Medication Disposal: The Final Step in Medication Safety

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Overview

About ten million prescriptions are filled and dispensed across the nation every day.[1] When these medications are no longer needed, or unused, or expired, it is important to dispose of them properly to avoid harm.[2] Of the nearly 4 billion prescriptions dispensed in 2016, about 1.6 billion prescriptions were unused, but only 7.5 million prescriptions were returned (0.45% return rate) [3]. Without proper disposal, these unused medications may dwell in homes and risk accidental poisoning, drug abuse/misuse/diversion, and potentially harm the environment through groundwater contamination.[4] This article explores (1) risks associated with having unused medications accumulated in households, (2) current recommendations regarding disposal of unused medications, and (3) future implications of expanding public access to medication disposal.

1. Risk of keeping unused medications at home

Consumers have a tendency to save and store expensive and difficult-to-obtain prescription medications for a rainy day[5], leading to an increased risk of medications being used for unintended uses and possibly by unintended users. About 70% of Americans have reported obtaining prescription medications from friends and relatives.[4] Nearly 35,000 children are reported to have visits to the emergency rooms annually due to accidental poisoning by ingesting prescription medications.[6] In addition to the health and safety problems of unused medications at home, there is also the issue of economic strain. In 2010, the cost associated with unintentional poisoning was estimated at $68 million.[7] Awareness and education about appropriate medication disposal (including storage, inventory, and disposal instruction) is thus required for both consumers and providers (Table 1). These precautions are especially important as patients are increasingly prescribed potent oral chemotherapy tablets or advised self-administration with the intravenous, subcutaneous, and intramuscular injectable forms. There appears to be little information available on disposal of unused or expired chemotherapy agents.[8]

2.Current recommendations on proper medication disposal

Prior to 2014, there were no concerted efforts in raising awareness about medication disposal. The U.S. Drug Enforcement Agency (DEA) had held biannual Drug Take-Back events since 2010, but barring that, the option was to contact a law enforcement agency to check if it would accept unused medications.[9] Pharmacies and hospitals were banned from accepting unused prescription drugs, because it was construed as drug diversion. The FDA website published a list of 47 medications (especially those with a high potential for drug abuse and diversion) that could be flushed down the toilet. Given that the information was not standardized, most people just flushed unused medications down the toilet or threw them in the trash. The dangers of these practices were revealed by studies that reported a trace amount of pharmaceutical products, such as antibiotics, antiepileptics, mood stabilizers, and sex hormones, in groundwater and in drinking water across the United States and the possible impact on humans and animals.[10,11,12]

The hallmark policy change to improve the public's awareness of disposal of unused medicines happened on September 9, 2014[9], when the DEA expanded the disposal sites allowed to accept unwanted medications (Table 2). These designated entities were required to register with the DEA as an authorized collector. As of late 2015, there were 615 registered collection sites nationally.[13] In California, there are currently 468 registered collection sites, of which about 136 (29.0%) are retail pharmacies.[14] In addition to the DEA's expansion on the authorized collectors for safe disposal of unused medications, there have been noticeable efforts made at the national, state, and county levels.[15,16] The federal law was updated to allow end users (consumers) to return controlled substances to any DEA registered authorized collectors, including retail pharmacies. California recently passed Senate Bill 1229 (Jackson) to encourage pharmacies to host drug take-back bins under the title "Home-generated pharmaceutical waste: secure drug take-back bins"[17] and joined 42 other states and Washington D.C. that include retail pharmacies as secure disposal sites for unused medications.[14]

In 2015, Alameda County initiated a project (Alameda MED-Project) with the ultimate goal "to provide county residents with convenient, safe and accessible methods to dispose of Unwanted Medicine." The project was targeted to install 20 kiosk collection receptacles and hold 12 take-back events in and around Alameda County, but there were unanticipated delays with establishing agreements with law enforcement agencies. Alameda County concurrently worked with a pharmaceutical company, Exelixis, Inc., to fund a mail-back program. In 2015, this drug maker's mail-back program was underutilized, as there were zero returns of the product.[18]

Although the law has allowed pharmacies to serve as regular take-back locations, pharmacies face some challenges because of the multiple steps and the cost involved in the process.

1. Collector needs to be registered with the DEA as an authorized collector.
2. Collector needs to purchase a receptacle (bin, kiosk, etc.) to install in a secure manner and according to the DEA regulations.
3. Collector needs to purchase new linings each time to replace when the old lining is full.
4. Receptacles need to be maintained and secured during the collection period.
5. Collector needs to contact a DEA-authorized pharmaceutical waste management company to securely transport and dispose of the collected drugs.

These challenges are especially highlighted for independent pharmacies. Some chain stores such as Walgreens have installed 500 kiosks in 39 states and Washington D.C.; however, these are not in every one of its 8,177 stores.[19] CVS pharmacy has been focusing on providing drug collection units to police departments and offering mail-back programs instead of installing kiosks at its retail pharmacies, potentially due to security reasons. Some pharmacies are still hesitant in assuming the responsibility as a collector due to concerns about safety, liability, and cost.[20]

Future Implications

Previous paragraphs have highlighted numerous challenges with medication disposal and with establishing a standardized disposal process, which make it difficult for a single entity to assume the responsibility. This section outlines key elements to consider when establishing convenient, safe, and accessible methods to dispose off unused medications.

Logistics

Establishing a sustainable drug take-back program needs an integrated approach by stakeholders in the drug supply chain. Although there is regulatory support to become an authorized collector, this needs to be paired with an incentive for pharmacies to balance the assumed responsibility and risk of establishing a medication disposal program.[9,17] In 2012, a group of pharmaceutical companies unsuccessfully sued Alameda County for passing the ordinance requiring drug makers to pay for collecting and destroying unwanted pharmaceuticals.[21] As a result, pharmaceutical companies were required to fund the drug take-back program in Alameda County, and the project's estimated cost is about $570,000 annually.[20] There are several ongoing battles between Pharmaceutical Research and Manufacturers of America (PhRMA) and local government agencies over this issue. The answer to the question "who is responsible for paying for collecting and destroying unwanted drugs?" is still unclear.

The Walgreens initiative on installing the drug collection kiosks is still at an infant stage. It will likely take a couple more years to determine the sustainability of the project. Unless government entities, pharmaceutical companies, or third-party payers financially support these programs, installing and maintaining the receptacles will continuously remain a challenge for both independent and chain pharmacies. An idea to integrate a "disposal fee" from the payer (similar to a dispensing fee) per every prescription dispensed could be a potential solution that would allow pharmacies to allocate funds to initiate and maintain drug take-back programs in routine practice.

Attitude

Retail pharmacies are a readily accessible and convenient place to drop off unused medications. In a survey report, a majority of the study respondents (73.0%) answered that they are willing to drop off medications anywhere that is convenient, and nearly all (93.8%) identified the nearest pharmacy as a convenient location.[22,23] As of August 2016, eight out of 10 Americans were living within five miles of a Walgreens store.[25] However, less than 1% of retail pharmacies in the United States are DEA authorized collection sites. Consumers are willing to clean up and throw away unwanted drugs at a nearby location, but finding an authorized collector is currently inconvenient for consumers because these services are not readily offered at most retail pharmacies.

Pharmacies are reluctant to offer drug take-back services because not only is it costly but it also exposes them to potential theft and vandalism. A number of case reports have surfaced such as (i) a pharmacist catching customers fishing medications out of the drop boxes with fishing poles and (ii) a clinic with a drop box outside of its pharmacy having someone pull a truck up to the box, wrap a chain around it, and rip it out of the wall. These anecdotal incidents are shared by word of mouth amongst professional colleagues, discouraging independent pharmacy owners from starting a potentially problematic and dangerous service. Currently, the California State Board of Pharmacy recognizes that a drop box in a pharmacy in some neighborhoods could be a risk to the customer, the pharmacy staff, and the pharmacy itself.[25]

Education

Numerous efforts have been made to raise the public's awareness on the importance of properly disposing of unused drugs from homes, but these efforts still have a long way to go. Each year, more and more people are dropping off unused medications at the DEA's National Drug Take-Back Event. In the recent 13th National Take Back day held by the DEA on April 28, 2018, the event collected a record-breaking 475.4 tons of unused medications from almost 5,800 sites across the nation.3 These events have been advertised through social media and the local news to raise awareness to the public, but many consumers find it challenging to participate in the event because it is held only for a single day during specified hours.

Unlike the nationwide effort on promoting the drug take-back events, one-on-one patient and provider education regarding how to properly dispose of unused medications may not be occurring as often in practice. An observational study reported that only 25% of patients received instructions about opioid disposal after receiving outpatient shoulder surgeries.[26] Results from a study demonstrated that patients who received medication disposal information were more likely to return unused drugs to a collection facility compared to those who did not receive education (28.6% vs. 6.8% return rates, respectively).[22]

Package inserts could begin to include information on medication disposal in addition to existing information about proper storage and handling of each medication. Currently it is sometimes available but difficult to access since the FDA directs consumers and health care professionals to one of the five sections on the package insert to find the disposal information. Pharmacists are a readily available resource to provide this infor-

mation to the public. However, counseling about proper disposal is not standard practice. When pharmacists (n=142) were asked to identify government agencies responsible for providing drug disposal information, only a few (n=19, 13.4%) correctly identified all three agencies (FDA, EPA, and DEA).27 Incorporating training within the PharmD curriculum or as continuing education to raise awareness on the importance of proper disposal of unused medications could be an effective way to achieve professional confidence in providing proper drug disposal information.

Table 1. Information about counseling patients who wish to dispose off medications.

Authorized Collector[12]	Household Trash[15]	Flushing Down the Toilet [15]
California residents who wish to locate an authorized collection site should visit 'www.calrecycle.ca.gov' and follow the following steps to locate the site: 1. Go to 'www.calrecycle.ca.gov' 2. Click 'Consumers' tab on the upper right corner 3. Click 'Facility Information Toolbox (FacIT)' 4. Click 'Detailed Facility Search' 5. Enter the location (by county, region, or zipcode) 6. Select 'Collection/ Transfer: Medication Collection' under Activity tab 7. Click 'Search'	In case the authorized collection site is not conveniently available, unwanted/unused medications can be disposed in household trash. 1. Mix medicines (do not crush tablet or capsules) with dirt, kitty litter and used coffee grounds 2. Place the mixture into a sealed plastic bag 3. Throw the sealed bag into a household trash 4. Scratch out all personal information on the prescription label	The FDA published a short list of medications recommended for disposal by flushing down the toilet. These medications may be especially harmful and fatal with just a small amount of ingestion. The list can be easily searched by 'Medicines Recommended for Disposal by Flushing' in any search engine.

Figure 1. States that allow retail pharmacies to take back controlled substances from the end users.

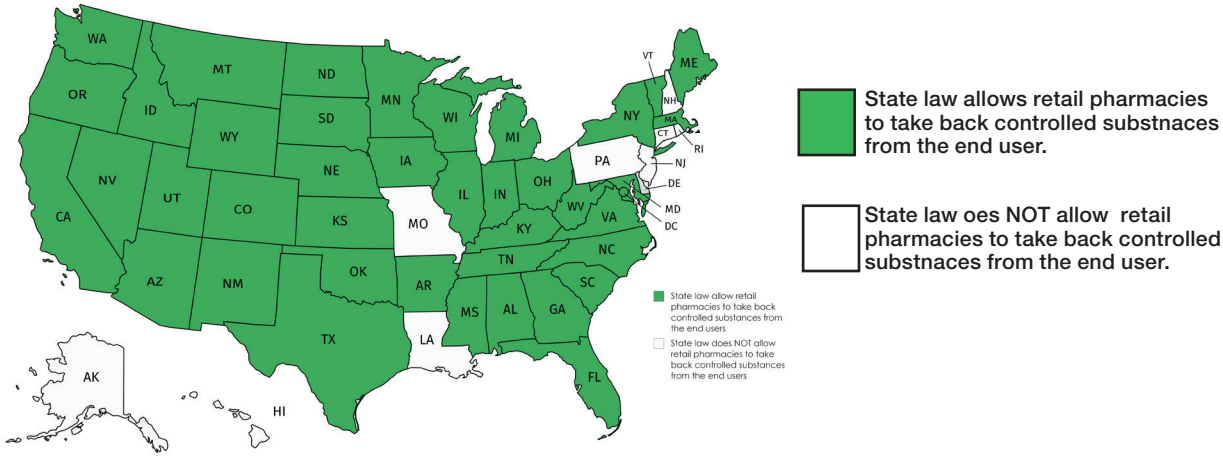

Table 2. Chronological update in regulations on drug take-back issue

Effective year	Title of the Act	Summary
1970	Comprehensive Drug Abuse Prevention and Control Act("Controlled Substance Act") [1]	The legislation created five classifications for controlled substances. Today, it is known as CS I, II, III, IV, and V. Consumers were prohibited from returning unwanted controlled substances to DEA registered entities, including retail pharmacies, for disposal purposes. Allowable methods include: • Surrender to law enforcement • Seek assistance from the federal DEA • Flushing or discarding at home
2010	Secure and Responsible Drug Disposal Act ("Disposal Act") [2]	• The legislation authorized consumers to deliver their controlled substances to another person for the purpose of disposal. • DEA began hosting Drug Take-Back Events biannually.
2014	Final ruling of the Disposal Act of 2010 [3]	This final ruling of the legislation expanded the options to collect controlled substances from consumers for secure destruction. Allowable methods include: • Take-back events • Mail-back programs • Collection receptables (permanent drop-off box) Allowable collectors include: Retail pharmacies, Hospitals/clinics with an onsite pharmacy, Drug manufacturers, Drug distributors, Reverse distributors and Narcotic treatment programs.

***Figure 2.**

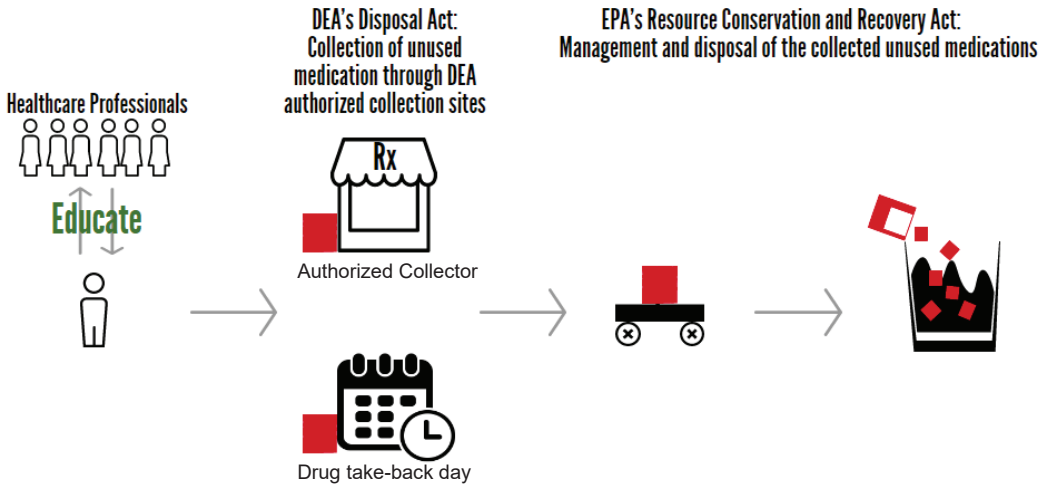

Table 3. Current challenges and future implications on proper medication disposal.

Problems	Solutions
There is limited training related to medication disposal in both the PharmD curriculum and continuing education programs	Incorporate 1-2 hours of classroom activities within the pharmacy curriculum on a topic related to proper medication disposal Provide CEs related to proper medication disposal methods and consumer education.
There are unknown cost and liability issues related to stolen/tampered receptacles	In California, the recently passed law provides immunity to civil and criminal liabilities for pharmacies hosting drug take-back bins (SB 1220, Jackson)
Medication disposal information is not a requirement in a package insert, and it is challenging to find the information. According to the FDA, the agency directs the consumers and health professionals to refer to one of the following sections of the prescribing information to find disposal instructions on individual drug products 1. Information for Patients and Caregivers 2. Patient information 3. Patient counseling information 4. Safety and handling instruction 5. Medication guide	Suggest a change in regulation to designate a specific section on the package insert dedicated to medication disposal information
Cost associated with installing and manning the take-back bins and receptacles	Establish a shared cost with drug manufacturers and/or managed care organizations on charging a disposal fee when prescriptions are filled and dispensed at the pharmacy

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