White Paper on Controlled Substances Diversion

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Executive Summary

Controlled substances are group of drugs that have in common that they are useful in the treatment of human disease, but also tend to be recreationally abused. Chapter 13 of Title 21 of the United States Code describes what drugs are controlled substances and entitles the Drug Enforcement Agency of the Department of Justice to classify and control these substances to prevent recreational abuse and classifies them into five classes representing varying levels of potential for abuse.

Controlled substances represent a small minority of the population of therapeutic drugs, but represent a significant public health problem because of the patient-safety issues and criminal behavior engendered by recreational users, especially addicts, who may subordinate all other concerns to acquisition of a desired drug.

Because most controlled substances have legitimate medical use, diversion and abuse of these substances by healthcare providers is of particular concern because diverters have legitimate access to these substances as part of their work responsibilities which masks their drug diversion behavior. Drug diversion behavior may deny patients needed care or subject them to significant safety risk. Further, the expectation of mutual trust among healthcare workers may impede detection of diversion.

Drug seeking behavior is highly adaptive; diverters will constantly challenge any control system looking for a way to defeat it and acquire the drugs they seek.

Current automated control systems have tightened security around controlled substances, but diversion still exists. Data captured by these systems has been shown to assist in identifying caregivers who are diverting drugs, but they only process a fraction of the available data, and serve only to stimulate what remains as a highly manual, and inferential forensic process that requires comparison of data from a hoard of documents.

More recent concern has been directed at a growing societal problem of abuse of prescription controlled substances, mostly opioids. A 2016 CDC report indicates that the number of opioid prescriptions has quadrupled and the deaths from opioid overdose have doubled since 2000.[1]

There has been an increase in media attention to diversion and related issues in the year ending in July, 2016, with the number of articles more than doubling.[2]

BD/Carefusion has a clear role to play in the management of diversion of opioids and other controlled substances in acute healthcare institutions. As care moves away from these venues to more ambulatory settings, we expect to find additional opportunities to assist in the management of diversion of controlled substances in the community environment.

Introduction

Title 21 of the United States Code (FOOD AND DRUGS) Chapter 13 (DRUG ABUSE PREVENTION AND CONTROL) authorizes the Attorney General of the United States to identify chemical substances whose potential for abuse require additional controls, to classify those substances as controlled substances, to group those substances and the regulations that affect them by their potential for abuse, and to promulgate laws and regulations surrounding commerce related to those substances with the purpose of controlling inappropriate access to, and use of, these controlled substances.

As described in the above-referenced code, the Attorney General determines what drugs are controlled substances, and in what schedule (I – V) based on the following criteria:

(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled [3]

Thus, a substance is a *controlled substance*, when it is determined to be abusable, has shown a pattern of abuse leading to dependency, and that abuse has been shown to create a risk to public health and safety.

In many instances controlled substances have legitimate medical therapeutic uses, and so may be purchased, stored, dispensed and administered to patients during the treatment of injury or disease. Thus healthcare institutions may be required to maintain stores of controlled substances for these uses, and those stores may attract individuals who wish to use them for other purposes, leading to abuse. Those individuals may be employees of the healthcare institution itself.

Additionally and more recently, prescribing of controlled substances, particularly opiates, for management of pain has seen a precipitous rise, clearly eclipsing heroin addiction. Indeed, it appears that attempts to control access to prescription opioids and to produce pain products that are more resistant to abuse has caused prescription opioid addicts to turn to heroin only when their prescription supplies become unavailable. In some markets, heroin is cheaper, and easier to obtain than prescription opioids.[4]

Similar to the problem of institutional diversion, prescription opioid abuse occurs largely because there are legitimate prescription uses of opioids for pain that may produce tolerance, dependence and addiction in the intended users. Additionally, such legitimate users may become the targets for attack and/or theft.

Community diversion/abuse of controlled substances is distinctive in terms of the sheer volume of medication available for diversion and misuse, as compared to the acute care space.

Common to both cases is the progression from tolerance, to dependence, and finally to addiction with resulting drug-seeking compulsion that eclipses all other considerations in the mind of the addict. In the health-system environment, this presents in behaviors in addicted caregivers that place patient health and safety at risk. In the non-acute environment, this can result in sociopathic behavior to earn the money to purchase medications, prescription "shopping" where money is available, and the theft/diversion of legitimate prescription supplies from their intended users by family and friends or even by individuals who have learned to identify and target patients who routinely purchase prescription pain medication.

Deaths from opioid overdose have reached epidemic proportions.

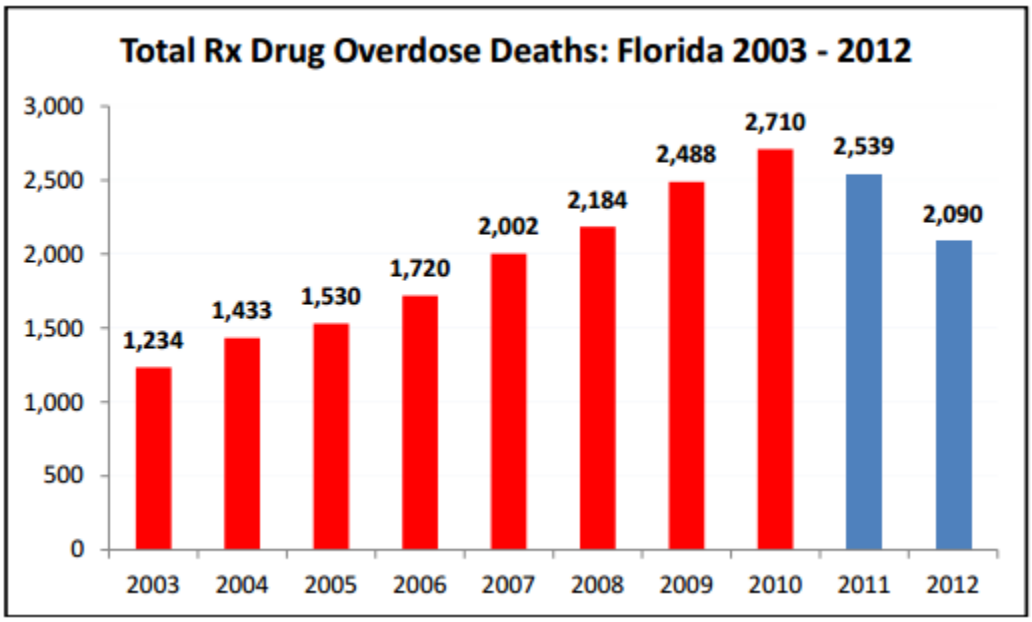

Chart taken from NAAGHELP Report June 25, 2014[5]

Additionally, some specific states (such as Florida) have become the hubs for "pill mills", physicians' offices or clinics that provide opioid prescriptions "…outside of the prevailing standards of medical practice in the community…" Such pill mills may see busloads of patients every day, actively soliciting patient complaints that appear to legitimize the prescribing of opioid pain medication.[6]

Identifying inappropriate prescribing remains troublesome because of the significant place that cancer and the resultant need for aggressive pain management occupies in the American healthcare landscape. The National Cancer Institute estimates that 1,658,210 new cases of cancer will be diagnosed in 2016, and that nearly 40% of individuals will be diagnosed with cancer at some point during their lifetime. Trends associated with cancer (e.g., age and obesity) are clearly increasing.[7]

The Problem of Diversion of Controlled Substances by Healthcare Workers in Acute Care Settings

Diversion of controlled substances by healthcare professionals is an old and chronic problem. Any organization that routinely uses controlled substances for valid therapeutic purposes can become a target for diversion.

Diversion of controlled substances by healthcare professionals can occur within any professions who have routine and appropriate access to these substances. The healthcare professionals with the most frequent access include physicians, nurses, pharmacists and pharmacy technicians. In general, when healthcare workers divert drugs, it is for personal use, and is symptomatic of addiction.[8]

Diversion among nurses was first publicly acknowledged in 1984. Subsequently it was acknowledged that substance abuse among nurses varies between 2% and 18%. A 1998 report from the Cincinnati Police Pharmaceutical Division indicates the arrest of one healthcare professional every six days, among whom 70% were nurses. It is generally recognized that most drug diversion goes undetected, and that the problem is far more prevalent than published statistics represent. [9] It is, in fact, questionable whether there are any reliable statistics on the prevalence of diversion by nurses.[10]

Nurses are not alone in diverting drugs. Anecdotally, this author has experience discovering a diverter on their pharmacy staff, and in attending a variety of State Board of Pharmacy meetings where a significant portion of the agenda was dedicated to discipline of pharmacists and pharmacy technicians for drug abuse and diversion.

Part of the problem in gathering statistics is the level of denial associated with the problem. Hrobak notes that coworkers may ignore signs and symptoms until the signs and symptoms become unmistakable[3]. This author notes having said the words "…anybody on my staff other than him!" about an individual eventually identified and caught.

Thus, while control systems limit the opportunity for diversion, they cannot entirely prevent it. They must, therefore, be accompanied regular programs of analysis looking for patterns of drug acquisition that may indicate that diversion is occurring. Since this behavior is generally driven by personal dependence, diverters constantly stress any control systems intended to prevent such diversion by changing their diversion behaviors to attempt to defeat those controls.[4]

Reports from the University of Michigan describe two different caregivers overdosing in separate parts of the campus on the same day, and a subsequent audit demonstrated nine (out of 2,588) users of the automated dispensing system that should not have had access to that system.[11]

Although it appears that most acute care diversion is for personal use, there are several recent cases in which large numbers of medications worth millions of dollars were diverted from healthcare facilities apparently for sale into the street market.[12,13,14]

Failure to monitor and control diversion has recently been associated with multi-million-dollar fines.[15]

The problem of diversion is not simply economic:

- Diversion activities may result in compromising the integrity, or sterility of sterile injectable medications, creating the possibility of treatment failure and/or nosocomial infections.[16,17]
- Diversion activities may result in recreational use of controlled substances while caring for patients, resulting in compromised medical judgment, poor techniques, oversights, and inadequate documentation, all of which could lead to medical error.
- Diversion activities may result in under-treatment of patient pain, resulting in loss of sleep, agitation, and other discomforts for the patient.
- Diversion activities may result in placing additional workload burdens on companion caregivers, increasing their likelihood of making a mistake.

Controlled substance diversion by healthcare personnel therefore represents a public health risk that needs to be identified, and controlled.[4,18,19] Indeed, recent cases of diversion involving substitution of used syringes refilled with saline for narcotic syringes have resulted in the potential exposure of thousands of patients to Hepatitis C, with clear genomic evidence that such exposure caused disease.[20,21,22]

Identification of Potential Diversion

In general, healthcare providers divert controlled substances by seeming to acquire those substances for legitimate purposes, and then redirecting them for personal use. A number of references describe signs and symptoms that a healthcare worker is diverting drugs.[5,23]

With the advent of electronic cabinets to manage controlled substances inventories, some of these signs and symptoms can be captured from the logs and reporting associated with these devices. These signs might include[2-24]

- Excessive use compared with other caregivers in the same area
- Excessive amounts of wasting compared to other caregivers in the same area
- A tendency to use higher doses for any particular patient in comparison to other caregivers
- A tendency to omit waste cosignature documentation, or significantly delay that documentation
- A tendency to always have waste documented by another high-using caregiver
- Increases in inventory discrepancies compared to other caregivers
- Unusual removal patterns inconsistent with ordered therapy
- Evidence of physical tampering with container packaging noticed during count
- Evidence that patients are not experiencing expected pain relief while under the care of the suspected caregiver (may require additional data sources)
- Evidence that the caregiver is removing drugs, documenting waste, or otherwise interacting with the system when not scheduled to work (may require additional data sources).
- A sudden change (usually an increase) in a caregiver's controlled substances usage for patients

Additionally, however, there are additional behavioral signs and symptoms that require observation for detection:

- Illness and absenteeism above the norm
- Frequent or prolonged absence from the work area when on duty
- Volunteering for overtime, or to care for patients with excessive need for pain medication
- Volunteering to "carry the keys"
- Performance declines as represented both by objective performance and complaints from co-workers
- Increasing professional isolation
- Poor or incomplete record-keeping
- Personality changes and deterioration in appearance and hygiene
- Defensive behavior; inability to accept criticism
- Visiting patients when not on duty

Culture trumps Policy

A review of a number of recently reported incidents makes it clear that diversion is unlikely to be systematically prevented, but can and should be managed by careful and continuous monitoring. That same review points out policies are of little use where practice circumvents them. In the David Kwiatkowski case, for example, it apparently was the habit in the cardiac catheterization laboratory to draw up a syringe containing Fentanyl just in case it was needed. It was relatively easy for him to exploit this habit, remove the syringe, inject himself with the drug, refill the syringe with saline and replace it atop the cabinet. In the process, he managed to infect a number of patients with Hepatitis C.[25]

Limitations of Current Tools

Current tools focus on comparing frequency of drug dispenses, drug wasting behavior, and acquisition timing from automated dispensing cabinets as a primary strong indicator of likelihood of diversion, using standard deviation of the mean across caregivers for a specific patient population as the primary indicator. It appears to be up to the system user to set the boundaries above which an individual becomes "suspicious".[26] In one report, using one of the more common tools, a hospital reports that it was able to focus on five investigations over a 6 month period, three of which were confirmed to involve drug diversion.[27] As these numbers indicate, high use isn't an indictment, but it is an indicator that more research is needed. Discussions with those interested in this problem (primarily nurse investigators) indicates that the process of investigating and dealing with a diverter only starts with these current tools, and relies on very labor-intensive manual investigation methods to finally reach a conclusion.

As evidenced by the much more extensive list of signs and symptoms it is likely that a properly constructed system could build a much more robust picture of individuals who might be diverting, especially if such a system could acquire key information from other programs, such as the electronic medical record.

Further, since the goal of the diverter is to mask their diversion behind the appearance of normal patient care behavior, it is likely that there are more successful diverters who would be unlikely to trip consumption limits, but who might show other behaviors that they do not realize are being observed and tracked.

An Augmented Approach

Thus what is needed is a more multi-axial approach to measurement of potential diversion based on two or three strong signals, for which further adjacencies are analyzed in an effort to better identify and target those whose total behavior picture suggests diversion activity. Specifically, the use of gross usage, suspicious wasting behavior, and elevated occurrence of discrepancies could serve as primary triggers, which would then be qualified by weaker signals focused on those suspicious providers.

One can imagine such a system building up a score on the strong signals, and then invoking a series of automated investigations, primarily around patient records for the patients being cared for by suspected diverters.

One can imagine building up a series of diversion scores around each measure summing to a total diversion score.

One can imagine a summary-level display containing a grid listing the top ten diverters in descending order by total diversion score, and, for each potential diverter, a series of graphic indicators, one for each signal, indicating the strength of that signal.

One can further imagine that clicking on the name of the potential diverter would cause the system to display reports on that user's behavior. Clicking on a column header listing a signal would cause different reports to display the statistics around that particular diversion behavior. Clicking on a particular graphic indicator on a particular row would display a report of summary individual indicator scores for that user for that diversion behavior indicator. From any of these points, the user could ultimately drill down to individual transactions.

Finally, one can envision such a system having links to a series of documents describing how to take the investigation forward, and what kinds of things to look for.

The Problem of Community Opioid Use

As with the acute care setting, the problem of community opioid use arises because there are legitimate and useful therapeutic applications for controlled substances. The community problem differs from the acute care setting in the following terms:

- The known death toll is substantially higher[1]
    - The CDC estimates that between 2000 and 2014 nearly half a million persons died from drug overdoses.
    - The number of deaths in 2014 represents the worst on record, and represents a significant increase from 2013
    - This represents 1½ times the number of deaths from motor vehicle crashes.
- The addict may be the patient themselves or someone who is diverting their supply
- The supplies of medication are less well controlled once issued to a patient
- The medications being diverted are more typically oral solids (tablets and capsules) than injections.
- The quantities of diverted or abused medication are much larger
- The motives for diversion or theft are as likely to be for financial gain as they are for personal use
    - Prescription quantities for up to 90 days' supply can provide very profitable street value
    - Pill mills in Florida and other states operate very profitable cash-only businesses in which they issue substantial prescriptions for opioids.[5]

Pill mills are clinics operated by physicians characterized by[5]:

- Cash only/no insurance accepted
- No appointments
- Armed guards
- Little or no medical records
- Inadequate physical examinations
- Large prescription doses of narcotics that exceed the boundaries of acceptable medical care

As previously noted, the aging of the US population and the increase in obesity within the population are both drivers for an increase in cancer, which often may require aggressive pain management. This, in turn, complicates identification of inappropriate prescribing.

Better control of the supply is a key component in managing this public health threat. In its report to the Senate HELP committee, the National Association of Attorneys General (NAAG) identified "The family medicine cabinet is the largest source for diverted prescription drugs in our nation. The safe disposal of expired, unused or unnecessary prescription drugs is therefore a key component in the States Attorneys General efforts to curb prescription drug abuse." Take back programs have resulted in the removal of over 2000 tons of prescription medications from cirtulation.[4]

As noted in the discussion on healthcare providers, drug seeking behavior is very adaptive. One such adaptive behavior is described as “prescription shopping” in which an addict will attempt to have the same prescription filled at a variety of pharmacies. The NAAG report identifies prescription drug monitoring programs as effective tools.

Another public health and safety impact of community opioid addition is abuse and neglect of children. The NAAG report cites increases in the incidence neonatal abstinence syndrome secondary to maternal addiction, in which babies are born in withdrawal, and require care in specialized nurseries or neonatal intensive care units to manage their withdrawal. Longer term effects may include poor growth in the uterus, premature birth, and birth defects.[28] Longer term effects may include delayed or altered brain maturation in neonates born to opioid-addicted mothers, potentially leading to cognitive delays, behavioral abnormalities, attention-deficit disorders, visual defects, and an increase in the frequency of sudden infant death syndrome.[29]

Very little seems to be written about the opioid abuse as a cause of abuse or neglect of children. Two reports of causes of child abuse and neglect found substance abuse disorders was found to be strongly associated with both abuse and neglect.[30,31] Comparatively, there appears to be a wealth of research on the impact of neglect and abuse, including post-traumatic stress disorder[32], and a tendency toward adolescent and adult substance abuse.[33]

Steps to ameliorate the problem

As has been described, the principal steps taken to address the community opioid problem to date have focused on:

- Education
- Removing unused medications from the marketplace in an organized way
- Identifying and closing “pill mills”
- Identifying and detoxifying pregnant addicts
- Development of non-addictive pain medications
- Prescription monitoring programs

A role for BD

Given the ubiquity of BD technology in the United States acute care marketplace, and the ability of that technology to aggregate usage data across our customer base, it can be asserted that BD has both a right and an obligation to leadership in this space. While much of what is known about diversion is anecdotal, our technology provides a laboratory in which usage of controlled substances can be studied across a wide swath of US acute care medicine. The results of that research can and should provide the evidence base needed to construct a more effective program for monitoring and policing controlled substances use to limit or prevent diversion. Recent significant penalties associated with failure to properly manage controlled substances use should provide our customer base with incentive to participate in such research.

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