Considerations When Tampering Occurs

Patient safety should be a foremost diversion consideration

By Kim New, JD, BSN, RN

In every case of drug diversion at a healthcare facility, the possibility of patient harm exists. Patients may receive substandard care or a paucity of care from an impaired provider. They may have untreated or inadequately treated pain, or be exposed to bloodborne pathogens and other dangerous substances as a result of tampered injectable drugs. Because the risk of harm is measurable, performing a patient harm risk assessment should be a priority part of every diversion response plan.

There are scenarios in which patients are more likely to be negatively affected. Patient harm almost certainly occurs in cases where there is documented pain yet the ordered “prn” medication is diverted. Similarly, when the patient has scheduled pain medication that is ordered to be administered around the clock, diversion of doses is likely to result in harm. Tampering and substitution also result in patient harm should any of the altered drug reach the patient.

Several cases of tampering have been reported recently, including some that raise substantial concerns about the well-being of the patients affected. Tampering can be done artfully and it is not always readily apparent. Even tamper-resistant or tamper-evident safeguards can be bypassed by a savvy diverter.

Make diversion difficult

The best way to address tampering is to hinder the ability of staff to divert. Preventive measures that facilities can employ include requiring a witness for all inventory counts. This prevents a staff member from removing intact stock and substituting tampered stock during the count.

It is also important to limit the number of Patient-Controlled Analgesia (PCA) keys available to staff to the smallest number possible, given the needs of the patient population being served. PCA keys should be stored in a single access compartment in an automated drug cabinet if possible, so staff that are inclined to tamper will know their transactions will be apparent to auditors.

A requirement that returns be witnessed is another way to inhibit the ability to tamper, along with a requirement that all returns go into a designated return bin, versus being returned directly to patient stock.

Using locking cases and portless tubing for continuous controlled substance infusions will help deter tampering at the bedside.

The most basic preventive measure is of course ensuring medications are kept secure at all times from the moment they are removed from the source until they are administered. In clinical settings where opioids are commonly removed in advance of administration, such as procedural and surgical suites, the staff should understand that the risk of tampering increases every moment the medication is left unattended. Medication must be placed in secondary secure storage, such as a locked bedside safe or drawer, or kept in the visual custody of the staff member. Being aware that colleagues could potentially tamper with medication is critical.

Means of detection

There are ways to detect tampering at the drug storage location and remote locations throughout the facility. Regular physical counts of controlled substance stock are one of the best ways to quickly detect tampering. I have
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### Common signs

Some transaction patterns are known to be associated with tampering. They include:

- Repeated cancelled removals of a specific drug
- Repeated returns of a specific drug
- Frequent inventory counts (which allow access to drug supply without registering a transaction)
- Excessively frequent access to Patient-Controlled Analgesia (PCA) keys, or access to PCA keys for patients not under the care of the staff member

### Staff education

Staff should be trained to report therapeutic failure immediately, when pain medication does not appear to have the desired effect. There should be a process in place to secure the medication in question and to inspect remaining stock for signs of tampering.

In one case in a cardiac catheterization lab, a dose of fentanyl seemed not to have any effect. The nurse retrieved another vial from the drug cabinet, also without apparent effect. It was only when a third vial was retrieved in an attempt to treat the patient's pain, that the nurse realized there were needle punctures in the rubber hubs of all the vials in the cabinet. A formal institutional policy should require fully documenting cases of suspected tampering, including photographing the medication in situ, securing it and having it analyzed.

### Conclusion

When diversion by tampering and substitution is suspected, there should be a defined process for assessing for the likelihood that patients have been harmed. The process should include a realistic discussion of the risks. Cases have been reported in which an ER nurse tampered with morphine or hydromorphone stock in a busy ER setting for over a year, yet the institution somehow reached the conclusion that no patients could have been affected.

Facilities should strongly consider offering confidential bloodborne pathogen testing of the diverting staff member in all cases of diversion of injectable medications, to facilitate assessment of the risk of patient harm.

When tampering is confirmed, reporting should be robust, including reporting to the FDA Office of Criminal Investigations (18 U.S.C. § 1365 et seq.), the professional and pharmacy boards, law enforcement and local public health officials, where appropriate. NP

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