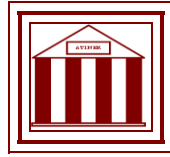


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**Analysis and Comparison of Pharmaceutical Waste
Collection Data by Multiple Methods; USA, State of
Maine**

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Abstract

Objective

There is a critical need for pharmaceutical (medication) waste collection and disposal programs that are accessible to the consumer, both in urban and rural areas. The goal of this project was to collect data regarding unused medications in order to inform public health policy, increase patient safety, improve pharmacy practice, decrease poisonings, abuse, misuse, and diversion of medications and to document medication disposal programs.

Methods

Medication drop-off events were conducted in April and October of 2011. Data entry into the Pharmaceutical Collection Monitoring System™ (PCMS) was analyzed based on medication classification, controlled substance category, therapeutic class, and medication percent waste (units returned divided by units dispensed). Mail-back data consisted of a convenience sample and utilized DAWN (Drug Abuse Warning Network) classifications.

Results

Medication drop-off events resulted in a collection of 3400 individual medications from 300 discrete participants. A total of 141,095 units (capsules, tablets, milliliters, patches, or grams) were collected representing 75.6% ($\pm 9.1\%$) medication waste when compared to the amount dispensed. The medications returned via the mail-back method totaled 11,382 individual items.

Conclusion

The significant quantity of medications collected including controlled substances and the high proportion of medication waste underscores the need for pharmaceutical waste collection programs. The need also exists for medication education for all health care providers, government officials, and communities in order to decrease poisonings, abuse, misuse, and diversion.

Keywords: Medication waste, Medication collection, Unused medication, Medication Disposal, Pharmaceutical waste, Pharmaceutical collection

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Introduction

The misuse, abuse, and diversion of medications are a growing national crisis. The lack of return programs have left households with unused and sometimes expired medications that are easily accessible to abusers, accidentally ingested by children and pets, and mistakenly taken by older adults. As a result, there is an increasing public health crisis with subsequent high annual medical costs related to morbidity, mortality, and addiction.¹ In an attempt to obtain medication return data, Maine hosted over 154 collection sites for the U.S. Drug Enforcement Administration (DEA) national medication drop-off events in 2011. Data was collected from eleven of those sites. The intent of this project was to collect data regarding unused medications in order to inform public health policy, increase patient safety, improve pharmacy practice, decrease poisonings, abuse, misuse, and diversion of medications and to document medication disposal programs.

Background

The 2007 Athens Declaration lists six reasons to address medication waste and disposal; ‘to curtail childhood overdoses, restrict household drug theft, limit accumulation of drugs by the elderly, protect our physical environment, restrain improper international drug donations, and eliminate waste in the international health care systems of all countries’.² The plea was made to all governments to address policy shortfalls in an attempt to deal with medical waste and community dangers. An additional plea was made to health care providers and organizations, as well as to patients, to properly dispense and use medications. The declaration asked for worldwide support for ‘the betterment of the health of the environment and patients worldwide’.²

In 2008, DAWN estimated that of 2 million drug related emergency room visits 1.1 million resulted from medication abuse or misuse.³ Of these, 60.4% were from the non-medical use of a pharmaceutical alone, 19% from pharmaceutical use with alcohol, 15.3% from pharmaceutical use with illicit drugs, and 7.8% from pharmaceutical use with illicit drugs and alcohol.³ The data presented by DAWN

represented a 97% increase in non medical use of pharmaceuticals alone, a 60% increase in non medical pharmaceutical use in conjunction with illicit drugs, and an increase of 50% in non medical use of pharmaceuticals and alcohol from 2004-2008.³ The increase in non medical use of pharmaceuticals occurred within all age groups. In 2009, the National Survey on Drug Use and Health revealed that of 7.0 million youth, age 12 and older, abusing or misusing pharmaceuticals, 55.3% obtained medications from a friend or family member.⁴ The misconception that pharmaceuticals are safe, and ease of access to the family medicine cabinet, have contributed to the large increase in pharmaceutical misuse, abuse, and diversion.

Faced with a national public health crisis the Executive Office of the President devised a plan, 'Epidemic: Responding to America's Prescription Drug Abuse Crisis'. The plan proposes action in four major areas; education, tracking and monitoring, proper medication disposal, and enforcement.⁵ The first step is aimed at increasing pharmaceutical education for society and health care providers. Common misconceptions need to be corrected; our prescribers need to have in depth training on appropriate prescribing and dispensing habits inclusive of the dangers of pharmaceutical misuse and abuse. Once education is addressed, the second step adds a formal method of tracking and monitoring the problem. Most states have implemented prescription drug monitoring programs; however, there is no consistency or regulation mandating their use. With over 3.8 million youth obtaining medications from friends or family members, proper medication disposal is crucial. In order to affect the problem, the third step addresses the need to clear households of unused medication that can be easily accessed and used for further abuse or misuse. In an effort to facilitate drug disposal while regulations are still being developed, the DEA hosted three national medication drop-off events. The final step, enforcement, focuses on the critical need for a partnership between the healthcare and legal systems to address this crisis.⁵

Recent state and federal reports indicate that Maine is suffering disproportionately from this national epidemic. According to the Treatment Episode Data Set (TEDS); Maine has led the country since 1998 in non-heroin opiate admissions.⁶ In 1998 Maine had a total of 28 admissions per 100,000 population; rising to 386 admissions per 100,000 population in 2008.⁶ Maine's pharmaceutical death rate has now surpassed motor vehicle accidents (165 deaths compared to 159, respectively).⁷ As the number of pharmaceutical deaths rose, the number of illicit drug deaths fell; perhaps indicating that abusers are shifting from illicit drug use to the use of pharmaceutical agents. In 2009, only 19 of the 185 statewide overdose deaths, were from illicit drugs.⁷ This brings a realization that our own medicine cabinets may be the main source for abuse, misuse, and overdose deaths.

In 2003 the state of Maine passed two public laws; Title 22, Chapter 1603 and Chapter 679 which enabled the Maine Prescription Monitoring Program (PMP) and the Safe Medicine Disposal for ME (SMDME) mail back program, respectively.⁸⁻¹⁰ The PMP database is utilized as a tracking and monitoring system for controlled substance prescribing and distribution.⁸ However, less than 40% of prescribers and 15% of pharmacists in Maine are registered to use the program. This represents a large proportion of prescribers who underutilize the PMP data. The PMP enables tracking and monitoring of the growing pharmaceutical problem within Maine but does nothing to clear community homes of unused pharmaceuticals. The SMDME program was developed as a statewide template for national replicability for the disposal of unused pharmaceuticals.¹¹ The program allows community members to anonymously utilize the U.S. Postal Service, which is a unique service provided by

Maine DEA, in order to easily return controlled and non controlled medication, free of charge, for proper incineration.¹¹ Within the state of Maine, local actions have initiated the process of dealing with the pharmaceutical public health crisis by tracking and monitoring the problem and removing unused medication from community homes. The intent of this project was to utilize the data obtained from the national medication drop-off events to inform policy. Furthermore, the SMDME program will serve to raise awareness of the growing need for medication disposal programs.

Methods

The eleven national medication drop-off collection sites were recruited independently via the PCMSTM coordinator in collaboration with Generation Rx, a subset of the American Pharmacists Association, Academy of Student Pharmacists, chapter at the University of New England (UNE), and all sites entered into a use contract with the tool designers. Institutional Review Board (IRB) exemption was granted by UNE. All data was collected by student pharmacists under direct supervision of pharmacists, independent of the DEA, with approval from local law enforcement. The PCMSTM tool allowed for consistency in all data sets through its interface with MICROMEDEX®, a comprehensive drug database, providing full drug information.

The first fifty participants, followed by a random 10% sample, were taken from each of the sites in Maine. Each participant was assigned a number based upon the order they arrived at the site. All returned items were de-identified, placed into bags, and labeled with the participant number prior to being logged. The data logged included classification (prescription, over-the-counter, or controlled prescription), name of medication or product, strength (including units), formulation, original quantity dispensed, quantity returned (manually counted), manufacturer, original fill date, expiration date, and indication of whether the medication was a sample, factory sealed, or mail order. Full medication information, including controlled substance category, was compiled using the PCMSTM tool. Excel reports were generated for data points entered.

The SMDME mail-back data was collected from 2008-2009. A random 10% convenience sample was taken from voluntarily returned DEA envelopes. All medications within the sample of envelopes were logged. Data points included classification (prescription, over-the-counter, or controlled prescription), name of medication or product, strength (including units), formulation, original quantity dispensed, quantity returned (manually counted), original fill date, and expiration date. The data was compiled using DAWN classifications.

Results

From the eleven participating sites in the national medication drop-off collection, 3400 individual medications were received from 300 discrete participants. The medications returned from the mail-back method totaled 11,382 individual items. The mail-back had higher percent returns than the drop-off of central nervous system (CNS), cardiovascular, and psychotherapeutic agents (19.8% vs. 5.1%, 25.2% vs. 14.7%, and 10.8% vs. 3.5%, respectively). The percentage of prescription medications

logged via the mail-back method was greater than that of the drop-off method (85.6% vs. 72.2%) whereas the drop-off method had a higher amount of over-the-counter medications logged (25.3% vs 12.4%, respectively). The medication category breakdown for each method of collection can be found in **Table 1**. Of the medications collected by the drop-off method, a total of 141,095 units (capsules, tablets, milliliters, patches, or grams) were collected. When compared to amounts dispensed, collections represented a total of 75.6% ($\pm 9.1\%$) medication waste. The medication category breakdown and percent waste for the drop-off method can be found in **Table 2**.

Controlled substances accounted for 10.4% (14,693 units) from the drop-off method. The controlled substance category breakdown and correlating percent waste can be found in **Table 3**. Of the controlled prescriptions returned, schedule II medications totaled 38.2%. Non-controlled prescriptions collected by the drop-off method totaled 81,680 units, 79% waste. The non-controlled medications and percent waste is broken into therapeutic classes in **Table 4**.

Discussion

The goal of this project was to obtain data in order to document the growing need for medication disposal programs which could also be used for comparison of different collection models. The national drop-off event in April 2011 was the first simultaneous medication disposal event utilized to collect data with a second event being held in October. The combined data collected allows for comparison of the drop-off medication disposal program to the mail-back disposal program, which utilizes a convenience sample method. The mail-back program had a total of 11,382 individual medications collected within their study compared to the drop-off event only having 3400. A higher proportion of individual medications returned through the mail-back program were controlled substances (1,903) than from the drop-off event (551). This represents a large difference when comparing a one year time frame. The numbers of controlled substances are important because these classes of medications have the highest potential for abuse, misuse, and diversion.

Based upon the data comparison of the two disposal programs, the mail back program has been more successful in removing larger amounts of unused medication from the community. The success of the program could be contributed to several factors including continuous collections, anonymity, and convenience of return process. Envelope locations are located throughout the state for the mail-back program. This allows community members to continuously return unused medications as they obtain them therefore preventing a buildup of medications within the home. The US Postal Service provides an easy way to return the medications regardless of how rural the community. Community members simply have to place the envelope with their unused medication waste into the mailbox at their homes, requiring no travel. The anonymity that the mail-back program achieves relieves community members of the embarrassment and anxiety associated with unused medications. People may fear having to explain why they have not used the medications as directed or have to relive a family member's death. These factors contribute to the success of the mail-back program.

When comparing the data between the two national medication drop-off events, some variations between the April event and the October event were observed. Some variation was to be expected due to increasing the number of sites for the October

event as compared to the April event. The most distinguished variations included the antibiotic and Schedule II medication returns. In October antibiotic returns totaled 1,997 units with 77.1% ($\pm 9.1\%$) waste, which represents an increase of 34.3% in six months. The increase in antibiotic returns in October could be due to seasonal changes which is often the cause of sickness. Schedule II medication returns for the April event totaled 1,156.75 units with 66.6% ($\pm 9.1\%$) waste. The October event totaled 4,379 units with 79.0% ($\pm 9.1\%$) waste representing an increase of 278.6%. Factors that may contribute to the increased schedule II collection and correlated increased waste in October could include prescribing trends, the increase in event sites, or injuries correlated to the season, such as fall and winter sports.

In addition to establishing the need for medication disposal programs, the recognition of pharmaceutical education is a necessary component in order to increase patient safety and decrease poisonings, abuse, misuse, and diversion. This is an area of concern because, as health care providers, we are directly related to the patient and associated medication adherence and waste problems. The health care system has largely neglected the various reasons for the growing medication crisis. Potential solutions for this problem include a pharmacist's role in addressing non-adherence, the prescriber's role in overprescribing and the insurer's role in excess fill policies, but these are only three parts in the multifactorial problem.

In 2009, New England Health Care Institute (NEHI) estimated the cost of poor medication adherence and other drug-related problems to be \$290 billion US dollars; 13% of annual healthcare expenditures.¹² Pharmacists are addressing non-adherence through patient education. Time constraints in the workplace lead to an abundance of information being given to a patient in a small amount of time or a lack of information being provided in an attempt to advise on the most important topics (i.e. severe side effects). In order to address growing concerns, MTM (medication therapy management) was implemented in 2006 as a provision of Medicare part D, to 'optimize therapeutic outcomes' through the review and education of all non/prescription medications, herbals, supplements, and their associated disease states.¹³ MTM allows the pharmacist to become part of the health care team in collaboration with all health care professionals in an attempt to reduce adverse effects, non-adherence complications, therapeutic duplications, and health care costs.

Prescribers are attempting to treat their patients while keeping in mind the cost associated with medications. Patients go to their health care providers to treat a condition they suffer from; however, most patients with multiple medical needs are older adults on a limited budget. The health care provider then has to weigh the benefit to risk ratio when dealing with these patients. If a medication is prescribed that the patient can't afford, they won't take it; which leads to adverse outcomes and increased medical costs. The medication could be given for a trial period of two weeks; however, unless prorated, the patients co-pay for that medication could double due to the multiple prescriptions being needed and the patient may not be able to afford it. The response to the problem is the prescriber writing a prescription for a 30 day supply and hoping, based on their medical judgment that the medication works as intended. Unfortunately not all medications work as intended due to variations in patient genetics and environmental factors which cannot be known by the prescriber.

Patient health illiteracy can also lead to non-adherence and further medical problems. All too often patients don't understand the information provided to them and are too embarrassed to state so. As health care providers we assume the lay language we use is being understood by our patients but, if we neglect to verify this, there's no way to be sure. As a health care community we need to collaborate with

each other and have a way to better educate our patients on the proper use of their medications and the dangers associated with non-adherence. The barriers of health literacy need to be broken for the benefit of society and programs should be implemented to ensure patient understanding.

In order to attempt to determine the multitude of reasons for unused medications, further data needs to be collected. There are limitations to the data collected from the drop-off event. The data was collected in only eleven locations within the state of Maine, only sampled 3400 individual items, and is not an ongoing event. The mail-back program has obtained data for 11,382 individual items throughout the state of Maine and is a continuous disposal process. In an attempt to fully understand the pharmaceutical waste epidemic further data should be collected utilizing the mail-back program. This may lead to a deeper understanding of the underlying causes of the pharmaceutical crisis.

Conclusion

A significant quantity of medications including controlled substances were collected through both drop-off and mail-back methods. Medication waste was high in both collection methods. These observations emphasize the need for legal and sustainable state and national medication collection programs. These programs are necessary not only to collect further data in order to inform public health policy but also to improve community health by removing dangerous and potentially addictive medications from residential areas in an environmentally safe manner.

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Table 1: Number of medication items returned by Mail-Back or Drop-Off method for each medication category.

Medication Category ^a	Returned Items ^b (%) Mail Back	Returned Items ^b (%) Drop Off
Noncontrolled Rx	7,838 (68.9)	1,905 (56)
Schedule II Rx	726 (6.4)	247 (7.3)
Schedule III Rx	478 (4.2)	149 (4.4)
Schedule IV Rx	643 (5.6)	144 (4.2)
Schedule V Rx	56(0.5)	11 (0.3)
Over-the-counter (OTC)	1,413 (12.4)	860 (25.3)
Unknown & Nonmedication	228 (2)	84 (2.5)
Total Combined^c	11,382 (100)	3,400 (100)

^a Controlled substance schedule is based upon the Controlled Substance Act of 1974.

^b Items are the individual medications returned.

^c Total percent may not add up to exactly 100 due to rounding.

Table 2: Medication returns by the drop-off method by number of units and percent waste for each medication category.

Medication Category ^a	Returned Units ^b (%) Drop-Off	Waste ^c (%; ±9.1) Drop-Off
Noncontrolled Rx	81,680 (57.9)	79.0
Over-the-counter (OTC)	41,735 (29.6)	68.4
Schedule II	5,536 (3.9)	76.1
Schedule III	4,259 (3)	73.5
Schedule IV	4,471 (3.2)	75.9
Schedule V	428 (0.3)	67.7
Nonmedication/Unknown	2986 (2.1)	N/A ^d
Total Combined^e	141,095 (100)	75.6

^a Controlled substance schedule is based upon the Controlled Substance Act of 1974.

^b Units are capsules, tablets, milliliters, patches, or grams returned.

^c Percent waste calculated by units returned divided by units dispensed.

^d Missing some original amounts.

^e Total percent may not add up to exactly 100 due to rounding.

Table 3: Medication returns by the drop-off method by number of units and percent waste for each controlled substance category.

Controlled Substance Category ^a	Returned (%)	Units ^b	Waste ^c (%)
Schedule II Opioid	3993 (27.2)		74.8
Schedule IV Benzodiazepine	2862 (19.5)		78.1
Schedule III APAP & Hydrocodone	2186 (14.9)		73.7
Schedule III Opioid	1656 (11.3)		78.2
Schedule II APAP & Oxycodone	1132 (7.7)		81
Schedule IV Opioid	899 (6.1)		78
Schedule IV Sedative/Hypnotic	710 (4.8)		65.8
Schedule II Stimulants	478 (3.3)		75.9
Schedule III APAP & Codeine	270 (1.8)		64.9
Schedule V Opioid	215 (1.5)		44.8
Schedule III Other Schedule III	147 (1)		49.2
Schedule V Antihistamine (without PPA)	128 (0.9)		64
Schedule V Anticonvulsant (exclude barbiturate)	54 (0.4)		52.9
Schedule V Other	31 (0.2)		34.4
Schedule II Barbiturate	3 (0.02)		100
Total^d	14,693 (100)		74.1

^a Controlled substance schedule is based upon the Controlled Substance Act of 1974.

^b Units are capsules, tablets, milliliters, patches, or grams returned.

^c Percent waste calculated by units returned divided by units dispensed.

^d Total percent may not add up to exactly 100 due to rounding.

Table 4: Medication returns by the drop-off method by number of units and percent waste for non-controlled prescriptions by therapeutic class.

Therapeutic Class ^a	Returned Units ^b (%)	Waste ^c (%)
Cardiovascular	20,713 (25.4)	81.6
Gastrointestinal	6,675 (8.2)	91.3
Hormone & Hormone Replacement	4,985 (6.1)	64.4
Miscellaneous	4,671 (5.7)	76.9
Antidepressant	4,189 (5.1)	79.7
Lotion	4,090 (5)	96.6
Anticonvulsant	3,967 (4.9)	83.2
Antibiotics	3,484 (4.3)	79.4
Diuretics	3,309 (4.1)	73
Asthma	2,999 (3.7)	76
NSAID	2,446 (3)	83.6
Antihistamine	2,406 (2.9)	99.9
Hypoglycemic	2,098 (2.6)	72.7
Anticoagulants	2,024 (2.5)	64.9
Opioid (non controlled)	1,465 (1.8)	N/A ^d

Sedative/Hypnotic (non-controlled)	1,429 (1.7)	N/A ^d
Antineoplastic	1,348 (1.7)	58.2
Antacids	1,079 (1.3)	63.7
Muscle Relaxants	1,036 (1.3)	77.3
Steroids (topical)	879 (1.1)	74.3
Antispasmodic	810 (1)	67.1
Electrolytes & Minerals	808 (1)	73.6
Other Non-controlled Rx	780 (1)	73
Cyclic Antidepressant	775 (0.9)	83.3
Vitamins	522 (0.6)	66.8
Analgesics	504 (0.6)	87.5
Other (combined)^e	2128 (2.6)	58
Total^f	81,680 (100)	79

^a Therapeutic class based upon MICROMEDEX® classification.

^b Units are capsules, tablets, milliliters, patches, or grams returned.

^c Percent waste calculated by units returned divided by units dispensed.

^d Original counts missing.

^e Includes all other non-controlled prescription therapeutic classes.

^f Total percent may not add up to exactly 100 due to rounding.