

**THE EPIDEMIC OF CONTROLLED SUBSTANCE DIVERSION RELATED TO
HEALTHCARE PROFESSIONALS**

by

Katelyn M Pontore

PharmD, West Virginia University School of Pharmacy, 2014

Submitted to the Graduate Faculty of
Graduate School of Public Health in partial fulfillment
of the requirements for the degree of
Master of Public Health

University of Pittsburgh

2015

UNIVERSITY OF PITTSBURGH
GRADUATE SCHOOL OF PUBLIC HEALTH

This essay is submitted

by

Katelyn M Pontore

on

December 16, 2015

and approved by

Essay Advisor:

David N Finegold, MD

Program Director

Multidisciplinary MPH Program

Professor

Human Genetics

Graduate School of Public Health

University of Pittsburgh

Essay Reader:

Julie M Donohue, PhD

Associate Professor

Health Policy and Management

Graduate School of Public Health

University of Pittsburgh

Copyright © by Katelyn M Pontore

2015

THE EPIDEMIC OF CONTROLLED SUBSTANCE DIVERSION RELATED TO HEALTHCARE PROFESSIONALS

Katelyn M Pontore, MPH

University of Pittsburgh, 2015

ABSTRACT

Purpose: Controlled substance diversion does not discriminate and is detrimental to healthcare facilities and professionals alike. The problems identified in literature today are significant public health concerns being investigated at hospitals across the country to improve controlled substance surveillance and develop proactive diversion prevention programs. Diversion is not a victimless crime. The primary goal of investigating controlled substance diversion is improving public health, patient safety, and preventing substandard care. Secondary goals are preventing and mitigating risks of the other components related to diversion such as the safety of health care worker, the environment, and the employer.

Methods: Current controlled substance practices will be investigated at a 631 bed tertiary care hospital and evaluated by direct observation, audits, and reporting. Implementation of process and work flow enhancement will occur after initial investigation of the current situation. A retrospective review of the controlled substance discrepancies will be audited for resolution. A discrepancy is an event in which the physical count of controlled substances is more or less than expected. The following data will be collected and assessed on a prospective basis for a 6 month period: discrepancies not resolved within 24 hours by nursing unit, and total discrepancies by nursing unit. All data will de-identified to maintain confidentiality.

Results: Following the initial intervention in April, the number of discrepancies not resolved within 24 hours fell from 144 to 66 (54.2% decrease) and total discrepancies from 242 to 172

(28.9% decrease). The streamlined controlled substance discrepancy surveillance implementation will assist in detection and prevention of diversion.

Conclusion: It is anticipated that this project will demonstrate the need for an interdisciplinary approach to prevention of controlled substance diversion and medication safety at healthcare facilities. The complexity and time intensive nature of controlled substance diversion identification, auditing, monitoring, education, and investigation will require a diverse team of healthcare professionals.

TABLE OF CONTENTS

1.0	INTRODUCTION.....	1
2.0	BACKGROUND	5
2.1	POLICY ENVIRONMENT	5
2.2	STATE ENVIRONMENT	6
3.0	METHODS	9
4.0	RESULTS	12
5.0	DISCUSSION	15
6.0	CONCLUSION.....	17
	APPENDIX: INITIAL ROAD MAP OUTLINE	18
	BIBLIOGRAPHY	26

LIST OF TABLES

Table 1. Controlled Substance Prevention Program Champions at Allegheny General
Hospital^{12,13}..... 13

LIST OF FIGURES

Figure 1. United States Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013 ₃	4
Figure 2. Comparing rates of heroin use in 2002-2004 and 2011-2013 ₁₅	8
Figure 3. 2015 Controlled Substance Discrepancies	13
Figure 4. Main Components of The Controlled Substance Diversion Prevention Program _{12,13..}	14

1.0 INTRODUCTION

Approximately 110 individuals die every day from a drug overdose.¹ The Centers for Disease Control and Prevention (CDC) state that prescription drug abuse and overdose are one of the top five health threats.² Those effected by drug abuse and overdose extend beyond the individual addict. Drug diversion is a dangerous method of obtaining drugs that leads to harm of all in contact with the addicted individual.

Drug diversion is the act of illegally obtaining or using prescription medications not intended by the prescriber. No one is immune to addiction or even the potential to divert prescription medications. Healthcare professionals are not exempt from diversion to help maintain their dependence habits. The scope of activities performed by individuals diverting medication may include personal use, sale, and illicit use. When these actions are executed by healthcare professionals, the stakes are exceedingly high (Figure 1). Figure 1 helps understand that healthcare professionals place unique threats to the health of themselves and others. The victim of diversion is never solely one person. Diversion is a multiple victim crime. For healthcare professionals the potential victims are patients, co-workers, employer, and themselves.⁴ The scope of potential harm of diverting healthcare professionals include patients, co-workers, employers, and themselves. Harm to patients may be substandard care from tampered medication, either complete absence or dilution of medication, experiencing pain and anxiety from inadequate treatment, infection spread, and general danger from intoxicated

healthcare professionals. Harm to co-workers may include injury from uncapped needles and broken glass vials, infection of blood pathogens, liability of shared risk with patient care responsibilities, and disciplinary action from unwittingly aiding the addicted employee in violation of policies and procedures. Harm to the employer may be through loss of revenue from medication, poor work quality, and absenteeism, liability of failure to prevent, recognize, or address signs of drug diversion, ethical obligation to past, present, and future patients, long term risk assessment management, mandatory reporting requirements of incidents becoming public knowledge and potentially highly publicized, and devastating effects on the institution from lack of patient trust, patients seeking care elsewhere, and damaging the ability to provide high quality patient centered care, which ultimately leads to decreased morale institution wide. Harm to the addict includes overdose, death, infection, withdrawal symptoms, felony prosecution, civil malpractice actions, and actions against professional licenses.⁴

The relation between workplace access to substances and prescription type dependence for healthcare professionals is limited. An anonymous survey revealed 20% of nurses misused at least one prescription drug.⁵ This data indicated perceived availability, frequency of administration, and degree of workplace control over storage and dispensing are associated with an increased use of controlled substances by nurses.⁵ One out of fifteen pharmacists, one out of ten nurses, and one out of eight physicians are at risk of being dependent on controlled substances and/or alcohol.⁶ The Bureau of Labor Statistics from 2014 claims 297,100 pharmacists, 2,751,000 registered nurses, and 708,300 physicians and surgeons currently exist in the United States.⁷ When combining these facts, the resulting numbers of possibly dependent pharmacist, nurses, and physicians are 44,565, 275,100, and 56,664 respectfully. Consequences from healthcare professional's diversion activities lead to widespread health issues. Below is a

timeline of outbreaks associated with drug diversion by healthcare professionals (figure 1). Figure 1 outlines instances of known diversion that has led to adverse health outcomes. Some healthcare professionals use dirty needles on themselves and patients, which increases the likelihood of disease spread. Care for all victims of diversion is essential, especially through the assistance from federal, state, and healthcare facility regulations and policies.^{8,9}

Investigating discrepancies will identify targets for enhanced surveillance and develop a foundation for a proactive controlled substance diversion prevention program. In order to achieve improved discrepancy surveillance a review of current controlled substance auditing and reporting practices for pharmacy and all nursing unit automated dispensing machines will be performed. Educational materials will be created and distributed covering hospital policy, state regulations, and processes for how to resolve discrepancies successfully. Monthly reports on discrepancies will be evaluated for pre and post educational implementation to identify areas in need of targeted surveillance and one-on-one education sessions. Other reports will be identified to enhance surveillance techniques. Pharmacy and nursing will reach out to administration, patient safety, quality, regulatory, and human resources with the results of the research to develop a proactive controlled substance diversion prevention plan.

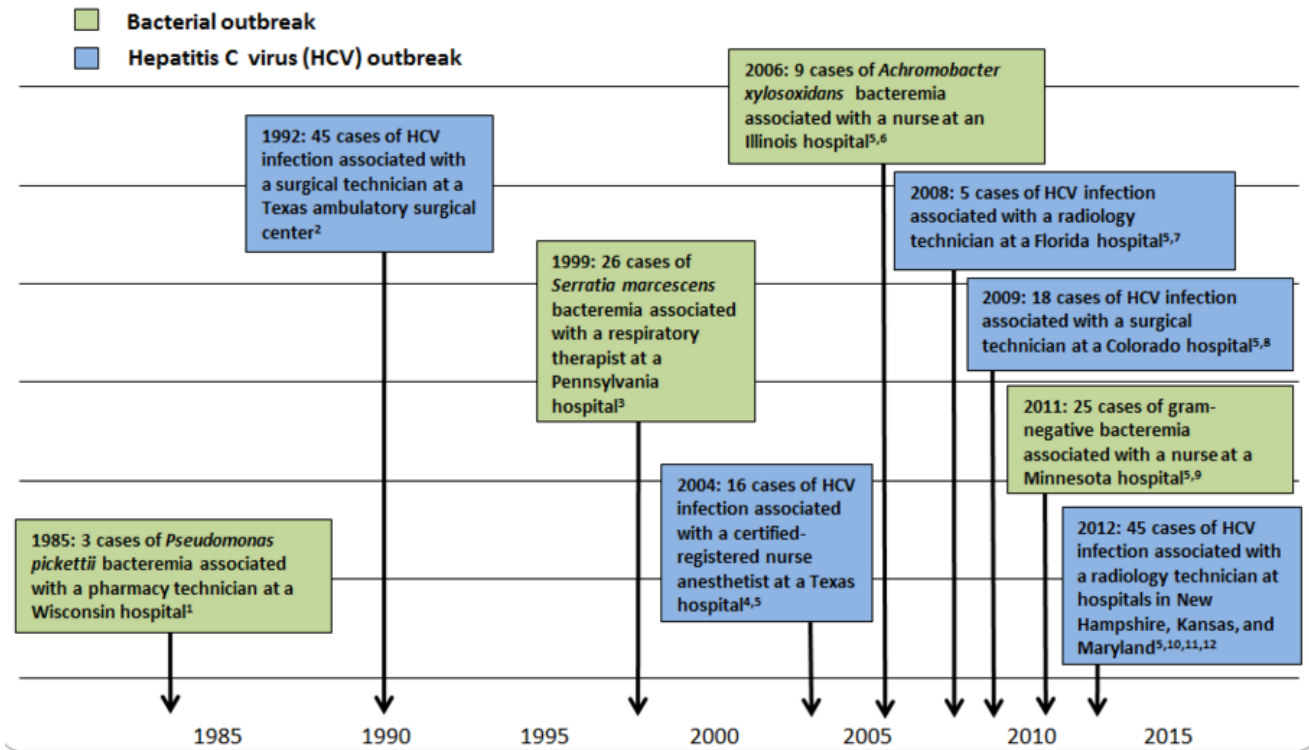


Figure 1. United States Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013³

2.0 BACKGROUND

2.1 POLICY ENVIRONMENT

Expectations for the handling and management of controlled substances have existed for decades. The basis for drug enforcement in the great majority of the states was established in 1934 by the Uniform Narcotic Drug Act (UNDA). The UNDA was replaced in 1970 by the Uniform Controlled Substance Act. The classification of controlled substances has been defined since 1938 in Title 21 of Code of Federal Regulations.¹⁰ Federal legislation bestows major responsibility on individual states for enforcement of stricter regulations on controlled substances. For example, the world of controlled substance discrepancies has become increasingly strained in Pennsylvania. The Pennsylvania Department of Health has issued final guidance for acute healthcare facility determinations of reporting requirements under the Medical Care Availability and Reduction of Error (MCARE) Act on September 27, 2014 to be implemented on April 1, 2015. The guidance is meant to enforce acute healthcare facilities to report all controlled substance discrepancies (resolved and unresolved). Discrepancies are defined as the physical count of controlled substances being more or less than expected. A discrepancy may include receiving orders from manufactures, removal, waste, or charting of controlled substances. Discrepancies will occur for numerous reasons and require time for investigation and proper resolution if a true issue arises. The most common forms of

discrepancies are human error of miscounting and operating system dysfunction, which are resolved in a timely manner. Discrepancies will stay in an unresolved state until proper resolution happens. The nature of guidance published by the Department of Health was clear and consistent standards for the MCARE Act's reporting requirements. All hospitals within the state were expected to enhance reporting efforts equipped with these clarifications, especially controlled substance discrepancies.¹¹ Controlled substance discrepancies are one method to report, investigate, and monitor for identification of diversion in healthcare facilities. The methods of diversion detection are in a state of change across the country. Diversion investigation is mainly reactive from anecdotal reports of behavior change or inconsistent practices. This reactive method is no longer considered effective when utilized alone. Proactive diversion detection and prevention methods are becoming the norm. Two states, Minnesota and California, have formed coalitions to outline road maps to proactive diversion prevention programs. These road maps are comprehensive in their approach to help find a solution to healthcare professional diversion.^{12,13}

2.2 STATE ENVIRONMENT

Pennsylvania's overdose death rate for 2010 is 15.3 per 100,000 population and above the national rate of 12.4 per 100,000 population.¹ This crisis does not spare the western parts of Pennsylvania and creates devastation for families. In 2014, approximately 2,489 Pennsylvanians died from a drug overdose.¹⁴ Reports on drug overdose deaths refer to all medications that are deemed the cause of death determined by toxicology results.¹⁴ Of the 2,489 overdose deaths, opioids, non-legal drugs, benzodiazepines, and antidepressants accounted for 25%, 24%, 18%,

and 17% of deaths, respectfully.¹⁴ The prescription opioid abuse cost insurers an estimated \$72.5 billion in 2007.¹⁵ This financial toll reached into Medicaid programs, 65,000 Medicaid beneficiaries in five states incurred over \$60 million in drug costs related to “doctor shopping” for opioid prescriptions.¹⁶ Fayette County has one of the highest death rates from drug overdoses in the country at 33.5 deaths per 100,000 residents. Fayette County is followed by Greene County with 28.2, Beaver County with 24.2, Washington County with 21.2 deaths, Allegheny County with 20.5 deaths, Westmoreland County with 20.4 deaths, and Butler County with 17 deaths (all deaths per 100,000 residents).¹⁷

The rate of heroin related overdose deaths has increased from 2002 to 2013 by 286% in the United States.¹ The majority of individuals who use heroin are also using at least one other drug and at risk to become addicted to heroin. Individuals who use alcohol are two times more likely, marijuana users are three times more likely, cocaine users are fifteen times more likely, and prescription opioid painkillers are forty times more likely to be addicted to heroin.¹⁸ Heroin use has increased when examining rate amongst different demographic groups.^{1,18}

Opioid Epidemic in Pennsylvania

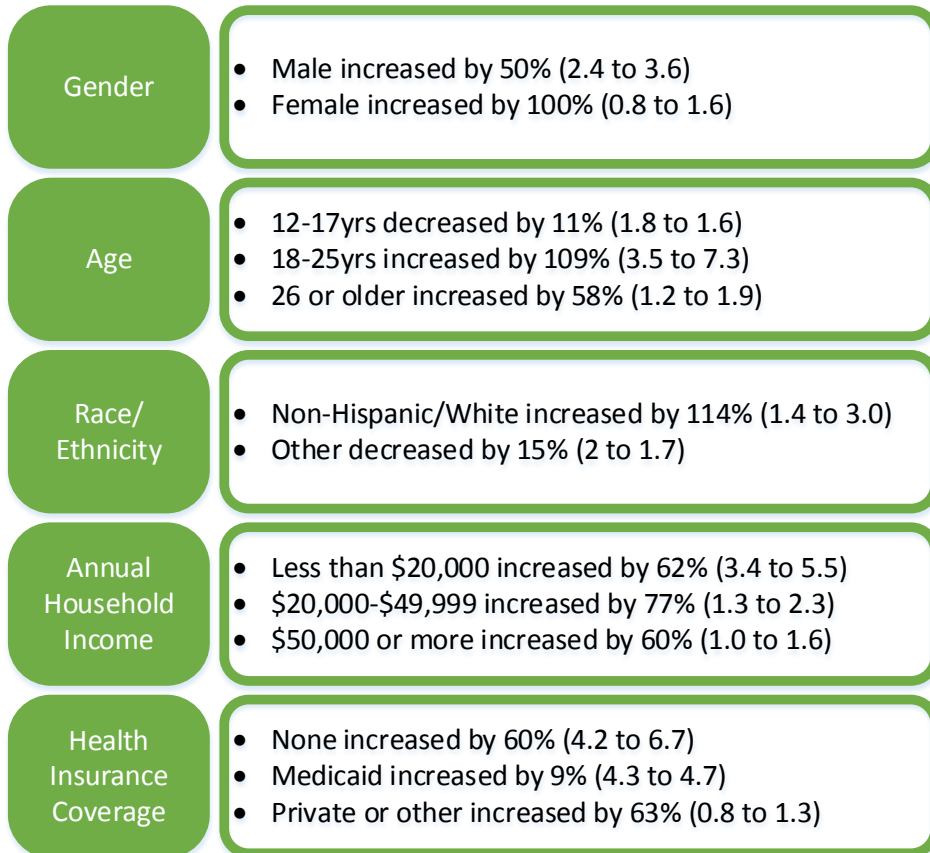


Figure 2. Comparing rates of heroin use in 2002-2004 and 2011-2013¹⁵

3.0 METHODS

The initial process was to review the current controlled substance auditing and reporting practices at Allegheny General Hospital (AGH). Allegheny General Hospital (AGH) is a 631 licensed bed tertiary academic teaching hospital in Pittsburgh, Pennsylvania. AGH is the largest of seven hospitals within the Allegheny Health Network. A 'Safe Infrastructure' approach was utilized to assess proper controlled substance practices at AGH and guide implementation of the educational intervention.¹³ The word safe in 'Safe Infrastructure' is an acronym that stands for **S**afety teams/organizational structure, **A**ccess to information, **F**acility expectations, and **E**ducate staff and patients.¹³ It was essential to have an understanding of the current state of controlled substance discrepancy reporting at AGH. Best practices for controlled substances focus on many areas including procurement, storage and security, prescribing, preparation, dispensing, administration, handling waste, and follow-up if diversion is suspected.¹³ These categories are outlined in Appendix as they relate to AGH. Controlled substance discrepancy reporting best practices include timely data collection to improve detection of questionable activity as outlined by Minnesota Department of Health and Minnesota Hospital Association.¹³ Timely data collection and discrepancy resolution is defined by institution. AGH states no one is to leave the unit at change of shift until the count is accurate or staff are dismissed by the Charge Nurse or Manager of Hospital Operations (MHO). An audit for all medications classified as controlled substances for all nursing units at AGH commenced. The implementation plan for the audit

includes running reports monthly, starting January 2015 to July 2015, tabulating the total number of discrepancies including unresolved discrepancies and comparing them by nursing unit each month. After the reports were analyzed and evaluated for three months the next step was to engage the nursing unit directors. Without buy-in from the nursing unit directors a plan for intervention would not be possible. The discrepancy findings from January 2015 to March 2015 were sent to the nursing unit directors for input on process improvement.

Education material was created to discuss proper discrepancy resolution methods, background information on discrepancies, and expectations moving forward. Initial education was focused on key stakeholder groups of nursing and pharmacy. The educational intervention was implemented on April 7, 2015 at the nursing managers meeting. Another educational session was aimed at the nursing practice council on April 8, 2015. The purpose of focused education for high level stakeholder groups was proper dissemination to front line employees. The educational content included review of AGH policy and procedures for controlled substances and discrepancy practice, description of MCARE Act reporting clarification, explanation of automated dispensing machine processes for creating, discovering, investigating and resolving discrepancies, demonstration of discrepancy practices through completed discrepancy examples, and contact information of key pharmacy employees to assist with investigation and reporting. Timing of educational reinforcement of discrepancy policy and regulations was planned close to the MCARE Act reporting guidance clarification execution date.

The targeted education phase of the discrepancy intervention happened one month later in May 2015. Nursing units in the top 10% regarding unresolved discrepancies within twenty-four hours were educated at huddles. Huddles or daily line ups are a component of the Ritz Carlton

leadership philosophy. Daily huddles are performed at the beginning of every shift and normally last fifteen minutes. These huddles serve as a method for team communication about strategy, roles of employees, and inspiration for winning attitudes.¹⁹ Brief education refreshers were covered at huddles for those targeted nursing units.

The final intervention will be education at orientation for all new employees. This will ensure dissemination to the entire nursing staff. Continued evaluation of users consistently creating discrepancies will be analyzed.

4.0 RESULTS

A streamlined controlled substance surveillance process and controlled substance task force team was developed in order to implement a proactive diversion prevention program. The data collection ended early in May (figure 3) to focus on development of the controlled substance task force featured in table 1 and figure 4. The number of discrepancies is not the amount of controlled substances, but the number of events. The amounts of controlled substances vary for every discrepancy.

During the interim data analysis a discussion with nursing leadership, pharmacy, and patient safety lead to an immediate action plan to form a committee. The central tenants of the committee would be to establish a proactive diversion prevention program to address best practice development and implementation at AGH. The states of Minnesota and California have developed and published roadmaps to proactive diversion prevention programs, which will serve as guidance for best practices.^{12,13} The beginning stages of AGH's roadmap is outlined in Appendix. The controlled substance prevention program champions are tasked to provide best practices and resources for AGH to prevent and increase awareness of controlled substance diversion, ensure all stakeholder groups work together toward common goals, create a better understanding of jurisdictional issues, and to meet state and federal reporting requirements of controlled substance diversion.¹³ The goals of the controlled substance program champions are based on the aforementioned published roadmaps.

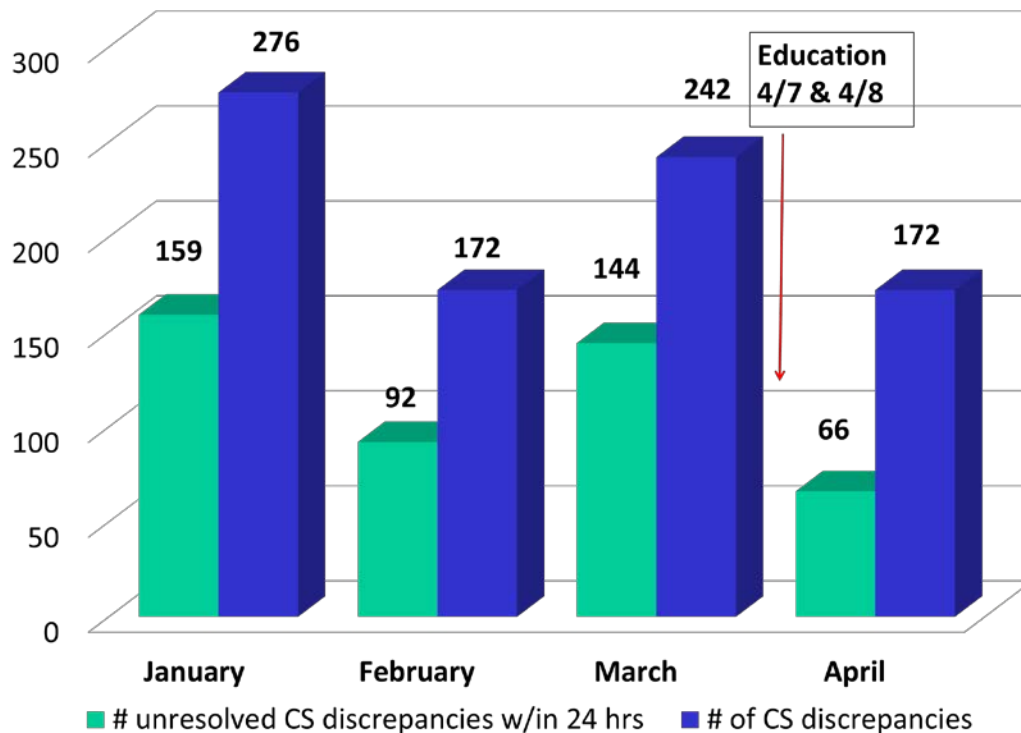


Figure 3. 2015 Controlled Substance Discrepancies

Table 1. Controlled Substance Prevention Program Champions at Allegheny General Hospital^{12,13}

Medical staff	Pain management physician Certified Registered Nurse Anesthetist Nursing Manager of Operating Room
Pharmacy	Manager of Operations Director of Pharmacy Health-System Administration Resident
Nursing	Directors of Nursing (x2)
Security	Head of Security
Human Resources	Director of Human Resources
Patient Safety	Manager of Patient Safety
Administration	Chief Nursing Officer Chief Operating Officer

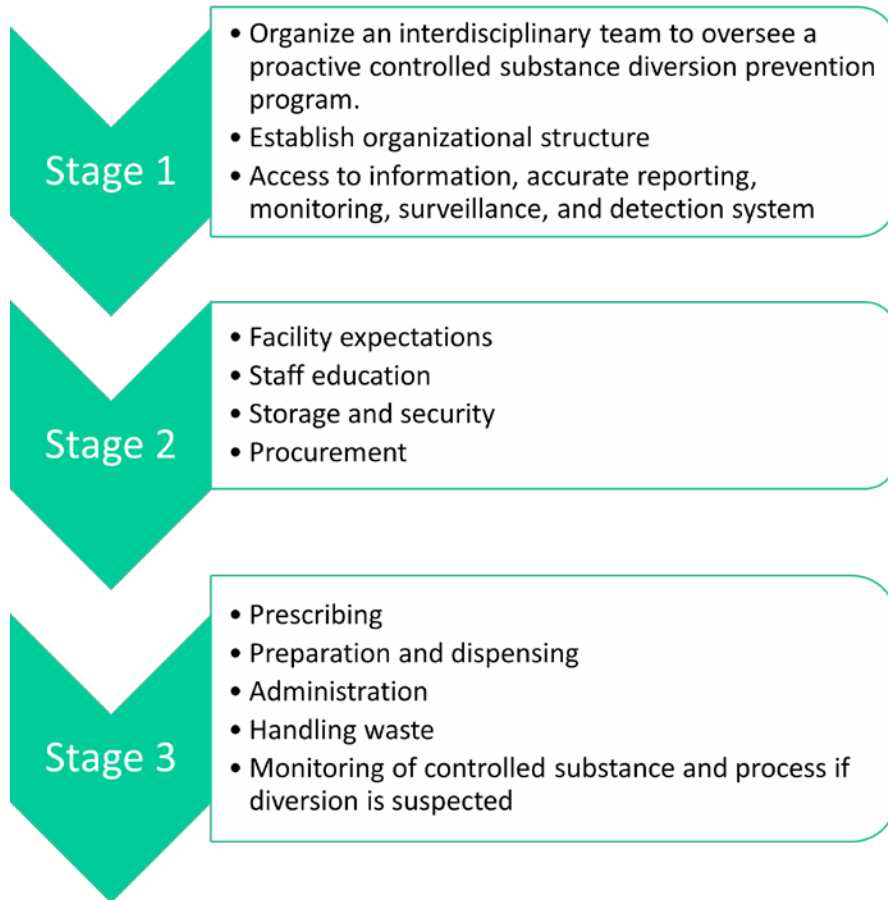


Figure 4. Main Components of The Controlled Substance Diversion Prevention Program^{12,13}

5.0 DISCUSSION

For the outlined research, several barriers existed. First and foremost, controlled substance discrepancies are a limited source of diversion data. Diversion is a complex process that will not be defined by any single act from an individual. Healthcare facilities are at constant risk of diversion from employees. The first basic steps are to comprehend regulations, policies, procedures, and the current status of diversion monitoring for any healthcare facility. Different approaches should be applied when monitoring diversion. Utilizing the same approach will teach diverters how to overcome monitoring tactics being used. Leveraging software available or purchasing diversion prevention software is essential. Most automated dispensing cabinet contracts include a software package such as CareFusion's Knowledge Portal or Omnicell's PandoraVIA or Medicast's RxAuditor. Without the software healthcare facilities are left to lengthy manual processes for monitoring controlled substance diversion. Discrepancies are a key measure to audit, monitor, and report. This enforces strict governance over controlled substances and denotes the severity when the counts do not match. In order to move forward controlled substance discrepancies needed to be addressed by AGH. Discrepancies were targeted and revealed the segments for further investigation, monitoring, and proactive prevention programming.

Beyond the sheer magnitude of diversion, other limitations exist. Nurses are under pressure when caring for high acuity patients, which places delays on resolving discrepancies

due to the busy workflow associated with this patient population. Discrepancies may be resolved within the appropriate twenty four hour time frame, yet there is the possibility of inaccurate resolution. Ensuring appropriate resolution of discrepancies involves time consuming investigation. Each week greater than eight hours are spent taking a deeper dive into investigation of discrepancy reports. Time is a major factor, which complicates the discrepancy resolution process. The time a discrepancy is created could be on a Friday, yet the controlled substance is not used very often and no one accesses that controlled substance again until Tuesday and finds the discrepancy. It has now been five days since the actual cause of the discrepancy, which makes resolution more difficult.

6.0 CONCLUSION

The scope of this project exposed opportunities for improvement amongst all healthcare facilities. Diversion prevention is not a simple cure. Resources and toolkits for understanding this epidemic plaguing individuals and methods of eradication are being developed. This research project has demonstrated a unique pharmacist-based role for prevention of controlled substance diversion and medication safety. Pharmacy is taking the lead on the controlled substance task force and building a road map to proactive diversion prevention at Allegheny General Hospital. Opportunities for process improvement are abundant after collecting and analyzing the discrepancy data. The controlled substance task force is committed to the following future actions:

- Annual controlled substance diversion competencies health system wide
- Development of a process for timely accurate discrepancy resolution
- Development of a proactive diversion program noted in the Appendix
- Upgrade controlled substance diversion software and technology

The importance of proactive diversion prevention is protection of the multiple victims being harmed by individuals afflicted with dependence from controlled substances and/or alcohol. This protection extends to the individual diverter themselves. Healthcare professionals and facilities, allow this to be your call to action. Care for yourself, your co-worker, your facility, and most importantly your patients.

APPENDIX: INITIAL ROAD MAP OUTLINE

Road Map to Controlled Substance Diversion Prevention		
Component	Specific Action(s)	Self-Assessment Checklist
Safety Teams/ Organizational Structure	1. Organization defines Controlled Substance (CS) Diversion Prevention Program.	<p>1a. The organization has an interdisciplinary team involve in developing and overseeing the CS Diversion Prevention Program.</p> <p>1b. The CS Diversion Prevention Program includes prevention, detection and investigation.</p> <p>1c. The CS Diversion Prevention Program is reviewed by the team and updated at least annually.</p> <p>1d. CS Diversion Prevention Program champions have been identified and have designated clear roles with expectations from the following areas:</p> <ul style="list-style-type: none"> • Medical Staff • Pharmacy • Nursing • Security • Human Resources • Patient Safety/Risk Management/Compliance • Administration • Legal (as necessary) • Communication (as necessary)

	<p>2. An organizational structure is in place that supports an effective CS Diversion Prevention Program.</p>	<p>2a. The organization has a designated coordinator(s) for the CS Diversion Prevention Program.</p> <p>2b. The coordinator(s) has dedicated time to serve in this coordination function.</p> <p>2c. The organization has a team prepared to respond to suspected CS diversion situations.</p> <p>2d. The organization has and regularly reviews policies and procedures addressing all aspects of the CS use processes.</p> <p>2e. The organization regularly reviews policies and procedures to assure compliance with state and federal laws.</p>
	<p>3. Organization proactively collaborates with local law enforcement.</p>	<p>3a. The organization (e.g. security) has engaged local law enforcement (e.g. county sheriff, chief of police) to discuss the CS Diversion Prevention Program and establish a communication strategy (including public) prior to CS diversion situations.</p>
	<p>4. Organization fulfills all reporting requirements for diversion or loss of CS.</p>	<p>4a. ► The owner reports to the Pennsylvania Board of Pharmacy within thirty days of discovery of any CS losses, including their amounts and strengths.</p> <p>4b. ► The DEA registrant or their designee reports any CS theft or significant loss to the DEA within one business day of discovery.</p> <p>4c. ► The organization follows other applicable requirements. For example, Medicare Conditions of Participation states: “Abuses and loss of controlled substances must be reported in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.”</p>
<p>Access to Information / Accurate Reporting / Monitoring / Surveillance /</p>	<p>1. Organization reviews and audits relevant data that could indicate potential CS diversion.</p>	<p>1a. ► The organization has a process to generate controlled substance data on a minimum monthly basis such as controlled substance surveillance reports, high user report, CS use through reports/log-sheets and CS “Disposition and Inventory” sheets.</p>

<p>Detection System</p>	<p>2. Organization tracks and reviews measures recommended by Medication Safety Committee or other designated groups reporting directly to a Medical Staff Committee.</p>	<p>2a. ► The organization has a process in place to review and analyze CS data on a regular basis.</p> <p>2b. ► The organization shares findings from the data analysis on a regular basis.</p> <p>2c. ► There is a process in place to activate a response team that includes a patient care manager, pharmacy Human Resources (HR) and security when diversion is suspected.</p> <p>2d. ► The organization has a process in place to contact law enforcement when diversion or theft is suspected.</p>
<p>Facility Expectations</p>	<p>1. Organization communicates the expectation that staff “speak up” when they become aware of an issue related to CS diversion.</p>	<p>1a. ► Senior leadership has clearly communicated that all staff are to speak up and will be supported in speaking up when they become aware of possible diversion.</p> <p>1b. ► The hospital treats such information as confidential and takes all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information.</p>
<p>2. Organization establishes full disclosure policy.</p>	<p>2a. ► The organization has a clearly define full disclosure policy and process to communicate to patients/families who are affected by CS diversion.</p>	
<p>3. The organization’s HR practices support an effective organization-wide CS Diversion Prevention Program.</p>	<p>3a. The organization has established and communicate ways for staff to speak up anonymously (e.g. hot line, paper or electronic submission).</p> <p>3b. The organization has a process in place to remove an impaired caregiver from patient care</p> <p>3c. ► The organization conducts pre-employment background checks for Licensed Independent Practitioners (LIPs) and employees.</p> <p>3d. A log of staff photographs and signatures are maintained as appropriate.</p> <p>3e. The organization has a process to manage employee access to CS in a timely fashion when terminated or transferred.</p> <p>3f. The organization has developed a “for cause” policy for drug testing.</p>	

	<p>4. Organization does not allow sharing of pass codes.</p>	<p>4a. ► The organization establishes and enforces a policy of not sharing pass codes such as electronic medical record (EMR), Automated Distribution Machine (ADM) and pharmacy door codes.</p>
<p>Educate Staff (and Patients)</p>	<p>1. Organization has in place an effective and comprehensive training and education program for all staff on CS diversion prevention.</p>	<p>1a. The CS Diversion Prevention Program team has attended CS diversion prevention and statutory requirement training (e.g. National Association of Drug Diversion Investigators [NADDI], professional associations, licensing boards, state, local and federal law enforcement).</p> <p>1b. Expectations and supporting education have be incorporated into training for all new staff and LIPs.</p> <p>1c. Expectations and training include, at a minimum, providing awareness training to know the signs of diversion.</p> <p>1d. Resources are available to support employees and LIPs, e.g. Employee Assistance Program (EAP) and Health Professional Services Program(HPSP).</p> <p>1e. The facility requires training on CS policies and procedures prior to authorizing staff to have CS access.</p> <p>1f. The facility provides ongoing staff education at least annually to promote safe handling of CS and CS diversion awareness.</p> <p>1g. The organization provides patient education on safe medication handling, including potential for diversion.</p>

<p>Handling Waste</p>	<p>1. The organization’s “waste” handling practices maintain chain of custody to minimize the risk for CS diversion.</p>	<p>Pharmacy:</p> <p>1a. CS waste from Compounded sterile Product (CSP) preparation in the Pharmacy is collected and randomly assayed.</p> <p>Areas outside Pharmacy:</p> <p>1b. ► Unusable product (UP) CS are to be immediately wasted and witnessed by health care professionals per specific hospital procedures.</p> <p>1c. All Potentially Reusable Product (PRP) drugs are returned to the pharmacy for evaluation of re-use/re-issue.</p> <p>1d. The organization has identified the high-risk areas (e.g. surgical, anesthesia, procedural) where CS diversion occurs.</p> <p>1e. The organization has identified specific high-risk CS medications (e.g., fentanyl) that are randomly assayed.</p> <p>1f. The organization has a process to randomly obtain and assay UP CS. For random assays, the UP CS would not be subject to immediate witnessed waste.</p>
------------------------------	--	---

2. The organization's practices for handling unused CS, empty CS containers or CS returned to pharmacy minimize the risk of diversion.

Wasting of UP CS:

- 2a. ► Approved methods for wasting a CS are defined per federal, state and county laws and regulations
- 2b. ► The wasting of all CS requires an independent license witness and must be documented in the ADM or via proof of use form, except when UP CS are returned to pharmacy for assay.
- 2c. ► An individual witnessing CS wasting verifies the volume/amount being wasted matches the documentation and physically watches the medication being wasted per policy.
- 2d. ► Empty containers of CS (e.g., vials) are discarded in limited access waste containers.
- 2e. ► Waste containers with trace UP CS are secured to prevent tampering.
- 2f. ► The pharmacy accounts for manufacturer overfill in injectable containers. All overfill amounts are captured, verified, documented, and wasted accordingly. Controlled substance overfill should be considered unusable product (UP).

PRP Returns:

2g. PRP ADM managed CS are returned to a secure return bin/pocket and not to the original ADM pocket.

2h. ► All PRP CS returns to pharmacy require chain of custody documentation in the patient care area and in pharmacy

Waste or Reverse Distribution:

- 2i. ► DEA registrant or their designee assists with all phases of transfer of CS to a reverse distributor and/or hazardous waste disposal company.
- 2j. Expired CS that are quarantined for reverse distribution are properly accounted by way of a log or inventory list. The items sent back via reverse distribution could be reconciled with the reverse distribution log of CS.

Monitoring of CS and Process if Diversion is Suspected	<p>1. Organization removes access to CS if diversion is suspected.</p>	<p>1a. ► All personnel actions (.g. suspension, terminations and resignations) are promptly communicated to pharmacy so access to CS can be removed.</p> <p>1b. ► If the hospital becomes aware of an arrest of an employee for illicit use of CS, the hospital immediately conducts its own investigation. The organization assesses whether to suspend, transfer, terminate or take other action (e.g., remove access to CS) against the employee.</p>
	<p>2. Organization regularly monitors CS through inventory, reports and audits.</p>	<p>2a. CS purchase invoices are compared to CS orders and receipt into the pharmacy’s perpetual inventory. Any CS purchases outside of the pharmacy department are tracked. Since the invoice-receipt pair may both be removed with CS diversion, invoices also are reconciled to statements or wholesale purchase history reports to detect missing invoices.</p> <p>2b. Movement of CS throughout the hospital is tracked. For example, reports match narcotic vault transactions with receipt into ADM and/or paper inventory record with RN signature of receipt.</p> <p>2c. ► CS within an ADM or narcotic vault are inventoried at least monthly.</p> <p>2d. Non-automated CS storage areas are inventoried at each shift change.</p> <p>2e. ADM reports are reviewed at least monthly by pharmacy or patient care managers as define by the organization. Reports compare ADM activity with medication administration record.</p> <p>2f. ADM CS activity is compared to peers with similar staffing responsibilities and FTE appointments.</p> <p>2g. Transaction activity (e.g. inventory abnormalities removal of quantities greater than prescribed dose, cancellations, returns and waste) is compared to peers.</p>

	<p>2h. Patient MAR: amount and quantity administered, is compared to what other caregivers administer on subsequent shifts (without patient change in condition).</p> <p>2i. Non-ADM CS storage area record of use is compared with MAR (e.g. anesthesia record, sedation record, eMAR) to assure appropriate documentation of waste.</p>
<p>3. A process is in place to resolve CS discrepancies.</p>	<p>3a. ► CS discrepancies are resolved upon discovery, no later than end of shift. Discrepancies that cannot be resolved are jointly reviewed by pharmacy and patient care leadership with resolution within 24 hours (e.g. metric: unresolved nursing unit CS discrepancies > 24 hours/total nursing unit CS discrepancies should be ≤ 8 percent).</p>
<p>4. Organization creates standard process to investigate potential diversion cases.</p>	<p>4a. ► There is a standard process in place to investigate potential diversion cases.</p>

► Indicated a legal or regulatory requirement.

BIBLIOGRAPHY

1. Centers for Disease Control and Prevention. National Vital Statistics System [database]. Web 10 September 2015.
2. Centers for Disease Control and Prevention. CDC's top ten: 5 health achievements in 2013 and 5 health threats in 2014 (December 17, 2013). <http://blogs.cdc.gov/cdcworksforyou24-7/2013/12/cdc%e2%80%99s-top-ten-5-healthachievements-in-2013-and-5-healththreats-in-2014/> Web. 10 September 2015.
3. Centers for Disease Control and Diversion Prevention, Risks of Healthcare-associated Infections from Drug Diversion, (September 2015) <http://www.cdc.gov/injectionsafety/drugdiversion/>
4. Berge, K., Dillon, K., and Sikkink. "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention". *Mayo Clin Proc.* 2012;87(7):674-682.
5. AM Trinkoff, CL Storr, MP Wall: "Prescription-type drug misuse and workplace access among nurses." *J Addict Dis.* 1999;18(1):9-17. <http://1.usa.gov/19rWjN2>
6. Ron Buzzeo and Machel Neale: "Hospital Drug Diversion and Abuse – Creating an Effective Surveillance and Prevention Program." Cedegim Company, January 2013. <http://bit.ly/1Fsn1RC>
7. U.S. Department of Labor: Occupational Employment and Wages, May 2014. <http://www.bls.gov/home.htm>
8. Hawk, K., Vaca, F., and D'Onofrio, G. "Reducing Fatal Opioid Overdose: Prevention, Treatment and Harm Reduction Strategies." *The Yale Journal of Biology and Medicine* 88.3 (2015): 235–245.
9. Drug Enforcement Administration. "DEA dialogues with registrants on preventing pharmaceutical diversion at conference this week". DEA Headquarters News, September 25, 2015.
10. Food and Drugs, 21 C.F.R. 1300-1499 (2015).

11. Patient Safety Authority Department of Health. Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under the Medical Care Availability and Reduction of Error (MCARE) Act. The Pennsylvania Bulletin, September, 2014; 44 Pa.B.61781.
12. "Reducing Controlled Substances Diversion in Hospitals." *Http://www.chpso.org/sites/main/files/fileattachments/controlled_substance_diversion.pdf*. California Hospital Association, 2013. Web. 5 May 2015.
13. "Minnesota Controlled Substance Diversion Prevention Coalition." *Http://archive.leg.state.mn.us/docs/2012/other/120452.pdf*. Minnesota Hospital Association and Minnesota Department of Health, 1 Mar. 2012. Web. 5 May 2015.
14. Pennsylvania State Coroners Association. Report on overdose death statistics 2014. [http://www.pacoroners.org/Uploads/Pennsylvania State Coroners Association Drug Report 2014.pdf](http://www.pacoroners.org/Uploads/Pennsylvania%20State%20Coroners%20Association%20Drug%20Report%202014.pdf). Web. 10 October 2015.
15. National Drug Control Strategy – A 21st Century Drug Strategy: Relying on Science, Research and Evidence to Improve Public Health and Safety in America. Office of National Drug Control Policy. (2014) Downloaded 09.11.15 from www.whitehouse.gov.
16. General Accounting Office. Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States. Washington, DC: General Accounting Office; 2009.
17. Pennsylvania Department of Health, Bureau of Health Statistics and Research. [database] Wed. 11 September, 2015.
18. National Survey on Drug Use and Health (NSDUH) [database]. Accessed Sept 10, 2015.
19. Sucher, Sandra J., and Stacy McManus. "Ritz-Carlton Hotel Company, The." Harvard Business School Case 601-163, March 2001. (Revised September 2005.)