition, the discrepancy rate per inpatient hospital day was 1.17%. Vending activities accounted for the majority of controlled substance discrepancies in this hospital. These findings suggest that trauma centers and hospitals need to improve their policies to prevent diversion of controlled substance drugs. ■

Author Disclosure Statement

Dr Anyanwu and Dr Egwim have no conflicts of interest to report.

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STAKEHOLDER PERSPECTIVE

Dramatic Increase in Misuse of Controlled Substances a Concern for All Stakeholders

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The prevalence and increasing use and subsequent misuse of controlled substance medications in the United States is dramatic and disconcerting. The major contributing class of agents to this trend is opioid analgesics. In a 2016 review, Wilkerson and colleagues describe the growing epidemic of opioid abuse in the United States.¹ The authors point out that opioids prescribed to treat painful conditions have had a profound increase in subsequent abuse, addiction, overdose, and death.¹ This phenomenon, however, is not restricted to the United States. Karanges and colleagues have recently examined the problem in Australia, noting that the issue is significant but less severe than in the United States and Canada.² David B. Nash has observed that there is little doubt that opioids are effective pain management therapies, but this efficacy comes with a price.³

POLICYMAKERS: The link between inpatient opioid prescribing and long-term use of these agents is concerning and is garnering a significant amount of attention at the federal and the state levels in the United States. Clarke and colleagues suggest a 3-tier approach to the issues surrounding opioid dependence that involves (1) prevention of adverse drug events; (2) promotion of multimodal care; and (3) reduction of misuse, abuse, and diversion of opioids.⁴ Sefali Luthra has recently observed that the costs related to opioid use and dependence have skyrocketed in the United States in the past decade.⁵ The costs for treating opioid-related care amounted to close to \$15 billion in 2012. Finally, according to the Centers for Disease Control and Prevention, at least 50% of all opioid overdose deaths involve a prescription opioid medication.⁶

PHARMACY DIRECTORS/PAYERS: In the current article in this issue of *American Health & Drug Benefits*, Anyanwu and Egwim discuss their extensive

and informative analysis of controlled substance discrepancies conducted in a large Level 1 trauma hospital during a 1-year period.⁷ In their study, they found a disturbing rate of medication discrepancies for prescribed controlled substances, the majority of which were opioid medications, in a Medicare subpopulation of patients over this 1-year period. These findings are presented in a well-constructed research design and analytic study, and point to the additional problem of diversion of controlled substances that occurs in a theoretically safe and well-monitored environment.

This study highlights a substantive additional factor of drug diversion in institutional environments that needs to be addressed when dealing with the opioid epidemic in the United States. Those involved in differing practice environments need to heed the advice of these authors to improve efforts to ensure the proper and safe use and monitoring of controlled substances for ensuring the care and positive outcomes that patients, their families, and society at large deserve. ■

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