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Knowledge and Barriers to Safe Disposal of Pharmaceutical Products Entering the Environment

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Abstract

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MS, New Jersey Institute of Technology, 1997

MPH, University of South Florida, 1991

BS, State University of New York, 1990

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health—Epidemiology

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Abstract

The use of pharmaceutical products has steadily increased in the United States from 2 billion prescriptions in 1999 to 3.9 billion in 2009. Half of patients do not comply with the recommended prescription regimen and dispose of unused drugs in the environment. The U.S. Environmental Protection Agency and many researchers have highlighted the human-health risks associated with improperly disposing of pharmaceutical products. This quantitative cross-sectional study examined the potential correlations between people's actual disposal practices and their knowledge of the impact of disposal practices on the environment and human health, and availability of disposal options. The conceptual framework selected for this study comprised 2 models: the health belief model and the theory of planned behavior. Respondents to an online survey were 485 residents of the northeast United States, polled from the general population. Descriptive statistics and logistic regression were used to model responses from the dependent variable actual disposal practice (ADP) across the independent variables, and analysis of variance explored whether ADP differed across demographic variables. Statistically significant associations emerged among individuals' knowledge of environment and human-health impact, recommended disposal practices, disposal options, and that person's likelihood to practice recommended disposal. Demographic variables did not impact disposal behavior. To promote positive social change, it is recommended that policymakers plan and implement the expansion of convenient drug disposal options, as well as information campaigns on proper disposal practices. In parallel, health care professionals should stress to their patients the importance of complying with prescribed regimens, thus minimizing the amount of unused or expired medications.

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Dedication

This dissertation is dedicated to those people who feel there is an unequivocal need to restore the ecological balance of our planet. Humans need to make it a goal to support the health of the myriads of ecosystems that make up our planet's global health. Proper disposal of pharmaceutical products in the environment requires a social-change approach at different levels, as well as strong dedication from all involved.

Although the topic of this dissertation may be viewed as a minuscule contribution toward our planet's global health, its recommendations, if implemented, could still provide meaningful improvements.

This dissertation is also dedicated to those people who, for whatever reason, are not yet seeing the "big picture": the one where humans, animals, skies, oceans, the flora, and all their related ecosystems contribute to "global health." It is my hope that this dissertation will at least inspire these people to ask questions, demand answers, and further develop their own awareness.

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Last, but not at all the least, I would like to thank all the Walden University faculty who have supported my growth as a researcher and content expert, through well-designed coursework and residencies.

Although my PhD journey is at its conclusion, I feel that my research process will and must continue. I have the tools, the methodology, and the expertise to do it.

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Chapter 1: Introduction

For more than a century, indispensable elements of human and veterinary medicine—pharmaceutical agents—have been entering the natural environment (de Cazes, Abejou, Belleville, & Sanchez-Marcano, 2014). Notably, it was in the United States that investigators first discovered evidence of the active ingredients of pharmaceutical drugs in water, revealing the presence of analgesics, heart medications, and contraceptive drugs in wastewater (World Health Organization [WHO], 2011). These early studies (Garrison, Pope, & Allen, 1976; Hignite & Azarnoff, 1977; Tabak & Bunch, 1970), published in the 1970s, spurred ongoing domestic and international research, documenting in detail not only the presence of pharmaceuticals in the environment, but also their adverse effects on organic life. In fact, even miniscule concentrations of pharmaceutical ingredients have been implicated in abnormalities found in fish populations (Corcoran, Winter, & Tyler, 2010; Ortner & McCullagh, 2010). Beyond the adverse effects on aquatic life, recent ecotoxicity studies, with more sensitive analytical techniques, have demonstrated that pharmaceutical pollutants are capable of affecting the growth, reproduction, and behavior of birds, invertebrates, plants, and bacteria, even at very low levels of concentrations (de Cazes et al., 2014). Directly connected with food and drinking water, trace concentrations in soils present a hazard to human health (de Cazes et al., 2014). Moreover, the levels of pharmaceuticals in soils and sediments tend to exceed concentrations detected in water (Fatta-Kassinos, Meric, & Nikoalaou, 2011).

Pharmaceuticals differ from other environmental pollutants in that they are created to be biologically active and will interact with cell tissue following specific absorption, distribution, metabolism, and excretion properties (Fatta-Kassinos et al., 2011). These properties can be beneficial at the prescribed dose, but they can have adverse effects when dispersed into the environment or in uncontrolled concentrations, as is the case when the drugs are flushed down the toilet or drained into the sink. Furthermore, to boost their intended action, pharmaceuticals are designed to resist biodegradation. Many drugs are extraordinarily potent. Oral chemotherapy agents, for example, represent the new generation of cancer treatments (Lester, 2012). From a consumer perspective, one of the many advantages of these drugs is that they allow patients the convenience and comfort of taking their medication at home. At the same time, the increasing presence of powerful pharmaceutical agents in U.S. homes underscores concerns regarding safe and proper disposal.

The use of prescription drugs in the United States has been labeled an epidemic (Maxwell, 2011). In the course of a decade, from 1999 to 2009, the number of drug prescriptions nearly doubled from 2 billion to 3.9 billion (Tong, Peake, & Braund, 2011). In addition, most households contain over-the-counter (OTC) prescription drugs, such as nonsteroidal anti-inflammatory drugs (NSAIDs), the most widely used drug class, which includes aspirin and ibuprofen. These drugs have the potential to cause kidney damage; kidney failure has been observed in animals exposed to NSAIDs in water (Ortner & McCullough, 2010). Tetracycline, a common antibiotic, was one of the first drugs discovered in water (Zhang, Zhang, & Fang, 2009). Significantly, the growth of tetracycline-resistant bacteria has been reported ever since. Hundreds of antibiotic resistant genes (ARGs) associated with resistance to a wide range of antibiotics have been detected in wastewaters, wastewater treatment plants, surface water, ground water, and drinking water (Fatta-Kassinos et al., 2011). All carry the potential to be transferred to humans through direct and indirect contact.

For decades, recommendations by researchers and international and U.S. health organizations for disposing of unused or expired medications were guided by concerns about inadvertent or intentional poisoning. Flushing them down the toilet or rinsing them down the drain was considered the safest and simplest way to dispose of unwanted drugs (McCullagh, Schim, & Ortner, 2012; Ortner & McCullagh, 2010). Given increasing awareness of the consequences of pollution from pharmaceuticals on the environment and its potential effects on human health, numerous international and government bodies recommend adopting strategies to minimize the amount of pharmaceuticals that enter the natural environment (WHO, 2011). Unfortunately, these recommendations have left the timeline for implementing the policies and the funding for providing consumers with safe disposal options to the respective governments. These strategies include drug take-back programs, guidelines and regulations, increased public awareness, and consumer education aimed at promoting the proper disposal of unused, unwanted, and expired medications. All take-back programs in the United States are administered by the Drug Enforcement Administration (DEA), which provides the destruction of the drugs through incineration.

According to Nisbet and Gick (2008), who envisioned a key role for health psychology in environmental protection, people generally desire a “safe, healthy environment” (p. 296). However, the concept of a safe, healthy environment is fairly abstract and, as a result, many people do not comprehend or do not link the issue of problems in the environment with the potential impact on human health. Moreover, even public-awareness campaigns designed to educate consumers about the impact of their behavior on the environment do not necessarily result in behavior change. A long history of public health campaigns has failed to produce the desired results, especially in changing behaviors that are deeply entrenched. Most consumers are so accustomed to disposing of drugs in the sink or toilet that they may not question their behavior, despite health and environmental concerns. Even nurses, pharmacists, and other health care staff who are highly aware of proper and improper disposal practices dispose of unused pharmaceuticals in the toilet or drain (Abahussain, Waheedi, & Koshy, 2012; McCullagh et al., 2012; U.S. Environmental Protection Agency [EPA], 2010).

A critical flaw in many public health and awareness campaigns is that they underestimate the complex array of factors that underlie human behavior (Nisbet & Gick, 2008). It has become a cliché in health and behavioral psychology that education is essential but not sufficient to effectively change people's behavior. In 2008, the White House Office of National Drug Control Policy (ONDCP) presented the first federal guidelines for the disposal of prescription drugs by consumers and health professionals (McCullagh et al., 2012). Initially, regulations governing transportation of controlled substances posed an obstacle to the return of consumer drugs for proper disposal. In 2009, the DEA conducted a public-opinion survey to get input on developing a safe disposal policy, which led to the Secure and Responsible Drug Disposal Act of 2010 and the Safe Drug Disposal Act of 2010, paving the way for drug take-back programs that allow for the return of controlled and uncontrolled substances (Fass, 2011).

In February 2016, Walgreens launched the first national initiative to promote proper drug disposal by a pharmacy retail chain by installing safe medication disposal kiosks in more than 500 locations, mostly in stores, open 24 hours daily (Walgreens, 2017). This pioneering effort, which began in California, encompassed drugstores in 39 states and the District of Columbia and was scheduled to be completed by end of 2016. As of September 2017, Walgreen has installed disposal kiosks in more than 600 pharmacies across 45 states.

The purpose of this quantitative cross-sectional study was to examine knowledge and behavior regarding drug disposal practices in a sample of residents in the northeast United States. Specifically, I examined people's disposal practices, local availability of disposal options, awareness of proper disposal practices, and the potential correlations between people's actual disposal practices and their knowledge of the impact that disposal practices may have on the environment and human health.

I started Chapter 1 with a high-level overview of the issue around drug disposal, and why it is a relevant and important topic to be studied within the realm of public health; I also introduce the research gaps, the conceptual framework, research questions and hypotheses, study design and sampling approach, data analysis plan, overview of the literature, and limitations of the study.

The scholarly literature has a glaring gap regarding the pharmaceutical disposal practices of the general population. Although drug take-back programs date back to the mid-2000s when they were recommended by the federal government, they inspired few empirical studies. The program "Safe Medication for ME" was implemented in the State of Maine in response to excessively high rates of deaths from prescription drug overdoses, and has been hailed as a model program for drug disposal (Ruhoy & Kaye, 2010). This unique program, which initially ran in conjunction with DEA take-back events, allowed people to anonymously return controlled and uncontrolled substances free of charge, through the mail. The program is currently under the direction of the University of Maine Center on Aging; consumers can obtain prepaid, tamper-resistant envelopes from community distributors, including pharmacies, medical offices, community organizations, police departments, hospice, and other sites located throughout the state. Each envelope includes explicit instructions for safely packaging and mailing pharmaceuticals of various types.

Although advocates of the Maine program often point to the ease of returning drugs through the mail as its defining characteristic, according to Ruhoy and Kaye (2010), the most notable feature is that the program systematically gathers data in a database on the returned medications. The first published study of the Maine Prescription Monitoring Program focused on detailed information on the types and amounts of drugs returned through six DEA take-back events (Stewart et al., 2015). However, the Ruhoy and Kaye study did not provide information on participants' attitudes toward the program, or their motivations to take part in it. Only two studies of take-back events surveyed participants, one covering 11 take-back events in the rural Appalachian region of northeast Tennessee and southwest Virginia (Gray & Hagemeier, 2012), and one involving 11 take-back events in Hawaii (Ma, Batz, Juarez, & Ladeo, 2014).

As drug take-back programs become more prevalent, it is likely more studies will query feedback to help improve such programs. However, research is still limited in disclosing relationships between consumers' knowledge, attitudes, and behaviors, in that such knowledge involves only those individuals who have actively made the decision to avail themselves of safe medication disposal options. A dearth of research explores the drug disposal habits of the general public; in fact, studies of pharmaceutical disposal practices tend to focus on nurses (McCullagh et al., 2012), pharmacists (Abahussain et al., 2012), or Veterans Affairs (VA) hospital outpatients (Seehusen & Edwards, 2006; Trovato & Tuttle, 2014). In view of this gap in the literature, it was necessary to extrapolate from the research on recycling to gain insight on consumer knowledge, attitudes, and behaviors related to environmental protection (Best & Mayerl, 2013; Culiberg, 2014; Nigbur, Lyons, & Uzzell, 2010; Pearson, Dawson, & Breitkopf, 2012; Seacat & Northup, 2010; White, Smith, Terry, Greenslade, & McKimmie, 2009).

The framework selected to guide this study comprised two models: the health belief model (HBM) and the theory of planned behavior (TPB). Despite parallels between health and environmental behavior, the fields of health promotion and health behavior change are rarely applied to environmental issues (Nisbet & Gick, 2008). Environmental behavior is multifactorial, and consequently, I considered more than one model to address the complexity of this environment–human health-related issue. By surveying members of the general public on their attitudes and behaviors related to disposal of pharmaceuticals, I was able to address the knowledge gap on this significant public health and environmental issue.

Problem Statement

Guided by recommendations from poison-control centers, or only by convenience, health professionals and consumers alike have customarily disposed of unused pharmaceuticals into the public water system by flushing them down the toilet or rinsing them down the drain (McCullagh et al., 2012; Ortner & McCullagh, 2010). This practice was standard until the discovery of measurable amounts of pharmaceutical chemicals in water triggered alarm about the consequences of pharmaceutical pollution in the environment, and its potential effects on human health (Blair, Crago, Hedman, & Klaper, 2013; Fatta-Kassinos et al., 2011; Kotchen, Kallaos, Wheeler, Wong, & Zahller, 2009; A. Kumar, Chang, & Xagoraraki, 2010; Musson, Townsend, Seaburg, & Mousa, 2007; Nikoalaou, Meric, & Fatta, 2007; WHO, 2011). In the United States, this situation is magnified by the sheer number of prescriptions given to consumers, coupled with poor medication adherence, which increases the amount of unused and expired drugs in the home (Daughton & Ruhoy, 2013).

The first federal guidelines for prescription-drug disposal were issued in 2007, providing consumers with a list of options for disposing of medications (Ortner & McCullagh, 2010; Ruhoy & Daughton, 2008). In 2010, the ONDCP announced that the guidelines for individual medication disposal had been replaced by official take-back days. At the same time, challenges existed in the widespread implementation and availability of take-back programs (Fain & Alexander, 2014). Of the options cited in the original guidelines, the U.S. Food and Drug Administration (FDA) continues to recommend consumers to mix unused drugs with unpalatable substances and place the mixture in sealed containers as a safe disposal technique (FDA, 2011); this process renders the drugs unusable to those for whom they were not prescribed, but the impact that these mixtures could have on the environment when placed in a landfill is unknown. The guidelines explicitly state that drugs should not be flushed down the toilet unless the instructions specifically say to do so, which the FDA recommends for a small number of drugs that could be "especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom the medicine was prescribed, as, for example, fentanyl patches for pain" (FDA, 2017, para 11).

The few studies of drug take-back events suggest they are well-received by community members (Gray & Hagemeier, 2012; Ma et al., 2014). However, no recent studies explored the knowledge of community members on human health as the consequence of pharmaceutical disposal in the environment, general disposal practices, and the potential relationship that may exist between people's knowledge of the disposal options and their actual disposal practices. I designed my study to help address that gap.

Purpose of the Study

The purpose of this quantitative cross-sectional study was to investigate consumer knowledge of the environmental and human-health impact of pharmaceutical disposal, knowledge of recommended disposal practices, and actual practices for disposing of unwanted, unused, and expired drugs. According to research using the HBM across numerous studies and types of behaviors, perceived barriers are the decisive factor in adopting health-related behaviors (Strecher & Rosenstock, 1997). In view of this predisposition, I also examined the relationship of locally available disposal options to consumers' actual disposal practices.

The sample for this study consisted of adults (aged 18 years or older) who were residents of the northeast United States and had taken a prescription drug in the past 2 years. A questionnaire designed for this study was administered via the Internet. The U.S. Census Bureau (n.d.) defined the northeast region as comprising nine states: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, and Pennsylvania. As of 2013, the estimated size of this population was approximately 56 million residents. Findings from this study intend to provide insights on the hypothesized associations between disposal practices and knowledge, attitudes, and disposal options.

This study contributes to increasing overall knowledge on pharmaceutical product disposal processes and helps identify key factors that may promote or inhibit safe disposal practices in the target population. The results of the study may create momentum for the future development of strategies that will promote positive social change and additional research opportunities. A change of behavior in disposal practices will translate into a reduction of the toxic substances released into the environment, minimizing the negative impact on human health.

Significance of the Study

Compelling evidence suggests that pharmaceutical substances often accumulate in one’s home due to various disposal habits. For example, some patients may stop the full course of their medication regimen because they experience changes in symptoms or dosage requirements, or they may begin to feel better. In aggregate, these behaviors become a threat to the environment and ultimately impact public health. Research detecting the presence of pharmaceuticals in waters began in the 1970s, gaining momentum during the next 3 decades (WHO, 2011). The most widely cited work in the scholarly literature on the presence of drugs in surface water involves a study conducted by the U.S. Geological Survey in 1999 and 2000 that discovered more than 50 pharmaceuticals in 139 streams across 30 U.S. states. An alarming 80% of the streams explored yielded at least one contaminant, with an average of seven contaminants per stream (Ortner & McCullagh, 2010). Nearly a decade later, a 2008 report entitled *PharmaWater I* described the findings of an Associated Press (AP) Investigative Team, disclosing that at least 41 million Americans are served by water supplies with evidence of pharmaceuticals including anticonvulsants, antibiotics, mood stabilizers, and hormones (Ortner & McCullagh, 2010).

Studies conducted in Europe produced comparable results. In Germany, for example, a research synthesis documented the presence of cholesterol medications, analgesics, and anticonvulsants in groundwater and surface water (Ortner & McCullagh, 2010). Researchers from the United States and the United Kingdom reported that treatment plants were not completely effective in removing active pharmaceutical agents from treated water. In fact, a major concern is that conventional treatment plants are not equipped to completely remove micropollutants such as pharmaceuticals from wastewaters (de Cazes et al., 2014; Fatta-Kassinos et al., 2011; Milic et al., 2013; Uslu, Jasim, Arval, Bewta, & Biswas, 2013; WHO, 2011). Moreover, even the most advanced and expensive treatment techniques leave detectable traces of pharmaceuticals (Li, Shi, Lik, Zhang, & Gan, 2014).

The United States lags behind many other developed countries in establishing formal guidelines and policies for the safe disposal of pharmaceuticals. Countries such as Australia, France, Sweden, Portugal, Spain, New Zealand, and the United Kingdom have had formal programs for collecting unused medications for quite some time (Ruhoy & Daughton, 2008). A study conducted by Health Canada (2009) compared the status of the recommended disposal practices across the European Union and member states to establish a benchmark against which to compare those established in Canada. For example, the report illustrated that Sweden has one of the most successful programs for the proper disposal of pharmaceuticals (Health Canada, 2009). Apoteket B is the

Swedish, government-owned pharmacy chain that oversees an environmental program driven by targeted public-awareness campaigns to educate the public about the harmful effects of flushing drugs down the drain or throwing them into the trash. In response, more than 70% of Swedish consumers return unused drugs to the pharmacy (Health Canada, 2009). Another reported example is in Spain, where the Spain Integrated Waste Management System also conducts intensive public-awareness campaigns, successfully generating large volumes of returned medications (Health Canada, 2009). From a broader, global perspective, it is important to acknowledge that global awareness of the issue of drug disposal has increased. For example, Pfizer, one of the largest pharmaceutical companies, has addressed the issue of proper drug disposal (Pfizer, 2017), and Asian countries, such as Japan (Nagaizumi Town, 2014) and India (Udupa, Muragundi, Nagappa, & Janodia, 2013), have either implemented or are in the process of finalizing drug disposal recommendations and the infrastructure to support them.

It seems evident that national policies and programs facilitate successful drug return programs; in the case of Sweden, through a unique retail-pharmacy system organized into a single government-owned chain (Health Canada, 2009). In contrast, disposing of unused drugs in the United States has historically been complicated by contradictory regulations from various agencies and legal regulations on controlled substances that, even with DEA involvement, continue to result in conflict with state laws (Ortner & McCullagh, 2010; Ruhoy & Kaye, 2010). The federal government has advocated for drug take-back programs as the gold standard for safe drug disposal since 2010, but these programs often take the form of occasional one-day or weekend events. Thus far, only the Maine Prescription Monitoring Program has produced evidence of a successful, ongoing statewide effort to encourage consumers to return unused and expired drugs (Stewart et al., 2015).

After years of disposing of pharmaceuticals into the drain or toilet, which may seem the most convenient method of disposing of unused drugs, gathering unused or expired drugs and taking them to a designated location for proper disposal, or even mixing the drugs with unappetizing substances (e.g., coffee grounds or cat litter as the FDA [2011] recommended), represents a radical change of behavior. Frameworks such as the HBM and the TPB have been applied to understand what motivates or inhibits health-related behavior change (Nisbet & Gick, 2008) in drug disposal practices. Pharmaceutical disposal differs from changing behaviors related to health issues that may present an immediate threat to the individual, such as obesity or cardiovascular risk. However, empirical research into recycling behavior demonstrates that behavior-change models can be effectively applied to environmental protection. Improper disposal of pharmaceuticals threatens the environment and human health (Fatta-Kassinos et al., 2011).

A review of the literature has shown a lack of research in exploring the knowledge, attitudes, and behavior of the general public toward the proper disposal of pharmaceuticals. Given this gap, limited evidence exists on the success of campaigns to promote proper disposal and, thus, no empirical foundation exists to design successful public-awareness and education campaigns or improve those that exist. Findings from this study provide valuable insight into disposal practices, and the factors that motivate individuals to properly dispose of unused and expired medications or, alternatively, what inhibits them from doing so. The ultimate goal of this study is to create momentum for the future development of strategies that will promote social change, reducing the impact on human health from toxic substances that are released in the environment.

With the advent of programs such as Walgreens' (2016) initiative to provide local disposal kiosks available 24 hours a day, residents in communities across most of the United States will have greater access to a convenient disposal option. However, a large body of health-psychology research demonstrates that subjective perceptions, rather than structural barriers or knowledge per se, play a pivotal role in changing health-related behavior, especially when it is deeply ingrained (Nisbet & Gick, 2008). Findings from this study are significant for public health officials and health professionals who advocate the safe and proper disposal of pharmaceuticals. In particular, this information should be useful to health professionals (e.g., nurses, pharmacists) who are at the forefront of patient education on the safe administration, storage, and disposal of pharmaceutical products. Above all, these findings may guide the development of strategies that improve public awareness (e.g., public health promotion campaigns and local community programs to educate consumers on proper disposal of pharmaceuticals) as well as the availability of flexible and convenient options for disposing of pharmaceutical products.

Theoretical Framework

Environmental behavior is multifactorial; consequently, I considered two conceptual models for behavior change: the HBM and the TPB. I deemed the TPB most relevant to the issue of proper pharmaceutical disposal from the perspective of the motivation that results into the intention to perform an action or behavior. Will motivation be triggered by the consumers' knowledge or perceptions of disposal practices and their impact on human health? Will motivation be triggered by the information received, if any, on disposal recommended practices? Will both factors motivate consumers and to what degree? The key aim of this study was to examine these research objectives.

The HBM aligns with studies that involve recycling and environmental protection. Strecher and Rosenstock (1997) discussed how perceived barriers were the decisive factor in adopting health-related behaviors. Consequently, one objective of this study was to examine the degree to which the availability and convenience to reach and use locally available disposal options may impact consumers' actual disposal practices.

Despite extensive interest by the public in protecting the environment and improving personal health, many public health campaigns fail to generate changes in peoples' behavior. A critical reason for this perennial problem is that program designers and policymakers fail to recognize marked discrepancies among attitudes toward health, the environment, and related behavior (Nisbet & Gick, 2008). Virtually all guidelines, reports, policy and position papers, and standards issued by government agencies, international bodies, and professional associations stress the importance of consumer and patient education in the safe use and disposal of medications. Education is an essential prerequisite; however, information, per se, is notoriously ineffective in altering human behavior, especially when it is deeply entrenched.

Campaigns designed to inspire healthy and proenvironmental behavior are typically "information-intensive" on the assumption "that once people are informed they will act differently" (Nisbet & Gick, 2008, p. 297). The failure of a myriad of public health programs to produce the desired effects underscores the misguided nature of that approach. Indeed, the development of the HBM in the 1950s arose from the poor response to public health campaigns to promote disease screening (Strecher & Rosenstock, 1997).

Building on detailed analyses of probability samples of adults in cities that offered tuberculosis screening, Hochbaum identified the beliefs that underpin the HBM: perceived susceptibility and perceived benefits of action (Strecher & Rosenstock, 1997). Hochbaum also recognized the role of intrinsic and extrinsic cues or triggers in motivating people to act. Decades later, the HBM has been refined and expanded and has a firm empirical base (Strecher & Rosenstock, 1997). The model includes several essential components. *Perceived susceptibility* refers to an individual's subjective perception of experiencing a health or medical condition. This dimension encompasses susceptibility to illness in general in addition to vulnerability to a specific condition. *Perceived severity* is a related factor, denoting the seriousness of experiencing the condition or allowing it to remain untreated or unaddressed. This aspect includes medical consequences (pain, disability, and death) and social consequences (such as the impact of the condition on work and social relationships). In conjunction, perceived susceptibility and perceived severity produce *perceived threat.*

Although acceptance of a perceived personal threat is a prerequisite for taking action, the specific course of action an individual chooses to take rests on the *perceived benefits* of the available options (Strecher & Rosenstock, 1997). Bringing unused and expired drugs to a take-back event or disposal center neutralizes the potential hazard to people and pets and does not contribute to environmental pollution. Beyond the practical benefit, this action might produce the intrinsic reward of believing one has done the right thing. A drug take-back event can offer an opportunity for socializing with friends or neighbors or meeting others in the local community. For young people in particular, peer pressure to engage in environmentally friendly behavior might influence drug disposal practices.

Despite awareness of the potential benefits of a given health behavior or behaviors, *perceived barriers* serve as obstacles to the recommended course of action. In a comprehensive research review of the HBM, perceived barriers emerged as the single most important factor in health behaviors across all studies and behaviors (Strecher & Rosenstock, 1997). For preventive behaviors, perceived susceptibility and perceived barriers are the best predictors of behavior, whereas for behavior related to a current health problem (such as adhering to medication), perceived severity and perceived barriers are most significant (Nisbet & Gick, 2008). Notably, poor medication adherence is a key contributor to pharmaceutical pollution (Daughton & Ruhoy, 2013). Although it is not the focus of this study, it is possible that efforts to promote the proper disposal of pharmaceuticals may have the additional benefit of improving consumers' adherence to their prescribed medications.

The TPB is an extension of Ajzen and Fishbein's theory of reasoned action (TRA) (Ajzen & Madden, 1986). The TPB and TRA models hinge on *intention*; that is, the immediate antecedent of any action is the person's intention to perform it. According to the TRA, two key determinants of intention are *attitude toward the behavior* and *subjective norm,* representing an individual and a social factor, respectively. The TRA also addresses the antecedents of these two factors. *Behavioral beliefs* are presumed to influence attitudes toward a behavior, whereas *normative beliefs* underpin subjective norms. Cote, Gagnon, Houme, Ben Abdeljelil, and Gagnon (2012) included moral norms in their research model, and they identified this attribute in nurse intentions when performing their duties in caring for patients; in their study, these researchers identified moral norms as the strongest predictive factor in drug disposal behavior. This finding may be valuable in explaining nurse decisions to dispose of unused medications. Moral and ethical perspectives may be especially useful for examining behavior related to environmental protection.

Researchers have also used the TPB model to examine behavior in organizations. Sanchez-Medina, Romero-Quintero, and Sosa-Cabrera (2014) applied the TPB to the study of environmental measures taken by managers of small and midsized firms. Waste disposal was one of the practices they investigated.

Studies by Culiberg (2014), Nigbur et al. (2010), White et al. (2009), and Sanchez-Medina et al. (2014) added to a small but growing body of research using the TPB as a framework to investigate behaviors related to environmental protection. Most studies in this line of research focus on recycling behavior (Nisbet & Gick, 2008). In their review of this research, Nisbet and Gick (2008) found that, on the whole, intentions to recycle arise from positive attitudes toward recycling and that “people feel their own contribution is important” (p. 298).

Cues to action are important factors in health behaviors but have not been systematically investigated (Strecher & Rosenstock, 1997). In general, it is difficult to quantify cues because they are often subtle. In addition, they rest markedly on individual perceptions.

The HBM has been applied to a wide range of health behaviors, including cancer screening, sunscreen use, dental hygiene, medication adherence, and HIV risk behaviors

(Nisbet & Gick, 2008). Nisbet and Gick (2008) found only one published study in which the HBM was applied to behaviors related to environmental protection, specifically recycling. Given that improper disposal of pharmaceuticals may adversely affect personal health as well as the natural environment, the HBM was useful in helping understand the connection between the more abstract threat (environmental pollution) and the more proximal threat (personal health) in consumers' adherence to recommendations for proper disposal of medications. The TPB model complemented the HBM by providing a broader perspective on *attitude toward the behavior* and *subjective and moral norms,* which were useful in exploring the possible rationale for why people do what the accepted social norms indicate, such as bringing unused drugs to a take-back event or disposal site.

Background of the Study

It seems ironic that the same substances that have been helping people live longer and healthier lives are polluting our natural environment and posing a threat to the future of human health. Virtually all classes of drugs have been detected in the environment. Abundant evidence shows that medications containing estrogens, such as contraceptives and hormone-replacement therapy, antidepressants, and antibiotics, all link to abnormalities in aquatic life (Corcoran et al., 2010; Ortner & McCullagh, 2010). The phenomenon now known as *endocrine disruption* was first identified in the 1970s, when zoologist and former pharmacist Theo Colbern presented evidence derived from hundreds of studies examining how pollution impacted wildlife in the Great Lakes (Ortner & McCullagh, 2010). The detrimental effects of estrogens on fish populations are probably the most heavily documented consequences of pharmaceutical pollution (Corcoran et al., 2010; Ortner & McCullagh, 2010). These numerous adverse effects include changes in mitochondrial activity, energy metabolism, and cell-cycle regulation, as well as the feminization of male fish and the development of genital abnormalities. In some cases, entire fish colonies have collapsed due to reproductive failure (Ortner & McCullagh, 2010).

Anti-infectives refer to several bioactive compounds with the ability to inhibit the growth or survival of microorganisms without harming the host (Segura, François, Gagnon, & Sauvé, 2009). This category includes some antifungal agents and synthetic drugs, as well as antibiotics, which have become a key focus in the literature on pharmaceutical pollution due to the presence of ARGs found in water supplies, soils, and sediments, and their potentially harmful impact on human health (Fatta-Kassinos et al., 2011; Marti, Jofre, & Balcazar, 2013; Milic et al., 2013; Uslu et al., 2013; Zhang et al., 2009). ARGs can be transferred to humans from the environment through direct and indirect contact, and miniscule levels of antibiotics may act as “signaling agents in microbial environments” (Fatta-Kassinos et al., 2011, p. 228) to various plants equipped with receptors for antibiotics and disinfectants.

Adding to the prospective threat presented by ARGs in the environment, these microorganisms are also resistant to wastewater treatment (de Cazes et al., 2014; Milic et al., 2013; Zhang et al., 2009). Technological advances have enabled researchers to detect increasingly smaller traces of pharmaceuticals in the natural environment, but the techniques for removing them have not kept up and are inadequate. As Segura et al. (2009) observed, “Anti-infectives, the miracle drugs of the 20th century have become environmental contaminants of emerging concern in the 21st century” (p. 682).

Pharmaceuticals enter the environment through various pathways. Manufacturing and agriculture unquestionably play a prominent role. Through individual drug consumers, household pharmaceuticals enter the environment in three ways. The first is through natural excretion, as only a fraction of medication, whether ingested, injected, or infused, is metabolized by the body (Daughton & Ruhoy, 2013; Harvard Health, 2011; Ortner & McCullagh, 2010; Rodriguez-Mozaz & Weinberg, 2010; Ruhoy & Daughton, 2008). The unmetabolized compound and its metabolites are excreted in urine and feces, and to a lesser extent, perspiration. A second pathway is the removal of topical products while bathing. The third pathway, which is the focus of this research project, is the disposal of unused, unwanted, and expired medications.

At the same time, the three routes of environmental pollution are interrelated. The terms *upstream* and *downstream* have been used to describe two approaches to reducing the amount of presence of pharmaceuticals in the environment (Daughton, 2014a). The upstream approach concentrates on minimizing the amount and toxicity that a given pharmaceutical product would release when discarded in the environment. Also called “green pharmacy” or “eco-friendly pharmacy,” this approach starts by designing drugs with maximum absorption potential, such that smaller traces are excreted. For drugs currently on the market, an upstream approach involves limiting overprescribing, curtailing aggressive drug marketing, and improving patient adherence to the prescribed drug regimen (Daughton & Ruhoy, 2013; Ruhoy & Daughton, 2008; Ruhoy & Kaye, 2010). Diligent monitoring of drugs released in the environment is another element of the upstream approach (Daughton, 2014b; Ruhoy, 2009).

The downstream approach focuses on promoting the safe and proper disposal of unused, unwanted, and expired medications (Ruhoy & Daughton, 2008). This approach is exemplified by drug take-back programs that allow consumers to bring unused pharmaceuticals to a designated site where the drugs are collected and transported to be destroyed. According to preliminary findings, drug take-back events are successfully attracting people and collecting millions of tons of pharmaceutical waste for safe disposal (Fain & Alexander, 2014; Fass, 2011; Gray & Hagemeier, 2012; Lubick, 2010; Ma et al., 2014; Stewart et al., 2015; Tucker, 2011). However, many drug take-back programs are no more than annual events. For drug return strategies to effectively reduce the massive amount of pharmaceutical chemicals systematically entering the natural environment, consumers need return sites that are readily accessible and available daily.

Pharmacies are considered the ideal venue for returning unused medications (Abahussain et al., 2012; Fain & Alexander, 2014; Fass, 2011; Zimmermann, Wengler, & Popowski, 2011). Pharmacies are also excellent places to educate the public about proper medication management and disposal. However, challenges exist to the widespread adoption of pharmacy returns. Although providing consumers with access to receptacles is typically recommended and likely to be popular with the public, some pharmacies have raised concerns about the burdens and costs of requisite measures as well as potential legal liability. The effectiveness of this strategy depends on the voluntary participation of pharmacies, as well as adequate funding to offset the costs involved in adhering to DEA requirements (Fain & Alexander, 2014). With Walgreens in the lead, other large pharmacy chains may adopt similar programs, thereby greatly expanding the access of local communities to safe and convenient drug disposal options.

Upstream approaches may be preferable theoretically, but they do not address the drugs that already proliferate in household medicine cabinets. Medication take-back programs appear to be promising. Ultimately, their success depends on the active participation of stakeholders, including local pharmacies or other sites, and above all, the everyday consumers of prescription and OTC drugs.

Research Questions

This cross-sectional, quantitative study is driven by the following research questions:

RQ1: Is there an association between knowledge of the environmental and the human-health impact of pharmaceutical disposal and actual disposal practices?

RQ2: Is there an association between knowledge of recommended disposal practices and actual disposal practices?

RQ3: Is there an association between available disposal options and actual disposal practices?

RQ4: To what degree can actual disposal practices (the dependent variable) be explained by the combined and differential contribution of the three independent variables: knowledge of the environmental and human-health impact, knowledge of recommended disposal practices, and locally available disposal options?

RQ5: Do differences exist among RQ1, RQ2, and RQ3 across demographic groups?

Research Hypotheses

The following hypotheses derived from the research questions:

$H_0$1: No significant association exists between knowledge of the environmental and the human-health impact of pharmaceutical disposal and actual disposal practices.

$H_1$1: A significant association exists between knowledge of the environmental and the human-health impact of pharmaceutical disposal and actual disposal practices.

$H_0$2: No association exists between knowledge of recommended disposal practices and actual disposal practices.

$H_1$2: An association exists between knowledge of recommended disposal practices and actual disposal practices.

$H_0$3: No association exists between available disposal options and actual disposal practices.

$H_1$3: An association exists between available disposal options and actual disposal practices.

$H_0$4: Actual disposal practices cannot be explained to a significant degree by the combined and differential contribution of knowledge of the environmental and the human-health impact, knowledge of recommended disposal practices, and locally available disposal options.

$H_1$4: Actual disposal practices can be explained to a significant degree by the combined and differential contribution of knowledge of the environmental and the human-health impact, knowledge of recommended disposal practices, and locally available disposal options.

$H_0$5: No significant demographic differences exist in the relationships of knowledge of the environmental and the human-health impact, knowledge of recommended disposal practices, and locally available disposal options to actual disposal practices.

$H_1$5: Significant demographic differences exist in the relationships of knowledge of the environmental and the human-health impact, knowledge of recommended disposal practices, and locally available disposal options to actual disposal practices, when controlling by demographic variables (e.g., age, race, education level).

Nature of the Study and Study Design

Research Design

The research design for this study was quantitative and cross-sectional. When a researcher's goal is to examine associations between quantifiable and objectively measurable concepts, a quantitative method is appropriate (Howell, 2010). The main objective of this study was to investigate the hypothesized association between consumers' actual disposal practices (outcome of interest/dependent variable) and the factors (independent variables) that may influence them. Because the variables under investigation are quantifiable and objectively measurable, a quantitative method was appropriate. Specifically, I selected a cross-sectional design because my aim was to examine associations between variables measured at a single point in time.

Typical disadvantages of using a cross-sectional design include the challenges associated with establishing causal inferences, and the notion that the findings represent the phenomenon in a specific single time and place (Pine, Pitts, & Nugent, 1997). To inspire social change, results from this study can be applied toward the design of health-promotion programs that encourage optimal drug disposal practices, encourage the simplification of disposal options, improve patient drug compliance, and generate momentum for the development of drugs that are less toxic to the environment. In aggregate, if adopted, the aforementioned approaches could reduce the posed risks to human health by improper disposal of pharmaceutical products in the environment.

Dependent and Independent Variables

Actual disposal practices was the outcome (dependent) variable. As suggested by the reviewed literature, this study used the following key independent variables: (a) knowledge of environmental and human-health impacts, (b) knowledge of recommended disposal practices, and (c) availability of disposal options. Data on the outcome variable and the independent variables were collected using a questionnaire.

Survey Instrument

The contents of the survey instrument for this study were adapted from items used by Seehusen and Edwards (2006). Approval for the use and adaptation of the questionnaire was given by Dr. Seehusen and can be found in Appendix A. The final draft version of the questionnaire was pilot tested after Institutional Review Board (IRB) review and approval, following the process recommended by Radhakrishna, Francisco, and Baggett (2003).

The questionnaire consists of content questions used to measure the constructs of interest as well as demographic questions. The survey questionnaire was administered via the Internet by SurveyMonkey, an online survey service provider, using web-based, electronic forms for data input. Cottrell and McKenzie (2010) argued that researchers cannot assume that most U.S. residents would be sufficiently computer literate and have Internet access to complete a survey online. Within the last few years, however, Internet access and broadband have become so widely available that large government programs, such as the Affordable Care Act (U.S. Department of Health and Human Services [HHS], n.d.), are administered via the Internet. On the basis of these considerations, I deemed the online approach to be a practical and efficient medium for the administration of the survey questionnaire.

The questionnaire consists of content questions used to measure the constructs of interest, as well as demographic questions. The first question of the survey asks, "What is your most used method for disposing of unused or expired medications?" Participants answered this question by selecting one of eight possible response options that included "I flush them down the toilet" and "I follow the disposal instructions that accompany the medicine," among others. This question was used to measure the dependent variable: actual disposal practices.

The next questions on the survey were, "In your area, is there a designated collection location where you can dispose of your unused or expired medication?" and "How convenient is it for you to reach the designated disposal location?" These questions represented the independent variable: available disposal options. Next, participants were asked, "Do you believe that improper disposal of medications in the environment could have negative consequences on human health?" Participants responded to this question on an ordinal scale and their responses represented the independent variable: knowledge of environmental and the human-health impact. Participants were also asked four questions, which were answered on categorical and ordinal scales that assessed the participants' knowledge of disposal practices. These questions were used to represent the independent variable: knowledge of recommended disposal practices. Finally, participants were asked to provide basic demographic information. Specifically, they were asked to report their gender, year of birth, race, highest level of education completed, and their state of residence.

Questions related to knowledge and awareness were scored using a coded ordinal scale, as suggested by Monnin and Perneger (2002). In contrast, data from the dependent variable, *actual disposal practices*, were categorical. A dichotomous Yes/No outcome was used to assess and code the dependent variable.

Population and Sample

The sampling approach for this study was convenience sampling. A convenience-sampling method is appropriate when a true random sample is not feasible to obtain. Because I was unable to randomly sample all possible residents in the northeast United States, a convenience sample was appropriate. Participants in this study had to meet the following three inclusion criteria: (a) resident of the northeast United States, (b) aged 18 or older, and (c) having used a prescription drug in the prior 2 years. The U.S. Census Bureau (n.d.) defined the northeast region as comprising nine states: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, and Pennsylvania. As of 2013, the estimated size of this population was approximately 56 million residents. Participants who met these criteria were recruited online from SurveyMonkey's participant pool. The appropriate sample size was calculated using as input in the algorithm the following parameters: (a) population size = 55,943,073, corresponding to the entire northeast region (U.S. Census Bureau, n.d.), (b) confidence level = 95%, and (c) margin of error = 5%. The resulting sample size was 385 (SurveyMonkey, 2016).

Data Collection

After obtaining IRB approval to conduct the study, I used SurveyMonkey to recruit participants who met the eligibility criteria of the study. The study consisted of an online survey hosted by SurveyMonkey. Cottrell and McKenzie (2010) argued that researchers could not assume that most U.S. residents would be sufficiently computer literate and have Internet access to complete a survey online. In recent years, however, Internet access and broadband have become so widely available that even large government programs, such as the Affordable Care Act (HHS, n.d.), are administered through the Internet. On the basis of these considerations, I deemed the online medium to be practical and efficient to administer the survey questionnaire.

Aligned with Walden University's IRB policy regarding participation in online surveys, given that participants had the option to take or ignore the survey, I had no need to include a separate consent form; however, the survey included a section that described the participants' rights and provided contact information for Walden's IRB and me. Individuals who agreed to participate after indicating they met the three inclusion criteria were directed to the survey. The survey was intended to be open to potential participants for up to 3 weeks; however, the target sample size was achieved in a much shorter time.

Participants received no compensation for participation in the study. At the end of the recruitment period, SurveyMonkey provided me with two data files on their secure server for download: one Excel and one SPSS-formatted file. I stored the survey data files on a password-protected personal computer that is only accessible to me. The data are also backed up on a password-protected storage medium, stored safely and securely.

Data Analyses

I performed all data analyses using SPSS. Prior to the analyses, and upon collection, I cleaned the data to ensure all records had sufficient and accurate data for analysis. I accomplished the data cleaning by running frequency distributions for each variable, ensuring the data were within the acceptable range of values. Given that the data were collected electronically using a web-based form that only accepts predefined input values, there were no values entered outside the acceptable range; however, there were several cases in which the survey participants had skipped some questions, and this resulted in fields with missing data. In addition to descriptive statistics, the key statistical procedures to address the research questions and test the stated hypotheses were binary logistic regression and analysis of variance.

Definition of Key Terms

The following terms are defined for the purpose of this study:

Downstream approach: Approach to reducing the amount of pharmaceutical substances in the environment by promoting the safe and proper disposal of unused, unwanted, and expired drugs (Ruhoy & Daughton, 2008).

Drug take-back programs: Under the auspices of the DEA, drug take-back programs allow consumers to return unused OTC and prescription human and pet medications to specific locations equipped with receptacles for their safe disposal (Fain & Alexander, 2014).

Endocrine-disrupting chemicals: Chemicals that can interfere with endocrine functioning to cause damage to the developmental, reproductive, neurological, and immune systems of human and animal life (Ortner & McCullagh, 2010).

Green pharmacy or ecofriendly pharmacy: A key component of the upstream approach focuses on designing drugs with highly specific drug action and the capacity for maximal absorption by the body so smaller trace amounts are excreted (Daughton & Ruhoy, 2008).

Nonsteroidal anti-inflammatory drugs (NSAIDs). The most widely used class of drugs including acetylsalicylic acid (aspirin), ibuprofen, and diclofenac; NSAIDs have the potential to cause kidney damage, which has been observed in animals exposed to NSAIDs in water (Ortner & McCullagh, 2010).

Pharmaceuticals: Compounds manufactured for medicinal purposes, pharmaceuticals are distinguished from other environmental pollutants because they are made to be biologically active (Fatta-Kassinos et al., 2011).

Upstream approach: A proactive approach to reducing the amount of pharmaceutical substances in the environment by minimizing the amount and toxicity of drugs with the potential to contaminate the environment, and for drugs already on the market, curbing overprescription, ensuring patients are prescribed the most effective drugs in precise doses, and improving patient medication adherence (Ruhoy & Daughton, 2008).

Brief Review of the Literature

Disposal Practices Among Nurses

Nurses counsel and educate patients; thus, they are ideally positioned to inform patients about proper medication disposal procedures. However, few studies examined practices among nurses. McCullagh et al. (2012) examined the medication disposal practices and attitudes toward medication disposal of home hospice nurses. Educating patients and caregivers regarding how to store, manage, and dispose of medications is a key aspect of the professional role of nurses. Upon a patient's death, however, the nurse is often entrusted with discarding unused medications. A total of 138 home hospice nurses completed an online survey. Almost half of the nurses (44%) reported disposing of 11 or more medication doses upon a patient's death. Although close to two-thirds (64%) of the nurses reported always or often mixing the drugs with unpalatable substances, as recommended, more than half discarded them in the toilet or drain with the same frequency.

The vast majority of nurses considered mixing medications with an unpleasant substance as acceptable (94%) and safe (91%). Striking about the study was the notable discrepancy between the almost unanimous endorsement of the safety and acceptability of mixing drugs with an undesirable substance, and the number of participants who regularly disposed of drugs in that manner (McCullagh et al., 2012). The nurses gave high priority to ensuring that drugs were not diverted, which could help to explain why they were inclined to dispose of medication to sewage. Nevertheless, it was clear that their actions were not consistent with their beliefs about how drugs should be discarded.

Most nurses drew their information on safe medication disposal from their own reading rather than from formal training in nursing school or on the job.

Disposal Practices Among Patients

In a unique study on the handling, storage, and disposal practices of patients taking anticancer drugs at home, Trovato and Tuttle (2014) surveyed 42 patients (95% male) being treated at a VA hospital. In the course of a year, the use of oral chemotherapy by outpatients increased substantially. Patients received education from medical, nursing, and pharmacy staff, but had no standardized practices.

Overall, storage practices among patients conformed to recommended guidelines (Trovato & Tuttle, 2014). All kept their medication away from children and pets, most kept the drugs free of extreme temperatures or humidity, and those who did not keep the drugs in the original container made use of a pill sorter to simplify adherence to the prescribed regimen. Few participants had unused drugs.

The gaps between recommended practices for the safe handling and disposal of anticancer drugs were attributed to lack of patient education (Trovato & Tuttle, 2014). Close to half of the patients (45%) had not received information on safe handling and storage practices. Those who were informed had acquired their information from nurses and pharmacists, and to a lesser extent, physicians. Health professionals who counsel cancer patients on medication often focus primarily on administration and potential side effects (Trovato & Tuttle, 2014). With limited time, health professionals are likely to give precedence to these critical issues. However, a definite need exists for better patient education on the storage, handling, and disposal of anticancer drugs. The pharmacist authors altered their practices in response to the survey to ensure the safe management and disposal of the powerful chemotherapy drugs.

Drug Take-Back Programs

Gray and Hagemeier (2012) examined the characteristics of rural residents who participated in 11 take-back events held between 2009 and 2011, and the medicines they brought. A total of 752 individuals returned 16,956 containers of medications prescribed for 1,210 patients. Participants were mostly White, on average about 40 years old, and women accounted for more than half of the group (57%). In descending order, the dominant reasons for participating were a desire to clean out their medicine cabinets (68%), environmental concerns associated with disposing of drugs and other waste materials (45%), and concerns about accidental poisoning (14%). The surveyed participants were those who participated in the take-back events and were therefore already motivated to comply with the proper disposal of expired or unused drugs. Most participants lived within 10 miles of the take-back site, leading to the conclusion that geographic distance is a consideration in people's attendance at take-back events (Gray & Hagemeier, 2012). For urban and suburban residents, other issues such as time concerns may emerge as more relevant perceived barriers.

Ma et al. (2014) presented the results of 11 drug take-back events held in Hawaii. These events were advertised in the media (television, radio, and newspapers), through brochures and flyers in pharmacies and medical offices, and by word of mouth. Participants at the 2011 Good Life Senior Expo were surveyed regarding prior experiences with unused or expired drugs. Most discovered the event through newspaper or TV advertisements. Before the take-back events, the predominant methods for managing unused medications were throwing them in the trash (34%), keeping them at home (32%), or flushing them down the toilet (24%). Only 10% had returned medications to a pharmacy or medical office. Two-thirds of the participants kept unused medications at home for a year or longer. All participants (> 99%) wanted the take-back events to continue.

The 11 events yielded 8,011 pounds of medication, primarily pills or tablets (Ma et al., 2014). The largest proportion was categorized as “Other” or miscellaneous. Antihypertensives were the next largest drug class, similar to the prevalence of cardiovascular drugs in the Maine take-backs (Stewart et al., 2015). Other drugs returned in large quantities were gastrointestinal drugs and analgesics. The most common OTC drugs fell into this last category: aspirin, naproxen, and ibuprofen. A substantial amount of pseudoephedrine was returned, used in the manufacture of methamphetamine, and one of the most common OTC drugs returned. Controlled substances accounted for 10% of the drugs. This occurrence seemed to be fairly consistent, as similar proportions of controlled substances were returned in Maine (Stewart et al., 2015) and Appalachia (Gray & Hagemeier, 2012).

Ma et al. (2014) did not collect participant information as did Gray and Hagemeier (2012). However, both studies generated enthusiastic responses. As staunch advocates of drug take-back programs, Ma et al. called for efforts to identify prospective process champions and stakeholders, including consumers, government organizations, and “all parties involved in the medication chain of manufacturing, ordering, prescribing, dispensing, administering, and monitoring” pharmaceuticals (2014, p. 30).

Assumptions

The main assumption guiding this study was that the participants would respond to the questionnaire honestly and accurately. Participation was entirely voluntary, the survey was completed anonymously, and participants were assured of complete confidentiality. The anonymity of this online survey is assumed to have facilitated truthfulness and has reduced the potential for responses based on social desirability.

Limitations

Participation in this study was limited to adults residing in the northeast United States. This region is known for its diverse demographic composition (U.S. Census Bureau, n.d.). According to the 2010 U.S. Census (recounted in the U.S. Census, 2011), the socioeconomics characteristics of the northeast region of the United States include the following:

- Median household income = $53,283, compared to the Midwest = $48,445, the South = $45,492, and the West = $53,142.
- Percent in poverty level = 11.8, compared to the Midwest = 13.3, South = 15.7, and the West = 14.8
- Number of people without health insurance coverage = 11.8, compared to the Midwest = 12.7, the South = 19.2, and the West = 17.7

These data illustrate how the northeast appears to have socioeconomic characteristics more favorable than those of other regions. Consequently, the generalization of the results of this study to the general U.S. population can be drawn with caution. In fact, socioeconomic characteristics such as income, employment status, and health insurance coverage have been associated with health care use and interaction with health care professionals (Blackwell, Martinez, Gentleman, Sanmartin, & Berthelot, 2009), and, by inference, these factors may have influenced the likelihood of receiving drug disposal information.

Given the emphasis on prescription drugs in the national strategy to reduce the amount of pharmaceuticals in the environment, this study was restricted only to individuals who have used at least one prescription. However, OTC drugs, especially NSAIDs, are widely used, and like prescription drugs, have the potential to pollute the environment and present a threat to human health. Thus, this study had intrinsic limitations by excluding a sizable proportion of consumers of common pharmaceuticals, who may be less likely than those with prescription drugs to have accurate knowledge of recommended disposal practices.

The use of the Internet may have also excluded those people who are unfamiliar or uncomfortable with this technology. In spite of optimistic figures of large diffusion of the use of the Internet, groups of people, due to age or financial condition, may not have had the opportunity to be part of the population sample. The survey was only in the English language; therefore, people who were not fluent in English may not have completed it. Consequently it is unknown what disposal practices are being used by that population group.

This chapter began with an introduction to the problem area, significance of the study, theoretical frameworks, research questions, and study design. In Chapter 2, I present a review of the literature on the theoretical framework, types of drugs and their effects, and the evolution of policy. In Chapter 3, I provide the research design, methodology of the study, and the data analysis plan. In Chapter 4, I present the results of the study, and Chapter 5 includes conclusions and recommendations for social change and future research and practices.

Chapter 2: Literature Review

For decades, poison-control centers in the United States recommended disposing of unused or expired medications by flushing them down the toilet or rinsing them down the drain to prevent inadvertent or intentional poisoning (McCullagh et al., 2012; Ortner & McCullagh, 2010). Health professionals believed they were acting responsibly by disposing of drugs in the safest possible way, and few consumers would reject such a simple and convenient mode of disposal. However, detection of measurable amounts of pharmaceutical substances in water raised alarm about the consequences of pollution from pharmaceuticals on the environment and its potential effects on human health (Blair et al., 2013; Fatta-Kassinos et al., 2011; Kotchen et al., 2009; A. Kumar et al., 2010; Musson et al., 2007; Nikoalaou et al., 2007; WHO, 2011).

The presence of pharmaceuticals and personal-care products as traces of environmental pollutants first gained attention in the 1980s (Daughton, 2003a). Developments in analytical techniques have allowed scientists to detect, quantify, and document trace amounts of pharmaceutical substances in wastewaters, sediments, groundwater, surface water, and even drinking water (Bound & Voulvoulis, 2005; Daughton, 2014b; de Cazes et al., 2014; Fatta-Kassinos et al., 2011; A. Kumar et al., 2010; Larsson, 2014; Nikoalaou et al., 2007; Orton & McCullagh, 2010; Rodriguez-Mozaz & Weinberg, 2010; Segura et al., 2009; Uslu et al., 2013; WHO, 2011; Zhang et al., 2009). Pharmaceuticals are unique among environmental pollutants in that they are designed to be bioactive. Numerous studies of water samples have detected antibiotics, anticonvulsants, analgesics, mood stabilizers, hormones, and chemotherapy agents (Bound & Voulvoulis, 2005; Corcoran et al., 2010; Harvard Health, 2011; McCullagh et al., 2012; Ortner & McCullagh, 2010; Uslu et al., 2013). These substances have been linked with disruptions to aquatic life, such as genital abnormalities in fish, foot detachment in frogs, and, in some cases, the collapse of entire fish populations.

In 2009, the WHO (2011) formed a working group composed of experts in the fields of pharmacology, toxicology, water chemistry, water quality and health, water treatment, and water regulation and policy. The group conducted an exhaustive and detailed review of the existing literature and called in additional experts to consult and further review scientific evidence. According to the WHO experts, trace concentrations of pharmaceutical substances in drinking water are low enough that they are unlikely to present risks to human health. At the same time, the same experts acknowledged that limited understanding exists of potential health risks associated with long-term exposure to low levels of pharmaceutical substances in drinking water or of the combined effects of mixtures of pharmaceutical compounds.

Other experts raise the question of the potential effects of pharmaceutical exposure on sensitive populations such as pregnant women, children, elders, and individuals with compromised immune systems (A. Kumar et al., 2010). The discovery of ARGs in treated wastewater also raises the issue of whether that resistance might transfer to microbes capable of affecting human health (Lubick, 2011; Marti et al., 2013; Sahoo, Tamhankar, Johansson, & Lundborg, 2010; Segura et al., 2009; Zhang et al., 2009).

WHO (2011) is one of many international and government bodies that recommend adopting strategies to minimize exposure to pharmaceuticals in water, such as take-back programs, guidelines and regulations, public-awareness campaigns, and consumer education to promote the proper disposal of unused, unwanted, and expired medications and reduce the amount of pharmaceuticals that enter the environment. In 2008, the White House ONDCP formulated the first federal guidelines for the disposal of prescription drugs by consumers and health professionals (McCullagh et al., 2012). However, regulations governing the transport of controlled substances presented a barrier to the return of consumer drugs for proper disposal. In 2009, the DEA solicited public opinion on the issue of disposing of controlled substance dispensed to individual patients to develop a safe disposal policy (Fass, 2011). This led to the enactment of the Secure and Responsible Drug Disposal Act of 2010 and the Safe Drug Disposal Act of 2010, thereby paving the way for drug take-back programs that allow for the return of controlled and uncontrolled substance. The ONDCP (2011) emphasized the importance of proper medication disposal to protect human health and the natural environment.

The purpose of this quantitative cross-sectional study was to examine the disposal practices and disposal attitudes of a sample population in the northeast United States. This study was guided by five research questions:

1. Is there an association between knowledge of the environmental and the human-health impact of pharmaceutical disposal and actual disposal practices?
2. Is there an association between knowledge of recommended disposal practices and actual disposal practices?
3. Is there an association between locally available disposal options and actual disposal practices?
4. To what degree can people’s actual disposal practices be explained by the combined and unique contributions of knowledge of environmental and

human-health impact, knowledge of recommended practices, and locally available disposal options?

5. Do differences exist among RQ1, RQ2, and RQ3 across demographic groups?

Numerous theories and models have evolved in health psychology to explain health-related attitudes, beliefs, and motivations and their influence on individual behavior (Bandura, 1997; Nisbet & Gick, 2008; Strecher & Rosenstock, 1997). Environmental behavior is multifactorial; consequently, I found it important to consider more than one model as the theoretical framework for behavior change: the HBM and the TPB.

Search Strategy

The literature presented in this review drew primarily from PubMed/MEDLINE and the following EBSCO databases: Academic Search Premier, MasterFILE Premier, Business Source Premier, PsycINFO, and PsycARTICLES. I did not restrict the searches to peer-reviewed scholarly articles, as I deemed reports and guidelines from government agencies as well as international bodies such as the WHO to be important sources of information on the topic. In the initial searches, keywords, used either individually or in conjunction, included *pharmaceuticals*, *drugs*, *medication*, *disposal*, *waste*, *pollution*, *contamination*, *contaminants*, *toxins*, *environment*, and *health*. This strategy produced a large number of research studies. Many were from the biochemistry and environmental-science literature. These articles provided compelling evidence of what is happening to the physical environment as a result of massive amounts of pharmaceuticals entering the environment. A review of these articles generated additional searches including the following keyword searches: *antibiotics, antibiotic resistance, analgesics,* *antidepressants, hormones, endocrine disrupting chemicals, measurement, evaluation, water treatment, water treatment facilities, wastewater, drinking water, soils, sediments,* and *removal.*

Environmental studies also confirmed the role of human actions in the accumulation of pharmaceutical pollutants. Many studies in this line of research advocate strategies such as drug take-back programs to reduce the amount of pharmaceutical compounds entering the natural environment. However, they do not directly relate to the behavioral aspects of drug disposal by consumers or health care professionals who handle unused or expired drugs. Thus, I needed to conduct additional searches. The keywords *drug disposal programs*, *drug take-back programs*, and *take-back events* produced a number of articles on the topic. Although take-back programs date to the mid-2000s when they were recommended by the federal government as a strategy for safe medication disposal, they generated few empirical studies. The new generation of take-back programs under the auspices of the DEA is a recent phenomenon. Highlighting the relative newness of the DEA programs, the first study of the Maine Prescription Monitoring Program (the most publicized program) appeared in the January 2015 issue of the *American Journal of Public Health* (Stewart et al., 2015).

The theoretical frameworks selected for this study were the TPB and the HBM. These models, as well as the *keywords health, health psychology, public health, knowledge, awareness, beliefs, education, information, attitudes, behavior,* and *environment,* produced several studies, although more research appeared to focus on the attitudes and practices of health professionals than the general public. I added the terms *patients* and *consumers* to the search criteria. *Theory of planned behavior* and *health* *belief model* and *environment* revealed several studies involving recycling behavior and other environmental-protection activities, and they are included in this chapter.

The articles that I selected for this review span the years 2003 to 2015, with the exception of theoretical material. Numerous scientific studies were published during the 1990s documenting the presence of pharmaceutical substances in water. Not until the early to mid-2000s, however, did this knowledge spur calls to take action to address the burgeoning problem. The selected dates cover the time frame from which pharmaceutical waste captured global attention as an important environmental and public health concern, from warnings by environmentalists of polluted waterways—including drinking water supplies—to government recognition of the potential public threat. Calls ensued to educate the general public about proper medication disposal and to encourage this behavior through patient education, public-awareness campaigns, medication take-back events, and the provision of disposal sites at pharmacy chains and health care facilities. The literature reveals glaring gaps in knowledge of the potential effects of pharmaceuticals in the environment on human health due to weaknesses in the existing research, as well as a dearth of empirical studies examining the medication disposal practices of consumers and the effectiveness of programs and strategies to encourage proper disposal.

Organization of the Literature Review

This chapter began with an introduction to the problem of pharmaceutical pollution in the environment, its potential impact on human health, and steps being taken to address the problem. I followed with a brief statement of the purpose and research questions of this study, the organization of the literature review, the theoretical framework guiding the study, the presence of pharmaceuticals in the environment, the evolution of policies and programs, knowledge, attitudes, and disposal practices of health professionals and consumers, medication take-back groups, recycling attitudes, and behavior, and a brief summary and conclusion.

Theoretical Framework

According to Nisbet and Gick (2008), despite parallels between health and environmental behavior, the fields of health promotion and health-behavior change are not often applied to environmental issues. Environmental behavior is multifactorial; consequently, I decided to consider more than one model as the theoretical framework of behavior change: the HBM and the TPB. I deemed the TPB most relevant to the issue of proper pharmaceutical disposal, whereas the HBM aligned with studies that involved recycling and environmental protection.

Theory of Planned Behavior

The TPB is an extension of Ajzen and Fishbein’s TRA (Ajzen & Madden, 1986). Both models hinge on *intention*; that is, the immediate antecedent of any action is the person’s intention to perform it. According to the TRA, people have two key determinants of intention: attitude toward the behavior and subjective norm, representing an individual and a social factor, respectively. The theory also addresses the antecedents of these two factors. Behavioral beliefs are presumed to influence attitudes toward the behavior, while normative beliefs underpin subjective norms.

Missing from the original model, according to Ajzen and Madden (1986), was the issue of behavioral control, and the extent to which an individual has the control to achieve the behavioral goal. Given that numerous factors can interfere with the actual control one has over carrying out a given behavior, behavioral control was conceptualized as *perceived control,* “the person’s belief as to how easy or difficult performance of the behavior is likely to be” (Ajzen & Madden, 1986, p. 457). The more internal and external resources and opportunities people perceive they have and the fewer obstacles they anticipate, the stronger their sense of perceived control over performing the target behavior. Attitudes, subjective norms, and perceived behavioral control all have distinct effects on behavior (Ajzen & Madden, 1986).

Ajzen and Madden (1986) tested two versions of the TPB in two experiments. Both experiments confirmed that the TPB was superior to its predecessor. Consistent with expectations, the addition of perceived behavioral control greatly enhanced the ability of the theory to predict intentions and subsequent achievement of behavioral goals.

Since its inception, researchers have used the TPB extensively in examining health-related behaviors such as smoking cessation, health screening, and dental flossing (Nisbet & Gick, 2008), as well as the behavior of health care professionals (Cote et al., 2012; Ward, 2013). Ajzen recognized that subsequent research was likely to disclose additional factors that influence intention and outcomes (Ward, 2013). Furthermore, Ajzen and Fishbein (as cited in Ajzen & Madden, 1986) acknowledged that social norms did not necessarily represent a unitary construct. Rather, *descriptive norms*, denoting perceptions of others’ behavior, and *injunctive norms,* denoting perceived expectations for how one should act, may have independent effects on intentions (Nigbur et al., 2010; White et al., 2009). Nigbur et al. (2010) and White et al. (2009) explored the respective influences of descriptive and injunctive norms, as well as aspects of social identity in their application of the TPB to household recycling behavior.

Culiberg (2014) added moral perspectives, applying the TPB to recycling behavior. Also expanding the TPB in this direction, Cote et al. (2012) included moral norms in research exploring nurse intentions to incorporate research evidence into clinical decision making. In fact, moral norms emerged as the strongest predictive factor. This finding may be valuable for explaining nurse decisions in disposing of unused medications. Moral and ethical perspectives may be especially useful in examining behavior related to environmental protection.

Researchers also used the TPB to examine behavior in organizations. Sanchez-Medina et al. (2014) applied the TPB to the study of environmental measures taken by managers of small and midsized firms. Waste disposal was one of the practices investigated. For health care facilities, proper pharmaceutical disposal must be managed at the organizational as well as the individual level (EPA, 2008, 2010).

Studies by Culiberg (2014), Nigbur et al. (2010), White et al. (2009), and Sanchez-Medina et al. (2014) added to a small but growing body of research using the TPB as a framework to investigate behaviors related to environmental protection. Most studies in this line of research focused on recycling behavior (Nisbet & Gick, 2008). In their review of this research, Nisbet and Gick (2008) found that intentions to recycle arose from positive attitudes toward recycling and perceived behavioral control, provided that “people feel their own contribution is important” (p. 298). The influence of subjective norms on recycling was less consistent. Nigbur et al. and White et al. deliberately chose to focus on the influence of subjective norms on recycling.

In summary, the behaviors that trigger the disposal of unused or expired pharmaceutical products are multifactorial and can therefore be best explained by using two theoretical frameworks: the TPB and the HBM. The TPB model (Ajzen & Madden, 1986) hinges on the concept of intention to perform an action, given that the individual has the perception of having behavioral control. In the context of this study, the TPB has provided clues on the need for individuals to have feasible (and available) disposal options. Culiberg (2014), Nigbur et al. (2010), White et al. (2009), and Sanchez-Medina et al. (2014) used the TPB to investigate behaviors related to environmental protection, whereas Nisbet and Gick (2008) used the TPB to explore behaviors related to recycling.

Health-Belief Model

Hochbaum developed the HBM in the 1950s in response to the poor success of public health campaigns to promote disease screening (Strecher & Rosenstock, 1997). Based on detailed analyses of probability samples of adults in cities that offered tuberculosis screening, Hochbaum identified the beliefs that form the basis of the model: perceived susceptibility and perceived benefits of action. Hochbaum also recognized the role of intrinsic and extrinsic cues or triggers in motivating people to take action, although never empirically investigating that feature of the model (Strecher & Rosenstock, 1997).

Decades later, the HBM has been refined and expanded, and has a strong empirical foundation (Strecher & Rosenstock, 1997). The model has several essential components. *Perceived susceptibility* denotes the person's subjective perception of experiencing a health or medical condition. This dimension encompasses susceptibility to illness in general, as well as vulnerability to a specific condition. A related factor is perceived severity, referencing the seriousness of experiencing the condition or allowing it to remain untreated. This component includes medical consequences (pain, disability, and death) and social consequences (for example, the impact of the condition on work and social relationships). Taken together, perceived susceptibility and perceived severity produce perceived threat.

Although acceptance of a perceived personal threat is a prerequisite for taking action, the specific course of action the person chooses to take depends on the perceived benefits of the available options (Strecher & Rosenstock, 1997). Bringing unused and expired medications to a take-back event or disposal center neutralizes the potential threat those drugs might present to people and pets, and does not contribute to environmental pollution. The action might carry the intrinsic reward of feeling one has done the right thing. A drug take-back event might offer an opportunity for socializing. For young people in particular, peer pressure to engage in environmentally friendly actions might influence drug disposal behavior.

Despite awareness of the potential benefits of a given health behavior or behaviors, perceived barriers can arise as obstacles to the recommended course of action. A comprehensive research review of the HBM found perceived barriers to be the single most important factor in health behaviors across all studies and behaviors (Strecher & Rosenstock, 1997). For preventive behaviors, perceived susceptibility and perceived barriers are the best predictors of behavior, whereas for behavior related to a current health problem (such as adhering to medication), perceived severity and perceived barriers are most important (Nisbet & Gick, 2008).

Cues to action are recognized as important factors in health behaviors, but have not been systematically examined (Strecher & Rosenstock, 1997). In fact, it is difficult to quantify cues because they are often subtle and highly individual. For example, people who love nature or are aware of the toxic impact of improperly disposing of medications in the environment might be more likely to change behavior and implement a proper disposal practice. The HBM has been applied to a wide variety of health behaviors. A short list includes cancer screening, wearing sunscreen, dental hygiene, medication adherence, and HIV risk behavior (Nisbet & Gick, 2008). To date, the HBM has been used in only one published study related to the environment: recycling behavior. In a 1997 study by Lindsay and Strathman, individuals who viewed the consequences of not recycling as more of a serious threat were more inclined to comply. Self-efficacy and greater perception of benefits (or lower perceived costs) also aligned with recycling. Self-efficacy has been applied to a myriad of health behaviors. The more confident people feel in executing a course of action and accomplishing the desired results, the more likely they are to undertake the behavior and persist through challenges to achieve their goals (Bandura, 1997).

According to Nisbet and Gick (2008), health psychology is a model with an important role in the realm of environmental protection. In Canada, the environment has supplanted health as *the* Canadians' top concern, although health still ranks high on the list. In Canada, as in the United States, the majority of consumers continue to dispose of a large proportion of unused and expired medications in the toilet and drain (Health Canada, 2009). In a fashion similar to the United States, Canada has a federal structure whereby programs that encourage the proper disposal of pharmaceuticals are being enacted at the provincial level, with a substantial degree of variation between provinces. In the United States and Canada, results have been promising, but many people are unaware of the options for safe disposal of drugs, and barriers do exist. Barriers to the return of medications to pharmacies and other disposal sites include lack of locally available facilities and limited hours for return, as well as lack of awareness.

Nisbet and Gick (2008) pointed out that, in general, people desire a “safe, healthy environment” (p. 296). However, the concept of a safe, healthy environment is relatively abstract, and many people do not understand the potential and actual consequences of environmental problems such as climate change, habitat destruction, and pollution impact on human health. Despite widespread interest by the public in protecting the environment and improving personal health, many public health campaigns fail to elicit changes in people’s behavior. A key reason for this persistent problem is that program designers and policymakers fail to recognize inconsistencies between attitudes toward health and the environment and related behavior. Virtually all guidelines, reports, position papers, and standards issued by government agencies, international bodies, and professional associations emphasize the importance of consumer and patient education on the safe use and disposal of medications. Education is an essential prerequisite for behavior change, but information per se is notoriously ineffective for changing human behavior.

Nisbet and Gick (2008) observed, “Attempts to inspire healthy and pro-environmental behavior often rely on information-intensive messages, assuming that once people are informed they will act differently” (p. 297). A plethora of public health programs that have failed to produce the intended effects that rely on that assumption. However, the problem is that the complexity of factors affecting behavior is underestimated (Nisbet & Gick, 2008). External factors such as lack of transportation, lack of recycling or drug disposal centers, and low socioeconomic status are impediments to proenvironmental and health behavior. Proximity is an important concern in encouraging rural residents to participate in medication take-back events (Gray & Hagemeier, 2012).

Furthermore, many health and environmental behaviors are deeply entrenched. Most consumers are so used to disposing of medications in the sink or toilet that they may not give a second thought to their behavior, despite health and environmental concerns. Even nurses, pharmacists, and other health care staff who are aware of proper and improper disposal practices dispose of unused pharmaceuticals in the drain or toilet (Abahussain et al., 2012; McCullagh et al., 2012; EPA, 2010).

Another reason that inhibits behavior change is the belief that the risk (to the environment or to one's health) is low (Nisbet & Gick, 2008). The use of prescription drugs in the United States has been labeled an epidemic (Maxwell, 2011; ONDCP, 2011). Publicity for medication take-back programs emphasizes the dangers of keeping unused and expired medications in the home. If the perception is that it is more hazardous to keep medication at home than to discard it to sewage (a more immediate versus a more distant risk) in the absence of a conveniently accessed disposal program, the messages may inadvertently reinforce the continued use of improper disposal practices. Threats to personal health from subtle changes to the environment may be perceived as not happening in one's lifetime. People with young children may be most receptive to messages about the human-health threat of discarding drugs to sewage.

Nisbet and Gick (2008) also pointed out that people are prone to unrealistic optimism regarding health and environmental risks that have not yet happened and are thought to be unlikely. Even if individuals are convinced of the seriousness of a health or environmental threat, their optimism may lead them to believe they are less vulnerable than others, and thus would be less likely to take action to change their behavior. Other individual attributes such as a sense of responsibility toward nature and the environment are likely to influence behavior related to environmental protection and health.

In conclusion, the HBM hinges on a strong empirical foundation (Strecher & Rosenstock, 1997), whereby an individual's perceived susceptibility and perceived severity of a threat are at the core of its conceptual framework. For example, the results of the study by Nisbet and Gick (2008) suggested that the more people were concerned about the threat (consequences) of missing a dose of their prescribed medication, the more likely they were to comply with their medication intake. Certain behaviors, such as that of disposing of pharmaceutical drugs in the drain or toilet, are deeply entrenched; therefore suggesting that the perceived threat to one's health from a polluted environment is either too low to be worth considering, or nonexistent.

Toward Managing Pharmaceutical Disposal

Daughton and Ruhoy (2013) referenced the increasing presence of pharmaceuticals in the environment as a side effect of medication prescribing. The same substances that have been helping people in contemporary society to live longer, healthier lives are polluting the natural environment. Pharmaceuticals enter the environment through various routes. The manufacturing process certainly plays a key role in the way it impacts the environment; for example, in a region of India that serves as a manufacturing hub for the global production of pharmaceuticals, the wastewater has registered levels of some pharmaceuticals that surpass the amount in the blood of patients on that medication (Larsson, 2014). Agricultural practices also contribute to pharmaceutical pollution; for example, antibiotics are dispersed in the environment through the excretion of antibiotics by animals which are provided antibiotics with their feed to promote growth (K. Kumar, Gupta, Baidoo, Chander, & Rosen, 2005).

However, for household pharmaceuticals, pharmaceuticals enter the environment in three pathways. The first is through natural excretion: the body metabolizes only a fraction of medication ingested, injected, or infused (Daughton & Ruhoy, 2013; Harvard Health, 2011; Ortner & McCullagh, 2010; Rodriguez-Mozaz & Weinberg, 2010; Ruhoy & Daughton, 2008). The unmetabolized compound and its metabolites are excreted in urine and feces and to a lesser degree, sweat. A second pathway is the removal of topical medications while bathing. The third pathway, which is the focus of this study, is the disposal of unused, unwanted, and expired medications.

However, the three pathways interrelate and contribute to the overall impact on the environment. Daughton (2014a) used the terms upstream and downstream to denote two approaches to reducing the amount of pharmaceutical substances in the environment. The upstream approach focuses on minimizing the amount and toxicity of substances that have the potential to contaminate the environment. This approach can also be called green pharmacy or ecofriendly pharmacy (Daughton, 2003a, 2003b; Daughton & Ruhoy, 2008). The upstream approach begins with the design of drugs with maximum potential to be absorbed by the body so smaller trace amounts are excreted. Drugs in this category are designed to increase the specificity of drug action at the target cells, and can be prescribed in lower dosages.

For drugs that are already on the market, an upstream approach involves curbing the overprescribing of medications, limiting aggressive marketing that encourages patients to request medications that may not be necessary and leaves household medicine cabinets with samples of numerous drugs that go unused. Improving diagnostic procedures for such drugs allows patients to be prescribed the most effective drugs and precise dosages, thereby improving patient adherence to the prescribed medication regimen; poor medication adherence is a major contributor to the unused drugs that find their way into the waterways (Daughton, 2003a, 2003b; Daughton & Ruhoy, 2013; Ruhoy & Daughton, 2008; Ruhoy & Kaye, 2010).

Diligent monitoring is another aspect of the upstream approach (Daughton, 2014b; Ruhoy, 2009). Gathering inventory data from coroner's offices provides a novel and effective mechanism to identify precisely how much of a particular pharmaceutical ingredient has been disposed of in a given geographic region and the frequency with which the substance is disclosed in the disposal inventories. Researchers investigating the unusual variability in pharmaceutical concentrations in water surrounding a college town found that variations in the chemical composition aligned with changes in the average age of the population when students were on vacation or on campus (Ottmar, Colosi, & Smith, 2013). Specifically, the effect they observed was due to higher and lower levels of oral contraceptives. When students were absent, more evidence accrued of cardiovascular drugs. Researchers were able to track the prescribing and use volume of tamiflu during real or anticipated flu epidemics by analyzing their concentrations in the environment

(Singer et al., 2008, 2014). Knowledge of where drugs accumulate and the factors leading to that accumulation provide a foundation to curb the accumulation of pharmaceutical waste.

The downstream approach involves promoting the safe and proper disposal of the unused, unwanted, and expired medications that accumulate in most households (Ruhoy & Daughton, 2008). This approach is exemplified by drug take-back programs that allow consumers to bring unused pharmaceuticals to a specific site where the drugs are collected and transported to be destroyed. These programs have been carried out since 2010 under the direction of the DEA so that controlled substances can be returned and transported (Fain & Alexander, 2014). Preliminary data indicate that drug take-back events across the United States effectively draw people and collect millions of tons of pharmaceutical waste, nationally, for safe disposal (Fain & Alexander, 2014; Fass, 2011; Gray & Hagemeier, 2012; Lubick, 2010; Ma et al., 2014; Stewart et al., 2015; Tucker, 2011). Participants at a take-back event in Honolulu were virtually unanimous in wanting to see the event repeated (Ma et al., 2014). However, annual take-back events remain sporadic, and for drug return strategies to effectively reduce the huge amount of pharmaceutical substances that enter the environment, consumers should be able to access return sites whenever they have a need.

Pharmacies are routinely hailed as the ideal venue for returning unused medications (Abahussain et al., 2012; Fain & Alexander, 2014; Fass, 2011; Zimmermann et al., 2011). Pharmacies are also excellent sites to educate the public about proper medication management and disposal. However, the widespread adoption of pharmacy returns has marked challenges. Medication-return programs existed before the DEA became involved to allow the return of controlled substances (Musson et al., 2007; Thompson, 2007). In September 2014, the DEA issued a regulation requiring pharmacies to follow specific guidelines to implement take-back programs (Fain & Alexander, 2014). The regulation stipulates specific ways patients are allowed to return unused and expired drugs, such as through collection boxes at registered pharmacies. Indeed, providing consumers with access to receptacles is often recommended and likely to be popular with the general public. However, some pharmacies have raised concerns about the burdens and costs of requisite measures, as well as potential legal liability.

The effectiveness of this strategy also rests on the voluntary participation of pharmacies and adequate funding, especially to offset additional costs due to DEA requirements (Fain & Alexander, 2014). Many pharmacies have enthusiastically participated in drug take-back events and are interested in continuing. Upstream approaches may be preferable in theory, but they do not address the drugs that are already in medicine cabinets. Medication take-back programs have shown a good deal of promise, but their success depends on the active involvement of stakeholders.

Environmental Impact: Empirical Evidence

Pharmaceutical compounds have been steadily entering the natural environment since their introduction into human and veterinary medicine more than a century ago (de Cazes et al., 2014). The first studies documenting the presence of drugs in environmental waters date back to the 1970s, when researchers in the United States detected evidence of analgesics, heart medications, and contraceptive drugs in wastewater (WHO, 2011). This line of research gathered momentum in the 1980s and 1990s. The most extensively cited work in the peer-reviewed literature of the presence of drugs in surface water is an investigation conducted by the U.S. Geological Survey in 1999 and 2000, revealing more than 50 pharmaceuticals in 139 streams across 30 U.S. states. Of the streams examined, 80% contained at least one contaminant, with an average of seven contaminants per stream (Ortner & McCullagh, 2010).

Similar studies conducted in Europe showed comparable results. A research synthesis published in 1997 reported the presence of cholesterol medications, analgesics, and anticonvulsants in surface waters and groundwater in Germany (Ortner & McCullagh, 2010). In March 2008, the AP released a report entitled *PharmaWater I*, detailing the findings of an AP investigative team. The report revealed that at least 41 million Americans were served by water supplies with evidence of pharmaceuticals, including anticonvulsants, antibiotics, mood stabilizers, and hormones (Ortner & McCullagh, 2010). The team found drugs in the water supplies of 24 major metropolitan areas across the United States. Studies from the United States and the United Kingdom disclosed treatment plants were not completely effective in removing active pharmaceutical ingredients from treated water.

Indeed, a key concern is that conventional treatment plants are not equipped to fully remove micropollutants such as pharmaceuticals from wastewaters (de Cazes et al., 2014; Fatta-Kassinos et al., 2011; Milic et al., 2013; Uslu et al., 2013; WHO, 2011). Advanced treatment techniques such as ozonation, advanced oxidation, activated carbon, and membrane are capable of removal rates exceeding 99% for specially-targeted pharmaceutical compounds (WHO, 2011). However, even the most advanced and expensive treatment techniques leave detectable levels of pharmaceuticals. Prevalence of advanced treatment plants across the United States was estimated as 18.3% of the total budgeted needs for clean watersheds, aligned with the EPA survey conducted in 2012 (EPA, 2016).

For conventional methods, the effective removal of pharmaceuticals ranges substantially, from more than 90% to less than 20%. To an extent, this variation depends on the nature of the wastewater treatment plant and treatment techniques employed; in fact, the EPA (2016) listed several categories of treatment that have distinct functions, for example secondary, advanced, and storm-water management. Even more significant, the pharmaceuticals currently produced represent more than 4,000 molecules with varying properties related to absorption, bioactivity, and biodegradability (de Cazes et al., 2014).

ARGs have been discovered in treated wastewater, raising concern as to whether that resistance might transfer to microorganisms capable of affecting human health (Lubick, 2011; Marti et al., 2013; Sahoo et al., 2010; Segura et al., 2009; Zhang et al., 2009). Wastewater-treatment plants reduce the total amount of bacteria in water, but are not effective enough to remove ARGs (Marti et al., 2013; Milic et al., 2013; Zhang et al., 2009). Furthermore, beyond being inefficient in removing ARGs from wastewater, treatment plants may facilitate the “horizontal transfer of resistance determinants” among an array of microorganisms, thus treatment plants may actually “contribute to the occurrence, spread and persistence of both antibiotic-resistant bacteria and antibiotic resistant determinants in the environment” (Marti et al., 2013, p. 2).

Pharmaceuticals are distinguished from other environmental pollutants because they are made to be biologically active. Unique characteristics of pharmaceuticals include their highly complex chemical structure, polymorphism (the ability of a molecule to crystallize into more than one crystalline form), and their ability to be ionized and have multiple ionization sites dispersed throughout the molecule (Fatta-Kassinos et al., 2011). To strengthen their intended action, pharmaceuticals are created to be resistant to biodegradability, and many drugs are extremely powerful. The complex nature of compounds that are typical of pharmaceutical products is a challenge, even to more advanced treatment plants and technology.

An additional distinction is that pharmaceuticals often enter the environment after being metabolized by human or veterinary patients. In addition, drugs also enter the environment in an unmetabolized form, by direct disposal to sewage. Sales of pharmaceuticals have been increasing annually at about 5% to 7% (Corcoran et al., 2010). In the United States, hospitals, care facilities, and pharmacies discard an estimated $1 billion of unused drugs each year, exceeding the amount of drugs discarded by consumers.

Because pharmaceuticals have been detected in a wide range of environmental sources with concentrations typically ranging from traces to even smaller concentrations in the order of parts per billion has led to some speculation that pharmaceuticals are not likely to have a harmful impact on the environment (Fatta-Kassinos et al., 2011; WHO, 2011). However, Fatta-Kassinos et al. (2011) are among a number of sources that are skeptical of that assumption, citing weaknesses in the existing research, ambiguous findings, and glaring knowledge gaps (de Cazes et al., 2014; Daughton, 2014b; A. Kumar et al., 2010; Ortner & McCullagh, 2010; Rahman et al., 2010; Rodriguez-Mozaz & Weinberg, 2010). Ortner and McCullagh (2010) pointed out that, “Active pharmaceutical ingredients have been found in the ambient environment that not long ago were considered infinitesimally low” (p. 18). Even these very low concentrations have been implicated in abnormalities found in fish populations (Corcoran et al., 2010; Ortner & McCullagh, 2010). In addition to the adverse effects on fish, ecotoxicity studies have shown that pharmaceutical pollutants are capable of affecting the growth, reproduction, and behavior of birds, invertebrates, plants, and bacteria, even at very low levels (e.g., a few nanograms per liter; de Cazes et al., 2014). According to de Cazes et al. (2014), trace concentrations in soils, which directly link with food and drinking water, present a hazard to human health. Notably, concentrations of pharmaceuticals in soils and sediments tend to be higher than levels detected in water (Fatta-Kassinos et al., 2011).

Analytical and Research Techniques

The discovery of very low concentrations of pharmaceuticals in the environment is due primarily to the development of increasingly sensitive, sophisticated, and accurate detection equipment and analytical techniques (Fatta-Kassinos et al., 2011; WHO, 2011). Gas chromatography with mass spectrometry or tandem mass spectrometry and liquid chromatography with mass spectrometry or tandem mass spectrometry are capable of discerning target compounds near a nanogram per liter. Technicians routinely use these advanced techniques to detect pharmaceuticals in water and wastewater. The precise choice of method depends on the chemical and physical properties of the target compound. Similarly, the inherent degree of variability increases the challenge of understanding the potential effects of pharmaceuticals on the environment and human health. Specifically, the absence of standardized methods or protocols for sampling and analyzing the presence of pharmaceuticals in water, soils, sediments, or other environmental features precludes the ability to ensure “the comparability and quality of the data generated” (WHO, 2011, p. 2).

Daughton (2014b) raised a particularly interesting and significant criticism of the existing research on pharmaceutical pollution. According to Daughton, risk-assessment studies on pharmaceutical pollution were governed by the “Matthew Effect.” That is, monitoring surveys tend to focus on active pharmaceutical ingredients (APIs) that have already been the subject of previous research, ignoring the vast majority of pharmaceuticals discharged into the environment and resulting in research findings that are redundant and incomplete. For example, a review of research on the presence of 203 common APIs in 41 countries found that most monitoring efforts focused on only 14 APIs, representing a scant 7% of the drugs.

Daughton (2014b) referenced chemicals marked by a dearth of research as “Matthew Effect Orphaned Chemicals” (MEOCs). In a case study of more than 200 drugs designed to discern the scope of MEOCs, Daughton found 73 MEOCs, with 33 having no published data, 20 with minimal published data (one or two published reports), and 20 with limited published data (a maximum of three to six studies reporting positive findings). Daughton noted that these 73 APIs had been previously described as high-volume pharmaceuticals that had not been captured in research, but were “estimated to be persistent and/or bioaccumulative” (Howard & Muir, 2011, as cited in Daughton, 2014b, p. 319). Notably, Daughton pointed to the lack of occurrence data on 14 APIs still classified as MEOCs as early as 2001. These still unmonitored but widely prescribed drugs include alendronate, amiodarone, benazepril, chlorthalidone, clonazepam, cyclobenzaprine, doxazosin, glipizide, guaifenesin, pramipexole, quinapril, ropinirole, spironolactone, and terazosin. With respect to half-life of pharmaceutical products, a large spectrum of variability exists across compounds, even in the same category of products. For example, a study conducted by Halling-Sorensen, Lutzhoft Holten, Andersen, and Ingerslev (2000) to assess biodegradability compared three types of antibiotics: mecillinam, ciprofloxacin, and trimethoprim. Study results indicated that mecillinam and ciprofloxacin were readily biodegradable whereas trimethoprim was not. These findings pose an additional challenge to the overall strategy for water treatment; however, they also provide hope that it may be possible to engineer pharmaceutical compounds that are environment friendly.

Daughton (2014b) acknowledged that the absence of data on some APIs may be due to presumed pharmacokinetic properties, for example based on the properties of a parent drug that is “extensively metabolized” (p. 322). However, Daughton (2014b) argued that the pharmacokinetics of many drugs is poorly understood. In addition, this approach ignores the fact that regardless of pharmacokinetic properties, these drugs will enter the sewage system directly when people dispose of their unused medications in the sink or toilet. Inadherence is a major reason to discard medications, often due to a drug’s toxic side effects. If not completely removed by wastewater treatment, virtually all APIs are capable of interacting with other drugs. Daughton (2014b) also noted that seven of the 73 MEOPs are highly active topical medications released through bathing or sweat. Transdermal and transmucosal devices retain significant amounts of their original content, even after several days of use (Ortner & McCullagh, 2010). Thus, these devices, when discarded without being used, are likely to be heavily bioactive.

Two main approaches can manage APIs in the environment (Daughton, 2014b). The first is monitoring a more extensive number of APIs, which should lead to greater detection of previously ignored, potentially hazardous pharmaceuticals. A second, highlighting the upstream approach, is that knowledge of the relative impact of specific APIs could lead to prescribing those drugs that intrinsically provide minimal toxic risk and impact on the environment. Daughton's ongoing extensive research highlights numerous knowledge gaps that have persisted for more than a decade (Daughton, 2003a, 2003b, 2014a, 2014b; Daughton & Ruhoy, 2008; Ruhoy & Daughton, 2008).

The most prevalent and powerful criticism of the existing research is that most studies focus on the short-term effects of individual agents, whereas little is known about the cumulative and synergistic effects of the plethora of bioactive chemicals discharged into the environment on a daily (and increasing) basis (Corcoran et al., 2010; Daughton, 2014b; de Cazes et al., 2014; Fatta-Kassinos et al., 2011; A. Kumar et al., 2010; Ortner & McCullagh, 2010; Rahman et al., 2010; Rodriguez-Mozaz & Weinberg, 2010; WHO, 2011). Among the pharmacokinetic properties of APIs is their interaction with other drugs (Daughton, 2014b). The effects of drug interactions in the human body are not necessarily well understood. The current trend in research examining single APIs in geographic isolation as well as isolation from other substances precludes greater understanding of the potential synergistic effects of drug interactions in the natural environment. A. Kumar et al. (2010) could find no studies investigating the effects of mixtures of pharmaceuticals. They described this lack of knowledge of pharmaceutical interactions as an "important uncertainty" (p. 3946). In fact, the uncertainty attached to long-term persistent exposure to bioactive chemicals in water, soil, and sediments, even at low concentrations, is a pervasive theme in the literature.

Types of Drugs and Effects

Virtually all classes of drugs have been detected in the environment. Estrogens, antidepressants, and antibiotics have all aligned with abnormalities in aquatic life (Corcoran et al., 2010; Ortner & McCullagh, 2010). The term *endocrine disrupting chemical* entered the lexicon in 1991 at a conference organized by Colbern, a zoologist and former pharmacist who first called attention to the phenomenon of endocrine disruption in the 1970s after reviewing hundreds of studies investigating the impact of the contamination of wildlife in the Great Lakes (Ortner & McCullagh, 2010). A study conducted to assess the status of the water quality of Lake Huron, the second-largest of the Great Lakes, revealed the presence of atrazine, fluoxetine, and carbamazepine at trace concentrations (> 58 ng/L) in at least four samples, and ibuprofen and atorvastatin in one sample (Rahman et al., 2010). Although not widely prescribed, carbamazepine emerged in numerous samples, due to its low biodegradability (Corcoran et al., 2010). According to Rahman et al. (2010), the presence of atrazine in Lake Huron has particular health implications because it has the potential to contaminate drinking water in downstream regions. The researchers acknowledged that "the occurrence of these compounds … does not necessarily confirm health risk" but "neither does non-detection guarantee safety" (p. 227). This statement highlights the uncertainty that runs through the literature.

No uncertainty exists, however, on the impact of endocrine-disrupting chemicals on the aquatic environment. The adverse effects of estrogens on fish populations are probably the most documented consequences of pharmaceutical pollution (Corcoran et al., 2010; Ortner & McCullagh, 2010). These effects include alterations in mitochondrial activity, energy metabolism, and cell-cycle regulation, as well as the feminization of male fish and the development of genital abnormalities, in some cases leading to the collapse of fish colonies due to reproductive failure.

NSAIDs are the most widely used class of drugs (Ortner & McCullagh, 2010). NSAIDs reduce inflammation by inhibiting the synthesis and release of prostaglandins. Examples of NSAIDs include acetylsalicylic acid (aspirin), ibuprofen, and diclofenac. These drugs have the potential to damage the kidneys, an effect documented by kidney failure in animals exposed to NSAIDs in water. One striking study reported the deaths of vultures in India and Pakistan due to kidney failure from feeding on the carcasses of livestock treated with diclofenac (Rahman et al., 2010; Rodriguez-Mozaz & Weinberg, 2010). The vulture population declined dramatically in the course of 3 years.

The term *anti-infectives* encompasses several bioactive compounds with the capacity to inhibit the growth or survival of microorganisms without harming the host (Segura et al., 2009). This category includes some antifungal agents and synthetic drugs, but in particular, antibiotics, which have become a major focus of attention in the literature on pharmaceutical pollution due to the presence of ARGs found in water supplies, soils, and sediments and their potential negative impact on human health (Fatta-Kassinos et al., 2011; Marti et al., 2013; Milic et al., 2013; Uslu et al., 2013; Zhang et al., 2009). Tetracycline was one of the first drugs detected in the environment, and the growth of tetracycline-resistant bacteria has been reported ever since (Zhang et al., 2009). In fact, hundreds of ARGs linked with resistance to a wide variety of antibiotics have been discovered in wastewaters, wastewater treatment facilities, surface water, ground water, and drinking water. These microorganisms have the potential to be transferred to humans from the environment through direct and indirect contact. Even at very low levels, antibiotics may act as “signaling agents in microbial environments” to various plants that have receptors for antibiotics and disinfectants (Fatta-Kassinos et al., 2011, p. 228).

Adding to the prospective threat posed by ARGs in the environment, ARGs are also resistant to wastewater treatment and advanced treatment techniques (de Cazes et al., 2014; Milic et al., 2013; Zhang et al., 2009). Advances in removing pharmaceuticals from the environment have not kept up with the ability to detect them. Segura et al. (2009) stated that: “Anti-infectives, the miracle drugs of the 20th century have become environmental contaminants of emerging concern in the 21st century” (p. 682). Upstream and downstream approaches are needed to address the problem of the increasing pollution of the environment by pharmaceutical compounds. Green pharmacy is still in a fledgling state, but consumers, pharmacists, nurses, and other health professionals, as well as concerned businesses, have the power to reverse the increasing dispersal of pharmaceuticals into the environment by proper disposal of unused and expired medications.

Evolution of Medication Disposal Policy and Practice

A number of countries, including Australia, France, Sweden, Portugal, Spain, the United Kingdom, and New Zealand, have had formal programs to collect unused drugs for some time (Ruhoy & Daughton, 2008). European Union directives require member states to have suitable collection systems in place for the return of unused and expired drugs (Health Canada, 2009). Australia’s Return Unwanted Medicines Project is financed by the federal government. Sweden has an unusual retail-pharmacy system organized into a single government-owned chain called Apoteket B. Apoteket B operates an environmental program driven by targeted public-awareness campaigns to educate the public about the adverse effects of flushing medications down the drain or throwing them into the trash. The focus on public awareness seems to be working: more than 70% of consumers with leftover drugs return them to the pharmacy. The Spain Integrated Waste Management System also carries out intensive campaigns to raise public awareness, successfully producing large volumes of returned medications. In contrast, in Poland, environmental awareness is low, and consumers have few places to return unused drugs, resulting in improper medication disposal (Zimmermann et al., 2011).

Disposing of unused drugs in the United States has long been complicated by contradictory regulations from various agencies, and legal regulations on controlled substances that even with DEA involvement still clash with state laws. The first federal guidelines for the disposal of prescription drugs were issued in 2007 (Ortner & McCullagh, 2010; Ruhoy & Kaye, 2010). Consumers were provided a list of options for disposing of medications:

- Take advantage of community take-back programs that allow the public to bring unused pharmaceuticals to a designated location for proper disposal.
- Remove unused prescription drugs from their original containers and throw the loose medications in the trash.
- Mix prescription medications with an unappetizing substance such as coffee grounds or cat litter and put them in impermeable, nondescript containers to ensure they are not diverted.
- If the patient information specifically instructs, flush prescription medications down the toilet.

The guidelines were issued with the dual goals of preventing prescription drugs from being diverted and protecting the environment (Thompson, 2007). Although these guidelines represented an important step forward, they became a source of derision for the inclusion of cat litter as a disposal option (Knopf, 2013). In 2010, the White House announced that the guidelines for individual medication disposal had been replaced by official take-back days. However, the FDA (2011) still recommends mixing unused drugs with unpalatable substances and putting the mixture into sealed containers. The recent federal guidelines do *not* recommend throwing loose medications in the trash, and are quite explicit about taking advantage of take-back programs and properly disposing of drugs. The guidelines also state to not flush medications down the toilet unless the instructions specifically say to do so. The FDA recommends flushing 26 drugs because of the high risk associated with keeping these drugs in the house, such as fentanyl patches for pain. The FDA estimated that in 2009, about 5,000 children had accidental exposure to drugs in the house, and about 100 died (Mitka, 2009).

In the 1990s, people saw a proliferation of numerous studies documenting the presence of pharmaceuticals in the environment and effects on aquatic life. In the early to mid-2000s, a few studies emerged in the United States and other countries examining consumers' medication disposal knowledge and attitudes. At the time, the outpatient pharmacy at Madigan Army Medical Center at Fort Lewis in Washington State had a policy that allowed patients to return unused or expired medication, which would be disposed of as medical waste (Seehusen & Edwards, 2006). Controlled substances were excluded from the program. Information about the policy was clearly stated on the instruction sheets that patients received when they received medication, specifying that this was the preferred mode of medication disposal. In addition, patients also had the option to return unused or expired drugs to a provider.

In another study, the researchers' goal was to gain insight into hospital patient practices for disposing of medication and their beliefs about medication disposal techniques. A total of 301 patients completed the survey, most taking no more than five medications or having more than five medications at home (Seehusen & Edwards, 2006). Less than 20% of participants had received any guidance from a health professional about proper disposal of medication. Given the time of the study and lack of professional advice, it is unsurprising that more than half the participants kept unused or expired drugs at home, and a similar proportion flushed drugs down the toilet. Slightly more than one-third rinsed drugs down the drain. Only 14% returned unused drugs to a health care provider, and 23% returned drugs to a pharmacy.

A marked contrast arose between participants' beliefs about drug disposal and their behavior (Seehusen & Edwards, 2006). The portions of individuals who deemed it acceptable to return drugs to a pharmacist or health care provider far surpassed the proportion of those who actually did so, whereas the reverse was true for disposing of drugs in the toilet or sink. In other words, people were disposing of drugs in ways they did not really consider acceptable. Their behavior might have been dictated by habit or by lack of awareness of alternative options.

Notably, having been educated about safe disposal practices strongly linked with returning drugs to a pharmacy or to a health care provider. Patterns between frequent pharmacy visits, being prescribed more drugs, and returning unused drugs, suggested patients were given advice on drug disposal when they returned for new medications

(Seehusen & Edwards, 2006). Seehusen and Edwards (2006) strongly advocated patient education. They proposed that health professionals and pharmacy staff could discuss drug disposal with patients, and that patients could be provided written information when receiving medications or medication labels or pill bottles could display information about disposal. This last suggestion is admirable but misguided. Patients routinely do not read the label or simply ignore instructions (Bound & Voulvoulis, 2005).

Seehusen and Edwards (2006) asserted that persuading patients to believe it is desirable to return drugs to a health professional or pharmacy is a prerequisite for getting them to actually carry out the behavior. However, their own findings revealed a gap between beliefs and behaviors. Even pharmacists (Abahussain et al., 2012) and nurses (McCullagh et al., 2012) do not always act in accordance with their knowledge of proper drug disposal. Models of behavior change rest on recognition that education is a requisite, but not sufficient to change behavior (Bandura, 1997; Nisbet & Gick, 2008; Strecher & Rosenstock, 1997).

In the United Kingdom, Bound and Voulvoulis (2005) examined household practices in disposing of unused and expired medication in a general population survey of 400 respondents in southeastern England. They broke down disposal practices by drug type. Virtually all respondents had some medications at home. Most households had a combination of prescription and OTC drugs (60.2%), and close to one-third had only OTC drugs. Most respondents reported using all the painkillers they purchased or were prescribed (80%). However, the figure for antibiotics was striking: only 16% of respondents consumed all the antibiotics they had acquired. Many people stop taking antibiotics as soon as their symptoms disappear, even though they are told to finish the supply. Antibiotics are also notoriously overprescribed (Daughton & Ruhoy, 2013; Ruhoy & Daughton, 2008). Overprescribing and poor adherence to antibiotics contributes to the presence of antibiotics in the environment and drives concerns about antibiotic resistance (Lubick, 2011; Marti et al., 2013; Sahoo et al., 2010).

Most UK respondents disposed of drugs with household trash (Bound & Voulvoulis, 2005). Only a small fraction (11.5%) disposed of drugs in the sink or toilet, and no respondents who took hormone medications disposed of their medication in that manner; all returned unused medications. That effect might have been due to awareness of the effects of hormones on the aquatic environment.

The most striking finding was the comparison by Bound and Voulvoulis (2005) of their findings with data from the United States. In the British sample, 21.8% returned their medication to the pharmacy compared to a scant 1.4% in the United States. In contrast, 11.5% of the UK respondents flushed medication down the toilet or sink versus 35.4% in the United States. The researchers speculated this result might have reflected different regulations and advice in the two countries. In fact, U.S. residents were instructed to dispense of medications in the sink or toilet, and at the time of the survey, few available locations existed for returning unused medicines.

The presence of leftover prescription drugs beyond antibiotics suggested that many respondents were not adhering to their medication as prescribed. Bound and Voulvoulis (2005) concluded that a substantial amount of pharmaceuticals were finding their way into the environment. The United Kingdom has since adopted a formal medication-return program (Health Canada, 2009). At the same time, deeply ingrained practices can be difficult for people to change.

It is important to recognize that in the United States in particular, changes to federal guidelines and regulations and the implementation of the DEA program are driven primarily by dangers posed by rampant prescription-drug abuse (ONDCP, 2011). Replacing flushing medications with returning them reflects recognition of the harmful effects of pharmaceuticals on the natural environment and their potentially harmful effects on human life, but the emphasis in awareness campaigns is on the hazards of keeping unused medications in the home. That may actually be advantageous to changing behavior in that it emphasizes the more immediate threat (poisoning) over the more distant threat (pollution). At the same time, environmental protection is a powerful motivator for many participants at take-back events (Gray & Hagemeier, 2012). For health care facilities that have large quantities of unused pharmaceuticals, protecting the environment is a major issue.

Attitudes and Behavior of Health Professionals and Patient Health Care Facilities

In response to compelling evidence of detectable levels of various pharmaceutical compounds in waterways across the United States, the EPA (2008, 2010) embarked on research investigating the pharmaceutical disposal practices of health care facilities. The study was driven by the assumption that health care facilities continue to discard large quantities of unused pharmaceuticals to sewers, to the detriment of the environment and public health. For the most part, federal, state, and local regulations governing the disposal of medical waste were the main influence on disposal practices. However, size, ease, and access of disposal, and financial cost also impacted unused pharmaceutical disposal. Due to differences in regulations governing hospitals and long-term care facilities, long-term care facilities had more constraints on returning unused medications.

The investigators concluded that the widespread adoption of best management practices could have a substantial impact on the amount of unused pharmaceuticals entering the aquatic environment (EPA, 2008, 2010).

To encourage proper disposal, the EPA (2010) developed a list of best-practice guidelines for health care facilities. The first step in the process entails conducting an inventory of pharmaceuticals used at the institution, and identifying the unused pharmaceuticals, the reasons for waste, and the practices currently used for management and disposal (EPA, 2010). Taking inventories and maintaining a comprehensive database is essential to the practice of green pharmacy (Daughton, 2003a, 2003b).

The initiation of a waste-management program includes a set of diverse techniques for waste segregation to meet all relevant regulations and potentially minimize costs (EPA, 2010). An essential component of a good waste-management program is staff training for pharmacists, nurses, and other personnel involved in managing unused pharmaceuticals. The EPA recommends that staff members are trained to recognize when unused medications should be returned to the pharmacy or when they should be discarded, and in what manner. Training should be ongoing with refresher sessions to keep staff members current, and their feedback should be solicited for continuous quality improvement. Other strategies include prominent signs and posters to remind staff members of the disposal policy, and waste-management audits conducted at the time of pharmaceutical stocktaking. Sapkota, Gupta, and Mainali (2014) presented the case study of a hospital in Nepal that radically transformed poor waste-management practices with the implementation of a program reflecting the EPA best-practice guidelines.

Intervention

Sapkota et al. (2014) presented the first study from Nepal to examine the impact of a training intervention on the health care waste-management practices of hospital staff. Prior to the intervention, the government hospital in Katmandu had no formal policy or protocols for handling health care waste. Under the leadership of the hospital's executive director, a health care waste-management committee was organized, with the director assuming responsibility for all the committee's activities. Representatives from all hospital units and departments served on the committee, which drew up a policy and standard operating procedures aligned with national waste-management and environmental regulations. Participants in the training program were nurses, doctors, and waste handlers from the hospital's obstetrics, gynecology, pediatrics, medicine, and orthopedic wards. Based on safe health care waste-management practices recommended by WHO, the program included orientation to health care waste management, standard operating protocols, and legal provisions for safe waste management, segregation, collection, and handling techniques for different types of hospital waste, along with safe occupational health and safety issues and safe injection practices.

A nurse from each ward was entrusted to counsel and record activities related to waste management (Sapkota et al., 2014). As each new patient was admitted, the nurse would give caregivers a brochure developed by the committee, containing comprehensive information on the hospital's waste-management protocol. The committee enacted detailed procedures for handling, collecting, storing, and transporting hazardous and nonhazardous waste.

Pre- and postinformation on the waste-management practices, before the study and 8 months later, was compared using the Individualized Rapid Assessment Tool created by the United Nations Development Program Global Environment Project (Sapkota et al., 2014). The preintervention assessment revealed highly inadequate waste-management practices. Prior to the study, the hospital tended to work on the principle of *reduce, reuse, and recycle*, which could be dangerous in a hospital setting. Procedures changed dramatically after the intervention. Procedures were carried out meticulously. Improvements were captured in postintervention Individualized Rapid Assessment Tool scores, which soared from a dismal 26% to 86% (Sapkota et al., 2014).

Several positive features contributed to the success of the project: a dedicated waste-management team, effective leadership, diligent planning, sound organization, sufficient funding, and the enthusiastic involvement of trained staff (Sapkota et al., 2014). These attributes are valuable, if not indispensable, for any change-management initiative. In addition to standardizing and improving waste management in health care settings, the same type of leadership, teamwork, planning, and organization could transfer to community programs for encouraging safe and environmentally friendly disposal of pharmaceutical waste.

Nurses

Given the holistic and caring orientation of nursing, the nursing literature is replete with calls to adopt safe practices that protect the environment (McKown & Pawloski, 2013; Ortner & McCullagh, 2010; Shaner-McRae, McRae, & Jas, 2007). Nurses counsel and educate patients, which provides them with excellent opportunities to inform and educate patients about safe medication disposal. At the same time, it is unclear if nurses follow best practices in disposing of pharmaceuticals. In particular, nurses who work in home care are not governed by the stringent regulations for disposing of hospital waste.

McCullagh et al. (2012) explored the medication disposal practices and attitudes toward medication disposal of home hospice nurses. Home hospice nurses provide holistic palliative care to terminally ill patients and their families. Educating patients and caregivers regarding how to safely store, manage, and dispose of medications is an essential part of their professional role. Upon a patient's death, however, the nurse is often entrusted with the responsibility of discarding unused medications.

McCullagh et al. (2012) developed their survey based on items drawn from a previous study. The researchers pretested the items with a group of five home hospice nurses, and revised based on their feedback. McCullagh et al. designed two parallel measures to capture drug disposal practices among nurses and related attitudes and beliefs among nurses. A total of 138 home hospice nurses completed the online survey. As a group, participants were experienced health care professionals and close to two-thirds (64%) had been working in hospice care for more than 5 years. Almost half the nurses (44%) reported disposing of 11 or more medication doses upon a patient's death. Although roughly two-thirds (64%) of the nurses reported always or often mixing the drugs with undesirable substances, as recommended, more than half reported discarding them in the toilet or drain with the same frequency.

The nurses overwhelmingly endorsed the practice of mixing medications with an unpleasant substance as acceptable (94%) and safe (91%). Most deemed it unacceptable to return the drugs to the hospice (79%) as unsafe or extremely unsafe (61%). The nurses' rejection of returning drugs to the hospice aligned with legal restrictions on nurses transporting controlled substances (McCullagh et al., 2012).

Nurses obtained their information on medication disposal mainly from the hospice manual, regulations, other documents, or in-service training (McCullagh et al., 2012). A substantial proportion of nurses, close to one-third, acknowledged they were unfamiliar or only minimally familiar with the Centers for Medicare & Medicaid Services Hospice Conditions of Participation rules for disposing of medications. Most of the group expressed concern about legal and environmental issues, but considered the prospect of drug diversion as the foremost issue.

McCullagh et al. (2012) noted that gap between nurses' regular practices in disposing of medication and federal guidelines for disposing of drugs in home hospice care. A marked gap emerged between the almost unanimous endorsement of the safety and acceptability of mixing drugs with an unpleasant substance and the number of participants who regularly disposed of drugs in that manner. Nurses placed high priority on ensuring drugs were not diverted, which could help explain why they were inclined to dispose of medication in the toilet or drain. In fact, McCullagh et al. attributed their strong concern for drug security to a sociopolitical environment where the "war on drugs" is heavily publicized, and health care professionals are acutely aware of their role in ensuring drug security: lax drug disposal practices could jeopardize their professional license. At the same time, the guidelines for supplanting sewage disposal with the mixing technique come from federal agencies.

In-service training was one source of information on proper medication disposal, although it did not appear to be prevalent, as most nurses acquired information though reading materials. Only 16% of nurses had learned about safe medication disposal in nursing-education programs. However, McCullagh et al. (2012) acknowledged that this could be due to the emphasis on direct patient care in undergraduate nursing education, with medication management perceived as the pharmacist's role. Another reason may be that respondents had completed their education before environmental issues were recognized as a public health concern.

The proposed explanation of McCullagh et al. (2012) that nurses' continued disposal of medications to sewage might be due to the high priority they place on drug security is consistent with the finding of Cote et al. (2012) that nurses are motivated by strong moral norms. In their research, Cote et al. used the TPB to explore the intentions of nurses at a Quebec hospital to integrate research evidence into their clinical decision making. The researchers noted that since the 1990s, a powerful drive has taken place to implement evidence-based practice in health care. Nurses not only represent the largest group of health professionals but are considered uniquely important due to their closeness to individual patients, sensitivity to community needs, and involvement in virtually all aspects of health care, including health promotion, disease prevention, and clinical care. Nurses are entrusted with educating patients and caregivers on safe medication storage and disposal (McCullagh et al., 2012). Theoretically, nurses' integration of best-practice guidelines for proper medication disposal into their daily decision making constitutes evidence-based nursing practice.

In addition to expanding the TPB to include moral norms, Cote et al. (2012) also explored the influence of past behavior. Together, moral norms, normative beliefs, perceived behavioral control, and past behavior accounted for 70% of the variation in nurse intentions to integrate research evidence into their practice. Past behavior may be especially salient to understanding medication disposal, because disposing of drugs to sewage was the accepted practice for so many years (McCullagh et al., 2012; Ortner & McCullagh, 2010). Findings by McCullagh et al. (2012) and Cote et al. suggested nurses should be educated on why and how current guidelines for medication disposal represent clinical best practices.

Pharmacists

Abahussain et al. (2012) examined the attitudes and practices of pharmacists in Kuwait toward returning unused pharmaceuticals for disposals. The Kuwaiti Ministry of Health established guidelines for the disposal of medical waste by hospitals and other health care facilities, but with no parallel measures guiding the disposal of medications returned by the general public, nor does Kuwait have take-back programs for unused medications. Abahussain et al. believed pharmacists are ideally positioned to influence the medication disposal practices of consumers. A previous study disclosed that 54% of Kuwaiti pharmacists deemed it appropriate for consumers to return unused medications. Abahussain et al. addressed the question of whether pharmacists actually received unused medications from the public and how they managed their disposal, along with their knowledge of environmental knowledge and opinions of medication disposal.

The sample consisted of 144 pharmacists from six large government hospitals and 12 specialized clinics (Abahussain et al., 2012). Close to three-quarters of the participants (72%) had received unused medications and disposed of them (71%) at their workplace. Most participants (73%) simply threw the materials in the trash. Only 16% followed the Ministry of Health guidelines for disposing of medical waste.

At the same time, the overwhelming majority of pharmacists agreed that environmental damage results from disposing of medications in the trash (83%) or in the sink or toilet (83%). Virtually all (97%) agreed that protecting the environment is one of their personal responsibilities (Abahussain et al., 2012). Most pharmacists viewed their workplace as a good venue for disposing of unused medications (86% from clinics, 88% of the hospital pharmacists). Other venues suggested were private pharmacies (67%) and supermarkets (70%).

Abahussain et al. (2012) noted that the disposal practices of pharmacists—throwing unused drugs in the trash or in the sink or toilet—were the same practices used by the general public in Kuwait. Therefore, carrying out an effective drug take-back program would entail developing guidelines to dispose of returned medications. An obvious dichotomy emerged between pharmacist recognition that their disposal practices were detrimental to the environment and their sense of responsibility for environmental protection. The absence of a formal policy and system for managing unused pharmaceuticals that are not classified as medical waste seemed to be the main barrier to proper disposal.

According to Abahussain et al. (2012), pharmacy students "have a golden opportunity to participate in promoting awareness and establishing a national drug take-back program" (p. 199). Pharmacy students represent the future of the profession and have the potential to draw effective guidelines and promote their implementation. The authors envisioned a central role for pharmacists in conducting patient and community education and raising awareness and understanding of the damaging consequences of accumulating unused pharmaceuticals and improperly disposing of them.

Abahussain et al. (2012) cited a study from the United States documenting a successful collaboration between pharmacy students and local officials and businesses in providing safe and appropriate medication disposal for the community. Pharmacy students often play a central role in drug take-back events in the United States. Ma et al. (2014) described the Drug Take-Back events that arose from partnership between the Hawaii Narcotics Enforcement Division and the University of Hawaii at Hilo Daniel K. Inouye College of Pharmacy. In Broward County's Operation Medicine Cabinet events, pharmacy students and pharmacists count, identify, separate, and document all uncontrolled medications, which greatly aids the data-collection process (Fass, 2011). In addition, pharmacists and pharmacy students disseminate medication-safety information and answer questions raised by consumers, consistent with the role Abahussain et al. envisioned.

Participation by pharmacy students in the United States also reflects the vision of pharmacy students as the future direction of the profession. Fourth-year students participate in drug take-back events as part of their advanced pharmacy-practice drug-information rotation (Fass, 2011). Before participating in drug take-back events, students are educated on all relevant issues, including prescription-drug abuse, national and statewide trends, pharmacology, drug disposal laws and regulations, drug information resources, and the role of pharmacists in preventing prescription drug abuse. Students must be equipped with requisite knowledge and skills to counsel consumers. The training they receive in preparation for drug take-back events is equally applicable to their future careers and professional roles when interacting with consumers and educating them about medication use and disposal. Pharmacy students and pharmacists also educate law-enforcement officials about drugs being returned (Fass, 2011).

Patients

The use of oral anticancer medications has increased tremendously since the early 2000s (Lester, 2012). According to an analysis of insurance claims in Massachusetts, 16.1% of patients being treated with chemotherapy received oral chemotherapy, and that figure is expected to reach 25% as new drugs are continually being developed in response to consumer demand (Neuss et al., 2013). Oral medications offer many advantages to patients, including the convenience and comfort of being able to administer the drugs at home, fewer side effects, less disruption to daily activities, enhanced quality of life, sustained exposure to medication, decreased reliance on health care resources, and satisfactory outcomes (Lester, 2012; Trovato & Tuttle, 2014). An additional psychosocial benefit of taking medication at home is a shift in perspective that views cancer as a chronic condition conducive to self-management.

However, despite the benefits, the new cancer agents have raised concerns regarding safe storage and disposal. If not stored properly, the drugs can become degraded or contaminated, compromising safety and efficacy. Indoors, the drugs can pose a risk to other people and pets, and if disposed of improperly, they can be hazardous to the environment.

Lester (2012) declared, “Information about safe handling and disposal practices should be incorporated into professional, patient, and family education” (p. e192). In addition, institutions should have standard operating protocols to educate patients and family members about safety. In many facilities, however, patient education is not standardized (Trovato & Tuttle, 2014). Standard guidelines exist for the preparation, handling, and administration of parenteral chemotherapy in the health care setting, but lack parallel guidelines for handling and disposing of oral chemotherapy medications at home.

Various recommendations address the handling of oral anticancer medications derived from expert opinion, published recommendations, and policies adopted at the government or hospital level (Trovato & Tuttle, 2014). Recommendations for patients and caregivers include following written instructions for storing a medication, wearing gloves to administer a drug, washing hands after medication administration, limiting others' access to the medication, and returning unused medication to the pharmacy, doctor's office, or hospital. Also included in recommendations are practices to avoid, such as exposing the drug to direct sunlight or moisture, leaving medication where children or pets can reach it, crushing or breaking pills, and disposing of medication in the garbage or toilet.

The Oncology Nursing Society and the American Society of Clinical Oncology jointly developed national standards for the safe administration of oral chemotherapy, revised, updated, and expanded in 2012 (Neuss et al., 2013; Trovato & Tuttle, 2014). The most recent guidelines, which expound on issues raised by the growing reliance on oral chemotherapy, include a detailed section on patient consent and education (Neuss et al., 2013). Information on the storage, handling, preparation, administration, and disposal of oral chemotherapy is an essential component of patient education.

Adherence is an important issue with a prescribed drug regimen, as inadherence adversely affects the ability of the medication to control or eliminate the cancer (Lester, 2012). Adherence to anticancer drugs has also become a greater challenge due to the increased amount of drugs, drugs that are taken in combination, the longer duration of therapy, and the increasing age of patients with cancer. Broadly, all these factors involve the increasing presence of pharmaceuticals in the environment (Daughton, 2003a, 2003b; Ruhoy & Daughton, 2008; Ruhoy & Kaye, 2010).

In a rare study on the handling, storage, and disposal practices of patients taking anticancer drugs at home, Trovato and Tuttle (2014) surveyed 42 patients (95% male) under treatment at a VA hospital. The use of oral chemotherapy at the hospital outpatient chemotherapy clinic escalated in the course of a year. Patients were receiving education from medical, nursing, and pharmacy staff, but without standardized practices, yielding information that was unreliable.

Of participants who did have unused medication, six returned any leftover drugs to the pharmacy (Trovato & Tuttle, 2014). However, another six threw extra medication in the garbage. Two participants were uncertain of what they should do with the extra medication. Close to half the patients (45%) had not received information on safe handling and storage practices. Those who were informed received their information from nurses and pharmacists and, to a lesser extent, from physicians.

Most patients (79%) felt their oral chemotherapy drugs were safe from the perspective that the side effects were tolerable (Trovato & Tuttle, 2014). However, several raised concerns related to storage, handling, and disposal. Health professionals who counsel patients about anticancer drugs often concentrate primarily on administration and potential side effects (Trovato & Tuttle, 2014). Time may be a factor, so the issues viewed as the most important from the perspective of health professionals are given top priority. The responses clearly revealed a need for better patient education on the topic of storage, handling, and disposal of anticancer agents. Notably, the pharmacist authors changed their practices following the survey. The pharmacist provides patient education immediately after the patient and physician have completed the consent process, and the new patient-education guidelines include standard criteria for proper drug storage, handling, and disposal that could be adopted by all health care professionals. As an additional safeguard, the pharmacist provides a follow-up phone call to the patient to reinforce safe-handling procedures, as well as to monitor the patient for adverse effects.

Drug Take-Back Programs

In 2010, the DEA held the first national Take-Back Days, which produced more than 4.1 million pounds of medications in little more than a week (Fain & Alexander, 2014). However, Fain and Alexander pointed out that although that figure may seem impressive, it represents only a small fraction of the medications stored in U.S. homes. Fain and Alexander (2014) put forth that retail pharmacies are the ideal venue for returning unused medications. More than 70% of people across the United States live within 5 miles of a pharmacy chain and make frequent trips to the pharmacies not only to fill prescriptions, but to purchase items on a regular basis. In addition to the convenience to consumers, pharmacies are well-equipped to develop and implement take-back programs, given that they already have systems in place to manage and dispose of unused drugs from their inventory.

Pre-DEA Involvement in Take-Back Programs

Pharmacy programs to promote the safe disposal of unused medication predate DEA sponsorship. A program involving seven clinic-associated Group Health Cooperative pharmacies in Washington State began operations in fall 2006 (Thompson, 2007). Each pharmacy has a medication disposal bin in their public area. The Washington State Board of Pharmacy and Department of Ecology were both involved in the pilot program (Thompson, 2007). Pharmaceuticals From Households: A Return Mechanism tested two return-and-disposal program models. One model, which works with clinics and pharmacies, was designed for consumers, school districts, childcare centers, hospice patients' families, and hotels. The second model was developed for nursing home residents. Both models dispose of unused pharmaceuticals through incineration.

Other programs emerged in other parts of the country. Good Samaritan Hospital in San Jose, CA, held a Safe Drug Drop at its pharmacy during National Patient Safety Week (Thompson, 2007). The city's major newspaper provided publicity for the event. Plastic storage bags were provided for people to empty the drugs they brought, and a pharmacy technician poured the contents into pharmaceutical waste bins. After eight hours, the drug drop produced 144 gallons of medication, including one supply that had been purchased when Ronald Reagan was president. The pharmacy locked the bins and sent them to a firm that incinerates pharmaceuticals. After the 1-day event, the pharmacy began keeping a locked disposal box outside so people could simply discard their unused pharmaceuticals without help. This practice is now recommended to make it easy for people to return unused drugs (Fain & Alexander, 2014).

Musson et al. (2007) initiated a self-serve pilot project in Florida, introduced to enable people to properly dispose of prescription and nonprescription medications. In an area that includes small communities and the city of Gainesville, the researchers chose sites to reach the largest number of people. Participants deposited their medications directly into a collection container containing tap water or an aqueous acidic solution that rendered the medication unrecognizable and unusable. An extensive advertising campaign to inform local residents of the program accompanied the inception of the program. The campaign made use of newspapers, local cable television, and the Internet.

Challenges encountered in developing the program highlighted how much drug disposal programs have progressed in the last decade (Musson et al., 2007). Despite multiple attempts to gain their participation, major pharmacy chains declined to participate, due to possible public perceptions that pharmacies would reuse the returned medications, legal implications of accepting drugs dispensed by another pharmacy, concerns that patient confidentiality would be compromised, concerns over the security of controlled substances, and lease provisions that prohibited the acceptance and storage of returned merchandise. In spite of the obstacles, Florida residents did have access to a simple and convenient way to dispose of medications. Recent take-back programs addressed some of the concerns expressed by pharmacies, and with the involvement of the DEA, returning controlled substances is not a barrier. Some pharmacies have raised issues about cost due to new DEA regulations (Fain & Alexander, 2014). Now, as when Musson et al. (2007) began the self-serve pilot project, consumers are attracted to an option to dispose of drugs that is simple and available.

Post-DEA Involvement Take-Back Programs

Gray and Hagemeier (2012) investigated characteristics of individuals who participated in medication take-backs, and the medicines they disposed of in the rural Appalachian area of northeast Tennessee and southwest Virginia. The study covered 11 events held between 2009 and 2011. During that time, 752 individuals donated 16,956 containers of medications prescribed for 1,210 patients. Donors were overwhelmingly White, averaged 40 years old, and women comprised more than half of the group (57%). In descending order, the main reasons for participating were a desire to clean out their medicine cabinets (68%), environmental concerns related to disposing of drugs and other waste materials (45%), and concerns about accidental poisoning (14%).

Safe Medicine Disposal for the State of Maine (ME) has been hailed as a model program for medication disposal (Ruhoy & Kaye, 2010). The unique program allows people to anonymously mail controlled and uncontrolled drugs free of charge through the postal service. High rates of deaths from prescription drug overdose throughout the state drove the Maine initiatives (Stewart et al., 2015). In 2009, prescription overdose surpassed all other causes of death among Maine residents, and in 2012, the Centers for Disease Control and Prevention reported that of all states, Maine has the highest rate of prescriptions for high-dose opioid pain relievers.

The mail-in program accompanied DEA take-back events until 2013 (Stewart et al., 2015) and currently runs under the direction of the University of Maine Center on Aging. Consumers obtain prepaid tamper-resistant envelopes from roughly 150 community distributors, including pharmacies, medical offices, community organizations, police departments, hospice, and other sites located throughout the state

(Ruhoy & Kaye, 2010). Each envelope has clear, explicit instructions for safely packaging and mailing pharmaceuticals in various forms. Although program advocates often cite the ease of returning drugs through the postal services as its defining characteristic, Ruhoy and Kaye (2010) viewed its outstanding feature as that the program systematically collected data on the returned medications and the people participating in the program. Ruhoy and Daughton (2008) consistently called for a comprehensive database on returned medications (Daughton, 2003a, 2003b; Ruhoy, 2009; Ruhoy & Daughton, 2008).

According to the collected data, each returned envelope contained roughly seven ounces of drugs and an average of four medications (Ruhoy & Kaye, 2010). Controlled substances constituted nearly 14% of the returned drugs. Painkillers, antianxiety drugs, antidepressants, and cardiovascular drugs comprised about 25%. Accompanying surveys provided valuable information. Nearly half of participants reported they would have flushed the drugs down the toilet without the simple option of the mail-back program, and one-third would have discarded them in the trash. The survey data also revealed numerous reasons for accumulating drugs in the home, including discontinuation due to allergies or side effects, death of the patient, explicit instructions by the doctor to discontinue the medication, feeling better, and not wanting to take the drug as it was prescribed.

Ruhoy and Kaye (2010) attributed much of the program's success to collaboration across multiple agencies. Furthermore, the process is simple and user friendly, has numerous quality and safety checks built into the design, minimizes the number and cost of intermediary staff, and demands minimal effort on the part of the participants. Safe

Medicine Disposal for ME was initially funded by the Aging Initiative to serve Maine's aging population. The program also sponsors a cadre of older adults who provide presentations on medication disposal to community groups. These volunteers are the cornerstone of the program's outreach and education initiative. They offer community members opportunities to discuss various issues relevant to their communities.

Safe Medication Disposal for ME is a model program for several reasons (Ruhoy & Kaye, 2010). First and foremost, the program prevents the damaging environmental impacts and health hazards of disposing of drugs by flushing or throwing them in household trash. Second, the process is easy, convenient, and anonymous. Third, the program takes advantage of the security protocols of the postal service. Fourth, Maine has a large rural population, and the program is easily accessible to individuals residing in rural areas with no take-back events or drug disposal sites. Moreover, the program also appeals to individuals who might not be able to take advantage of events, such as those who are ill or infirm. Finally, the program is able to accept controlled substances because the drugs are mailed directly to the Maine Drug Enforcement Agency.

The program builds on a unique collaborative partnership between environmental, drug enforcement, and health care officials at the federal, state, and local levels (Ruhoy & Kaye, 2010). From a social perspective, the program addresses the concerns of multiple stakeholders because it has the capacity to reduce the number of drug-related crimes and opportunities for drug abuse. It is also cost efficient because it provides consumers with a safe alternative to keeping drugs at home. As information about Safe Medication Disposal for ME has been disseminated, it has become a model for shaping state and national public policy, medical prescribing practices, and health-education outreach tactics. Reflecting the green pharmacy or upstream approach to reducing medical waste in the environment (and opportunities for drug abuse), in 2009, Maine began limiting first-time prescriptions to 15 days for certain drugs prescribed for Medicaid recipients. Subsequently, the state has added more drugs to that list.

The Maine Prescription Monitoring Program database acts as a tracking and monitoring system for the prescription and distribution of controlled substances. However, at the time of their study, only about half the state's prescribers were registered with the program (Stewart et al., 2015). Despite widespread publicity on prescription-drug misuse nationwide, researchers noted remarkably little knowledge attests to prescription waste in communities across the country. Stewart et al. (2015) analyzed data on unused medications collected in 11 Maine cities from 2011 to 2013, covering six DEA take-back events. The researchers had two major goals: to provide information to health care providers and public health officials about the amount and types of prescription-drug waste, and to raise awareness of medication waste in local communities and its potential consequences in poisoning, abuse, misuse, and diversion of prescription drugs.

Doctor of pharmacy candidate volunteers carried out the project, supervised by licensed pharmacists, with direct oversight from local law-enforcement officials (Stewart et al., 2015). The take-back events generated 13,599 medications of all types returned by 1,049 participants. Controlled substances represented 9.1% of the drugs collected, virtually identical to the proportion reported in the Appalachia study (Gray & Hagemeier, 2012). Uncontrolled prescription drugs accounted for 56.4% of the medications collected (Stewart et al., 2015). Cardiovascular drugs consistently formed the largest proportion of drugs returned. Beyond medication disposal programs, "medication education is an essential component of the overall solution" to the escalating public health problem of prescription drug overuse (Stewart et al., 2015, p. e69). The ONDCP (2011) report contained a large section on education. The report pointed out that antidrug campaigns have such great emphasis on illicit drugs that people are unaware of the dangers of prescription drugs. Education covers health care providers as well as consumers (with special attention to parents and youth), and is an important strategy to reduce overprescribing. Safe medication disposal is an essential component of education for health professionals and the general public. One strategy in the ONDCP (2011) report involves working with private-sector groups to create an evidence-based media campaign on prescription-drug abuse tailored to parents, to inform them of the risks and importance of storing drugs securely and disposing of them properly.

Ma et al. (2014) presented the results of 11 drug take-back events in which the University of Hawaii, College of Pharmacy collaborated with the Narcotics Enforcement Division. The events took place in 2011 and 2012. The Good Life Senior Expo in Honolulu, an annual 3-day exposition, hosted two of the largest events. Several Kaiser Permanente clinics hosted the remaining nine events. Both events were advertised in the media (television, radio, and newspapers), through brochures and flyers in pharmacies and doctors' offices, and by word of mouth. All returned medications were recorded with their generic name, drug class, dose, quantity, and dosage format. Narcotics Enforcement Division agents and students and faculty of the pharmacy college counted, identified, and documented the drugs. As with all drug take-back events, law-enforcement officials were present at all times, and were responsible for the destruction of the drugs.

Ma et al. (2014) surveyed participants at the 2011 Good Life Senior Expo regarding their prior experiences with unused or expired medications. Most participants learned about the event through newspaper or TV advertisements. Before the take-back events, the most common methods for managing unused drugs were throwing them in the trash (34%), keeping them at home (32%), or flushing them down the toilet (24%). Only 10% had returned medications to a pharmacy or medical office. Two-thirds of participants kept unused medications at home for a year or more. Virtually all participants (> 99%) wanted the take-back events to continue.

The 11 events produced a total of 8,011 pounds of medication, with most drugs taking the form of pills or tablets (Ma et al., 2014). Participants returned few liquids, intravenous drugs, dermal patches, lotions, creams, or suppositories. The largest quantity fell into the category of "Other" or miscellaneous. Antihypertensives were the next largest drug class, consistent with the overriding presence of cardiovascular drugs in the Maine take-backs (Stewart et al., 2015). Other drugs returned in large quantities were gastrointestinal drugs and analgesics. The most prevalent OTC drugs were in this last category: aspirin, naproxen, and ibuprofen. In addition, participants returned a substantial amount of pseudoephedrine. Pseudoephedrine is used in the manufacture of methamphetamine and is one of the most common OTC drugs returned.

Controlled substances comprised 10% of the drugs returned (Ma et al., 2014). Similar proportions seem to be relatively consistent with other take-back programs (Gray & Hagemeier, 2012; Stewart et al., 2015). Although consumers returned most of the drugs, clinics and other facilities also returned drugs such as long-term-care facilities and clinical trials. The researchers did not collect demographic information about participants.

Ma et al. (2014) are staunch advocates for continuing and expanding medication take-back programs. Clearly, the results of their survey confirmed the popularity of take-back for the Hawaiian public. Following the example of Alameda County, California, the researchers called for efforts to identify potential champions and stakeholders including consumers, government organizations, and “all parties involved in the medication chain of manufacturing, ordering, prescribing, dispensing, administering, and monitoring” pharmaceuticals (Ma et al., 2014, p. 30). Soliciting involvement from all entities would greatly expand the number and type of facilities to which consumers could return medications. To facilitate ease and convenience and make disposal immediately accessible, Ma et al. recommended strategies such as installing take-back lock boxes in pharmacies and law-enforcement offices, regularly scheduled medication take-back events in accessible venues, and the distribution of prepaid return envelopes with all medications dispensed.

Kotchen et al. (2009) queried respondents on their willingness to pay for a medication disposal program in their survey of medication disposal preferences and practices. One problem with surveys of medication disposal is that most are based on small convenience samples. Kotchen et al. gathered data from respondents to the annual Central Coast Survey covering 1,005 California households. In addition to questions regarding general awareness of pharmaceutical pollution, disposal practices, and willingness to participate in a disposal program, the authors added the question of paying to establish a drug disposal program. The cost would be a surcharge added to prescriptions.

The effect derived from their analysis was that starting with a mean bid of $1.07, every increase of $.10 decreases the likelihood of an affirmative response by 0.01. Overall, however, Kotchen et al. (2009) found that a substantial proportion of respondents were willing to pay. Less than half the respondents (43%) were aware that pharmaceutical substances had been found in their wastewater. For disposal practices, the findings were largely consistent with most studies, with disposal in the trash as most prevalent (45%), followed by disposal in the sink or toilet (25%). Only 5% returned their unused drugs to a pharmacy or a hazardous-waste site; 12% of the sample kept medications at home. Knowledge proved to be an important predictor of behavior. Respondents who were aware of environmental pollution were less likely to dispose of medications to trash or sewage, and three times more likely to return them to a pharmacy or bring them to a hazardous waste site. Older respondents were more than twice as likely to return drugs to a pharmacy than were younger adults, possibly because they used more prescriptions and thus had more pharmacy visits.

Recycling and Environmental Protection

Pearson et al. (2012) examined attitudes and behavior regarding recycling among low-income Latina women attending a clinic in southeast Texas. The influence of sociocultural factors, including acculturation, was a key focus of study. According to Pearson et al., the women held two contrasting viewpoints on the environmental attitudes of individuals born in developing countries. From one perspective, participants thought they were less likely to engage in behavior to protect the environment as a result of more immediate concerns about economic security. However, that viewpoint would seem to be more of a matter of socioeconomic status than cultural influence, and might be equally applicable to low-income individuals regardless of heritage. According to the contrasting perspective, individuals from developing countries might be more sensitive to environmental issues due to environmental damage in their home countries. The literature on pharmaceuticals and the environment suggested the problem draws extreme concern in developing countries due to the latter reason, and a lack of government regulations on medication disposal (Abahussain et al., 2012; A. Kumar et al., 2010; Sahoo et al., 2010; Sapkota et al., 2014).

Participants were 1,512 Latinas, with 37% born in the United States and the remaining participants born in Mexico, Puerto Rico, and various Central American and South American countries (Pearson et al., 2012). An acculturation scale accompanied a survey designed to assess knowledge, beliefs, behavior, and the type of recycling services offered in their locale. Highlighting the importance of having convenient, accessible facilities, women residing in areas where recycling facilities included both curbside services and drop-off facilities were more likely to recycle than those living in areas with no recycling facilities or only one of the two services.

Knowledge and convenience positively linked with recycling, whereas lack of knowledge and inconvenience were major barriers to recycling (Pearson et al., 2012). Acculturation inversely linked with recycling, and income was not a factor, possibly due to the relatively small variation in income among participants. As a group, the women who were less predisposed to recycle were not aware that recycling saves landfill space, and considered it too time-consuming. Less than half the women recycled or lived with someone who recycled. These findings are congruent with the HBM (Nisbet & Gick, 2008; Strecher & Rosenstock, 1997). It seems probable that similar patterns would emerge in returning medications to a disposal site. The difference is that recycling facilities are far more prevalent in most communities. The Pearson et al. assertion that education would overcome lack of awareness of the importance of recycling runs throughout the literature on medication disposal.

Focus groups can serve as excellent vehicles to solicit input from prospective participants on what community programs may need to be successful in managing hazardous substances. Smolenske and Kaufman (2007) aimed to guide the design of a community-education program to raise awareness of hazardous substances in the home and promote safe storage and disposal practices. The project began with a pilot survey based on data analyzed from calls to a poison-control center in Genesee County, Michigan. The researchers selected a total of 10 substances that presented the greatest hazard to children. Smolenske and Kaufman gave prescription medications the highest hazard rating of substances, which also included ibuprofen, acetaminophen, bleach, cosmetics, birth-control pills, silica gel packets, vitamins with iron, hydrogen peroxide, and mercury thermometers. Notably, more than half the hazardous substances are pharmaceuticals.

Smolenske and Kaufman (2007) chose 13 residents for the focus group and used their input to refine the survey (Smolenske & Kaufman, 2007). The survey covered four broad areas: (a) room location and storage elevation, (b) awareness of the Poison Control Center, (c) sources of information about hazardous household materials, and (d) residents' participation in activities such as recycling and pickup programs for hazardous household materials. The survey proved to be an effective assessment tool to understand consumers' perceptions of poisoning risk. The level of awareness was low, confirming the need for an education campaign. Others can use a similar strategy to create an educational campaign to raise people's awareness of the risk of storing medication at home and of proper disposal practices. Focusing the campaign at the community level also provides an opportunity to solicit opinions and preferences related to drug take-back programs and other options to dispose of unused pharmaceuticals.

Summary and Conclusions

During the 1990s, a proliferation of scientific studies documented the presence of trace amounts of pharmaceuticals in the aquatic environment. Pharmaceutical pollution of the environment is a global problem (WHO, 2011). In the United States, previous advice to consumers and health care professionals alike had been to dispose of unused medication by flushing it down the toilet or rinsing it down the sink drain (McCullagh et al., 2012; Ortner & McCullagh, 2010). Pharmaceutical compounds remain in treated sewage and have even been found in drinking water. Thus, improper disposal of medication is a threat to the natural environment and to public health.

With collaboration from the DEA and laws that include the disposal of controlled substances, drug take-back programs are the best mode for disposing of unused and unwanted medications. Current data is preliminary, but programs have brought in millions of pounds of pharmaceuticals and have been greeted favorably by participants (Fain & Alexander, 2014; Gray & Hagemeier, 2012; Ma et al., 2014). Participants who attended take-back events expressed a desire for ongoing programs. Availability and convenience emerged as key factors in participation. Providing consumers with a locked disposal bin that they can access at all times may be critical to promoting widespread participation.

Education is another important concern in raising awareness of drug take-back programs, but also of proper (and improper) medication disposal practices and the dangers of keeping unused or expired medications in the home. Similarly, numerous studies by health psychologists demonstrate that knowledge per se is inadequate to change behavior (Nisbet & Gick, 2008). Even nurses and pharmacists displayed a gap between what they consider best practices in medication disposal, and their actual behavior (Abahussain et al., 2012; McCullagh et al., 2012). Based on the limited research on medication take-back programs and studies involving recycling behavior, removing barriers and easing access to drug return sites may be the most effective way to encourage proper disposal practices. Maine’s mail-back program requires minimal effort by consumers and is successful (Ruhoy & Kaye, 2010). Stakeholders have hailed the program as a model program, and other states and communities are learning from the features that contribute to its success.

This study examined the associations of knowledge of the environmental and human-health impacts of medication disposal, knowledge of proper medication disposal practices, and the availability and convenience of disposal sites in a sample of residents in the northeast United States. In Chapter 3, I describe the methodology that I used to conduct and analyze the data from this study.

Chapter 3: Research Method

Introduction

The purpose of this quantitative cross-sectional study was to investigate consumers’ practices in disposing of unwanted, unused, and expired pharmaceutical prescriptions drugs. In addition, I provide insights as to whether disposal practices are influenced by consumers’ knowledge of the impact of pharmaceutical disposal on the environment and human health, and awareness of the recommended disposal options. An analysis of the most applicable theoretical frameworks in the context of pharmaceutical disposal has provided important insights, identifying key dependent and independent variables used in this study.

According to Nisbet and Gick (2008), despite parallels between health and environmental behavior, the fields of health promotion and health behavior change are rarely applied to environmental issues. Environmental behavior is multifactorial; consequently, I considered two theoretical frameworks for behavior change: the HBM and the TPB.

The TPB was most relevant to the issue of proper pharmaceutical disposal from the perspective of the motivation that results in the intention to perform an action or behavior. The aim was to discern whether consumers’ knowledge or perceptions of disposal practices and their impact on human health precipitated motivation. In addition, I aimed to determine whether information received, if any, on disposal recommended practices motivated consumers. Finally, I evaluated whether both factors influenced consumer action and to what degree.

In the literature, the HBM aligned with studies that involved recycling and environmental protection. Strecher and Rosenstock (1997) discussed how perceived barriers were the decisive factor in the adoption of health-related behaviors. Consequently, one objective of this study was to examine the degree to which the availability and convenience to reach and use locally available disposal options impacted consumers' actual disposal practices.

This chapter contains a discussion of the research design and the methodology of the study. In the next section, I discuss the rationale for the research design, followed by discussions of the population, the sample, data collection, and instrumentation. I describe the data-analysis plan, followed by discussions of validity and ethical issues of the study. Finally, I conclude this chapter with a brief summary.

Research Design and Rationale

Actual disposal practices was the outcome (dependent) variable in this study. As suggested by the reviewed literature, this study used the following key independent variables: (a) knowledge of environmental and human-health impact, (b) knowledge of recommended disposal practices, and (c) availability of disposal options. Data on the outcome variable and the independent variables were collected using a questionnaire.

The research design was quantitative and cross-sectional. A quantitative method is appropriate when the researcher's goal is to examine associations between quantifiable and objectively measurable concepts (Howell, 2010). My main objective in this study was to investigate the hypothesized association between consumers' actual disposal practices (outcome of interest/dependent variable) and the factors (independent variables) that may have influenced them. Because the variables under investigation are quantifiable and objectively measurable, a quantitative method was appropriate. Specifically, I selected a cross-sectional design because my aim was to examine the associations between variables measured at a single point in time. Typical disadvantages of using a cross-sectional design include the challenges associated with establishing causal inferences, and the notion that the findings represent the phenomenon in a single time and place (Pine et al., 1997). To inspire social change, results from this study provide the basis for recommendations that include the design of health-promotion programs that encourage optimal drug disposal practices, encourage the simplification of disposal options, improve patient drug compliance, and generate momentum for the development of drugs that are less toxic to the environment. In aggregate, if adopted, the aforementioned approaches could mitigate the risks to human health posed by pharmaceutical contaminants in the environment.

Methodology

Population

The population of this study was a sample of residents of the northeast United States. The U.S. Census Bureau (n.d.) defined the northeast region as comprising nine states: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, and Pennsylvania. As of 2013, the estimated size of this population was approximately 56 million residents.

Sampling and Sampling Procedures

The sampling approach for this study was convenience sampling. A convenience sampling method is appropriate when a true random sample is not feasible to obtain. Because I was unable to survey all possible residents in the northeast United States, a convenience sample approach was appropriate. The participant sample for this study consisted of residents of the northeast region of the United States who were aged 18 years or older and had used a prescription drug in the prior two years. I recruited participants who met these criteria using SurveyMonkey's online participant pool. I calculated the appropriate sample size using the SurveyMonkey sample-size tool, using the following parameters: (a) population size = 55,943,073, corresponding to the entire northeast region (U.S. Census Bureau, n.d.), (b) confidence level = 95%, and (c) margin of error = 5%. The resulting sample size was 385 (SurveyMonkey, 2016)

Procedures for Recruitment, Participation, and Data Collection

After obtaining IRB approval to conduct the study, I employed SurveyMonkey's online survey platform to recruit participants for this study. Cottrell and McKenzie (2010) argued that researchers could not assume that most U.S. residents would be sufficiently computer literate and have Internet access to complete a survey online. In the last few years, however, Internet access and broadband have become so widely available that even large and popular government programs, such as the Affordable Care Act (HHS, n.d.), are administered through the Internet. In addition, according to the U.S. Census Bureau, the northeast United States has one of the highest rates of Internet access in the country (File, 2013). Thus, I deemed the online medium to be practical and efficient for the administration of the survey questionnaire. The survey was anonymous, compliant with the data-privacy rule (HHS, 1996), and administered electronically through the Internet using a secure (encrypted) line. Potential participants were people who had used SurveyMonkey's Audience services in the past, and had participated in other surveys. SurveyMonkey sent an invitation to these potential responders to participate in the survey; for each completed survey, SurveyMonkey made a donation to a charitable institution; participants did not receive any monetary incentive from participating except that completion of the survey would result in a donation to charity.

Aligned with Walden University's IRB policy regarding participation in surveys in which the participants have the option to take or decline to take a survey, I had no need for a separate consent form; however, I informed potential participants of their rights and provided them with contact information for the Walden University IRB and me, in case they had any questions. Individuals who agreed to participate and met the inclusion criteria were directed to the survey that contained the study instrument. I planned the survey to be open to potential participants for 3 weeks; however, the target sample size was reached and exceeded in a shorter period of time. At the end of the survey recruitment period, SurveyMonkey made available for download from their secure server two files with all the data: one Excel and one SPSS-formatted file. I stored the data files on a password-protected personal computer to which I was the only one with access. In addition, all data were backed up onto a password-protected external storage medium, stored safely in a location different from that of the personal computer.

Instrumentation and Operationalization of Constructs

The contents of the survey instrument for this study were adapted from items used by Seehusen and Edwards (2006). I received approval for the use and adaptation of the questionnaire from the main author, and the approval letter can be found in Appendix A. The final draft version of the questionnaire was pilot tested after IRB review and approval, following the process recommended by Radhakrishna et al. (2003) and Bolarinwa (2015). The process for pilot testing consisted of providing the questionnaire to a convenient subsample, separate and in addition to the final target sample (*N* = 385). The subsample was originally planned to be 10% of the final target sample, and thus to include 39 participants; however, the final number of the subsample consisted of a larger number of participants, thanks to an efficient recruitment by SurveyMonkey's service. As part of the pilot testing, subsample participants evaluated each question of the questionnaire for clarity, legibility, and comprehensiveness. Seehusen, author of a published study on medication disposal, reviewed the content and provided favorable feedback. I archived Seehusen's feedback and e-mail exchanges (see Appendix A).

The survey (see Appendix B) consisted of content questions used to measure the constructs of interest, as well as demographic questions. The first question of the survey was intended to measure the dependent variable—actual disposal practices—and asked survey participants, "What is your most used method for disposing of unused or expired medications?" Participants answered this question by selecting one of eight possible response options that included "I flush them down the toilet, " and "I follow the disposal instructions that accompany the medicine," among others.

The next questions on the survey were, "In your area, is there a designated collection location where you can dispose of your unused or expired medication?" and "How convenient is it for you to reach the designated disposal location?" I used these questions to represent the independent variable: available disposal options. Next, participants answered the question, "Do you believe that improper disposal of medications in the environment could have negative consequences on human health?" Participants responded to this question on an ordinal scale, and I used their responses to represent the independent variable: knowledge of environmental and human health impact. I also asked participants four questions using categorical and ordinal response scales to assess knowledge of disposal practices. I used these questions to represent the independent variable: knowledge of recommended disposal practices. Finally, I asked participants to provide basic demographic information. Specifically, I asked them to report their gender, year of birth, race, highest level of education completed, and state of residence.

I scored questions related to knowledge and awareness using a coded ordinal scale, as suggested by Monnin and Perneger (2002). In contrast, data from the dependent variable, actual disposal practices, were categorical. A dichotomous, Yes/No outcome was used to assess and code the dependent variable.

Data-Analysis Plan

I conducted all data analyses using SPSS (IBM, 2016). SPSS is a software package used to perform statistical analysis. In 2009, IBM acquired SPSS Inc., and since then, its official name has become IBM SPSS Statistics. Although originally intended to be used in the realm of social sciences, this software is used in a variety of fields, such as data mining, market research, government, and education. The latest version of SPSS Statistics v 24.0 was released on March 15, 2016.

Upon completion of the data collection, I reviewed and cleaned the data to ensure all the records had sufficient and accurate data for analysis. I accomplished this process by running frequency distributions for each variable, ensuring the data were within the acceptable range. Given that the data were collected electronically, using a web-based form that only accepts predefined input values, there were no out-of-range data values; however, there were records with missing data. In Chapter 4, I describe the specific information regarding missing data and the records that had to be removed from the analyses due to incomplete data inputs.

In addition to descriptive statistics, binary logistic regression was the key statistical procedure employed to address and explore the following research questions and hypotheses:

RQ1: Is there an association between knowledge of the environmental and the human-health impact of pharmaceutical disposal and actual disposal practices?

$H_0$1: No significant association exists between knowledge of the environmental and the human-health impact of pharmaceutical disposal and actual disposal practices.

RQ2: Is there an association between knowledge of recommended disposal practices and actual disposal practices?

$H_0$2: No association exists between knowledge of recommended disposal practices and actual disposal practices.

RQ3: Is there an association between available disposal options and actual disposal practices?

$H_0$3: No association exists between available disposal options and actual disposal practices.

RQ4: To what degree can actual disposal practices (the dependent variable) be explained by the combined and differential contribution of the three independent variables, specifically, knowledge of the environmental and human health impact, knowledge of recommended disposal practices, and locally available disposal options?

$H_0 4$: Actual disposal practices cannot be explained to a significant degree by the combined and differential contribution of knowledge of the environmental and the human-health impact, knowledge of recommended disposal practices, and locally available disposal options.

RQ5: Do differences exist among RQ1, RQ2, and RQ3 across demographic groups?

$H_0 5$: No significant demographic differences exist in the relationships of knowledge of the environmental and the human-health impact, knowledge of recommended disposal practices, and locally available disposal options to actual disposal practices.

Binary logistic regression is an appropriate statistical-analysis procedure when the researcher's aim is to determine whether significant associations exist between multiple independent variables and a single dichotomous dependent variable. In this analysis, the dependent variable was actual disposal practices. I coded actual disposal practices as a dichotomous variable where 0 = unrecommended disposal practice, and 1 = recommended disposal practice, based on participants' responses to the question, "What is your most used method for disposing of unused or expired medications?" The independent variables were the survey questions pertaining to knowledge of environmental and human-health impacts, knowledge of recommended disposal practices, and availability of disposal options. I assessed the significance of the overall model using the chi-square fit statistic at a significance level of .05. I calculated

McFadden's R^2 to assess model fit, where values of .2 or greater indicated good model fit (Louviere, Hensher, & Swait, 2000). The plan was that if the overall model was significant, I would explore individual model coefficients to determine which independent variables were significantly associated with the dependent variable.

Given that logistic regression is heavily influenced by multicollinearity, I used SPSS to run collinearity diagnostics to measure the degree to which the independent variables related to each other. Ideally, independent variables strongly relate to the dependent variable and do not strongly relate to each other. To this end, I assessed multicollinearity using the variance inflation factors (VIF). According to Menard (2009), VIF values greater than 10 indicate a multicollinearity problem. The plan was that if I detected multicollinearity, I would remove the predictors with the highest VIF values.

After conducting a binary logistic regression that included the key independent variables (i.e., knowledge of environmental and human health impact, knowledge of recommended disposal practices, and availability of disposal options), I conducted a second binary logistic regression with the demographic variables included as predictors. I conducted this second regression model to address Research Question 5. I evaluated this regression in the same manner as the first regression, then compared the second regression model to the initial model to determine the influence of the demographic variables.

Threats to Validity

External validity is the extent to which the results of the study may be generalized to other populations or contexts. Because the population under investigation included only residents of the northeast United States, the results of this study may not be generalizable to other regions of the United States or to other countries. As indicated in the 2010 U.S. Census (U.S. Census Bureau, 2011), the socioeconomics characteristics of the northeast region of the United States include the following:

- Median household income ($53,283), compared to the Midwest = $48,445, the South = $45,492, and the West = $53,142.
- Percent in poverty level (11.8), compared to the Midwest = 13.3, South = 15.7, and the West = 14.8
- Number of people without health insurance coverage (11.8), compared to the Midwest = 12.7, the South = 19.2, and the West = 17.7

These data illustrate that the northeast has socioeconomic characteristics more favorable than those of other regions. Consequently, the generalization of the results of this study to the general U.S. population had to be considered with caution. In fact, socioeconomic characteristics such as income, employment status, and health insurance coverage have aligned with health care use and interactions with health care professionals (Blackwell et al., 2009), and, by inference, may have impacted the likelihood of consumers receiving drug disposal information.

Additionally, results from this study may not apply to the disposal of nonprescription drugs or other substances. Given the emphasis on prescription drugs in the national strategy to reduce the amount of pharmaceuticals in the environment, this study was restricted only to individuals who have used at least one prescription drug. However, OTC drugs, especially NSAIDs, are widely used, and, like prescription drugs, have the potential to pollute the environment and present a threat to human health. Thus, this study is limited by excluding a sizable proportion of consumers of common pharmaceuticals who may be less likely than those with prescription drugs to have accurate knowledge of recommended disposal practices.

The use of the Internet may also have excluded those people who are unfamiliar or uncomfortable with this technology. In spite of optimistic figures of a large diffusion of Internet use, groups of people, due to age or financial condition, may not have had the opportunity to be part of the population sample. The survey was in English only; therefore the chance exists that people who are not fluent in English did not complete it, and consequently it may not be known what disposal practices that population group uses.

Internal validity is the extent to which the results of the study are attributable to the independent variables, and that the study survey measured the variables that it intended to measure. To increase internal validity, I pilot tested (N=65) the survey instrument prior to conducting the main study. Additionally, to help ensure participants provided honest and accurate responses, I assured participants that their responses would be anonymous and kept confidential. Finally, statistical-conclusion validity is the extent to which the results of the data analysis are statistically valid. To ensure statistical-conclusion validity, I performed an a priori sample-size calculation to determine the minimum number of participants needed to obtain statistically valid results.

Ethical Procedures

I conducted this study in accordance with the ethical procedures required by the Walden University IRB. I obtained IRB approval prior to collecting any data (approval number 03-07-17-0129575). To protect participants' rights, I informed each participant that input in the study was completely voluntary, and that participants had the right to stop taking the survey at any point in time without consequence. I also informed participants that their responses would remain anonymous and kept confidential. In addition, I assured participants I am the only one with access to the data, and the data will be stored on my password-protected computer and backed up on a secure medium. Aligned with Walden University IRB procedures, the survey included information on participants' rights and contact information for the IRB and me.

Summary

The key objective of this cross-sectional retrospective study was to attempt to close a knowledge gap about the disposal practices of pharmaceutical products in the general population. The data accrued from a convenient sample of the population residing in the northeast region of the United States. The key research questions explored the hypothesized relationship between actual disposal practices and people's knowledge of appropriate disposal practices, the potential impact these practices could have on human health, and the availability of convenient disposal options. Although a retrospective cross-sectional study is, by definition, unable to establish a causal relationship, the results of the statistical analyses provided important insights and clues to the development of social-change strategies. The ultimate goal of this study was to learn how to improve drug disposal practices, and thus reduce the likelihood that improperly disposed pharmaceutical products in the environment will negatively impact human health.

In Chapter 4, I am providing an in-depth description of the statistical analyses that were performed, and the interpretation of the study findings with respect to the stated research questions and hypotheses.

Chapter 4: Results

Purpose of Study

The purpose of this study was to assess the prescription drug disposal practices of adults living in the northeast United States, and how an individual's knowledge of environmental and human health impact, knowledge of appropriate disposal practices, and locally available disposal options influence one's disposal practices. My aim in this study was to identify the key factors that may influence compliance with the recommended disposal practices (e.g., returning unused pharmaceuticals to a pharmacy), so that future work can take steps to promote safe disposal practices, in turn protecting the environment and human health. The Walden University IRB reviewed and approved this study design and its survey tool on March 7, 2017.

This chapter begins by reviewing the five research questions of interest and the hypotheses for each. Subsequently, I present and discuss the results of the pilot study (n = 62), and those of the main study (n = 485).

Research Questions and Hypotheses

Research Question 1. Is there an association between knowledge of the environmental and the human-health impact of pharmaceutical disposal and actual disposal practices?

$H_0 1$: No significant association exists between knowledge of the environmental and the human-health impact of pharmaceutical disposal and actual disposal practices.

$H_1$1: A significant association exists between knowledge of the environmental and the human-health impact of pharmaceutical disposal and actual disposal practices.

Research Question 2. Is there an association between knowledge of recommended disposal practices and actual disposal practices?

$H_0$2: No association exists between knowledge of recommended disposal practices and actual disposal practices.

$H_1$2: An association exists between knowledge of recommended disposal practices and actual disposal practices.

Research Question 3. Is there an association between available disposal options and actual disposal practices?

$H_0$3: No association exists between available disposal options and actual disposal practices.

$H_1$3: An association exists between available disposal options and actual disposal practices.

Research Question 4. To what degree can actual disposal practices (the dependent variable) be explained by the combined and differential contribution of the three independent variables, specifically, knowledge of the environmental and human health impact, knowledge of recommended disposal practices, and locally available disposal options?

$H_0$4: Actual disposal practices cannot be explained to a significant degree by the combined and differential contribution of knowledge of the environmental and the human-health impact, knowledge of recommended disposal practices, and locally available disposal options.

$H_1$4: Actual disposal practices can be explained to a significant degree by the combined and differential contribution of knowledge of the environmental and the human-health impact, knowledge of recommended disposal practices, and locally available disposal options.

Research Question 5. Do differences exist among RQ1, RQ2, and RQ3 across demographic groups?

$H_0$5: No significant demographic differences exist in the relationships of knowledge of the environmental and the human-health impact, knowledge of recommended disposal practices, and locally available disposal options to actual disposal practices.

$H_1$5: Significant demographic differences exist in the relationships of knowledge of the environmental and the human-health impact, knowledge of recommended disposal practices, and locally available disposal options to actual disposal practices, when controlling by demographic variables (e.g., age, race, education level).

Pilot Study

I first conducted a pilot study with two objectives: to assess the legibility of the questions to be used in the actual survey, and to estimate the number of respondents who did not meet the inclusion criteria, enabling me to adjust the study's target sample size (see Appendix C). Given these objectives, only descriptive statistics and related figures are being reported for the pilot study. In contrast, I employed descriptive- and inferential-statistical procedures to address the research questions of the actual study.

Participants

Participants for the pilot study consisted of 71 adults aged 18 to 75 years, 37 of whom were female, living in the northeast United States (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, Pennsylvania). Pilot participants completed the survey using the SurveyMonkey web-based data-collection platform between April 17, 2017, and April 19, 2017. I excluded data from six participants (8.5% of the data) because they had not taken a prescription drug in the past 2 years and I excluded data from an additional three participants (4.2% of the data) because they did not complete the survey (see Figure 1). As a result of the information on these exclusions, the target sample for the study was adjusted and increased from 385 to 485 to account for participants potentially not meeting inclusion criteria or not completing the survey.

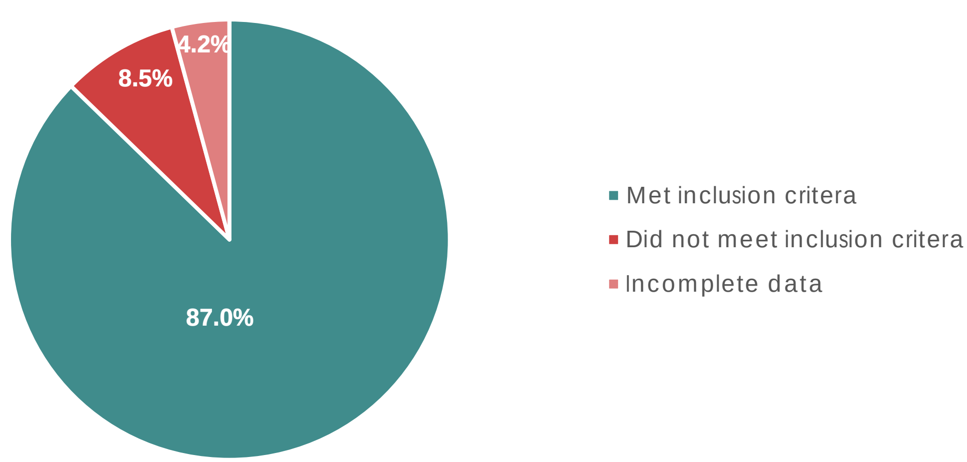

Figure 1. Participants in the Pilot Study.
Note. Figure shows inclusion criteria and data breakdown.

Of the remaining 62 adults, the largest number were aged 30 to 44 years (see Figure 2). A large majority (41) of participants identified themselves as Caucasian (see Figure 3). More than half had completed college (n = 13) or graduate school (n = 18; see Figure 4).

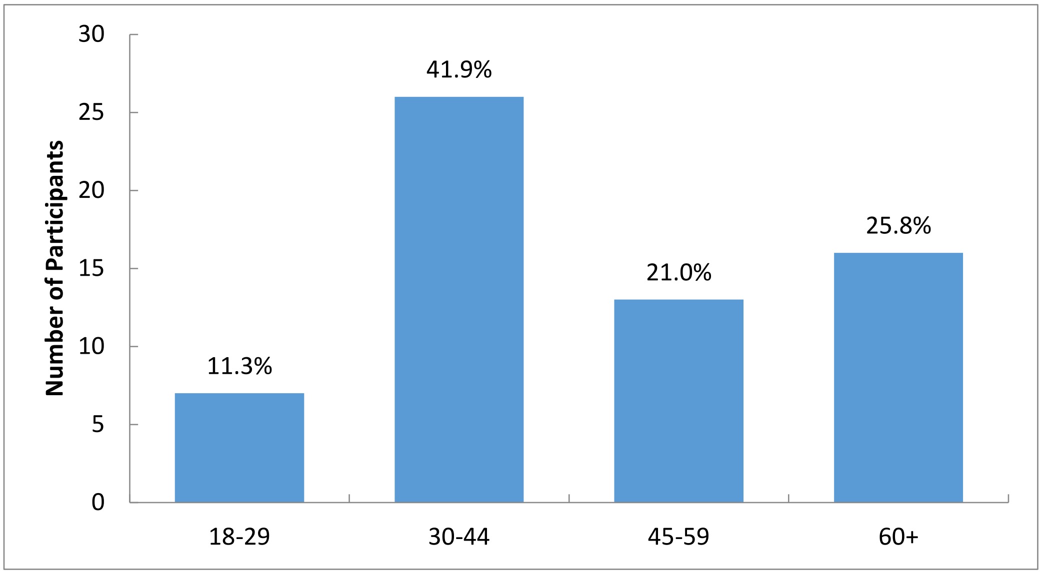

Figure 2. Pilot Study Participants by Age Group.
Note. Percentage of total participants presented above each bar.

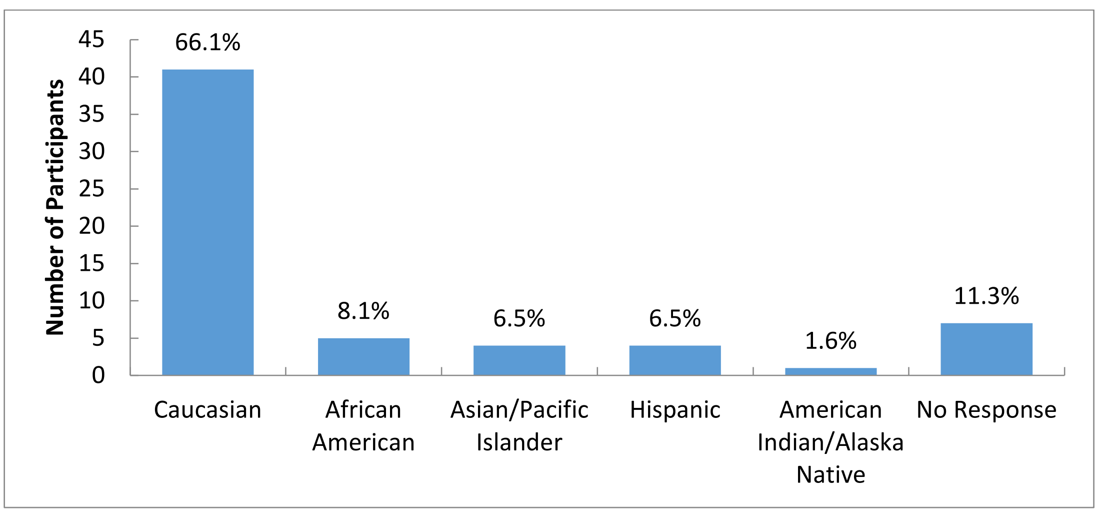

Figure 3. Pilot Study Participants by Race/Ethnicity.
Note. Percentage of total participants presented above each bar.

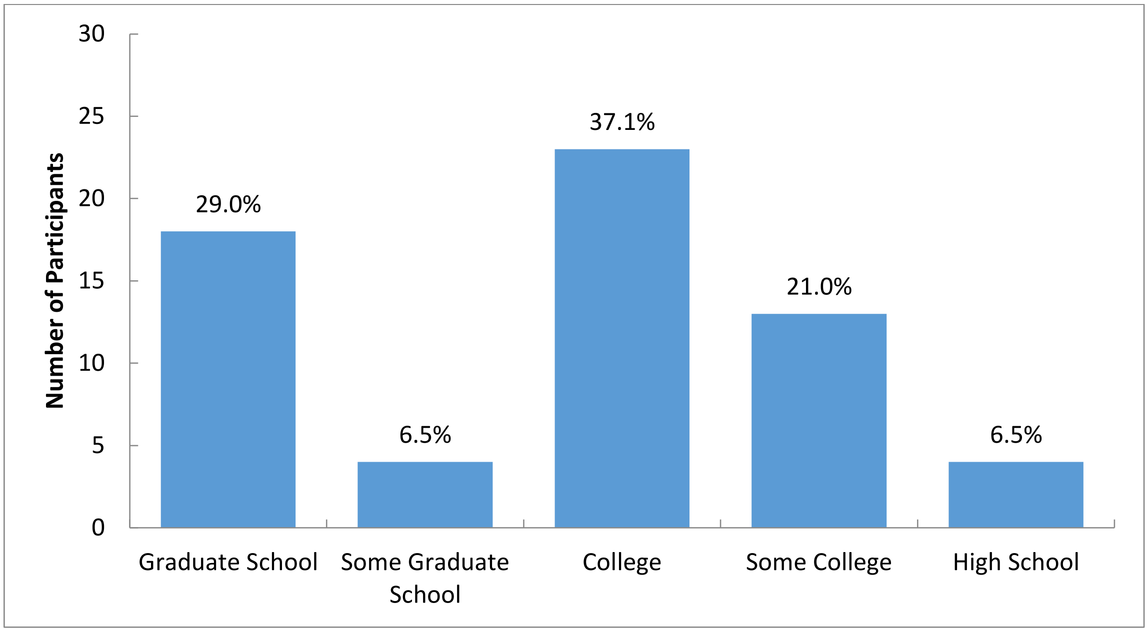

Figure 4. Pilot Study Participants by Education Level.
Note. Percentage of total participants presented above each bar.

Survey: Assessment of Legibility

After every survey question, participants indicated if the question was easy to understand. If the participant answered "no," they had the opportunity to explain how the question could be improved. The vast majority of the time (96.6% of all responses for all questions combined), respondents indicated the question was legible. Thus, I considered the survey suitable to use to collect a full sample, with only minor changes in wording. Figure 5 depicts, for each question, the percentage of respondents who considered the questions easy to comprehend.

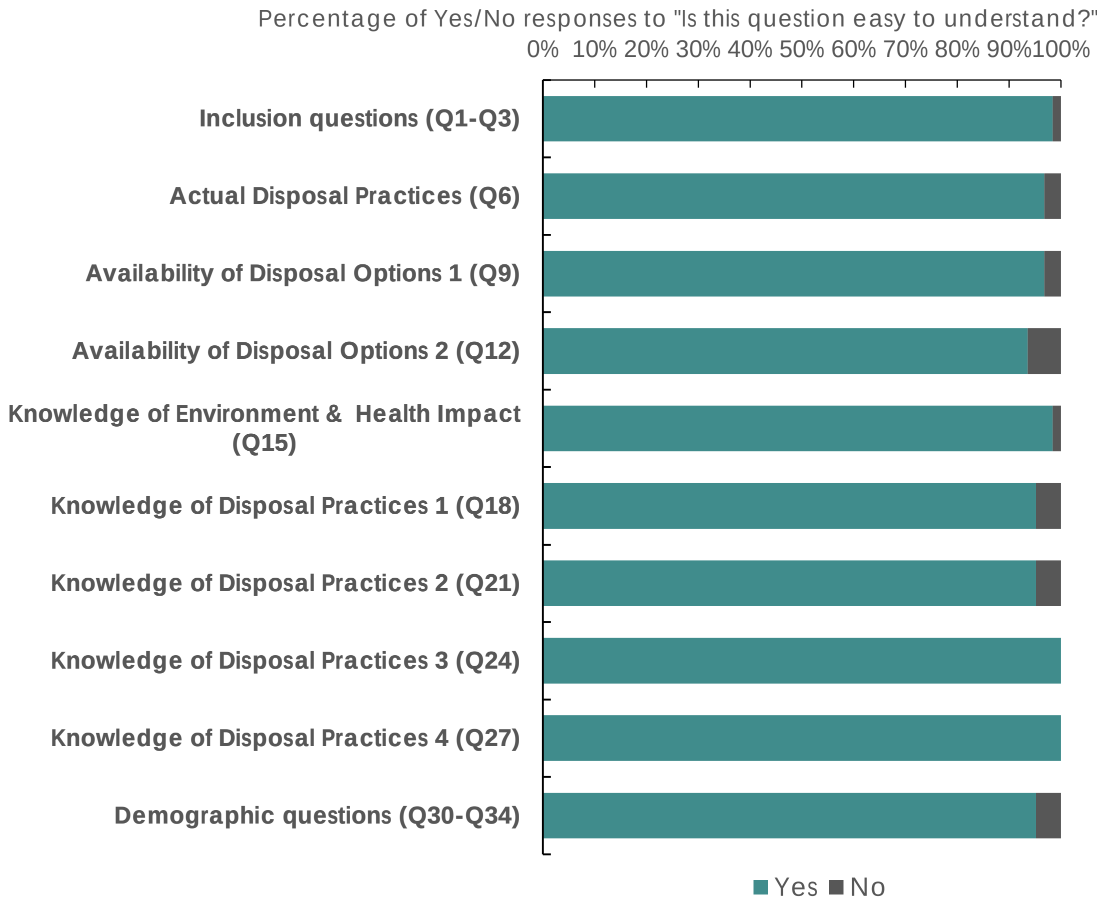

Figure 5. Legibility Assessment by Question.

Data Collection

A total of 681 individuals completed the survey using the SurveyMonkey web-based data-collection platform between April 21 and 24, 2017. Of the total number of respondents, 515 met the inclusion criteria: they were at least 18 years of age, had taken a prescription drug in the past 2 years, and resided in the northeast United States. Data from an additional 30 respondents were excluded for not completing the survey in its entirety.

Thus, the final sample consisted of 485 participants. This target sample size is above the previously calculated one of 385 and can be considered representative of the target population. The target 95% confidence level and the 5% margin of error remained unchanged. Survey participants were aged 19 to 87, 265 of whom were female. Of these 485 adults, 174 were aged 60 or older (see Figure 6). Identified as Caucasian were 410 of the 485 participants (see Figure 7). A third had completed college (n = 105) and a quarter had a graduate degree (n = 122). By state of residence, 39 participants lived in Connecticut, 19 in Maine, 78 in Massachusetts, 20 in New Hampshire, 79 in New Jersey, 138 in New York, 94 in Pennsylvania, 8 in Rhode Island, and 9 in Vermont (1 declined to respond). Graphical representation of the study's key demographic variables follows:

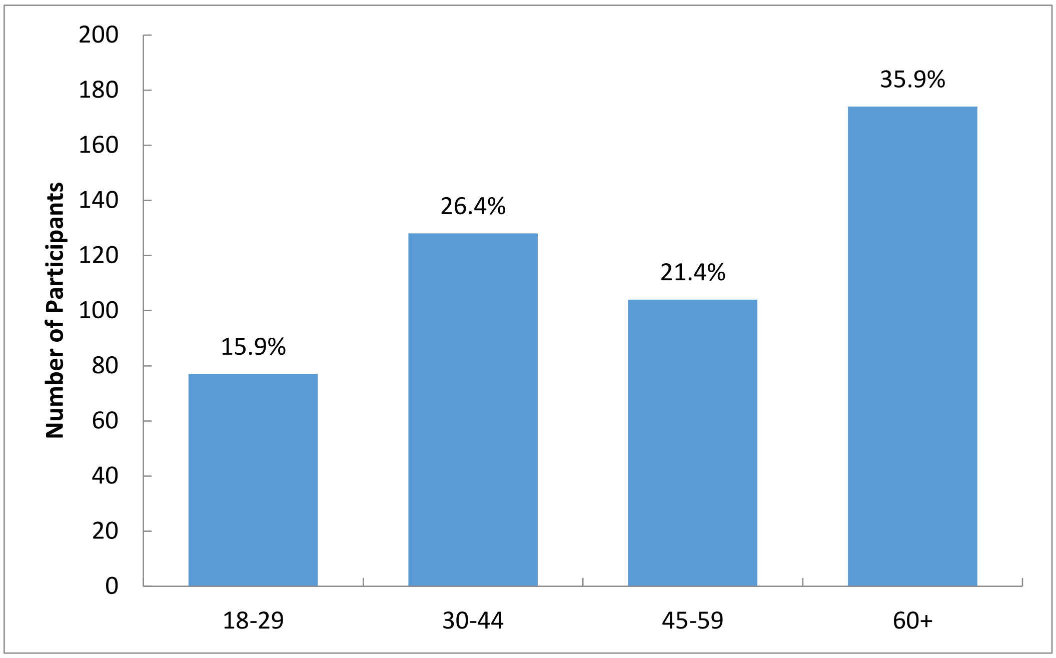

Figure 6. Study Participants by Age Group.
Note. Percentage of total participants presented above each bar.

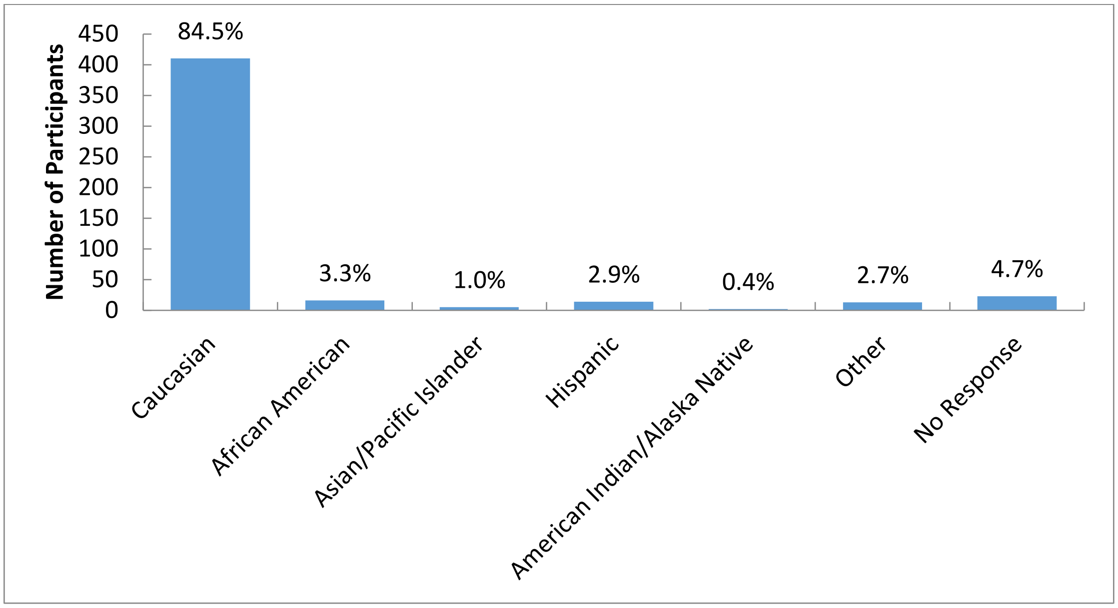

Figure 7. Study Participants by Race/Ethnicity.
Note. Percentage of total participants presented above each bar.

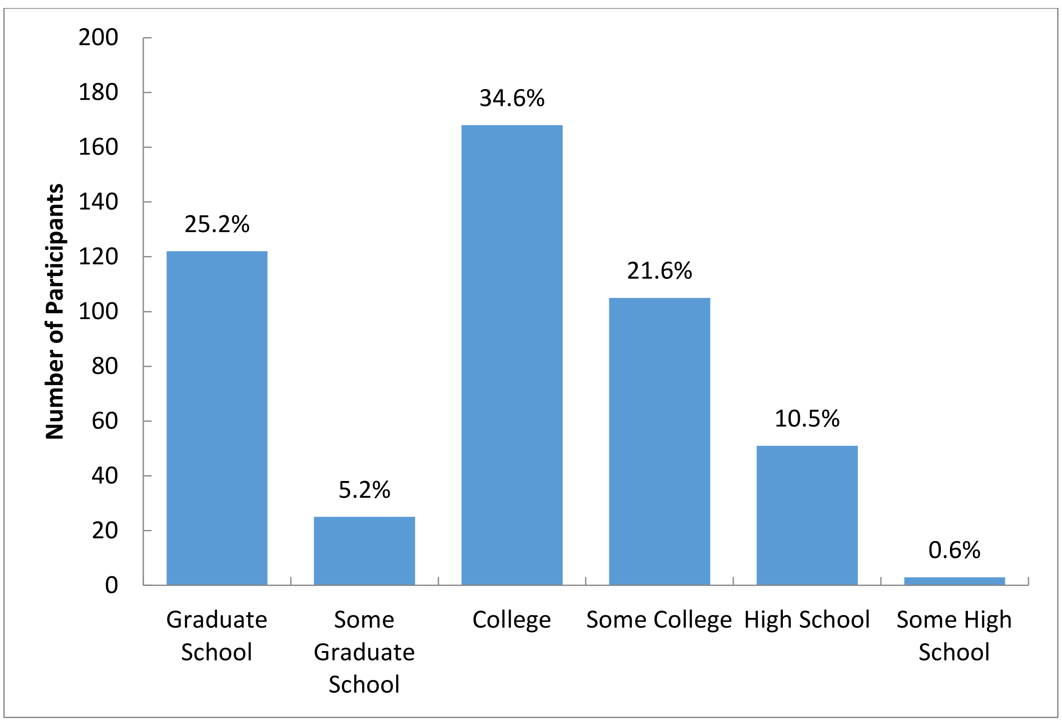

Figure 8. Study Participants by Education Level.
Note. Percentage of total participants presented above each bar.

Results

After providing a description of the sample and its demographic characteristics in the previous sections, Table 1 shows the study variables and their attributes, as they were used in the data-analysis process.

Table 1

Dependent and Independent Variable Key Characteristics

Variable name	Dependent/ independent	Variable type	Variable code name	Comments
Actual disposal practices	Dependent	Dichotomous categorical	ADP	Coded as either "recommended disposal practice" or "unrecommended disposal practice."
Knowledge of environment and human-health impact	Independent predictor	Ordinal	KEH	Represents knowledge and beliefs regarding impact of medications disposal practices on the environment and human health.
Knowledge of disposal practices	Independent predictor	KDP1 = Dichotomous Categorical KDP2 = Dichotomous Categorical KDP3 = Ordinal KDP4 = Dichotomous Categorical	KDP1–4	The survey had four questions addressing knowledge of disposal practices, hence variable names: KDP1–4.
Availability of disposal options	Independent predictor	ADO1 = Dichotomous Categorical ADO2 = Ordinal	ADO1–2	The survey had two questions addressing the availability of disposal options, hence variable names: ADO1–2.

Note. ADP = actual disposal practices.

Descriptive Statistics

Descriptive statistics for the dependent variable as well as each independent variable are presented here, with missing data discussed.

Actual disposal practices (ADP). Responses to the question, "What is your most used method for disposing of unused or expired medications?" represented the dependent variable of interest, ADP. I coded the eight possible response options either as a recommended disposal practice (*I return them to the pharmacy or to another designated take-back location, I mix them with coffee grounds or kitty litter or dirt and then in the trash, using a non-permeable container to avoid spill, I follow the disposal instructions that accompany the medicine, Not applicable—I always take my medications as prescribed; n* = 226) or un-recommended disposal practice (*I flush them down the toilet, I rinse them down the sink drain, I simply put them in the trash, I store them in my house for possible future use of family or friends, Other*; *n* = 259). Therefore, I treated ADP in all analyses as a dichotomous categorical variable.

Knowledge of environment and human health impact (KEH). I coded participants' responses to the question, "Do you believe that improper disposal of medications in the environment could have negative consequences on human health?" on an ordinal scale to represent the independent variable Knowledge of Environment and Human Health Impact. Participants had four possible response choices: *Not sure—no idea* (*n* = 25), *No—not at all* (*n* = 174), *Yes—somewhat* (*n* = 158), and *Yes—definitely* (*n* = 228).

Knowledge of disposal practices (KDP1–4). Participants answered four questions that represented the independent variable Knowledge of Disposal Practices. The first question (KDP1) was, "To your knowledge, are there any local, or state, or federal guidelines for the proper disposal of unused or expired medications?" I treated responses as a dichotomous categorical variable: *No/I don't know* (*n* = 350) or *Yes* (*n* =

135). I treated responses to the second question (KDP2), “Do you know what the current recommended disposal practices are?” as a dichotomous categorical variable, with possible answer choices being *No* (*n* = 185) and *Yes* (*n* = 300). The third question (KDP3) asked, “How often has a health care provider informed you about the proper way to dispose of your unused or expired medications, in the past two years?” I treated responses to this question as an ordinal variable with four levels: *Never* (*n* = 421), *Sometimes* (*n* = 41), *Often* (*n* = 13), and *Always* (*n* = 10). Finally, Question 4 (KDP4) asked, “Are you aware of any promotion material (such as pamphlets, posters, web info) that deal with the proper disposal of unused or expired medications?” Respondents had two possible response options, *No* (*n* = 375) and *Yes* (*n* = 110), making this a dichotomous categorical variable.

Availability of disposal options (ADO1–2). Responses to two questions represented the independent variable Availability of Disposal Options. The first question was, “In your area, is there a designated collection location where you can dispose of your unused or expired medication?” I treated responses to this question (ADO1) as a dichotomous categorical variable with possible responses of *No/I don’t know* (*n* = 350) and *Yes* (*n* = 185). I also treated responses to the second question (ADO2), “How convenient is it for you to reach the designated disposal location?” as an ordinal variable with three levels: *Almost impossible to reach* (*n* = 6), *It takes some effort* (*n* = 76), and *Convenient* (*n* = 128). Due to the high amount of missing data for variable ADO2 (*n* = 210 total observations), it was excluded from further analyses.

Assumptions

I chose a binary logistic regression as the statistical method to answer Research Questions 1–4, with ADP as the dependent variable and KEH, KDP1-4, and ADO1 as independent variables. A binary logistic regression assumes independence of errors, which was true for the present data, as each case represents a single unrelated participant. Additionally, a binary logistic regression assumes that none of the independent variables in the present data set highly correlated with one another. To assess whether multicollinearity was an issue in the present data set, I obtained the VIF and tolerance statistics, as suggested by Zuur, Ieno, and Elphick (2010). As shown in Table 2, all VIF values were well under 10 and tolerance values were more than 0.1, thereby indicating that multicollinearity was not an issue (Bowerman & O’Connell, 1990; Myers, 1990), and the analysis could proceed.

Table 2

Questions 1–4: Variance Inflation Factors and Tolerance Values

Variable	VIF	Tolerance
KEH	1.053	0.950
KDP1	1.201	0.832
KDP2	1.186	0.843
KDP3	1.162	0.860
KDP4	1.223	0.818
ADO1	1.216	0.822

Research Question 5 asked whether ADP differ by demographic group. Thus, I conducted an additional binary logistic regression with the demographic variables of gender, race, education, and age included. To assess multicollinearity for this model, I carried out VIF and tolerance statistics. The obtained values indicated that the variable, age, was causing an issue with perfect collinearity and the VIF statistics could not be computed. Consequently, I removed this variable from further analyses. The VIF and tolerance statistics for a model without age appear in Table 3 and indicate that multicollinearity is not an issue for this model (i.e., VIF values are below 10 and tolerance values are above 0.1).

Table 3

Question 5: Variance Inflation Factors and Tolerance Values

Variable	VIF	Tolerance
KEH	1.223	0.818
KDP1	1.217	0.821
KDP2	1.211	0.825
KDP3	1.282	0.780
KDP4	1.253	0.798
ADO1	1.261	0.793
Gender	1.375	0.727
Race	1.948	0.513
Education	1.849	0.541

Research Questions 1–4

To determine whether KEH, KDP, or ADO align with ADP (Research Questions 1–4), I performed a binary logistic regression with ADP as the dependent variable and KEH, KDP1–4, and ADO1 as the independent predictor variables. Logistic regression is the ideal tool for modeling a binary-response variable; in this case ADP, which can be either categorized as "recommended disposal practices" or "unrecommended disposal practices" on the independent variables KEH, KDP1–4, and ADO1. I used the Hosmer–

Lemeshow test, best suited for a sample size greater than 400, to assess the goodness of fit of the model (Bewick, Cheek, & Ball, 2005). Table 4 shows the result of the model analysis.

Table 4

Actual Disposal Practices and Knowledge of Environment and Human-Health Impact, Knowledge of Disposal Practices 1–4, and Availability of Disposal Options

Variable	*B*	*SE*	*p*	95% confidence intervals	
Constant	-2.937	0.453	< .001	0.021	0.126
KEH	0.724	0.129	< .001	1.612	2.670
KDP1	0.280	0.258	.278	0.799	2.200
KDP2	0.685	0.231	.003	1.262	3.122
KDP3	-0.114	0.203	.575	0.607	1.353
KDP4	0.137	0.281	.626	0.661	1.200
ADO1	0.970	0.241	< .001	1.652	4.253

Note. Model as a whole: R^2 = .171 (Hosmer–Lemeshow). Model $X^2(6)$ = 114.522, $p < .001$, Table shows the unique impact of each predictor toward explaining ADP, KEH = knowledge of environment and human-health impact, KDP = knowledge of disposal practices, ADO = availability of disposal options.

Research Question 1 asked whether ADP align with an individual’s KEH. The regression analysis indicated a significant and positive relationship between the variables ADP and KEH ($p < .001$), in line with hypothesis $H_1 2$. People who believe that improperly disposed pharmaceuticals will harm the environment or human health are more likely to practice recommended disposal practices. This trend can be further observed in Figure 9.

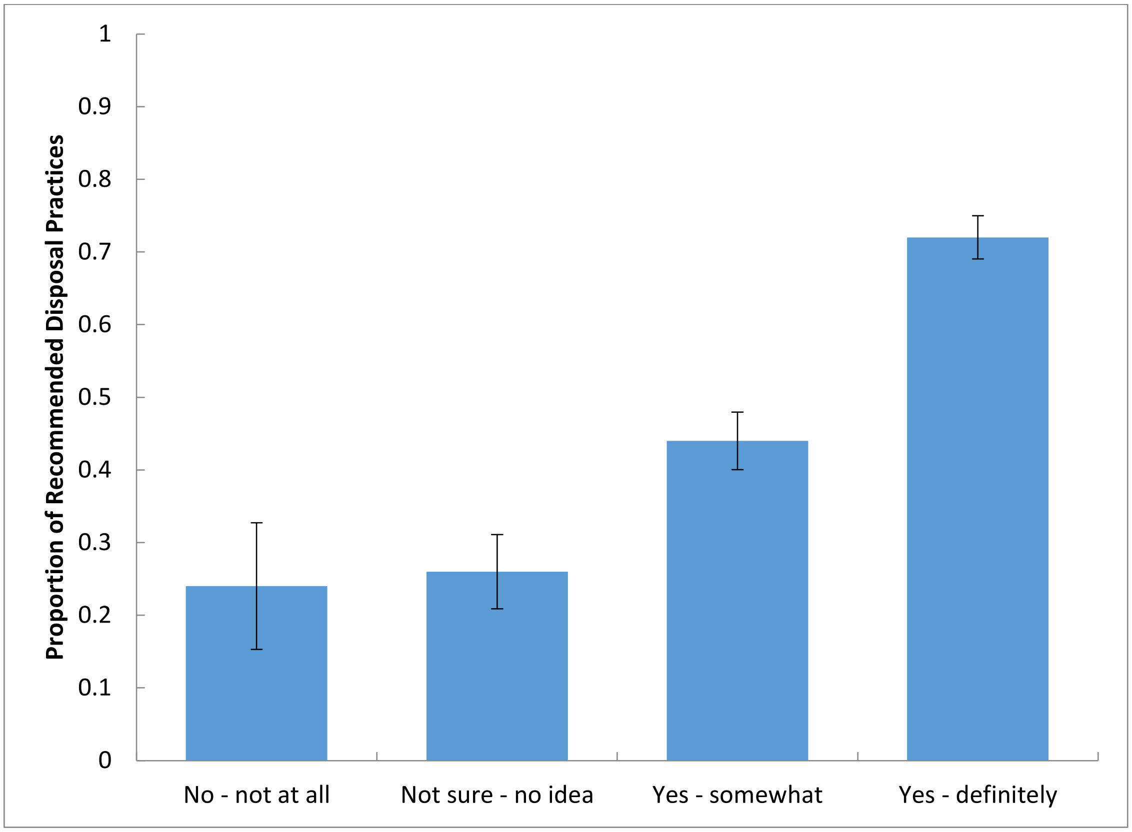

Figure 9. Proportion of Actual Disposal Practices by Knowledge of Environment and Human Health Impact.
Note. Error bars represent -/+ 1 standard error of the mean.

Research Question 2 asked whether an individual's KDP aligns with their ADP. The results of the regression show partial support for Hypothesis $H_1 2$; three of the four variables meant to represent KDP do not significantly align with ADP. Specifically, those are KDP1 ("To your knowledge, are there any local, or state, or federal guidelines for the proper disposal of unused or expired medications?"), KDP3 ("How often has a health care provider informed you about the proper way to dispose of your unused or expired medications, in the past two years?"), and KDP4 ("Are you aware of any promotion material (such as pamphlets, posters, web info) that deal with the proper disposal of unused or expired medications?"). However, KDP2 ("Do you know what the current recommended disposal practices are?") did significantly and positively align with ADP (p = .003, see Table 4). Figures 7–10 display the relationships between ADP and KDP1, KDP3, KDP4, and KDP2. However, only KDP2 significantly aligned with ADP.

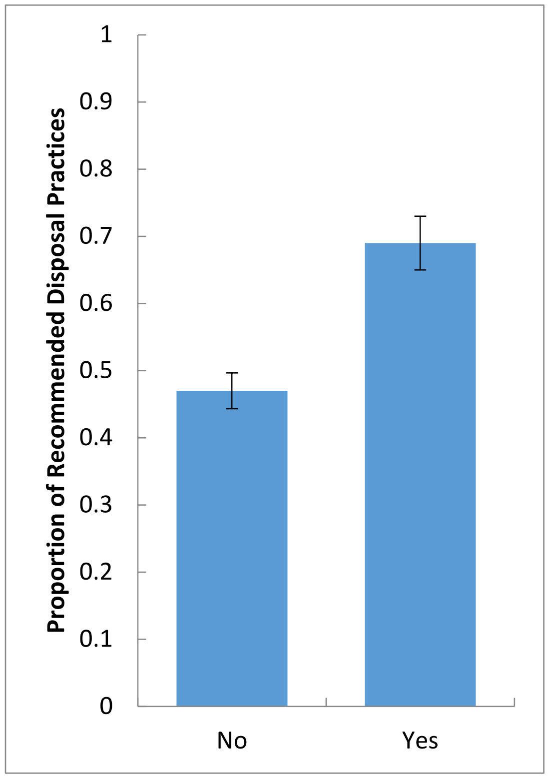

Figure 10. Proportion of Actual Disposal Practices by KDP1.
Note. Answering, "To your knowledge, are there any local, or state, or federal guidelines for the proper disposal of unused or expired medications?" Error bars represent -/+ 1 standard error of the mean.

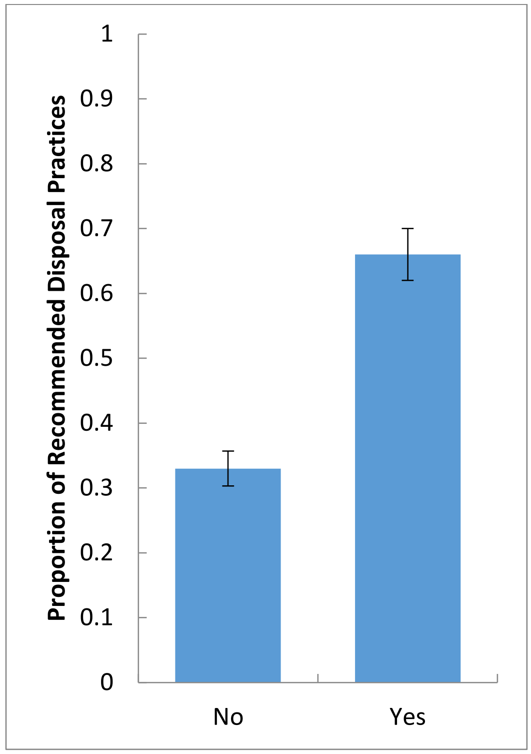

Figure 11. Proportion of Actual Disposal Practices by KDP2.
Note. Answering "Do you know what the current recommended disposal practices are?" Error bars represent -/+ 1 standard error of the mean.

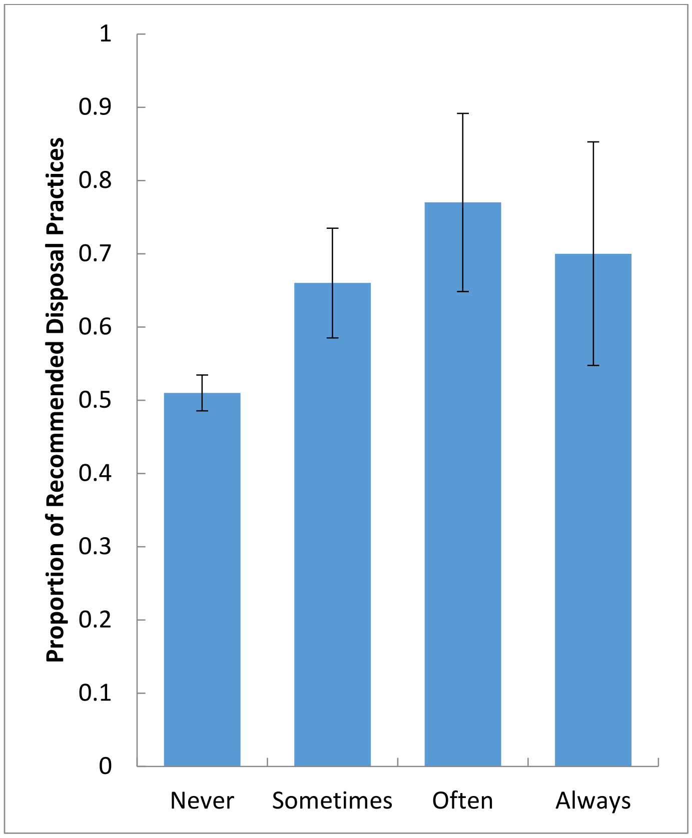

Figure 12. Proportion of Actual Disposal Practices by KDP3.
Note. Answering “How often has a health care provider informed you about the proper way to dispose of your unused or expired medications, in the past two years?” Error bars represent -/+ 1 standard error of the mean.

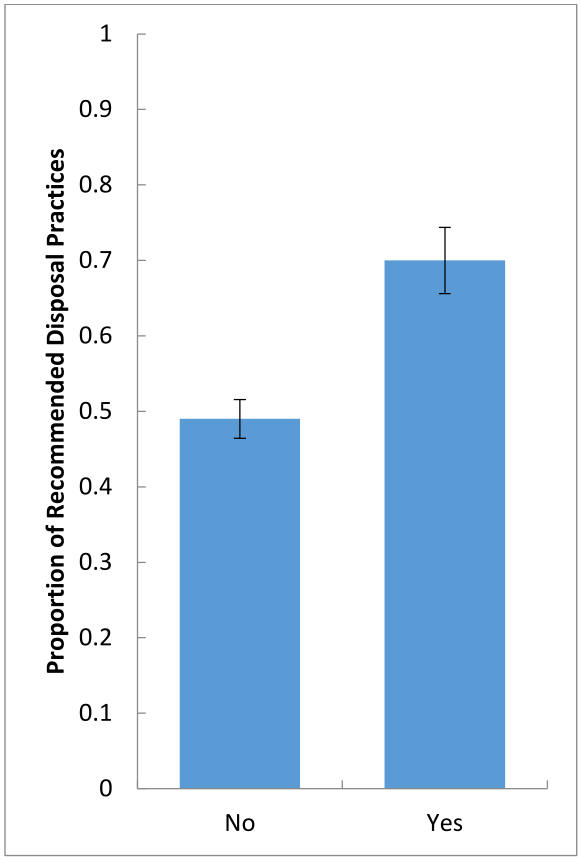

Figure 13. Proportion of Actual Disposal Practices by KDP4.
Note. Answering "Are you aware of any promotion material (such as pamphlets, posters, web info) that deal with the proper disposal of unused or expired medications?" Error bars represent -/+ 1 standard error of the mean.

Research Question 3 concerns the hypothesized association between ADP and ADO (as measured by the question "In your area, is there a designated collection location where you can dispose of your unused or expired medication?"). The regression model shows a significant positive relationship between ADP and ADO ($p < .001$, see Table 4). Participants who were aware of the existence of a designated pharmaceutical-collection location were more likely to practice recommended disposal practices, in line with Hypothesis $H_1 3$. This trend can be further observed in Figure 14.

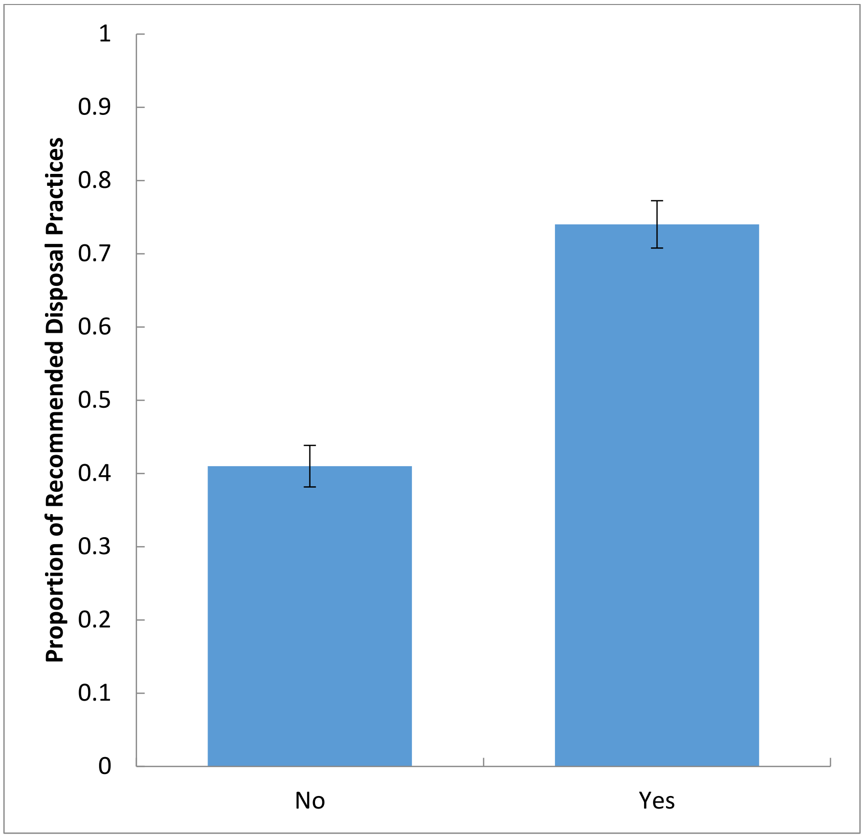

Figure 14. Proportion of Actual Disposal Practices by Available Disposal Options.
Note. Error bars represent -/+ 1 standard error of the mean.

Research Question 4 asked to what degree variance in ADP can be explained by the three independent variables KEH, KDP, and ADO. The results of the regression model showed that, in support of Hypothesis $H_1 4$, ADP is predicted significantly better by a model that includes KEH, KDP, and ADO as compared to a model that includes the intercept only (i.e., a model without the predictor variables), $X^2(6) = 114.522$, $p < .001$, $R^2 = .171$.

Research Question 5

Research Question 5 asked whether ADP varied by demographic variables. To that purpose, I conducted a binary logistic regression with ADP as the dependent variable and KEH, KDP1-4, ADO1, gender, race, and education as independent predictor variables. As shown in Table 5, the model is not significantly better than a model without the demographic variables included, $X^2(16) = 21.994$, $p = .143$, $R^2 = .033$. Thus, I concluded that no demographic differences exist in the present data set, in line with Hypothesis H_05.

Table 5

Model Coefficients for Logistic Regression

Variable	*B* (SE)	*SE*	*p*	95% Confidence Intervals	
Constant	-2.331	2.834	.411	0.001	40.122
KEH	0.844	0.143	<.001	1.769	3.105
KDP1	0.290	0.266	.276	0.794	2.258
KDP2	0.673	0.239	.005	1.227	3.140
KDP3	-0.222	0.216	.306	0.530	1.247
KDP4	0.283	0.292	.332	0.750	2.365
ADO1	0.943	0.251	<.001	1.575	4.229
Gender: Female	0.610	2.812	.828	0.020	741.364
Gender: Male	1.199	2.812	.670	0.037	1357.401
Race: American Indian	-0.663	2.438	.786	0.004	63.113
Race: Asian/Pacific Islander	-0.704	1.938	.717	0.009	22.952
Race: Black or African American	-0.761	1.756	.665	0.011	14.818
Race: Hispanic	-2.489	1.823	.172	0.002	2.889
Race: Other	-0.446	1.821	.806	0.014	23.011
Race: Prefer not to answer	-0.696	1.749	.691	0.012	15.537
Education: Completed graduate school	-1.134	1.317	.389	0.013	3.336
Education: Some graduate school	-0.610	1.380	.659	0.020	6.537
Education: Completed College	-1.133	1.315	.389	0.013	3.316
Education: Some college	-0.456	1.320	.730	0.025	6.653
Education: Completed high school	-0.833	1.340	.534	0.017	4.733
Education: Some high school	-1.920	2.057	.351	0.002	7.761
Education: Prefer not to answer	0.045	1.626	.978	0.028	23.822

Note. KEH = knowledge of environment and human-health impact, KDP = knowledge of disposal practices, ADO = availability of disposal options. $R^2 = .033$ (Hosmer-Lemeshow). Model $X^2(16) = 21.994$, $p = .143$.

Kruskal–Wallis Rank-Sum Test (Nonparametric Equivalent of One-Way ANOVA)

An additional set of analyses determined whether ADP differed across levels of individual demographic variables, irrespective of other factors. I ran a series of one-way ANOVAs, one for each demographic variable (education, race, age, and gender) with ADP as the dependent variable. I considered only the 453 participants who had provided responses for the four demographic questions for inclusion in the analyses. However, ANOVA procedures can be effectively carried out if the two key assumptions are met: homogeneity of variances and normal distribution of the residuals of the dependent variable at each level of the independent one. I assessed the assumption for homogeneity of variances using Levene's tests (Levene, 1960). These tests provided a *p* value greater than .05 (statistically nonsignificant), indicating that the assumption was met for all planned analyses (see Table 6). I assessed the ANOVA assumption for normal distribution of the residuals of the dependent variable at each level of the independent variable using Shapiro–Wilk tests. The obtained *p* values were smaller than .05 (statistically significant), indicating that this assumption was violated in all cases (see Table 7). Consequently, I could not use the ANOVA procedure and conducted the Kruskal–Wallis rank-sum tests—the nonparametric equivalent of the one-way ANOVA—instead.

The Kruskal–Wallis test with education as the independent variable and ADP as the dependent variable did not reach significance, $\chi^2(5) = 4.811$, $p = .439$, suggesting that pharmaceutical disposal practices do not differ by education level (see Figure 15). The corresponding Kruskal–Wallis test for race was also nonsignificant, $\chi^2(5) = 6.286$, *p* = .279, indicating that the race of an individual does not affect pharmaceutical disposal practices (see Figure 16).

Table 6

Levene's Tests for Demographic Changes in Actual Disposal Practices

	df	*F*	*p*
Education	6	0.491	.783
Race	6	0.710	.616
Age	3	0.410	.746
Gender	1	0.557	.456

Table 7

Shapiro-Wilk Tests for Demographic Changes in Actual Disposal Practices

	W	*p*
Education	0.721	< .001
Race	0.672	< .001
Age	0.723	< .001
Gender	0.661	< .001

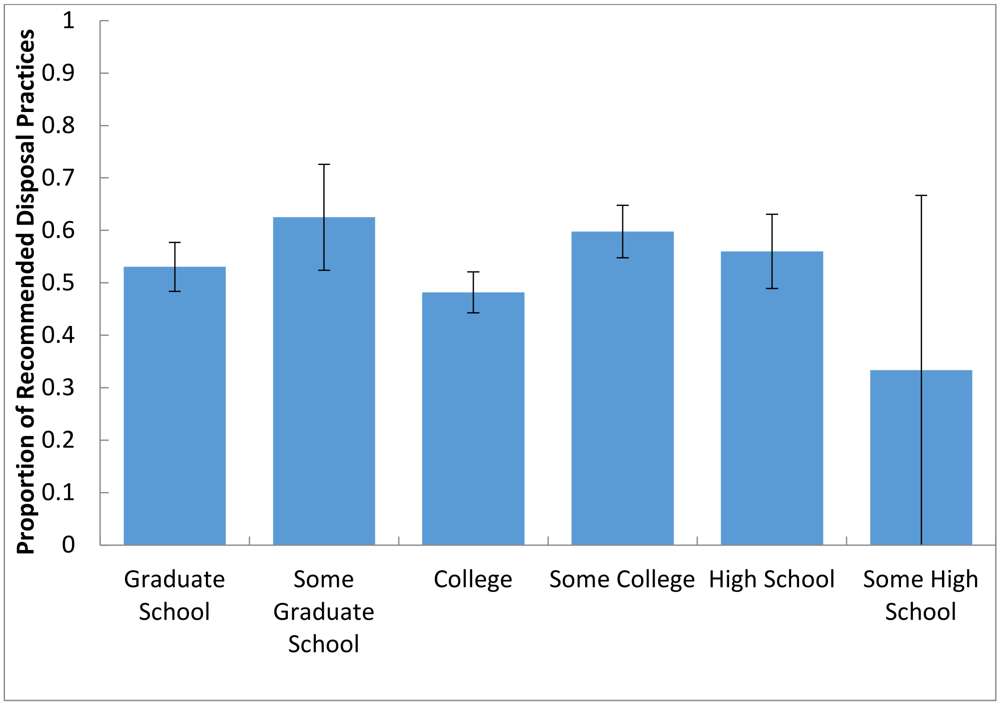

Figure 15. Actual Disposal Practices by Education Level.
Note. Error bars represent -/+ 1 standard error of the mean.

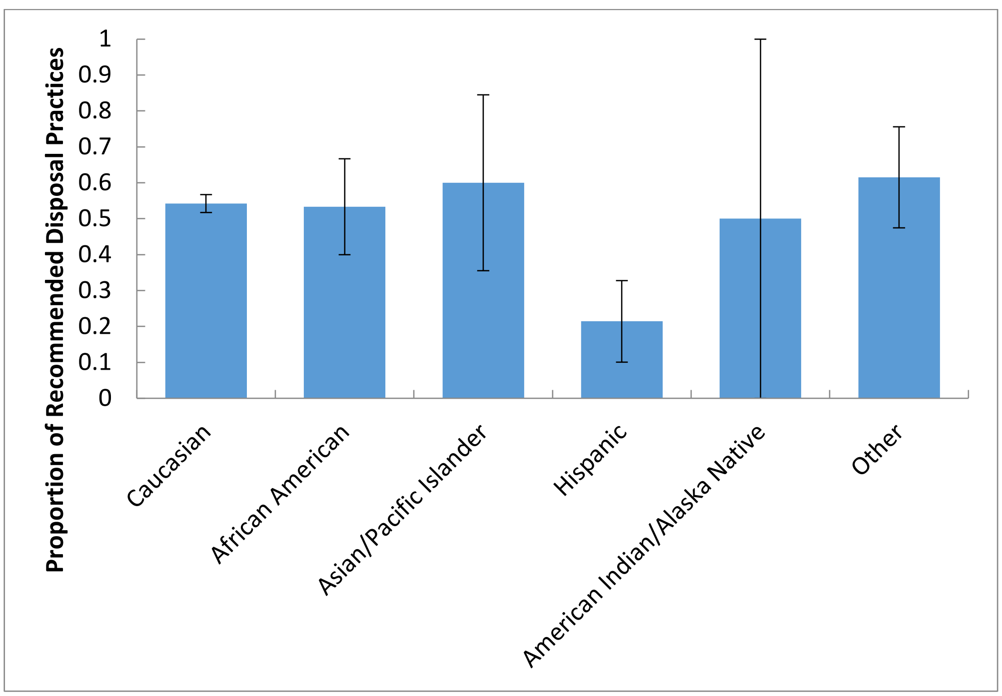

Figure 16. Actual Disposal Practices by Race.
Note. Error bars represent -/+ 1 standard error of the mean.

The Kruskal–Wallis test with age as the independent variable and ADP as the dependent variable did not reach significance, $\chi^2(3) = 5.789$, $p = .122$ (see Figure 17). In other words, ADP did not vary across age groups. Finally, the Kruskal–Wallis test for gender indicated that ADP did not differ between men and women, $\chi^2(1) = 0.557$, $p = .455$ (see Figure 18).

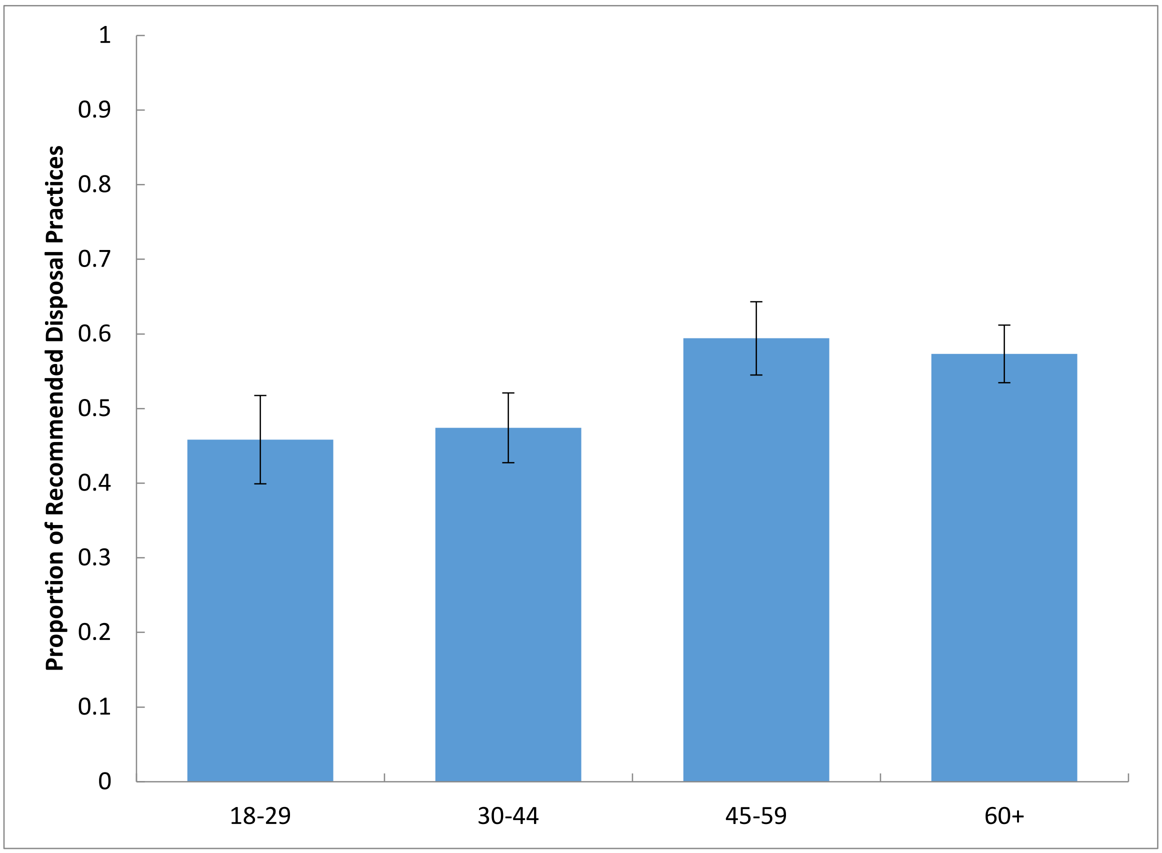

Figure 17. Actual Disposal Practices by Age Group.
Note. Error bars represent -/+ 1 standard error of the mean.

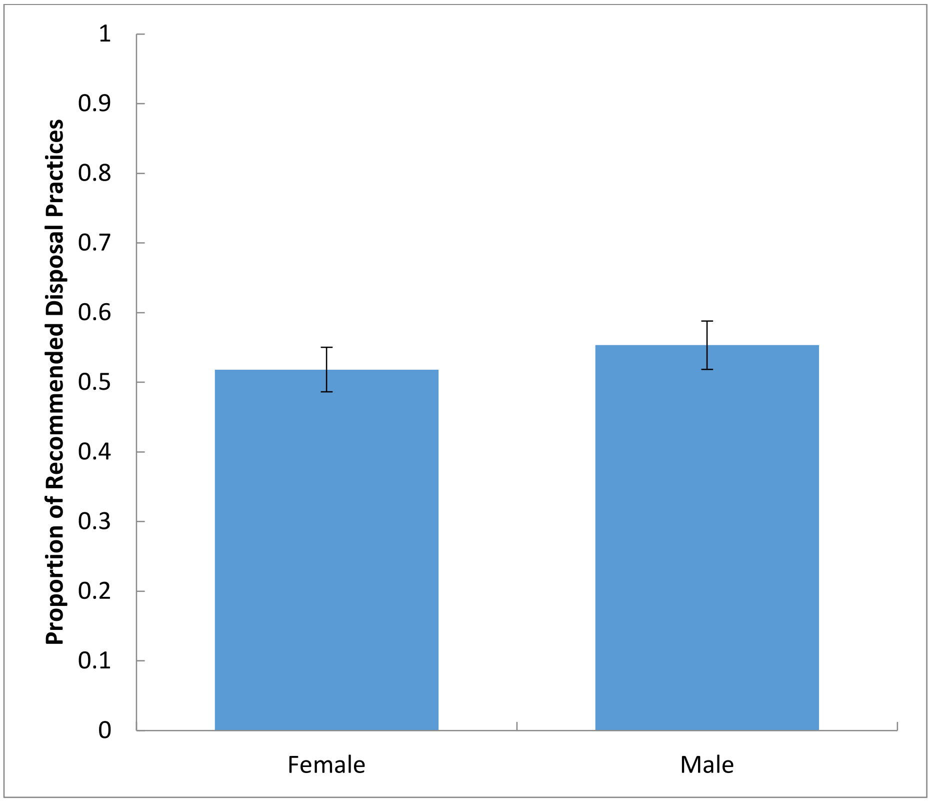

Figure 18. Actual Disposal Practices by Gender.
Note. Error bars represent -/+ 1 standard error of the mean.

In conclusion, the Kruskal–Wallis rank-sum test confirmed the results obtained using the logistic regression procedure. In the sampled population, the demographic variables (i.e., education level, age, ethnicity, gender) do not have a significant impact on people's behavior with respect to their disposal practices of unwanted pharmaceuticals.

Summary

The results of a large-scale survey spanning the northeast United States showed significant associations between an individual's knowledge of environmental and human-health impacts, knowledge of recommended disposal practices, and locally available disposal options, with a person's likelihood to practice recommended pharmaceutical disposal practices. Specifically, people who are more knowledgeable about recommended disposal practices, the environmental and health impacts of improper disposal, and who live in an area with official disposal options are more likely to practice recommended disposal of prescription drugs. These three factors significantly predict an individual's likelihood to practice recommended prescription-drug disposal. Moreover, these relationships are stable across various demographic groups, suggesting no specific group should be targeted with, for example, promotional material explaining how to properly dispose of unwanted pharmaceuticals. Rather, interventions may seek to focus on increasing knowledge of environmental and health impact for people of all demographics, as well as increasing the availability of official disposal locations.

In the next chapter, I discuss the findings of the study through the perspective of the conceptual framework, the implications for social change, and recommendations for potential actions. In addition, I discuss the limitations of the study and provide recommendations for future research.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

For decades, recommendations for disposing of unused or expired medications were guided by concerns about inadvertent or intentional poisoning. Flushing them down the toilet or rinsing them down the drain were considered safe and simple ways to dispose of unwanted drugs (McCullagh et al., 2012; Ortner & McCullagh, 2010). A 2008 report entitled *PharmaWater I* (Donn, Mendoza, & Pritchard, 2008) described how at least 41 million Americans were served by water supplies with evidence of pharmaceuticals including anticonvulsants, antibiotics, mood stabilizers, and hormones. Researchers have documented the consequences of pollution by pharmaceuticals on the environment's ecosystems and its potential effects on human health and studied the disposal practices of specific populations (e.g., nurses and pharmacists). However, a gap existed in the scholarly literature regarding the disposal practices for pharmaceuticals in the general population.

I conducted this study to address the disposal practices of unused or expired prescription medications in a sample of the general population residing in the northeast United States. In this study, I examined people's disposal practices, local availability of disposal options, awareness of proper disposal practices, and the potential correlations between people's ADP and their knowledge of the impact that disposal practices may have on the environment and human health.

My aim in this study was to identify the key factors that may influence compliance with the recommended disposal practices (e.g., returning unused pharmaceuticals to a pharmacy), so future work can take steps to promote safe disposal practices. My final goal for this study was to acquire the necessary data to support a social-change strategy that could translate into an actual behavioral shift. To select an appropriate study design, I had to identify a conceptual framework so research questions could align with time-tested behavioral models. To this end, an extensive literature review pointed to the HBM and the TPB to support the behavior-inquiry aspect of this study. The HBM was applicable for its approach in defining barriers to the adoption of health-related behavior (Strecher & Rosenstock, 1997). The TPB was relevant from the perspective of motivation factors that precipitate the intention to perform an action or behavior (i.e., proper disposal practices). In summary, the HBM and the TPB conceptual frameworks guided the development of the study design and the survey tool for data collection.

I used a cross-sectional approach to investigate measurable hypothesized associations at a specific point in time, despite the difficulties in definitively determining cause–effect relationships (Pine et al., 1997). The research questions, and the key findings of the study follow:

Finding 1

RQ1: Is there an association between knowledge of the environmental and the human-health impact of pharmaceutical disposal and actual disposal practices?

Greater knowledge of the environmental and health threats resulting from improperly disposed drugs aligned with higher rates of proper disposal practices.

Finding 2

RQ2: Is there an association between knowledge of recommended disposal practices and actual disposal practices?

Greater knowledge of recommended disposal practices aligned with higher rates of proper disposal practices.

Finding 3

RQ3: Is there an association between availability of disposal options and rates of actual disposal practices?

Having safe disposal options available aligned with higher rates of proper disposal practices.

Finding 4

RQ4: To what degree can actual disposal practices (the dependent variable) be explained by the combined and differential contribution of the three independent variables: knowledge of the environmental and human health impact, knowledge of recommended disposal practices, and locally available disposal options?

A statistically significant model using the independent variables (predictors) combined, and differential contribution of knowledge of the environmental and health impact, knowledge of recommended disposal practices, and locally available disposal options could predict the dependent variable: participants' disposal practices. These findings suggest that participants' disposal practices aligned with the combined contribution of the independent variables.

Finding 5

RQ5: Do differences exist among RQ1, RQ2, and RQ3 across demographic groups?

No significant differences emerged with respect to knowledge of the environmental and human-health impact of pharmaceuticals, knowledge of recommended disposal practices, and locally available disposal options across demographic variables.

Discussion

The purpose and the results of this study need to be viewed through the optics of a larger context. Environmental contaminants generated by the inappropriate disposal of prescription drugs by consumers may be merely a portion of the total pharmaceutical contaminants that reach the environment through various routes. The results of this study suggested that social and organizational programs need to take appropriate steps, discussed in this chapter, to facilitate broad social change and improve disposal practices. In practice, pharmaceutical companies and governmental agencies, at federal and local levels, will need to demonstrate their commitment to social responsibility by ensuring the entire development and marketing lifecycle of pharmaceutical products are controlled and pose minimal environmental and human-health risks. In line with these considerations, Daughton (2014a) considered the lifecycle development by defining upstream and downstream approaches to minimizing environmental contamination by pharmaceutical products.

The upstream approach consists of minimizing the amount and toxicity that a given pharmaceutical product would release when discarded in the environment. From the upstream approach, pharmaceutical companies should prioritize adopting the so-called green pharmacy or ecofriendly pharmacy" in their development portfolio to adopt and design drugs with maximum absorption potential, ensuring that smaller traces would be excreted in the environment. For drugs currently on the market, an upstream approach would leverage on the social responsibility of pharmaceutical companies in various activities to improve patient adherence to the prescribed drug regimen. For example, field staff, during their routine interactions with health care personnel (e.g., physicians and nurses), could promote not only the drugs, but also the drugs' optimal disposal practices.

The downstream approach focuses on promoting the safe and proper disposal of unused, unwanted, and expired medications (Ruhoy & Daughton, 2008). From a social-change perspective, this approach would leverage on the social responsibility of local health departments to ensure they have the budget and the resources to support drug take-back programs, media campaigns on proper disposal practices, and conveniently located disposal options (e.g., malls, supermarkets, pharmacies, and post offices). To ensure consistency, various stakeholders—local health departments, schools, pharmacies, hospitals, clinics, and health care providers—would coordinate effort to communicate strategy on drug disposal standards that clearly align with current research. Such strategies should be designed to be easily adaptable to change, and customizable to local as well as specific populations' needs.

The HBM and the TPB conceptual-framework models were quite helpful in the design of this study. The HBM model, which has been used in previous studies of environmental and health-related behaviors, was employed in the past to explore how consumers perceive the potential benefits of safe pharmaceutical disposal at take-back centers. Perceived barriers crucially limit the likelihood of safe disposal practices as well as other health-related preventive behaviors (Strecher & Rosenstock, 1997), a finding confirmed by this study. In the TPB model, ethical norms (Cote et al., 2012) are key predictive factors. The TPB model relates to the motivations that trigger certain environmental behaviors; in the present study, I used the TPB to explore and identify factors that may precipitate, inhibit, or be of no consequence to specific drug disposal practices. One key finding from this study was that the ease of access to disposal options increases the likelihood of proper disposal. This finding is consistent with the outcome of Ruhoy’s (2009) study, determining that the ready availability of medication disposal options was a significant predictor of safe medication disposal behaviors. Similarly, Ma et al. (2014) found that the majority of participants in a take-back program in Hawaii would have discarded drugs improperly without this program and the instructions received on best practices, again underscoring the significance of convenient safe disposal options and clear disposal instructions as predictors of safe disposal practices.

Examining prior research conducted on drug disposal helps provide context for the interpretation of the present study findings. For example, Gray and Hagemeier (2012) surveyed 752 participants in the Appalachian regions of Tennessee and Virginia between 2009 and 2011. The researchers considered demographic factors such as race, age, and gender, along with reasons for participation in the take-back program. Gender stood out as a demographic factor predicting higher return rates, as more women than men participated in the take-back program (Gray & Hagemeier, 2012). This result stands in contrast to the present study, in which particular demographic factors did not align with higher rates of safe disposal practices.

The present study supported the finding of Kotchen et al. (2009), who determined, in a survey of consumers in California, that those with higher levels of environmental awareness were more likely to practice safe disposal. Comparing the rates of safe disposal in Sweden and Poland underscored this study's findings regarding the significance of environmental awareness, knowledge of safe disposal methods, and available safe disposal options in predicting environmentally sound disposal behaviors (Zimmermann et al., 2011). In addition to the United States, several European countries, Australia, and New Zealand have initiatives in place to safely dispose of unused drugs (Ruhoy & Daughton, 2008). Swedish consumers have high levels of environmental awareness and knowledge of safe disposal methods due to effective public education campaigns by a government-owned pharmacy chain with a convenient take-back program; as a result, more than 70% of Swedish consumers with unused drugs returned them to local pharmacies. In Poland, in contrast, consumers had lower levels of environmental awareness and few safe disposal options, resulting in high rates of unsafe drug disposal (Zimmermann et al., 2011).

A high degree of knowledge about environmental impacts has not always resulted in optimal disposal practices. Even trained, knowledgeable health care professionals such as pharmacists (Abahussain et al., 2012) and nurses (McCullagh et al., 2012) did not always practice safe drug disposal, underscoring that knowledge is not invariably the only driving force in behavior change (Bandura, 1997; Nisbet & Gick, 2008; Strecher & Rosenstock, 1997). Seehusen and Edwards (2006), who surveyed 301 consumers at a medical center in Washington State, discovered gaps between knowledge and safe disposal practice, and highlighted the lack of access to safe disposal options in reducing the likelihood of safe disposal practices.

Implications of the Findings: Potential Impact for Social Change

The envisioned outcome of this research is to inspire positive social change by improving the rates of safe pharmaceutical disposal, and, in doing so, increase the ease and availability of safe disposal options, enhance patient adherence to medication recommendations, and advocate for “green pharmacy”, all of which will help protect the environment and reduce the risks to human health. One key finding of the present study was that the availability of safe medication disposal options was a significant predictor of safe medication disposal behaviors. This finding confirmed the research of Ruhoy and Kaye (2010), who investigated a program in Maine called Safe Medicine Disposal and found that convenient safe disposal options predicted a higher likelihood of safe disposal practices. In Maine, a state in the present study’s geographic focus that was hard hit by the opioid crisis and high death rates from prescription medication (Stewart et al., 2015), patients were able, through this drug take-back program, to anonymously mail back medications at no cost. The program was remarkable for providing an easily available option for medication disposal, and also provided helpful data on returned drugs and program participants (Ruhoy & Daughton, 2008). Significantly, without the program, the majority of participants indicated they would have either disposed of the unused medications by flushing them down the toilet or throwing them away in the trash. Ruhoy and Kaye concluded that Safe Medicine Disposal for ME was a user-friendly, low-cost, effective program that could serve as a model for initiatives elsewhere. The research, then, is clear about the importance of taking steps to ensure safe, convenient disposal methods in promoting the envisioned social change.

The key findings of the present study have advanced knowledge of a significant public health and environmental problem by demonstrating, in the general population of the northeast United States, the significant association between the dependent variable (recommended methods of pharmaceutical disposal) and the three dependent variables: knowledge of the impact of unused prescription drugs on the environment and human health, knowledge of best practices in drug disposal, and easily available, user-friendly disposal options. No significant associations emerged between demographic factors and pharmaceutical disposal practices; rather, consistency arose across the demographic cohorts surveyed. Key findings confirmed the importance of knowledge of environmental and health impacts, safe disposal practices, and availability of user-friendly take-back programs and disposal options in increasing adherence to recommended pharmaceutical disposal practices.

This study extends knowledge of disposal practices to the general population of the northeast United States and complements findings previously obtained in studies conducted in specific populations (e.g., nurses and pharmacists) in other regions of the United States. Recommendations for practice include promoting awareness of the impact of improperly disposed pharmaceuticals on the environment and human health across demographic cohorts, and promoting user-friendly return programs and disposal locations. The potential impact for positive social change at the levels of individuals, families, organizations, and policymaking is significant. With safer disposal methods involving multiple stakeholders, the harm caused by improper pharmaceutical disposal to the environment and to public health will diminish.

The data for this study was collected by administering an Internet questionnaire to a sample of adult residents of the northeast United States who had taken a prescription medication within the previous 2 years. I designed the study to learn about the disposal practices in the general population, and how these practices could be linked to people's knowledge of the environmental and health effects resulting from improper disposal. It was also important to explore the degree to which the availability of locally available disposal options could be linked to disposal practices. By studying current disposal practices in the sample and learning about what promotes or inhibits the likelihood of safe disposal practices, this study has contributed to a better understanding of the problem and to ways to increase a collective social-change process.

The ultimate goal of this study was to provide the data, and the rationale to promote a series of actions, including additional research, that encompass a broad strategy, at multiple organizational and functional levels, in both the private and public domains. The strategy for optimal disposal will have to include broad public education campaigns aimed at all demographic groups, as well as to health care providers. Equally important, the strategy will have to engage pharmaceutical companies, policymakers, and the DEA, for providing the budgets and the scientific support for a coordinated, effective, and efficient approach at reducing and ultimately eliminating the human health risk associated with pharmaceutical entering the environment. Educating the public on the risks of improper disposal is not enough. There has to be an infrastructure (i.e., scientific, organizational, budget, staff) in place to adequately sustain and monitor the health of our environment, which directly and indirectly supports human health, and the life of the eco-systems that sustain global health on the planet.

Limitations of the Study

I adapted a questionnaire administered online by SurveyMonkey, using items by Seehusen and Edwards (2006), following these authors' formal approval (see Appendix A). Given widespread Internet use and availability, an online questionnaire was ideal for this study, though some authors have noted that some cohorts of Americans may lack access to the Internet (Cottrell & McKenzie, 2010).

This study had some limitations and the results may be generalizable with caution. The northeast United States has unique demographic factors, such as more favorable socioeconomic characteristics (U.S. Census Bureau, 2011), that may limit to the degree to which it may be possible to generalize the results of this study to other geographic regions of the United States or to other countries. Researchers have cited the role of socioeconomic factors such as income and health insurance coverage in individuals' interactions with the health care system (Blackwell et al., 2009), which, in turn, may impact the information they receive about recommended pharmaceutical disposal. This study was also limited to prescription drug disposal practices; therefore, the study generated no new information about disposal practices pertaining to widely-used OTC drugs, which also impact the environment and human health. Because this study involved an Internet survey in English, two subpopulations—those who do not use the Internet and individuals with limited English—were excluded from the population sample and no new knowledge was gained about their disposal practices.

In spite of these limitations, this study surveyed a significant sample of the general population of the northeast; the target sample size was exceeded by 100 participants, as 485 successfully completed the survey compared to the calculated target sample of 385. Furthermore, I successful examined the survey's content validity by using a pilot survey, and addressed validity of the statistical conclusions by assessing, a priori, the assumptions of the statistical tests leading to the acceptance or rejection of the null hypotheses and answering the research questions.

This study's theoretical framework involved the use of the HBM and TPB models. The study was innovative in bridging the knowledge gap between health and environmental behavior. Despite being related fields, models used to study health behavior change have not often been used in environmental studies (Nisbet & Gick, 2008).

Recommendations for Future Research

When considering the original scope of this study, its research questions, findings, and potential limitations, a number of future lines of research have emerged. In the northeast, new studies could be carried out to determine which kinds of public-education campaigns are particularly effective, when, as noted, becoming more knowledgeable does not invariably lead to behavioral change. Researchers could study which messages, and in which contexts (e.g., schools, pharmacies, hospitals, and health departments) are most effective in promoting environmentally sound disposal behaviors that focus on increasing knowledge of the environmental and health impact, recommended disposal practices, or awareness of safe disposal locations.

Researchers could conduct comparative studies in other regions of the United States in order to address regional or population specific needs. The comparative context could be extended further, with additional studies conducted across countries; ideally coordinated on a global basis, such studies could use the same study design and protocol to ensure results could be easily compared. Other populations to consider might be consumers in developing nations where pollution and public health threats are serious problems and environmental awareness is low. Previous studies have focused largely on North America, Western Europe, and Australia and New Zealand. Researchers could use other research designs, such as interviews, focus groups, rather than Internet surveys, to investigate drug disposal practices in developing nations where fewer people have access to the Internet.

The EPA has been tracking pharmaceutical contaminants in public water systems (in addition to other chemicals used in commerce, agriculture, etc.) in their “Contaminant Candidate List 4-CCL4,” as part of the EPA’s Federal Register Notices (EPA, 2016). However, these contaminants are not subject to any national regulation or policy aiming at reducing them. Future researchers should target this list of contaminants not only to assess their public health impact, but also to discern the potential synergistic effect that several contaminants may have when reacting with one another in the same medium (e.g., potable water). As noted by the EPA, this synergistic impact is currently unknown, as is its potential impact on human health.

Summary and Conclusion

Ultimately, the main goal of this study was to promote positive social change by using research-based evidence to address the knowledge gap on drug disposal in the general population, and facilitate the development of strategies that aim at the protection of the environment, and minimize human health impact. A range of constituencies, from consumers to health care professionals, health and environmental policymakers, and leaders of pharmaceutical companies could be interested in this study's findings. The greater the knowledge of the environmental and health impact, of recommended disposal practices, and the availability of convenient disposal options, the greater the likelihood that safe disposal methods will be implemented effectively and efficiently.

Although the contamination from prescription drugs is only a small portion of the contaminants that reach and harm the environment, their dissemination remains an issue that has the potential to impact human health. In retrospect, given the analyses conducted in this study, the mitigation to this problem area is not difficult and could be achieved if the appropriate social change were implemented at various levels and across key stakeholders. Pharmaceutical companies should demonstrate their corporate responsibility and focus on the green pharmacy drug development process. Local and federal agencies need to provide the policies, budget, resources, and guidance to facilitate optimal disposal practices thru education and logistical solutions. Finally, consumers need to comply with the prescribed medication regimen to optimize efficacy and lessen the need to discard unused or expired medications.

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Appendix A: Survey Instrument Permission

Fidora, Aldo

From:	DEAN SEEHUSEN <dseehusen@msn.com>
Sent:	Thursday, August 25, 2016 10:53
To:	Fidora, Aldo
Subject:	RE: Greetings ! Attn: Dr. Dean Seehusen / regarding your article on medication disposal (Aug 2006)
Attachments:	Pharmacy Survey.doc

Aldo,

Here is my survey. I grant you permission to use it as is, or modify it to meet your needs. Best of luck to you.

Dean A. Seehusen, MD, MPH
Professor of Family Medicine, USUHS
706-495-5368

Appendix B: Survey

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

Dear Survey Participant,

Information on the goals of this survey as well as your rights as a survey participant are provided on this cover page.

You can start the survey by scrolling down this cover page and clicking on "Next"
Thank you for your support in this research project!

Information on how to dispose of unused or expired prescription medications is often unclear to most people. Several studies have shown how improper disposal may contaminate the water supply, the environment, and impact human health. This survey is part of a doctoral research project at Walden University that aims at studying this issue.

Benefits to you if you participate:

Thanks to your input and involvement it will be possible to better understand the disposal practices in the general population, and to recommend approaches on how to reduce the risk of contaminating the environment. In addition, you will be able to see the current 'official' recommended practices for disposing of unused or expired medications.

Other important points about this survey:

Inclusion criteria: in order to participate in this study you must be 18 years or older, reside in the Northeast U.S., and have used a prescription medication in the past 2 years.

The survey is anonymous and none of the info that you will provide can be linked to you.

Privacy: no one, not even the researcher will know who you are.

You will be asked no personal questions, such as your health status, medications you take, etc.

You were randomly selected by Survey Monkey © Audience to participate in this study. Survey Monkey © will donate $0.50 to a charity of your choice as a 'thank you' for your participation. There is no other compensation.

The researcher has no conflict of interest in the recruitment of survey participants.

Your participation is completely voluntary – you are free to withdraw from this survey at any time,

without any consequence.

There are no physical, financial, or psychological risks in participating in this survey.

The data that you provide will be maintained on a secure, pass-word protected computer system, backed up, and archived for five years.

Completing the survey should take you between 5-8 minutes.

For questions on this research project:

Please contact the researcher at: medsdisposal.research@gmail.com.

For questions on your rights as participant:

Please contact the Walden University representative at irb@mail.waldenu.edu

Walden University's approval number for this study is 03-07-17-0129575 and it expires on March 6, 2018.

Your Consent

If you feel you understand the study well enough to make a decision about it, please indicate your consent by clicking the link below to start the survey. (Please feel free to print or save the consent form for your records)

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

Please answer the following questions

* 1. Are you 18 years of age or older?

- ◯ Yes
- ◯ No

* 2. Have you taken a prescription drug in the past two years?

- ◯ Yes
- ◯ No

* 3. Are you a resident of one of the states in the Northeast region of the United States? (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, and Pennsylvania.)

- Yes
- No

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

DISPOSAL PRACTICES OF PRESCRIPTION MEDICATIONS

INSTRUCTIONS:

FOR EACH QUESTION, PLEASE SELECT YOUR RESPONSE IN THE PROVIDED OPTIONS LIST.

4. What is your most used method for disposing of unused or expired medications?

- **I flush them down the toilet**
- **I rinse them down the sink drain**
- **I return them to the pharmacy, the police station, or another designated take-back location**
- **I mix them with coffee grounds or kitty litter or dirt and then in the trash, using a non-permeable container to avoid spill**
- **I follow the disposal instructions that accompany the medicine**
- **I simply put them in the trash**
- **I store them in my house for possible future use of family or friends (I do not throw them away)**
- **Not applicable. I do not have unused or expired prescription medications to dispose of – I always take my medications as prescribed.**

Other (please specify)

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

5. In your area, is there a designated collection location where you can dispose of your unused or expired medication?

- Yes
- No
- I do not know

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

6. How convenient is it for you to reach the designated disposal location?

- Convenient
- It takes some effort
- Almost impossible to reach
- Not applicable. There is no designated disposal location available in my area.
- Not applicable. I do not know if there is a designated disposal location available in my area.

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

7. Do you believe that improper disposal of medications in the environment could have negative consequences on human health?

- Yes - definitely. [our environment is being poisoned and so is human health]
- Yes - somewhat [however, improper disposal of medications is not the major cause of human disease]
- No - not at all [the quantities of medications that are disposed in the environment are too small to harm human health]
- Not sure - no idea

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

8. To your knowledge, are there any local, or state, or federal guidelines for the proper disposal of unused or expired medications?

- Yes
- No
- I do not know

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

9. Do you know what the official recommended disposal practices are?

Please see below the list of the current official recommended disposal practices. Select "Yes" if you are already aware of one or more of them, otherwise select 'No.'

The current recommended practices include:

- (1) Following instructions on the drug labeling or patient information sheet.
- (2) Returning medicines to a designated take-back pharmacy or other registered collectors (such as the Police station/department).
- (3) Throwing them in the trash after having mixed them with undesirable substances such as coffee grounds, dirt, or kitty litter; ensure that all identifying info has been removed from the label in order to protect your identity and privacy of personal health information.
- (reference: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm)

- Yes
- No

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

10. How often has a health care provider informed you about the proper way to dispose of your unused or expired medications, in the past two years?

- Always
- Often
- Sometimes
- Never

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

11. Are you aware of any promotion material (such as pamphlets, posters, web info) that deal with the proper disposal of unused or expired medications ?

- Yes
- No

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications

Demographic Information

12. What is your gender?

- Female
- Male

13. In what year were you born? (enter 4-digit birth year; for example, 1976)

14. Which race/ethnicity best describes you? (Please choose only one.)

- ◯ **American Indian or Alaskan Native**
- ◯ **Asian / Pacific Islander**
- ◯ **Black or African American**
- ◯ **Hispanic**
- ◯ **White / Caucasian**
- ◯ **I prefer not to answer**
- ◯ **Other**

Other (please specify)

[ ]

15. What is the highest level of education you have completed?

[ ]

16. In which State of the Northeast do you reside?

- ◯ Connecticut
- ◯ Maine
- ◯ Massachusetts
- ◯ New Hampshire
- ◯ Rhode Island
- ◯ Vermont
- ◯ New Jersey
- ◯ New York
- ◯ Pennsylvannia

Appendix C: Pilot Survey

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

Dear Survey Participant,

Information on the goals of this survey as well as your rights as a survey participant are provided on this cover page.

You can start the survey by scrolling down this cover page and clicking on "Next"
Thank you for your support in this research project!

Information on how to dispose of unused or expired prescription medications is often unclear to most people. Several studies have shown how improper disposal may contaminate the water supply, the environment, and impact human health. This survey is part of a doctoral research project at Walden University that aims at studying this issue.

Benefits to you if you participate:

Thanks to your input and involvement it will be possible to better understand the disposal practices in the general population, and to recommend approaches on how to reduce the risk of contaminating the environment. In addition, you will be able to see the current 'official' recommended practices for disposing of unused or expired medications.

Other important points about this survey:

Inclusion criteria: in order to participate in this study you must be 18 years or older, reside in the Northeast U.S., and have used a prescription medication in the past 2 years.

The survey is anonymous and none of the info that you will provide can be linked to you.

Privacy: no one, not even the researcher will know who you are.

You will be asked no personal questions, such as your health status, medications you take, etc.

You were randomly selected by Survey Monkey © Audience to participate in this study. Survey Monkey © will donate $0.50 to a charity of your choice as a 'thank you' for your participation. There is no other compensation.

The researcher has no conflict of interest in the recruitment of survey participants.

Your participation is completely voluntary – you are free to withdraw from this survey at any time,

without any consequence.

There are no physical, financial, or psychological risks in participating in this survey.

The data that you provide will be maintained on a secure, pass-word protected computer system, backed up, and archived for five years.

Completing the survey should take you between 5-8 minutes.

For questions on this research project:

Please contact the researcher at: medsdisposal.research@gmail.com.

For questions on your rights as participant:

Please contact the Walden University representative at irb@mail.waldenu.edu

Walden University's approval number for this study is 03-07-17-0129575 and it expires on March 6, 2018.

Your Consent

If you feel you understand the study well enough to make a decision about it, please indicate your consent by clicking the link below to start the survey. (Please feel free to print or save the consent form for your records)

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

Please answer the following questions

* 1. Are you 18 years of age or older?

◯ Yes

◯ No

* 2. Have you taken a prescription drug in the past two years?

◯ Yes

◯ No

* 3. Are you a resident of one of the states in the Northeast region of the United States? (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, and Pennsylvania.)

- ◯ Yes
- ◯ No

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

Feedback on questions on questions 1-3.

Please provide feedback on the questions on the previous page.

4. Were questions 1 - 3 legible, clear to understand and comprehend?

- ◯ Yes
- ◯ No

5. If your answer was 'No' - please explain why and possibly suggest a better way to ask the question(s).

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

DISPOSAL PRACTICES OF PRESCRIPTION MEDICATIONS

INSTRUCTIONS:

FOR EACH QUESTION, PLEASE:

- **Select the best response in the possible options list, and**
- **Evaluate how legible and easy to understand was the question by selecting a "Yes" or "No." In case you selected "No" - please feel free (optional) to propose an improved way to ask the question in the provided text box.**

6. What is your most used method for disposing of unused or expired medications?

- I flush them down the toilet
- I rinse them down the sink drain
- I return them to the pharmacy or to another designated take-back location
- I mix them with coffee grounds or kitty litter or dirt and then in the trash, using a non-permeable container to avoid spill
- I follow the disposal instructions that accompany the medicine
- I simply put them in the trash
- I store them in my house for possible future use of family or friends (I do not throw them away)

Other (please specify)

7. Was question 6 legible, clear to understand and comprehend?

- Yes
- No

8. If your answer was 'No' - please explain why and possibly suggest a better way to ask the question.

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

9. In your area, is there a designated collection location where you can dispose of your unused or expired medication?

- Yes
- No
- I don't know

10. Was question 9 legible, clear to understand and comprehend?

- Yes
- No

11. If your answer was 'No' - please explain why and possibly suggest a better way to ask the question.

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

12. How convenient is it for you to reach the designated disposal location?

- ◯ **Convenient**
- ◯ **It takes some effort**
- ◯ **Almost impossible to reach**
- ◯ **Not applicable. There is no designated disposal location available in my area.**

13. Was question 12 legible, clear to understand and comprehend?

- ◯ **Yes**
- ◯ **No**

14. If your answer was 'No' - please explain why and possibly suggest a better way to ask the question.

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

15. Do you believe that improper disposal of medications in the environment could have negative consequences on human health?

- ◯ **Yes - definitely. [our environment is being poisoned and so is human health]**
- ◯ **Yes - somewhat [however, improper disposal of medications is not the major cause of human disease]**
- ◯ **No - not at all [the quantities of medications that are disposed in the environment are too small to harm human health]**
- ◯ **Not sure - no idea**

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

18. To your knowledge, are there any local, or state, or federal guidelines for the proper disposal of unused or expired medications?

- ◯ **Yes**
- ◯ **No**

19. Was question 18 legible, clear to understand and comprehend?

- ◯ **Yes**
- ◯ **No**

20. If your answer was 'No' - please explain why and possibly suggest a better way to ask the question.

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

21. Do you know what the current recommended disposal practices are?

Please check the list below, and select "Yes" if you know any of them, otherwise select No.

The current recommended practices include:

- following instructions on the drug labeling or patient information sheet.
- returning medicines to a designated take-back pharmacy or other registered collectors.
- throwing them in the trash after having mixed them with undesirable substances such as coffee grounds, dirt, or kitty litter; ensure that all identifying info has been removed from the label in order to protect your identity and privacy of personal health information.
  (reference: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm)

◯ **Yes**

◯ **No**

22. Was question 21 legible, clear to understand and comprehend?

◯ **Yes**

◯ **No**

23. If your answer was 'No' - please explain why and possibly suggest a better way to ask the question.

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

24. How often has a health care provider informed you about the proper way to dispose of your unused or expired medications, in the past two years?

◯ **Always**

◯ **Often**

◯ **Sometimes**

◯ **Never**

25. Was question 24 legible, clear to understand and comprehend?

- Yes
- No

26. If your answer was 'No' - please explain why and possibly suggest a better way to ask the question.

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

27. Are you aware of any promotion material (such as pamphlets, posters, web info) that deal with the proper disposal of unused or expired medications ?

- Yes
- No

28. Was question 27 legible, clear to understand and comprehend?

- Yes
- No

29. If your answer was 'No' - please explain why and possibly suggest a better way to ask the question.

How do you dispose of Unused or Expired Prescription Medications?
Survey: Disposal Practices of Prescription Medications (Pilot)

Demographic Information

30. What is your gender?

- ◯ **Female**
- ◯ **Male**

31. In what year were you born? (enter 4-digit birth year; for example, 1976)

32. Which race/ethnicity best describes you? (Please choose only one.)

- ◯ **American Indian or Alaskan Native**
- ◯ **Asian / Pacific Islander**
- ◯ **Black or African American**
- ◯ **Hispanic**
- ◯ **White / Caucasian**
- ◯ **I prefer not to answer**

33. What is the highest level of education you have completed?

34. In which State of the Northeast do you reside?

- ◯ Connecticut
- ◯ Maine
- ◯ Massachusetts
- ◯ New Hampshire
- ◯ Rhode Island
- ◯ Vermont
- ◯ New Jersey
- ◯ New York
- ◯ Pennsylvannia

35. Were questions 30 - 34 legible, clear to understand and comprehend?

- ◯ **Yes**
- ◯ **No**

question.