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Enhancing Pharmaceutical Waste Management: Insights from Pharmacists' Perspectives on the Drug Take-Back Program

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Enhancing Pharmaceutical Waste Management: Insights from Pharmacists' Perspectives on the Drug Take-Back Program

A THESIS IN

Health and Well-being Management

Presented to the Faculty of the Rochester Institute of Technology in partial fulfilment of the requirements for the degree

MASTER OF SCIENCE IN HEALTH AND WELL-BEING MANAGEMENT

By

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Title: Enhancing Pharmaceutical Waste Management: Insights from Pharmacists' Perspectives on the Drug Take-Back Program

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I would like to extend my heartfelt gratitude to my advisor, Dr Barbara Lohse, for her support, guidance, and continuous follow-up throughout the entirety of this thesis project. Her expertise and encouragement have been important in shaping this work, and I am profoundly grateful for her mentorship.

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Pharmaceutical waste poses a significant environmental and public health concern globally, with improper disposal leading to adverse ecological and societal impacts. In response to this pressing issue, this thesis adopts a manuscript format to explore the multifaceted dimensions of pharmaceutical waste management.

Chapter 1 serves as the foundational background, introducing the problem of pharmaceutical waste. It delves into the environmental and public health consequences of improper disposal practices, highlighting the need for effective solutions to mitigate these impacts.

Chapter 2 of this thesis comprises a journal manuscript intended for submission to the Journal of the American Pharmacists Association (JAPhA). It follows the format prepared for a journal manuscript, including an abstract, keywords and points, methodology, results, and discussion sections. This manuscript offers insights into the current state of research in the field of pharmaceutical waste management. Through an examination of the strengths and limitations of existing approaches, it contributes to the ongoing discourse on effective strategies in this area..

Chapter 3 extends the discussion by exploring the implications for practice derived from the findings presented in Chapter 2. This section identifies practical recommendations for stakeholders involved in pharmaceutical waste management. Additionally, the thesis includes five appendices, which serve as supplementary materials essential for comprehending the research process as a whole. These appendices encompass diverse aspects such as the literature review, recruitment communication, research instrument, consent form, and survey questionnaire. Moreover, appendix 5 incorporates participants' suggestions for enhancing drug disposal programs, offering insights for future initiatives

Chapter 1 and 3 have a combined bibliography located after the appendices section. Chapter 2, the journal manuscript, includes its standalone bibliography at the end of the chapter.

Chapter 1

BACKGROUND INTRODUCTION

I- Pharmaceutical Waste

Definition

Pharmaceutical waste encompasses a broad spectrum of materials from the healthcare sector. Both, the World Health Organization (WHO) and The Pharmacy and Poisons Board (PPB) define pharmaceutical waste as waste that includes expired, contaminated, split, unused, and no longer needed medicines, along with items containing or contaminated by pharmaceuticals, waste material containing chemotherapeutics, and excess medicine. Three categories of pharmaceutical waste exist: hazardous, non-hazardous, and chemo-pharmaceutical waste. Hazardous waste, which poses risks to the environment and human health, includes Environmental Protection Agency (EPA)-coded pharmaceutical waste with toxic, reactive and ignitable properties. Non-hazardous waste encompasses expired medicines, manufacturer samples, loose pills, damaged or contaminated patient medication, and their packaging.[1]

In 2014, the WHO released guidelines, emphasizing effective healthcare waste disposal defining pharmaceutical waste as a spectrum of expired, unused, contaminated drugs and vaccines. It includes medications that have surpassed their expiration dates, those left unconsumed due to changes in dosage or treatment discontinuation, and substances that have been compromised in quality or safety. This category extends beyond medications intended for human use to include veterinary pharmaceuticals.[2]

The life cycle of pharmaceutical products involves numerous stages, from manufacturing to patient use, each contributing to the generation of waste. Pharmaceutical waste involves not only the materials themselves, but the complex processes and considerations related to their disposal. Understanding the multifaceted nature of pharmaceutical waste is essential for developing effective strategies and initiatives aimed at minimizing its environmental impact and safeguarding public health.

Scope of Issue

In an era where global pharmaceutical spending has surged from $887 billion in 2010 to a staggering $1.27 trillion in 2020, the implications of pharmaceutical waste on our environment and public health cannot be underestimated.[3] Pharmaceutical waste has emerged as a pressing concern with far-reaching consequences.[1] This burgeoning issue calls for urgent attention and a proactive approach.

The impact of the pandemic on healthcare waste cannot be underestimated. During the peak of the COVID-19 pandemic, the United States witnessed an astounding increase in healthcare waste generation, soaring from 5 million tons annually before the pandemic to an astonishing 2.5 million tons per month. This drastic escalation places unprecedented stress on waste management systems, further exacerbating the problem.[4]The drastic increase in the number of regions, countries, and people infected with SARS-CoV-2 led to global problems related to proper healthcare waste management.[5]

Moreover, the disposal of regulated medical waste, including pharmaceuticals, is 119% more expensive per pound than regular trash.[6] It's a financial burden that impacts healthcare institutions and, by extension, the patients they serve. However, the cost is just one facet of the problem. As global consciousness shifts towards environmental sustainability and ecological

preservation, the environmental impact of pharmaceutical waste has emerged as a paramount concern.[7]

In today's modern healthcare landscape, the significance of medications cannot be overstated. They serve as vital agents for treating medical conditions in both human and veterinary medicine. However, their impact extends far beyond the realms of direct patient care. Residues of active pharmaceutical ingredients found in medications can leave a significant environmental footprint, particularly when medications are improperly discarded.[8] The accumulation of these unwanted medications in our society poses a global concern that goes unnoticed all too often. The consequences of this improper disposal of unwanted medications ripple through our ecosystems and can severely affect both human health and the environment.[5] The primary entry points for active pharmaceutical ingredients into the environment include excretion by patients, bathing, and, most alarmingly, the careless disposal of unwanted medications.[9] they can accumulate in our landfills and contaminate our wastewater, raising alarming concerns about their adverse effects on aquatic organisms and, consequently, on humans who may ingest these contaminated resources.[10] Even at minute concentrations in drinking water, these contaminants can pose risks to sensitive populations, including developing fetuses.[11] Furthermore, the improper handling of unwanted medications can lead to the poisoning of individuals and pets, drug abuse, and addiction, adding another layer of complexity to this already multifaceted issue.[12]

The accumulation of unused, expired, or contaminated medications is influenced by various factors, including the practices of manufacturers, distributors, prescribers, dispensers, and the patients themselves. The reasons for having unwanted medications at home are diverse, encompassing changes in dosage, discontinuation of treatment due to side effects, and even

death.[10] However, the environmental consequences of active pharmaceutical ingredients APIs present in wastewater and landfills are the central concern in the context of unwanted medications disposal.[11]

The improper disposal of pharmaceutical waste has escalated into a grave environmental crisis over the last three decades. The global surge in medical waste generation, fueled by population growth and the proliferation of healthcare facilities, has amplified the problem. Dumping medical waste in landfills without proper segregation poses a significant threat. Harmful microorganisms, hazardous chemicals, and pharmaceuticals find their way into the soil and groundwater, resulting in widespread contamination with severe implications for both the environment and public health.[11]

Environmental concerns

One of the major concerns is the environmental contamination caused by pharmaceutical waste. In the USA, a society where nearly 70 percent of people use prescription drugs, and the pharmaceutical industry invests billions in developing new products, a significant amount of pharmaceutical wastewater is generated annually when unused or expired pharmaceuticals are carelessly disposed of into sewage systems.[12] These potent substances infiltrate various environmental niches, including groundwater, surface water, and soil. The range of pharmaceuticals detected in environmental samples encompasses antibiotics, hormones, non-steroidal anti-inflammatory drugs, beta blockers, lipid regulators, and anti-depressants.[13]

To address these concerns, researchers from the United States Geological Survey (USGS) conducted a study in early 2014, examining 59 headstreams in the US Piedmont ecoregion, all affected by wastewater treatment facility (WWTF) effluent.[4] These facilities play a crucial role in purifying wastewater before releasing it into the environment, with primary treatment removing

about 60 percent of contaminants. However, some contaminants inevitably remain in the effluent, making WWTFs a significant source of pharmaceutical waste entering stream environments and contributing to freshwater contamination. The study revealed a shocking presence of 108 pharmaceutical compounds, with 68 being widespread across all sites. Notably, medications like metformin and caffeine were detected in alarming percentages.[14]

Health concerns:

Wantonly disposing of unused or expired pharmaceuticals into sewage systems leads to the infiltration of these potent substances into various environmental reservoirs, including groundwater, surface water, and soil. The contaminated pharmaceutical waste samples would include antibiotics, hormones, non-steroidal anti-inflammatory drugs, beta blockers, lipid regulators, and anti-depressants.[15]

1.Health Concerns of Pharmaceutical Waste on Humans:

Improper disposal of pharmaceutical waste poses significant health risks to humans. Although, part of the water treatment process involves removing contaminants, including pharmaceutical waste, it is not always entirely effective in eliminating all traces of these substances. The treatment process typically targets common pollutants but may not specifically target pharmaceutical compounds due to their diverse chemical compositions and low concentrations. Additionally, the sheer volume and variety of pharmaceuticals being consumed and disposed of make it challenging for water treatment facilities to adequately remove all traces of these substances. Therefore, despite efforts in water treatment, pharmaceuticals can still persist in water sources and contaminate drinking water supplies, highlighting the inadequacy of current disposal methods and the need for more comprehensive solutions.[16] Exposure to these substances can lead to a range of health issues, including disruptions to the endocrine system,

antibiotic resistance, and potential harm to vital organs. Certain populations, such as developing fetuses, are particularly vulnerable, emphasizing the need for stringent measures to prevent pharmaceutical waste from infiltrating water supplies. Even at minute concentrations, these contaminants can have adverse effects on human health. Additionally, the improper handling of unwanted medications, if left accessible in households, can lead to accidental ingestions, resulting in poisoning and potential overdoses.[17] More than half of all prescription drug misuse begins when individuals consume medication not prescribed for them; usually the drugs are prescribed for a friend or family member. About two-thirds of teens who misused prescription drugs reported getting them from friends and family, often without their knowledge.[15] Furthermore, pharmaceutical waste may contribute to the development of antibiotic resistance, posing a serious threat to public health by diminishing the effectiveness of critical medications.[15]

2.Health Concerns of Pharmaceutical Waste on Animals:

The presence of pharmaceutical residues in water sources can lead to acute and chronic health issues in aquatic organisms, affecting their behavior, reproduction, and overall well-being. For instance, certain medications, when introduced into ecosystems, have been linked to reproductive disorders in fish and amphibians.[18] In terrestrial environments, the exposure of animals to pharmaceutical waste may occur indirectly through contaminated food and water sources. Notably, pharmaceuticals like diclofenac have had catastrophic effects on vulture populations, causing widespread kidney failure.[19] The potential for bioaccumulation and biomagnification of pharmaceutical residues in the food chain raises concerns about the long-term impact on animals and, subsequently, on the ecosystems in which they reside. This includes behavioral alterations, reproductive disorders, and the development of antibiotic resistance in certain bacterial strains.[20] The ecological repercussions extend beyond individual animals to

disrupt entire ecosystems, emphasizing the interconnectedness of environmental health and the well-being of animal populations. As such, addressing pharmaceutical waste is crucial not only for human health but also for the preservation of biodiversity and the integrity of ecosystems. Additionally, antihistamines containing fexofenadine, known to impair aquatic insect species' flight responses, pose threats to invertebrate communities.[19]

Studies have shown that common drugs, such as antidepressants, birth control, and beta-blockers, can affect spawning and fertility among fish living in contaminated waters.[20] There is additional concern that long-term exposure to low concentrations of antibiotics may result in the evolution of antibiotic-resistant bacteria.

Overall, the health concerns for both humans and animals underscore the critical need for proper pharmaceutical waste management to safeguard public health and ecological balance.

II- Problem Solutions

World Health Organization (WHO) Recommendations:

In response to these challenges, the World Health Organization (WHO) issued crucial recommendations pertaining to the segregation and collection of healthcare waste. These recommendations include color-coding waste containers: designating general waste containers as black, marking sharp, infectious, and pathological waste containers as yellow, and assigning brown for chemical and pharmaceutical waste containers. These guidelines are a significant step towards better management of pharmaceutical waste.[1]

Conventional treatment.

The conventional methods employed for managing medical waste entail significant risks. Steam-based treatments, encompassing autoclaving, microwaving, and frictional heat treatments, proficiently disinfect highly infectious and sharp waste through moist heat and steam.

Conversely, pharmaceutical waste is predominantly addressed through incineration. However, when conducted inadequately or in subpar facilities, incineration emits toxic substances into the environment. This poses potential health hazards, as carcinogenic substances like dioxins and furans are released during the incineration process, especially when operated at suboptimal temperatures.[4] Additionally, emissions contain toxic metals like mercury, lead, arsenic, and cadmium, posing substantial risks to the immune and neurological systems, along with vital organs such as the kidneys, brain, and lungs. The ashes resulting from the incineration of hazardous medical waste are similarly hazardous.[21]

Improper incineration or landfill disposal of pharmaceutical waste can culminate in leachate materials penetrating the soil, contaminating crops, surface water, and groundwater resources, posing risks to human health when consumed. Consequently, it is imperative to explore alternative solutions, such as ozone treatment, alkaline hydrolysis, composting, and vermicomposting, to mitigate the dangers associated with pharmaceutical waste .[1,22]

Alternative solutions

In the quest to revolutionize pharmaceutical waste management, alternative solutions like ozone treatment, alkaline hydrolysis, composting, and vermicomposting are being rigorously researched. Although these methods show promise in offering more environmentally friendly disposal options compared to traditional incineration, they are still under ongoing investigation and require further research and validation.[23]

Amidst these innovations, a focus lies on minimizing pharmaceutical waste generation at its source. By implementing strategies that focus on minimizing unnecessary drug production, optimizing medication quantities, and promoting responsible medication use, the overall volume of pharmaceutical waste can be significantly reduced. This approach aligns with the broader

goals of sustainability, emphasizing the importance of prevention and reduction alongside innovative waste management techniques. Together, these alternative solutions and waste reduction strategies form a comprehensive framework to mitigate the environmental impact of pharmaceutical waste.

III-The Drug Take-Back Program

Drug Take-Back Program Overview:

The importance of properly disposing of unwanted medications has gained international recognition, and various countries have initiated programs to address this pressing concern and minimize the waste generated. In the United States, the Drug Take-Back program stands out as a notable effort to combat the environmental and health challenges associated with the disposal of medications.[24] This program seeks to encourage the responsible disposal of unwanted medications, thereby reducing the negative impact on the environment and human health.[15]

The Drug Take-Back Program is a proactive initiative aimed at providing a safe and responsible means for individuals to dispose of unused or expired medications. This program helps to prevent the misuse, abuse, or accidental ingestion of pharmaceuticals, and reduce the environmental impact associated with improper disposal. The program involves authorized collection sites or events where the public can safely and securely drop off their medications.

Initiation and Legislation:

The Drug Take-Back Program in the United States gained significant traction with the introduction of various state-level legislations.[25] It is part of a broader effort to address the environmental and health challenges linked to pharmaceutical waste. The federal government also plays a role in supporting and regulating the program. As of November 2021, 26 states have legislated, and four states have administratively enacted drug take-back programs.[26]

In an effort to keep unused pharmaceuticals from being misused, the New York State legislature required chain pharmacies and nonresident pharmacies (such as mail-order or internet-based pharmacies that fill prescriptions for delivery to New York residents) to provide pharmaceutical collection to their customers. Chain pharmacies, defined as those with 10 or more locations, could offer collection through collection receptacles, mail-back envelopes, or another option approved by the DEA. Nonresident pharmacies would have been required to offer mail-back envelopes to customers. Collection would have been free of charge to consumers, except in the case of mail-back envelopes, which could cost up to $2. [27]

In the past, best practices encouraged households and healthcare facilities to flush unused or expired drugs. However, there has been a general shift away from recommending flushing as a disposal method of unwanted and expired pharmaceuticals, including in New York State. The U.S. Food and Drug Administration (FDA) now recognizes that drug disposal via a take-back program or a DEA-authorized collector is the safest disposal method for both humans and the environment, and only recommends flushing for extremely potent pharmaceuticals or if preferred methods are not readily available.[14] Despite this, little has been done at the federal level to ensure that take-back disposal methods are easily accessible.[26]

Stakeholders and Their Roles:

The Drug Take-Back Program is a collaborative effort involving multiple stakeholders. As identified in their legislations, the key participants include:[27]

1. Pharmacists: They play an important role in educating patients, collecting medications, ensuring compliance with regulations, and advocating for the program. They serve as intermediaries between patients and proper disposal methods.

2. Patients and the Public: They actively participate by disposing of their unused or expired medications through authorized collection sites or events, contributing to the program's success. Individuals can lawfully dispose of medications prescribed for themselves, dependents, or those under their care, including those of deceased persons.
3. Pharmaceutical Manufacturers, Distributors, and Healthcare Facilities: The support of pharmaceutical companies bear responsibility throughout the product life cycle, from manufacturing to clinical use. Collaborative efforts are essential to minimize pharmaceutical waste and promote proper disposal. Pharmaceutical companies can contribute by optimizing medication quantities, designing eco-friendly pharmaceuticals, and supporting responsible disposal methods. Implementing Extended Producer Responsibility (EPR) places the focus on manufacturers for safe product disposal, potentially involving program funding.[28]
4. Drug Enforcement Administration (DEA): Authorizes collectors of controlled substances and ensures compliance with federal regulations, adding regulatory oversight to the program. State-run Drug Take-Back programs that handle controlled substances require coordination with DEA-authorized collectors. Various entities, including pharmacies and drug manufacturers, can acquire DEA authorization for this purpose.[27]
5. State and Local Governments: They provide regulatory oversight, ensuring the program aligns with local, state, and federal regulations.[26]
6. Environmental Agencies: They work to protect the environment from pharmaceutical waste contamination, collaborating with other stakeholders to ensure proper disposal.

7. Community Organizations, NGOs, Law Enforcement, and Legislators**:** They engage in collective efforts to promote safe medication disposal, raising awareness and contributing to the success of the program.[26]

Pharmacist's Role:

Pharmacists play a crucial role in the Drug Take-Back Program, as outlined in New York state regulations under Section 60-4.4. This section emphasized that any pharmacy in the state must voluntarily participate in an authorized drug take back program, even if not mandated by Article 2-B of the Public Health Law, is included. Pharmacists engaged in these programs are required to be properly registered under Education Law Section 6808.[26] If a pharmacy maintains an onsite collection receptacle, they should secure authorization from the DEA to be a collector.[27] Within the regulatory framework of this initiative, pharmacists occupy a substantial portion, carrying out various responsibilities that contribute significantly to the program's objectives. Pharmacists are not only responsible for educating the public about the importance of proper unwanted medications disposal but also play an active role in the collection and safe disposal of these unwanted medications. Pharmacists serve as key intermediaries between patients and proper disposal methods, offering a critical link in the chain of responsibility.[27]

Their responsibilities include:

Collection and Storage: Pharmacists often set up collection points within their pharmacies where individuals can safely drop off their expired or unused medications. They ensure secure storage until proper disposal.

Education and Awareness: Pharmacists educate patients and the community about the importance of safe medication disposal, providing guidance on which medications can be returned and how to prepare them for disposal.[28]

Compliance with Regulations: Pharmacists ensure their involvement complies with local, state, and federal regulations, adhering to guidelines on handling and disposing of collected medications.

Promotion of Responsible Medication Use: Beyond participating in the Drug Take-Back Program, pharmacists have a broader role in promoting responsible medication use to minimize waste generation.

Supporting Green Pharmacy Initiatives: Pharmacists can contribute to "green pharmacy" initiatives by advocating for sustainable medication use, reducing adverse effects, and designing pharmaceuticals for minimal environmental impact.

Challenges and Effectiveness:

Challenges in the Drug Take-Back Program include limited public awareness, logistical issues in organizing collection events, and ensuring widespread participation.[29] Studies evaluating the program's effectiveness highlight its positive impact on reducing the quantity of pharmaceuticals entering the environment and preventing accidental poisonings.

Some key points and general findings related to drug take-back programs and pharmaceutical waste management include:

1. Reduction of Environmental Contamination: Studies emphasize that Drug Take-Back programs contribute significantly to reducing the quantity of pharmaceuticals entering the environment. Proper disposal through these programs prevents the flushing or discarding of medications, which can lead to water contamination and harm to aquatic life.[27]
2. Prevention of Accidental Poisoning and Misuse: Proper disposal of medications through drug take-back programs helps prevent accidental poisonings, particularly in

households with children or individuals with substance use disorders. By providing a safe and secure method for the public to dispose of their unwanted medications, the programs reduce the risk of unintended exposure.[28]

3. Public Health Impact: Specific studies focus on different aspects of pharmaceutical waste management; they collectively highlight the positive impact of drug take-back programs on public health. These programs contribute to minimizing the presence of pharmaceuticals in water sources, protecting vulnerable populations, and promoting responsible medication disposal.[29]
4. Stakeholder Collaboration: Research often underscores the importance of collaborative efforts involving pharmacists, healthcare facilities, law enforcement, government agencies, and the public in the success of drug take-back programs. Stakeholder engagement and awareness campaigns are integral to the programs' effectiveness.[27]

Several states, such as Arizona, Missouri, New York, Oregon, South Carolina, Vermont, and Washington, have enacted statutes or regulations requiring the promotion of public awareness about Drug Take-Back and disposal programs.[26]

The success of the program depends on continuous efforts to raise awareness, enhance accessibility, and engage various stakeholders in promoting safe medication disposal practices. Ongoing research and assessments are crucial to refining and improving the program's efficacy in pharmaceutical waste management.

IV-Research Objectives

Expanding upon existing studies and regulations that emphasize the significance of the pharmacist's role, this thesis undertakes a nuanced exploration. Herein, the aim is to unravel the

personal perceptions of pharmacists regarding their involvement in the Drug Take-Back Program. The assumption is that, given their expertise and central position in medication management, pharmacists hold an important role. This study seeks to uncover their views on the importance of their participation, their attitudes and beliefs concerning the program's effectiveness, and the value they ascribe to it as a service to the community.
Simultaneously, the thesis is guided by specific objectives:

1. To assess the awareness level among pharmacists regarding their participation in the Drug Take-Back Program (DTBP).
2. To investigate the attitudes, beliefs, and perceived barriers that influence the pharmacist's role in the DTBP.
3. To identify recommendations from pharmacists for improving the accessibility and effectiveness of the DTBP.

We endeavor to understand the challenges pharmacists encounter in the implementation of this program and gather their suggestions for refining and advancing its impact. In this way, the thesis not only aims to provide in-depth perspective on the pharmacist's role in pharmaceutical waste management but also aligns with clear objectives that will guide the exploration of their perceptions and contribute valuable insights to the ongoing enhancement of the Drug Take-Back Program.

Chapter 2. JOURNAL MANUSCRIPT

TITLE: Enhancing Pharmaceutical Waste Management: Insights from Pharmacists' Perspectives on the Drug Take-Back Program.

ABSTRACT:

Pharmaceutical waste management is essential for mitigating environmental risks associated with improper medication disposal, with pharmacists playing a pivotal role in drug take-back programs (DTBPs). However, there is limited understanding of pharmacists' engagement, perceptions, and challenges within these initiatives. This study aimed to address this gap by investigating these aspects among licensed pharmacists in the United States.

A mixed-methods survey was distributed to 2200 pharmacists, yielding 81 responses (3.7% response rate). The findings revealed that familiarity with DTBPs did not significantly differ by state or practice setting, but positively correlated with experience and perceived effectiveness. Interestingly, on-the-job learning emerged as the primary training method, with no significant impact on program effectiveness.

Moreover, logistical challenges, particularly pronounced in New York, were associated with lower perceived effectiveness. Qualitative analysis provided deeper insights into determinants of program effectiveness and reasons for non-participation. These insights informed recommendations focused on enhancing public awareness, education, and streamlining processes to improve program participation and effectiveness.

The study underscores the importance of targeted educational efforts, logistical support, and interdisciplinary collaboration in promoting responsible medication disposal practices. Despite limitations such as sample size and geographic scope, the findings offer valuable insights for future research and policy initiatives aimed at optimizing pharmaceutical waste management efforts.

KEYWORDS:

- Pharmaceutical waste
- Pharmacist
- Drug Take-Back Program
- Sustainability

KEY POINTS:

What was already known:

- The importance of pharmacist involvement in medication disposal initiatives.
- The existence and significance of Drug Take Back Programs in managing pharmaceutical waste.
- Growing awareness about the need for sustainable practices in medication disposal.

What this study adds:

- Insights into pharmacist perspectives on pharmaceutical waste management.
- Exploration of the effectiveness and challenges of Drug Take Back Programs from a pharmacist standpoint.
- Recommendations for enhancing sustainability in medication disposal practices.
- Identification of key factors influencing pharmacist engagement in drug disposal programs.

INTRODUCTION

Pharmaceutical waste, a complex challenge within the healthcare sector, encompasses a wide array of materials, including expired, unused, and contaminated medicines.[1] The surge in global pharmaceutical spending, reaching a staggering $1.27 trillion in 2020, underscores the

pressing environmental and public health concerns associated with pharmaceutical waste[2]. The COVID-19 pandemic has further intensified the issue, leading to a drastic increase in healthcare waste generation, reaching 2.5 million tons per month in the United States alone.[3]

The World Health Organization (WHO) has provided guidelines for safe pharmaceutical waste disposal, emphasizing the importance of effective healthcare waste management.[1,4] The life cycle of pharmaceutical products, from manufacturing to patient use, contributes to waste generation, necessitating a comprehensive understanding of the issue for developing impactful strategies.[5]

In an era where environmental sustainability is a global priority, the environmental impact of pharmaceutical waste has become a paramount concern. The improper disposal of pharmaceuticals, including active pharmaceutical ingredients (APIs), leads to contamination of landfills and wastewater, posing risks to aquatic organisms and, consequently, human health.[6] The accumulation of unused, expired, or contaminated medications is influenced by various factors, ranging from manufacturing practices to patient behaviors, creating a multifaceted issue. The escalating problem of pharmaceutical waste has become a grave environmental crisis over the last three decades. The surge in medical waste generation, driven by population growth and the proliferation of healthcare facilities, amplifies the threat.[7] Improper disposal methods, such as dumping medical waste in landfills without proper segregation, pose significant risks, contaminating soil and groundwater with harmful microorganisms, hazardous chemicals, and pharmaceuticals.[8]

Environmental contamination is a major concern, particularly in the United States, where nearly 70 percent of the population uses prescription drugs.[2] The fate of pharmaceutical wastewater generated annually raises questions about its impact on groundwater, surface water,

and soil. Studies conducted by the United States Geological Survey (USGS) in 2014 revealed the presence of 108 pharmaceutical compounds in headstreams affected by wastewater treatment facility effluent. This contamination includes medications like metformin, related to nicotine, and caffeine, highlighting the extent of the issue.[9]

Beyond environmental concerns, pharmaceutical waste poses significant health risks. Improper disposal can lead to the contamination of drinking water supplies with antibiotics, hormones, anti-inflammatory drugs, beta blockers, and antidepressants.[8] The exposure to these substances can result in disruptions to the endocrine system, antibiotic resistance, and potential harm to vital organs.[10] Vulnerable populations, such as developing fetuses, are particularly at risk, emphasizing the need for stringent measures to prevent pharmaceutical waste from infiltrating water supplies.[11]

Pharmaceutical waste also affects animal populations, both aquatic and terrestrial, leading to acute and chronic health issues.[12] The presence of pharmaceutical residues in water sources has been linked to reproductive disorders in fish and amphibians.[13] In terrestrial environments, animals may be exposed indirectly through contaminated food and water sources, contributing to behavioral alterations, reproductive disorders, and antibiotic resistance.[14]

Addressing the challenges posed by pharmaceutical waste requires comprehensive solutions. The World Health Organization (WHO) has issued crucial recommendations for the segregation and collection of healthcare waste, including color-coding waste containers to designate different types of waste.[15] Conventional treatment methods, such as incineration, pose environmental and health risks, necessitating exploration of alternative solutions like ozone treatment, alkaline hydrolysis, composting, and vermicomposting.[16]

Amidst these innovations, a significant focus lies on minimizing pharmaceutical waste generation at its source. Strategies that emphasize reducing unnecessary drug production, optimizing medication quantities, and promoting responsible medication use can significantly contribute to waste reduction. This approach aligns with broader sustainability goals, emphasizing prevention and reduction alongside innovative waste management techniques.[17] The Drug Take-Back Program emerges as a proactive initiative to address the challenges of pharmaceutical waste. In the United States, this program aims to encourage the responsible disposal of unwanted medications, reducing environmental impact and health risks. The program involves authorized collection sites or events where the public can safely drop off their medications.[18]

Initiated through state-level legislations, the Drug Take-Back Program has gained traction, with federal support and regulation. As outlined in the legislation, pharmacists play a crucial role in the program, serving as intermediaries between patients and proper disposal methods.[19] Their responsibilities include educating the public, collecting, and safely storing medications, ensuring compliance with regulations, and promoting responsible medication use.[20] Despite the program's positive impact, challenges persist, including limited public awareness and logistical issues in organizing collection events. Evaluating its effectiveness reveals reduction in environmental contamination and prevention of accidental poisonings.[21] Stakeholder collaboration involving pharmacists, healthcare facilities, law enforcement, government agencies, and the public is crucial for the program's success.[22]

The focus of this research is to delve into the perspectives of pharmacists regarding their role in the Drug Take-Back Program. Building upon existing studies and regulations, this thesis aims to unravel pharmacists' views on the importance of their participation, their attitudes and

beliefs concerning the program's effectiveness, and the value they ascribe to it as a service to the community.

Simultaneously, the research is guided by specific objectives:

1. To assess the awareness level among pharmacists regarding their participation in the Drug Take-Back Program (DTBP).
2. To investigate the attitudes, beliefs, and perceived barriers that influence the pharmacist's role in the DTBP.
3. To identify recommendations from pharmacists for improving the accessibility and effectiveness of the DTBP.

METHODOLOGY

Study Design.

The study employed a cross-sectional approach online questionnaire with both quantitative and qualitative components.

Participant Recruitment.

To obtain a sample of participants for this study, a convenience targeted sampling method was employed. The primary focus was on securing participation from licensed pharmacists in New York, with an extension of the recruitment effort to include pharmacists from Ohio and other states. Although this approach may not provide a fully representative or diverse national sample, it was strategically chosen to gather insights from pharmacists in targeted regions relevant to the study objectives where partnerships with key institutions were established to facilitate survey promotion and outreach.

Contact was made with the director of experiential education and continuing professional education at Wegmans School of Pharmacy in St. John Fisher University to seek support for survey dissemination among pharmacists. The Director expressed interest contingent upon the survey's quality and ethical approval. Following the approval from the Institutional Review Board (IRB) for Human Subject Research, the survey link was shared via email with numerous licensed pharmacists in New York on November 10, 2023 (Appendix 2: Recruitment Communication). The survey targeted members of the Board of Pharmacy in New York State (NYS)

The survey was distributed via email to the entire membership list in NYS. The exact number of emails sent out corresponds to the total membership count, which is estimated at 2000 licensed pharmacists. Each member received a personalized email invitation containing a link to the survey.

Qualtrics-XM was used to design, distribute, and collect responses for surveys. The platform ensured anonymity and confidentiality for participants. To enhance response rates, reminder emails were sent 15 days after the initial distribution to encourage participation. 2200 individuals were targeted for this study. Specifically, 2000 emails were sent to members in NYS, facilitated by the database in the NYS association with the assistance of the director of experiential education and continuing professional education at St. John Fisher University's Wegmans School of Pharmacy. Additionally, around 200 emails were sent to Ohio pharmacists, sourced from the Ohio Board of Pharmacy to selected pharmacists implementing the DTBP.

Data Collection.

Instruments

Data were collected with a survey developed specifically for this study (Appendix 4). The survey comprised 16 questions organized into 8 sections that addressed the following factors:

1. **Participants' Profiles:** This included questions about location, work setting, age, years of experience, and professional role.
2. **Program Familiarity:** Participants' involvement in the program, agreement with the program's societal value rated on a 5-point scale where 1 represents 'not familiar at all' and 5 represents 'extremely familiar'.
3. **Current Participation Status and Reasons for Non-participation.**
4. **Perceived Role Importance.**
5. **Training Experiences:** Focused on the types of training received and the adequacy of training.
6. **Encountered Challenges:** Participants were invited to provide detailed descriptions of the challenges faced during their participation in the Drug Take Back program.
7. **Perceived Effectiveness:** Participants were asked to reflect on the perceived effectiveness of the Drug Take-Back program and factors contributing to its effectiveness.
8. **Suggestions for Enhancement:** The questionnaire concluded with an open-ended query for participants to share suggestions or recommendations.

In designing the survey instrument, a careful arrangement of demographic inquiries helped to enhance participant engagement and survey completion. Questions pertaining to location and work setting were positioned at the beginning to establish a contextual foundation for subsequent inquiries, fostering participant familiarity and a smooth transition into the substantive aspects of the Drug Take-Back program. To maintain a logical flow and prevent potential survey fatigue, detailed information related to participants' individual profiles, including age, years of

experience, and professional role, was placed towards the end of the questionnaire. This approach allowed participants to initially focus on substantive elements before providing more personal details towards the conclusion of their survey experience.

The 27-item Implementation Process Assessment Tool (IPAT)[23] guided development of the study survey. The IPAT is recognized as a feasible instrument for investigating the implementation process from the perspective of those making the change, these questions focused on understanding the reasons behind the respondent's decisions or situations. Aligned with IPAT constructs, the participants provided insights into individual and collective readiness, perceived challenges, and potential stages of change (Appendix 3: IPAT).

Additionally, some items of the questionnaire were developed based on identified needs in the literature regarding views and perceptions of veterinarians discussing their attitudes towards pharmaceutical waste disposal.[24]

Survey items are mapped to the rationale for inclusion in Table 1 (Appendix 4: Consent form, Survey questionnaire, and survey items.)

Survey Administration

The survey underwent a two-week pilot testing phase to assess face validity. Participants were purposefully selected to ensure comprehensive feedback, with active engagement from academic pharmacists based in Lebanon, particularly those working in universities and possessing expertise in the field of pharmaceutical waste. They helped in pilot test surveys, providing valuable insights.

The questionnaire underwent an iterative refinement process through collaborative efforts with research experts.

Additionally, individuals with experience in research were involved in the pilot testing phase and verifying the wording and ease of handling the questionnaire. The diverse perspectives collected during this phase facilitated the refinement of the quality of the questionnaire, ensuring its appropriateness for the targeted audience.

Qualtrics-XM platform was used to disseminate the survey, which remained open from November 10, 2023, until the end of the month.. A follow-up email was sent on November 28, 2023, to encourage participation.

Data Analysis

Data were analyzed with IBM SPSS software version 28 (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp)

. **1.Descriptive Statistics**

Descriptive statistics provided an overview of the participants' characteristics and responses. Using measures of central tendency (mean) and variability (standard deviation) for continuous variables such as age and years of experience, as well as frequency distributions for categorical variables such as familiarity with the Drug Take-Back Program (DTBP) and perceptions of its effectiveness.

2.Group Comparisons

Independent samples t-tests and chi-square tests were conducted to examine differences in participants' familiarity with the DTBP and perceptions of its effectiveness based on their geographic location. This analysis aimed to assess whether there were significant variations between participants working in New York State and those in other states.

Crosstabulations and chi-square tests were used to explore differences in program familiarity and effectiveness across different pharmacy practice settings, including independent community

pharmacies, corporate chain pharmacies, and hospital/clinic pharmacies. This analysis sought to determine whether perceptions of the DTBP varied based on participants' professional contexts.

3.Correlation Analyses

Pearson correlation coefficients were computed to explore the relationships between continuous variables e.g., participants' familiarity with the DTBP, perceptions of its effectiveness, and demographic variables such as age and years of experience as a pharmacist. Additionally, partial correlations were conducted to assess the associations while controlling for continuous variables such as age and years of experience.

4.Challenges Faced by Participants

An additional variable was created by counting the number of challenges reported by participants in implementing the DTBP. Descriptive statistics summarized the frequency and distribution of these challenges, and independent samples t-tests were performed to examine differences in number of reported challenges between participants working in New York State and those in other states.

5.Qualitative Analysis for Open-ended Questions:

The qualitative dimension of the study involved analyzing open-ended responses provided by participants to gain insights into challenges faced and suggestions for improving pharmaceutical waste management and Drug Take-Back programs.

Thematic analysis was employed to systematically identify recurring themes and patterns in the qualitative data. Through this process, open-ended responses were categorized and organized into themes,. Furthermore, open-ended responses were also examined to extract common themes related to factors contributing to program effectiveness.

By integrating qualitative insights with quantitative data, a more comprehensive understanding of the factors influencing program effectiveness was achieved.

RESULTS

1.Participant Information:

The study enrolled 81 participants comprising pharmacists from various practice settings and regions across the United States, with a majority from New York (n=55), followed by Ohio (n=15) and other states. Participants represented diverse practice settings, including independent community pharmacies (n=8; 9.9%), corporate chain pharmacies (n=15; 18.5%), hospital/clinic pharmacies (n=43; 53%), and other settings (n=15;18.5%). Average age was 37.5 years old (SD = 9.36), with an experience range of 2 to 43 years and a mean of 17.19 years (SD = 10.83). More than half (55.6%) reported holding managerial roles in their pharmacy practices. The participation details are delineated in Table 1.

The overall mean results indicate that participants in the study exhibit varying levels of familiarity with the objectives of the Drug Take-Back program, with an average score of 1.86 out of 2, suggesting a generally high level of familiarity among respondents. When assessing the perceived importance of the pharmacist's role in the program, participants reported a mean score of 4.11 out of 5, indicating a strong belief in the significance of pharmacists' involvement. Furthermore, participants expressed agreement with the statement that participation in the Drug Take-Back program is a valuable service for the community, as evidenced by a mean score of 2.00 out of 2. However, their perceptions of the current program's effectiveness in achieving its objectives were slightly lower, with an average score of 1.91 out of 2, suggesting room for improvement. These findings collectively underscore the participants' recognition of the

importance of their role in the Drug Take-Back program and the value it brings to the community, despite some reservations regarding the program's current effectiveness.

2. Perceived Familiarity of pharmacists with the Drug Take Back Program

Familiarity with the DTBP did not differ between pharmacists in New York State and pharmacist in other states (mean=1.85; SD= 0.36). No statistically significant difference was found between the two geographic groups ($t = 0.49$, $p = 0.63$). Moreover, the difference in DTBP familiarity across different practice settings was not significantly different ($\chi^2 = 1.573$, $df = 2$, $p = .455$).

Years of experience and familiarity with DTBP objectives were significantly and positively correlated ($r = .97$, $p < .001$). However, years of experience was not correlated with perceptions of program effectiveness ($r = -.129$, $p = .403$; $n=44$). Notably, familiarity with DTBP objectives was positively correlated with perceptions of program effectiveness ($r = .311$, $p = .04$), a robust relationship even when controlling for age ($r = .39$, $p = .01$; $n = 41$).

3.Perceived Effectiveness of the Drug Take Back Program.

No significant difference in perceived effectiveness was observed across practice settings ($\chi^2 = 1.517$, $df = 2$, $p = .468$). Among participants familiar with DTBP, the majority perceived it as effective ($n = 40$), with a significant positive association between familiarity and perceived effectiveness ($r = .311$, $p = .040$).

4.Training to administer/deliver the Drug Take Back Program.

The majority of respondents (54%) provided information about the types of training they received. On-the-job learning was the most common type of training reported (25%). Informal training from personal reading or conversations was the second most common format (14%). Formal training was the least frequently reported type (Fig 1)

Perceived effectiveness did not differ between those with formal or informal training (p=.277). In addition, whether or not a respondent had a managerial role was not related to training type ((χ^2=2.309, p=.129). Perceived effectiveness of the Drug Take-back Program was not different for those with or without managerial role. ($F(1, 42) = .08$, $p = .779$)

5. Challenges Faced

The number of challenges was wide ranging, and the most significant challenge faced by participants was logistic challenge followed by lack of awareness among the customers (Table2). Logistical challenges in implementing the Drug Take-Back Program (DTBP) encompass a range of factors that can significantly impact operational efficiency. These challenges may include limited access to disposal facilities, particularly in rural or underserved areas where such facilities may be scarce or inaccessible. Additionally, inadequate storage space poses a significant hurdle, especially in busy pharmacy settings where space constraints can impede the safe and secure storage of collected medications. Moreover, transportation and handling protocols present logistical complexities, as the proper transport and disposal of pharmaceutical waste require adherence to stringent safety and environmental regulations. Furthermore, logistical challenges extend to administrative aspects, such as ensuring seamless integration with policy departments and regulatory agencies responsible for overseeing medication disposal programs. Insufficient staffing levels can exacerbate these challenges, as pharmacy personnel may already be stretched thin with existing responsibilities, leaving limited capacity to manage additional tasks associated with the DTBP.

Moreover, technological infrastructure limitations, including outdated computer systems or lack of connectivity, can hinder efficient tracking and reporting of collected medications. Inadequate

provision of collection barrels or bins for medication disposal at pharmacies can also impede program participation and effectiveness.

Participants reported facing challenges related to DTBP, with significant variations observed between geographic locations. Pharmacists in New York reported significantly ($t = 2.24$, $p = .014$) more challenges ($M = 1.09$ $SD=1.07$) compared to other states ($M = 0.50$ $SD=1.17$), a significant inverse correlation existed between number of challenges encountered and perceptions of program effectiveness ($r = -0.455$, $p = .002$) indicating that as the number of challenges increased, participants were more likely to perceive the DTBP as less effective in achieving its objectives. No significant correlation was found between the number of challenges and other variables such as age or years of experience.

6.Qualitative analysis.

1..Factors Related to Perceived Program Effectiveness:

The first subjective question was: " **What are some key factors that may contribute to the effectiveness of this program?"**

A total of 44 respondents (54%) provided insights into various factors influencing the perceived effectiveness of the Drug Take-Back program. These responses were categorized into four themes: Convenience, law enforcement support, public awareness initiatives, and pharmacist engagement emerged as essential components:

a. Participants emphasized the significance of easy access to disposal facilities, advocating for convenient drop-off locations accessible to patients. Additionally, participants appreciated the presence of stand-alone kiosks available 24/7, free of charge to pharmacies and customers. Some respondents also noted the helpfulness of strategically placing disposal bins within pharmacy settings, enhancing convenience for both patients and staff.

b. Participants recognized the importance of law enforcement support in bolstering the program's effectiveness. They mentioned collaboration with sheriff's offices and police departments as integral to program security and public awareness. This acknowledgment underscored the value of partnerships with law enforcement agencies in ensuring the success and sustainability of pharmaceutical waste disposal initiatives.

c. Public awareness emerged as a key theme in participants' responses that played an important role to increase awareness of the program among the public such as utilizing posters and facility support to notify people about the program, as well as implementing community education initiatives.

d. Participants highlighted the importance of pharmacist involvement in promoting the program and facilitating patient awareness. They underscored the significance of training pharmacy staff to manage disposal bins effectively and educate patients about the program's availability. Additionally, some participants mentioned the role of pharmacists in communicating the program's existence to patients, indicating active engagement in promoting utilization.

2. Reasons for non-participation:

Almost fifty percent of the pharmacists were actively participating in the DTBP, another one-fourth (27%), expressed intentions to participate in the program in the future, suggesting a potential increase in involvement. DTBP participation was not planned for 14% of respondents. Reasons given for non-participation were varied.

- Work Setting Limitations: Various reasons for non-participation were mentioned, such as not working in a pharmacy, working in a physician's office, or being in an institutional setting without provisions for public access.

- Specific Scope of Practice: Some respondents cited specific aspects of their scope of practice, e.g., dealing with sterile injection products, as a reason for not participating.
- Local Alternatives: A few mention the presence of local sheriff's department drug take-back days, indicating reliance on existing community programs.
- Closed-Door Pharmacies: Closed-door pharmacies, primarily providing medications via mail, expressed challenges in participating because of limited public interaction.
- Internal Disposal Mechanisms: Some pharmacies had their own medication disposal units overseen by law enforcement or utilized services like Stericycle for drug waste removal.

3. Suggestions for Drug Take Back Program Enhancement:

The third open-ended question was: "**What are the recommendations or suggestions to improve pharmaceutical waste management and Drug Take Back Programs**?"

Participants offered diverse recommendations to enhance pharmaceutical waste management and Drug Take-Back programs, reflecting their varied perspectives and experiences. These suggestions can be categorized into 4 themes based on the recurring ideas and concerns raised by respondents:

a. Public Awareness and Education: Participants highlighted the importance of educating patients about proper medication disposal methods and the benefits of the Take-Back program. Some also recommended providing informational resources at disposal sites to further educate patients. Some respondents stated:

- "Again, public awareness and perhaps regulatory requirements would increase participation."
- "More advertisement and standardized process to make it easier for sites to participate. I think it would be highly utilized by smaller/rural communities."

- "The kiosk/bin could have literature available to further educate patients about the benefits of the Take-Back program."

b .Logistical Improvements and Accessibility: Participants suggested practical enhancements to improve the convenience and accessibility of disposal facilities. Recommendations included deploying easy-to-use disposable containers, implementing on-demand educational resources for customers, and exploring options for automatic pickup services to alleviate the burden on pharmacy staff. Respondents also proposed expanding the program to include medication safety initiatives and utilizing pharmacy staff and students for education outreach. Participants stated:

- "Easy to use disposable containers. Education for non-pharmacist management."
- "It would be nice if someone from the company who owns the bin could come around and empty the bins/exchange the liners when they are full."
- "Expand the program to include Medication Safety. Utilize students and pharmacy staff for education."

c .Policy and Funding Considerations: The importance of policy changes and financial support to optimize pharmaceutical waste management efforts were highlighted. Suggestions included advocating for cost coverage by drug manufacturers or insurance companies, securing state funds for disposal, and exploring grant opportunities to alleviate financial burdens on pharmacies. Some participants also emphasized the need for regulatory requirements to ensure program sustainability. Participants shared their opinions:

- "Cost of participation transferred to drug manufacturers or insurance companies rather than local pharmacies."
- "NY state should appropriate $$ for the destruction of the collected meds, so it doesn’t fall completely on the pharmacy."

- "I am assuming there are state funds available to pay for the disposal of the collected pharmaceuticals."

d .Enhanced Security and Safety Measures: Respondents expressed concerns about security and safety protocols associated with disposal facilities. Recommendations included implementing secure pickup arrangements, ensuring continuous surveillance of disposal bins, and enhancing safety measures to mitigate risks associated with potential misuse or contamination. Some participants underscored the importance of reducing stigma and ensuring a comfortable environment for patients to return medications. Participants quoted:

- "Safety is a big deal. There should always be two people involved in handling the bins that are swapped out when full."
- "Less stigma from the hospital for doing this. They did not want it to be seen in public."
- "Ensure safety of all involved. Reduce exposure with appropriate PPE.

DISCUSSION

The results of this study provided insights into pharmacists' engagement with the Drug Take-Back Program (DTBP), encompassing their perceptions of program effectiveness, the training they have received, the challenges they face, and their suggestions for program enhancement. The study revealed varying levels of participation among pharmacists in the DTBP, with some expressing robust support and active involvement, while others may encounter reservations or barriers to participation.

Additionally, the findings shed light on pharmacists' perspectives regarding the effectiveness of the DTBP in addressing medication disposal issues within their communities. While some areas of success were identified, such as increased awareness and participation, the

study also highlighted potential areas for improvement, including enhancing accessibility and addressing logistical challenges.

Moreover, the study examined the training received by pharmacists on medication disposal practices and identified key challenges they encounter in implementing the DTBP. These insights underscore the importance of providing comprehensive training and support to pharmacists to facilitate their role as facilitators of safe medication disposal.

Furthermore, pharmacists' suggestions for program enhancement provide actionable recommendations for optimizing the DTBP to meet the evolving needs of both pharmacists and the communities they serve.

Aligning with existing literature, the findings underscored the critical role these programs play in mitigating environmental concerns associated with medication disposal. The study encompassed a diverse sample of 81 pharmacists from various practice settings across the United States, primarily from New York.

Of the 81 surveyed pharmacists, 40 respondents participated in the Drug Take-Back Program (DTBP), and an additional 23 respondents expressed their willingness to participate in the future. This brings the total number of participating or potential participants to 63 pharmacists, constituting 78% of the total sample. This high level of potential participation reflected pharmacists' recognition of the importance of pharmaceutical waste management in mitigating environmental hazards.

Exploring the geographical distribution of the study's participants, and despite regional variations, a consistent level of awareness regarding the objectives of the Drug Take-Back Program (DTBP) was observed. This aligns with the observations made by Jankie et al, who similarly noted a consistent awareness trend among pharmacists in Trinidad and Tobago

regarding their awareness of DTBP objectives.[25] Providing more details on the Trinidad and Tobago study, Jankie et al, found that despite recognizing pharmaceutical contamination of the environment, there was a significant gap in knowledge among pharmacists regarding the specific risks associated with antibiotic disposal. This highlights the urgent need for continuing education initiatives aimed at improving awareness of proper medication disposal methods, particularly concerning antibiotics. Furthermore, the study underscores the importance of implementing a national medication take-back program to address the prevalent challenges and ensure environmentally responsible disposal practices. However, a notable gap emerged in the comprehension of the environmental consequences of improper disposal, particularly regarding the increased risk of antimicrobial resistance from antibiotics leaching into the environment. This highlights a critical need for tailored educational interventions, as emphasized by Shuleta-Qehaja & Kelmendi to equip pharmacists with comprehensive knowledge about pharmaceutical waste management practices.[26] In their study, the responsibility for disposal was misunderstood, with more than half of the respondents attributing this responsibility to the Ministry of Health rather than pharmacists. Furthermore, the government urgently needs to organize training sessions and workshops for healthcare professionals, including pharmacists and nurses, to ensure adherence to proper medication disposal protocols. Additionally, the study highlighted practical challenges in medication disposal regulations, emphasizing the importance of amending existing legislation to facilitate the return of medicines without imposing additional administrative burdens on consumers/patients which aligns with our findings. Our study similarly revealed a lack of clarity among pharmacists regarding their role in medication disposal, with a significant proportion erroneously attributing this responsibility to governmental bodies rather than themselves. This underscores the urgent need for educational interventions aimed at correcting misconceptions

and reinforcing pharmacists' understanding of their role in pharmaceutical waste management. Moreover, the identification of practical challenges in medication disposal regulations aligns study findings of concerns among pharmacists regarding the complexities of existing legislation, particularly in facilitating the return of medicines without imposing undue administrative burdens. These challenges highlight the necessity for legislative reforms to streamline the process..

As stated earlier, years of pharmacy experience positively correlated with familiarity with DTBP objectives, emphasizing the role of professional tenure in shaping pharmacists' knowledge of medication disposal initiatives.[27] This suggests that pharmacists, with more years of experience in the field, are more likely to be acquainted with the objectives of DTBP. Moreover, familiarity with DTBP objectives positively influenced perceptions of program effectiveness, highlighting the importance of awareness.[28]

These findings raise important considerations for the future of medication disposal initiatives. As pharmacists with extensive experience tend to exhibit greater familiarity and positive perceptions of DTBP, there may be implications for the continuity of knowledge and institutional expertise in this area. When pharmacists approaching retirement age,, there is a potential risk of losing valuable understanding and institutional knowledge about medication disposal programs in the years to come. This loss of expertise could impact the effectiveness and sustainability of DTBP and similar initiatives, as younger pharmacists may not have the same depth of experience or exposure to these programs. Therefore, healthcare organizations and regulatory bodies can implement knowledge transfer mechanisms and mentorship programs to ensure the seamless transition of expertise from retiring pharmacists to the next generation. Additionally, ongoing education and training programs could be prioritized to equip all pharmacists, regardless of

experience level, with the necessary knowledge and skills to effectively contribute to medication disposal efforts.

The majority of respondents in our study reported receiving some form of training related to their role in the DTBP, with on-the-job learning emerging as the most common type of training. However, the relatively low prevalence of formal training highlights potential gaps in structured educational initiatives aimed at equipping pharmacists with comprehensive knowledge and skills in pharmaceutical waste management. This finding suggests that although experiential learning plays a significant role in pharmacists' understanding of medication disposal practices, there remains a need for more structured and formalized training programs to address specific knowledge gaps and ensure consistency in practice. These insights align with previous findings by Shuleta-Qehaja & Kelmendi, which underscored the necessity of structured educational initiatives to supplement pharmacists' experiential learning and enhance their proficiency in pharmaceutical waste management.[26]

Interestingly, the quality of training significantly influenced the perceived effectiveness of the DTBP, with higher-rated training being associated with higher perception of program effectiveness. However, the specific type of training/education received did not seem to have a significant impact on program effectiveness. as supported by Painter et al. (2018).[29] Despite the positive intentions demonstrated by surveyed pharmacists to provide medication disposal education to patients, the study revealed significant gaps in their knowledge and practices. Although a majority of pharmacists recognized the importance of providing disposal education, a notable proportion expressed concerns about increased workload, which may hinder their willingness to offer such guidance. Additionally, the study highlighted the limited education and training on medication disposal during pharmacy school which underscores the need for

enhanced curricular emphasis in this critical area. Moreover, the study highlights inconsistencies in pharmacists' awareness of available resources and proper disposal methods, indicating a necessity for ongoing education and training initiatives to ensure pharmacists stay updated on regulations and best practices. Encouraging pharmacists to routinely inquire about medication disposal during patient consultations could further facilitate the dissemination of essential information and establish pharmacists as reliable sources in promoting medication safety highlighting the importance of prioritizing the effectiveness of training programs over their format.[30]

Participants in the present study identified logistical challenges and lack of customer awareness as the most significant barriers to DTBP participation, with pharmacists in New York reporting more challenges compared to other states. However, the majority of respondents in our study were from New York State (NYS). This potential regional disparity may be influenced by the skewed representation from NYS. Although, this could suggest a higher prevalence of reported challenges in NYS compared to other states, the limited representation from other regions might have skewed the perception of regional differences. This observation underscores the importance of larger, more geographically diverse samples in future studies to provide a comprehensive understanding of regional variations in DTBP participation barriers. Karim-Nejad & Pangilinan [31] emphasized the urgent need for collaborative action to address pharmaceutical waste. Specifically, they highlighted the pivotal roles of pharmaceutical companies, government entities, clinicians, and patients in promoting proper medication disposal practices and providing education and services to raise awareness among clinicians and patients.[31] This underscores the multifaceted nature of the issue and the importance of addressing it through coordinated efforts across various stakeholders. By fostering collaboration among these stakeholders and advocating

for pharmaceutical stewardship, the detrimental effects of pharmaceutical waste on ecosystems and public health can be mitigated. This aligns with the conclusion drawn from the present study regarding the need for increased education and awareness campaigns to empower pharmacists and patients in safeguarding public health and environmental integrity. Overall, this highlights the importance of collaborative efforts among stakeholders to promote proper medication disposal practices.

Pointing out a significant gap in current accreditation standards, it's important to note that bodies like the Accreditation Council for Pharmacy Education (ACPE) currently do not include considerations for pharmaceutical waste management (PWM) in their accreditation criteria.[32] This contributes to this systemic gap in pharmacist training. Without a mandate for comprehensive education on pharmaceutical waste management s an important aspect of pharmacist responsibility potentially perpetuates inadequate preparation to address environmental and public health challenges associated with medication disposal. The absence of coursework specifically addressing pharmaceutical waste management in pharmacy curricula, as noted by Athern et al,[33] reflects a systemic gap in pharmacist training. This highlights the urgent need for advocacy efforts to revise accreditation standards and ensure the integration of pharmaceutical waste management education into pharmacy curricula and better prepare pharmacists to tackle this pressing issue.

These educational enhancements align with broader efforts to promote environmental stewardship within healthcare professions. However, further research is needed to delve deeper into the underlying causes of pharmacists' perceptions and behaviors regarding medication disposal initiatives. Exploring the reasons behind logistical challenges, customer awareness

levels, and the effectiveness of training programs can provide insights for optimizing pharmaceutical waste management efforts.

STRENGTHS & LIMITATIONS

Strengths of the Survey

The survey was designed to be participant-centered, targeting licensed pharmacists registered with the pharmacy association to ensure expertise and firsthand experience in pharmaceutical management, thereby enhancing data credibility. The survey instrument was developed based on established methodologies to ensure validity and reliability. The questions included in the instrument were derived from validated sources, ensuring their applicability and relevance to the target audience. Its brevity minimizes respondent burden, thereby increasing completion rates. Anonymity fosters candid feedback, mitigating social desirability bias.

Limitations of the Study

The small sample size (<100) limited statistical power and representativeness. Its restricted geographic scope hindered broader applicability beyond specific regions. Unequal distribution of pharmacy types, predominantly hospital settings, may bias perceptions. Although the heterogeneity in participant experience and practice settings enhanced diversity but may lead to variations in responses, limiting generalizability.

Furthermore, the predominant representation of pharmacists from hospital settings in the sample may skew the focus towards challenges specific to this practice environment, potentially overlooking nuances present in other settings, such as community pharmacies.

These limitations underscore the necessity for future research endeavors to address these gaps. Larger and more diverse samples, spanning broader geographic areas and encompassing pharmacists from a range of practice settings, would facilitate a more comprehensive

understanding of the factors influencing the effectiveness of drug take-back programs. Such efforts would enhance the applicability and generalizability of findings, ultimately contributing to the advancement of pharmaceutical waste management practices and the optimization of the DTBP n a broader scale.

CONCLUSION

The findings of this study contribute to the existing literature on pharmaceutical waste management and highlight the importance of targeted educational efforts, logistical support, and interdisciplinary collaboration in promoting responsible medication disposal practices. Efforts to expand medication take-back programs, enhance public awareness, and integrate pharmaceutical waste management education into pharmacy curricula are suggested for promoting sustainable healthcare practices and safeguarding environmental health. Future research endeavors should focus on addressing the underlying factors influencing pharmacists' perceptions and behaviors regarding medication disposal initiatives, thereby informing evidence-based strategies to optimize pharmaceutical waste management efforts.

Upon reflection of the findings, although pharmacists play an important role in medication disposal programs, actively participating, providing perspectives on program effectiveness, and suggesting improvements. However, addressing the complex challenges of pharmaceutical waste management requires a multi-stakeholder approach. Despite that pharmacists are essential in facilitating safe medication disposal at the community level, other healthcare professionals, including physicians, regulatory bodies, waste management organizations, and government agencies, must also be involved to ensure a holistic and sustainable approach.

Moreover, ensuring the delivery of the right dose without excess is paramount for minimizing waste and potential moral hazards associated with overprescription. Physicians, in particular, bear responsibility for controlling medication dispensing to provide the precise dose required by the patient. This helps to prevent unnecessary waste and also enhances patient safety and adherence to prescribed treatment regimens. By avoiding excess medication, the risk of patients misusing or discarding unused medications is mitigated. Therefore, implementing robust policies and practices to ensure accurate and efficient medication dispensing is vital for optimizing healthcare outcomes and resource utilization. Collaborative efforts among various stakeholders can lead to the development of more effective strategies, improved infrastructure, heightened public awareness, and ultimately contribute to enhanced pharmaceutical waste management practices and environmental protection.

Tables and Figures

Table 1: Participation in the Drug Take back Program based on different years of experience as a pharmacist.

Years of experience as a pharmacist	Are pharmacists and their pharmacies currently participating in the DTBP?				
	Yes	Not at this time, but perhaps in the future	Not now, but participated in the past	No, not planning to participate	Total
2-10 years	8	7	3	2	20
11-20 years	13	6	0	8	27

Years of experience as a pharmacist	Are pharmacists and their pharmacies currently participating in the DTBP?				
	Yes	Not at this time, but perhaps in the future	Not now, but participated in the past	No, not planning to participate	Total
21-30 years	9	4	1	1	15
30+ years	10	6	0	3	19
Total	40	23	4	14	81

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647 *** DTBP: Drug Take-Back Program**

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649 **Table 2: Challenges encountered by pharmacists in implementing the Drug Take-Back**

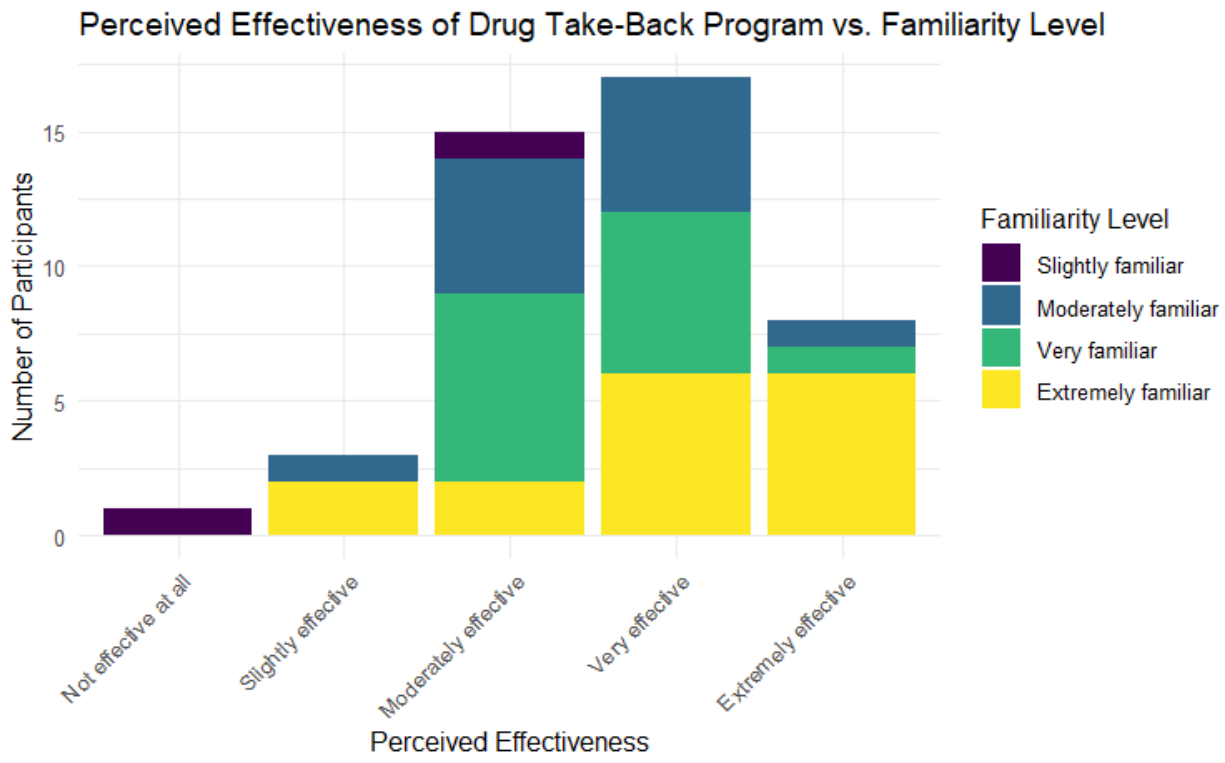
650 **Program DTBP**

651

Challenges in DTBP Participation	No of pharmacists	Percent %
Legal Concerns	8	9.9
Logistical Challenges	23	28.4
Resource Constraints	9	11.1
Lack of Awareness Among Customers	21	25.1
Lack of Effective Training	6	7.4
No Challenges Experienced	6	7.4

Total Responses	**81**	**100**

FIG 1:



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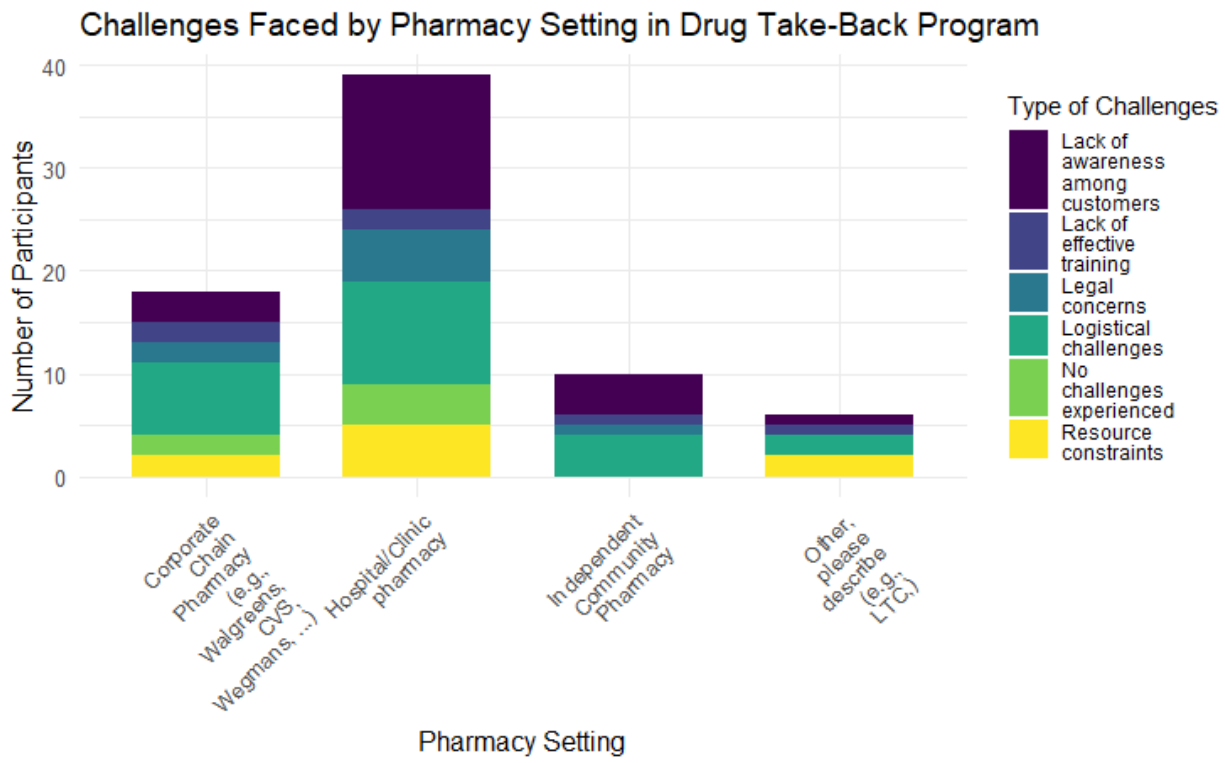
667

668 **FIG 2:**


Challenges Faced by Pharmacy Setting in Drug Take-Back Program
Number of Participants
0
10
20
30
40
Corporate Chain Pharmacy (e.g., Walgreens, CVS, Wegmans, ...)
Hospital/Clinic pharmacy
Independent Community Pharmacy
Other, please describe (e.g., LTC,)
Pharmacy Setting
Type of Challenges
Lack of awareness among customers
Lack of effective training
Legal concerns
Logistical challenges
No challenges experienced
Resource constraints

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Chapter 3. IMPLICATIONS FOR RESEARCH AND PRACTICE

1. **Research Implications:**

    - Longitudinal Studies: Future research could consider longitudinal studies to assess changes in pharmacist engagement and perceptions over time, providing insights into the sustainability of interventions and the effectiveness of policy changes.
    - Intervention Studies: Investigating the effectiveness of interventions, such as enhanced training programs or policy changes, can provide valuable evidence for optimizing pharmaceutical waste management practices.
    - Technology-driven Solutions: Exploring the integration of technology-driven solutions, such as digital platforms or automated tracking systems, could enhance the efficiency and effectiveness of pharmaceutical waste management programs.
    - Community-based Partnerships: Collaboration with community organizations and stakeholders could facilitate the implementation of sustainable healthcare initiatives and promote community engagement in pharmaceutical waste management efforts.

2. Implications for Practice

By examining the engagement of pharmacists with the Drug Take-Back Program (DTBP), perceptions of program effectiveness, training received, challenges faced, and suggestions for enhancement, this research sheds light on key areas for improvement within pharmacy practice.

2.1. Logistical Challenges and Practice Implications

Logistical challenges, such as limited infrastructure and lack of resources, emerged as significant barriers to effective medication disposal practices.[30] These challenges increase the risk of improper medication disposal, posing environmental and public health concerns. To address these challenges, pharmacy practices may prioritize streamlining collection processes, improving infrastructure, and fostering collaboration between stakeholders. The literature indicates that the utilization of technology, the development of public-private partnerships, and the advocacy for policy support have the potential to reduce logistical barriers and encourage sustainable medication disposal practices.[31-33.]

2.2.Factors Influencing Perceived Effectiveness and Practice Implications

Pharmacists' perceptions of program effectiveness are influenced by various factors, including public awareness, pharmacist education, and stakeholder collaboration. Enhancing program visibility, implementing targeted education initiatives, and fostering community engagement are essential strategies for improving program effectiveness. The literature underscores the significance of public awareness campaigns, pharmacist training programs, and policy advocacy to advance responsible medication disposal practices. Through the integration of these strategies into pharmacy practice, pharmacists can assume an important role in fostering sustainable healthcare practices and preserving environmental health.[34,35]

2.3 Relationship Between Challenges and Program Effectiveness and Practice Implications

The inverse relationship between logistical challenges and program effectiveness highlights the need to address barriers to enhance program efficacy. Pharmacy practices may prioritize addressing logistical challenges, such as inadequate infrastructure and resource constraints, to optimize program effectiveness. The literature indicates that efficient collection

processes, improved accessibility to disposal facilities, and strengthened stakeholder collaboration are essential for overcoming logistical barriers and fostering responsible medication disposal practices.[36,37]

2.4 Causes of Perceived Effectiveness and Practice Implications

Understanding the underlying causes of pharmacists' perceived effectiveness of medication take-back programs is important for informing practice. By addressing factors such as pharmacist training, public education, and policy support, pharmacy practices can enhance program effectiveness and promote sustainable medication disposal practices. The literature emphasizes the significance of comprehensive pharmacist education, community outreach initiatives, and policy advocacy in fostering responsible medication disposal practices.[38,39]

Research Process Reflection:

Reflecting on the research process, engaging with pharmacists across diverse practice settings and regions provided valuable insights into the challenges and opportunities in pharmaceutical waste management. Moving forward, refining survey instruments to capture nuanced perceptions and experiences related to pharmaceutical waste management could enhance the depth of future research. Additionally, incorporating qualitative research methods, such as interviews or focus groups, could provide deeper insights into the factors influencing pharmacist engagement and program effectiveness. The mixed-methods approach employed in this study facilitated a comprehensive understanding of the research questions and identified areas for improvement in pharmaceutical waste management efforts.

APPENDIX 1: Literature review on pharmaceutical waste Management

Introduction

The global healthcare industry has witnessed unprecedented growth, becoming one of the fastest-growing sectors globally. With worldwide health spending reaching approximately $7.8 trillion in 2017, accounting for around 10% of the global GDP, this surge is attributed to the expanding global population and the increasing demand for healthcare interventions. The projected rise in the global population, estimated to reach 8.6 billion by 2030 and 9.8 billion by 2050, coupled with the proliferation of medical facilities, adds complexity to waste management.[40]

Although the pharmaceutical industry plays an important role in advancing societal well-being through innovative drug, antibiotic, and supplement production, it also contributes to the global challenge of pharmaceutical waste. This includes unwanted residues containing active pharmaceutical ingredients (API) and volatile organics, posing substantial health and environmental hazards.[4]

An aging population contributes to the escalating costs associated with chronic diseases, leading to the phenomenon of multiple morbid conditions (MMCs). Individuals with MMCs frequently utilize primary and specialist care services, follow intensified medication regimens, and experience increased hospital admissions with a significant upsurge of up to 51% in clinician appointments with each additional chronic disease. As individuals age, the likelihood of developing multiple comorbidities increases, complicating the management of chronic conditions. This surge in chronic diseases has stimulated the growth of pharmaceutical waste disposal practices.[41,42]

Moreover, global efforts to manage pandemics like Ebola and COVID-19 have prompted both developed and developing countries to enhance contagion control practices, resulting in the generation of potentially hazardous medical waste. The prevalence of infectious diseases worldwide further contributes to the escalating volume of pharmaceutical waste.[43,44] Addressing pharmaceutical waste management, the European Union has enacted legislation categorizing pharmaceutical waste into three distinct types: (i) pharmaceutical waste with a risk of infection; (ii) pharmaceutical waste presenting a chemical hazard; and (iii) medicines and medicinally contaminated waste containing active pharmaceutical agents. In healthcare systems, various chemicals and pharmaceuticals used can be hazardous, with small amounts typically found in medical waste. Larger quantities may be present when unwanted or expired chemicals and pharmaceuticals are directed for disposal.[45,46]

Impact of improper disposal of pharmaceutical waste

The primary contributor to pharmaceutical pollution is human excreta resulting from medication usage. However, the improper disposal of unused medications significantly adds to this problem. In many countries, common disposal routes like toilets, drains, or household trash directly contribute to the accumulation of pharmaceuticals in the environment. Therefore, ensuring the sustainability of medication supply and use becomes crucial to protect both the healthcare budget and the environment.[47,48]

Medication waste, encompassing unused or unconsumed pharmaceutical products within the pharmaceutical supply and use chain, presents substantial challenges to both budgetary considerations and environmental sustainability. The financial impact of pharmaceutical waste is profound, resulting in annual losses of up to $5.4 billion in the United States, approximately £300 million in the United Kingdom, and a minimum of €100 million in the Netherlands. Beyond

fiscal concerns, the environmental ramifications are significant, with pharmaceutical pollution in aqueous environments adversely affecting ecosystems and posing potential hazards to humans because of incomplete removal by conventional drinking water treatment plants.[49,50]

Improper handling of unused or expired pharmaceuticals, mainly disposed into sewage systems, introduces pharmaceuticals into the environment. Pharmaceuticals have been detected in various places such as groundwater, surface water, and soil. The primary groups of pharmaceuticals found in environmental samples include antibiotics, hormones, non-steroidal anti-inflammatory drugs, beta blockers, lipid regulators, and antidepressant drugs. The prolonged presence of pharmaceuticals in the environment causes acute and chronic damage, behavioral changes, reproductive disorders, and inhibition of cell proliferation in animals. The negative impact on the environment is further evidenced by the development of antibiotic resistance in some bacterial strains. Therefore, it is crucial to decontaminate chemical and pharmaceutical waste before placing them in landfills to prevent improper disposal, which can cause contact between environmental bacteria and antibiotics, potentially leading to the evolution of antibiotic-resistant mechanisms.[51-55]

Hazard of pharmaceuticals for aquatic environment

Pharmaceuticals, designed to interact with living organisms, maintain their biological activity even at low concentrations. When released into the environment, especially in aquatic settings, these substances can adversely affect wildlife and ecosystem health. Various acute and chronic effects have been observed due to the exposure of non-target organisms to environmental concentrations of pharmaceutical residues. Specific pharmaceuticals may pose risks to aquatic plants and algae, comparable to certain herbicides. For example, fluoroquinolone antibiotics like enrofloxacin and ciprofloxacin, commonly found in wastewaters and surface waters, were

discovered to be toxic to algae. Some antidepressant drugs show adverse effects on invertebrates at concentrations commonly observed in the environment.[56-59]

The estrogenic steroid ethinyl estradiol (EE2), utilized in contraceptive pills, has been linked to the feminization of male fish in rivers and water bodies, even at concentrations of a few nanograms per liter . Additionally, the anti-inflammatory drug diclofenac raises concerns about its impact on aquatic organisms. The introduction of pharmaceutical residues into aquatic environments has raised significant ecological concerns, with observed effects ranging from toxicity to disruptions in reproductive patterns and hormonal imbalances among aquatic organisms.[60]

Impact of Covid pandemic

The COVID-19 pandemic has led to a significant disruption in waste recycling operations globally, with many countries postponing these activities to mitigate the transmission of the virus. Consequently, waste collection and recycling have emerged as critical concerns throughout the pandemic.[61]

The quantity and composition of medical waste have been dramatically affected by the ongoing global health crisis. The amount of waste generated, particularly infectious waste in landfills, has witnessed a substantial increase. This surge can be attributed not only to hospital waste but also to the rise in infectious waste from homes where individuals are undergoing care due to illness or suspicion of illness.[61]

According to the United Nations Environment Program, the surge in COVID-19-related medical waste globally is estimated to be 3.4 kg per person per day. It's noteworthy that developing countries contribute significantly to this increase, producing approximately 2.5 kg per bed per day. This disproportionate impact in developing nations highlights the substantial

challenges they face. The figure of 0.9 kg per person per day in developed countries indicates a notable contribution to the overall global increase. The excessive growth of biomedical waste, intensified by the widespread impact of COVID-19, poses a significant and concerning threat to both public health and the environment, with developing countries experiencing a larger share of this burden.[62,63.]

During the peak of the pandemic, Wuhan alone generated about 240 tons of healthcare waste per day, a nearly sixfold increase compared to pre-pandemic levels. In the United States, the estimated rise in healthcare waste generation surged from 5 million tons per year before the pandemic to 2.5 million tons per month during the pandemic. This notable increase in healthcare waste generation has consequently contributed to a substantial rise in pharmaceutical waste on a global scale.[4]

Responding to these challenges, the World Health Organization (WHO) has issued crucial recommendations regarding the segregation and collection of healthcare waste. These recommendations advocate for color-coding waste containers to enhance proper disposal practices. General waste containers should be black, sharp, infectious, and pathological waste containers should be marked yellow, while chemical and pharmaceutical waste containers should be brown. Additionally, the WHO recommends that almost all waste categories should be collected at least once per day or when three-quarters of the container is filled. Notably, pharmaceutical, chemical, and radioactive waste are exceptions and should be collected on demand.

In conclusion, the COVID-19 pandemic has also led to a significant increase in healthcare waste, including pharmaceutical waste, globally. The recommendations provided by the WHO aim to address these challenges and ensure proper waste segregation and collection,

emphasizing the need for a coordinated and sustainable approach to manage the rising volumes of biomedical waste**.**

Impact of Pharmaceutical Waste in Developing Countries.

Managing pharmaceutical waste in developing countries presents distinct challenges, adding layers of complexity to an already intricate issue. Bureaucratic inefficiencies within pharmaceutical supply delivery, inappropriate disposal methods, and factors contributing to pharmaceutical accumulation create a multifaceted scenario demanding immediate attention. The inefficiencies in supply delivery exacerbate waste management challenges, as these intricate processes result in the accumulation of pharmaceutical waste, straining already limited resources and complicating waste management efforts. Issues contributing to the accumulation of pharmaceutical waste, such as uncontrolled disposal practices and a lack of proper infrastructure, further amplify the challenges faced by developing countries posing significant risks to both public health and the environment. Moreover, developing countries often resort to unsafe disposal methods, intensifying the pharmaceutical waste dilemma. Practices like pollution and burning release toxic compounds into the atmosphere and water sources, exacerbating environmental pollution, and posing threats to both human and aquatic lives. This underscores the urgent need for improved waste management strategies in healthcare establishments of developing nations. Addressing these challenges requires comprehensive strategies and targeted interventions to enhance pharmaceutical waste management in developing regions.[64-66]

The lack of waste segregation within healthcare establishments hampers proper sorting, collection, and transportation of pharmaceutical waste for final disposal. This inadequacy significantly compounds the challenges associated with managing pharmaceutical waste in developing countries, impeding effective waste management practices. The World Health

Organization (WHO) recommends enhanced waste segregation methods, emphasizing their importance in addressing the unique challenges faced by these countries.[67]

Disposal Practices in Developed Countries

In developed countries, where advanced and regulated pharmaceutical waste management practices are the norm, healthcare facilities maintain established infrastructure and adhere to environmental regulations. Robust waste segregation processes ensure the proper categorization of hazardous and non-hazardous pharmaceutical wastes.[68]

Even in developed nations, the peak of the COVID-19 pandemic led to a substantial increase in healthcare waste generation. In the USA, the estimated surge ranged from 5 million tons/year before the pandemic to 2.5 million tons/month during the pandemic. High-income countries, on average, produce nearly 11 kg of hazardous waste per hospital bed per day, highlighting the global scale of the challenge.[4]

The global increase in medicine consumption, driven by advancements in healthcare delivery, population growth, and medical technology, poses significant challenges. Annual medicine expenses are expected to rise by 2–5%, surpassing $1.1 trillion in 2024, with over $165 billion spent solely on new brands of medicines. Patients worldwide underwent over 1.8 trillion days of therapy in 2019. Disposing of contaminated, unused, or expired medicine incurs substantial costs, estimated at $790/ton in the USA and £450/ton in the UK. Approximately £300 million worth of medicines are wasted annually in the UK, despite being prescribed and approved by the National Health Services. In the US, about two-thirds of prescription medicines are estimated to go unused after being dispensed. Improved waste management, and public education to reduce healthcare waste, underscore the importance of addressing pharmaceutical waste as a financial necessity and a crucial step in safeguarding the environment and public well-being.[69]

Treatment options and consequences

The management of medical waste typically employs steam-based methods such as autoclaving, microwave, and frictional heat treatments to disinfect and sterilize highly infectious and sharp waste through exposure to moist heat and steam. In contrast, pharmaceutical waste is often handled through incineration, a waste destruction process involving burning to eliminate hazardous components, reduce mass and volume, and transform them into ash. However, inadequately designed, operated, or maintained incinerators can emit toxic substances into the environment. Low-temperature incineration processes may generate emissions containing carcinogenic dioxins and furans. Meeting international emission standards for these substances requires incinerators to operate at temperatures ranging from 850–1100 °C and incorporate specialized gas-cleaning equipment. Volatile metals like mercury, lead, arsenic, and cadmium are released during incineration, posing risks to the immune and neurological systems, kidneys, brain, lungs, and other organs. Even in well-functioning incinerators, the resulting ashes remain hazardous and toxic.[70,71]

Furthermore, leachate from pharmaceutical waste can infiltrate the soil, contaminating crops, surface, and groundwater, and posing health risks to individuals who consume the contaminated water. To enhance safety, various alternative solutions are being explored, including ozone treatment and alkaline hydrolysis, as well as composting and vermicomposting.[4] Addressing the risk associated with pharmaceutical waste involves the development and implementation of improved policies and procedures to reduce waste sent for incineration.

The Drug Take-back program.

The Drug Take Back program is a proactive and community-oriented initiative designed to address the challenges associated with the improper disposal of pharmaceutical waste,

particularly unused or expired medications. This program encourages individuals to return their unused or unwanted medications to designated collection points for proper disposal, rather than discarding them in household trash or flushing them down the toilet. The primary goal is to minimize the environmental impact of pharmaceuticals and reduce the risks associated with their presence in landfills, water bodies, and soil.[72,73]

Key aspects and stakeholders involved in the Drug Take Back program include.[74,75.]

1. **Community Engagement:**
    - **Public Awareness Campaigns:** Drug Take Back programs often involve public awareness campaigns to educate communities about the importance of proper medication disposal and the environmental and health risks associated with improper disposal.
2. **Collection Points:**
    - **Pharmacies:** Local pharmacies play a crucial role as collection points for unused medications. They provide a convenient and accessible location for individuals to drop off their medications safely.
    - **Healthcare Facilities:** Hospitals and clinics may also participate by providing collection receptacles for unused medications.
3. **Pharmacists:**
    - **Educational Role:** Pharmacists are key educators in the community, providing information on the importance of the Drug Take Back program, proper medication disposal, and the potential risks of improper disposal.

- **Facilitating Returns:** Pharmacists facilitate the return process by accepting unused medications, ensuring they are properly packaged and labeled, and then arranging for their safe disposal through authorized channels.

4. **Government and Regulatory Bodies:**
    - **Policy Implementation:** Government agencies play a role in implementing and supporting policies that encourage the establishment and success of Drug Take Back programs.
    - **Regulation:** Regulatory bodies ensure that the collected medications are disposed of in an environmentally friendly and safe manner, adhering to regulations and guidelines.
5. **Pharmaceutical Manufacturers:**
    - **Extended Producer Responsibility (EPR):** Encouraging pharmaceutical manufacturers to take responsibility for the end-of-life disposal of their products can contribute to the success of Drug Take Back programs.
6. **Environmental Organizations:**
    - **Advocacy:** Environmental groups may advocate for and support Drug Take Back initiatives as part of broader efforts to address pharmaceutical pollution and promote sustainable waste management practices.

The role of pharmacists in the Drug Take Back program is particularly because of their direct interaction with patients. Pharmacists can educate individuals on the program's benefits, provide clear instructions on how to participate, and address any concerns related to medication disposal. Additionally, by serving as collection points in pharmacies, pharmacists contribute to the program's success by making it easy and convenient for the public to participate. Their

expertise ensures that the returned medications are handled appropriately and sent for proper disposal in accordance with regulations.[76]

COVID-19 Pandemic: A Catalyst for Change

The global response to the COVID-19 pandemic has spurred a reevaluation of waste management strategies, propelled by reduced air and water pollution in urban areas because of movement restrictions and economic slowdowns. However, the upsurge in medical waste, including pharmaceutical waste, has underscored the vulnerabilities in existing waste management systems. This has prompted discussions on the necessity of embracing sustainable practices, such as drug take-back programs, to educate the public on proper pharmaceutical waste disposal.[75]

In addressing the overarching challenge of global sustainability, collective effort and collaboration are imperative. All United Nations (UN) member states have committed to sustainable human development goals by 2030, emphasizing responsible production and consumption patterns. Within the pharmaceutical sector, the International Pharmaceutical Federation (FIP) calls upon stakeholders to minimize their contributions to pollution, advocating for green pharmaceutical practices involving environmental research on medicinal products, pollution reduction, waste disposal management, and the establishment of eco-friendly community pharmacies.[76]

Efficient pharmaceutical waste management necessitates shared responsibility across the entire supply chain, engaging manufacturers, distributors, prescribers, pharmacists, patients, and health authorities. Manufacturers can optimize medication shelf-life and package sizes, reducing unnecessary expiration and over-supply. Distributors play a vital role in minimizing waste during warehousing and distribution through efficient inventory policies and shorter shelf-life criteria.

Prescribers are essential in regulating medication quantities, employing shared decision-making, and adopting sustainable prescribing practices.

Pharmacists, in both community and hospital settings, can contribute by implementing effective stock management, optimizing medication preparation processes, and exploring the redistribution of unused medication. Patients, as end-users, can actively participate by avoiding over-ordering, adhering to prescribed regimens, and returning unused medication to pharmacies. Health authorities play a crucial role in enforcing waste minimization through education, awareness campaigns, and policy regulations, fostering a collaborative approach to sustainable pharmaceutical practices. This shared responsibility ensures that each stakeholder in the pharmaceutical chain contributes to reducing medication waste, promoting sustainability, and mitigating environmental impact.[14]

Global Concerns and Urgent Actions

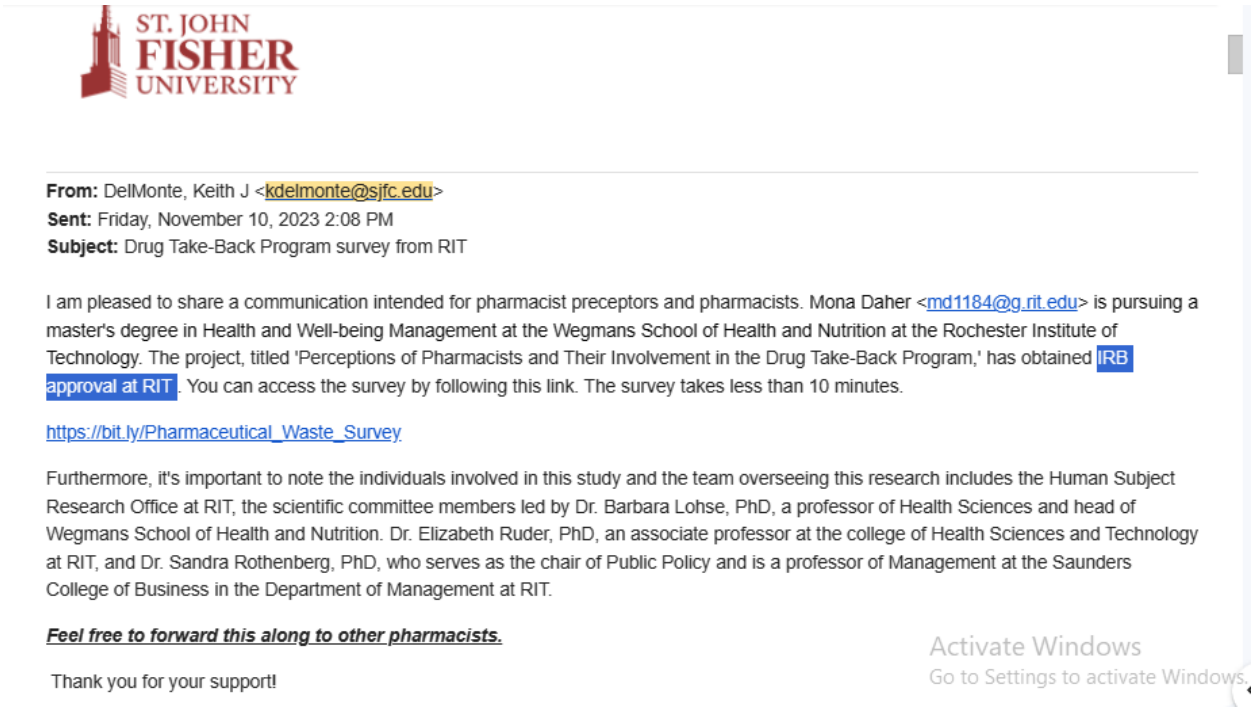
Global statistics underscore the enormity of the challenge, revealing that millions of people succumb to diseases caused by mismanaged medical waste annually. Developing countries, in particular, grapple with a surge in COVID-19-related medical waste, posing significant threats to public health and the environment. The mismanagement of pharmaceutical waste, compounded by the potential adherence of the virus to contaminated surfaces, amplifies the risk of COVID-19. By bolstering policies and educational efforts, including the adoption of drug take-back programs targeting unused medications, the management of pharmaceutical waste can be enhanced, leading to reduced risks associated with such waste and dispelling misconceptions about hazardous waste.

However, although the existing literature sheds light on the importance of these initiatives, a critical gap exists in understanding the specific impact and effectiveness of drug take-back

programs, particularly from the perspective of healthcare professionals including pharmacists . As per my knowledge, the perceptions, and views of pharmacists towards the Drug Take-Back Program have not been investigated. An in-depth investigation into pharmacists' attitudes, challenges, and recommendations related to the program could contribute valuable insights to inform policymakers and healthcare professionals yet lay the foundation for more targeted and efficient waste reduction strategies.

Appendix 2: Recruitment Communication

Email sent by the director of continuing education at St Fisher University, Wegmans school of Pharmacy.



ST. JOHN FISHER UNIVERSITY

From: DelMonte, Keith J <kdelmonte@sjfc.edu>
Sent: Friday, November 10, 2023 2:08 PM
Subject: Drug Take-Back Program survey from RIT

I am pleased to share a communication intended for pharmacist preceptors and pharmacists. Mona Daher <md1184@g.rit.edu> is pursuing a master's degree in Health and Well-being Management at the Wegmans School of Health and Nutrition at the Rochester Institute of Technology. The project, titled 'Perceptions of Pharmacists and Their Involvement in the Drug Take-Back Program,' has obtained IRB approval at RIT. You can access the survey by following this link. The survey takes less than 10 minutes.

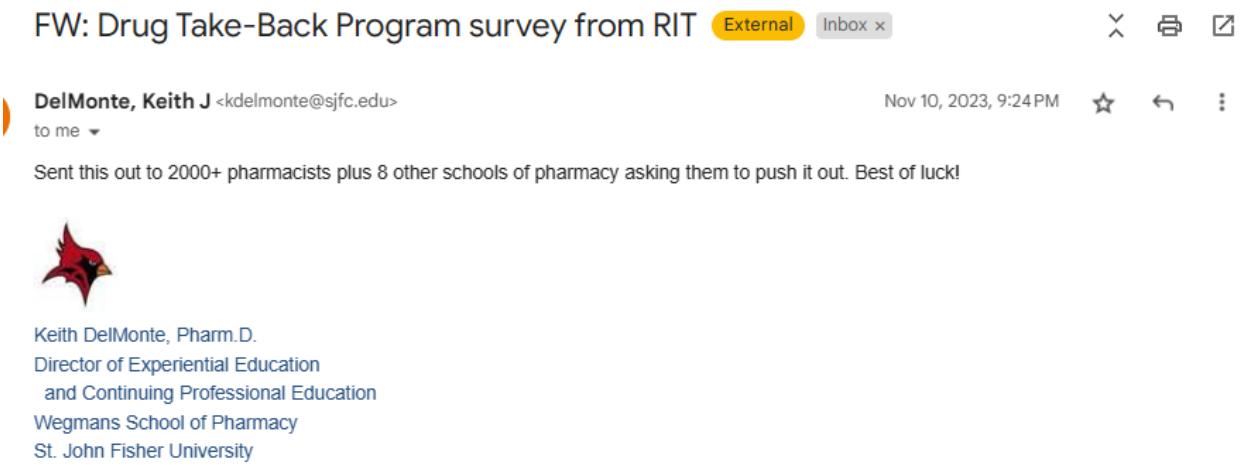
https://bit.ly/Pharmaceutical_Waste_Survey

Furthermore, it's important to note the individuals involved in this study and the team overseeing this research includes the Human Subject Research Office at RIT, the scientific committee members led by Dr. Barbara Lohse, PhD, a professor of Health Sciences and head of Wegmans School of Health and Nutrition. Dr. Elizabeth Ruder, PhD, an associate professor at the college of Health Sciences and Technology at RIT, and Dr. Sandra Rothenberg, PhD, who serves as the chair of Public Policy and is a professor of Management at the Saunders College of Business in the Department of Management at RIT.

Feel free to forward this along to other pharmacists.

Thank you for your support!

Activate Windows
Go to Settings to activate Windows.



FW: Drug Take-Back Program survey from RIT External Inbox ×

DelMonte, Keith J <kdelmonte@sjfc.edu> Nov 10, 2023, 9:24 PM
to me

Sent this out to 2000+ pharmacists plus 8 other schools of pharmacy asking them to push it out. Best of luck!

Keith DelMonte, Pharm.D.
Director of Experiential Education
and Continuing Professional Education
Wegmans School of Pharmacy
St. John Fisher University

Appendix 3: Survey Questionnaire Reliance on IPAT

Introduction.

The development of the survey questionnaire for this study is closely aligned with the Implementation Process Assessment Tool (IPAT), a robust framework recognized for its effectiveness in assessing the implementation process. IPAT introduces key constructs such as individual readiness, collective readiness, and stages of change, which are crucial for comprehending the dynamics of implementing healthcare practices. By integrating these constructs into our survey questionnaire, we ensure a nuanced exploration of pharmacists' insights and experiences within the context of the Drug Take-Back Program.

Alignment with IPAT Constructs:

1. **Individual Readiness:**
    - *Example Question:* In your opinion, how important is the role of the pharmacist in the Drug Take-Back Program?
    - *Rationale:* This question mirrors the IPAT's focus on individual stages for behavioral change and assesses individual pharmacists' readiness for their roles in the implementation process.
2. **Collective Readiness:**
    - *Example Question:* The current Drug Take-Back program is _____in achieving its objectives**. (perceived effectiveness)**
    - *Rationale:* This question aligns with the IPAT's emphasis on collective interpretation and assessment of the implementation environment, capturing the collective readiness and support within pharmacy teams.
3. **Stages of Change:**

- *Example Question:* “What would help you/your pharmacy decide to participate/ not participate in the Drug Take-Back program**?”**
- *Rationale:* this question aims to capture insights into the factors influencing decision-making, aligning with key stages of change:

Precontemplation: Participants in this stage may not be considering participation, and their responses could reveal a lack of awareness or interest in the program.

Contemplation: Individuals in this stage might be considering participation but may have specific conditions or requirements. Responses may provide insights into the factors that could sway their decision.

Preparation: Participants preparing to participate may highlight specific facilitators or barriers that could influence their decision. Their responses may indicate what resources or information they need.

Action: Those actively participating may outline the factors that motivated their decision, providing a glimpse into the immediate drivers for involvement.

Maintenance: This stage involves sustaining the behavior. Responses may include suggestions for continuous support or improvements to ensure ongoing and effective participation..

Comprehensive Approach:

The incorporation of IPAT-inspired questions throughout the questionnaire provides a structured yet comprehensive approach for understanding pharmacists' perspectives. Elements such as participation, training, and challenges are woven into the questionnaire, capturing essential facets of the implementation process as outlined by IPAT.

Credibility and Relevance:

By aligning the survey questionnaire with IPAT constructs, we underscore the adoption of a well-established and respected framework in implementation science. This alignment enhances the credibility of our research instrument and positions it as a tool for evidence-based practice and supporting effective healthcare implementation.

Appendix 4: Consent form/ Survey questionnaire/ survey items rational

You are invited to participate in a survey to share your insight on pharmaceutical waste management. Your perspective will help us to better understand the effectiveness and challenges in this important area.

This survey will take approximately 10 minutes to complete. Thank you!

CONSENT FORM

Principal Investigator: Mona Daher

This survey is a part of a research study conducted by Mona Daher Pharm.D a Health and Well-being graduate MS student at Rochester Institute of Technology, NY.

This research aims to understand pharmacists' experiences and opinions regarding the disposal of pharmaceuticals through Drug Take-Back Programs. Your input will contribute to improving the effectiveness of these programs and enhancing pharmaceutical waste management practices.

If you agree to participate, you will be asked to complete the following online survey. The survey will include questions about your experiences, recommendations, and perceived obstacles related to Drug Take Back Programs. The survey takes approximately 10 minutes to complete. Although there are no expected risks, you might face unforeseen risks, such as potential unauthorized data access that may exist in electronic data collection. Potential benefits are an increase in greater knowledge and understanding of pharmacists' role in the Drug Take Back Programs and pharmaceutical waste management practices.

Your participation in this study is entirely voluntary, and your responses will remain confidential. All data will be stored securely and anonymized to protect your identity. Your individual responses will not be shared with anyone else, and your responses will only be reported in aggregate form.

If you have any questions or concerns about the study, please feel free to contact Mona Daher at (585) 478-9814 or email: md1184@rit.edu. If you have any concerns about your rights as a research participant, you may contact the Rochester Institute of Technology Human Subjects Research Office (contact: Heather Foti, Associate Director, e-mail hmfsrs@rit.edu)

Consent: I have read and understood the information provided above. I understand that participating in this interview indicates that I agree to let my responses be included in this research study.

Yes, I consent.

No, I don't consent (if No skip to (Skip to the end of the questionnaire: Thank you for your interest. You are not eligible to participate)

Survey Questionnaire: Pharmacists' Perceptions and Involvement in the Take-Back Program

Please answer the following questions:

1. Please select the location that best describes where you work.

1. I work in New York State.
2. I work in a state other than New York (please specify which state you work in)----------

2. Which of the following best describes your practice setting?

- Independent Retail Pharmacy
- Corporate chain Pharmacy (e.g., Walgreens, CVS, Wegmans, ...)
- Hospital/Clinic pharmacy

- Other, please describe (e.g., LTC,): _____

3. How familiar are you with the objectives of the Drug Take-Back program?

- Not familiar at all.
- Slightly familiar.
- Moderately familiar.
- Very familiar.
- Extremely familiar.

4. Are you and/or your pharmacy participating in the Drug Take-Back program for safe disposal of unused medications?

a. Yes

b. **Not at this time, but perhaps in the future.**

4a. **What would help you/your pharmacy decide to participate in the Drug Take-Back program?**

c. **Not now, but we participated in a program in the past**

What reasons led to discontinuing participation? We appreciate you sharing this information.

d. No, and we are not planning to participate.

What are the main reasons for your pharmacy's decision not to participate in the Drug Take-Back program? then skip to demographic data

5. In your opinion, how important is the role of the pharmacist in the Drug Take-Back Program?

- Not important at all

- Slightly important
- Moderately important
- Very important
- Extremely important

6. How much do you agree with this statement: Participation in the Drug Take-Back program is a valuable service for the community.

- Strongly disagree
- Somewhat disagree
- Neither agree or disagree
- Somewhat agree
- Strongly agree

7.What type of training/education did you receive related to your role in the Drug Take-Back program? Please select all that apply.

- Formal training (e.g., classroom, webinars)
- Informal training (e.g., from my own reading or conversations)
- On-the-job learning
- More than one from the above
- I have not received any training (Skip logic to question 8)

8.Please rate the adequacy of the training provided in preparing you for your role in the program.

- Extremely inadequate
- Somewhat inadequate

- Neither adequate nor inadequate
- Somewhat adequate
- Extremely adequate

9.Indicate the most challenges or barriers you have encountered in your participation in the Drug Take-Back program.

- Legal concerns
- Logistical challenges
- Resource constraints
- Lack of awareness among patients
- Lack of effective training
- Other (please specify): _____
- None (SKIP logic to question 10)

10. I am interested in more information about the challenges you have faced. Please use the space below to describe them.

11.The current Drug Take-Back program is _____in achieving its objectives**.**

- Not effective at all (Skip logic to question 12)
- Slightly effective
- Moderately effective
- Very effective

- Extremely effective

12.What are some key factors that may contribute to the effectiveness of this program?

13.What is your age (in years)?

Drop down list. From 18 to 80

14. How many years have you been practicing as a pharmacist?

Drop down from 1 to 45

15.Does your current role as a pharmacist include a managerial role?

. Yes

. No

16. Please share your suggestions or recommendations for developing and/or improving the drug disposal programs including the Drug Take-Back program.

Thank you for completing the survey! Your feedback is greatly appreciated.

Table 1

Section	Survey Item	Rational
Demographic Information	Age	Age can influence perspectives and behaviors

	Years of Experience	Experience may impact knowledge and decision-making
	Location	Geographic differences can influence practices.
	Practice Setting	Different settings may entail distinct challenges.
	Professional Role	Roles may influence perspectives on pharmaceutical disposal.
Program Familiarity	Familiarity with Drug Take-Back Program Objectives	Understanding participants' baseline knowledge is crucial
Participation in the DTBP	Current Participation Status	Identifying active participants is essential for targeted insights.
	Reasons for Non-Participation.	Understanding barriers is crucial for engagement strategies.
Perceived Effectiveness	Perceived Effectiveness of DTBP	Perceptions impact engagement and future support.

Training and Education	Types of Training/ Education Received	Identifies the sources and formats of training or education participants have received. Varied sources contribute to a comprehensive understanding
	Adequacy of Training for Role	Assesses participants' perceptions of the adequacy of training in preparing them for their roles. Adequate training is crucial for effective participation
Challenges Encountered	Challenges Faced in Participation	Understanding challenges informs program refinement.
	Detailed Descriptions of Challenges	Invites participants to elaborate on the challenges they faced, providing context and depth and offer nuanced insights
Suggestions for Enhancements	Suggestions for DTBP Improvement	Program. Participant input and feedback is important for program refinement,

Appendix 5:Participants' suggestions for Drug Disposal Program Enhancement

Participants in the survey offered valuable insights and recommendations for developing and improving drug disposal programs, particularly focusing on the Drug Take-Back program. Their suggestions encompass diverse aspects, from operational logistics to community engagement and safety measures. The following is a compilation of participants' suggestions.

1. **Utilizing Reverse Distributors for Controlled Substances:**
    - *Suggestion:* "Institutional long-term care facilities could leverage reverse distributors for controlled substances. EPA guidelines for hazardous and non-hazardous bins can guide the disposal of other medications, enhancing safety and compliance."
2. **Increasing Public Awareness and Regulatory Measures:**
    - *Suggestion:* Participants emphasized the importance of public awareness and suggested that regulatory requirements could boost participation in drug disposal programs.
3. **Enhancing Accessibility:**
    - *Suggestion:* Participants recommended increasing the number of disposal locations, especially in different areas on the same day, to reduce the need for people to travel. Adjusting event dates for better weather conditions was also suggested.
4. **Community Promotion and Involvement:**
    - *Suggestion:* "Engaging local community and public safety entities, such as police and fire departments, was proposed to promote the program."
5. **Ensuring Safety Measures:**

- *Suggestion:* "Safety measures, including the use of appropriate personal protective equipment (PPE) and implementing a system similar to automatic UPS pick-up, were highlighted." Suggestions include "having two people handle bins for safety and incorporating camera views for monitoring."

6. **Information Dissemination and Education:**
    - *Suggestion:* "Providing users with information about safe sharps disposal and ensuring that literature is available at collection sites to educate patients about the benefits of the Take-Back program."
7. **Convenience and Comfort for Participants:**
    - *Suggestion:* Emphasizing the need for easy-to-use disposable containers and creating environments where patients of lower socioeconomic status feel comfortable returning medications were recommended.
8. **Program Expansion and Utilizing Resources:**
    - *Suggestion:* Expanding the program to include medication safety, utilizing students and pharmacy staff for education, and conducting surveys to determine the true needs of the program were suggested.
9. **Efficient Collection Bin Management:**
    - *Suggestion:* Participants proposed exploring technologies that alert the responsible company when bins are full, streamlining the collection process and reducing the burden on pharmacy staff.
10. **National Public Safety Campaign:**
    - *Suggestion:* Participants recommended the need for a national public safety campaign to raise awareness about drug disposal programs.

11. **Consideration of Medical Waste Impact:**
    - *Suggestion:* Reflecting on the broader impact of medical waste generated by individuals, participants suggested considering the environmental impact beyond pharmaceutical products.
12. **Ease of Participation and Education for Pharmacists:**
    - *Suggestion:* Providing guides on how to participate in Drug Take-Back programs, setting up medication disposal sites, and educating pharmacists about the process were recommended.
13. **Financial Responsibility and Vendor Engagement:**
    - *Suggestion:* Considering vendors specializing in the area and addressing financial responsibilities were raised as important considerations.
14. **Utilizing Existing Services:**
    - *Suggestion:* Participants recommended taking advantage of existing services like Medproject, which offers no-cost assistance and guidance.
15. **Promotion and Instruction Materials:**
    - *Suggestion:* "Creating posters and providing written instructions for customers on what to do with drugs were suggested to enhance communication."
16. **Government Funding for Medication Destruction:**
    - *Suggestion:* Proposals were made for state funding to support the destruction of collected medications, reducing the financial burden on pharmacies.

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