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Review

Int J Clin Pediatr. 2022;11(3):69-75

Development of a Policy and Procedure for Random Drug Screening of Healthcare Workers at a Tertiary Care Children's Hospital: Initial Implementation and Preliminary Results

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Abstract

During the past decade, substance abuse and addiction have continued to increase worldwide in both the general public and healthcare providers. Given the ongoing trend demonstrating an increase in the prevalence of drug diversion and its higher prevalence in various healthcare provider groups, several interventions have been initiated to decrease the availability of substances of abuse, as well as identify or uncover substance abuse in healthcare providers. This manuscript reviews techniques which have been implemented to prevent diversion in healthcare providers and outlines the steps taken in the development of a random drug screening program at our tertiary care children's hospital. Additionally, we review outcomes and the potential impact after the first 24 months of the random drug screening program. Six faculty or staff have been screened each quarter over a 2-year period. To date, we have not had a positive result. Service issues regarding timely screening of faculty and staff upon arrival to Employee Health have been limited with the process generally taken less than 60 min. There have been no significant disruptions in the work process of the operating room or pharmacies. The use of random drug testing is important not only for the safety of our patients, but the integrity of both the fields of anesthesia and pharmacy. The process can be introduced without interruption of workflow or impact on employee privacy. We believe that this process is one of several interventions which may be helpful in decreasing drug diversion.

Keywords: Opioid use disorder; Substance abuse; Addiction; Diversion; Random drug screening

Manuscript submitted July 7, 2022, accepted July 25, 2022
Published online October 31, 2022

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doi: https://doi.org/10.14740/ijcp495

Introduction

Over the past decade, the incidence of substance abuse and addiction have continued to climb worldwide in the general public and healthcare providers. Globally, the most prevalent substance abused is alcohol, with 100.4 million estimated cases in 2016 [1]. This is compared to the 76.3 million estimated cases reported by the World Health Organization in 2004 [2]. In 2017, the United Nations World Drug Report found that 271 million people, or 5.5% of the global population aged 15 - 64 years, had used drugs in the previous year, while 35 million people were estimated to be suffering from drug use disorders [3]. In the context of opioid use alone, it has been estimated that 40.5 million people were dependent on opioids in 2017, or 510 people per 100,000 population [4]. In the United States, our population leads these numbers, with a staggering prevalence of 1,347 per 100,000 people [4, 5]. These alarming numbers have prompted the need for improved surveillance, major policy changes, and novel therapeutic interventions to limit the availability of drugs of abuse as well as novel means to identify use of illicit substances.

These concerns are prevalent not only in the general population, but also in healthcare providers where substance abuse is not uncommon, occurring at roughly the same rate as the general population [6-9]. These two groups exhibit similar reasoning and risk factors for initiating substance use including curiosity, peer pressure, availability of a given substance, experimentation of substance use at a young age, and a family history of addiction [10-12]. However, the incidence of substance abuse and dependence problems in healthcare professionals can vary dramatically by group [13]. Specifically, nurses, dentists, pharmacists, and anesthesiologists have shown

Table 1. Techniques to Prevent Diversion of Controlled Substances

Intervention	Description
Educational programs regarding the impact of substance abuse	Lecture series (live, virtual, or recorded) discussing provider impairment and the risks, signs, and symptoms of substance abuse.
Automated or monitored medication dispensing systems	Dispensing of controlled substances by a centralized pharmacy or an automated medication dispensing system which records output and return.
Monitoring of unused and returned residual volumes	Unused portions of controlled substances are returned to pharmacy. Amount used verified against anesthetic record.
Closed-circuit video surveillance of medication dispensing and return	Video surveillance and recording of automated medication dispensing machines to identify variations or concerns with dispensing and return of unused medications.
Random assay of returned controlled substances to ensure that the appropriate medication is present	Returned samples randomly screened to rule out diversion of medication and substitution of saline.
Computer-based algorithms to identify abnormal medication use patterns including machine learning	Algorithms used to monitor electronic medical records including anesthesia documentation to identify variations in dosing and use of controlled substances.
Random drug screening of employees	Intermittent urine testing and screening of randomly identified employees.

greater rates of drug use within the healthcare population [6].

For both pharmacists and anesthesiologists, the proximity to significant quantities of various highly addictive medications, the potential ease of diverting small quantities of these agents for personal use, and the high stress environment in which both parties work contribute to the increased rates of substance abuse [13-17]. In studies observing physicians, pharmacists, pharmacy students and anesthesia residents, the incidence of substance use has been reported to be significant, with an alarming trend of an increasing incidence over the past several years [8, 18-25]. In both groups, there have been various efforts implemented to improve education on substance abuse as well as the development and institution of various control measures or interventions aimed at identifying those using these agents in an attempt to reduce the alarming trend [8, 19, 21, 26, 27]. However, an ongoing high rate of continued substance use, high relapse rate, and increased death rates indicate that these efforts at prevention within the fields of both anesthesiology and pharmacy have not achieved the desired results. As such, alternate or additional methods may be needed to address these issues and assure both provider and patient safety [20, 26, 28].

These issues have significant impacts on our healthcare system. The financial and social impact is significant. Drug diversion occurs not only for personal use, but to obtain medications for sale to others, including family members facing addiction, or for use in other illicit scenarios including sexual assault. The current manuscript reviews techniques which have been implemented to prevent diversion in healthcare providers, outlines the steps taken in the development of a random drug screening program within two departments (Pharmacy and Anesthesiology) at a tertiary care children's hospital, and reviews the first 24 months of the program after its initiation with the provision of preliminary data from screening.

Techniques to Prevent Theft and Diversion of Controlled Substances

Approaches to address substance abuse and prevent diversion of controlled substances by healthcare providers have grown significantly over the last decade (Table 1).

Educational programs

These presentations usually involve either a lecture series or sessions discussing provider impairment and the risks, signs, and symptoms of substance abuse. With the increased advent of electronic and virtual technology, some of these programs are presented as on-line modules to allow all faculty and staff to participate at their own convenience. Completion of such modules may be required for recredentialling of faculty and staff or may be mandatory prior to residents and fellows starting clinical work. These presentations may also be part of departmental grand rounds with inclusion of interactive role-play programs as alternate options for educational content distribution [29]. Typically, these sessions are mandatory for anesthesia providers and occasionally will involve all specialties within the hospital.

Addiction and drug diversion programs may be presented by physicians or healthcare providers who have confronted these problems personally and are providing not only a general overview, but a more personal account of how these problems can start, ways to avoid such issues, the personal and family impact of substance abuse, and how to identify these issues in fellow employees and healthcare providers. For pharmacists and pharmacy students, the American Association of Colleges of Pharmacy (AACP) states that pharmacy schools and colleges are responsible for ensuring that student pharmacists are equipped with the skills and knowledge about substance use and substance use disorders via substance use disorder-related education in both entry-level and continuing education programs [25, 30]. While in theory, the use of these educational sessions should impact the incidence of substance abuse and diversion, this may not be the case. In a study of anesthesia residents, it was found that more than 85% of participants did not recall receiving any substance abuse education during their training [21, 31].

Automated or monitored medication dispensing

Dispensing of controlled substances by a centralized pharmacy or an automated medication dispensing system may be helpful in decreasing the potential for drug diversion [29]. One example of an electronic system for dispensing controlled substances and other medications that has seen widespread application and adoption in the perioperative arena is The BD Pyxis™ Anesthesia Station ES. This automated medication dispensing system supports decentralized medication management without the need for the presence of a pharmacist in the operating room around-the-clock. Moreover, the Pyxis MedStation™ ES automated dispensing cabinet system includes automated storage and dispensing cabinets that perpetually track controlled substance inventory in the department of pharmacy and in nursing units. Another prevalent electronic system designed to inventory and dispense medications used specifically by anesthesia providers intraoperatively is the Omnicell™ XT Anesthesia Workstation. These workstations provide a platform to allow the dispensing of individual vials of controlled substances to anesthesia personnel and the return of unused amounts of medications for each individual patient or case according to the operating room schedule.

Monitoring of unused and returned residual volumes

In the practice of anesthesiology and for all operating room personnel, the return and monitoring of unused amounts (residual volumes) of controlled substances is equally as important. The potential impact of such concerns is magnified in the practice of pediatric anesthesiology. As vial sizes and volumes are generally standardized for adults, there may be significant quantities of unused medications after the provision of anesthesia to a neonate or infant. The smallest fentanyl vial contains 100 µg in 2 mL. This amount is appropriate for a brief outpatient adult case where the total dose would be less than 2 µg/kg in a 70 kg adult. However, the same 2 µg/kg dose in a 10 kg infant would result in 80 µg of fentanyl remaining. Even small amounts of highly addictive medications such as fentanyl may initiate the path of drug abuse and addiction. Such small volumes may be readily available from unused portions of vials or even from the overfill of some vials. Thus, as a means of best practice, the amount used and the amount returned is validated against what has been charted on the individual anesthesia record.

The return of unused portions of medications can be accomplished using an OR pharmacy or the same automated medication dispensing machines. These machines frequently include a lock box and controlled substance return bin with a rolling cannister that allows syringes and vials to be returned, but not accessed once they have been put into the bin. The amount returned is then verified against the anesthesia record so that the amount returned equals the amount dispensed minus the amount used. This is done not only for bolus medications, but also for intraoperative infusions of controlled substances such as midazolam, remifentanil, and sufentanil.

Closed-circuit video surveillance of medication dispensing and return

Diversion may occur at any point along the chain of custody, including during the return and final waste processes. To identify such concerns, closed-circuit video surveillance over the automated medication dispensing machine may be optimal, though difficult to operationalize with currently available technology. In the OR setting, this process adds another degree of difficulty as the camera should only focus on the person returning the medications or removing the returned medications. Patient rights, confidentiality, and privacy must be protected. The returned medications and their volumes are then validated against the electronic medical record (EMR).

Assay of returned medications to ensure accuracy

However, since diversion is still possible by substitution of saline or other liquids for the returned medications, a random sampling may be performed and a small percentage of returned medications assayed to ensure that the appropriate medication is present. Given the cost and time associated with this process, only a portion are generally assayed.

Computer-based systems to identify abnormal medication use patterns

These systems and records also allow the hospital or pharmacy personnel to track excessive use or waste and identify patterns of use or waste. The use of controlled drug dispensing systems and information management systems may provide an efficient automated screening and detection of drug diversion. Specifically, these systems can accurately identify the user, location, and timestamps through an extremely detailed log of medication and case information [32]. While these electronic and automated systems are a key to success in the prevention and identification of diversion, Epstein et al makes a crucial point that alternate diversion methods, which they decline to expand on to prevent further exploitation or new ideas, can be overlooked by the automated systems or those analyzing the data of those systems [32]. With this in mind, the needs to examine all angles of the problem are warranted. Technologies continue to emerge using machine learning or advanced algorithms to analyze seemingly disparate data from wholesaler ordering, pharmacy storage systems, automated dispensing systems, and with the goal of better identifying potential diversion.

Development of a Random Drug Testing Policy

At our institution, Nationwide Children's Hospital, efforts to continually support a healthy and safe environment for its patients, visitors, and staff remain a high priority. These initiatives from hospital leadership were key to achieving our strategic plan, the Journey to Best Outcomes, where significant focus is on improving quality and patient and employee safety.

For many reasons described and highlighted in the recent literature and based on hospital initiatives related to the strategic plan, hospital leadership at Nationwide Children's approached leadership in the Department of Anesthesiology & Pain Medicine and the Department of Pharmacy to evaluate and, if possible, implement a policy for random drug testing.

The initial stages of the policy development began in early March 2017, when both the Chief Pharmacy Officer and the Chief of the Department of Anesthesiology & Pain Medicine met with hospital leadership and Employee Heath. In addition to describing the goal of developing a policy, considerations surrounding confidentiality and the composition of drugs to be included in the testing panel were thoroughly discussed. In coordination with Employee Health, processes were created and reviewed to ensure confidentiality and provider privacy, and to avoid implicit bias against those sent for random drug screening. Proactive conversations surrounding the concerns of providers and pharmacy staff being stigmatized as suspects of drug abuse by staff completing screenings allowed for increased awareness and education of the Employee Health staff. More specifically, education was developed addressing the purpose of this program and importance of always treating staff with respect, regardless of indication for testing.

For the testing itself, discussions included particulars regarding the urine drug screen and which substances it would include. The decision on which drugs to test for was an important consideration for our policy, as the testing panel used may be different depending on if the intent is to identify diversion or abuse, as drugs associated with diversion are not necessarily the same as those used for personal abuse/addiction such as cocaine, marijuana, and alcohol. Options included testing for a comprehensive list of substances of abuse or a more focused list of substances which were used in the operating room and hospital setting (benzodiazepines, opioids) and thus subject to diversion. After considerable discussion, the decision was made to randomly test for drugs which are utilized at Nationwide Children's Hospital in patient care and not those subject to personal drug use such as alcohol or cannabinoids. Screening included opioids, 6-acetylmorphine (metabolite and marker for heroin), codeine, methadone, meperidine, hydromorphone, morphine, oxycodone, oxymorphone, and hydrocodone, fentanyl, benzodiazepines, barbiturates, and ketamine. Notably, this panel of drugs differs from the drug panel utilized when an employee is drug screened as a result of concern for fitness for duty, including for-cause drug testing as it does not include alcohol and cannabis (also does not include cocaine, amphetamine/methamphetamine, and phencyclidine). Any test that is positive during the screen is sent for a confirmatory test using gas chromatography/mass spectroscopy (confirmatory test). If the confirmatory test is positive, only then is the test reported as the positive.

The Departments of Pharmacy and Anesthesiology held meetings to discuss this initiative with their respective faculty and staff. Physician and nursing leaders of Employee Health attended these meetings to answer questions about the process, its intention, accuracy of the tests (false positives and negatives), what drugs would be screened for, and what the process would look like if there were to be a positive screen. Moreover, the process aimed to mirror random drug testing algorithms in other professions, such as commercial pilots and long-haul truckers, as a means of potentially eliminating areas of uncertainty. A similar process was already in place at Nationwide Children's Hospital for drivers and other employees.

Questions were raised about how the process would handle someone who is taking a prescription medication allowed during normal work hours but identified on the drug screen. One such example would be a prescription of opioids for chronic pain management or prescription of a benzodiazepine to treat anxiety. Thus, the process for a positive initial screen was thoroughly reviewed. If a positive screen occurred, the substance was further identified using high plasma liquid chromatography to rule out a false positive result and definitively identify the agent involved. For all employees with a verified positive drug screen, the Employee Health designated Medical Review Officer would review the test result and verify the presence or absence of a legitimate medical prescription for the safe therapeutic use of the identified substance by the employee through a standard process including an interview with the employee and review of relevant medical documentation. Talking points were further developed to ensure key points were covered and everyone understood why both departments were initiating random drug screening and to allow for open discussion and concerns to be raised. Prior to implementation, the legal department reviewed the process that had been developed and the final proposed policy.

To ensure equitable distribution of random drug screening of employees in both departments, the names of employees eligible for random drug testing are reviewed and submitted on a quarterly basis by Employee Health to a qualified, independent company. Each quarter, those to be screened are randomly selected out of the entire group including those who have been previously screened. The independent company randomly selects employee names to report for screening. Annually, 25% of the employee group are to be randomly drug tested. Employee Health notifies the employee's manager when the employee's name is selected, and the employee is notified at the discretion of the manager, taking into account patient care needs. Once notified by their manager, an employee selected for random testing shall immediately report to Employee Health Services for testing. If the selected employee is on vacation that week or not working, an alternate employee who is also identified by the random selection process is selected to maintain the number of employees that are screened each quarter. Any employee who refuses to submit to the testing is subject to termination. Screenings are administered by Employee Health Services. An employee selected for random testing then returns to work after reporting for and completing testing. This differs from the for-cause screening process where employees may not be allowed to return to work until the screen is negative. After screening, Employee Health Services is responsible for evaluating test results, conferring with Employee Health designated Medical Review Officer for positive results, and communicating the results to the respective departmental manager and Employee Relations. The Medical Review Officer verifies the presence or absence of a legitimate and safe medical rationale for any substance identified on the screen. As part of any Medical Review Officer interview in which the test subject believes a positive result to be an error, a split sample re-analysis

is offered. The same urine sample is sent for re-analysis.

If an employee's test were reported as positive and determined to be the result of drug abuse or diversion, the manager would consult with Human Resources and Hospital Legal Services in evaluating options such as rehabilitation or termination. Depending on the option selected, Employee Health Services would then periodically communicate with the employee's department director regarding compliance with a return-to-work agreement. At the hospital's discretion, an employee who self-reported his/her dependency prior to coming to work impaired and wants to overcome it may remain employed if he/she is actively involved in a recovery program and remains drug free. Employees in this case would be required to sign a return-to-work agreement with Nationwide Children's Hospital, Inc. which at a minimum will include random drug and alcohol screening.

Results

The implementation of our policy and procedure has continued over the course of 2 years with no significant concerns expressed by the faculty and staff who have been screened. A total of six faculty or staff have been screened each quarter for a total of 48 over a 2-year period. To date, we have not had a positive result. Service issues regarding timely screening of faculty and staff upon arrival to Employee Health have been limited. When they have occurred, Employee Health has been responsive to this feedback. The entire process has generally taken less than 60 min as the Employee Health unit is one floor below our general operating rooms and proximal to most health system pharmacies. There have been no significant disruptions in the work process of the operating room or pharmacies when getting the randomly selected faculty or staff to Employee Health for testing.

Discussion

As the rate of substance abuse continues to climb, the need for intervention remains. At our institution, we developed a random drug testing policy and procedure to combat the risk of substance abuse, continue our Journey to Best Outcomes, and support a healthy and safe environment for patients, visitors, and staff. Since the initial stages of policy development, we have included input from various sources, ranging from Employee Health leaders to departmental faculty members.

Although no positive results have been identified, we believe that this process is one of many interventions which may be helpful in decreasing drug diversion or identifying it in its early stages. We believe this process also demonstrates the ongoing commitment of safe care to our patients and further supports our dedication to patient and employee safety. Given the success of both development and implementation of random drug testing at our institution, we believe our model could possibly be used for similar size institutions. The use of random drug screenings in hospitals such as ours is increasing. The process seems to be more prevalent in adult institutions compared to specialized pediatric hospitals such as ours. Currently, outcomes demonstrating a significant impact of these initiatives on the overall incidence of drug diversion and drug abuse without our specialties remain limited. As many of these programs are relatively new, further investigation is required to truly demonstrate outcome differences. Future studies are also needed to determine what percentage of faculty, staff, employees, or residents/fellows need to be tested to achieve the desired goal. While some institutions have instituted random testing of all personnel in specific groups, others like ours have chosen a random sampling. Furthermore, the optimal interval for testing is unknown (monthly versus quarterly, etc.).

In a recent article by Fitzsimons et al, they discuss the implementation of random drug screening programs at large adult hospitals including Massachusetts General Hospital (MGH), Cleveland Clinic, and Vanderbilt University Medical Center (VUMC) [26]. While the implementation of random drug testing at these institutions proved to have a notable impact, such as the reduction of substance use disorders among MGH residents over a 13-year period, potential drawbacks of these policies were also noted. Specifically, these included the cost of the programs regarding conducting the tests, the risks of false-positives, privacy concerns, and the challenges associated with testing for substances that are legal in society.

The concerns regarding costs related to random drug testing can be found in some areas of current literature. In the case of MGH, their total cost consisted of two elements, test collection and analysis as well as administrative fees. This equated to approximately $20,000 per year. In the case of testing all residents in their program at their desired rate, it was estimated to cost $50,000 per year [26]. There are also indirect costs related to have employees away from their jobs when being tested as well as the cost of the time involved of Employee Health personnel who are providing the tests. Nonetheless, these costs pale in comparison to the associated costs of treatment even for a single substance abuse episode. In fact, the estimated cost of returning an affected physician to unrestricted practice generally exceeds $100,000, not including the lost income accrued by the provider if placed on leave [33]. For our institution, the estimated cost for the random drug testing was much lower as we were testing a limited number of randomly selected individuals. Obviously, the actual costs would vary based on the number of individuals tested per month. As other authors have concluded, the benefits to random drug testing greatly outweigh the negative accrued costs of administering the tests. Moreover, the goal of potentially preventing physicians or pharmacists from falling into a pattern of abuse and preventing possible substance related death is arguably a priceless endeavor.

Within our institution and nearly all other institutions conducting random drug testing, the concern for false positives remains a key discussion point. The impacts of a false positive drug test span far beyond a computer or human error, as a single false positive can cause dramatic psycho-social impacts to a medical professional. In the report by Fitzsimons et al, the authors discuss the impact a false positive for an anesthesia provider at MGH [34]. Within this case, there was an unexplained positive result for ketamine in the clinician's random drug test. The initial urine screen by enzyme-linked immuno-

sorbent assay (ELISA) was positive for ketamine; however, confirmatory gas chromatography/mass spectroscopy was indeterminate. Following this indeterminate test, the employee completed an additional outside drug screen, and it was found to be definitively negative. Within the discussion, the authors point out important aspects of this false positive, including anxiety and the potential financial hardships had the employee been put on leave. The confirmatory test using high plasma liquid chromatography or mass spectroscopy aids in significantly reducing the chance of a false positive. It is preferable to run this confirmatory test immediately on the same sample as the screening test, prior to stating that the test was positive. For any institution conducting random drug testing, we would recommend having a clear and expedited protocol in place for a positive test. This should include support addressing the psycho-social stresses, the provision of legal representation as requested, and options for rehabilitation.

Another key discussion point brought up by literature and our own institution is the possible invasion of privacy. In a 1992 study by Lemon et al, they found that 60% of surveyed physicians believed random drug testing infringed on their right to privacy [35]. However, courts have ruled that the protection of the public trumps personal rights when an individual has the safety of the public in their hands. This includes pilots, drivers, and Department of Transportation employees. At Nationwide Children's and at other institutions, careful consideration for clinician privacy is taken into account for those selected for random drug screening, such as utilizing a separate and confidential database that can only be accessed by Employee Health [26].

The final key discussion point regarding random drug testing is the controversy for testing for recreational substances that are currently legal in certain areas of the country, specifically marijuana. As pointed out by Fitzsimons et al, while certain states have restrictions or even a ban on testing for marijuana, the Federal Drug-Free Workplace Act clearly states that those involved in the protection of life, property, health, or safety are to be subject to drug testing [26]. In the case of pharmacists and anesthesiologists and certified registered nurse anesthetists (CRNAs), both professions fall under this umbrella and could be subject to testing for marijuana. However, at Nationwide Children's, we elected to include only substances immediately available in perioperative areas and substances that have been involved or could be involved in diversion. While the use of recreational substances such as marijuana can in theory lead to impairment and patient safety concerns, these would be screened during a Drug Free Workplace Program (DFWP), which should be considered separately from a random drug screening program to identify drug diversion.

The use of random drug testing is important not only for the safety of our patients, but the integrity of both the fields of anesthesia and pharmacy. As the concerns for substance abuse and possible avenues for diversion remain, our institution proactively created and enacted a policy and procedure for random drug testing. Since implementation, our institution has encountered zero positive results and minimal complications. Much like other institutions such as MGH, Cleveland Clinic, and VUMC, our policy and procedures are designed to ensure patient safety and maintain provider privacy and integrity. While concerns for cost, false-positives, provider privacy, and challenges associated with testing recreational substances are valid, we believe our policy and procedures properly address these concerns. However, the need for further investigation regarding provider and clinician attitudes about random drug testing, as well as long-term measurements on the success of these policies and procedures, is needed [35].

Acknowledgments

None to declare.

Financial Disclosure

None of the authors have any financial disclosures related to the content of this manuscript. No funding was received.

Conflict of Interest

None to declare.

Author Contributions

KEP: first draft, revisions, and final draft. CK and JDT: review and editing of revisions and final draft; policy development. PM and JCU: review and editing of revisions and final draft.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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