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Learner name(s): MADHURALEKSHMI PANKEY SADANAM OMANAKUTTAN

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Lecturer Name: PHILIP BYRNE

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GRIFFITH COLLEGE DUBLIN

*A thesis submitted to Griffith College, Dublin, as partial fulfilment of the requirements for an
M.Sc. in Pharmaceutical Business and Technology.*

**ASSESSING THE FEASIBILITY OF IMPLEMENTING A
PHARMACY-LED MEDICATION TAKE-BACK SYSTEM IN
KERALA: A COMPARATIVE ANALYSIS OF FRANCE'S
CYCLAMED MODEL**

STUDENT NAME: MADHURALEKSHMI PANKEY SADANAM OMANAKUTTAN

STUDENT NUMBER:

YEAR :2024-2025

DEGREE: MSC PHARMACEUTICAL BUSINESS AND TECHNOLOGY

SUPERVISOR NAME: PHILIP BYRNE


DECLARATION

I declare that this thesis is the result of my own independent research and work. It has not been previously submitted, either in whole or in part, for the award of any degree, diploma, or other qualification at this or any other academic institution. All references and sources used have been appropriately acknowledged.

Signed: 

Name: Madhuralekshmi Pankey Sadanam Omanakuttan

Date: 11/05/2025

Supervisor signature: 

Date: 11/May/2025

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2 ABBREVIATIONS

AKCDA	-	All Kerala Chemists & Druggists Association
AMR	-	antimicrobial resistance
CPCB	-	Central Pollution Control Board
DEA	-	Drug Enforcement Administration
EPA	-	Environmental Protection Agency
EPPPs	-	Environmentally Persistent Pharmaceutical Pollutants
EPR	-	Extended Producer Responsibility
FDA	-	Food and Drug Administration
FPC	-	Finite Population Correction
KAP	-	Knowledge, Attitude and Practice
ONDCP	-	Office of National Drug Control Policy
PPQS	-	Production and Pharmaceutical quality systems
PRO	-	program, accrediting a Producer Responsibility Organization
RLPB	-	Regulatory Landscape of Pharmaceutical business
RUM	-	Return Unwanted Medicines
UAE	-	United Arab Emirates
UEM	-	unused or expired medications
UMM	-	unused and expired medicines
UNESCO	-	United Nations Educational, Scientific and Cultural Organization
USEPA	-	United States Environmental Protection Agency

3 ABSTRACT

Improper disposal of unused and expired medicines poses significant risks to public health and the environment, particularly in areas like Kerala, India, where structured disposal systems are lacking. This research investigates the possibility of introducing a pharmacy-led medication take-back initiative in Kerala, inspired by the CYCLAMED program successfully implemented in France. The study utilized a quantitative methodology, collecting data from pharmacists in diverse settings across Kerala to assess existing disposal habits, awareness levels, practical challenges, and readiness for such a program. Additionally, secondary sources were reviewed to examine the operational strengths and outcomes of the CYCLAMED model.

Findings show strong support among pharmacists for a take-back initiative, with 73% willing to participate and over 70% believing their pharmacies have the resources to implement the system. Nonetheless, several challenges were identified, including unclear regulatory frameworks, limited public awareness, inadequate infrastructure, and financial constraints. Rural pharmacies, in particular, reported lower preparedness, emphasizing the need for tailored approaches in these regions. A majority of respondents highlighted the importance of government-led education campaigns, clear regulatory framework, and financial assistance as key enablers of success.

Overall, the study concludes that a pharmacy-led take-back system is both practical and needed in Kerala, provided that current gaps are addressed through coordinated policy, regulatory reform, and community engagement. Drawing insights from international practices, the research recommends a comprehensive strategy involving collaboration between healthcare stakeholders, government authorities, and the public. Such a system could play a crucial role in improving pharmaceutical waste management, safeguarding public health, and promoting environmental sustainability in the region.

5 CHAPTER 1

5.1 INTRODUCTION AND BACKGROUND

In the modern world, the use of medicines has become an essential part of everyday life. With more people relying on medications for both short-term and long-term health conditions, it is no surprise that many households end up storing unused or expired medicines. Often, these medications accumulate because of changes in prescriptions, skipping doses, or simply buying over-the-counter drugs “just in case.” Unfortunately, what happens to these leftover medicines is a growing concern, many are thrown in the trash or flushed down the toilet without much thought. These seemingly small actions can lead to serious environmental damage and pose risks to human health.

While healthcare professionals often advise patients on how to take and store medicines properly, they do not always talk about how to dispose of them safely. As a result, many people are left unsure of what to do with old or unused medications. This lack of awareness increases the risk of accidental poisoning, especially in children, and contributes to pollution in our water and soil. Even more worrying is the link between improper disposal, especially of antibiotics, and the rise of antimicrobial resistance (AMR), a major global health threat(Kaur and Bansal, 2021).

Around the world, some countries have made significant progress to tackle this issue. Australia and Canada, for example, have national programs where people can return unwanted medicines for safe disposal. The UK and Sweden also have systems in place to collect and manage unused medications. These initiatives show that with the right support and awareness, people are willing to dispose of their medicines responsibly(Kaur and Bansal, 2021).

However, in Kerala, a state in southern India, the picture is quite different. There is currently no structured system to help people safely dispose of unused or expired medications at home. Although hospitals and clinics are expected to follow Biomedical Waste Rules, the average person does not have clear guidance on what to do with leftover medicines. As a result, most people dispose of them in ways that can harm the environment and contribute to larger public health issues, like antibiotic resistance(CYCLAMED, 2025).

Looking at international examples, France offers an inspiring model. Since 1993, France has run a national program called CYCLAMED, where all pharmacies collect unused and expired medications from the public. These are then safely destroyed through eco-friendly incineration. The program has been widely embraced, with more than 60% of households participating. CYCLAMED proves that a simple, pharmacy-led approach can make a significant difference, not just in reducing waste, but also in protecting the environment and public health(CYCLAMED, 2025).

This study explores whether a system like CYCLAMED could work in Kerala. By understanding what healthcare professionals currently know, believe, and do about medicine disposal, the research aims to identify gaps and opportunities for improvement. The ultimate goal is to propose a practical and sustainable way to manage pharmaceutical waste in Kerala, one that raises awareness, protects health, and preserves the environment for future generations (CYCLAMED, 2025).

5.2 THE PURPOSE OF THE STUDY

The purpose of this study is to understand how people in Kerala, especially healthcare professionals, handle the disposal of unused and expired medications. Medicines that are no longer needed often end up in household trash or flushed into the sewage system, which can be harmful to the environment and public health. While healthcare workers guide patients on how to use medicines correctly, they rarely focus on what to do with leftover or expired ones. This study aims to find out what healthcare professionals know, think, and do when it comes to disposing of these medicines.

At the same time, this research looks at whether Kerala could adopt a system like CYCLAMED in France, a successful program where pharmacies help collect unused medicines from the public and ensure they are safely destroyed. By learning from this model and comparing it with the situation in Kerala, the study hopes to see if a similar pharmacy-led take-back system could work locally.

In addition, this research aims to offer practical suggestions that could help build a safer, cleaner way for people in Kerala to dispose of medicines they no longer need. The findings could also support policies that protect the environment, reduce health risks, and raise awareness about the importance of proper medication disposal.

5.3 SIGNIFICANCE AND JUSTIFICATION

This study is important because it addresses a real-world problem in Kerala, the improper disposal of unused and expired medications. Every day, pharmaceutical waste accumulates, leading to potential issues like water pollution, the spread of antibiotic-resistant bacteria, and harm to local ecosystems. By looking into whether a pharmacy-led medication take-back system (inspired by CYCLAMED program from France) can work in Kerala, this research aims to find a practical way to reduce these risks and protect both public health and the environment.

There are several reasons why this research matters:

- **Protecting the Environment and Public Health:** When medications are thrown away improperly, they can end up contaminating water sources and soil, which in turn increases the risk of accidental poisoning and helps create drug-resistant bacteria. A safe, organized take-back system could help prevent these problems.
- **Enhancing Pharmacy Practices:** Introducing a structured way for pharmacies to manage expired or unused medications can improve how they handle and store these drugs. This not only makes pharmacies safer but also helps ensure that they follow best practices in managing their inventory.
- **Driving Better Policies and Regulations:** Currently, Kerala does not have clear guidelines for disposing of unused medications at the consumer level. By highlighting these gaps and learning from successful models abroad, this study could provide the evidence needed to shape new policies and regulations, making the entire system more effective.
- **Wider Impact Beyond Kerala:** Although this study focuses on Kerala, the insights gained could be useful for other regions facing similar challenges. In the long run, these findings could promote more sustainable practices in managing pharmaceutical waste, benefiting communities and the environment on a larger scale.

In short, this study aims to offer a practical solution to a pressing local problem while also contributing to broader efforts in environmental protection, public health, and regulatory reform in the pharmaceutical industry.

5.4 PROBLEM STATEMENT

Every day, people and animals use a wide range of medications, yet much of what is purchased ends up unused or expired quite often more than 80% of all medicines bought remain unconsumed (Vellinga *et al.*, 2014). This situation is driven by various factors like changes in prescriptions, confusing usage instructions, adverse reactions, and the natural expiry of the products. When these unused drugs are discarded improperly, thrown in the trash or flushed down the drain, they can cause significant problems. They pollute our water, contribute to the rise of antibiotic-resistant bacteria, and may even end up in misuse or accidents, ultimately raising healthcare costs and risks to public health (Sonowal *et al.*, 2024).

In many European countries, systems like the CYCLAMED program have been established to tackle these issues. In these systems, community pharmacies play a crucial role in collecting unused medications, ensuring they are safely disposed of and do not harm the environment. However, in Kerala, there is no structured, pharmacy-led program for managing expired or unused medicines at the consumer level. This gap means that improper disposal remains common, leaving both the environment and public health vulnerable.

This research aims to explore whether a pharmacy-led medication take-back system, similar to the successful European models, can be introduced in Kerala. By understanding current disposal practices and identifying the challenges and opportunities, the study seeks to propose a practical, sustainable approach that protects both people and the environment.

5.5 RESEARCH AIM

To assess the feasibility of adapting pharmacy-led medication take-back system like CYCLAMED from France to the context of Kerala, focusing on the regulatory, infrastructural, and public and professional awareness challenges.

5.6 RESEARCH OBJECTIVES

Primary Objective:

To evaluate the feasibility of implementing a pharmacy-led medication take-back system in Kerala based on France's CYCLAMED model.

Specific Objectives:

1. Assess the current medication disposal practices in Kerala.
2. Analyze the operational structure, success factors, and impact of CYCLAMED model of France.
3. Compare regulatory policies, pharmacy involvement, and public participation in both regions.
4. Identify barriers and opportunities for implementing a similar system in Kerala.
5. Recommend policy and operational strategies for government and pharmacies of Kerala.

5.7 RESEARCH QUESTIONS

Primary Research Question

Is it feasible to implement a pharmacy-led medication take-back system in Kerala, based on CYCLAMED program from France?

Specific Research Questions

1. What are the current methods used by the public and healthcare professionals in Kerala to dispose of unused and expired medications?
2. What are the operational mechanisms, success factors, and environmental or public health impacts of the CYCLAMED model in France?

3. How do the regulatory policies, the role of pharmacies, and public awareness differ between France and Kerala regarding pharmaceutical waste disposal?
4. What challenges and opportunities exist for implementing a pharmacy-led take-back system in the context of healthcare and regulatory environment of Kerala?
5. What strategies and policy recommendations can be developed to support the implementation of an effective medication disposal system in Kerala?

5.8 RESEARCH HYPOTHESIS

HYPOTHESIS 1: Implementing a pharmacy-led medication take-back system in Kerala, inspired by CYCLAMED program from France, is realistic and can work well in the state, provided there is the right mix of infrastructure, government support, and public awareness.

HYPOTHESIS 2: People in Kerala are currently using unsafe or ineffective methods to dispose of unused medications, which is leading to environmental damage and health risks, highlighting the need for a better, organized system.

HYPOTHESIS 3: While there are challenges to setting up a medication take-back system in Kerala such as regulatory hurdles, lack of awareness, and gaps in infrastructure, these obstacles can be overcome with the right policies, public engagement, and resources.

5.9 LINK WITH THE MODULE

The topic of research ties in closely with several areas of my Masters program, especially when it comes to “**Process, Production and Pharmaceutical quality systems (PPQS)**”, and “**Regulatory Landscape of Pharmaceutical business (RLPB)**”. While my research focuses on managing pharmaceutical waste and public health, it also touches on how pharmacies handle and dispose of expired or unused medications, which is a key part of the pharmaceutical supply chain. It is also connected to the pharmaceutical quality system because the safe disposal of medications is essential for maintaining public health and preventing environmental harm, an important factor in any quality management system.

In terms of the regulatory landscape, implementing a take-back system in Kerala would require proper regulatory policies to ensure that medications are safely collected and disposed of. This would mean pharmacies and businesses must comply with environmental and health regulations. On a broader scale, pharmaceutical companies also play a role in supporting policies that promote safe disposal practices, often through public health initiatives or recycling programs. So, my research connects the dots between industry regulations, public health policies, and business practices, exploring how these areas can work together to tackle the issue of pharmaceutical waste.

5.10 ACCESS AND RESEARCH ETHICS ISSUES

This research aims to understand how a pharmacy-led medication take-back system could work in Kerala by gathering data from licensed pharmacists in Kerala. They play a crucial role in the medication lifecycle, from dispensing to advising on use and, potentially, disposal. To truly capture their insights, experiences, and the challenges they face, this study will gather information through a survey designed specifically for licensed pharmacists. Since their time and perspectives are highly valued, the approach will be respectful, transparent, and built on ethical principles that prioritize their comfort, confidentiality, and willingness to participate.

5.10.1 Access to Participants and Data

This study involved reaching out to pharmacists actively working in Kerala, both in community pharmacies and hospital settings. To connect with them, pharmacies were contacted directly, and efforts were also made through professional pharmacy associations, local pharmaceutical societies, and pharmacist networks. In certain structured or regulated environments, permission was sought from pharmacy managers before approaching the pharmacists.

Participation was entirely voluntary. Pharmacists were invited to take part through email, in-person visits, or online platforms. Understanding their busy schedules, the survey was designed to be simple, clear, and respectful of their time and professional responsibilities. Every effort was made to ensure that their insights could be shared comfortably and meaningfully.

5.10.2 Ethical Considerations

Throughout this research, great care was taken to ensure that every pharmacist who participated was treated with respect and fairness. Before beginning the survey, each participant was clearly informed about the purpose of the study, what was expected of them, and how their responses would be used. Their consent was asked before the beginning of the survey. Protecting the privacy of participants was a top priority, no names, specific workplaces, or personal details were collected or shared, and all responses were handled confidentially and reported only in summary form to protect anonymity. Participation was completely voluntary, with pharmacists free to skip questions or exit the survey at any point without any pressure or consequence. To keep their information safe, all data was stored securely on password-protected systems and used strictly for academic purposes. Once the study is complete, the data will be deleted in line with data protection guidelines of Griffith College Dublin. Ethical approval for the study was obtained from the authorized authority to ensure everything was carried out responsibly. Focusing on pharmacists allowed the research to tap directly into the insights of those closest to the issue, and every step was taken to make sure their contributions were respected and valued throughout the process.

5.11 OVERALL STRUCTURE OF THE RESEARCH

This thesis is organized into five main chapters, as illustrated in Figure 1.

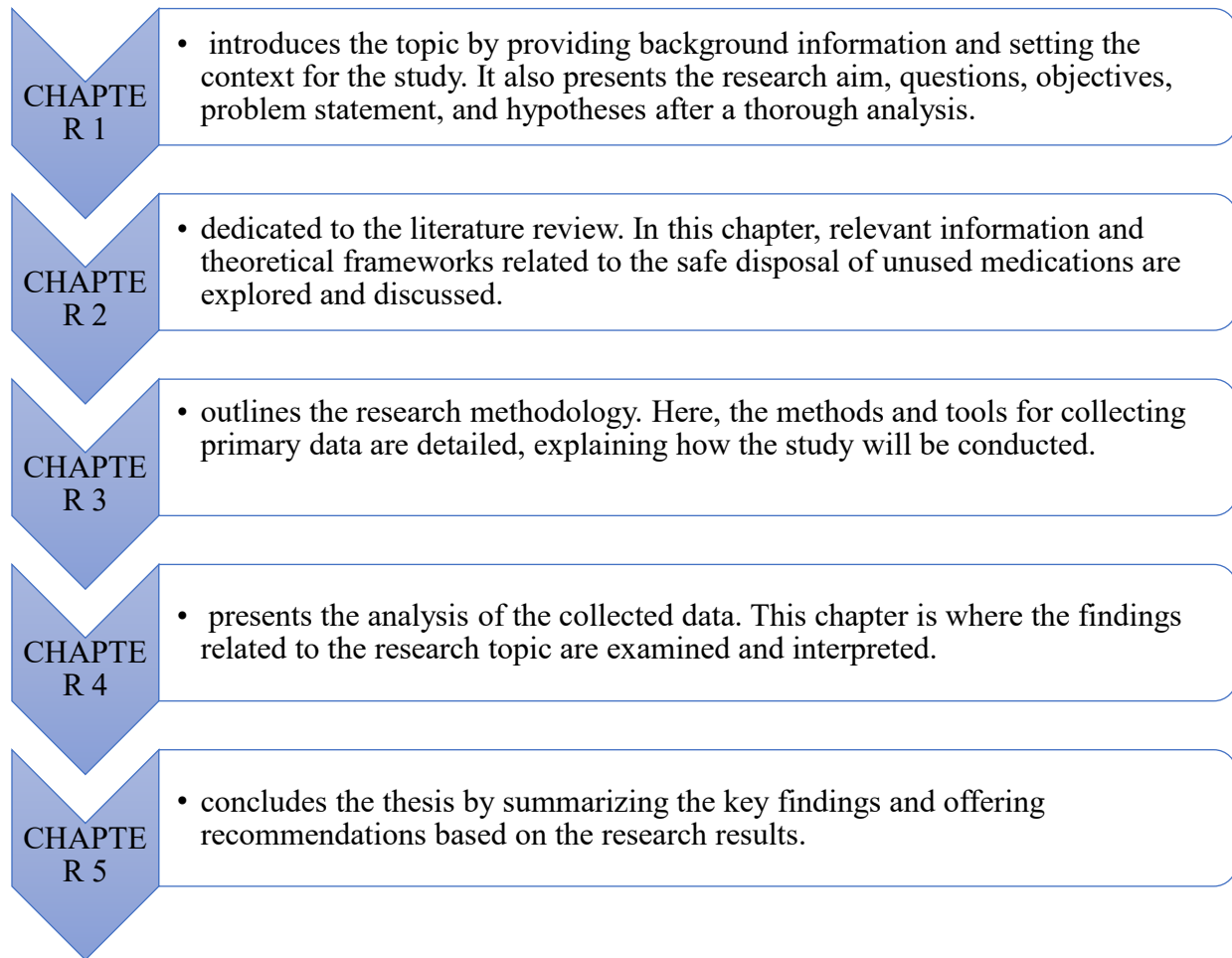


Figure 1: Overall structure of the research

6 CHAPTER 2

6.1 LITERATURE REVIEW

6.1.1 INTRODUCTION

Medicines have become a part of our daily lives. From treating common colds to managing chronic illnesses, they play a vital role in keeping us healthy and improving our quality of life. Whether they are available over the counter or prescribed by a healthcare professional, medications are meant to be used with care. However, the reality is that many of these medicines are often misused, overprescribed, or simply left unused, and what happens to them after that is something we do not talk about enough(Abruquah *et al.*, 2014).

Improper disposal of unused or expired medicines has quietly grown into a global concern. Many people throw unused medicines in the trash, flush them down the toilet, or store them indefinitely in medicine cabinets without realizing the potential harm. These actions, though common, can pose serious risks, ranging from accidental poisoning, especially in children, to drug abuse and environmental contamination. Traces of pharmaceutical substances have even been found in rivers, lakes, and drinking water supplies, raising red flags for both human and environmental health(Abruquah *et al.*, 2014).

In some countries, efforts are already underway to tackle this issue. Programs that encourage people to return unused medicines to local pharmacies have shown promising results, both in reducing health risks and protecting the environment. Unfortunately, in many developing countries, such systems are either lacking or not widely used. People are often unaware of the proper ways to dispose of medicines, and there is limited access to safe disposal options(Abruquah *et al.*, 2014).

6.1.2 REVIEW OF EMPIRICAL STUDIES

This section presents an analysis of previous empirical studies relevant to the research topic. It aims to explore how past research has addressed similar questions to provide insights that inform the current study.

6.1.2.1 HOW DO WE GENERATE PHARMACEUTICAL WASTE?

Pharmaceutical waste is not just one type of waste, it is made up of many different kinds, reflecting the wide range of chemicals used in medications. In healthcare settings, this kind of waste can come from everyday activities like preparing IV medications, mixing drugs, dealing with spills or breakages, handling partially used vials and syringes, or managing medications that are no longer needed, expired, or returned by patients. Even personal medicines and outdated stock of patients contribute to the problem.(Mburu, 2012)

In the U.S., the Environmental Protection Agency (EPA) sorts hazardous pharmaceutical waste into three main categories: the "P list" for highly toxic substances, the "U list" for toxic ones, and the "D list" for drugs that are flammable, corrosive, reactive, or toxic. Interestingly, it is not always the active drug itself that is hazardous, it can sometimes be the preservative or diluent in the formulation. Medications that do not fall under these hazardous categories are generally treated as solid, non-hazardous pharmaceutical waste (Daughton, 2007; Mburu, 2012).

Pharmacies see a variety of sources for this kind of waste. Common ones include expired stock, contamination, spills, poor storage conditions, broken containers, damaged packaging, returns from customers, and even product recalls. Sometimes, mishandling or pest damage can also lead to waste. Managing all these sources properly is essential for both safety and environmental protection (Mburu, 2012).

6.1.2.2 METHODS FOR SAFE DISPOSAL OF UNUSED OR EXPIRED MEDICINES

1. RETURN TO DONOR OR MANUFACTURER

When possible, expired or unusable medicines, especially hazardous ones like anti-neoplastics, should be returned to the manufacturer or donor for proper disposal. This is particularly useful for unsolicited or expired donations (Kharaba *et al.*, 2022).

2. CROSS-BORDER PHARMACEUTICAL WASTE TRANSPORT

Although there is no specific global law for moving pharmaceuticals across countries, expired medicines are classified as hazardous waste. Their transport is governed by the Basel Convention, which requires permits and can take several months to process (Minlarch, 2020).

3. LANDFILL DISPOSAL METHODS

Landfilling involves placing waste in designated sites, and there are three types:

- **Open Dumps (Uncontrolled Sites):**
Common in some developing areas but not recommended due to environmental hazards. If used, waste should be buried under municipal waste and, preferably, first stabilized.
- **Engineered Landfills:**
Offer better protection and are suitable for direct disposal of some medicines, though stabilized waste is preferred.
- **Sanitary Landfills (Highly Engineered):**
These are secure, well-managed sites that isolate waste from water sources. Waste of each day is compacted and covered with soil. These are considered a relatively safe option for pharmaceutical waste (WHO, 2025).

4. IMMOBILIZATION TECHNIQUES

- **Encapsulation:**

Medicines are sealed inside drums (usually up to 75% full), then filled with materials like cement or bitumen to lock the waste inside. Drums are then sealed and buried in a landfill.

- **Inertization:**

Medicines are crushed and mixed with water, cement, and lime to form a thick paste. This mixture is then poured into landfills where it solidifies, making it safer for the environment (Banjar *et al.*, 2022).

Ratio by weight:

- 65% waste
- 15% cement
- 15% lime
- 5% or more water

5. DISPOSAL THROUGH SEWER SYSTEMS

Small volumes of liquid medications (e.g., syrups or IV fluids) may be diluted and flushed into functioning sewer systems or fast-moving water sources, but only under expert guidance to avoid contamination (Abruquah *et al.*, 2014).

6. OPEN BURNING

Burning pharmaceuticals in open containers at low temperatures is strongly discouraged due to harmful emissions. Only very small amounts of non-PVC packaging may be burned if necessary.

7. MEDIUM-TEMPERATURE INCINERATION

If high-temperature incinerators are unavailable, older two-chamber incinerators (minimum 850°C with a 2-second retention time) may be used. Pharmaceutical waste should be heavily diluted with other waste (approx. 1:1000 ratio). However, these systems are not suitable for halogenated compounds (WHO, 2025).

8. HIGH-TEMPERATURE INCINERATION IN INDUSTRIAL PLANTS

Industries such as cement kilns, power plants, and foundries operate at very high temperatures (up to 2000°C), making them effective for destroying pharmaceutical waste. Cement kilns are particularly ideal due to:

- High operating temperatures
- Long burn time
- Tall chimneys for safe gas release
- High daily waste capacity
- Minimal environmental impact when regulated

Medicines should be introduced as no more than 5% of the total fuel feed. Pre-treatment like unpacking or grinding may be needed(WHO, 2025).

9. CHEMICAL DECOMPOSITION

This involves breaking down medicines using chemical reactions based on manufacturer guidelines, followed by landfill disposal. It is only suitable for small quantities due to the complexity, need for chemicals, and safety concerns. It is sometimes used for anti-neoplastics, but impractical for large volumes(WHO, 2025).

6.1.2.3 ENVIRONMENTAL ENTRY OF UNUSED PHARMACEUTICALS AND THEIR ASSOCIATED IMPACTS

Pharmaceuticals are now widely acknowledged as emerging environmental pollutants. UNESCO (2020) emphasizes the importance of addressing this issue as part of the global Sustainable Development Goals for 2030. Although these drugs often appear in water at extremely low levels, their long-term presence raises serious concerns for both ecosystems and human health(Vumazonke *et al.*, 2020; Paut Kusturica *et al.*, 2022)

Various medicines like antibiotics, antidepressants, hormones, painkillers, and anticancer drugs have been found to disrupt aquatic life, causing reproductive problems, organ damage, and behavioral changes even in tiny amounts. Some of these substances are especially harmful because they do not easily break down and can build up in the environment over time(Bilal and Iqbal, 2019; Paut Kusturica *et al.*, 2022)

The situation appears to have worsened during the COVID-19 pandemic, with an incline in the use and improper disposal of antibiotics and mental health medications. This has contributed to growing antibiotic resistance and increased pharmaceutical contamination in water systems. These pollutants do not stay isolated they can enter the food chain and eventually impact human health, potentially affecting brain development and worsening chronic illnesses (Abbey-Lee *et al.*, 2018; Paut Kusturica *et al.*, 2022).

Despite increased awareness, many pharmaceutical pollutants still go undetected due to limited testing methods. As a result, the full impact remains unclear, highlighting the urgent need for better waste management, stricter regulations, and continued research in this area (Klaus K"ummerer, 2009).

Pharmaceuticals are used around the world, but the way they are consumed and managed varies widely. Some countries allow over-the-counter sales of medications that are tightly regulated elsewhere. Cultural practices, healthcare access, and regulatory systems all influence usage patterns. Beyond human use, pharmaceuticals are also applied in agriculture, such as in fruit farming and beekeeping, raising concerns about antibiotic resistance(Kümmerer, 2009).

Animal farming is another major source of pharmaceutical pollution. Antibiotics and other drugs are often used not just to treat animals, but also to promote growth, especially in large-scale farming. In countries with intensive livestock operations, this leads to significant environmental exposure.

Although manufacturing plants are expected to follow strict environmental standards, especially in Europe and North America, recent evidence shows that factories in some Asian countries are releasing high concentrations of drug residues into wastewater. Hospitals also contribute through their wastewater, which contains higher concentrations of drugs, although it is usually diluted within municipal systems(Kümmerer, 2009).

Households, however, play a surprisingly large role. Many people dispose of unused or expired medicines by flushing them down the toilet or throwing them in the trash. These practices can send active pharmaceutical ingredients into landfills and water systems, where they may persist and cause harm over time.

While take-back systems exist in some countries, awareness and participation remain low. This highlights the urgent need for public education and the development of safer, more sustainable disposal methods to reduce the environmental impact of pharmaceuticals.

In countries like India, where the pharmaceutical industry is one of the largest in the world, this issue is especially prevalent. Rapid industrial growth has led to pharmaceutical plants releasing untreated or only partially treated wastewater into local streams and rivers. While the concentrations of these compounds are often low, their presence is still concerning. These chemicals can accumulate in the water and enter the food chain, impacting both aquatic organisms and the wider ecosystem(Patneedi and Prasadu, 2015).

Pharmaceutical manufacturing also generates large amounts of waste, including not just the drugs themselves, but also other harmful chemicals. Unfortunately, standard wastewater treatment processes are not always effective at removing these substances, which is why they are often detected in drinking water sources. Although the concentrations in drinking water are usually low, long-term exposure to these substances could still pose risks to human health and wildlife.

While there is little immediate risk to human health from these trace amounts, the effects on aquatic life are much more significant. For example, fish exposed to trace levels of certain pharmaceutical

drugs have shown signs of reproductive problems, which could threaten whole populations. These pollutants can also disrupt the delicate balance of microorganisms in water systems. Drugs like antibiotics, hormones, and painkillers have been found to have a profound effect on ecosystems, emphasizing the need for better regulation and waste management (Patneedi and Prasadu, 2015).

Unfortunately, regulatory standards for pharmaceutical contamination in water are still lacking in many parts of the world, including in India. Although countries like the United States have started to recognize the problem and added certain pharmaceutical compounds to their contaminant lists, there is still much more to be done globally. More research is needed to fully understand the extent of pharmaceutical pollution and to find effective ways to reduce it. This is a growing issue, and without more action, it could continue to affect both our health and the environment in the future.

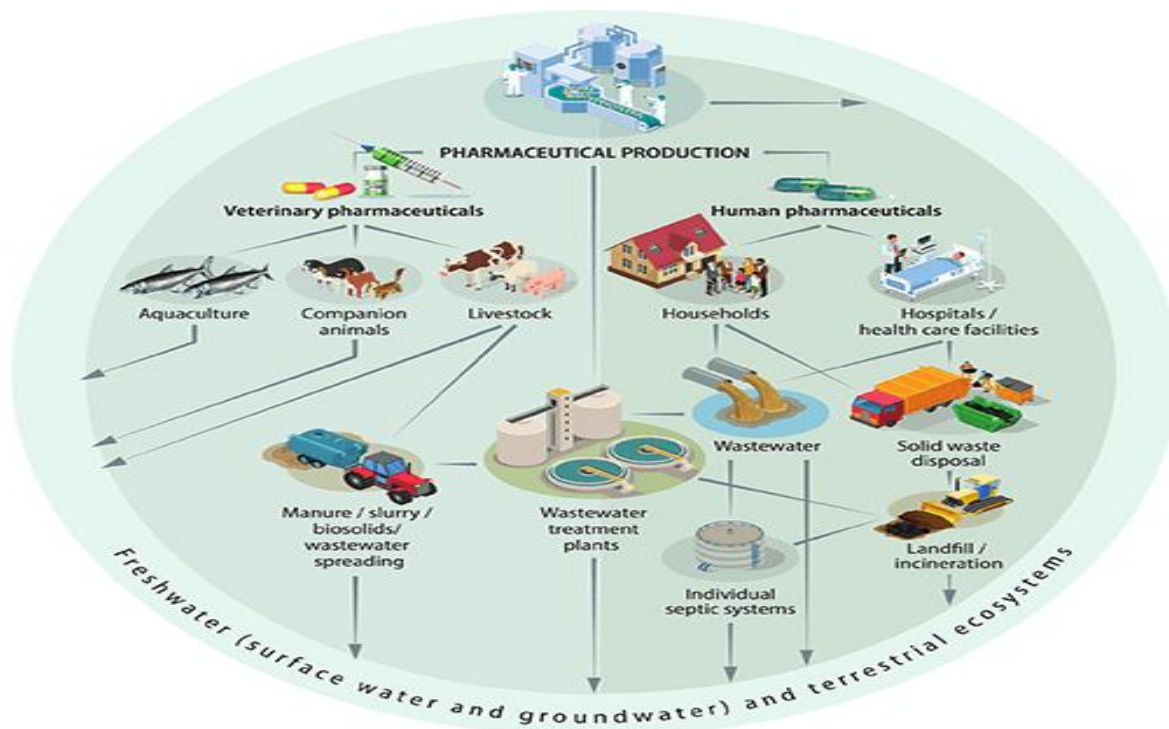


Figure 2: ENVIRONMENTAL ENTRY OF UNUSED PHARMACEUTICALS (Environment, 2020)

6.1.2.4 PRACTICE OF MEDICATION DISPOSAL IN FRANCE

CYCLAMED: France's National Model for Sustainable Pharmaceutical Waste Management



Figure 3: THE OFFICIAL LOGO OF CYCLAMED(National Order, 2017)

Founded in 1993 and recognized by French public authorities, CYCLAMED is a non-profit eco-organization leading the way in pharmaceutical waste management across France, including its overseas territories. The primary mission of the organization is to facilitate the safe collection and environmentally sound disposal of unused and expired medicines (UMM) returned by the public. By aligning environmental protection with public health priorities, CYCLAMED serves as a model for how a large-scale initiative can effectively address the pressing issue of pharmaceutical waste(CYCLAMED, 2024).

At the heart of the CYCLAMED operations is a coordinated network that brings together all key parts in the pharmaceutical supply chain such as community pharmacies, wholesale distributors, and pharmaceutical manufacturers. Community pharmacies function as official collection points, equipped with secure containers supplied by CYCLAMED. Individuals can easily dispose of their unused medicines at these pharmacies. Once full, the containers are collected by wholesale distributors as part of their regular delivery schedules. The collected waste is temporarily stored in pharmaceutical facilities before being transported to authorized energy recovery units (UVEs) located throughout the country.

These UVEs incinerate the pharmaceutical waste at high temperatures, effectively neutralizing active pharmaceutical ingredients while simultaneously producing energy in the form of heat or electricity. This waste-to-energy process not only ensures safe disposal but also supports sustainable energy use, also producing enough energy annually to meet the heating and lighting needs of small towns like Honfleur or Cassis. Approach of CYCLAMED demonstrates the

principles of a circular economy, transforming pharmaceutical waste into a resource rather than simply eliminating it(CYCLAMED, 2024).

To guarantee the security and traceability of this system, CYCLAMED enforces rigorous protocols under pharmaceutical oversight. Each stage of the process, from collection to energy recovery, is carefully documented and monitored, ensuring compliance with national regulations and minimizing risks such as accidental ingestion, drug misuse, or environmental harm. This strict oversight reinforces dedication of CYCLAMED to safety, transparency, and accountability.

Public education plays a central role in effectiveness of CYCLAMED. The organization implements wide-reaching awareness campaigns aimed at consumers, healthcare providers, and institutional partners. These campaigns utilize multiple communication channels including television and radio broadcasts, in-pharmacy materials, and collaborative outreach events to educate the public on the dangers of improper medication disposal and the importance of returning unused drugs. These efforts have led to significant shifts in public behavior. According to a 2024 survey by the BVA polling institute, 81% of French citizens now report returning their unused or expired medications to pharmacies, with 60% doing so consistently. The survey also revealed that 87% of respondents properly separate and recycle empty medication packaging, such as blister packs, bottles, and leaflets(CYCLAMED, 2024).

The guiding slogan “Sort, Bring, Preserve” has become a familiar and influential message across the country, illustrating the depth of cultural impact CYCLAMED. Environmental protection remains the top motivation for participating in the program, cited by 59% of respondents outpacing even concerns about household health safety. Notably, the campaign has contributed to a measurable reduction in pharmaceutical waste: the quantity of unused medications collected dropped from 9,415 tons in 2022 to approximately 8,500 tonnes in 2023. This decline, despite demographic trends such as an aging and growing population, points to enhanced treatment adherence, fewer prescriptions, and the success of CYCLAMED combined operational and educational efforts(CYCLAMED, 2024).

CYCLAMED also embodies the principles of Extended Producer Responsibility (EPR), under which pharmaceutical manufacturers are legally accountable for the end-of-life management of the products they introduce to the market. The organization manages this responsibility on behalf of the industry, providing an efficient, transparent, and compliant system for pharmaceutical waste recovery.

In summary, CYCLAMED represents a forward-thinking, collaborative model that integrates environmental sustainability with public health protection. Its comprehensive infrastructure, strong regulatory alignment, effective stakeholder cooperation, and high levels of public participation demonstrate how national-scale programs can responsibly manage pharmaceutical

waste. As other countries explore sustainable waste management solutions, the CYCLAMED initiative offers a well-established blueprint built on practicality, trust, and long-term impact.

In France, returning unused or expired medications to pharmacies is not just a good idea, it is the law, and this policy has been in place since 2007. This makes it easy for individuals to safely dispose of their leftover medications at local pharmacies, free of charge. Since 2009, pharmaceutical waste has been part of Extended Producer Responsibility (EPR) system of France, which holds pharmaceutical companies responsible for funding the collection and proper disposal of these unused drugs. Pharmacies serve as the collection points for this waste.

The French Ministry of Environment oversees this program, accrediting a Producer Responsibility Organization (PRO) to manage the initiative. Since 2022, CYCLAMED has been in charge, with the accreditation set to run through 2027. What makes this system truly remarkable is its 100% participation rate, every one of 22,000 pharmacies, 191 pharmaceutical companies, and 195 wholesale distributors of France is involved. This broad commitment has turned CYCLAMED into a rare example of successful national coordination in managing pharmaceutical waste(OECD, 2022).

It is not just the professionals who are on board, 78% of patients in France report returning their unused medications to pharmacies, showing how deeply embedded the practice has become in the public mindset. The results are impressive: in 2018, France collected over 10,800 tons of unused medications, which were then sent to specialized incineration facilities where they were safely destroyed while recovering useful energy, like heat or electricity(OECD, 2022).

What is even more impressive is how efficiently the program is funded. With an annual budget of just €10 million, the whole initiative is financed through a small contribution from pharmaceutical producers, only €0.0032 per medication pack (excluding VAT). One of the most encouraging signs is the decline in pharmaceutical waste at home. In 2010, French households had an average of 878 grams of unused medications per person. By 2018, that number had dropped to 614 grams, showing that improved awareness, smarter prescribing, and better adherence to medications are making a real difference(OECD, 2022).

CYCLAMED operates under Extended Producer Responsibility (EPR) of France framework for pharmaceutical waste, which was established through the Environmental Code (Code de l'Environnement). The legal foundation for managing the collection and disposal of unused pharmaceutical products was set by Decree No. 2006-1011 on August 4, 2006. The EPR system was formally integrated into French legislation in 2007 to ensure that pharmaceutical producers take responsibility for the waste generated by their products(OECD, 2022).

One of the key provisions in this legislation is Article 32 of Law No. 2007-248, passed on March 20, 2007. This article specifically addresses the obligation for producers of certain products,

including pharmaceuticals, to manage the collection, recycling, and disposal of their products once they are no longer in use or have become waste. Article 32 laid the legal groundwork for the creation of a Producer Responsibility Organization (PRO), tasked with the take-back and safe disposal of unused and expired medicines from households. This is where CYCLAMED plays a critical role(CYCLAMED, 2025).

CYCLAMED, accredited by the French Ministry of Environment, coordinates the national system for pharmaceutical waste management. It serves as the PRO, ensuring the safe collection, recycling, and disposal of pharmaceutical waste. This accreditation is granted for a period of six years, with the current accreditation awarded in 2022 running through 2027. The organization works with pharmacies, pharmaceutical companies, and distributors to ensure that unused medications are collected and disposed of in an environmentally responsible manner(CYCLAMED, 2025).

The overarching goal of this legislation is to reduce the environmental impact of pharmaceutical waste, with the producers funding the system. CYCLAMED, as the designated PRO, helps to achieve this by implementing the system across France and ensuring compliance with the regulations. By placing responsibility on producers, Article 32 encourages waste reduction and promotes sustainable practices within the pharmaceutical industry(CYCLAMED, 2025).

6.1.2.5 PRACTICE OF MEDICATION DISPOSAL IN KERALA

In many places, people still throw away old medicines in the trash, flush them down toilets, or throw them into open spaces and water bodies, often without realizing the environmental harm they are causing. These actions not only pollute water sources and endanger aquatic life but also contribute to the growing threat of antimicrobial resistance (AMR). This is especially concerning in a state like Kerala, known for its strong healthcare system, where such a gap in proper medicine disposal clearly demands urgent attention(S, 2024).

To tackle this issue, Kerala launched the nPROUD Program (Programme for Removal of Unused Drugs) in April 2019. The initiative was a joint effort by the State Drugs Control Department and the All Kerala Chemists & Druggists Association (AKCDA). It started as a pilot project in Thiruvananthapuram, with 35 locked bins installed in select pharmacies to collect expired and unused medicines. These bins were specially designed to safely hold tablets, capsules, and other household pharmaceutical waste. Once a month, the waste is collected, sorted centrally, and sent for safe, eco-friendly incineration at IMAGE, the only authorized facility for such disposal in Kerala(admin, 2019).

Despite its promise, PROUD faces several roadblocks. For starters, most of the medicines sold in Kerala come from other states, and many pharmaceutical companies do not take responsibility for what happens to unused or expired stock. On top of that, the rise of marketing firms and branded

generics has led to more medicines in circulation without a solid plan for how to get rid of them properly(S, 2024).

Another major issue is the lack of clear regulations. Drugs and Cosmetics Act of India does not spell out how expired or unused medicines should be handled, and with only one incineration plant already burdened by hospital waste, the infrastructure simply cannot keep up. Add to this the costs of setting up and managing collection bins, transportation, and disposal and it is clear why many stakeholders find it difficult to commit to the process. Public awareness is still low, as well. Many people do not even know that safe disposal options exist(admin, 2019).

For PROUD to succeed in the long run, several things need to happen. We need clearer laws that lay out who is responsible for drug waste and how it should be handled. We also need more disposal facilities and should consider newer technologies like plasma pyrolysis. Expanding PROUD to all districts in Kerala is a key next step. And perhaps most importantly, we need to spread the word that people need to know why these matters. Pharmacists, healthcare workers, and the media can all play a big role in building that awareness(S, 2024). Looking to international models like CYCLAMED from France, where pharmacies lead the way in take-back programs, can also offer inspiration.

In connection with these issues, a group of researchers, Divya Raj, Densy Davis, Githin Jose, Kezia Joy, and Sandra Johnson were conducted a study in 2020 titled "*A Qualitative Study on Drug Waste Management Among Drug Distributors, Kochi.*" They set out to understand how distributors in Kochi, especially in the Ernakulam district, manage drug waste, what challenges they face, and how much they know about proper disposal practices(Divya Raj, 2024).

The team interacted with around 45 drug distributors, of which 30 agreed to participate. Many were hesitant at first, unsure about sharing their practices. The absence of registered pharmacists in distribution centers were something not required by current Indian regulations, which was a key reason behind the poor awareness levels and the vague understanding of pharmaceutical waste(Divya Raj, 2024).

Surprisingly, about two-thirds (66.6%) of the participants were unaware of how to manage drug waste properly. And even those who claimed they were familiar with it often referred to non-pharmaceutical waste like cartons and packaging. This confusion shows just how misunderstood the issue is(Divya Raj, 2024).

Most of the waste collected by distributors came in the form of expired medicines returned from pharmacies. Other types, like spilled or non-reusable drugs, were often rejected by manufacturers. With no proper system to manage this waste, some distributors ended up stockpiling it on their premises, handing it over to municipal waste collectors, or even reducing prices on nearing-expiry drugs to avoid waste(Divya Raj, 2024).

Returning expired stock to manufacturers is also tricky. Many drugs come from northern India or abroad, and transporting them back is expensive. Kerala has only a few local manufacturers and just one authorized disposal facility, making it hard for distributors to follow through with safe disposal (Divya Raj, 2024).

Even more concerning was that very few distributors were aware of the PROUD initiative. The ones who had heard about it were surprised to learn that it had already collected around five tons of pharmaceutical waste, which had to be transported all the way to Mangalore for safe disposal, costing nearly Rs. 200,000, mostly in transportation. This highlights the urgent need for local disposal infrastructure.

Government inspections of distribution centers are rare, and without clear guidelines or strong enforcement, most distributors are left to handle things on their own. Many pointed out that they lacked support, both from the government and manufacturers and felt that more awareness campaigns and mandatory training were necessary.

When asked about possible solutions, distributors emphasized the need for collaboration between manufacturers, distributors, pharmacists, and the government. They also called for stronger laws, proper waste collection infrastructure, and better public education on the environmental and health risks of drug waste.

In overall, this study adds valuable insight to a topic that does not get nearly enough attention in Kerala. It uncovers systemic issues, knowledge gaps, and infrastructural shortcomings in the drug distribution chain. Addressing these challenges through better education, regulation, and investment is crucial for ensuring that unused and expired medications are disposed of safely for the health of both the public and the environment.



Figure 4: nPROUD COLLECTIONBOX (Drug Control.org, 2025)

6.1.2.6 LESSONS FROM DIFFERENT GEOGRAPHIES

EU

In recent years, the European Union has become increasingly aware of the dangers that come with improper disposal of household medicines. When unused or expired medications are disposed into the trash, flushed down the toilet, or poured down the sink, they can find their way into our environment thereby contaminating water sources, harming wildlife, and even posing health risks to humans. To tackle this growing concern, the EU updated its regulations through Directive 2004/27/EC, encouraging all Member States to set up proper collection systems where people can safely return their old medications. Pharmacies are typically the go-to spots for this, acting as collection points where trained professionals can handle pharmaceutical waste correctly (Mitkidis *et al.*, 2021).

When these return systems are used as intended, they play a big role in reducing pollution from pharmaceutical substances and preventing accidental poisonings especially among children and vulnerable individuals. On top of that, they help educate the public about the impact of medicine waste, all while offering a relatively low-cost and accessible solution compared to complex water treatment technologies (Mitkidis *et al.*, 2021).

However, putting this idea into practice across all EU countries has not been without its challenges. While most countries have some kind of system in place usually involving pharmacies, not everyone knows about them, and not everyone finds them easy to use. In some places, people still see it as inconvenient or simply are not aware that returning medications is even an option. A major EU-wide survey in 2013 revealed that nearly half of pharmaceutical waste still ends up being disposed of improperly (Mitkidis *et al.*, 2021).

There is also the human factor, sometimes pharmacists themselves may not accept returned medicines due to confusion about the rules or lack of support. This kind of rejection can discourage people from trying again. For these systems to really work, it is not just about having the infrastructure, it is about making sure both the public and pharmacy staff are informed, supported, and on the same page. Clearer, harmonized regulations across the EU could go a long way in ensuring that everyone knows how to safely dispose of medications, helping protect both our health and our environment (Mitkidis *et al.*, 2021).

USA

Improper disposal of unused or expired medications has been a persistent issue in the United States, with many people still flushing drugs down the toilet, rinsing them down the sink, or throwing them in the trash. Years ago, poison control centers recommended flushing medications as a way to prevent accidental poisonings, but this practice has led to bigger environmental problems. Wastewater treatment plants are not designed to remove pharmaceuticals, so they end up in rivers,

lakes, and oceans, causing harm to aquatic life. Similarly, medications thrown in the trash often end up in landfills, where they can leak into the environment or be accessed by children, pets, or even those seeking to misuse them. Unfortunately, a lot of people still use these risky disposal methods, even though there are safer options, like returning medications to collection programs. Surveys have shown that many households continue to stockpile unused medicines or dispose of them in harmful ways, putting both people and the environment at risk(Susan, 2025).

In response, the U.S. government has made efforts to address the problem. The White House Office of National Drug Control Policy (ONDCP) issued guidelines to stop flushing medications and instead suggested mixing them with things like kitty litter before throwing them away. The “SMARxT Disposal™” program was also launched to raise awareness about the dangers of improper disposal. Still, challenges remain because of the complicated rules around controlled substances. Agencies like the FDA, DEA, and USEPA each play a role in regulating how medications should be disposed of, but the laws can sometimes create confusion and make it harder to implement effective solutions. To make real progress, we need better coordination between policies and more education to help the public understand the risks and how to properly dispose of medications(Susan, 2025).

AUSTRALIA

The Return Unwanted Medicines (RUM) Project in Australia is an essential initiative that helps people safely dispose of unused or expired medications. This national program allows consumers to return unwanted medicines to their local pharmacies, where they are then incinerated at high temperatures to prevent them from ending up in landfills or contaminating waterways. In 2016 alone, the RUM Project collected over 704 tons of unwanted medicines, including everything from prescription drugs to over-the-counter medications. By keeping potentially harmful medicines out of the environment, the program plays a key role in protecting both public health and wildlife(Bettington *et al.*, 2018).

However, despite its success, the program faces some challenges. A 2016 audit revealed that many people still do not know about the service, with less than 18% of survey respondents being aware of it. Interestingly, when people were informed about the program, over 90% said they would use it. This highlights the need for greater awareness. The audit also revealed that a significant amount of the returned medicines were for short-term conditions like pain or asthma, pointing to a larger issue of overprescribing, where patients end up with more medicine than they actually need(Bettington *et al.*, 2018).

Another concern is the improper disposal of sharps, like needles and syringes, which were found in around 11% of returned medicine bins. This suggests that more education is needed for both pharmacy staff and consumers on how to properly dispose of these items. While the RUM Project has made a big difference in ensuring the safe disposal of medicines, it also brings attention to the

importance of better prescribing practices and the role pharmacists play in educating patients about proper disposal. If awareness of the program grows and more people get involved, the RUM Project can continue to make a positive impact on both our health and the environment(Bettington *et al.*, 2018).

UAE

In the United Arab Emirates (UAE), there is a well-established system for safely disposing of expired and unused medications, with a strong focus on protecting both public health and the environment. According to health regulations, all healthcare facilities, including pharmacies, are required to have a waste management plan in place to ensure that expired medications, particularly narcotics and other controlled substances, are disposed of properly(Prakash, 2020).

There are two main methods for disposing of pharmaceutical waste in the UAE. The first involves working with specialized waste management companies approved by health authorities. These contractors regularly collect expired medications from community pharmacies, and pharmacies pay a fee for this service. The second option allows pharmacies to return expired products to the agency of their distributors, based on prior agreements between the two parties(Kharaba *et al.*, 2022).

Pharmaceutical waste is classified as biomedical waste in the UAE, which also includes contaminated materials. The country follows international standards to ensure these substances are disposed of safely. Incineration is the primary method for destroying pharmaceutical waste, with companies like Salamul Ansar Waste Management in Dubai managing the entire process, from collection to incineration. This ensures that hazardous substances are fully destroyed, preventing any environmental contamination(Mohamed Nour *et al.*, 2017).

A key initiative in the waste management strategy of UAE is the Integrated Waste Management Strategy 2021-2041, launched with a budget of AED 74.5 billion. This long-term plan focuses on reducing waste, increasing recycling, and exploring waste-to-energy technologies. Dubai Municipality plays a significant role in implementing this strategy, including ensuring the safe disposal of pharmaceutical waste(Kharaba *et al.*, 2022).

In addition to these efforts, the UAE government has launched public awareness campaigns to educate people about the importance of proper medication disposal. These campaigns encourage individuals to return expired or unused medications to pharmacies instead of throwing them away in household trash, preventing contamination of water sources and minimizing environmental harm(Mohamed Nour *et al.*, 2017; Kharaba *et al.*, 2022).

SWEDEN

Sweden has developed a well-established system for safely disposing of unused or expired medications, aiming to protect both public health and the environment. This system was first introduced in 1971 by Apoteket AB, former state-run pharmacy chain of Sweden, to prevent accidents like children ingesting medications or substances being misused. Over time, the focus of the system has expanded to address the environmental risks of improper drug disposal, particularly the impact on water and soil(Persson *et al.*, 2009).

In Sweden, pharmacies provide special transparent bags with clear instructions on how to dispose of unused medications. These bags make it easy for people to return unwanted medications without needing to stand in line. Once returned, the medications are sealed in boxes and transported to incineration facilities, where they are burned at high temperatures. The emissions are carefully filtered to prevent harm to the environment, and the resulting ash is disposed of at authorized waste sites(Persson *et al.*, 2009).

In 2007, Sweden sent around 1,020 tons of unused drugs (including packaging) for incineration, a 12% increase from the previous year. Studies show that about 65% of returned drug packages were either still full or had more than 65% of the contents left. Medications typically go unused due to expired dates, patients passing away, therapy changes, or improvements in health(Persson *et al.*, 2009).

To ensure people are aware of how to properly dispose of drugs, Apoteket AB, along with other organizations, has launched multiple public awareness campaigns. These campaigns educate people on the dangers of flushing medications down toilets or throwing them in the trash, both of which can lead to environmental contamination(Persson *et al.*, 2009).

While the disposal system is well in place, several researches suggest that more efforts are needed to encourage people to return their unused medications to pharmacies. Despite these challenges, Sweden continues to lead in environmentally responsible drug disposal, prioritizing both safety and sustainability.

6.1.2.7 CHALLENGES AND OPPORTUNITIES FOR KERALA IN IMPLEMENTING SIMILAR PROGRAMMES

The widespread issue of improper medicine disposal reflects a critical gap in public and professional awareness. A qualitative study titled “*Knowledge, Attitude and Practice (KAP) Towards Disposal of Medicines: A Qualitative Study Among Health Care Professionals in South India*” by Lagishetty Radhakrishna, Prabhu Nagarajan, Suvidya Sushima Vijayanandhan, and Thirumalaikolundusubramanian Ponniah sheds light on this concern. Many individuals, including healthcare professionals, often dispose of unused or expired medications by throwing them in the

trash or flushing them down sinks and toilets. While these methods may seem convenient, they pose serious risks to both the environment and public health. Pharmaceutical compounds, particularly antibiotics, can enter water systems because traditional sewage treatment plants are not equipped to remove them. This contamination has been linked to harmful effects on aquatic life, including reproductive and hormonal disruptions in fish, and the tragic decline of species such as vultures that consume contaminated animal remains. Furthermore, storing unused medicines at home, especially in households with children, can lead to accidental poisonings, as reported in numerous cases worldwide. Hospitals and outpatient facilities also contribute significantly to pharmaceutical waste, yet many lack structured disposal systems. In countries like India and across South Asia, where medicine use is high and infrastructure may be limited, the situation is especially alarming. Surveys and studies from various regions, including North America and Europe, consistently report that a large percentage of people are unaware of or do not follow proper disposal practices. Of particular concern is the improper handling of antibiotics, which contributes to the growing threat of antimicrobial resistance, a challenge already recognized as a global health crisis. These insights highlight the pressing need for well-designed public education initiatives, clear regulatory frameworks, and accessible medication take-back programs. Addressing this issue at both the community and institutional levels is essential to safeguard environmental health and ensure the responsible management of pharmaceutical waste (Radhakrishna *et al.*, 2014).

Similarly, from the study by Raj *et al.*, "*A Qualitative Study on Drug Waste Management Among Drug Distributors, Kochi*" it is clear that there is a significant gap in both knowledge and systems around pharmaceutical waste management, especially at the distributor level. The findings show that many drug distributors are not well-informed about proper disposal practices for expired or unused medicines. Instead of following safe disposal methods, most return expired drugs to manufacturers. However, when it comes to other forms of waste like spilled or non-reusable medications, manufacturers often refuse to take them back, leaving distributors with a problem they cannot easily solve (Divya Raj, 2024).

Additionally, the study titled "*Knowledge, Attitude and Practice (KAP) Towards Disposal of Unused and Expired Medications: An Assessment Among Healthcare Professionals*" by Kumar *et al.* brings attention to the limited awareness among healthcare workers about appropriate methods for disposing of unused and expired medicines. Although these professionals play a key role in promoting safe healthcare practices, the research indicates that many are not well-informed about the environmental and health risks linked to improper disposal. Commonly used methods such as throwing medicines into regular trash or flushing them into sewage systems were frequently reported, despite being unsafe and harmful (Kumar *et al.*, 2024).

The study highlights a concerning gap in knowledge and practice. While most respondents expressed positive attitudes towards safe disposal and recognized its importance, they lacked the necessary guidance, access to facilities, and training to follow through with responsible practices.

This mismatch between belief and behavior suggests a need for better institutional support and structured disposal systems within healthcare settings(Kumar *et al.*, 2024).

Furthermore, the article aligns with similar findings from other developing countries, where poor infrastructure, insufficient regulation, and low public and professional awareness contribute to improper medication disposal. Kumar *et al.* emphasize that targeted awareness campaigns, continuous professional education, and clear regulatory frameworks are essential for equipping healthcare professionals with the knowledge and tools needed to manage pharmaceutical waste effectively. The research clearly underlines that without such interventions, healthcare workers remain underprepared to ensure the safe and environmentally responsible disposal of medicines(Kumar *et al.*, 2024).

A key issue here is the lack of awareness. Many distributors do not even consider the medications themselves as waste, focusing more on things like packaging. This lack of understanding is partly due to the absence of healthcare professionals, like registered pharmacists, in distribution centers. Without proper guidance or oversight, most distributors are unaware of the hazardous effects of improper drug disposal(Divya Raj, 2024).

Additionally, there is little regulatory support. Drug inspectors rarely visit distribution centers, and the government has not put strict guidelines in place to ensure manufacturers are responsible for collecting expired or unused medications. The financial burden of returning waste to manufacturers, especially when they are located far away, is also a major obstacle. In some cases, distributors resort to storing the waste indefinitely or mixing it with regular trash, which leads to environmental and health risks(Divya Raj, 2024).

While initiatives like the PROUD project, aimed at safe drug disposal, are in place, many distributors are not even aware of them. This lack of awareness and infrastructure makes it clear that more efforts are needed, like targeted awareness campaigns, better training for distributors, and affordable disposal systems, to tackle the growing problem of pharmaceutical waste. Achieving a sustainable solution requires collaboration between manufacturers, distributors, healthcare professionals, and regulatory bodies(Divya Raj, 2024).

However, Kerala has a real chance to build a successful pharmaceutical waste management program by bringing together a variety of stakeholders like healthcare providers, distributors, pharmaceutical companies, and government bodies. Working together in public-private partnerships could make a big difference in ensuring the success of the program. The government can help raise awareness through educational campaigns that inform both the public and professionals about the dangers of improper disposal and the benefits of taking part in drug take-back programs. Local initiatives like PROUD have shown promise on a smaller scale, and expanding these efforts could go a long way. By improving collection points, ensuring regular waste pickups, and encouraging safe disposal, Kerala can build on what is already working. A key

opportunity lies in involving healthcare professionals, especially pharmacists, to educate patients about responsible disposal. With proper training, pharmacists could not only guide people but also serve as drop-off points for unused medications. On top of that, technology could make a real difference, helping to streamline the process of managing pharmaceutical waste through digital tracking systems. Lastly, raising public awareness about the environmental and health risks of improper drug disposal is crucial. Campaigns aimed at households and communities can help change attitudes and reduce waste going into landfills or water systems. By seizing these opportunities, Kerala can create a more sustainable and effective approach to pharmaceutical waste disposal (Radhakrishna and Nagarajan, 2015; admin, 2019; Divya Raj, 2024).

6.1.3 CONCLUSION

The growing issue of pharmaceutical waste is becoming a serious concern not just for the environment, but for our health too. When unused or expired medicines are flushed down the toilet or thrown in the trash, they do not just disappear. These substances often end up in our water systems, harming aquatic life and contributing to major problems like antimicrobial resistance. Even though the amounts might seem small, many of these chemicals do not break down easily and can build up over time, creating long-lasting damage to both nature and human health.

In countries like India, the problem is made worse by the lack of clear rules, limited public knowledge, and not enough proper disposal options. Studies from parts of South India, including Kochi, show that even people working in healthcare like pharmacists and distributors, often are not fully aware of safe disposal practices. This highlights a big need for change, through better education, training, and stronger policies that make pharmaceutical waste management a priority.

Looking at global examples, CYCLAMED program France offers a great model to learn from. It works under the idea of Extended Producer Responsibility, meaning pharmaceutical companies help fund and run a national system for collecting and safely destroying unused medicines. Thanks to this coordinated effort, CYCLAMED has seen impressive results, like turning waste into energy, getting the public involved, and making safe disposal easy and accessible.

Kerala, with its strong healthcare foundation, is in a good position to lead the way in India. By building on initiatives like PROUD and creating pharmacy-led collection systems, the state can take meaningful steps toward responsible medicine disposal. Collaborating with manufacturers, distributors, and government bodies and using digital tools to track and manage waste they can make the system even more effective. With regular collections, public-private partnerships, and ongoing education, Kerala has the opportunity to create a model that protects both people and the planet.

6.2 THEORETICAL FRAMEWORK

In this section, I will explore a few theories that help support the research topic, giving a better understanding of the research question and explaining why the study is important. The theory that best fits the research on a pharmacy-led medication take-back system in Kerala, inspired by the CYCLAMED model, is likely to be the Sustainability Theory.

6.2.1 SUSTAINABILITY THEORY

Sustainability Theory is really relevant to my study on creating a pharmacy-led medication take-back system to handle pharmaceutical waste. This theory is all about finding a balance between environmental, social, and economic needs to make sure that what we do today does not harm future generations. For my research, it means that any solution we come up with should tackle the issues of waste disposal now, but also ensure we are not leaving a burden for the future.

On the environmental side, it is about safely getting rid of unused or expired medications to prevent pollution and protect our ecosystems. Economically, it is about building an infrastructure that is not only efficient but also sustainable in the long run, something that works without wasting resources or causing harm. And socially, it is about ensuring health and well-being of people, creating awareness, and making sure communities have safe disposal options(BerkshirePubGrp, 2024).

By applying Sustainability Theory to my study, I can show how a pharmacy-led take-back system is not just a practical solution for managing waste but also one that supports the environment, public health, and long-term growth, benefiting both the present and future generations(Meadowcroft, 2025).



Figure 5: CONCEPT OF SUSTAINABILITY THEORY (Plug and go, 2010)

6.2.2 ASSUMPTION AND LIMITATION OF THE THEORY

Sustainability Theory operates on the idea that the environment, society, and economy are all interconnected and must be considered together for long-term well-being. For my research on a pharmacy-led medication take-back system, it assumes that solving the issue of pharmaceutical waste will help protect the environment, improve public health, and even create economic opportunities through better waste management practices. It also assumes that achieving sustainability is not just the responsibility of one group, but everyone, from the government to pharmaceutical companies, healthcare providers, and the public, needs to work together. Another assumption is that solutions should be accessible and fair, making sure everyone has the opportunity to participate in safe medicine disposal.

However, there are some practical limitations. Finding the perfect balance between environmental, social, and economic goals may be challenging, especially when resources are limited or there are political hurdles. The broad perspective of the theory may also overlook specific local conditions, like infrastructure or cultural aspects of Kerala, which could influence the implementation of the take-back system. While the theory paints an ideal picture of sustainability, achieving it in pharmaceutical waste management might take time, and immediate results may not be possible. In addition, financial constraints might limit the full implementation and sustainability of the system in Kerala.

6.3 CONCEPTUAL FRAMEWORK

A conceptual framework helps to visualize how different variables in a research study are connected. It highlights the two main types of variables: dependent and independent. The framework for this research, which shows how these variables relate to each other, is outlined below:

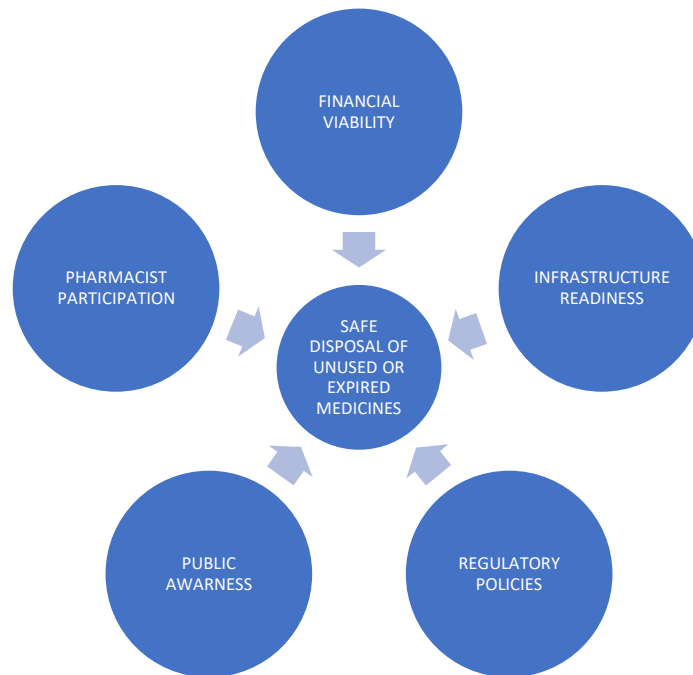


Figure 6: CONCEPTUAL FRAMEWORK

6.4 DISCUSSION OF THE VARIABLES

In my study, the main focus is on the successful setup of a pharmacy-led medication take-back system in Kerala, inspired by the CYCLAMED model. The success of this system depends on several factors, which are the independent variables of my study. These include things like the regulations and policies that shape how medicines are disposed of, the level of involvement from pharmacists, how aware the public is about the issue, the readiness of the infrastructure to handle the process, and whether the system can sustain itself financially. Each of these elements plays a significant role in determining how effective and long-lasting the take-back program will be. By looking at these factors, my research will explore how they all come together to make a medication disposal system that benefits both public health and the environment in Kerala.

6.5 GANTT CHART

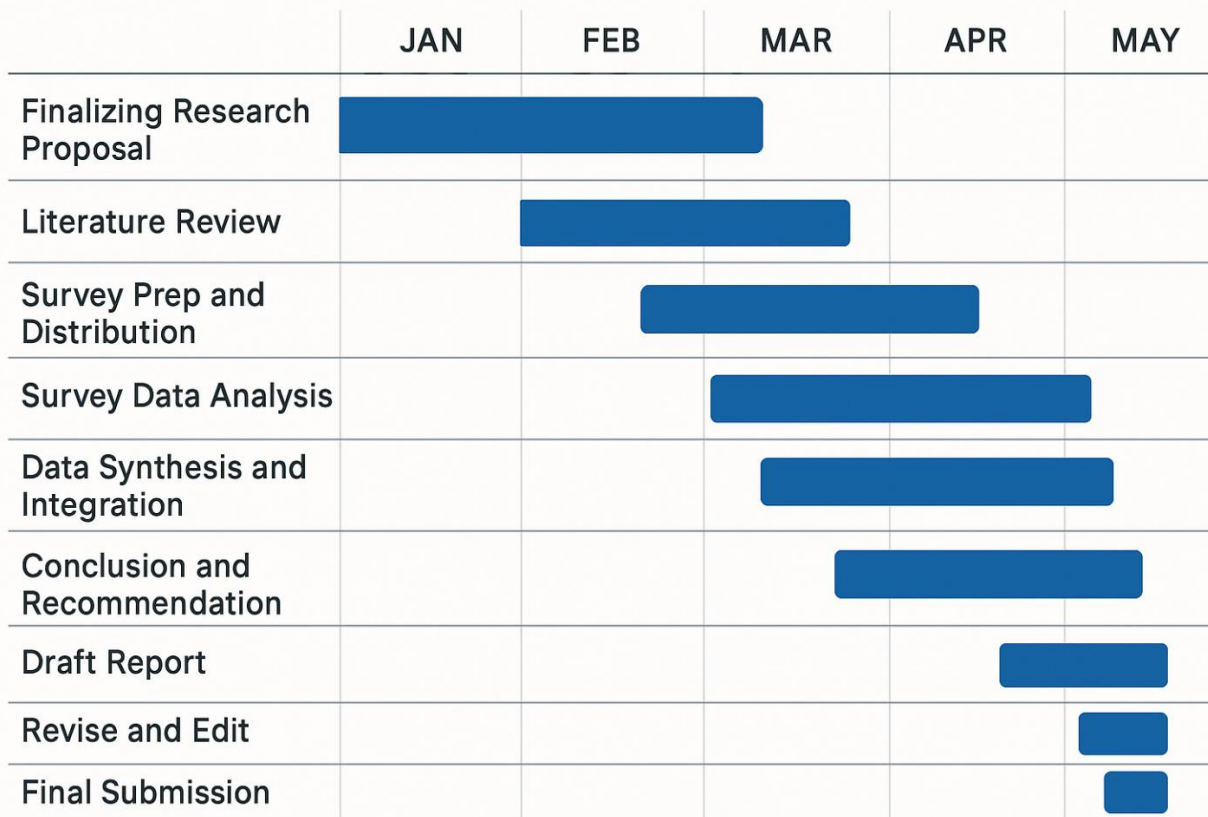


Figure 7: GANTT CHART OF THIS RESEARCH

6.6 RESEARCH GAP

The research gap in this study stems from the limited exploration of pharmacy-led medication take-back systems in Kerala, especially when looking at models like CYCLAMED from France. While concerns about the environmental and public health risks of improperly disposing of unused medicines are growing, especially in South India, there is not much research focused on the practical side of implementing such systems in Kerala specifically.

Most existing studies focus on general pharmaceutical waste management but often miss the detailed challenges of setting up a take-back system at the local level. They also do not dive into the role of pharmacists or the involvement of key players like pharmaceutical companies, the government, and the public in making these systems work.

This research aims to fill that gap by looking at factors like how willing pharmacists are to participate, the level of public awareness, the readiness of infrastructure, and the financial sustainability of a take-back program. By addressing these aspects, the study will offer valuable insights into how a pharmacy-led medication take-back system can be successfully implemented in Kerala, helping to create a more sustainable and effective way to manage pharmaceutical waste in the region.

7 CHAPTER 3: RESEARCH METHODOLOGY

7.1 OVERVIEW

Research is a systematic process of inquiry undertaken to explore specific issues, establish facts, and generate new knowledge. At the core of this process lies the research methodology, which provides the overall framework for addressing the research problem. It involves selecting appropriate strategies, tools, and techniques that guide the collection, analysis, and interpretation of data in a coherent and credible manner.

The choice of methodology is crucial, as it reflects the assumptions a researcher makes about what constitutes valid knowledge and how it can be acquired. Since research topics vary in scope, complexity, and context, there is no single methodology that applies to all studies. Therefore, the methods adopted must align with the specific aims, objectives, and data requirements of the research.

This study investigates the feasibility of implementing a pharmacy-led medication take-back system in Kerala, drawing inspiration from the successful CYCLAMED model in France. It explores current medication disposal practices, the awareness and participation of healthcare professionals, and the regulatory and infrastructural challenges that may influence the adoption of such a system. In addition, the study aims to provide practical recommendations that can contribute to policy development and improved public health and environmental safety.

To ensure a logical and well-founded research design, this study adopts the structure of the Research 'Onion' (Saunders *et al.*, 2009). This model outlines the key layers of research planning such as philosophical stance, research approach, methodological choice, strategy, and data collection methods, allowing for a comprehensive and aligned research process.

The sections that follow will present the research philosophy, approach, methodological choices, and data collection strategies employed in this study, along with a justification for each decision.

7.2 RESEARCH PHILOSOPHY

Research philosophy plays a critical role in shaping the overall direction and approach of a study, guiding everything from the formulation of research questions to the interpretation of results. It encompasses beliefs of a researcher about the nature of reality (ontology), how knowledge is obtained (epistemology), and the influence of personal values in the research process (axiology).

This study adopts a relativist ontological stance, recognizing that reality is shaped by unique experiences and perspectives individuals. As the research explores how healthcare professionals in Kerala perceive and manage medication disposal, it acknowledges that their views may differ based on their roles, backgrounds, and contexts. Epistemologically, the study follows a pragmatic

approach, emphasizing practical problem-solving and gathering measurable, generalizable data through quantitative surveys. The research focuses on understanding knowledge, awareness, and behaviors of participants, with the ultimate goal of assessing the feasibility of a pharmacy-led medication take-back system. Additionally, the study incorporates axiological awareness, acknowledging that the values of the researcher may influence the formulation of questions, interpretation of data, and policy recommendations, particularly in the socially relevant context of public health. Methodologically, the study strictly adheres to a quantitative approach, using surveys to gather data and derive practical, actionable outcomes.

These philosophical foundations directly affect the choice of research methods and the techniques used for data analysis. In the field of social science, four primary research philosophies such as positivism, interpretivism, critical realism, and pragmatism, each offer distinct perspectives on the process of knowledge acquisition and understanding. A clear grasp of these philosophies is essential for developing a well-structured research methodology that aligns with the goals and objectives of the study(Prime, 2024).

Positivism is a research philosophy that focuses on objective, observable facts, relying primarily on quantitative methods. It is grounded in the belief that there is a singular, measurable reality that can be studied through scientific observation and experimentation. While initially associated with the natural sciences, positivism has also been adapted for use in social science research. This approach aligns closely with the scientific method, emphasizing hypothesis testing and statistical analysis to derive conclusions. Researchers employing a positivist philosophy typically use structured research designs and aim to generate findings that are broadly applicable. Although it has been critiqued for its limitations in addressing the complexities of social phenomena, positivism remains an important approach, particularly in fields that demand rigorous quantitative analysis(Saunders *et al.*, 2009).

Interpretivism, also known as interpretive research philosophy, contrasts with positivism by emphasizing the subjective nature of reality and the need to understand social phenomena from the perspectives of participants. It is closely linked to qualitative research methods and is commonly used in the social sciences. Interpretivist researchers argue that reality is socially constructed and can be best understood through a deep exploration of human experiences and the meanings individuals assign to them. They typically gather high quality, qualitative data through methods such as interviews, focus groups, and participant observation. This approach recognizes the role of the researcher in co-constructing knowledge and highlights the importance of context when interpreting research findings(Saunders *et al.*, 2009).

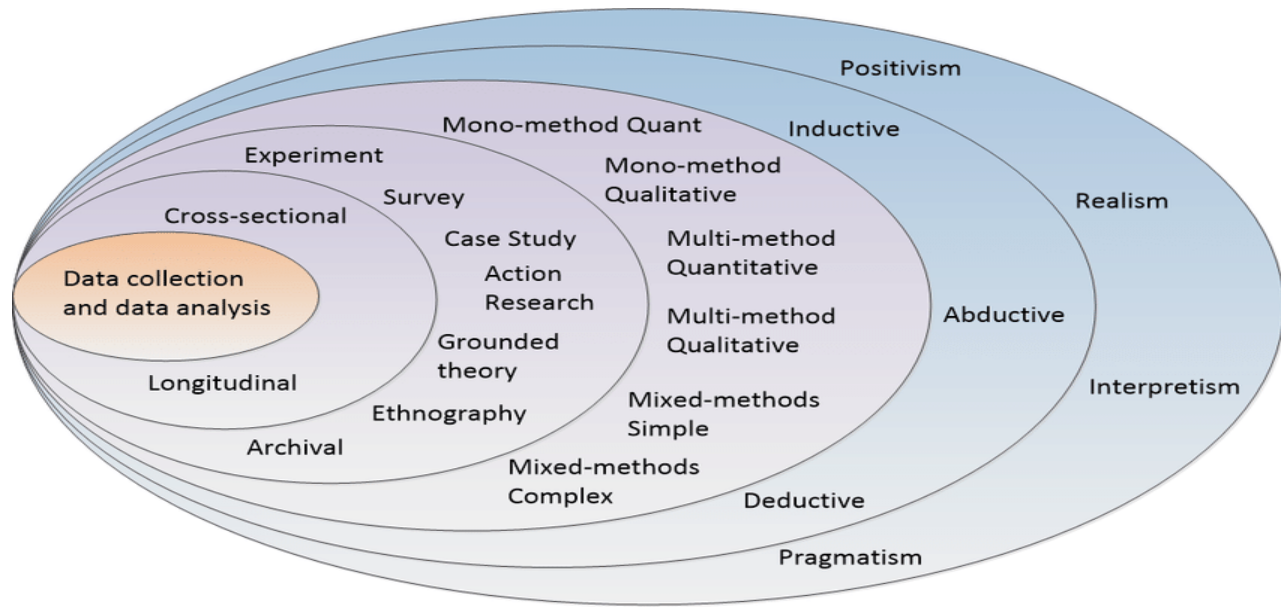


Figure 8: The Research 'Onion' (Saunders et al., 2009)

Critical realism is a research philosophy that bridges the gap between positivism and interpretivism by acknowledging an objective reality while recognizing that our understanding of it is shaped by social and historical contexts. It assumes that reality consists of three layers: the empirical (what can be observed), the actual (the events that occur), and the real (the underlying mechanisms). Critical realist researchers typically use a combination of quantitative and qualitative methods to explore both observable phenomena and the deeper, often hidden structures that influence them. This approach is especially useful for studying complex social systems, providing insights that inform both theoretical frameworks and practical interventions (Saunders *et al.*, 2009).

Pragmatism is a research philosophy that emphasizes practical solutions to problems, focusing on outcomes rather than adhering strictly to a particular ontological or epistemological stance. Researchers who adopt this approach prioritize finding effective answers to research questions, often utilizing a combination of quantitative and qualitative methods. Pragmatism values the flexibility to choose research methods that best address the problem at hand, ensuring the approach is practical and relevant. This philosophy is especially beneficial for applied research and projects with real-world implications, as it allows for a dynamic integration of various philosophical perspectives and methodological techniques to achieve the most effective results (Saunders *et al.*, 2009).

This study adopts a pragmatic philosophy, which is well-suited for addressing real-world challenges, such as evaluating the feasibility of implementing a pharmacy-led medication take-back system in Kerala. The research focuses on the practical issue of improving the collection and disposal of unused and expired medications by drawing on the successful CYCLAMED model from France. The primary objective is to not only understand the current situation in Kerala but

also assess the potential for adapting the French model to fit the local context. Pragmatism encourages the use of the most effective methods to answer the research questions, whether qualitative, quantitative, or a combination of both. In this case, a quantitative approach through surveys has been selected to gather measurable, actionable insights into the feasibility of implementing a similar system in Kerala.

7.3 RESEARCH APPROACH

According to Saunders et al. (2009), the three approaches, deductive, inductive, and abductive represent different strategies for developing theory, with deduction moving from theory to data, induction going from data to theory, and abduction combining both processes to create and refine theories based on observations and existing data.

The Deductive Approach, commonly used in scientific research, involves creating a theory or hypothesis and then testing it through a series of propositions. It is primarily applied in the natural sciences to explain causal relationships between concepts or variables. The process includes forming a hypothesis, deriving testable propositions from existing literature, and validating them by collecting and analyzing data. If the results align with the hypothesis, the theory is confirmed; if not, it must be revised or discarded. Deductive research is structured, focused on quantifiable data, and emphasizes generalization, often aligning with the positivist research philosophy, which is based on measurable observations and the scientific method (Saunders *et al.*, 2009).

The Inductive Approach to theory development begins by gathering qualitative data, typically through interviews, to gain insight into the issue being studied. Unlike deductive reasoning, where a theory is tested, the goal here is to build a theory from the data collected. This method is more open-ended, allowing for multiple interpretations and emphasizing the context of the phenomenon. Inductive reasoning aligns with the interpretivist philosophy, which prioritizes understanding human behavior and subjective experiences, in contrast to the more structured, hypothesis-driven deductive approach (Saunders *et al.*, 2009).

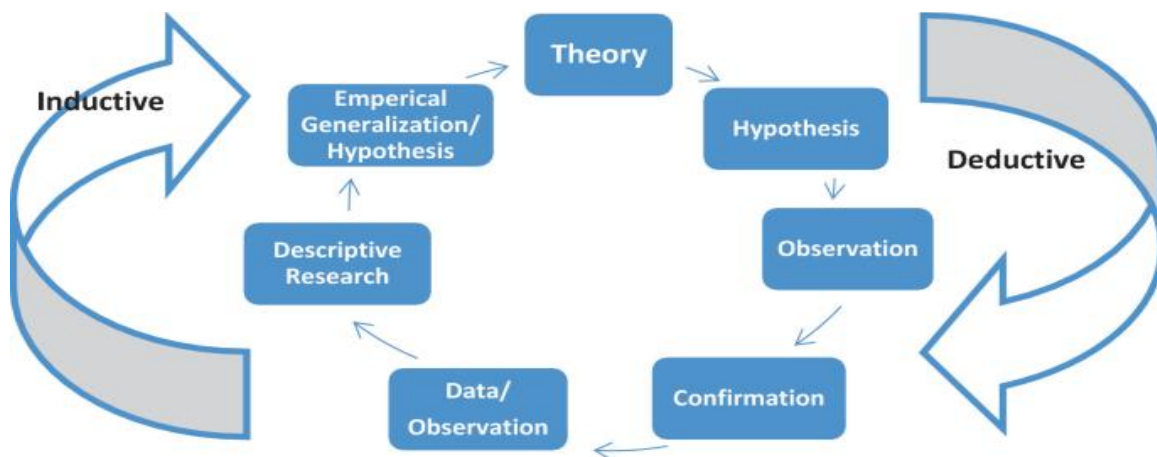


Figure 9: Induction and Deduction (Haque, 2022)

The Abduction Approach, also known as "retroduction," is a research method that integrates both deduction and induction. It starts with a surprising observation or phenomenon and generates plausible theories to explain it. Unlike deduction, which moves from theory to data, and induction, which progresses from data to theory, abduction involves an ongoing process of theory development, testing, and refinement. Researchers gather rich, detailed data to uncover patterns and themes, forming a conceptual framework that explains the observed phenomenon. This framework is then tested and adjusted based on new and existing data, ensuring that the theory remains relevant and accurate. Abduction is particularly useful for exploring complex, real-world issues where simple cause-and-effect relationships may not be sufficient. It is a flexible approach that can be applied within various research philosophies, including pragmatism, postmodernism, and critical realism, making it a valuable tool for researchers seeking to develop and refine theories through continuous data-driven insights (Saunders *et al.*, 2009).

For my research, I adopted a deductive approach, which was ideal for testing an established theory or hypothesis. In this case, I evaluated the feasibility of implementing a pharmacy-led medication take-back system in Kerala, using the CYCLAMED model from France as a potential framework for adaptation. The study tested the hypothesis that this model could be successfully applied in the context of Kerala. To achieve this, I used a structured, quantitative method, specifically surveys, to gather measurable data. This allowed me to assess whether the system could be effectively implemented in Kerala, as well as identify any challenges or factors that could impact its success. By following a deductive approach, I rigorously tested existing theories and produced objective, replicable results, ensuring that the research was focused and grounded in evidence.

7.4 RESEARCH METHODOLOGY CHOICE

After establishing the research philosophy and approach, the next essential decision is selecting the appropriate research method: **Quantitative**, **Qualitative**, or **Mixed-Methods**, depending on the nature and aim of the study. Each of these methodologies offers distinct advantages and is suited for different kinds of research inquiries.

Quantitative Research focuses on the collection and analysis of numerical data. This method is ideal for studies aiming to measure the extent, frequency, or quantity of particular variables. By applying structured tools such as surveys with closed-ended questions, researchers can convert responses into statistical data, allowing them to identify patterns, test hypotheses, and draw generalizable conclusions. Quantitative methods are especially suitable for answering questions like "How many?" or "How much?" and require a larger sample size to ensure the reliability and validity of results. This approach is beneficial when the goal is to produce objective, measurable findings that can be analyzed statistically (Club, 2024).

On the other hand, **Qualitative Research** is geared towards understanding meanings, experiences, and perceptions in depth. Instead of numerical data, it uses rich, textual information gathered

through interviews, focus groups, observations, or open-ended survey responses. This approach is ideal for exploring complex social settings, personal motivations, and the reasons behind certain behaviors or attitudes. Questions such as “Why does this happen?” or “How do people experience this?” are best addressed through qualitative methods. While the sample sizes are often smaller than in quantitative research, the depth and detail of insights gained can be substantial. This method prioritizes context and human interpretation, making it particularly suitable for uncovering subtle perspectives(Club, 2024).

Mixed-methods Research combines elements of both quantitative and qualitative approaches to offer a more holistic understanding of the research problem. This integrated approach is useful when a single method is insufficient to fully explore a multifaceted issue. Mixed-methods research may be conducted sequentially, where one type of data collection follows another or concurrently, where both data types are collected and analyzed at the same time. For instance, qualitative data might first be used to explore a problem and then be followed by a quantitative survey to test those insights across a broader population. Alternatively, both types of data can be gathered simultaneously to triangulate findings and increase the credibility of the results(Club, 2024).

Ultimately, the choice of method depends on the research objectives, the type of data required, and the specific questions being investigated. While quantitative research offers breadth and generalizability, qualitative research provides depth and context. Mixed-methods research combines the strengths of both, making it a robust choice for addressing complex research questions. Selecting the right methodology enhances the overall rigor and relevance of the study, ensuring that the findings are both meaningful and actionable.

In this study, a quantitative research approach was employed to assess the feasibility of implementing a pharmacy-led medication take-back system in Kerala, inspired by CYCLAMED model from France. This approach was chosen for its ability to produce measurable, objective data from a broad sample of registered pharmacists. Using structured survey questionnaires, the research collected numerical data that could be statistically analyzed to identify trends, levels of awareness, participation, and the challenges faced by pharmacists in managing unused and expired medications. The use of quantitative methods allowed for consistency and comparability across responses, ensuring reliability in the findings. It also facilitated the development of evidence-based conclusions that can inform potential policy adaptations and practical strategies for improving medication disposal practices in Kerala. This method was particularly suitable for the aim of generating generalizable insights to support the design of a scalable, pharmacy-led take-back initiative.

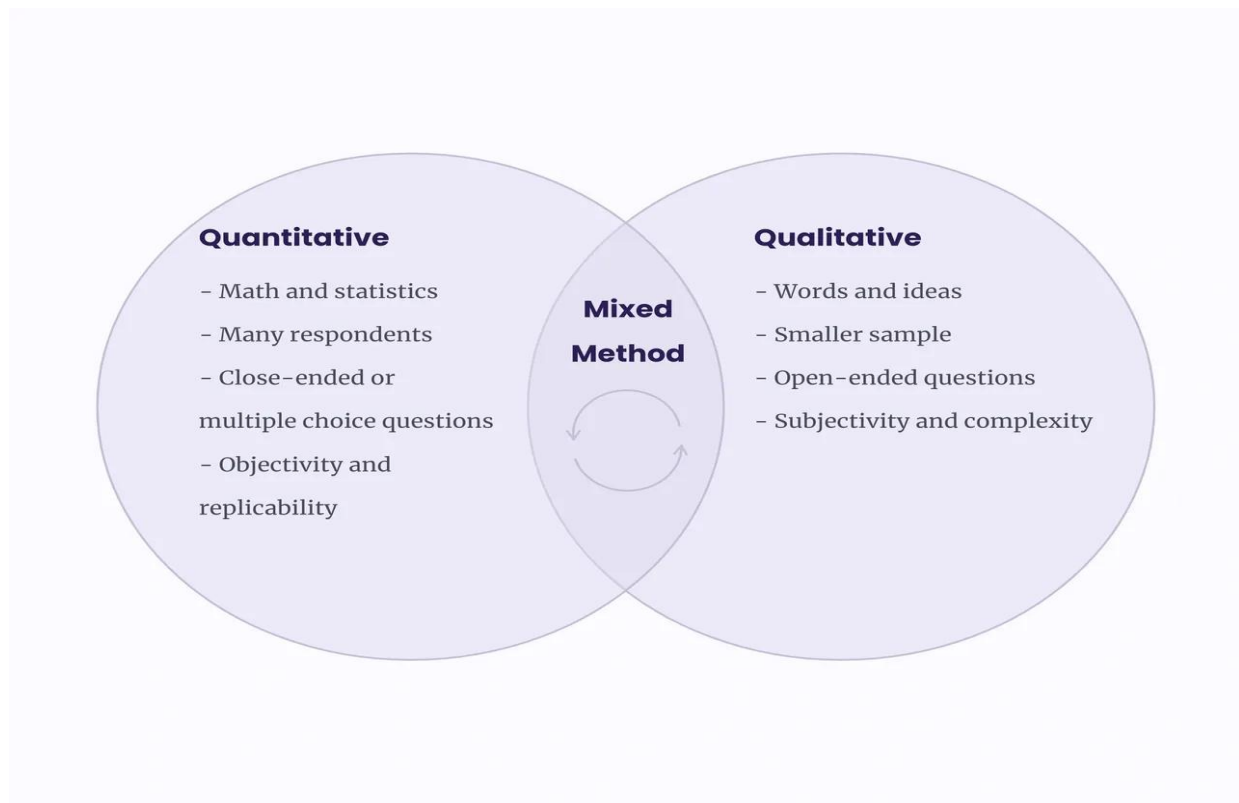


Figure 10: Methodology Choice (Club, 2024)

7.5 RESEARCH STRATEGY

In research, the strategy represents the comprehensive plan that guides how data will be gathered and how the study will be executed in practice. Selecting the right strategy is essential for ensuring that the research design aligns effectively with goals of the study. Some strategies are better suited for quantitative research, while others are more appropriate for qualitative investigations. Ultimately, the choice depends on the specific research questions and the type of data needed to answer them. Commonly used strategies include experiments, surveys, case studies, and ethnography, each offering unique advantages depending on the context and purpose of the research (Club, 2024).

Following the perspective of Saunders et al. (2020), who highlight surveys as a valuable method in descriptive and exploratory research for collecting data from a specific population, this study employs an online survey as its primary research strategy. Since the focus of the research is to evaluate the feasibility of implementing a pharmacy-led medication take-back system in Kerala, drawing inspiration from CYCLAMED model from France, the use of an online survey enables the efficient collection of quantitative data from a wide range of participants. The survey is distributed digitally through a secure link, ensuring that participation is both informed and

voluntary. Respondents include registered pharmacists from Kerala, with the aim of gathering information on current practices related to unused or expired medicine disposal, levels of awareness, and attitudes toward a potential structured return program. The online approach not only streamlines the data collection process but also allows for broad outreach, enhancing the reliability and depth of the findings.

Online surveys have become a popular method for data collection due to their affordability, speed, and convenience. Despite these advantages, they present distinct ethical and methodological challenges. A primary ethical concern is ensuring informed consent. To address this, researchers often provide an information sheet on the first page of the survey and require participants to check a consent box before proceeding(Nayak, 2019).

Privacy, anonymity, and confidentiality are crucial in online surveys. Anonymity ensures that participant identities are not revealed, whereas confidentiality involves protecting the shared information. Many online survey tools collect data such as IP addresses or use unique email links, which can compromise anonymity if not carefully managed. Therefore, it is essential to remove identifying information and secure geo-location data to maintain ethical standards(Nayak, 2019).

Additionally, low response rates remain a concern, as emails may be ignored, filtered as spam, or contribute to survey fatigue. Forced answering can help reduce missing data but may compromise autonomy of participants.

Data from online surveys is typically stored in real time on secure servers, minimizing editing risks. However, regular backups are necessary to prevent data loss from technical failures or cyberattacks. While online platforms offer basic data visualization through charts and graphs, more detailed analysis requires external tools. Online surveys are also beneficial for collaborative and multicenter research, although coordination and data security become vital when multiple researchers are involved(Nayak, 2019). Overall, with proper ethical safeguards and technical controls, online surveys can serve as an effective and reliable method for research.

7.6 SAMPLE SIZE CALCULATION

A selection of 150 licensed pharmacists as the sample size for this study is based on the Finite Population Correction formula, which ensures statistical reliability while maintaining practical feasibility. With an estimated population of 79,601 licensed pharmacists in Kerala, the sample size was calculated using a 95% confidence level, an assumed population proportion of 50% (0.5), and an 8% margin of error. This yielded an approximate sample size of 150.

This sample size is considered sufficient for capturing knowledge, practices, and attitudes of pharmacists towards participating in a pharmacy-led medication take-back system. The survey employed in this research includes both closed-ended and open-ended questions. The chosen

sample size is also manageable within the scope of the time and resource limitations of study, facilitating efficient data collection and analysis. Overall, a sample of 150 participants offers a balanced and justifiable approach to achieving the research objectives.

The Finite Population Correction (FPC) formula:

$$n' = \frac{n}{1 + \frac{z^2 * \hat{p}(1-\hat{p})}{\epsilon^2 * N}}$$

Where:

- N = 79601 (estimated number of pharmacists in Kerala)
- Z = 1.96 (Z-score for a 95% confidence level)
- p = 0.5 (assumed proportion of pharmacists supporting take-back programs)
- e = 0.8 (8% margin of error)(Kallio, 2022)

7.7 SOURCE AND SELECTION OF PARTICIPANTS

This study focused on licensed pharmacists in Kerala, recognizing their critical role in medication dispensing, disposal, and regulatory compliance. As primary stakeholders in a pharmacy-led medication take-back system, their feedback on current disposal practices, legal barriers, and willingness to participate was essential for assessing the feasibility of such a system. A stratified sample of 150 pharmacists was chosen to ensure broad representation from various practice environments and locations, providing a balanced approach between statistical reliability and practical feasibility.

To recruit participants, I used a multi-channel approach targeting licensed pharmacists across Kerala. I partnered with professional pharmacy associations, such as the Kerala State Pharmacy Council, and local pharmacist networks to help distribute the survey. I also reached out to community, hospital, and chain pharmacies via email and phone calls, seeking permission from pharmacy owners or managers where needed. Additionally, I utilized social media platforms and professional networks like WhatsApp pharmacist groups and LinkedIn to extend the reach of the survey. An informed consent process was implemented, ensuring participants were fully informed about the objectives, confidentiality measures, and the voluntary nature of their participation before taking part in the survey.

7.8 DATA COLLECTION METHOD

For this study, both primary and secondary data were gathered to provide a comprehensive understanding of the research topic. Primary data was collected through online survey, which were distributed to the selected respondents. This method facilitated efficient data collection from registered pharmacists from Kerala through an online survey regarding their awareness and practices related to medication disposal. Secondary data was sourced from reliable references, including peer-reviewed articles, academic journals, published books, and official government websites. These secondary sources contributed valuable background information and contextual understanding, complementing the primary data. By integrating both primary and secondary data, the research ensures a robust analysis of the feasibility and potential impact of implementing a pharmacy-led medication take-back system in Kerala (Taherdoost, 2021).

7.9 DATA ANALYSIS METHODS

In this research, I analyzed the data collected from an online survey to understand how participants dispose of unused medicines. I used Microsoft Excel and Minitab to organize and analyze the data. These tools helped me summarize the information and present it using simple bar graphs. Minitab was also used for more detailed statistical analysis to ensure the results were accurate. Overall, these methods allowed me to clearly understand the responses of participants and draw meaningful conclusions.

7.10 TIME HORIZON

This study used a cross-sectional research design to explore the feasibility of implementing a pharmacy-led medication take-back system in Kerala (Club, 2024). Data were gathered at a single point in time through structured quantitative surveys aimed at assessing current awareness, involvement, and opinions of pharmacists on medicine disposal practices. This method offered a snapshot of the existing scenario without observing changes over time. The choice of a cross-sectional approach was based on goal of the study to evaluate whether CYCLAMED model from France could be adapted to healthcare setting of Kerala. By capturing existing practices and perceptions, the study provided important insights into the preparedness of pharmacists and the local infrastructure to support such a system. The approach also allowed for efficient data collection and analysis within the available timeframe and resources, making it appropriate for the academic setting. Overall, the findings served as a foundation for assessing the potential implementation of the model in the region.

7.11 INCLUSION AND EXCLUSION CRITERIA

The inclusion and exclusion criteria for this study were carefully chosen to ensure the data collected was relevant and useful to the research objectives. The study focused on licensed pharmacists who are currently working in Kerala. To ensure participants had sufficient experience,

only those with at least one year of professional practice were included. Participation was entirely voluntary, and only response of participants those gave the consent were taken, in keeping with ethical research standards.

At the same time, certain groups were excluded to maintain focus and accuracy. Pharmacy students and interns were also excluded due to their limited real-world experience. Pharmacists working outside Kerala were left out since the study is specific to the state. Anyone who did not consent or did not complete the survey was also excluded, along with those who had less than a year of experience, to ensure all responses were based on meaningful professional insight.

7.12 ETHICAL CONSIDERATIONS

In this study, ethical considerations were carefully addressed by providing participants with a clear explanation of purpose of the research at the start of the survey. A detailed description of goals, objectives, and procedures of the study was given, along with a request for their consent to participate. This ensured transparency and allowed participants to make an informed decision about their involvement.

Autonomy of the participants were respected, as they were able to voluntarily agree to participate after fully understanding the nature of the research. They were also informed that their participation was entirely voluntary, and they could withdraw from the survey at any point without any adverse consequences.

To ensure confidentiality, all survey responses were anonymized, and no personal identifiers were collected. This helped protect privacy of the participant throughout the study. The research followed ethical guidelines for conducting surveys with human participants, ensuring their rights were upheld. Finally, the study complied with the ethical standards set by the relevant institutional review board or ethics committee, ensuring that all research practices were in line with the required protocols.

7.13 CONCLUSION

In summary, this research utilized a pragmatic research philosophy, which emphasizes the collection of objectives, measurable data to examine the feasibility of implementing a pharmacy-led medication take-back system in Kerala. The study applied a deductive approach, testing a set hypothesis about how CYCLAMED model from France could be adapted to the Kerala context, which aligns with the quantitative focus of the study on confirming or disproving the hypothesis through data analysis.

A survey-based strategy was employed, using structured questionnaires to gather data from pharmacists in Kerala. This method was ideal for obtaining a large volume of responses, allowing

for statistical analysis and offering a comprehensive understanding of awareness, participation, and opinions of pharmacists on medication disposal practices.

The study followed a cross-sectional time horizon, with data collected at a single point in time. This provided a snapshot of current practices, challenges, and potential opportunities regarding medication take-back in Kerala, without tracking changes over a prolonged period.

For data collection, quantitative surveys were used, enabling standardized data to be collected from a broad participant base. This method allowed for clear, objective insights, making it a suitable approach for evaluating the feasibility of the proposed system and providing a foundation for further investigation into the subject

8 CHAPTER 4

8.1 FINDINGS AND ANALYSIS

Initially, I have distributed the survey to 150 participants for my research; however, due to a lower response rate, I received only 87 completed responses. Nonetheless, the data gathered from these 87 responses offers valuable insights for assessing the feasibility of implementing a pharmacy-led medication take-back system in Kerala.

8.2 DEMOGRAPHIC INFORMATIONS

8.2.1 Type of Pharmacy

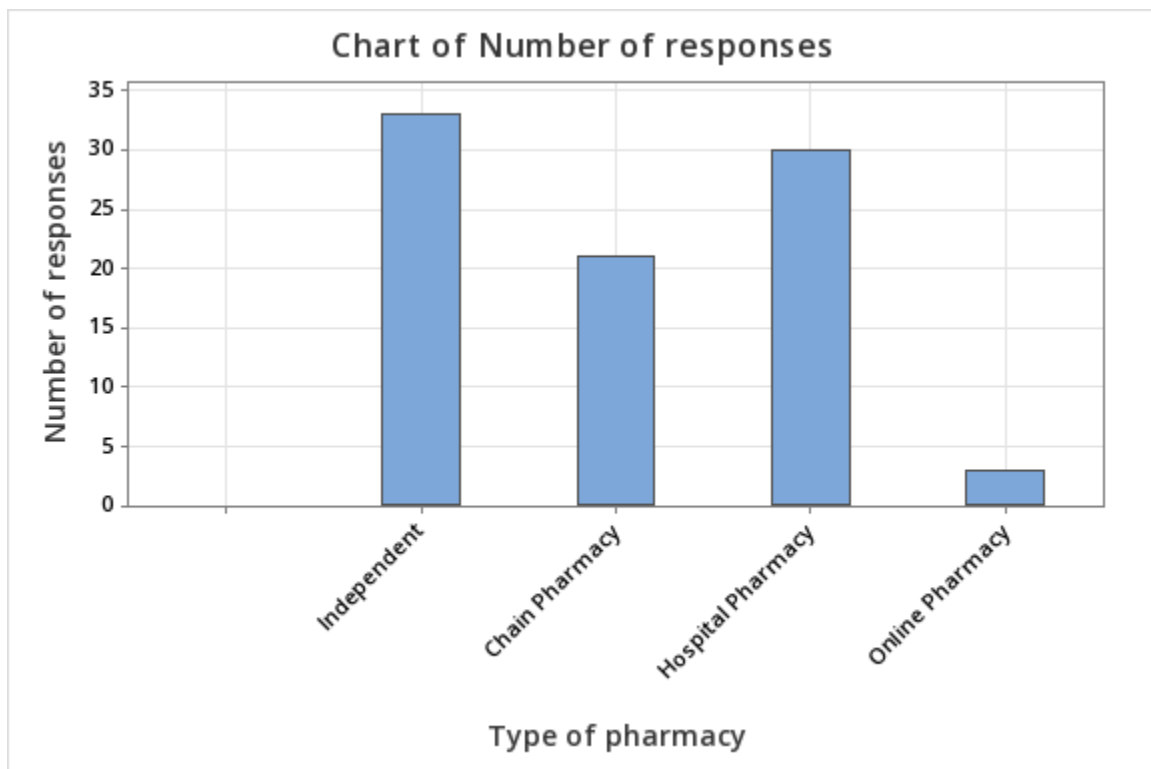


Figure 11: Chart of type pharmacy

The above bar graph illustrates the distribution of survey responses across four different pharmacy categories: Independent, Chain, Hospital, and Online. The x-axis represents these pharmacy types, while the y-axis displays the number of responses, ranging from 0 to 35. This visual offers a clear comparison of the varying levels of participation among the different pharmacy sectors in the study.

Independent pharmacies received the highest number of responses, with a total of 33(37.9%), reflecting their significant presence and willingness to engage. This high participation rate could

be attributed to their widespread accessibility, particularly in semi-urban and rural areas, and their flexible operational structure, which likely allows for faster decision-making and easier involvement in surveys. Their independence positions them as potential leaders in adopting pharmacy-led medication take-back programs.

Hospital pharmacies also demonstrated notable participation, with 30(34.5%) responses. Their engagement is likely due to their integration within regulated healthcare systems and established protocols for medication disposal. Their structured environment and professionally trained staff make them well-equipped to support and implement formalized disposal programs.

Chain pharmacies garnered a moderate response rate of 21(24.1%), which may be influenced by their centralized corporate structures that restrict the autonomy of individual branches in research participation. Their involvement in community health initiatives often requires higher-level coordination and approval, which might limit their responsiveness.

On the other hand, online pharmacies contributed the fewest responses, with only 3(3.4%), likely due to their limited physical presence and the challenges of reaching them through traditional survey methods. Operating primarily in the digital space, these pharmacies may currently play a minimal role in local medication disposal efforts.

The disparity in response rates highlights important considerations for the representativeness of the study and the design of future programs. The findings suggest that independent and hospital pharmacies are the most viable partners for implementing a pharmacy-led medication take-back system in Kerala, while additional strategies will be required to better engage chain and online pharmacies.

8.2.2 Location of Pharmacy

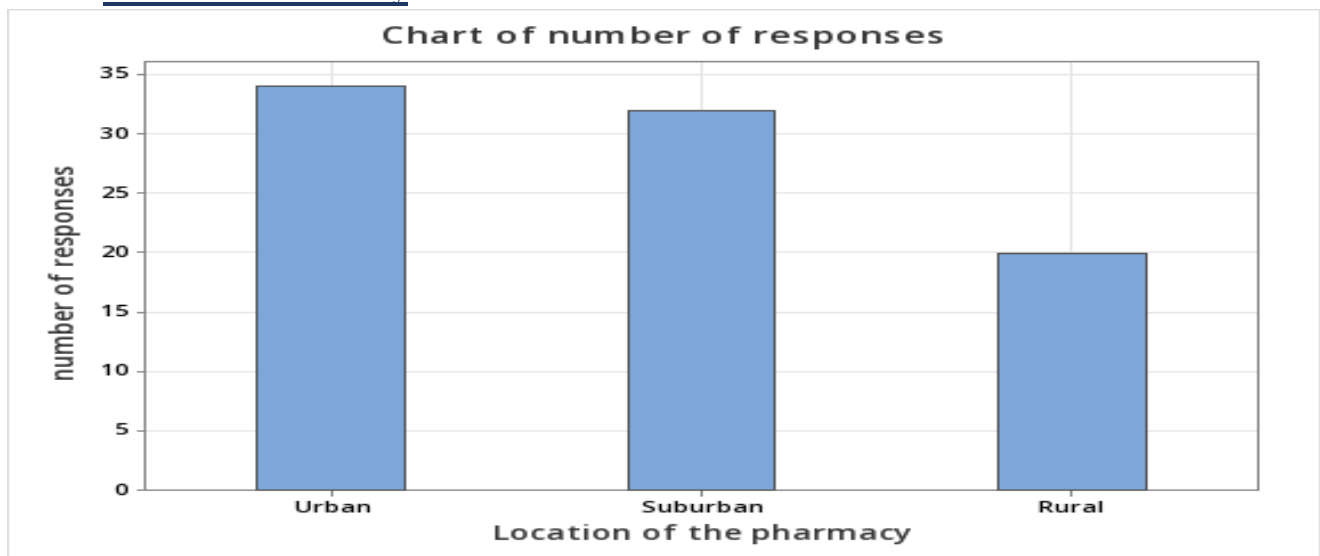


Figure 12: Location of pharmacy

The above bar chart compares the responses from pharmacies in Urban, Suburban, and Rural areas. The y-axis shows the number of responses, ranging from 0 to 35, and the x-axis represents the three pharmacy locations.

Urban Pharmacies received the highest number of responses, just under 35(39.5%). With more pharmacies and healthcare resources, urban pharmacies are more likely to participate in surveys or studies, contributing to the higher response count.

Suburban Pharmacies received slightly fewer responses, just above 30(37.2%). Suburban areas, with moderate population density and infrastructure, show a balanced level of engagement.

Rural Pharmacies received the least responses, around 20(23.3%). This is expected given the lower population density and fewer healthcare resources in rural areas.

8.2.3 Pharmacy Size

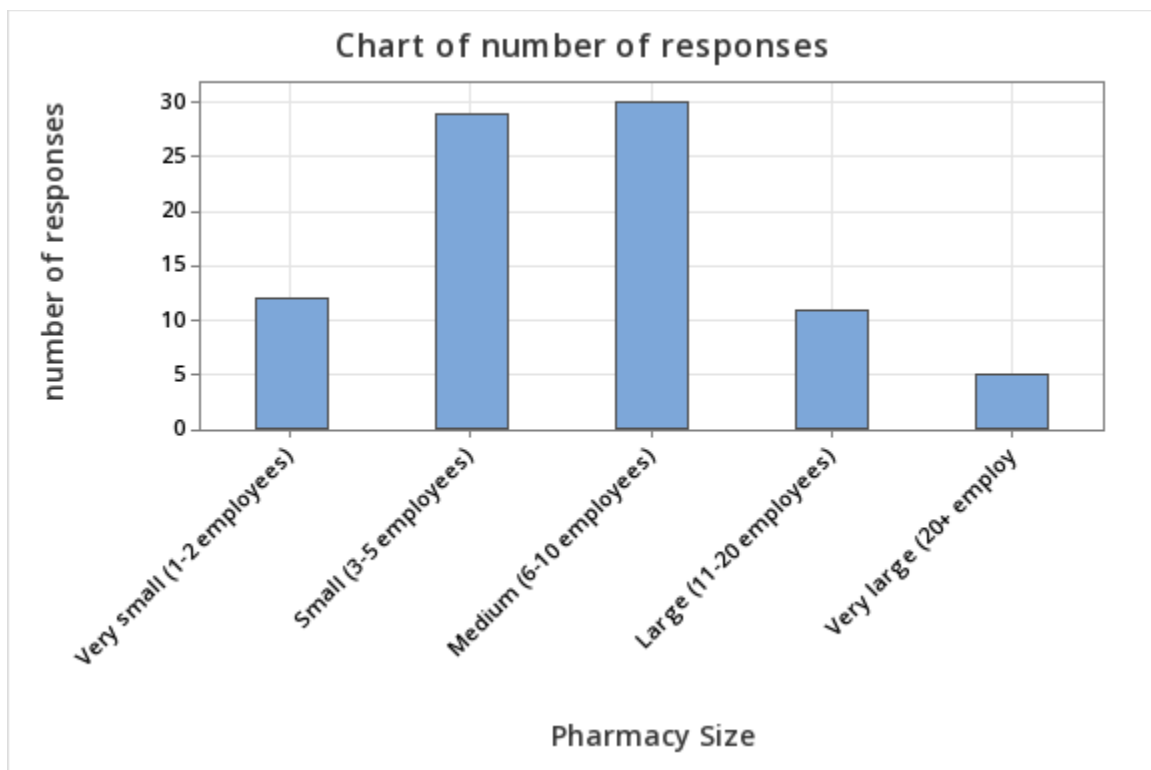


Figure 13: Pharmacy size

The above chart shows the number of responses gathered from pharmacies, grouped by their size based on the number of employees. The x-axis features five categories: Very Small (1–2 employees), Small (3–5), Medium (6–10), Large (11–20), and Very Large (more than 20 employees), while the y-axis indicates the number of responses, ranging from 0 to 30.

Pharmacies with a medium workforce (6–10 employees) had the highest participation, with nearly 30 responses (34.5%). Small pharmacies (3–5 employees) followed closely 33.3%, also showing a strong level of engagement.

Pharmacies classified as very small (1–2 employees) (13.8%) and large (11–20 employees) (12.6%) each received around 12 responses, reflecting a moderate level of participation. On the other hand, very large pharmacies (20+ employees) recorded the lowest number of responses, with only about five (5.7%).

Notably, the similar response levels seen in very small and large pharmacies imply that response rates do not necessarily scale with the size of the workforce. Instead, survey participation appears to peak among mid-sized pharmacies, highlighting a non-linear trend in engagement.

8.3 Analysis of Objective 1: CURRENT MEDICATION DISPOSAL PRACTICES

8.3.1 Frequency of Receiving Unused or Expired Medications from Patients for Disposal

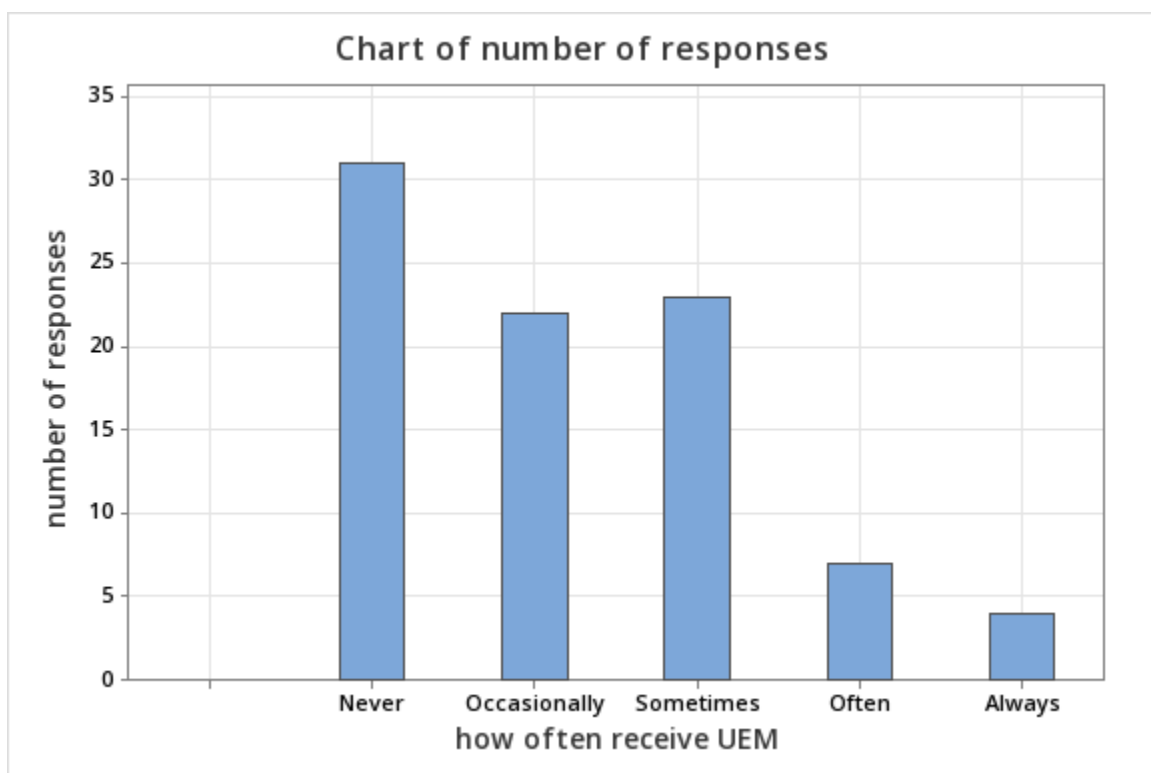


Figure 14: Frequency of Receiving Unused or Expired Medications from Patients for Disposal

The above bar chart illustrates the frequency with which pharmacies receive unused or expired medications (UEM) from patients for proper disposal. The response options include: Never, Occasionally, Sometimes, Often, and Always.

The most frequently selected option was "Never," with around 31 (35.6%) pharmacies indicating that they do not receive such medications from patients. This was followed by "Sometimes" and "Occasionally," each garnering approximately 23 (26.4%) to 22 (25.3%) responses. In contrast, the "Often" and "Always" categories had the least number of responses, at about 7 (8%) and 4 (4.6%), respectively.

The data suggests that most pharmacies rarely receive UEM from the public, indicating limited patient participation in returning leftover or expired medicines. However, a notable share of pharmacies reported receiving these medications occasionally, pointing to differences in practices based on location, staffing, or community engagement.

The low figures for the "Often" and "Always" categories confirm that consistent returns of UEM are not the norm. This may reflect broader issues such as inadequate awareness among patients about proper disposal methods or a lack of formal take-back mechanisms. Furthermore, the findings imply that many pharmacists might not be aware of how patients are disposing of unused medications, which raises concerns about improper disposal practices in the community.

8.3.2 Frequency of Providing Guidance on Safe Medication Disposal

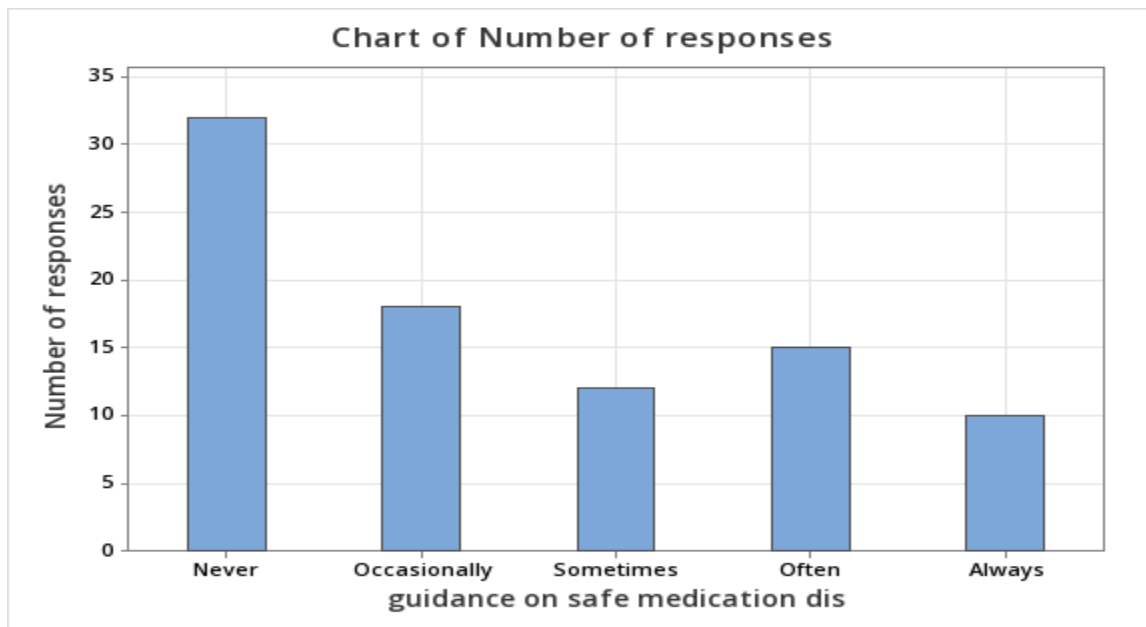


Figure 15: Frequency of Providing Patients with Guidance on Safe Medication Disposal

The above chart illustrates the frequency with which pharmacies or pharmacists provide guidance on safe medication disposal. The x-axis categorizes responses into five groups: Never, Occasionally, Sometimes, Often, and Always, with the y-axis showing the number of responses, ranging from 0 to 35.

The largest group, with approximately 32 (36.8%) responses, indicated that they never provide guidance on safe medication disposal. The Occasionally category had around 18 responses (20.7%), while Sometimes received about 12 (13.8%) responses. The Often category had approximately 15 responses (17.2%), and the Always category had the smallest number, around 10 responses (11.5%).

The findings clearly show a lack of regular guidance on safe medication disposal in pharmacies or pharmacists. The fact that 32 pharmacists reported never offering such guidance indicates a significant lack of patient education regarding proper disposal methods.

Furthermore, only a small portion of pharmacists reported providing guidance often (15 responses) or always (10 responses), suggesting that such advice is not a common practice in these pharmacies. This highlights that safe disposal guidance is not a consistent part of pharmacy operations.

A moderate number of pharmacists (18 responses) reported offering guidance occasionally, while 12 pharmacists provide it sometimes. While this shows that some guidance is being given, it is not part of a systematic approach. Overall, the trend demonstrates that pharmacies or pharmacists are not consistently informing patients about proper disposal practices, with the frequency of guidance decreasing as the responses move from Never to Always.

8.3.3 Effectiveness of Current Disposal Methods in Preventing Environmental Harm

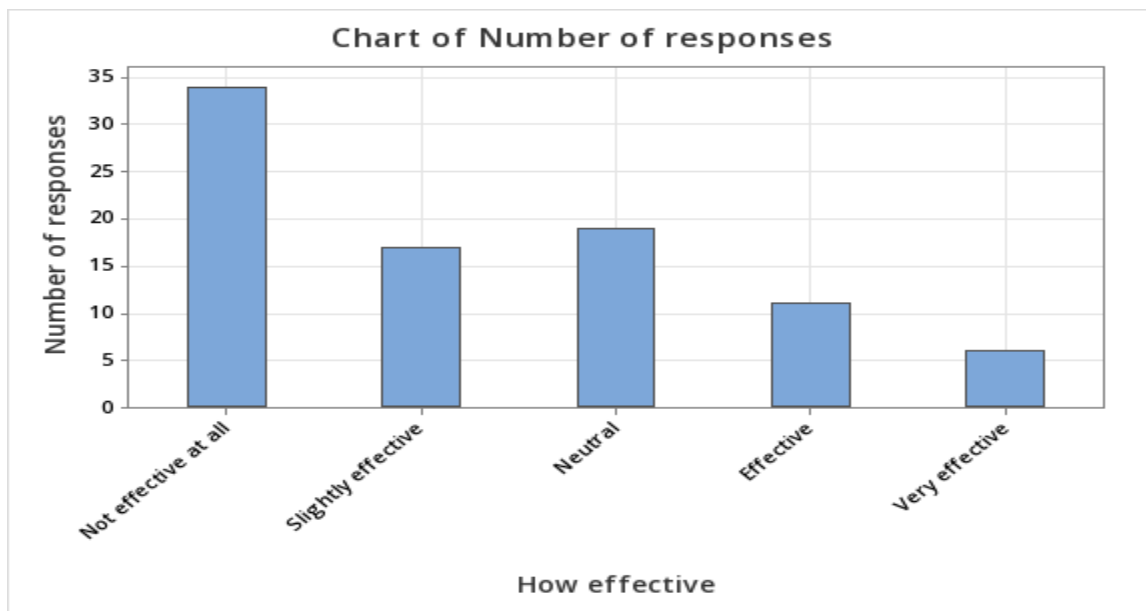


Figure 16: Effectiveness of Current Disposal Methods in Preventing Environmental Harm

The above chart illustrates how respondents assess the effectiveness of current disposal methods in reducing environmental harm. The x-axis is divided into five categories: Not effective at all,

slightly effective, Neutral, Effective, and Very effective, with the y-axis showing the number of responses, ranging from 0 to 35.

The largest group of respondents (around 34) (39.1%) stated that the disposal methods are not effective at all, highlighting a widespread belief that the current methods fail to prevent environmental damage. The second-largest group (about 19) (21.8%) expressed a neutral opinion, suggesting some level of uncertainty or lack of strong conviction regarding the effectiveness of the methods. Additionally, 17 respondents (19.5%) rated the methods as slightly effective, indicating some approval but acknowledging that improvements are needed.

A smaller number of respondents considered the methods to be effective (12.6%) or very effective (6.9%), indicating that few believe the disposal systems are adequate in addressing environmental harm. Overall, the trend clearly shows that most respondents feel the methods are either ineffective or only marginally effective.

8.3.4 Commonly Used Method for Disposing of Unused or Expired Medications in Pharmacies

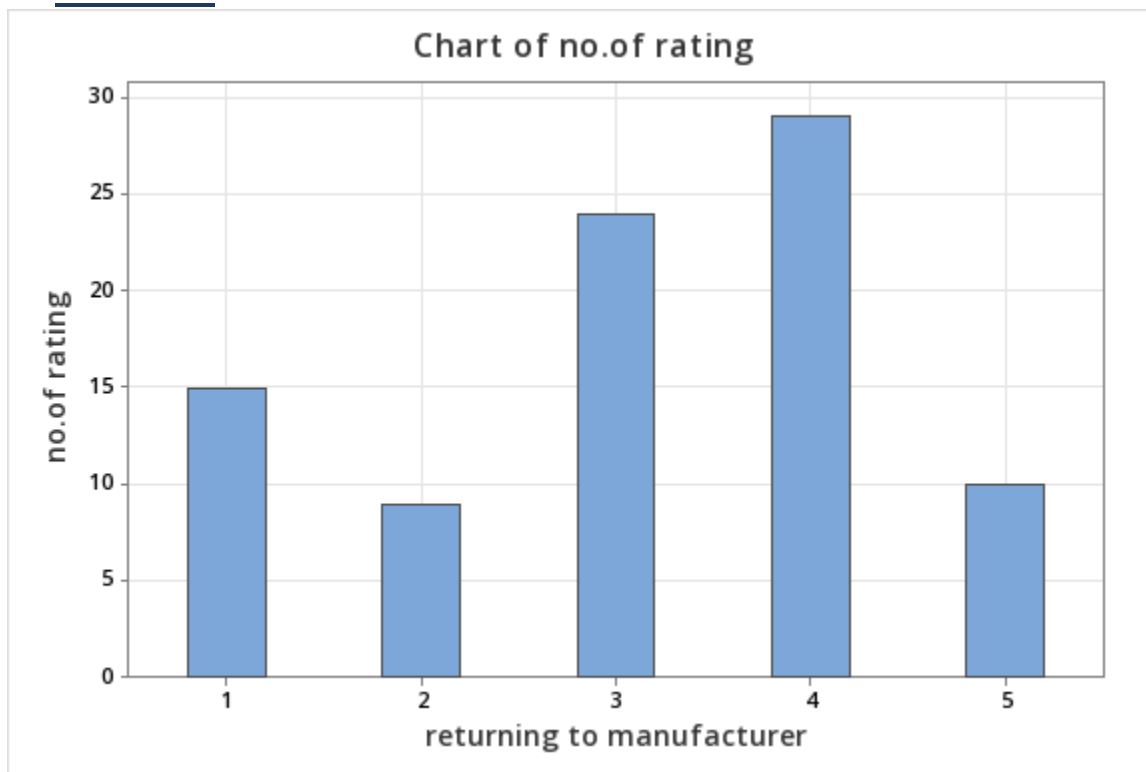


Figure 17: *Returning to the manufacturer*

The above bar chart evaluates how difficult pharmacists find the process of returning unused or expired medications (UEM) to manufacturers, using a scale from 1 to 5, where 1 means "Not challenging at all" and 5 means "Very challenging." Out of 87 respondents, 15 selected 1, 9 chose 2, and 24 marked 3, indicating a neutral perception. The largest group, 29 respondents, rated it as

4, while 10 selected 5. These results reveal that a majority of respondents find the process moderately to highly challenging, with a notable portion selecting ratings of 3 or 4. Only a small number of pharmacists found it relatively easy, reflected in the lower ratings. This suggests that returning UEM to manufacturers is considered a complex task, likely due to practical and regulatory barriers. Addressing these challenges could potentially improve the medication disposal process.

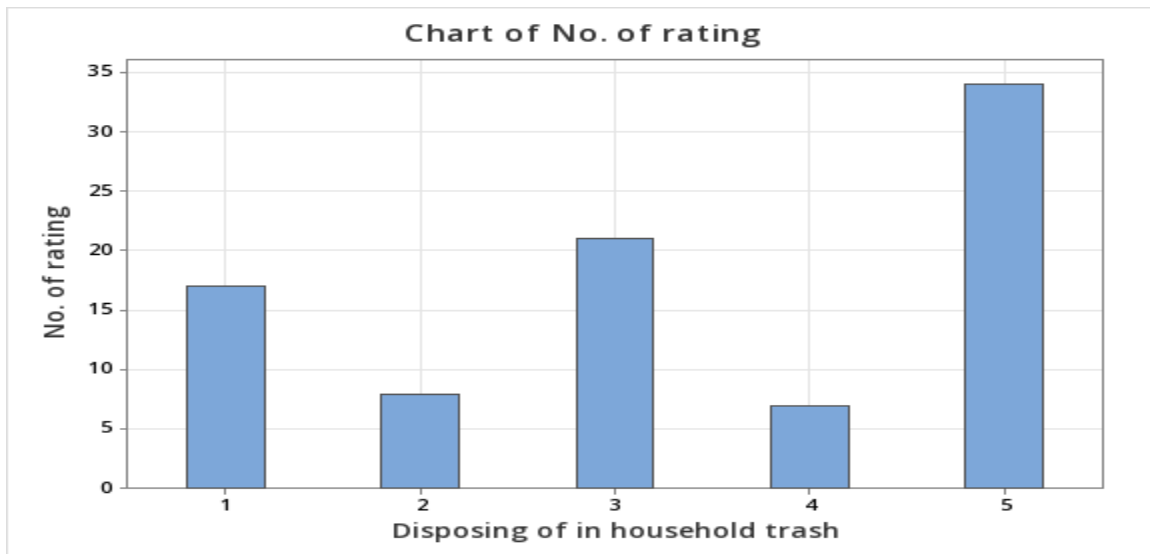


Figure 18: Disposing of in household trash

Similarly, to assess the challenge of disposing unused or expired medications in household trash, using a scale of 1 to 5, where 1 represents "Not challenging at all" and 5 represents "Very challenging (figure 8)." Out of 87 respondents, 17 rated it as 1, indicating no difficulty, while 8 rated it as 2, showing slight challenges. A larger group, 21 respondents, rated it as 3, suggesting a moderate level of difficulty. However, 34 respondents rated it as 5, marking it as very challenging, with 7 respondents rating it as 4. These findings reveal that while a small number of pharmacists find household trash disposal relatively easy, the majority view it as a significant challenge, likely due to concerns over its safety and environmental impact. This highlights the need for better alternatives or clearer disposal guidelines for pharmacies.

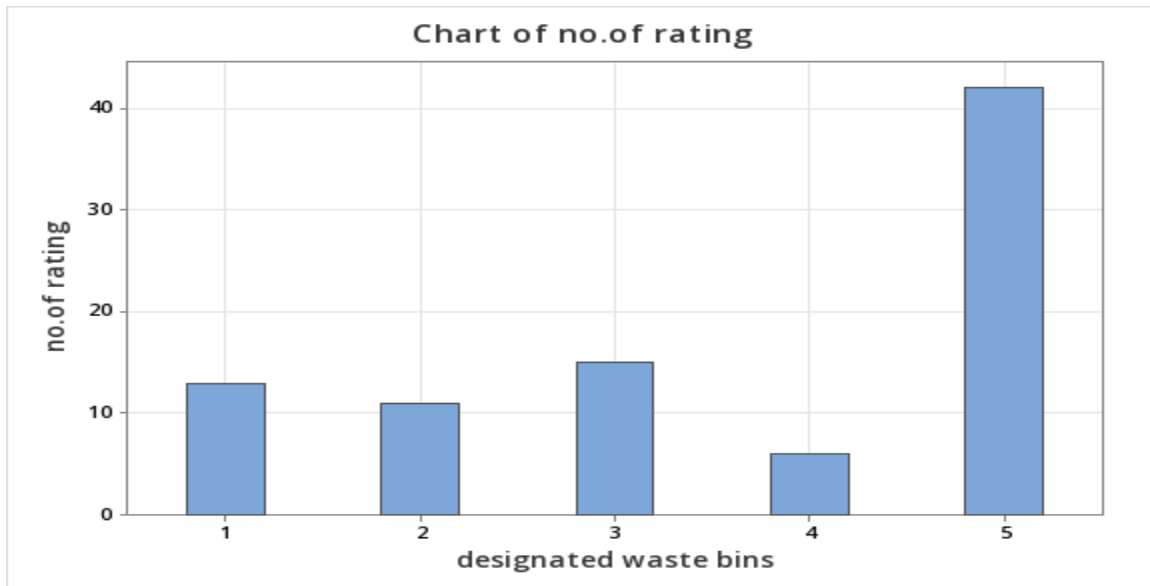


Figure 19: Disposing in designated waste bin

When assessing the challenge in disposing of unused or expired medications in designated bins, participants rated the difficulty on a scale of 1 to 5, where 1 represents "Not challenging at all" and 5 signifies "Very challenging (figure 9)." Out of 87 respondents, 13 rated it as 1, indicating little to no challenge, and 11 rated it as 2, suggesting a minor challenge. Fifteen participants chose 3, reflecting a moderate difficulty level. Six rated it as 4, showing a higher degree of challenge, while 42 respondents selected 5, indicating that they find this disposal method very challenging. The results highlight that while some pharmacies find designated bins relatively easy to use, a significant number view the process as difficult. The predominance of "very challenging" ratings could point to issues like insufficient infrastructure, lack of resources, or challenges in adherence to proper disposal regulations.

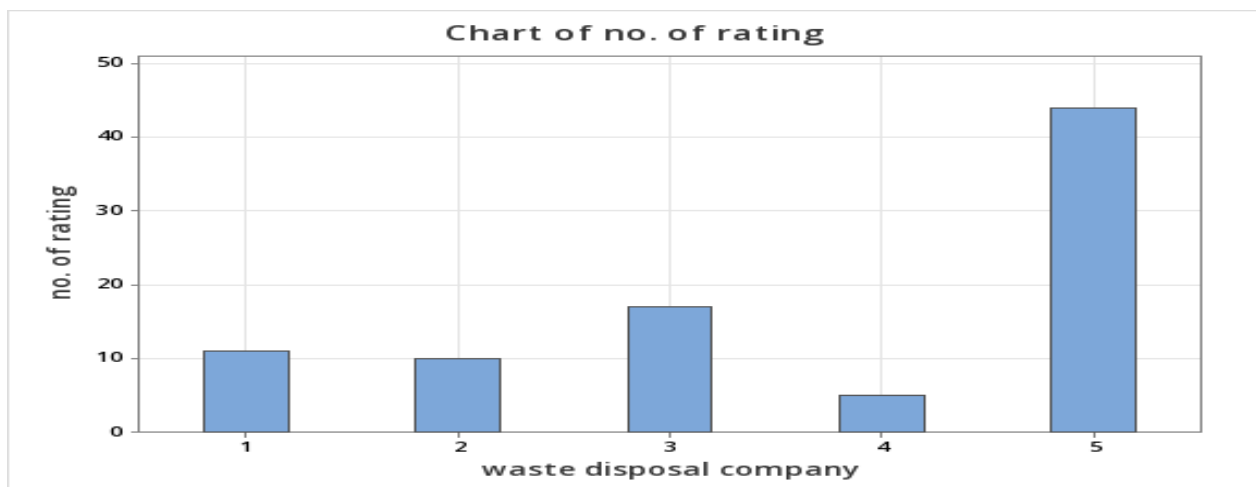


Figure 20: collected by waste disposal company

Finally, to evaluate the considered difficulty of having unused or expired medications collected by a waste disposal company, 87 pharmacists rated using a scale from 1 (not challenging at all) to 5 (very challenging) (figure 10). According to the responses, 11 participants rated it as 1 and 10 rated it as 2, indicating that a minority found this method relatively unproblematic. Seventeen respondents gave a neutral rating of 3, suggesting a moderate level of difficulty. Notably, 44 participants considered it very challenging (5), while 5 rated it as challenging (4).

These results show that a significant portion of respondents view the collection of medications by waste disposal companies as a major challenge. This may be due to logistical issues, limited availability of services, or a lack of clear protocols. The high number of responses at the upper end of the scale highlights the need for better support systems and policies to facilitate easier and more efficient waste collection in pharmacies.

8.3.5 Considered Challenges in Current Medication Disposal Practices

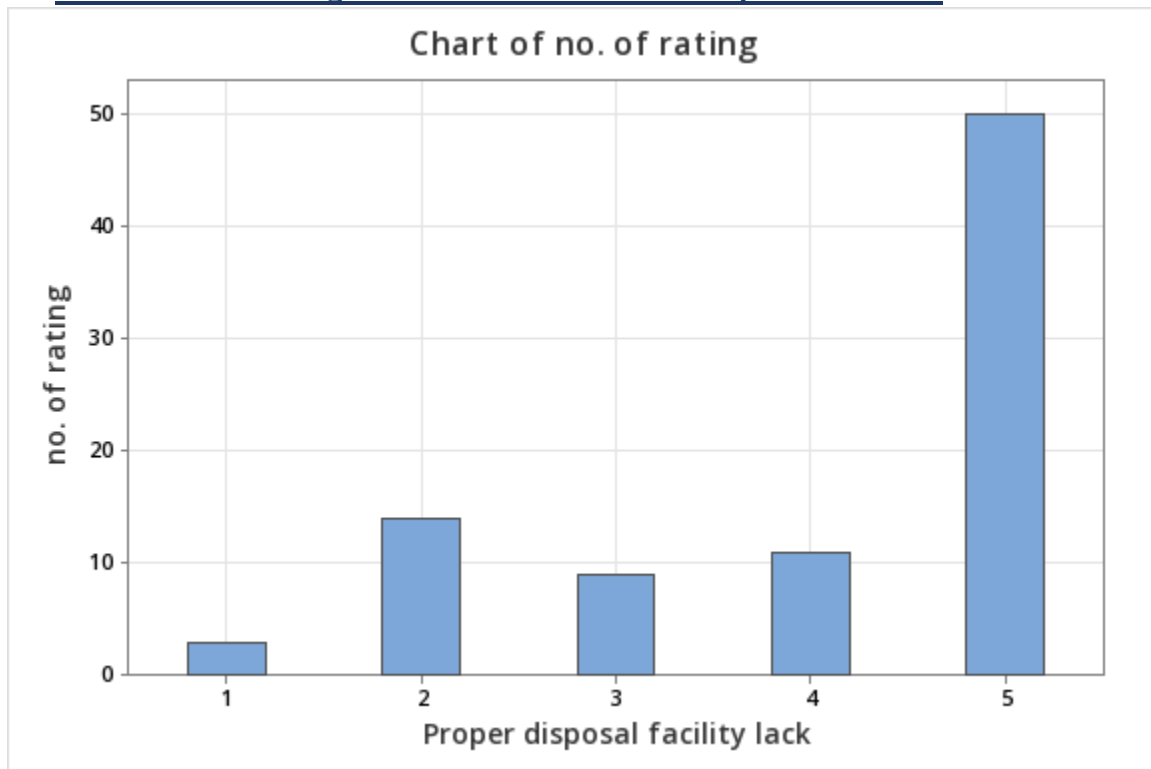


Figure 21: Lack of proper disposal facility

The first portion of the bar chart evaluate the extent to which the absence of suitable disposal facilities hinders proper medication waste management, 87 pharmacists were rated using a scale from 1 (not challenging at all) to 5 (very challenging) (figure 11).

The results show that a substantial portion of participants, 50 respondents consider this issue to be very challenging, reflecting a strong concern about the inadequacy of current disposal infrastructure. Additionally, 11 respondents rated it as 4, reinforcing the perception that this is a

serious obstacle. A moderate level of challenge was reported by 9 participants who selected a neutral score of 3. On the lower end of the scale, 14 respondents rated it as slightly challenging (2), while only 3 believed it posed no challenge at all (1).

These findings clearly indicate that the lack of appropriate disposal facilities is a critical issue, emphasizing the need for improved infrastructure to support safer and more effective medication disposal practices.

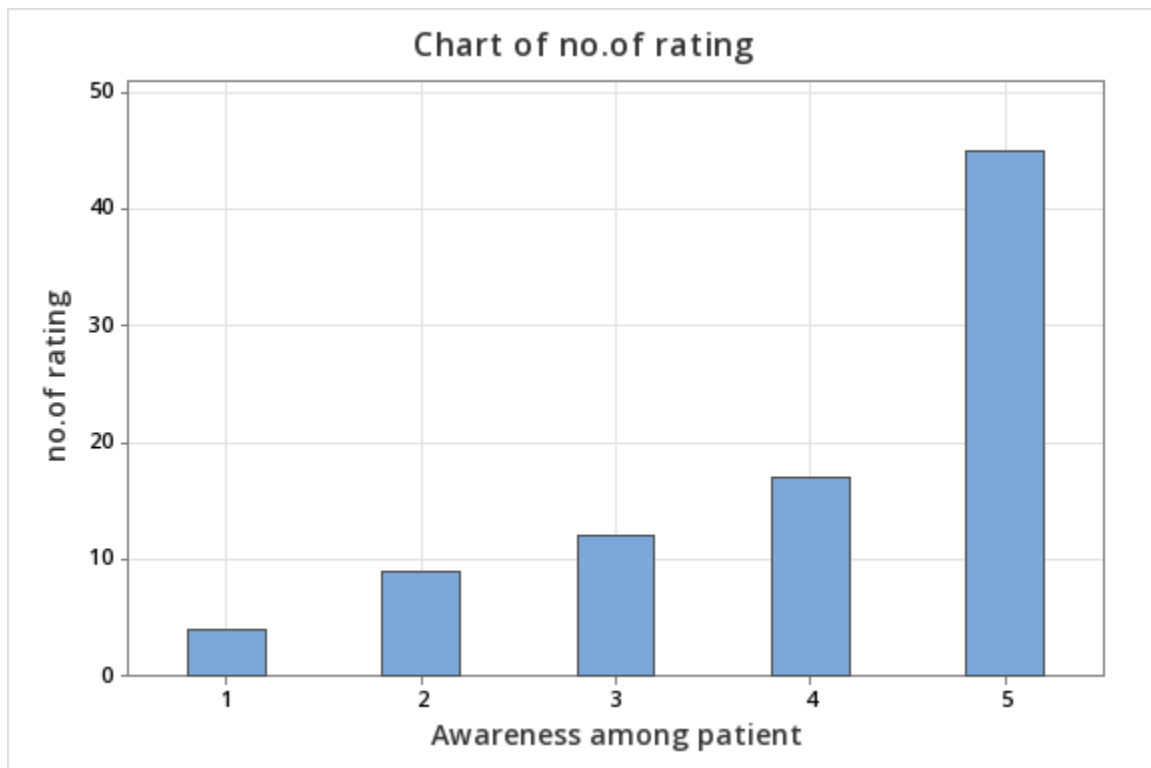


Figure 22: Lack of awareness among patient

While assessing the challenge posed by the lack of patient awareness in current medication disposal practices, the same 87 pharmacists rated it using the same rating scale from 1 (not challenging at all) to 5 (very challenging) (figure 12).

The results show that 45 respondents view this issue as very challenging (5), highlighting the significant impact of inadequate patient awareness. An additional 17 participants rated it as challenging (4), further reinforcing the concern. A moderate number of 12 respondents considered it neutral (3), indicating mixed or uncertain views on the issue. Fewer participants deemed it less of a challenge, with 9 selecting slightly challenging (2) and only 4 rating it as not challenging at all (1).

Overall, the data reveals that a lack of patient awareness is seen as a major barrier to proper medication disposal.

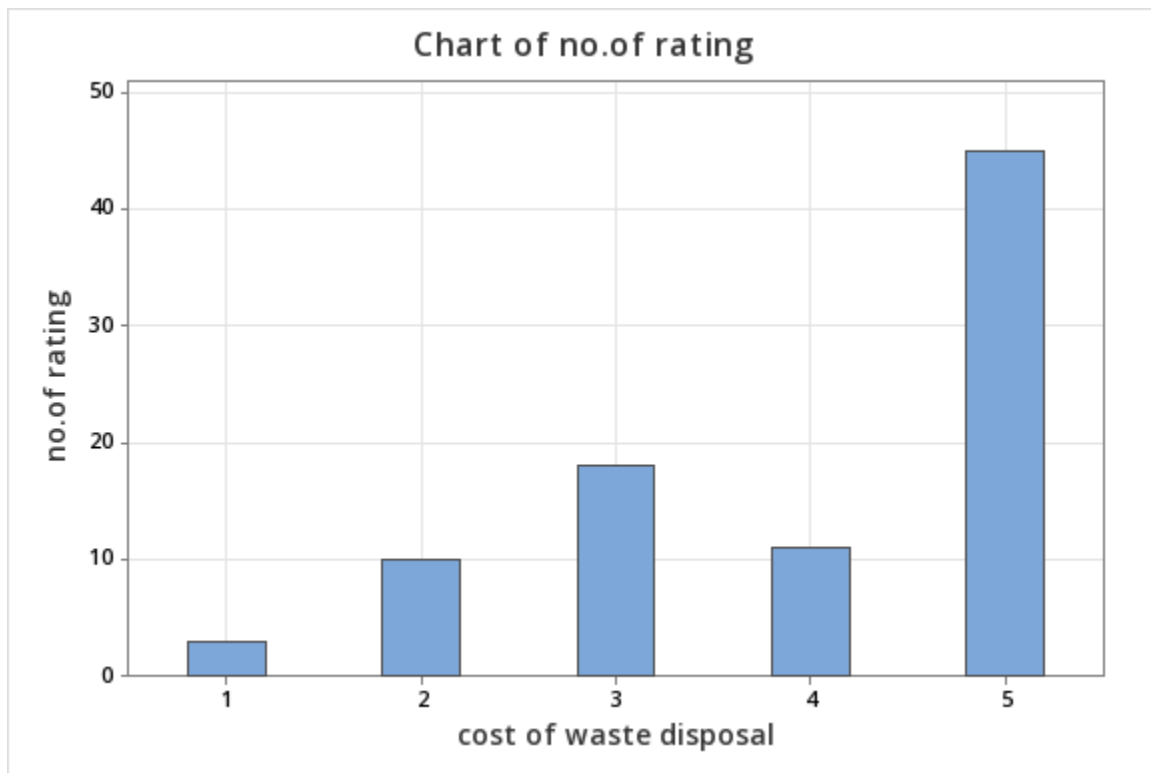


Figure 23: High cost of waste disposal

The challenge of high disposal costs was evaluated by 87 respondents using a scale from 1 to 5 (figure 13). A significant portion of respondents, 45, rated it as very challenging (5), indicating that the expense is a considerable barrier. Additionally, 11 respondents found it challenging (4), further highlighting the impact of cost. 18 respondents marked it as neutral (3), suggesting that while the cost is recognized, it isn't considered as overly burdensome. A smaller number of respondents, 10, considered it slightly challenging (2), and only 3 viewed it as not challenging at all (1).

In summary, the data indicates that high disposal costs are a major challenge for most respondents, pointing to the need for more cost-effective solutions to improve medication disposal practices.

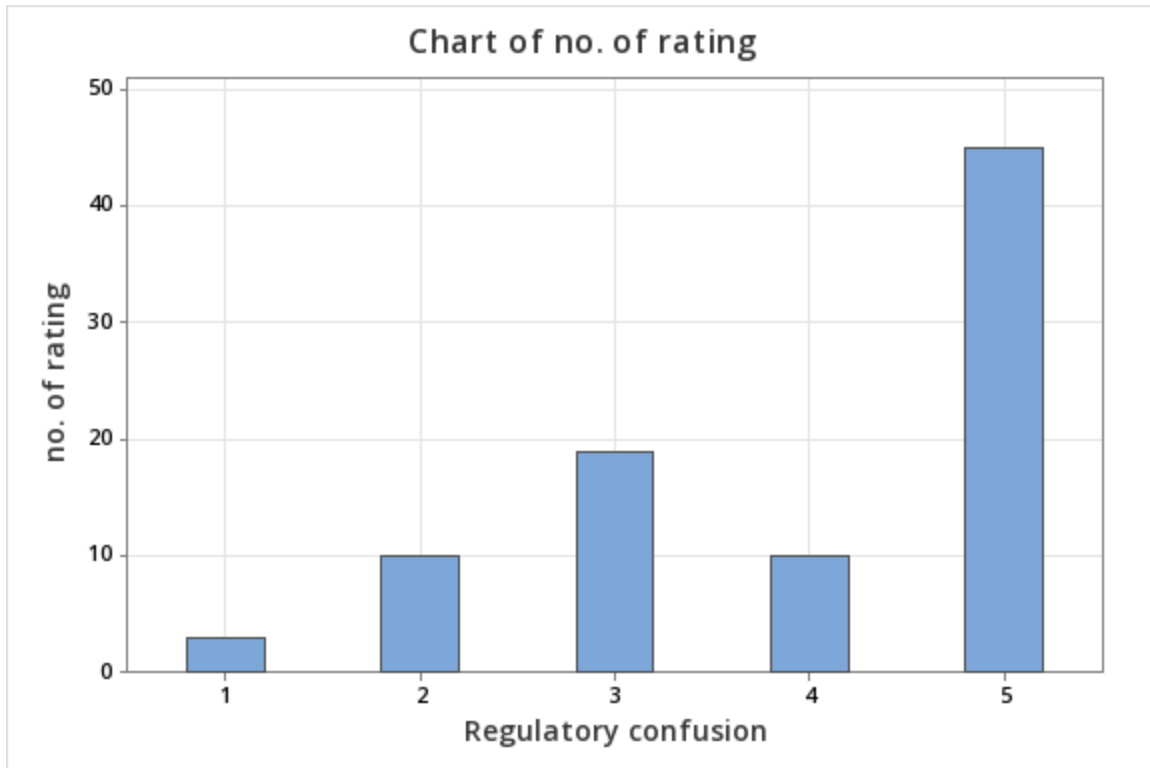


Figure 24: Regulatory confusion

Finally, the assessment of regulatory confusion in medication disposal practices, based on responses from 87 participants, shows that it poses a considerable challenge for many (figure 14). A large portion, 45 respondents, rated it as very challenging (5), indicating that unclear or complex regulations are a significant barrier to proper disposal. 19 respondents rated it as neutral (3), suggesting that while it is not universally problematic, it still remains an issue for some. 10 respondents viewed it as challenging (4), while another 10 rated it as slightly challenging (2). Only 3 respondents felt it was not challenging at all (1).

These findings underscore that regulatory confusion is a major obstacle for most respondents, pointing to the need for clearer, more accessible regulations to improve medication disposal practices.

8.3.6 Importance of Patient Education in Improving Medication Disposal Practices

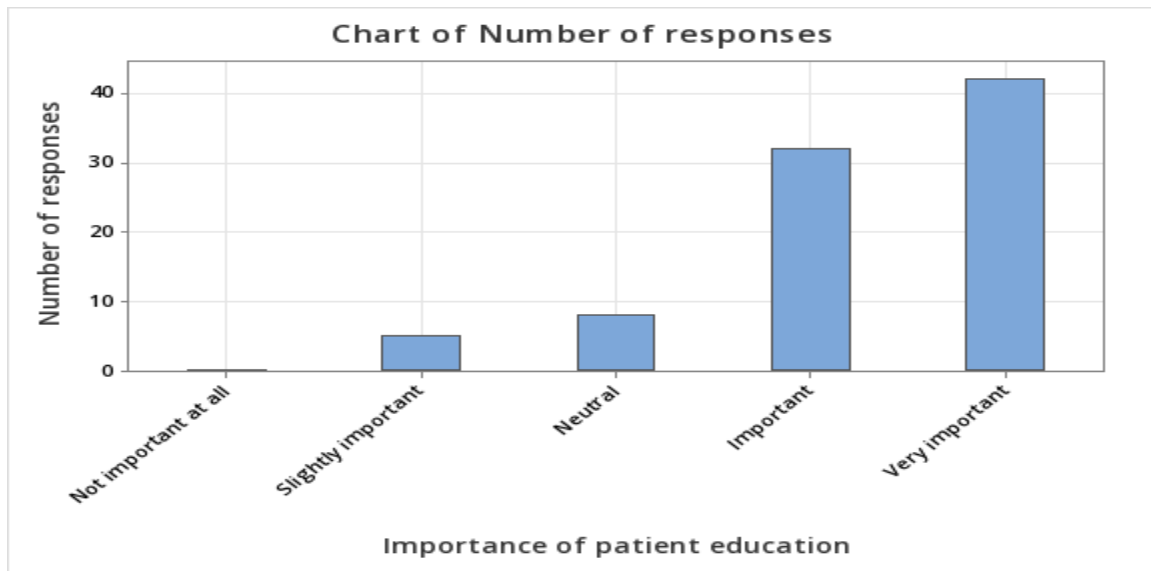


Figure 25: Importance of Patient Education in Improving Medication Disposal Practices

The above bar chart evaluates the responses from 87 pharmacists regarding the importance of patient education in improving medication disposal practices show a clear concern on its crucial role. The majority, 42 pharmacists (48.3%), regarded it as very important, and 32 pharmacists (36.8%) considered it important, together making up more than 85% of the responses. This highlights that a strong majority of pharmacists recognize the need for patient education in improving disposal methods.

A smaller group, 8 pharmacists (9.2%), remained neutral, indicating that while they acknowledge patient education's role, they don't see it as a top priority. Additionally, 5 pharmacists (5.7%) considered it slightly important, suggesting a more reserved view but still recognizing its potential impact.

Notably, no respondents rated patient education as not important, further reinforcing the opinion that educating patients is essential for better medication disposal practices. This highlights the general belief that informed patients are key to promoting safer and more environmentally sustainable disposal practices for unused or expired medications.

8.4 Analysis of Objective 2: AWARENESS OF CURRENT REGULATIONS IN KERALA

8.4.1 Familiarity with Kerala's Medication Waste Management Regulations

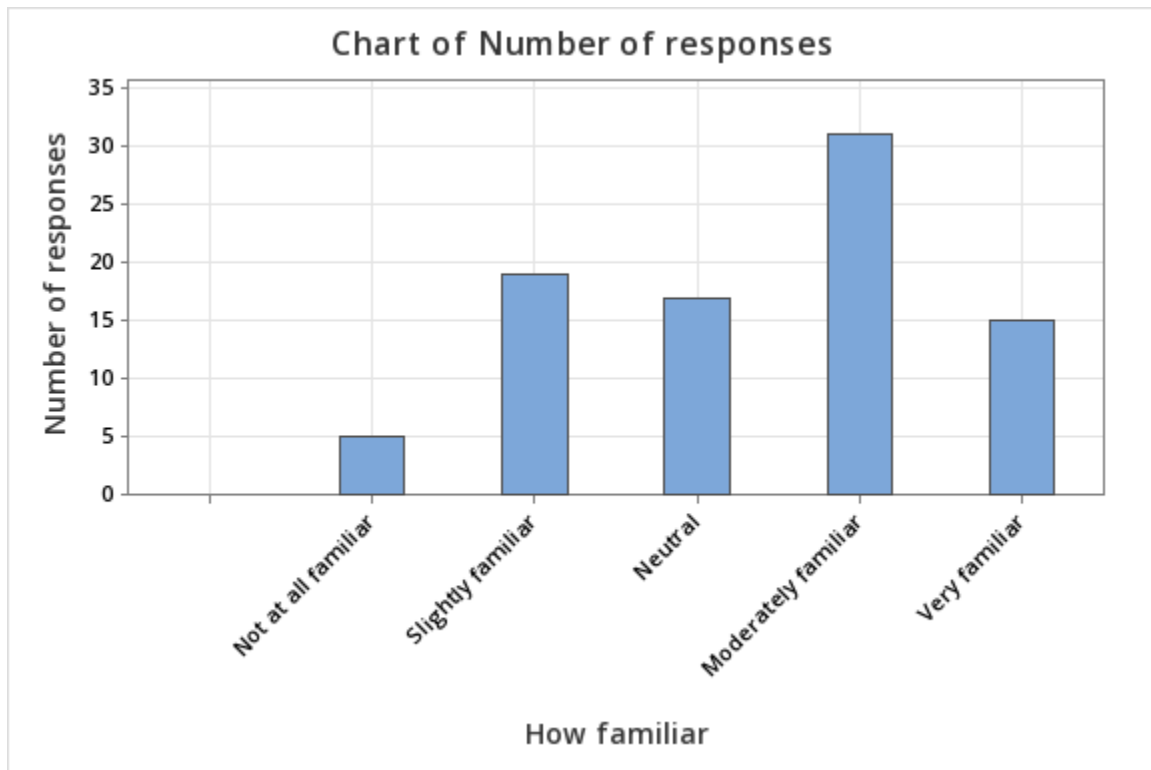


Figure 26: Familiarity with Kerala's Medication Waste Management Regulations

The above bar chart illustrates how respondents rated their level of familiarity with current Kerala Medication Waste Management Regulations. The x-axis displays five levels of familiarity, from "Not at all familiar" to "Very familiar," while the y-axis shows the number of participants selecting each level.

The highest number of respondents, approximately 31 (35.6%), identified as "Moderately familiar," indicating that a considerable portion has a decent understanding of current regulations. The "Slightly familiar" category followed with around 19 responses (21.8%), suggesting that some participants have a basic level of awareness.

The "Neutral" category received about 17 responses (19.5%), showing that a group of participants neither felt familiar nor unfamiliar with the regulations. Around 15 individuals (17.2%) selected "Very familiar," indicating a group with strong knowledge about regulations. The fewest responses, roughly 5 (5.7%) were in the "Not at all familiar" category, suggesting that only a small number of participants lacked any familiarity.

The data suggest that the majority of respondents possess at least some awareness of the medication waste management regulations in Kerala. The relatively small number of respondents who are completely unfamiliar implies that educational efforts could focus on improving the depth of knowledge among the moderately and slightly familiar groups, rather than starting from scratch.

8.4.2 Clarity of Existing Regulations on Medication Disposal in Kerala

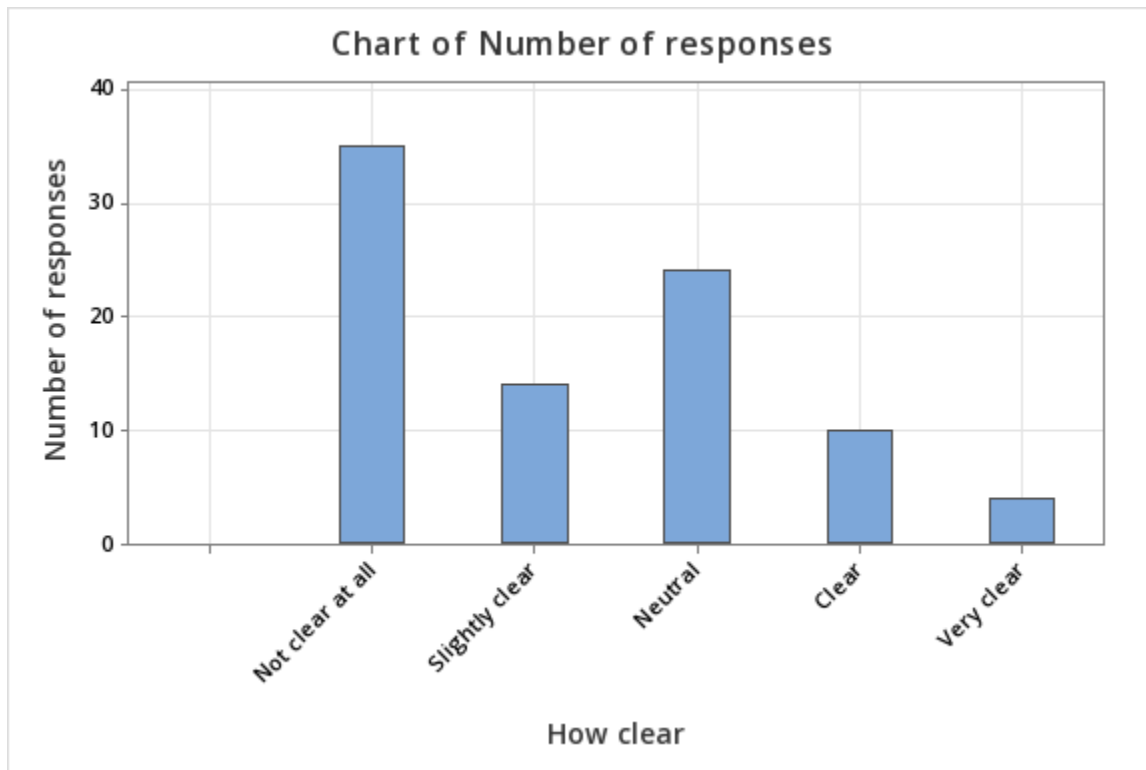


Figure 27: Clarity of Existing Regulations on Medication Disposal in Kerala

The bar chart depicts the perceptions of 87 pharmacists regarding the clarity of existing medication disposal regulations in Kerala. Approximately 35 respondents (40.2%) indicated that the regulations are “Not clear at all” suggesting that many find the guidelines confusing or not well explained. Around 24 respondents (27.6%) selected the “Neutral” option, implying uncertainty or indifference about the clarity of the regulations. Only 14 pharmacists (16.1%) considered the guidelines “Slightly clear,” indicating some awareness but still a sense of some uncertainty. A mere 10 respondents (11.5%) found the regulations “Clear,” and only 4 (4.6%) considered them as “Very clear,” highlighting that a small minority believe the guidelines are adequately explained and easy to follow.

These findings underscore a widespread concern among pharmacists regarding the current state of medication disposal regulations in Kerala. The predominant perception of ambiguity or lack of

clarity suggests an urgent need for enhanced communication, training, and dissemination of regulatory information.

8.4.3 Compliance with Medication Disposal Regulations in Kerala

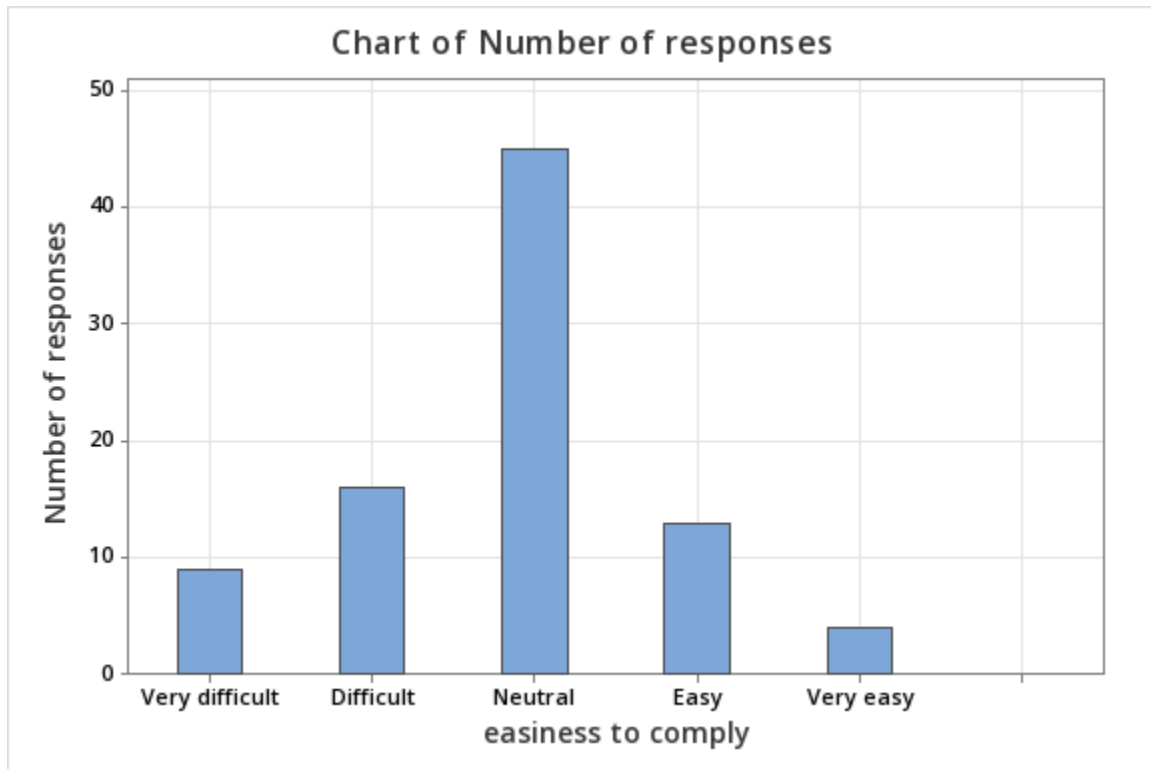


Figure 28: Compliance with Medication Disposal Regulations in Kerala

The bar chart illustrates the responses of 87 pharmacists in Kerala regarding the ease of complying with current regulations, categorized into five levels: Very difficult, Difficult, Neutral, Easy, and Very easy. Of the respondents, 9 pharmacists (10.3%) chose "Very difficult," 16 (18.4%) selected "Difficult," 45 (51.7%) answered "Neutral," 13 (14.9%) found it "Easy," and 4 (4.6%) considered it "Very easy."

The absence of clear regulations on unused or expired medication (UEM) disposal in Kerala is evident in the responses from pharmacists. The large number of "Neutral" answers (45 out of 87) points to uncertainty, as many pharmacists may be unsure how to handle UEM disposal due to the lack of specific guidelines.

The 25 pharmacists who found compliance challenging (9 "Very difficult" and 16 "Difficult") likely face difficulties navigating this regulatory void, as they lack clarity on the proper procedures. In contrast, the 18 pharmacists (13 "Easy" and 4 "Very easy") who reported ease in compliance

may have developed their own methods or use alternative resources, though this is not the case for most.

These responses suggest that the absence of clear regulations leads to confusion and inconsistent practices, emphasizing the need for formal guidelines and support to improve UEM disposal processes in Kerala.

8.4.4 Sufficiency of Current Regulations for Safe Medication Disposal in Kerala

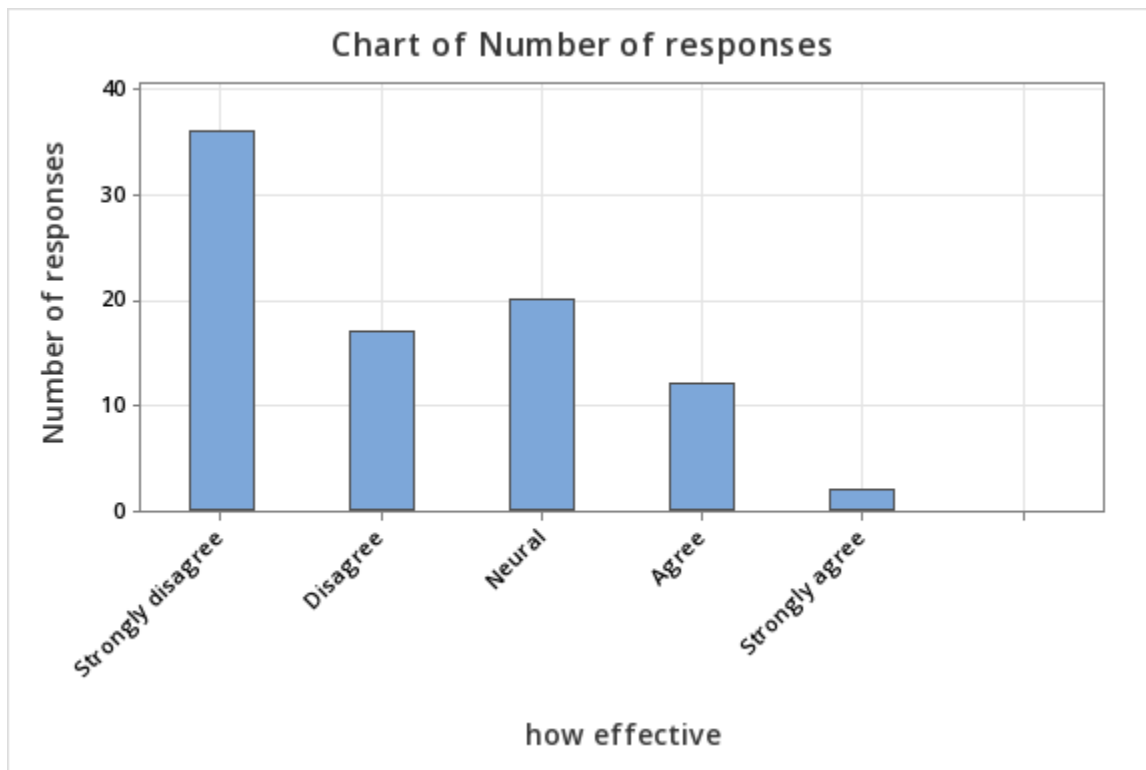


Figure 29: Sufficiency of Current Regulations for Safe Medication Disposal in Kerala

The bar chart displays the responses of 87 pharmacists in Kerala to the question, "Do you believe the current regulations are sufficient to ensure safe medication disposal?" The answers were categorized into five levels: Strongly disagree, Disagree, Neutral, Agree, and Strongly agree. The responses are as follows: approximately 36 (41.4%) pharmacists chose "Strongly disagree," 17 (19.5%) selected "Disagree," 20 (23%) marked "Neutral," 12 (13.8%) agreed, and only 2 (2.3%) strongly agreed.

A significant proportion of pharmacists (36 out of 87) strongly disagreed with the adequacy of current regulations, while another 17 disagreed, meaning that over half (51 out of 87) of the respondents feel the regulations are insufficient for safe medication disposal. This reflects widespread dissatisfaction with the current regulatory framework.

Additionally, 20 pharmacists selected "Neutral," which may indicate uncertainty or a lack of clarity regarding the effectiveness of the regulations. This could suggest mixed experiences or indifference toward the existing measures. Only 12 respondents agreed, and just 2 strongly agreed, showing that very few hold a positive view of the regulations.

The data suggests that most pharmacists in Kerala are dissatisfied with the current regulations on safe medication disposal. With around 60% of respondents expressing concerns, there is a clear need for a review and enhancement of the regulations to improve the safety and effectiveness of disposal practices.

8.4.5 Pharmacists' Training on Pharmaceutical Waste Disposal Regulations in Kerala



Figure 30: Pharmacists' Training on Pharmaceutical Waste Disposal Regulations in Kerala

The bar chart outlines the responses from 87 pharmacists in Kerala regarding whether they have received sufficient training on pharmaceutical waste disposal regulations. The responses were divided into five categories: Strongly disagree, Disagree, Neutral, Agree, and Strongly agree. Around 36 (41.4%) pharmacists responded with "Strongly disagree," 13 (14.9%) with "Disagree," 21(24.1%) were "Neutral," 15(17.2%) agreed, and only 2 (2.3%) strongly agreed.

The majority of respondents, particularly the 36 who strongly disagreed and 13 who disagreed, reflect a widespread perception of inadequate training together accounting for over half of the

participants (56%). This highlights a significant shortfall in the professional training and knowledge transfer related to pharmaceutical waste handling in Kerala.

The neutral responses from 21 pharmacists may indicate uncertainty or inconsistent experiences with training programs, or perhaps a lack of awareness of what proper training entails. Meanwhile, only 17 respondents indicated that they had received adequate training, suggesting limited confidence in the current system.

These results underscore a critical need for improved access to structured, high-quality training on pharmaceutical waste disposal regulations. The findings clearly reveal that the majority of pharmacists feel underprepared, pointing to the necessity for regulatory bodies to strengthen educational efforts and ensure consistent, comprehensive training across the sector.

8.4.6 Considered Support from Regulatory Authorities in Managing Pharmaceutical Waste

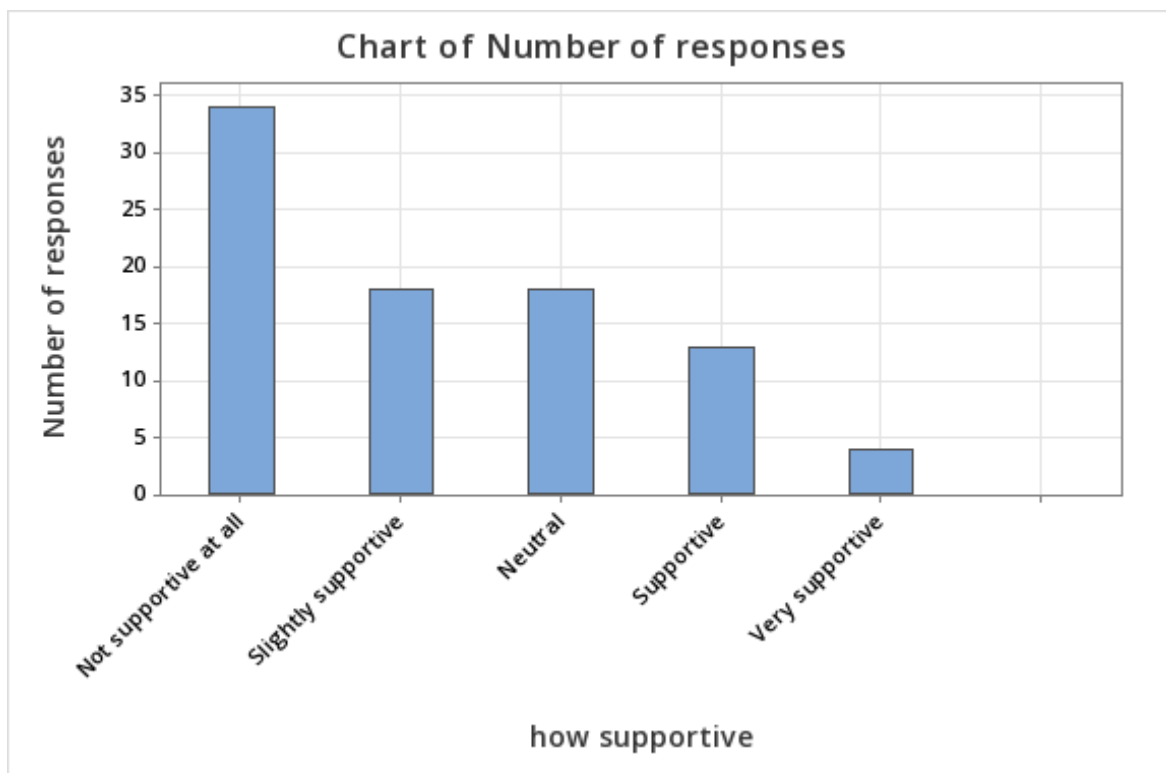


Figure 31: Considered Support from Regulatory Authorities in Managing Pharmaceutical Waste

The bar graph reflects the opinions of 87 pharmacists in Kerala on the extent of support received from regulatory authorities in managing pharmaceutical waste. Participants were asked to rate the support as Not supportive at all, Slightly supportive, Neutral, Supportive, or Very supportive. The largest portion, 34 pharmacists (39.1%), felt that regulatory authorities were not supportive at all.

Additionally, 18 respondents (20.7%) rated the support as slightly supportive, while another 18 (20.7%) chose a neutral stance. A smaller group of 13 pharmacists (14.9%) believed the authorities were supportive, and only 4 (4.6%) found them to be very supportive.

The results point to a widespread perception of insufficient support. More than half of the pharmacists (58%) viewed the assistance from regulatory bodies as minimal or entirely lacking, indicating a lack of confidence in the current system.

The neutral responses may suggest uncertainty or inconsistent experiences with regulatory involvement. On the other hand, the small number of pharmacists who felt supported (18%) reveals that positive engagement from authorities is limited.

The data emphasize the need for stronger and more visible support from regulatory authorities in Kerala. Improved communication, clearer guidelines, and active involvement are essential to help pharmacists manage pharmaceutical waste more effectively and ensure compliance with safety standards.

8.5 AWARENESS OF CYCLAMED OR SIMILAR PROGRAMS

8.5.1 Pharmacists' Awareness of the CYCLAMED Model Implemented in France

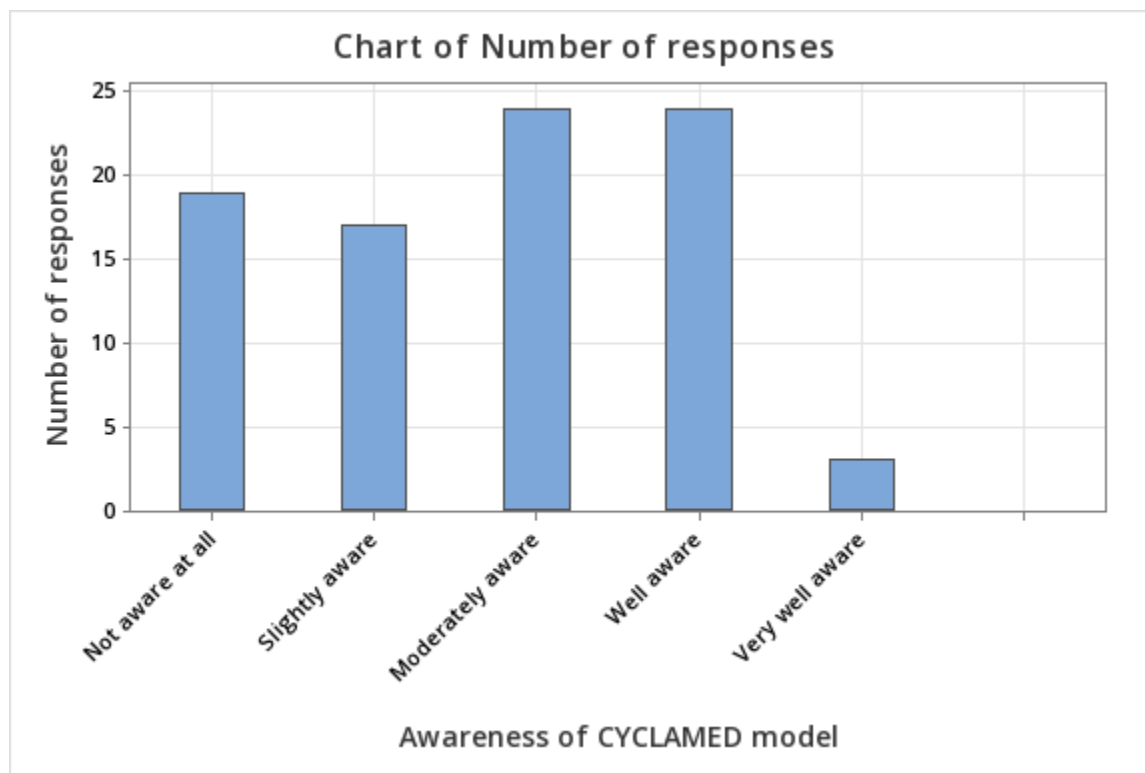


Figure 32: Pharmacists' Awareness of the CYCLAMED Model Implemented in France

The bar graph illustrates the responses from 87 pharmacists regarding their awareness of the CYCLAMED model, a medication take-back system led by pharmacies in France. The levels of awareness were categorized as "Not aware at all," "Slightly aware," "Moderately aware," "Well aware," and "Very well aware."

Among the respondents, 19 pharmacists (21.8%) reported being "Not aware at all," and 17 (19.5%) were "Slightly aware." A larger group, 24 pharmacists (27.6%), were "Moderately aware," and 24 (27.6%) were "Well aware." Only 3 pharmacists (3.4%) considered themselves "Very well aware" of the CYCLAMED model.

The highest awareness was found in the "Moderately aware" and "Well aware" categories, with 24 respondents (27.6%) in each. However, just 3 pharmacists (3.4%) had a high level of awareness, describing themselves as "Very well aware." A combined total of 36 pharmacists (41%) reported either limited awareness or none at all, while 51 pharmacists (59%) displayed at least moderate awareness.

These findings suggest that, although many pharmacists in Kerala have some awareness of the CYCLAMED model, a significant portion still lacks in-depth knowledge or only has a basic understanding. While many pharmacists are aware of the model to some extent, the relatively small number of those with comprehensive knowledge highlights the need for further education.

8.5.2 Familiarity with the Structure and Operation of the CYCLAMED Model

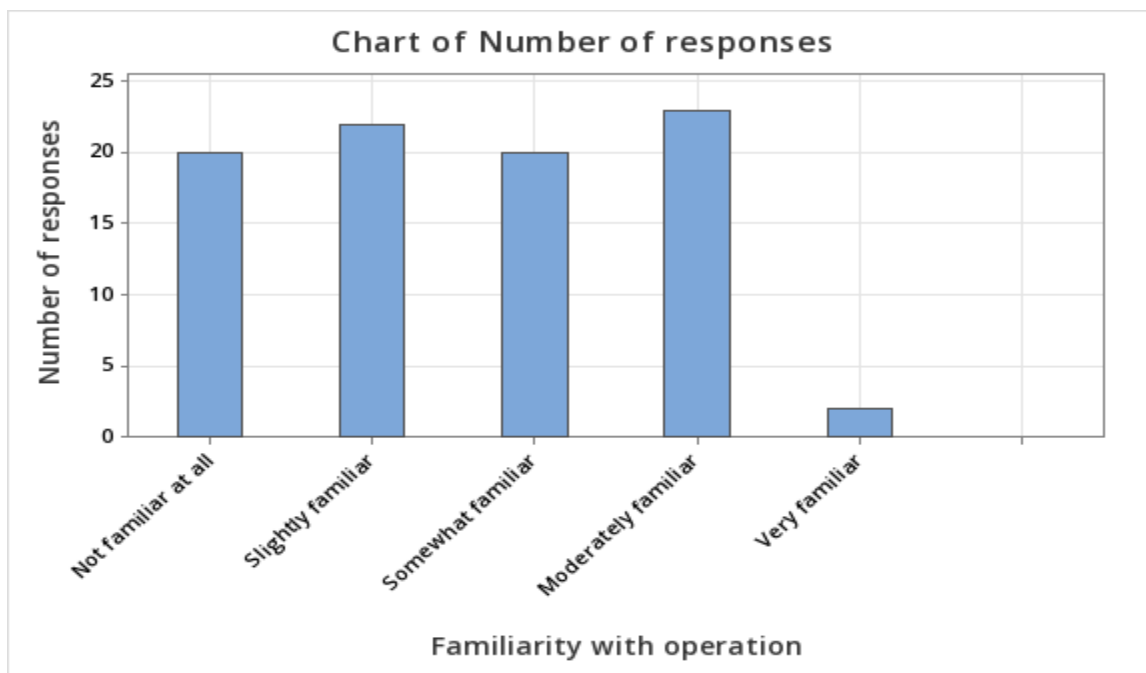


Figure 33: Familiarity with the Structure and Operation of the CYCLAMED Model

The bar graph illustrates how familiar pharmacists in Kerala are with the structure and functioning of the CYCLAMED model, a pharmacy-led medication take-back initiative implemented in France. Respondents rated their familiarity on a scale ranging from "Not aware at all" to "Very well aware."

Among the participants, 20 (23%) pharmacists indicated they had no awareness of the model, similarly 20 (23%) described they are somewhat familiar. Together, these groups represent 40% of the total respondents, showing that a significant number have little to no exposure to the CYCLAMED system. On the other hand, the highest numbers were seen in the "Moderately aware" with 23 respondents (26.4%) and "Well aware" category with 22 (25.3%). Only 2 pharmacists (2.3%) reported being "Very well aware," revealing that an in-depth understanding is uncommon.

These findings suggest that while a fair number of pharmacists are somewhat familiar with the model, a large proportion still lacks meaningful insight into how the system operates. The moderate awareness seen in many responses indicates surface-level knowledge rather than a comprehensive understanding. This shortfall in detailed familiarity could limit the potential for adopting or replicating such a system in Kerala without additional support.

The data point to an urgent need for awareness-building and educational efforts to strengthen pharmacists' understanding of international models like CYCLAMED. By improving familiarity with how such systems are structured and managed, pharmacists in Kerala could be better equipped to support the development and implementation of similar medication take-back programs in their own region.

8.5.3 Considered Feasibility of a Pharmacy-Led Medication Take-Back Program in Kerala

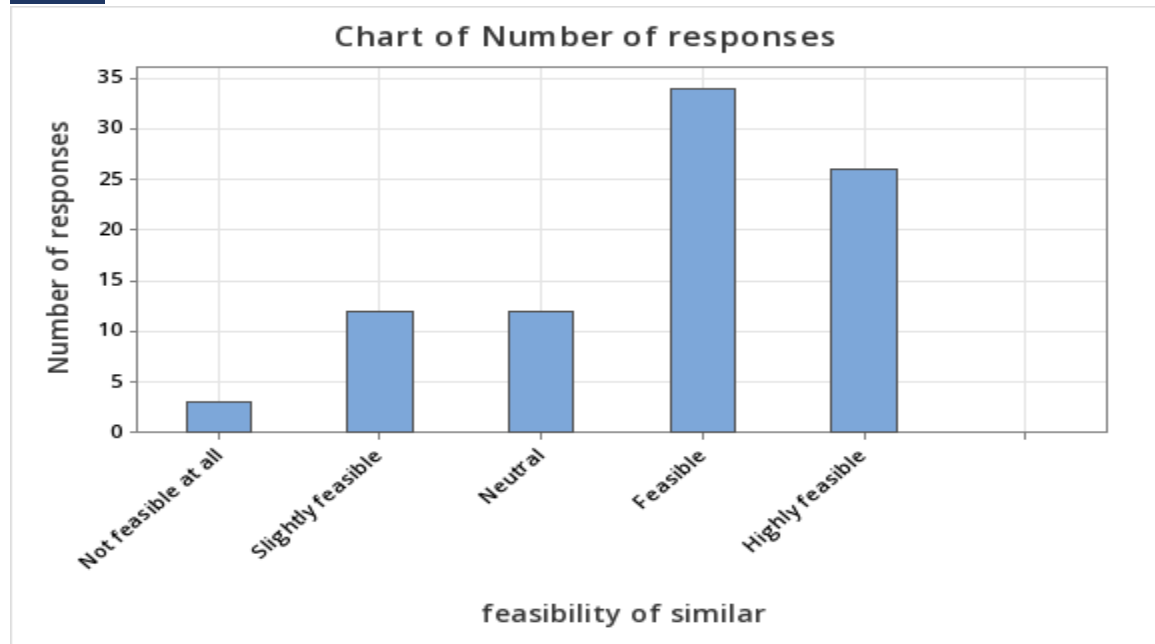


Figure 34: Considered Feasibility of a Pharmacy-Led Medication Take-Back Program in Kerala

The bar graph illustrates the perspectives of 87 pharmacists in Kerala regarding "To what extent do they think a pharmacy-led medication take-back program could work in Kerala" Responses were categorized into five levels: Not feasible at all, Slightly feasible, Neutral, Feasible, and Highly feasible.

Out of the total participants (87), 34 pharmacists (39.1%) believed the program is feasible, while 26 pharmacists (29.9%) considered it highly feasible. This means that nearly 70% of respondents view the initiative positively. On the other hand, only 3 pharmacists (3.4%) felt it was not feasible at all.

Twelve respondents each (roughly 14%) selected Slightly feasible and Neutral, indicating a degree of hesitation or lack of certainty among a small portion of the group. This could be attributed to concerns over potential challenges such as implementation barriers, cost, or lack of supporting infrastructure.

Overall, the responses reveal a strong inclination among pharmacists towards supporting a pharmacy-led medication take-back system in Kerala. The relatively low level of opposition suggests that most professionals are open to the idea. However, the responses in the middle categories point to the need for further clarification or confidence-building measures.

The results suggest substantial professional support for introducing such a program in Kerala. This backing creates a favorable environment for piloting or rolling out the initiative. At the same time,

attention should be given to addressing the uncertainties expressed by some pharmacists through awareness programs, stakeholder consultations, and demonstrations of how the system could be effectively implemented.

8.5.4 Considered Benefits of a Pharmacy-Led Medication Take-Back System in Kerala for Various Aspects

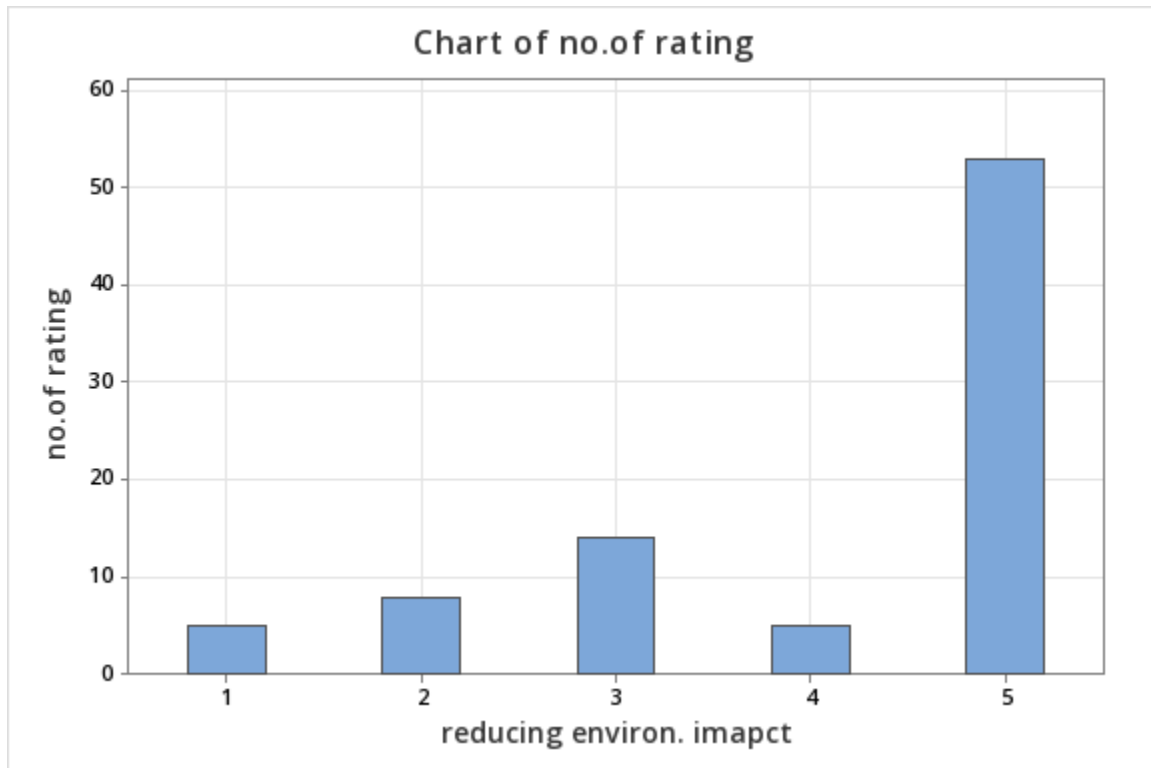


Figure 35: Reducing environmental impact

The above bar graph demonstrates the views respondents on the environmental benefits of implementing a pharmacy-led medication take-back system. The first portion of the graph shows how participants rated the impact of pharmacy-led medication take-back system on reducing environmental impact on a scale from 1 to 5, where 1 represented "not beneficial at all" and 5 indicated "highly beneficial."

The results reveal strong overall support for the initiative. A majority of the pharmacists, 53 out of 87, selected the highest rating of 5, signifying their firm belief that such a system would significantly help reduce environmental harm caused by improper disposal of medicines. This response accounts for over 60% of the total participants, indicating a strong belief about the value of the program in addressing environmental concerns.

Additionally, 5 respondents rated the system as a 4, and 14 gave it a score of 3. These responses suggest a moderate level of confidence in the potential of the program, possibly reflecting cautious

optimism or a belief that its effectiveness may depend on implementation quality and public engagement.

On the other hand, only a small number of pharmacists were less convinced. Eight rated the system as a 2, and five selected 1, together comprising just about 15% of the sample. This minority might represent a group with reservations due to lack of awareness, concerns over feasibility, or considered limitations of the initiative.

The findings suggest that most pharmacists in Kerala view a pharmacy-led take-back program as a highly effective tool for mitigating environmental risks, with only minimal opposition or doubt expressed among respondents.

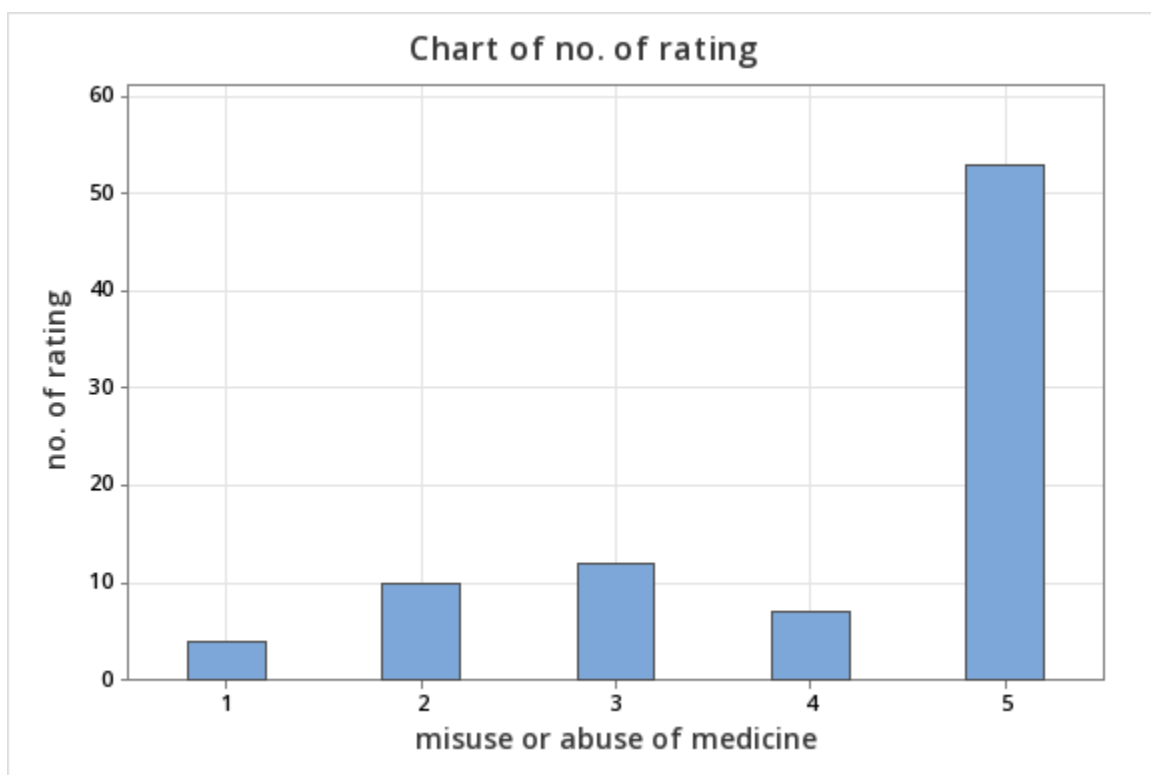


Figure 36: Preventing misuse or abuse of medications

The above bar chart (figure 26) highlights how the respondents rated the effectiveness of a pharmacy-led medication take-back system in preventing medication misuse or abuse. Participants were asked to rate the system on a scale from 1 to 5, where 1 meant "not beneficial at all" and 5 meant "highly beneficial."

A large majority, about 53 pharmacists rated the system a 5, indicating they believe it would be highly effective in reducing the misuse of expired or unused medications. This response represents over 60% of the participants, suggesting a strong belief among pharmacists that such a system

could help reduce the risk of medications being improperly accessed, particularly in households where they might be vulnerable to misuse.

Additionally, 7 pharmacists rated the system a 4, and 12 gave it a 3, together making up about 22% of the respondents. These participants likely recognize the potential of the system but might believe its success depends on factors such as public awareness and proper implementation.

On the lower end, 10 pharmacists rated the system as a 2, and 4 rated it as 1, combining for 16% of the responses. This smaller group may have concerns about the practicality or impact of the system, possibly due to doubts about its implementation or effectiveness in reaching those who need it most.

The data indicates that most pharmacists in Kerala strongly support the idea of a pharmacy-led take-back system, believing it could play an important role in preventing medication misuse and promoting safer disposal practices.

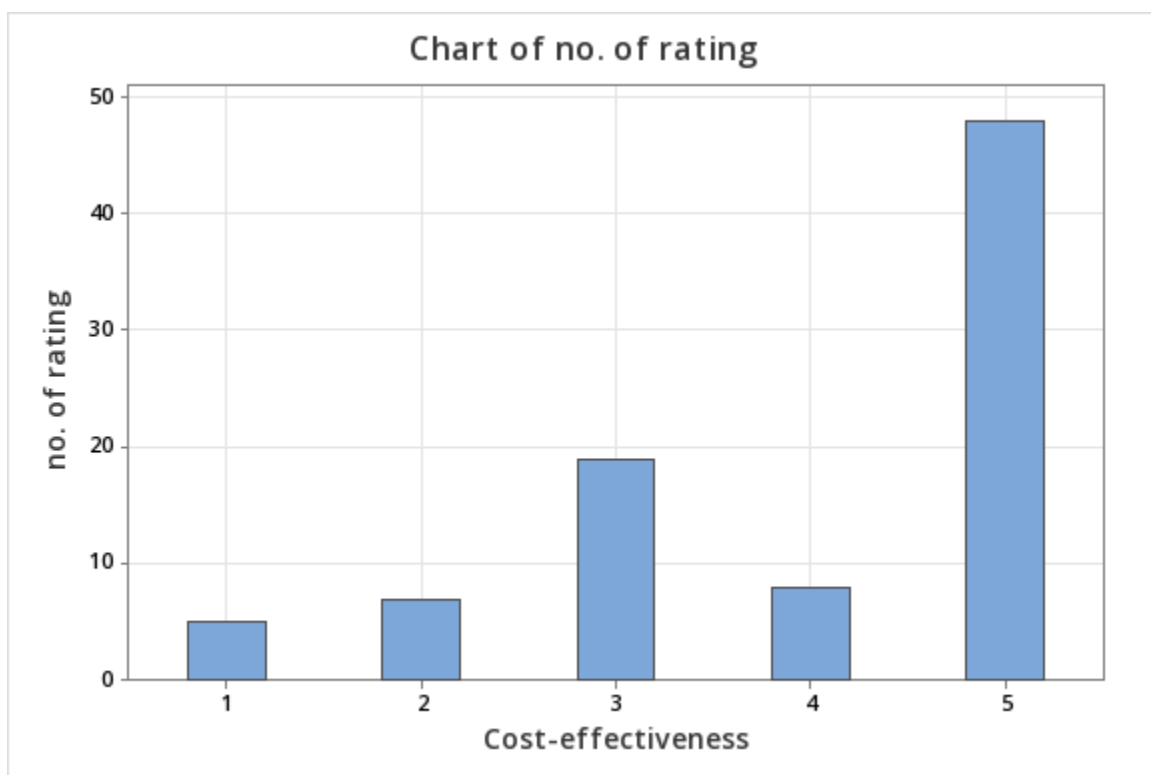


Figure 37: Cost-effectiveness for pharmacies

The given bar chart illustrates (figure 27) how 87 pharmacists in Kerala rated the cost-effectiveness of a pharmacy-led medication take-back program. A large proportion, about 48 out of 87 rated it as highly cost-effective (5), indicating that most pharmacists believe the program would offer financial benefits to pharmacies. This represents more than 55% of the respondents.

Additionally, 8 pharmacists gave a rating of 4, and 19 rated it a 3, suggesting moderate support for the cost-effectiveness of the program. Together, these 27 responses make up around 31% of participants, who may see potential advantages but are likely considering practical challenges that could impact its financial feasibility.

On the lower end, 7 respondents rated it a 2, and 5 rated it a 1, representing 14% of participants who may have doubts about the program's financial viability.

The majority of pharmacists consider the take-back program to be cost-effective, though some express caution regarding its financial feasibility.

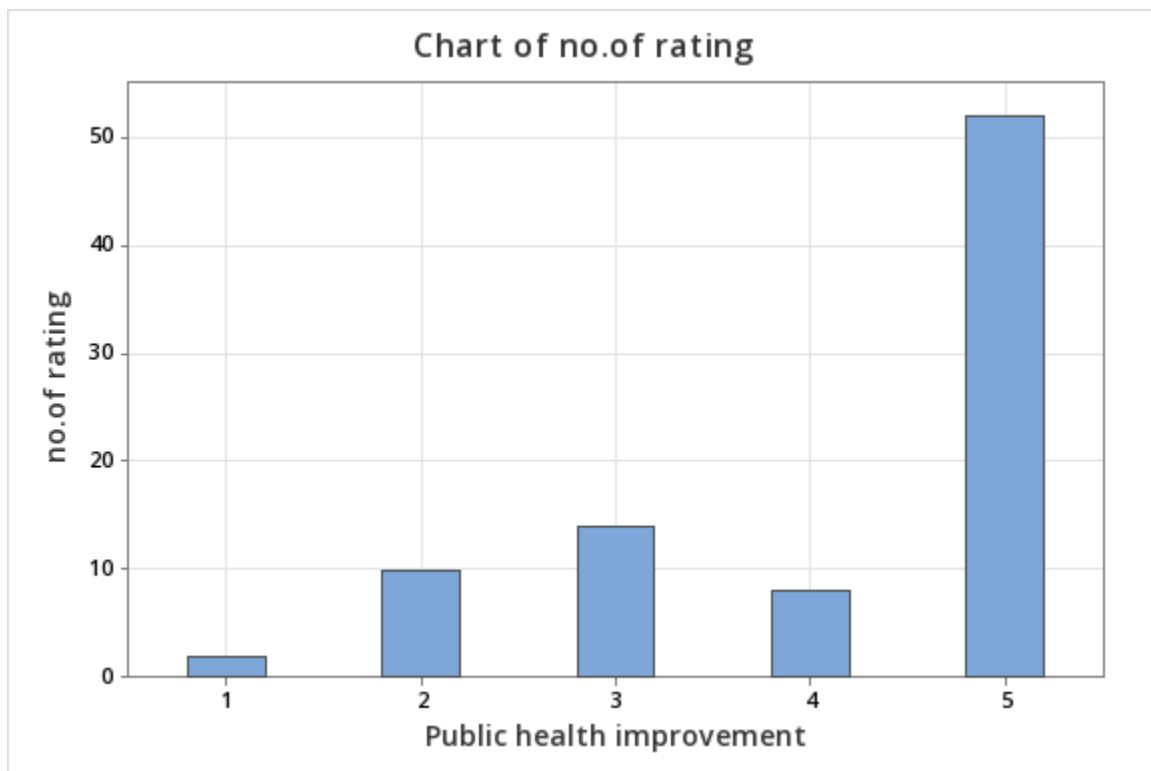


Figure 38: Public health improvement

The given bar chart (figure 28) outlines how respondents rated the impact of a pharmacy-led medication take-back program on public health improvement. The participants rated the program on a scale from 1 to 5, where 1 signifies "not beneficial" and 5 represents "highly beneficial."

A significant majority, about 52 out of 87 pharmacists rated the program a 5, indicating they believe it would have a major positive effect on public health. This makes up nearly 60% of the responses, reflecting a strong consent among pharmacists that the program could improve public health by ensuring proper disposal of unused or expired medications, reducing the risk of misuse, and minimizing environmental impact.

Additionally, 8 pharmacists rated the system a 4, and 14 rated it a 3, combining for about 25% of respondents. These pharmacists acknowledge the potential benefits but might consider other factors, such as awareness campaigns or effective implementation, as important for the success of the program.

On the lower end, 10 respondents rated it a 2, and 2 rated it a 1, representing 14% of the participants. This group may have doubts about the direct public health benefits of the program or concerns about its feasibility.

The data show that most pharmacists believe the pharmacy-led medication take-back program would improve public health, although a small number express caution or uncertainty regarding its overall effectiveness.

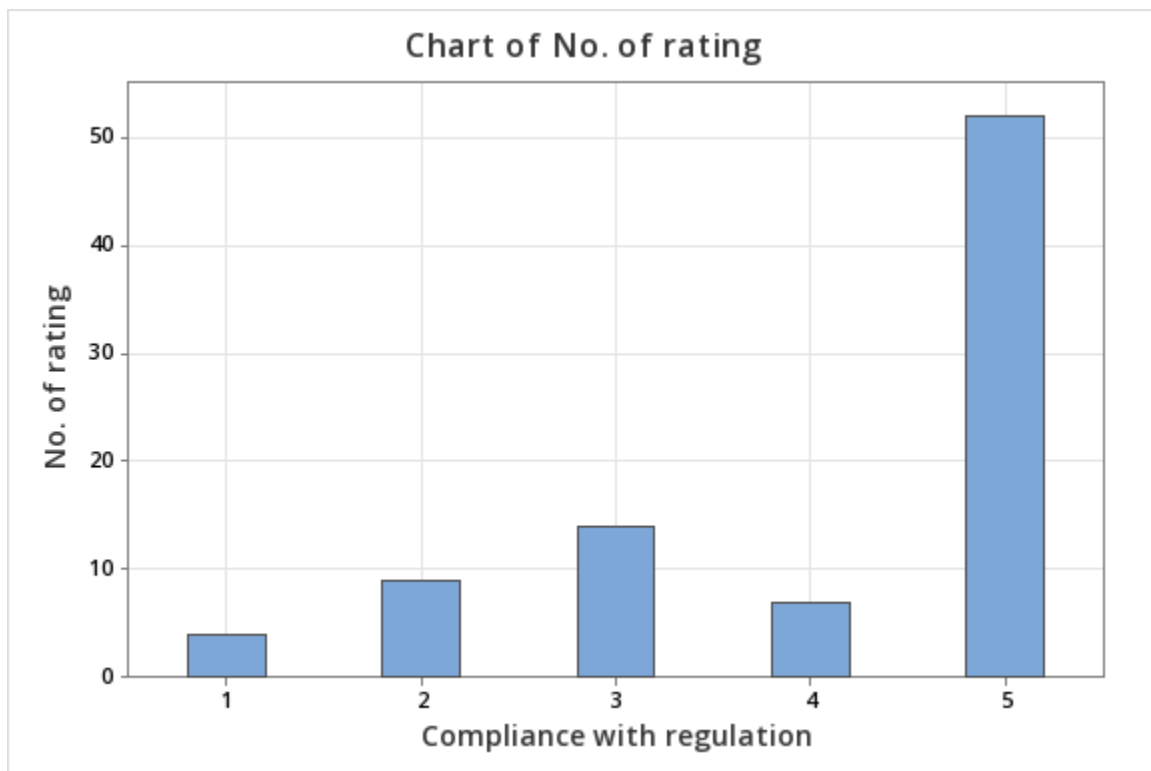


Figure 39: Compliance with regulations

The given bar chart (figure 29) reveals how the respondents rated the potential impact of a pharmacy-led medication take-back program on regulatory compliance. Since Kerala does not currently have clear regulations regarding medication disposal, respondents were asked to evaluate how such a program could improve adherence to existing or future regulations.

A significant majority of 52 out of 87 rated the program a 5, indicating that they believe it would greatly improve regulatory compliance. This represents nearly 60% of the respondents, suggesting

that most pharmacists view the program as a valuable tool for encouraging better regulation, even in the absence of formal rules. These pharmacists likely see it as an important step in formalizing medication disposal practices and guiding pharmacies toward best practices.

Additionally, 7 pharmacists rated it a 4, and 14 rated it a 3, accounting for around 24% of the total. These pharmacists acknowledge the potential of the program but may feel that clearer regulations and enforcement would be needed for it to reach its full potential.

On the lower end, 9 pharmacists rated the program a 2, and 4 rated it a 1, making up approximately 15% of responses. These participants may be doubtful about the ability of the program to improve compliance without established regulations.

The data reveal that most pharmacists believe that a pharmacy-led medication take-back program could positively impact regulatory compliance in Kerala. However, a smaller group remains hesitant, reflecting concerns over the absence of formal regulations.

8.5.5 Belief in the Impact of a Pharmacy-Led Take-Back Program on Improving Medication Disposal Practices in Kerala

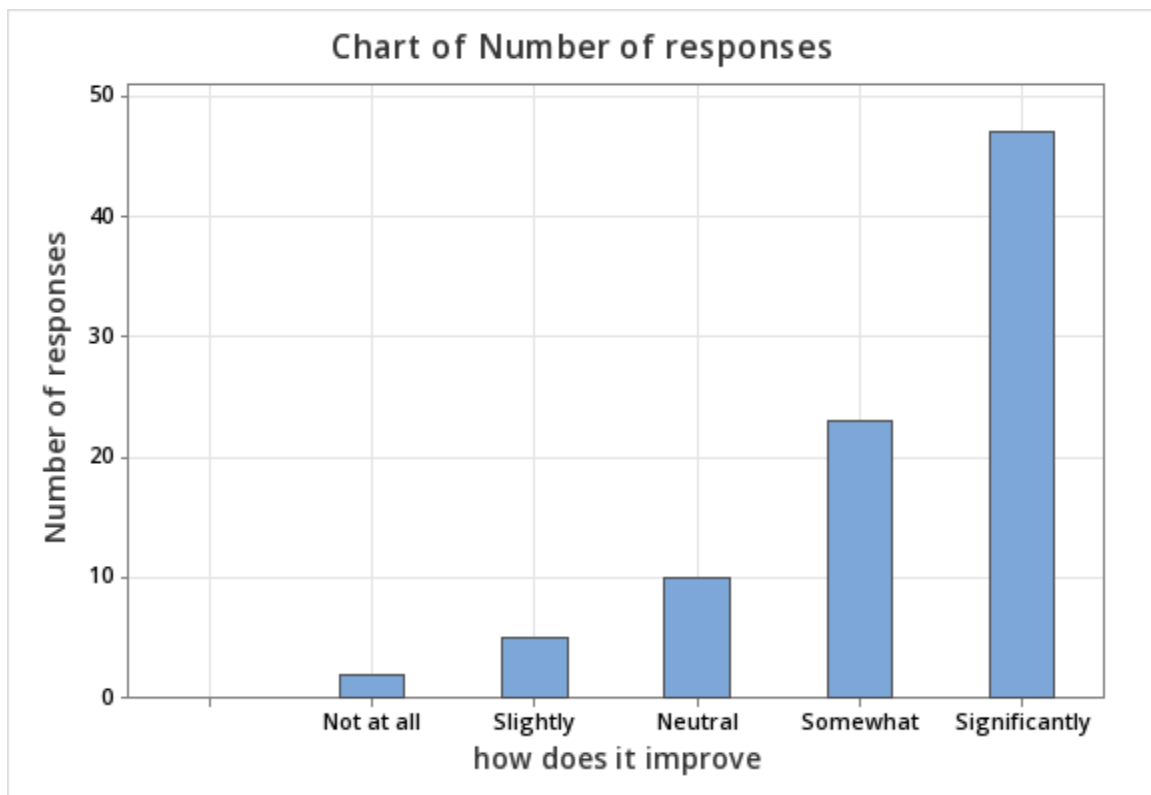


Figure 40: Belief in the Impact of a Pharmacy-Led Take-Back Program on Improving Medication Disposal Practices in Kerala

The feedback from 87 pharmacists in Kerala regarding a potential pharmacy-led medication take-back program reveals a largely favorable attitude. Based on the visual data representation, a significant portion about 47 pharmacists (54%) believe that the introduction of such a program would greatly enhance current medication disposal practices. This indicates a strong acknowledgment of existing shortcomings and the belief that pharmacies can play a key role in resolving them.

Furthermore, 23 respondents (26.4%) indicated that the program would moderately improve disposal methods, further emphasizing its considered value. When combined, the greatly and moderately supportive responses total 70, making up over 80% of the participants. This highlights a strong overall agreement among pharmacists about the potential benefits of implementing the program.

Meanwhile, 10 pharmacists (11.5%) opted for a neutral position, which could suggest either limited awareness or uncertainty about how such a system would operate. Only a small fraction expressed doubts, 5 respondents (5.7%) felt the program would have only a minor impact, and just 2 (2.3%) believed it would have no effect. These numbers point to minimal opposition among the group surveyed.

The results demonstrate a clear and widespread endorsement of a pharmacy-led medication take-back system among pharmacists in Kerala. The strong majority of positive responses signals both a recognition of the need for improved disposal practices and a willingness among pharmacy professionals to be part of the solution.

8.6 Analysis of Objective 3: WILLINGNESS TO PARTICIPATE IN A TAKE-BACK PROGRAM

8.6.1 Willingness to Participate in a Pharmacy-Led Medication Take-Back Program

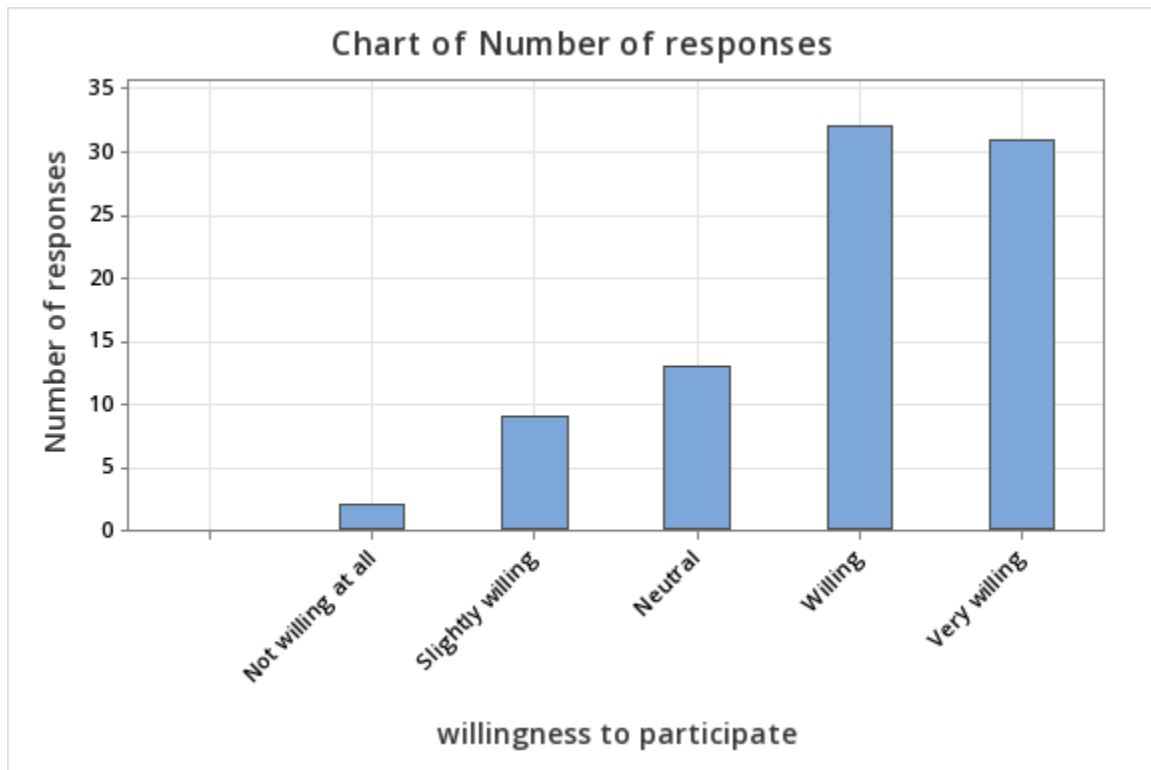


Figure 41: Willingness to Participate in a Pharmacy-Led Medication Take-Back Program

The bar chart presents insights into the level of willingness among participants to participate in a pharmacy-led medication take-back program. Responses were measured on a five-point scale: from "Not willing at all" to "Very willing." The results provide a clear understanding of the pharmacists' readiness to engage in such an initiative.

A large portion of the respondents demonstrated strong support, with 32 (36.8%) indicating they were "Willing" and 31 (35.6%) selecting "Very willing." Together, these responses account for almost 73% of the total, showing a notable level of enthusiasm among pharmacists to contribute to the implementation of a structured medication disposal system. This reflects a collective sense of responsibility and openness to supporting public health and environmental safety.

However, 13 (14.9%) pharmacists chose the "Neutral" option, suggesting indecision or the need for more information before committing. These individuals represent a target group that could potentially be influenced through awareness efforts or policy-driven motivation.

Only a minor portion of respondents expressed reluctance. Nine (10.3%) were "Slightly willing" and just 2 (2.3%) reported being "Not willing at all." This indicates that opposition is minimal, and most pharmacists are at least somewhat receptive to the idea.

Overall, the data reveal a high level of interest and willingness among pharmacists to participate in a take-back program. The low resistance and strong supportive majority indicate that such a program could be successfully launched and sustained in Kerala, offering a promising step toward improving medication disposal practices.

8.6.2 Preparedness of Pharmacies to Implement a Pharmacy-Led Medication Take-Back Program

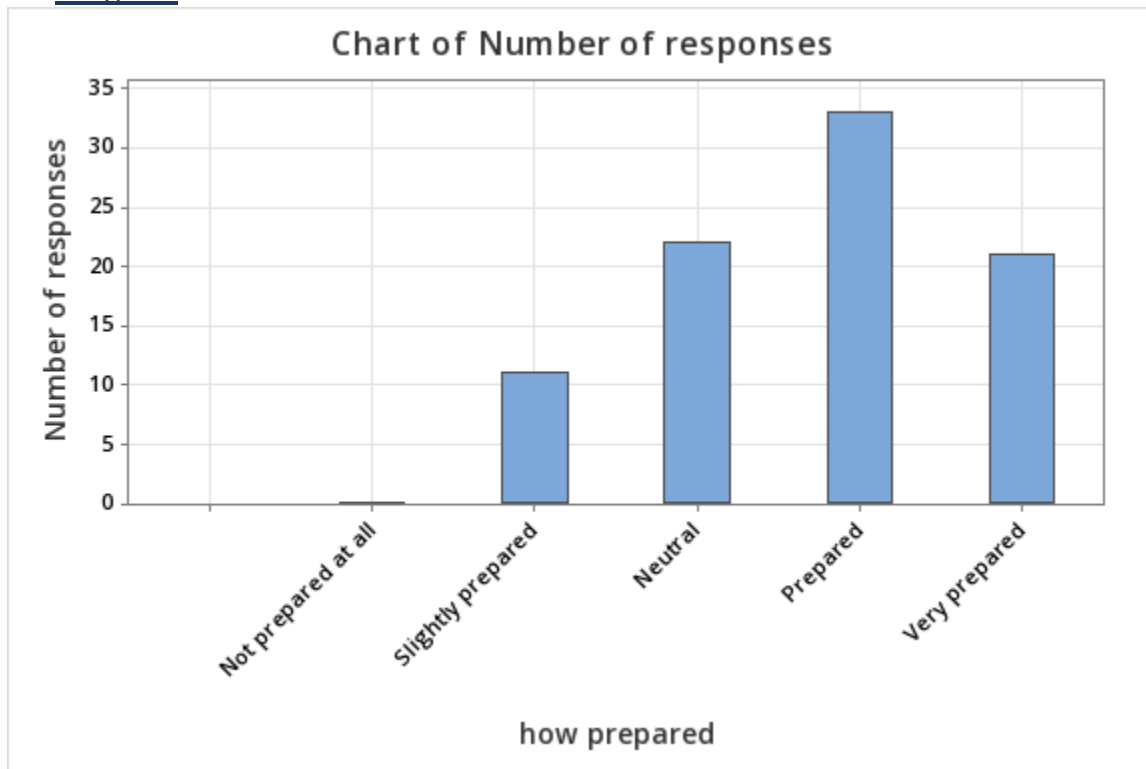


Figure 42: Preparedness of Your Pharmacy to Implement a Pharmacy-Led Medication Take-Back Program

The bar chart represents how pharmacists in Kerala view readiness of their pharmacy to adopt a pharmacy-led medication take-back program. Respondents rated their level of preparedness using five categories: "Not prepared at all," "Slightly prepared," "Neutral," "Prepared," and "Very prepared," offering a clear overview of current perceptions.

Most respondents conveyed a positive view of their readiness. A total of 33 (37.9%) pharmacists reported being "Prepared," and 21 (24.1%) indicated being "Very prepared," making up 54 out of 87 participants, approximately 62%. This shows that a majority believe their pharmacy is adequately equipped to implement the program.

Meanwhile, 22 (25.3%) respondents chose the "Neutral" option, reflecting some hesitation or uncertainty. These individuals may require additional clarification, training, or resources to feel more confident in their level of preparedness. A small portion, 11 (12.6%) pharmacists, felt "Slightly prepared," and notably, none considered their pharmacy to be "Not prepared at all." The lack of responses in the lowest category implies that no pharmacies are seen as completely incapable of participating.

Overall, these findings suggest that most pharmacies are viewed as ready to support a medication take-back system, with only a minority expressing doubt or limited preparedness. To ensure successful and widespread implementation, it may be helpful to provide extra support to those who are uncertain, reinforcing a smooth and inclusive rollout of the program across the region.

8.6.3 Belief in Patient Willingness to Return Unused Medications to Pharmacies in the Event of a Take-Back Program

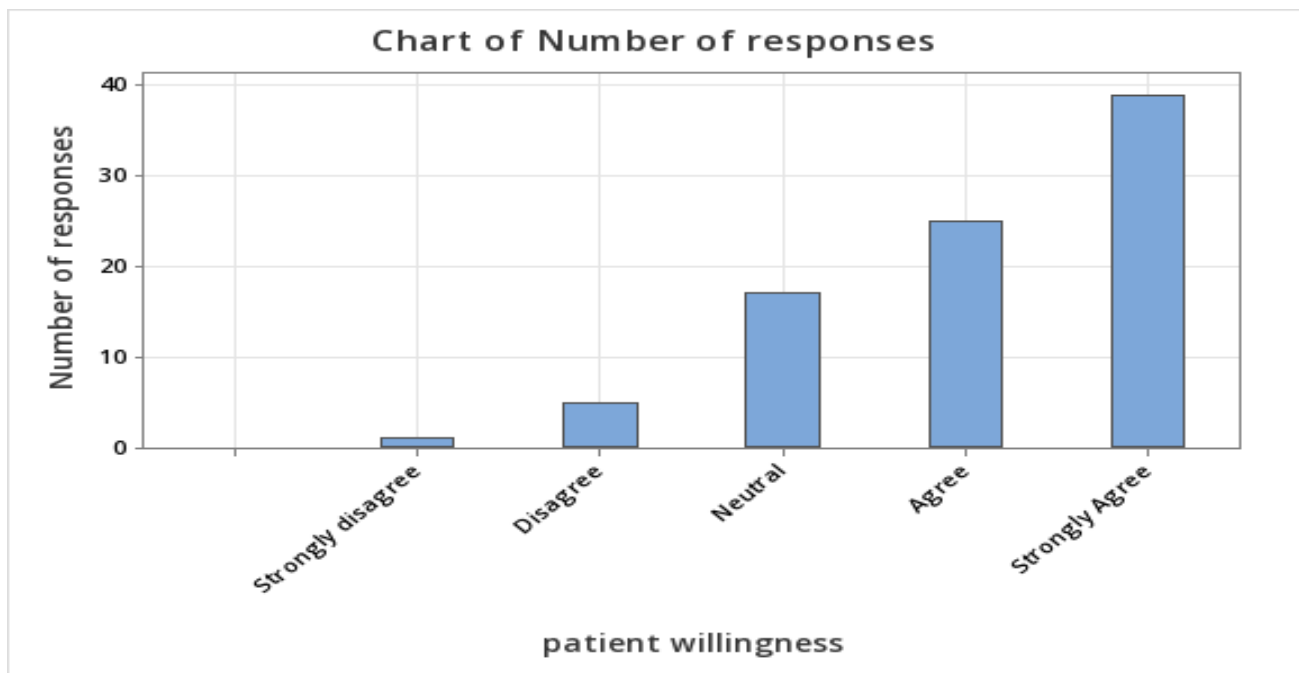


Figure 43: Belief in Patient Willingness to Return Unused Medications to Pharmacies in the Event of a Take-Back Program

The bar chart illustrates how pharmacists view willingness of patients to return unused medications if a pharmacy-led take-back program were introduced. Respondents rated their perceptions using five categories: "Strongly disagree," "Disagree," "Neutral," "Agree," and "Strongly agree," giving insight into their expectations regarding patient participation.

A large majority of pharmacists expressed confidence that patients would take part in the program, with 25 (28.7%) choosing "Agree" and 39 (44.8%) selecting "Strongly agree." Together, these

responses represent 64 out of 87 participants, or around 74%, indicating strong support for the idea that patients would actively engage in returning unused medications.

Seventeen (19.5%) respondents selected "Neutral," which suggests some uncertainty or belief that patient willingness might depend on factors such as program awareness, accessibility, or incentives. These pharmacists appear unsure about patient involvement but remain open to the possibility.

Only a small number of respondents expressed skepticism, with 5 choosing "Disagree" and 1 selecting "Strongly disagree," making up just 7% of the total responses. This low level of disagreement indicates minimal concern about patient participation.

The results reveal a generally positive outlook among pharmacists regarding patient willingness to return unused medications. With minimal opposition and a significant number of positive responses, the data suggest that with proper implementation, such a program could see strong patient participation in Kerala.

8.7 Analysis of Objective 4: BARRIERS TO IMPLEMENTATION

8.7.1 Impact of Public Awareness on the Implementation of a Pharmacy-Led Medication Take-Back Program

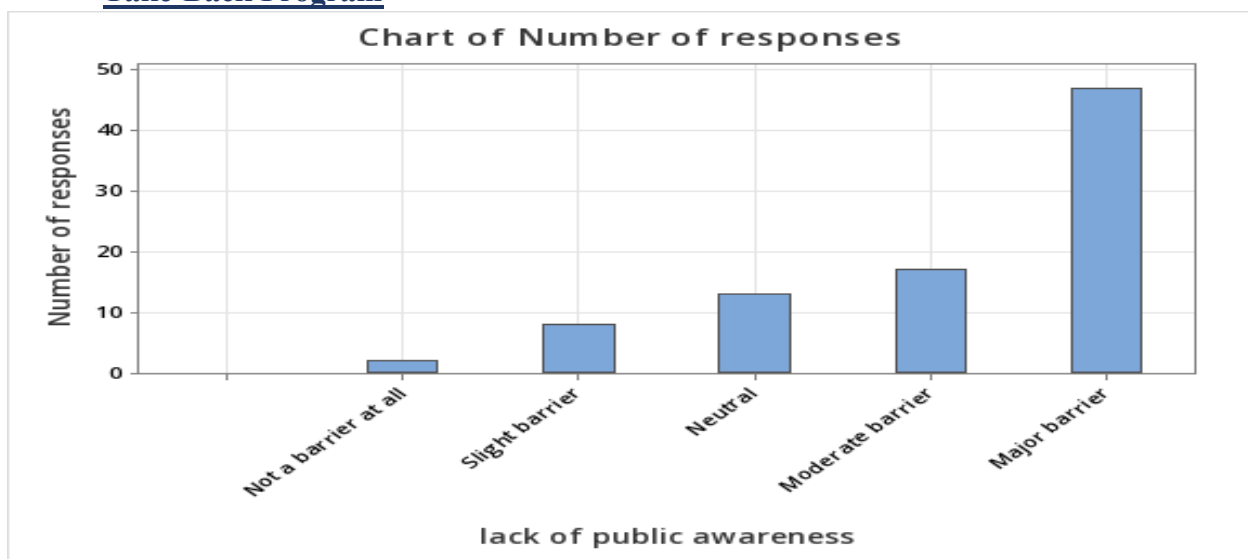


Figure 44: Impact of Public Awareness on the Implementation of a Pharmacy-Led Medication Take-Back Program

The bar graph reflects views of pharmacists on the role of public awareness in the effective implementation of a pharmacy-led medication take-back program. The responses are categorized into five levels: "Not a barrier at all," "Slight barrier," "Neutral," "Moderate barrier," and "Major barrier."

A majority of respondents, 54% (47 out of 87) consider the lack of public awareness to be a "Major barrier," indicating widespread concern about the need for public education to ensure the success of the program. Another 17 (19.5%) respondents viewed it as a "Moderate barrier," further emphasizing the importance of addressing this issue. Additionally, 13 (14.9%) respondents chose "Neutral," suggesting uncertainty or a belief that the effect of public awareness may depend on other factors. Only a small number of pharmacists (8(9.2%)) rated it as a "Slight barrier," and just 2 respondents felt it is "Not a barrier at all."

Overall, more than 73% of respondents (64 out of 87) consider the lack of public awareness to be either a moderate or major obstacle. This points to a general concern that improving public awareness is critical for the success of the program. The low number of respondents who downplay its importance suggests that most pharmacists recognize its significance.

The data highlights that public awareness is seen as a significant barrier to implementing a pharmacy-led medication take-back program. Therefore, focused public awareness initiatives will be essential for ensuring the effectiveness of the program and widespread participation.

8.7.2 Perceptions of Insufficient Infrastructure as a Barrier to Implementing a Pharmacy-Led Medication Take-Back Program

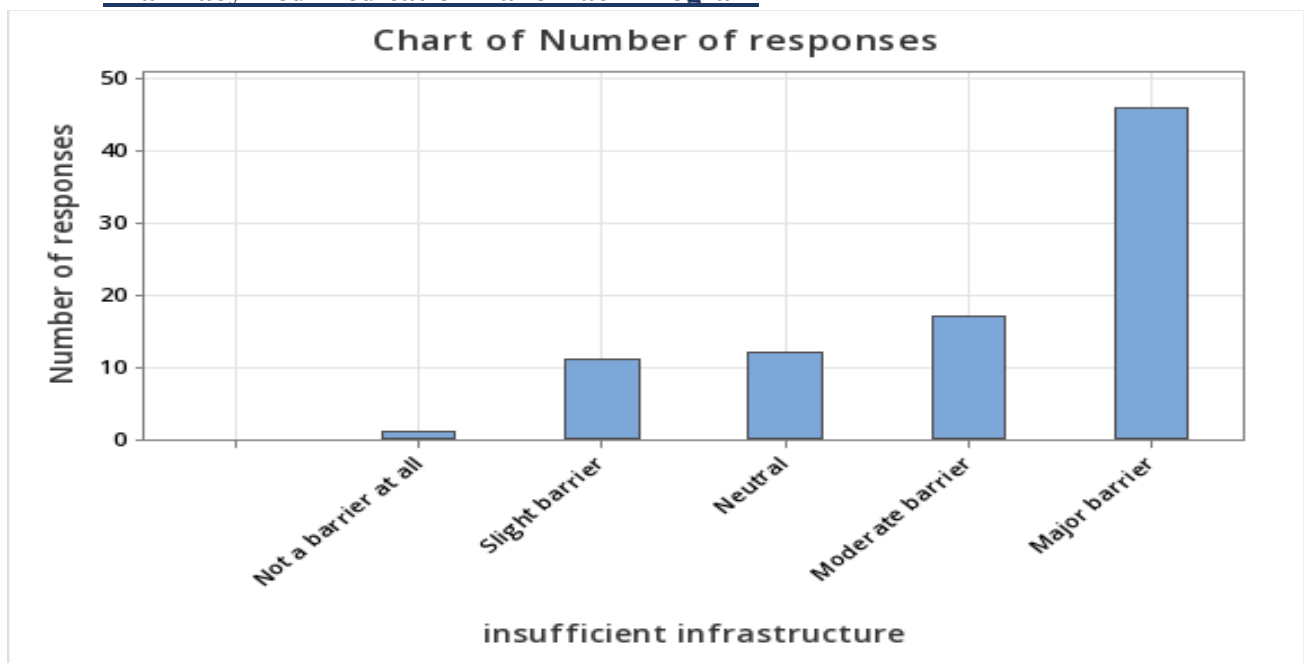


Figure 45: Perceptions of Insufficient Infrastructure as a Barrier to Implementing a Pharmacy-Led Medication Take-Back Program

The bar chart presents insights from 87 respondents on the extent to which they believe insufficient infrastructure as a barrier to implementing a pharmacy-led medication take-back program. Respondents categorized their views into five levels: "Not a barrier at all," "Slight barrier," "Neutral," "Moderate barrier," and "Major barrier."

A significant proportion of participants, 52.9% (46 out of 87) identified insufficient infrastructure as a “Major barrier,” while 17 (19.5%) considered it a “Moderate barrier.” Together, these responses represent approximately 72% of the total, underscoring a strong perception that inadequate infrastructure is a considerable challenge to implementation. Another 12 (13.8%) respondents chose “Neutral,” suggesting some uncertainty or a belief that other factors may also play a role in the success of the program. A smaller group of 11 (12.6%) respondents rated it as a “Slight barrier,” and only one participant felt it was “Not a barrier at all.”

These findings reveal that most pharmacists recognize the crucial role infrastructure plays in supporting a successful medication take-back initiative. Without reliable components such as secure collection containers, designated storage areas, and efficient systems for transportation and disposal, the program may face serious limitations. The high number of respondents identifying this issue as a major barrier signals the urgent need for investment in infrastructure development.

8.7.3 Impact of Regulatory Hurdles on Implementing a Pharmacy-Led Medication Take-Back Program

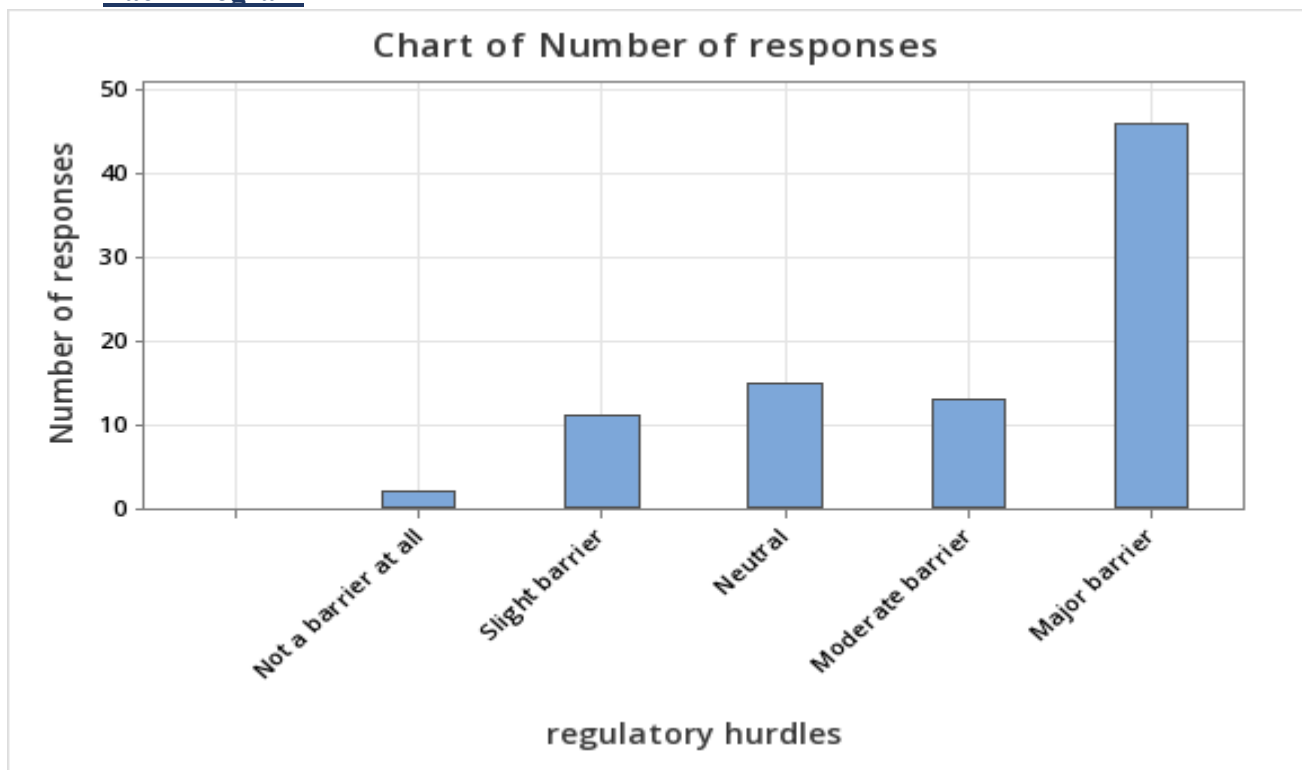


Figure 46: Impact of Regulatory Hurdles on Implementing a Pharmacy-Led Medication Take-Back Program

The bar chart presents views of respondents on the extent to which regulatory barriers hinder the implementation of pharmacy-led medication take-back programs. Participants rated these barriers on a scale of five categories: “Not a barrier at all,” “Slight barrier,” “Neutral,” “Moderate barrier,” and “Major barrier.” The majority of respondents (46 out of 87) considered regulatory issues to be a “Major barrier,” indicating significant concern about the role of regulations in preventing the

success of these programs. A smaller group (13 respondents) saw it as a “Moderate barrier,” while 15 were “Neutral,” suggesting some uncertainty or varied perspectives on the matter.

In contrast, only 11 (12.6%) respondents felt regulatory challenges were a “Slight barrier,” and just 2 believed they were “Not a barrier at all,” indicating limited disagreement with the general sentiment that regulatory hurdles are an issue.

This suggests that the majority of respondents view regulatory obstacles as a major or moderate challenge to the implementation of medication take-back programs. The results suggest the need for regulatory reform or clarification to make such programs more feasible. Addressing these concerns through policy changes could be key to overcoming this barrier and facilitating the adoption of pharmacy-led medication take-back systems.

8.8 Analysis of Objective 4: SUPPORT FOR IMPLEMENTATION

8.8.1 Financial Support and Subsidies for Implementing a Pharmacy-Led Medication Take-Back Program

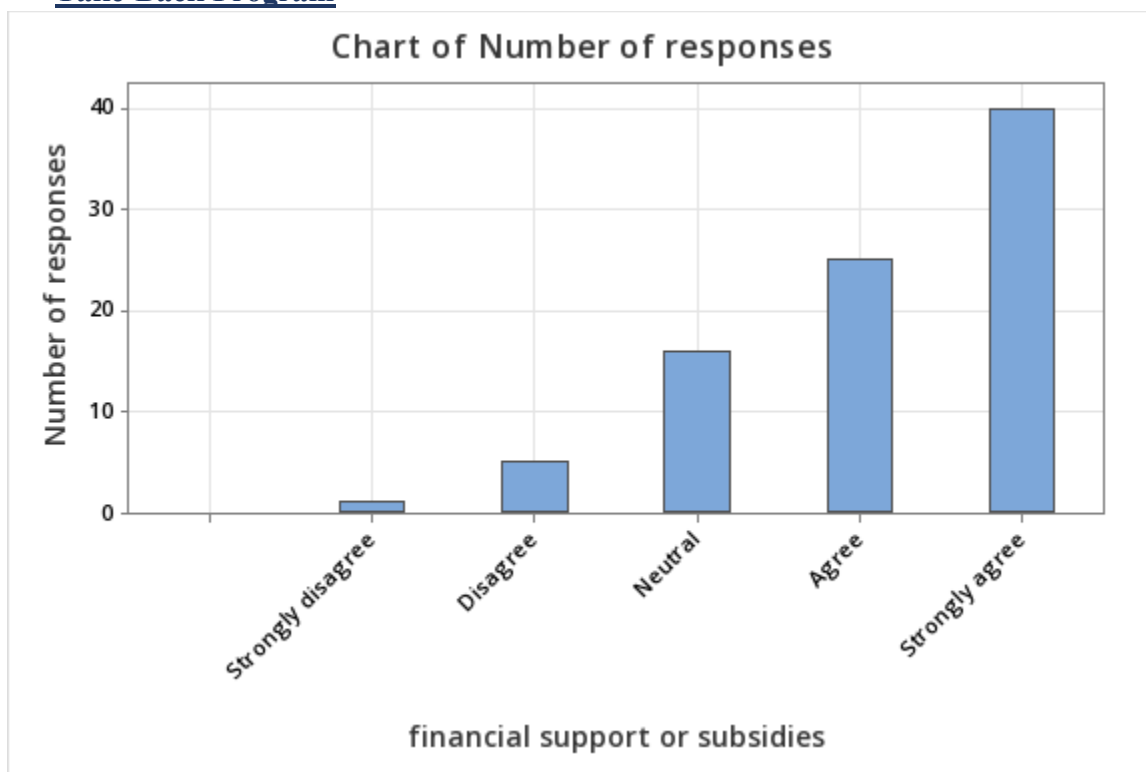


Figure 47: Financial Support and Subsidies for Implementing a Pharmacy-Led Medication Take-Back Program

The bar chart presents the views of 87 respondents on the statement of whether "Financial support or subsidies would assist in implementing a pharmacy-led medication take-back program." The responses are categorized into five groups: Strongly disagree, Disagree, Neutral, Agree, and Strongly agree.

The majority of respondents given that financial support or subsidies would play a critical role in the successful implementation of a pharmacy-led medication take-back program by 25 responding "Agree" (28.7%) and 40 responding "Strongly agree" (46%). A moderate number of 16 (18.4%) remained neutral, possibly due to uncertainty or lack of strong opinion. Only a small fraction of respondents (6 in total) disagreed, with 5 disagreeing and just 1 strongly disagreeing.

The data highlights a strong concern regarding the necessity of financial backing for the success of program. About 75% of respondents agree that financial support or subsidies are vital for the effective establishment of the program. The relatively low level of disagreement (6 respondents) suggests that financial support is widely recognized as an essential factor. The neutral responses suggest that further clarification or evidence may be needed to change their stance.

8.8.2 Agreement on the Necessity of Clear Regulatory Guidelines for Implementing a Pharmacy-Led Medication Take-Back Program

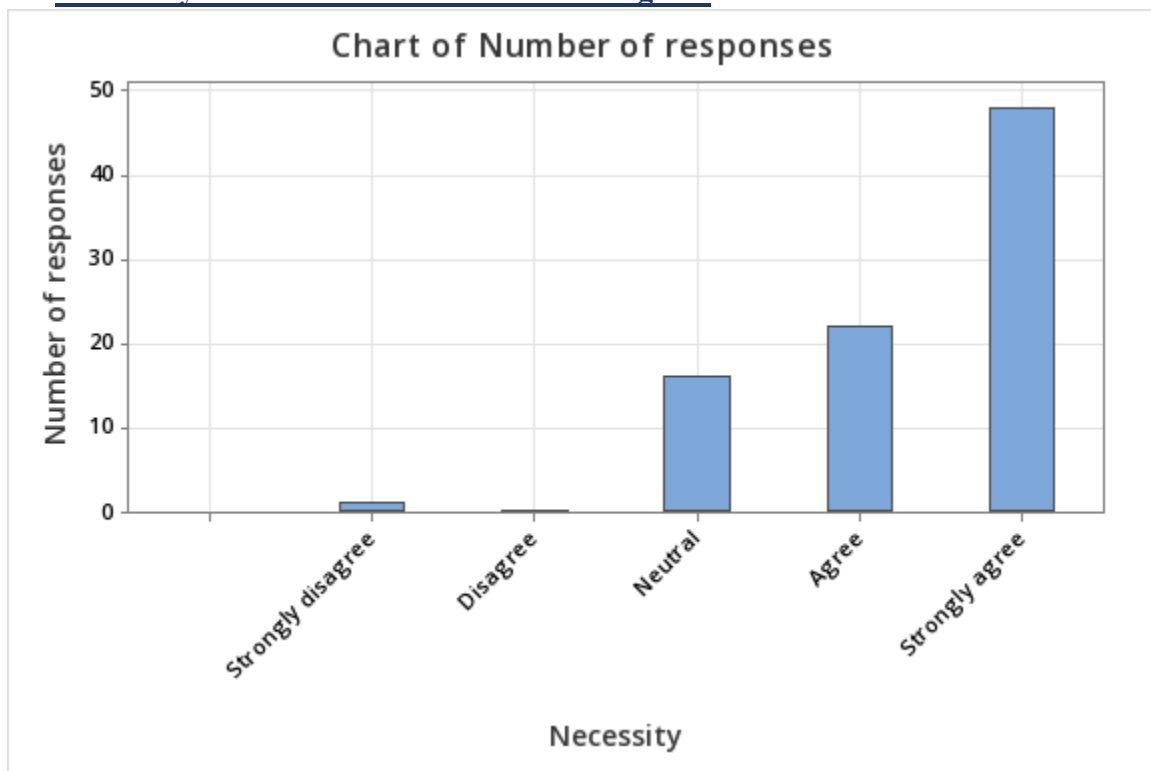


Figure 48: Agreement on the Necessity of Clear Regulatory Guidelines for Implementing a Pharmacy-Led Medication Take-Back Program

The responses from 87 pharmacists demonstrate a strong agreement on the importance of having clear regulatory guidelines for the successful implementation of a pharmacy-led medication take-back program. Out of the total respondents, 48 (55.2%) strongly agreed and 22 (25.3%) agreed, resulting in a combined 80.5% who support the necessity of such guidelines. This significant majority suggests that pharmacists view regulatory clarity as a critical component in initiating and maintaining an effective program.

A smaller portion of the respondents, about 16 pharmacists (18.4%) chose a neutral position, reflecting either uncertainty or a lack of strong opinion on the matter. Only one pharmacist (1.1%) strongly disagreed, and none selected disagree, indicating minimal resistance to the idea.

These findings reflect a widespread belief among pharmacists that well-established regulations are essential to support their involvement in medication take-back efforts. The limited number of neutral and opposing opinions further highlights general readiness of the profession to engage in such programs, as long as appropriate regulatory frameworks are in place.

8.8.3 Importance of Public Awareness Campaigns for the Success of a Pharmacy-Led Medication Take-Back Program

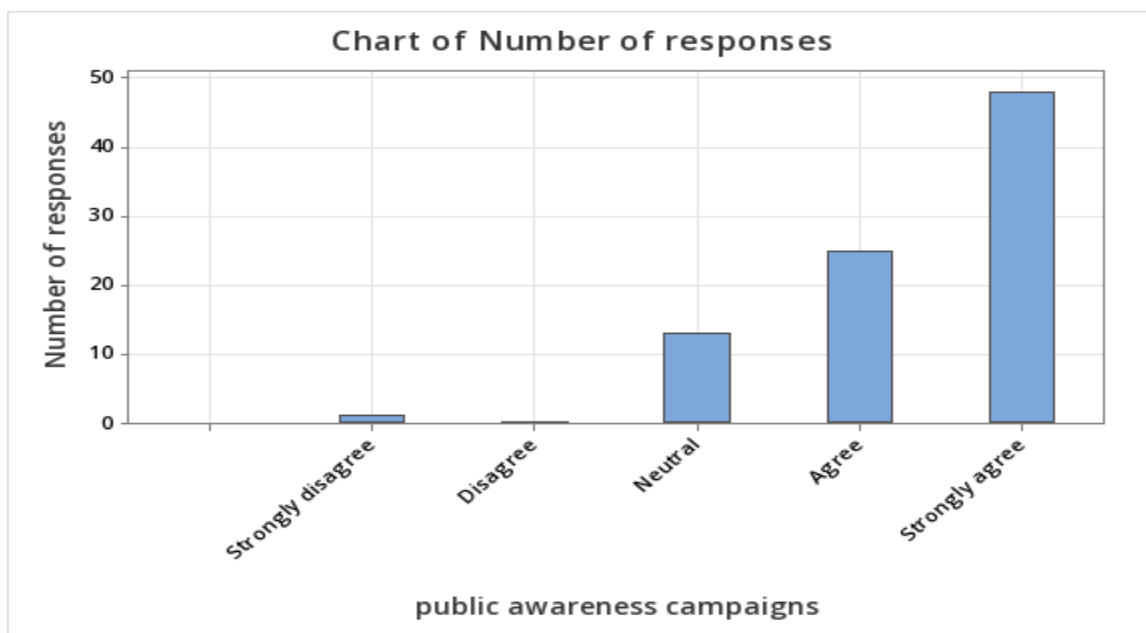


Figure 49: Importance of Public Awareness Campaigns for the Success of a Pharmacy-Led Medication Take-Back Program

The above bar graph illustrates the opinion of 87 respondents about inclusion of public awareness campaigns in pharmacy-led medication take-back programs. A majority of respondents, about 48 (55.2%) strongly agreed, and 25 (28.7%) agreed that such campaigns are essential for program success, amounting to roughly 84% in agreement. This suggests that most participants recognize the crucial role that public education plays in promoting responsible medication disposal.

A smaller proportion, 13 respondents (14.9%), remained neutral, possibly reflecting indecision or a lack of sufficient information on the topic. Only one individual (1.1%) strongly disagreed, and none selected disagree, indicating virtually no opposition to the idea.

These responses highlight the general belief that engaging and informing the public is key to ensuring the effectiveness of take-back initiatives. The minimal number of opposing opinions

points to a shared understanding that awareness efforts are fundamental in encouraging community participation and proper use of the system.

8.9 Analysis of Objective 3: PUBLIC AWARENESS AND ENGAGEMENT

8.9.1 The Importance of Public Education in Improving Medication Disposal Practices

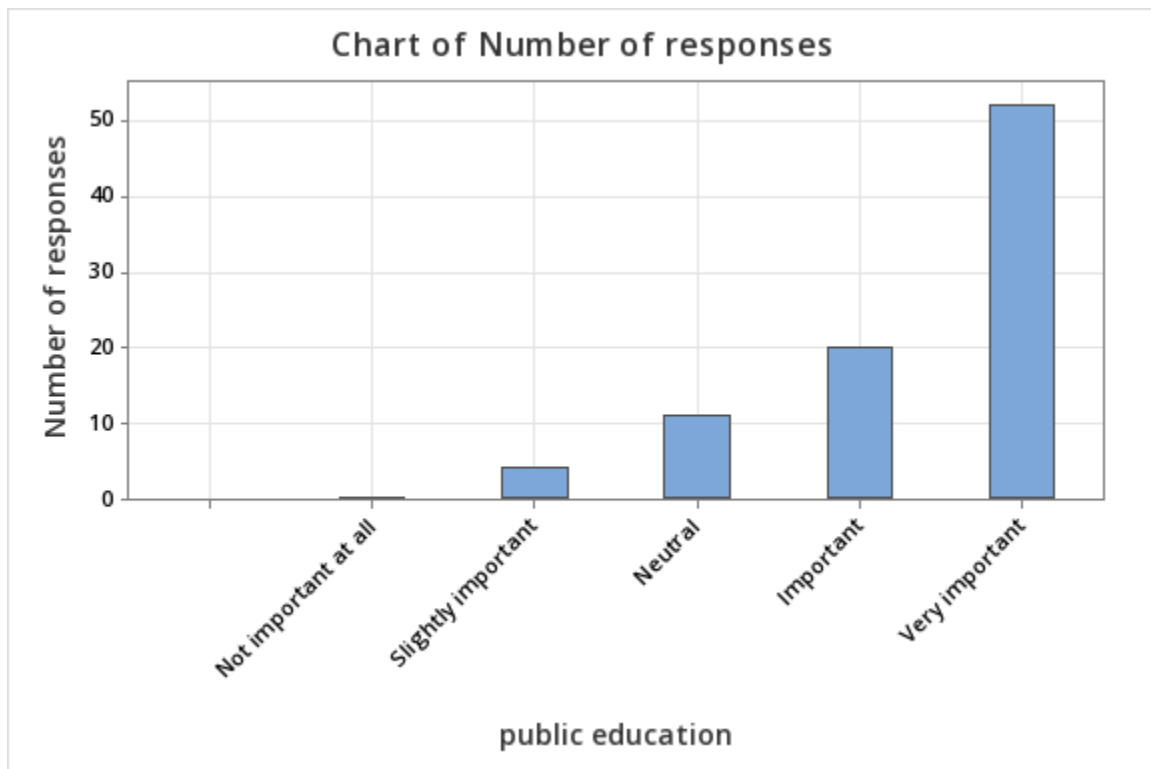


Figure 50: The Importance of Public Education in Improving Medication Disposal Practices

The above bar graph shows the response from 87 participants regarding agreement on the importance of public education in improving medication disposal practices. A significant majority, 72 respondents (82.7%) view public education as either important (20 respondents) or very important (52 respondents). This demonstrates a broad recognition of the crucial role education plays in promoting responsible medication disposal.

Only 11 respondents (12.6%) were neutral, suggesting some uncertainty or lack of a clear opinion, while just 4 respondents (4.6%) felt public education was slightly important. Notably, no participants selected not important at all, further reinforcing the general acknowledgment of the value of education in this area.

The largest group, 52 respondents (59.8%), rated public education as very important, highlighting the significant role it is believed to have in improving medication disposal practices. This indicates

that raising awareness and promoting safe disposal practices is viewed as a high priority by respondents.

8.9.2 Effectiveness of Pharmacy-Based Educational Campaigns in Increasing Public Awareness About Safe Medication Disposal

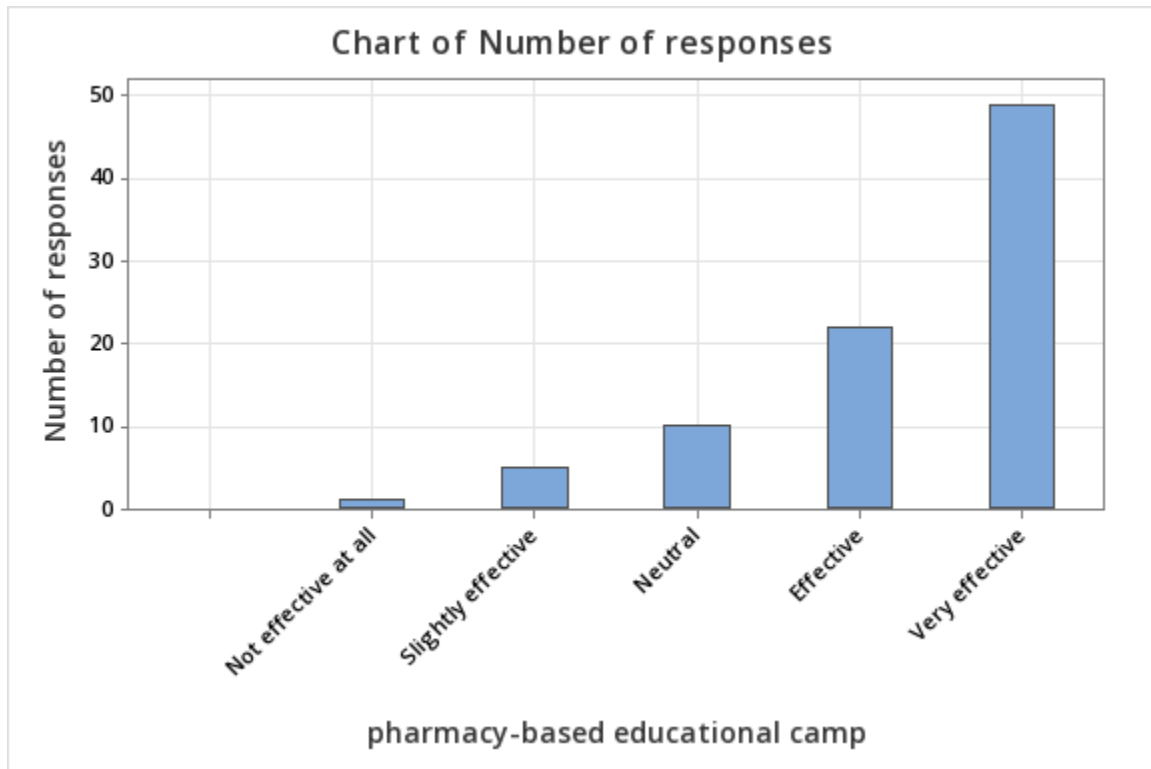


Figure 51: Effectiveness of Pharmacy-Based Educational Campaigns in Increasing Public Awareness About Safe Medication Disposal

The above bar graph illustrates the response from 87 participants regarding their belief in the effectiveness of pharmacy-based educational campaigns to raise awareness about safe medication disposal. A large majority, about 71 respondents (81.6%) view these campaigns as either effective (22 responses, 25.3%) or very effective (49 responses, 56.3%). This highlights a broad confidence in the role of pharmacy-led educational campaigns to enhance public knowledge and encourage proper disposal practices.

A small number of respondents, 1 (1.1%) felt these campaigns would not be effective at all, and 5 (5.7%) considered them slightly effective. These minimal negative responses suggest that doubt about the campaigns is minimal. Additionally, 10 respondents (11.5%) were neutral, indicating some uncertainty or lack of a strong opinion.

The largest group, 49 respondents (56.3%), rated the campaigns as very effective, reinforcing the strong belief in their potential to improve medication disposal practices. This widespread support highlights the importance of pharmacy-driven education in fostering safe disposal behaviors.

8.9.3 The Importance of Government Support for the Success of a Pharmacy-Led Medication Take-Back Program

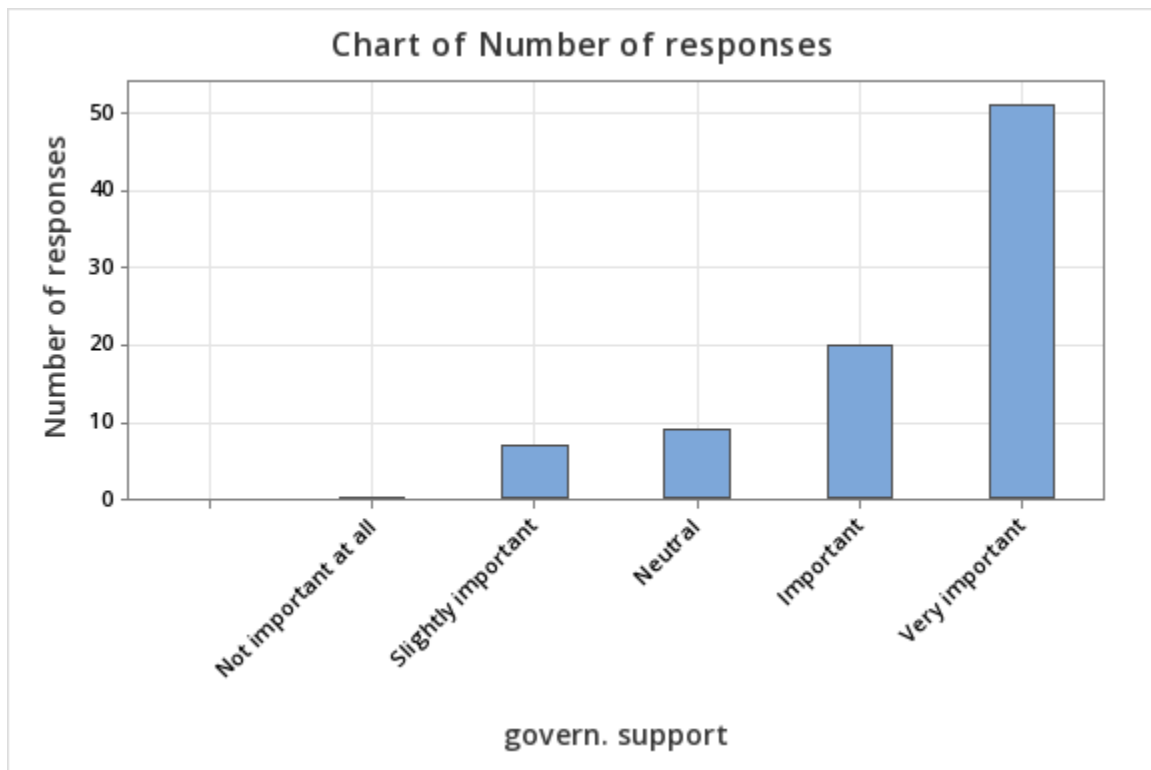


Figure 52: The Importance of Government Support for the Success of a Pharmacy-Led Medication Take-Back Program

The above bar graph demonstrates the response from 87 participants regarding the role of government support plays in the success of pharmacy-led medication take-back programs. A significant majority, about 71 respondents (81.6%) view government involvement as either important (20 responses, 23%) or very important (51 responses, 58.6%), highlighting the general agreement on its vital contribution to the success and sustainability of these initiatives.

A smaller group of 9 respondents (10.3%) expressed a neutral stance, suggesting some uncertainty or lack of a strong opinion on the issue, while 7 respondents (8%) considered government support to be slightly important. Importantly, no respondents selected "Not important at all," which highlights the recognition that government involvement holds some level of importance.

The largest group, 51 respondents (58.6%), rated government support as very important, emphasizing the belief that government action is essential for the successful implementation of

pharmacy-led medication take-back programs. This result points to a strong opinion that government backing is necessary to ensure the effectiveness and broad adoption of such programs.

8.9.4 Increasing Public Awareness of Safe Medication Disposal Practices

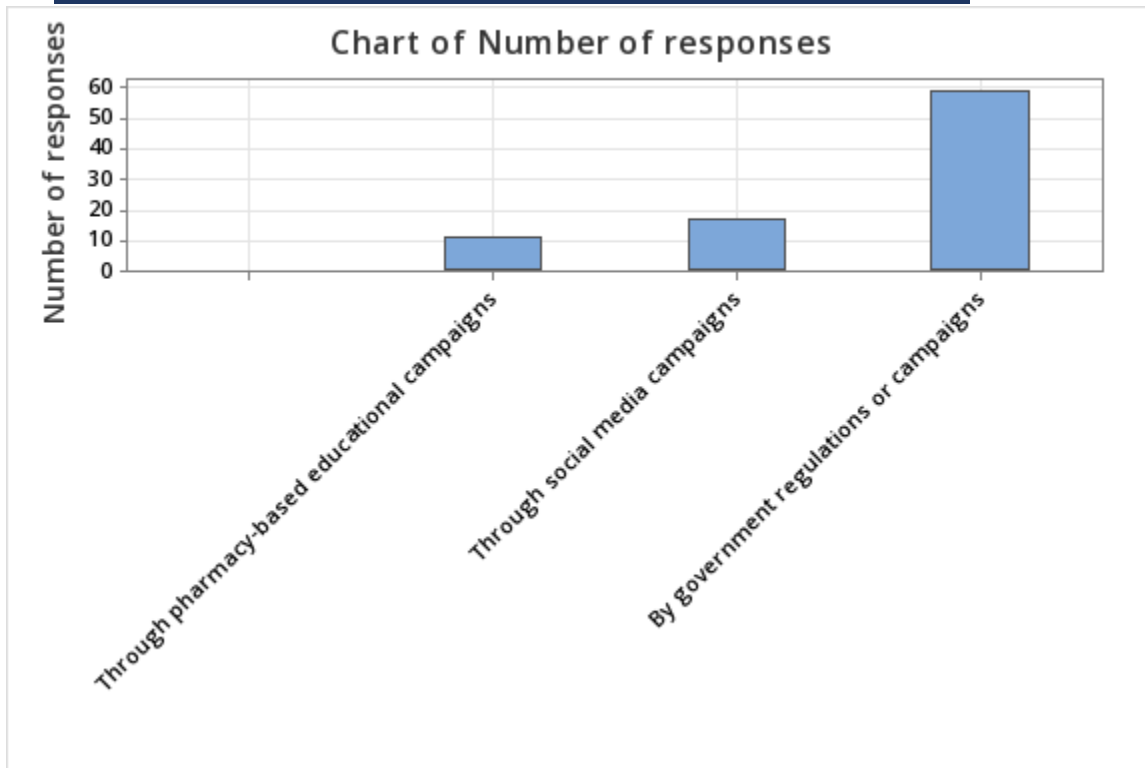


Figure 53: Increasing Public Awareness of Safe Medication Disposal Practices

This bar graph illustrates the opinions of 87 participants regarding the most effective method to improve public awareness about safe medication disposal. Respondents were asked to choose among three options: pharmacy-based educational campaigns, social media campaigns, and government-led regulations or campaigns.

A significant portion, approximately 68% or about 59 individuals believe that government interventions, such as regulatory measures or public campaigns, are the most effective. This preference indicates strong trust in authoritative, large-scale efforts to deliver consistent messaging and ensure broader public engagement on this important issue.

Around 17 participants (19.5%) selected social media campaigns as the best approach. While this suggests that digital platforms are recognized as useful tools for awareness. The relatively lower selection may reflect concerns over the credibility or reach of social media efforts compared to official government programs.

Only about 11 participants (12.6%) considered pharmacy-based educational initiatives the most effective. Though pharmacists are seen as reliable sources of health information, this method may be considered as limited in scope or audience reach when compared to larger-scale government initiatives.

8.9.5 The Role of a Government-Led Initiative in Promoting a Medication Take-Back Program

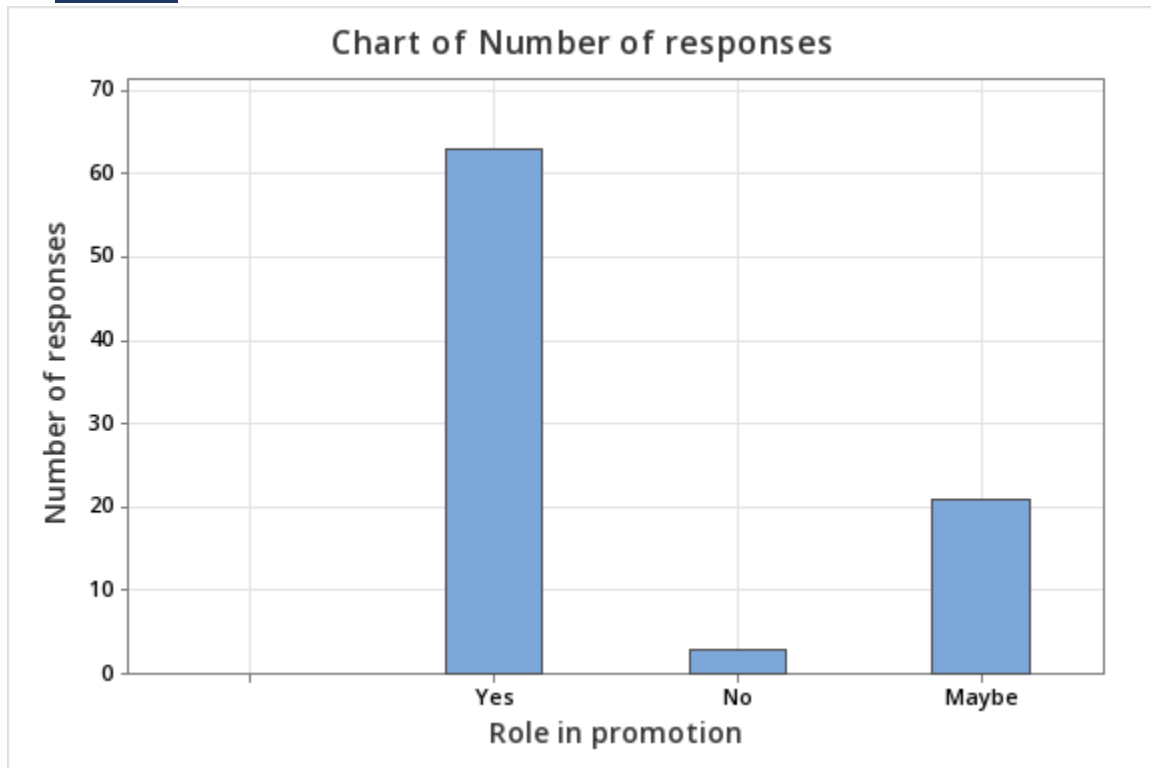


Figure 54: The Role of a Government-Led Initiative in Promoting a Medication Take-Back Program

The bar graph illustrates how 87 individuals responded to the question: “Do you believe that a government-led initiative could play a role in promoting medication take-back programs?” A significant majority, about 63 participants, or around 72.4% answered “Yes,” reflecting strong support for the idea that government involvement is crucial to advancing these programs. This highlights a broad acknowledgment of the potential of government to lead and influence public engagement in safe medication disposal efforts.

On the other hand, 21 respondents (roughly 24%) chose “Maybe,” indicating some uncertainty. This group may recognize possible advantages of such initiatives but feel the need for more clarity regarding their execution, scope, or long-term viability. Their responses suggest that while they are not opposed, they may require further evidence or assurances before fully endorsing government-led programs.

Only 3 participants (approximately 3%) selected “No,” showing very limited resistance to the idea of government participation. This small figure points to minimal disagreement and reinforces the general acceptance of the role of government in supporting medication return efforts.

8.9.6 Useful Outreach and Educational Materials for Promoting a Pharmacy-Led Take-Back Program

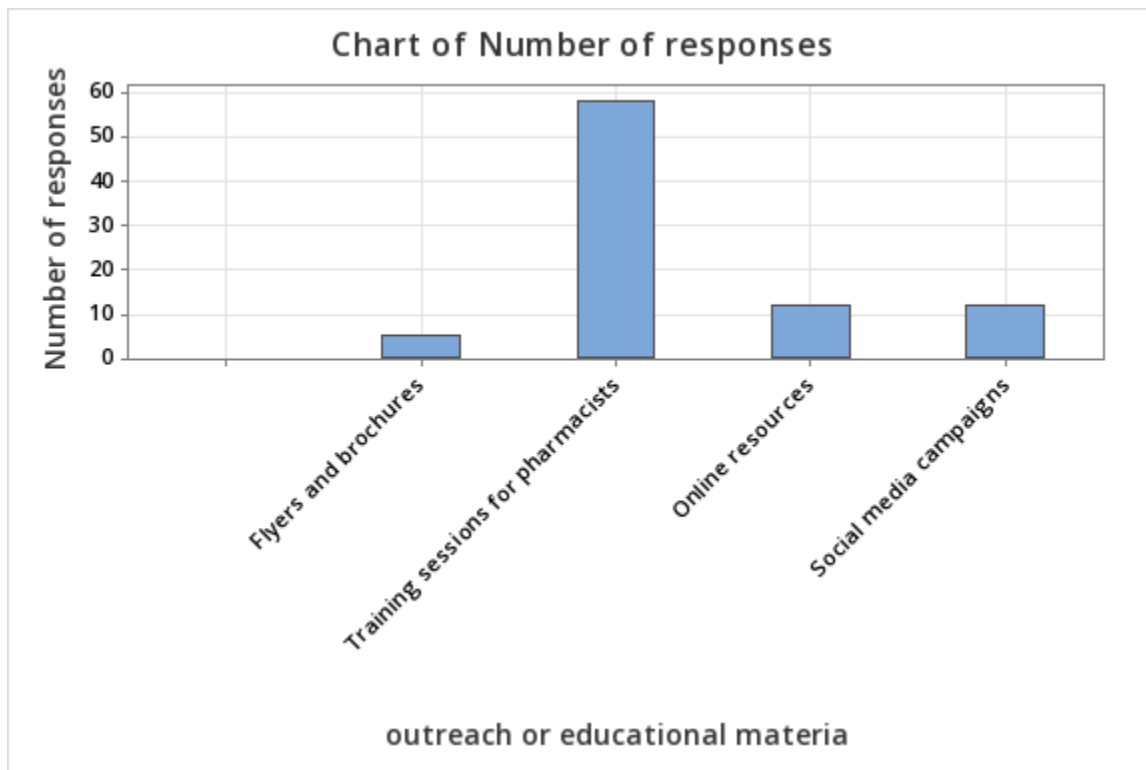


Figure 55: Useful Outreach and Educational Materials for Promoting a Pharmacy-Led Take-Back Program

The bar graph shows the responses of 87 participants to the question: "What kind of outreach or educational materials would you find useful in promoting a pharmacy-led take-back program?" The majority of respondents, around 66.7% (58 participants), identified training sessions for pharmacists as the most beneficial educational material. This indicates a clear preference for in-depth, practical training to equip pharmacists with the necessary skills to successfully manage take-back programs.

On the other hand, online resources and social media campaigns received moderate approval, both got 12 out of 87 of respondents. While these digital methods are appreciated, they are regarded as supplementary rather than essential for promoting the program.

Flyers and brochures were considered the least useful, with only 5.7% (5) of participants opting for them. This suggests that traditional printed materials may not be as engaging or effective in

raising awareness about a pharmacy-led take-back program compared to more interactive and professional learning methods.

8.10 Analysis of Objective 5: FINAL FEEDBACK AND SUGGESTIONS

The feedback from 87 participants regarding suggestions for improving medication disposal practices and establishing a pharmacy-led take-back system like CYCLAMED in Kerala highlights several recurring concerns and ideas. Many respondents emphasized the need for clear and effective regulations, better public education, enhanced professional training, improved infrastructure, and increased government support.

A notable number of responses (about 19) highlighted the necessity for stronger regulations and clear guidelines to regulate medication disposal. These comments suggest that respondents see regulatory measures as vital for the success of a pharmacy-led take-back initiative in Kerala.

The theme of public education emerged strongly, with approximately 17 respondents suggesting that social media could be a powerful tool in raising awareness about proper disposal practices. Furthermore, educating both the public and professionals was repeatedly mentioned as a key factor in increasing participation and understanding of medication disposal.

Professional training, especially for pharmacists, was another significant point raised by around 16 respondents. Many felt that pharmacists should be trained to effectively inform consumers about safe medication disposal methods.

Infrastructure gaps were also highlighted by several participants, with 7 responses pointing out the need for facilities like incineration points or collection centers to support a take-back program.

Lastly, 5 responses emphasized the importance of government support in terms of policy development and financial assistance. Some also suggested looking at successful international models to guide the development of a local system.

Overall, the feedback suggests that a comprehensive approach, involving regulation, professional education, public awareness, infrastructure, and government involvement, is crucial for the effective implementation of a pharmacy-led medication take-back system in Kerala.

8.11 DISCUSSION

In this portion, the survey findings are examined alongside relevant literature and theoretical perspectives to determine the practicality of establishing a pharmacy-led medication take-back program in Kerala, based on the framework of CYCLAMED model from France. The analysis centers on five main factors: existing regulations, the level of awareness and engagement among pharmacists,

public understanding of proper disposal practices, infrastructure availability, and economic feasibility.

8.11.1 Pharmacist Awareness and Participation

The survey results from Kerala suggest that although pharmacists are generally aware of the dangers linked to improper medication disposal, their actual engagement in appropriate disposal practices is relatively low. This observation is consistent with the literature, including the findings of Kumar et al. (2024), who reported that healthcare workers, despite understanding the importance of correct disposal, often fail to apply this knowledge due to limited training, resources, and institutional backing (Kumar *et al.*, 2024). Similarly, Lagishetty et al. (2015) found that many healthcare professionals dispose of medications incorrectly such as by discarding them in household waste or flushing them largely because of insufficient awareness and the absence of proper disposal infrastructure (Radhakrishna *et al.*, 2014).

The survey also reveals that, over 70% of pharmacists indicated familiarity with danger of improper disposal techniques, however, only a small proportion actively engaged in or supported take-back initiatives. This highlights a notable gap between knowledge and real-world practice. Raj et al. (2024) echoed this issue among medicine distributors in Kochi, (Divya Raj, 2024) where lack of manufacturer cooperation and proper waste protocols created additional challenges.

Participants also cited a lack of clear regulations and limited public awareness as barriers to taking initiative. Although many pharmacists were willing to contribute to safe disposal practices, they felt unsupported by the system due to the absence of collection points and standardized procedures.

8.11.2 Regulatory Framework

The findings from the survey reveal a clear lack of structured regulations concerning the proper disposal of expired and unused medicines in Kerala. A significant number of pharmacists admitted that existing guidelines are insufficient or unclear to implement effectively. This observation corresponds closely with the study by Raj et al. (2024), which highlighted the absence of comprehensive provisions within Drugs and Cosmetics Act of India for pharmaceutical waste disposal. Without clear legal direction, many professionals handle medicine waste inconsistently or rely on unsafe methods (Divya Raj, 2024).

PROUD initiative of Kerala, though a commendable step, has not yet been supported by a strong regulatory backbone. As reported by The New Indian Express, (S, 2024) the limited reach of the program, lack of engagement from pharmaceutical companies, and high costs related to waste transportation have all restricted its effectiveness. This was mirrored in the survey data, where respondents expressed limited knowledge about PROUD, by 42 responding designated bin collection as very challenging system and pointed out that the absence of mandatory rules and governmental support discourages active participation.

These insights, drawn from both literature and the survey, highlights the urgent need for clear, enforceable legislation outlining responsibilities and protocols for pharmaceutical waste management. Strengthening the regulatory framework with proper funding, infrastructure, and training would empower pharmacists and other stakeholders to manage drug disposal more responsibly.

8.11.3 Infrastructure and Logistical Feasibility

The survey highlighted that a majority (73%) of respondents identified poor infrastructure as a major challenge to implementing a pharmacy-led medication take-back system in Kerala. This observation is consistent with existing research, which shows that Kerala lacks the necessary infrastructure to manage pharmaceutical waste effectively. While the PROUD program has taken an important first step, its scope remains limited, operating only in select areas like Thiruvananthapuram with a single approved incineration facility, IMAGE (admin, 2019; S, 2024).

This concern is echoed in the findings of Divya Raj and colleagues (2024), who discovered that many drug distributors, due to the lack of proper waste disposal systems, either stored unused medications at their premises or handed them over to local waste collectors. The study also pointed out that the high cost and logistical difficulties of transporting waste such as the Rs. 2,00,000 spent on moving waste to Mangalore further complicate disposal efforts(Divya Raj, 2024).

These insights confirm that current infrastructure Kerala is insufficient to support a widespread take-back initiative. Building additional treatment facilities across the state, adopting newer technologies like plasma pyrolysis, and decentralizing the collection process would be essential steps forward. Unless these gaps are addressed, the rollout of a sustainable and effective medication disposal system across Kerala will continue to face serious limitations.

8.11.4 Public Awareness and Engagement

Raising public awareness is a critical factor in ensuring the success of pharmacy-led medication take-back programs, as reflected in the survey responses. An overwhelming 85% of participants stressed the importance of educating patients about how to safely dispose of unused or expired medications. This aligns with existing research, which highlights widespread public ignorance regarding appropriate disposal practices and limited awareness of initiatives like PROUD(Divya Raj, 2024).

Additionally, 84% of respondents agreed that awareness campaigns targeted at the general public could significantly improve the success rate of such programs. This indicates a clear need for well-structured communication strategies to inform people about the harmful consequences of improper medicine disposal.

Furthermore, 82% of those surveyed believed that educational initiatives led by pharmacies could effectively raise awareness about responsible disposal methods. Given their accessibility and trust within communities, pharmacists can serve as effective educators. Another 68% of participants indicated that such pharmacy-driven campaigns could directly influence public behavior, encouraging more responsible disposal practices.

These findings highlight the importance of community engagement and the vital role pharmacists can play in public education. By integrating disposal education into pharmacy services, conducting local outreach, and using media platforms to spread the message, Kerala can build a more informed public. Taking inspiration from successful international models like CYCLAMED from France, which integrates both education and collection at the pharmacy level, Kerala can strengthen its take-back efforts and increase public participation.

8.11.5 Financial and Operational Sustainability

The effective implementation of a pharmacy-led medication take-back program heavily depends on financial feasibility and operational readiness. In the current survey, nearly 75% of participants indicated that financial aid or subsidies would significantly support the establishment of such a program in Kerala. This perception is consistent with previous findings, which emphasize cost as a major obstacle.

For instance, the PROUD initiative revealed that only a small number of distributors were aware of the program, and those who were informed expressed surprise upon learning that it had collected around five tons of pharmaceutical waste. This waste had to be transported to Mangalore for incineration, incurring costs close to Rs. 200,000, primarily for logistics. These figures highlight the urgent necessity for localized waste treatment infrastructure to reduce financial and operational burdens (Divya Raj, 2024).

In contrast, the CYCLAMED program of France demonstrates a sustainable model through the Extended Producer Responsibility (EPR) framework. Under this approach, pharmaceutical companies are held accountable for the disposal of unused and expired drugs, providing both funding and logistical support (OECD, 2022).

Currently, India does not implement EPR policies in the pharmaceutical sector, posing a challenge to replicating such a system. To move in that direction, coordination with central regulatory bodies like the Central Pollution Control Board (CPCB) and cooperation from pharmaceutical manufacturers would be essential.

Introducing an EPR-based system in Kerala, along with the establishment of local disposal facilities, would greatly enhance the financial and operational viability of a pharmacy-led medication take-back program.

8.11.6 Feasibility Outlook and Policy Implications

The survey reveals that 69% of respondents believe implementing a CYCLAMED-inspired medication take-back program is feasible in Kerala, reflecting strong support for such a system among pharmacy professionals and other stakeholders. This indicates that the region is receptive to the idea, especially given its well-established healthcare infrastructure and the initial success of the PROUD initiative, despite facing several challenges.

CYCLAMED program serves as a prime example of how pharmacies can manage the collection of unused and expired medications effectively, supported by an Extended Producer Responsibility (EPR) framework. While Kerala currently lacks an EPR policy for pharmaceuticals, the belief in the feasibility of such a model signals an openness to adopting structured medication waste management practices, assuming the required regulatory and operational frameworks are developed.

Dense network of pharmacies and its strong healthcare participation in Kerala make it a promising environment for adapting key elements of the CYCLAMED model, such as designated disposal bins, central sorting, and environmentally responsible incineration. However, scaling this approach would require collaboration among government agencies, pharmaceutical companies, and pharmacy associations, alongside investment in infrastructure.

To determine whether the perceived feasibility of implementing a pharmacy-led medication take-back system was significantly greater than a neutral 50%, a binomial proportion test was conducted using Minitab.

Among the 80 pharmacists surveyed, 60 (80%) responded affirmatively regarding the feasibility of the model. The 95% confidence interval for this proportion ranged from 69.6% to 87.8%, indicating a high level of support.

The hypothesis test produced a p-value of 0.000, thereby rejecting the null hypothesis ($H_0: p = 0.50$). This result is statistically significant and demonstrates that the proportion of pharmacists who support the feasibility of a CYCLAMED-like model is substantially higher than neutral expectations.

This strong support suggests a promising environment for implementation, provided systemic challenges such as regulatory clarity and infrastructure readiness are addressed.

Table 1: Binomial Proportion Test

Variable	Value
Total Respondents (N)	80
Supportive Responses (Yes)	60
Proportion (p)	0.80 (80%)
95% Confidence Interval for p	69.6% – 87.8%
Hypothesized Proportion	0.50 (Neutral)
Test Method	Blaker's Exact Test
P-Value	0.000
Result	Statistically significant support for feasibility

In conclusion, the survey findings offer an optimistic outlook for the potential implementation of a CYCLAMED-like initiative in Kerala. To turn this vision into reality, it will be essential to align policies, secure financial resources, and foster engagement among relevant stakeholders. The support expressed by pharmacists lays a solid foundation for piloting such programs statewide.

9 CHAPTER 5: CONCLUSIONS AND FUTURE RECOMMENDATIONS

9.1 CONCLUSION AND SUMMARY

This research evaluated the potential for introducing a pharmacy-led medication take-back program in Kerala, using the CYCLAMED model from France as a benchmark. By combining insights from survey responses and supporting literature, the study identified key factors influencing feasibility and stakeholder readiness.

The highest participation was recorded among independent and hospital pharmacies, particularly in urban and suburban regions, where infrastructure and staffing levels are more favorable. These pharmacies represent ideal starting points for pilot programs. On the other hand, engagement from chain and online pharmacies was notably low, signaling the need for targeted interventions, awareness-building campaigns, and possible regulatory incentives to encourage their involvement.

The lower response rate from rural pharmacies reflects persistent barriers such as limited access and fewer resources. Existing studies echo the necessity of alternative solutions, to ensure these areas are not left behind in statewide implementation.

A key observation was that pharmacy size did not directly correlate with participation. Medium-sized pharmacies demonstrated the greatest engagement, suggesting that factors like operational flexibility and decision-making capacity may be more critical than staffing numbers alone.

Literature findings further stress that successful programs like CYCLAMED rely on robust legal frameworks, reliable funding sources, and coordinated efforts among stakeholders, all areas requiring development in the Kerala context.

The results of this study reveal that the majority of pharmacies in Kerala infrequently receive unused or expired medications (UEM) from the public, indicating that public participation in safe medication disposal is currently quite limited. While some pharmacies do report occasional returns, these instances vary and appear to depend on factors such as the location of the pharmacy, and staff availability. Similarly, effort of pharmacists to educate patients about proper disposal methods are inconsistent. Only a portion of respondents reported offering such guidance, and even then, it was not delivered regularly, demonstrating that educational outreach on this issue lacks a structured approach.

When evaluating current disposal methods, a significant number of respondents viewed them as largely ineffective. A notable portion of pharmacists rated the practices as failing to adequately mitigate environmental risks. Others expressed uncertainty or saw only slight benefit, while just a small minority believed the current systems were truly effective.

These observations are supported by secondary research, which points to the need for comprehensive, regulated, and professionally led medication disposal systems. Successful international models, such as CYCLAMED in France, show that consistent pharmacist involvement, strong legal backing, and well-informed public engagement are essential components of effective pharmaceutical waste management.

This research explored the difficulties faced by pharmacies in Kerala when disposing of unused or expired medications, drawing from survey responses and secondary research. It was found that many pharmacists consider current disposal methods such as returning medications to manufacturers, throwing them in household trash, and using designated bins challenging or not under use. Key issues include inadequate infrastructure, logistical hurdles, unclear regulations, high disposal costs, and low patient awareness.

The findings highlight the need for better disposal facilities, clearer guidelines, and improved public education. Additionally, most pharmacists agreed that educating patients is crucial for enhancing disposal practices. These results are consistent with international models, indicating that a pharmacy-led medication take-back system, supported by policy improvements and stronger infrastructure, could effectively address the disposal challenges in Kerala.

The analysis of medication waste management regulations of Kerala highlights critical shortcomings in both understanding and enforcement. Secondary research reveals that India lack clear regulations. Although a majority of pharmacists have some level of awareness of the regulations, many believe that the guidelines are unclear and insufficient to ensure proper disposal of medications. A significant portion of respondents expressed dissatisfaction with the current regulations, suggesting a need for more comprehensive and effective policies.

The survey results, along with insights from secondary research, reveal that inadequate training and limited support from regulatory authorities are major obstacles. Many pharmacists feel unprepared to handle pharmaceutical waste, and the perceived lack of support from regulatory bodies compounds the issue.

The results from both the survey and secondary research provide important insights into the feasibility, awareness, and potential benefits of introducing a pharmacy-led medication take-back system in Kerala. The survey indicates that while many pharmacists in Kerala have some familiarity with the CYCLAMED model from France, there is a noticeable lack of in-depth knowledge about its structure and functioning. This points to a clear need for targeted educational programs and awareness campaigns to enhance understanding of international models among pharmacists and how they might be adapted to specific needs of Kerala.

The survey also reveals strong support for the concept of a pharmacy-led medication take-back initiative, with nearly 70% of pharmacists seeing the program as feasible. Most respondents

recognized its potential advantages, including reducing environmental harm, preventing medication misuse, improving public health, and ensuring better regulatory compliance. Despite some concerns regarding logistical issues and costs, the overall sentiment is positive.

Moreover, pharmacists overwhelmingly believe that such a program could improve current medication disposal practices in Kerala. The majority of respondents see pharmacies as essential in addressing the existing gaps in disposal methods, which could lead to significant improvements in public health and environmental sustainability.

Secondary research reinforced these findings, demonstrating the success of similar programs like CYCLAMED in other countries. However, it also identified potential challenges such as regulatory constraints, infrastructure needs, and public awareness, all of which could pose obstacles to successfully implementing a take-back system in Kerala.

This study also shows that pharmacists in Kerala are largely supportive of a pharmacy-led medication take-back program. Approximately 73% of respondents expressed a willingness to participate, highlighting significant enthusiasm for the initiative. Furthermore, 62% of pharmacists believe their pharmacies are sufficiently prepared to implement the program, indicating that they are confident about necessary resources and infrastructure to ensure its success.

Additionally, pharmacists are optimistic about patient involvement, with 74% confident that patients would actively return unused medications. This suggests that, with proper awareness and access, patient participation is likely to be high.

Secondary research aligns with these findings, referencing successful models like CYCLAMED program from France, which has shown positive effects in reducing environmental harm, improving public health, and ensuring better regulatory compliance through pharmacy-led systems.

Similarly, research identifies several critical challenges that could hinder the successful implementation of a pharmacy-led medication take-back program in Kerala. The most significant barrier highlighted by pharmacists is the lack of public awareness, with over 73% of respondents viewing it as a major challenge. This emphasizes the need for comprehensive public awareness initiatives to ensure the effectiveness of the program. Furthermore, infrastructure limitations were also seen as a major issue by nearly 73% of respondents. The establishment of secure collection points, appropriate storage facilities, and efficient disposal systems is crucial for the proper functioning of the program.

Regulatory challenges were another key concern, with many pharmacists expressing apprehension about existing regulations that could complicate the rollout of the program. This points to the necessity for regulatory adjustments or clarification to simplify the process and make it more

feasible. These findings are supported by secondary research, which suggests that addressing these barriers is essential for the successful implementation of similar programs elsewhere.

Drawing from both the primary survey results and supporting literature, it is evident that financial assistance, regulatory clarity, and public education are critical for successfully launching a pharmacy-led medication take-back program in Kerala.

To begin with, nearly 75% of pharmacists surveyed believe that financial aid or government subsidies would be highly beneficial in facilitating the implementation of such programs. This aligns with prior studies that identify economic support as a major enabler, helping pharmacies manage costs related to setup, infrastructure, and safe disposal mechanisms.

Next, a strong majority, over 80% of respondents stressed the importance of having clear and well-structured regulatory guidelines. This suggests that pharmacists are open to participating, but require a defined legal framework to do so confidently. Literature on similar programs also highlights unclear or inconsistent regulations as a recurring barrier that needs to be addressed for effective execution.

Furthermore, about 84% of pharmacists agreed that raising public awareness is essential for the success of the program. They emphasized that informed communities are more likely to participate and properly dispose of unused medications. This insight is supported by secondary sources that point to the effectiveness of public education campaigns in enhancing engagement, as seen in established models like CYCLAMED system from France.

Based on the insights gathered from both the primary survey and secondary literature, it is evident that raising public awareness and engagement is essential for successfully implementing a pharmacy-led medication take-back program in Kerala. The majority of pharmacists surveyed (82.7%) emphasized the significance of public education in encouraging proper disposal practices, a finding that aligns with international research underscoring the value of awareness in promoting safe medication return behaviors.

Although 81.6% of participants believed pharmacy-led educational initiatives are effective, only a minority (12.6%) considered them the most impactful. Instead, a larger share (68%) favored government-led initiatives, indicating greater trust in centralized campaigns to drive public participation. This viewpoint echoes the success of established systems like CYCLAMED model, where strong government involvement has been instrumental. Furthermore, a similar percentage of respondents (81.6%) acknowledged the importance of government support, with 72.4% believing a government-led initiative would enhance program outreach, highlighting the need for regulatory and institutional backing.

When asked about the most helpful outreach tools, 66.7% of pharmacists preferred training sessions, pointing to a strong desire for capacity-building and skill development within the profession. Comparatively, fewer respondents found value in digital tools or printed materials, suggesting that hands-on, practical learning is viewed as more impactful.

In overall, the research reveals that a pharmacy-led medication take-back system in Kerala holds significant promise, but several challenges need to be addressed for successful implementation. Both the survey data and secondary research highlight the importance of clear regulations, proper pharmacist training, public education, and strong government support. While pharmacists show general support for the initiative, issues like insufficient infrastructure, unclear policies, and low public awareness must be resolved. To ensure effective implementation, a step-by-step approach involving legislative support, collaboration among stakeholders, and public awareness campaigns is required. Insights from international systems like CYCLAMED from France emphasize the need for regulatory clarity, institutional support, and public involvement. Additionally, facilities such as collection points or incineration sites and financial backing are essential for the success of the program. The findings suggest that adapting a pharmacy-led take-back program to specific needs in Kerala is not only feasible but necessary. By addressing current gaps and applying global best practices, Kerala can improve medication disposal, protect public health, and ensure environmental sustainability. Prompt and coordinated action will be crucial for the program's long-term success.

1.1 TESTING OF RESEARCH HYPOTHESIS

HYPOTHESIS 1: Implementing a pharmacy-led medication take-back system in Kerala, inspired by CYCLAMED program from France, is realistic and can work well in the state, provided there is the right mix of infrastructure, government support, and public awareness.

The survey results indicate this hypothesis is true, that government support, financial aid, and clear regulatory frameworks are essential for the success of a pharmacy-led medication take-back program in Kerala. Additionally, respondents emphasized the importance of robust infrastructure and public awareness. The literature review, particularly the CYCLAMED model from France, reinforces the notion that a similar system in Kerala can thrive if there is adequate government involvement, regulatory clarity, and public education. In conclusion, the findings suggest that with proper implementation of these key factors, a pharmacy-led take-back system in Kerala could be highly effective.

HYPOTHESIS 2: People in Kerala are currently using unsafe or ineffective methods to dispose of unused medications, which is leading to environmental damage and health risks, highlighting the need for a better, organized system.

The survey results imply a need for a more organized medication disposal system, emphasizing the importance of enhanced public education and infrastructure, which suggests that current disposal methods may be unsafe or ineffective. The literature review supports this view, highlighting the environmental and health dangers of improper disposal and the growing global concern over pharmaceutical waste. Studies from various regions also confirm the harmful effects of unsafe disposal practices on public health and ecosystems. Combined, the survey findings and literature provide strong support for the hypothesis that a structured medication take-back system is crucial to addressing these issues.

HYPOTHESIS 3: While there are challenges to setting up a medication take-back system in Kerala such as regulatory hurdles, lack of awareness, and gaps in infrastructure, these obstacles can be overcome with the right policies, public engagement, and resources.

The survey responses highlight regulatory obstacles, infrastructure shortcomings, and insufficient public awareness as major challenges to establishing a pharmacy-led medication take-back system in Kerala. However, respondents believe these issues can be resolved with clear regulations, improved public education, and strong government backing. The literature review reinforces this view, noting that such challenges have been overcome in other regions through strategic planning, collaboration among stakeholders, and the allocation of necessary resources. Overall, both the survey and literature review support the hypothesis that these barriers can be addressed with proper planning and stakeholder engagement.

9.2 CONTRIBUTIONS AND LIMITATIONS OF THE RESEARCH

CONTRIBUTIONS OF THE RESEARCH

This research provides valuable perspectives on the feasibility of introducing a pharmacy-led medication take-back program in Kerala, using CYCLAMED model from France as a reference. Drawing on survey responses from 87 pharmacists and supporting literature, it highlights the critical role of government policies, public awareness, pharmacist training, and proper infrastructure. The findings identify existing flaws in current disposal practices and offer practical recommendations for improvement. Overall, the study contributes to the broader discourse on pharmaceutical waste management in South India and proposes a structured strategy for policymakers and healthcare providers to consider.

LIMITATIONS OF THE RESEARCH

The scope of the study is constrained by its limited sample size, focusing solely on 87 pharmacists, which may not reflect the views of all relevant stakeholders. It does not incorporate feedback from the general public, regulatory bodies, or other healthcare professionals. Additionally, the research is based on theoretical analysis without implementing or testing the proposed system in practice.

The assumption that Kerala can replicate CYCLAMED's approach may overlook unique local challenges, including cultural and regulatory differences, that could affect its success.

9.3 RECOMMENDATIONS FOR PRACTICE AND FUTURE RESEARCH **PRACTICAL RECOMMENDATIONS**

1. **Establish Clear Pharmaceutical waste management regulations and Policies:** Health authorities of Kerala should introduce well-defined regulatory framework to support a pharmacy-led take-back system, taking references from proven international frameworks like CYCLAMED from France.
2. **Build Supporting Infrastructure:** Creating accessible collection centers, disposal sites, and transportation facilities will be essential for efficient and safe medicine return and disposal.
3. **Enhance Public Engagement:** Awareness programs using platforms like social media and local outreach through pharmacies should be initiated to inform citizens about the importance of safe medication disposal and enhance their participations.
4. **Equip Pharmacists Through Training:** Continuous professional development should be offered to pharmacists, enabling them to confidently advise the public on disposal methods.
5. **Secure Financial Support:** Financial sustainability is vital. Government funding, pharmaceutical industry contributions, or public-private partnerships should be explored to support the operation and encourage pharmacy involvement in the system.

FUTURE RESEARCH SUGGESTIONS

1. **Assess Financial Feasibility:** Conducting economic evaluations will help determine the long-term sustainability and cost-effectiveness of the program in the Kerala context.
2. **Study Public Awareness and Behavior:** Further research is needed to evaluate the current level of knowledge and disposal habits among the population.

9.4 REFLCETIONS

This research offered valuable insights into the intersection of healthcare, environmental safety, and policy. Investigating the potential for implementing a pharmacy-led medication take-back system in Kerala, inspired by CYCLAMED model from France, highlighted the importance of collaboration between pharmacists, government agencies, and the public. Survey responses demonstrated strong support from pharmacists, yet they also pointed out key challenges, such as inadequate infrastructure, lack training, limited public awareness, and unclear regulatory frameworks. These findings were reinforced by peer reviewed literatures, which emphasized the global consequences of improper medication disposal and the success of structured take-back programs. Through this study, I gained a better understanding of how international models can be adapted to local contexts and the importance of stakeholder cooperation in achieving sustainable change. Additionally, it deepened my appreciation for the evolving role of pharmacists in shaping public health and environmental policies.

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11 APPENDIX 1: SURVEY QUESTIONNAIRE

DEMOGRAPHIC INFORMATION

1.Type of Pharmacy:

- a) Independent
- b) Chain Pharmacy
- c) Hospital Pharmacy
- d) Online Pharmacy
- e) Other [Please specify]

2.Location of Pharmacy:

- a) Urban
- b) Rural

3.Which of the following best describes your pharmacy's size?

- a) Very small (1-2 employees)
- b) Small (3-5 employees)
- c) Medium (6-10 employees)
- d) Large (11-20 employees)
- e) Very large (20+ employees)

CURRENT MEDICATION DISPOSAL PRACTICES (OBEJECTIVE 1)

1. How often do you receive unused or expired medications from patients for disposal?

- a) Never
- b) Rarely
- c) Sometimes
- d) Often
- e) Very Frequently

2. How often do you provide patients with guidance on safe medication disposal?

- a) Never
- b) Rarely
- c) Sometimes
- d) Often

- e) Always
3. **How effective do you think your current disposal methods are in preventing environmental harm?**

- a) Not effective at all
b) Slightly effective
c) Neutral
d) Effective
e) Very effective

4. **To what extent do you rely on each of the following methods for disposing of unused or expired medications?**

(rate method on a scale of 1 to 5, where 1 = Never and 5 = Always)

4.a) Returning to the manufacturer

1 2 3 4 5

4.b) Disposing of in household trash

1 2 3 4 5

4.c) Disposing of in designated waste bins

1 2 3 4 5

4.d) Collected by a waste disposal company

1 2 3 4 5

4.e) Other (please specify in comments)

1 2 3 4 5

5. **How challenging do you find each of the following aspects of current medication disposal practices?**

(Rate each factor on a scale of 1 to 5, where 1 = Not challenging at all and 5 = Very challenging)

5.a) Lack of proper disposal facilities

1 2 3 4 5

5.b) Lack of awareness among patients

1 2 3 4 5

5.c) High cost of waste disposal

1 2 3 4 5

5.d) Regulatory confusion

1 2 3 4 5

5.e) Other (please specify in comments)

Comment:

6. How important do you think patient education is in improving medication disposal practices?

- a) Not important at all
- b) Slightly important
- c) Neutral
- d) Important
- e) Very important

AWARENESS OF CURRENT REGULATIONS IN KERALA (OBJECTIVE 2)**1. How familiar are you with Kerala's medication waste management regulations?**

- a) Not at all familiar
- b) Slightly familiar
- c) Neutral
- d) Moderately familiar
- e) Very familiar

2. How clear do you find the existing regulations on medication disposal in Kerala?

- a) Not clear at all
- b) Slightly clear
- c) Neutral
- d) Clear
- e) Very clear

3. How easy is it for your pharmacy to comply with the current regulations on medication disposal?

- a) Very difficult
- b) Difficult
- c) Neutral
- d) Easy
- e) Very easy

4. Do you believe the current regulations are sufficient to ensure safe medication disposal in Kerala?

- a) Strongly disagree

- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

5. Have you received adequate training on pharmaceutical waste disposal regulations in Kerala?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

6. How supportive do you think regulatory authorities are in helping pharmacists manage pharmaceutical waste?

- a) Not supportive at all
- b) Slightly supportive
- c) Neutral
- d) Supportive
- e) Very supportive

AWARENESS OF CYCLAMED OR SIMILAR PROGRAMS

1. How aware are you of the CYCLAMED model (pharmacy-led medication take-back system) implemented in France?

- a) Not aware at all
- b) Slightly aware
- c) Moderately aware
- d) Well aware
- e) Very well aware

2. How familiar are you with the structure and operation of the CYCLAMED model?

- a) Not familiar at all
- b) Slightly familiar
- c) Somewhat familiar
- d) Moderately familiar
- e) Very familiar

3. To what extent do you think a pharmacy-led medication take-back program could work in Kerala?

- a) Not feasible at all
- b) Slightly feasible
- c) Neutral
- d) Feasible
- e) Highly feasible

4. How beneficial do you think a pharmacy-led medication take-back system would be in Kerala for the following aspects?

(Rate each on a scale of 1 to 5, where 1 = Not beneficial at all and 5 = Highly beneficial)

4.a) Reducing environmental impact

1 2 3 4 5

4.b) Preventing misuse or abuse of medications

1 2 3 4 5

4.c) Cost-effectiveness for pharmacies

1 2 3 4 5

4.d) Public health improvement

1 2 3 4 5

4.e) Compliance with regulations

1 2 3 4 5

5. To what extent do you believe implementing a pharmacy-led take-back program would improve medication disposal practices in Kerala?

- a) Not at all
- b) Slightly
- c) Neutral
- d) Somewhat
- e) Significantly

WILLINGNESS TO PARTICIPATE IN A TAKE-BACK PROGRAM (OBJECTIVE 3)**1.Willingness to Participate in a Pharmacy-led Take-back Program**

How willing are you to participate in a pharmacy-led medication take-back program?

- a) Not willing at all
- b) Slightly willing
- c) Neutral
- d) Willing
- e) Very willing

2.How prepared do you believe your pharmacy is to implement a pharmacy-led medication take-back program?

- a) Not prepared at all
- b) Slightly prepared
- c) Neutral
- d) Prepared
- e) Very prepared

3.To what extent do you believe that patients would be willing to return unused medications to pharmacies if a take-back program were implemented?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

BARRIERS TO IMPLEMENTATION (OBJECTIVE 4)

1.To what extent do you think lack of public awareness is a major barrier to implementing a pharmacy-led medication take-back program?

- a) Not a barrier at all
- b) Slight barrier
- c) Neutral
- d) Moderate barrier
- e) Major barrier

2.How much do you think insufficient infrastructure is a major barrier to implementing a pharmacy-led medication take-back program?

- a) Not a barrier at all
- b) Slight barrier
- c) Neutral
- d) Moderate barrier
- e) Major barrier

3.To what extent do you believe regulatory hurdles are a barrier to implementing a pharmacy-led medication take-back program?

- a) Not a barrier at all

- b) Slight barrier
- c) Neutral
- d) Moderate barrier
- e) Major barrier

SUPPORT FOR IMPLEMENTATION (OBJECTIVE 4)

1.How much do you agree that financial support or subsidies would help in implementing a pharmacy-led medication take-back program?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

2.How much do you agree that clear regulatory guidelines would be necessary for implementing a pharmacy-led medication take-back program?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

3.How much do you agree that public awareness campaigns would be essential for the success of a pharmacy-led medication take-back program?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree

- e) Strongly agree

PUBLIC AWARENESS AND ENGAGEMENT (OBJECTIVE 3)

1.How important do you think public education is for improving medication disposal practices?

- a) Not important at all
- b) Slightly important
- c) Neutral
- d) Important
- e) Very important

2.How effective do you think pharmacy-based educational campaigns would be in increasing public awareness about safe medication disposal?

- a) Not effective at all
- b) Slightly effective
- c) Neutral
- d) Effective
- e) Very effective

3.How important do you think government support is for the success of a pharmacy-led medication take-back program?

- a) Not important at all
- b) Slightly important
- c) Neutral
- d) Important
- e) Very important

4.How do you think the public's awareness of safe medication disposal practices can be increased?

- a) Through pharmacy-based educational campaigns

- b) Through social media campaigns
- c) By government regulations or campaigns
- d) Other [Please specify]

5. Do you believe that a government-led initiative could play a role in promoting medication take-back programs?

- a) Yes
- b) No
- c) Unsure

6. What kind of outreach or educational materials would you find useful in promoting a pharmacy-led take-back program?

- a) Flyers and brochures
- b) Training sessions for pharmacists
- c) Online resources
- d) Social media campaigns
- e) Other [Please specify]

FINAL FEEDBACK AND SUGGESTIONS (OBJECTIVE 5)

Do you have any additional suggestions for improving medication disposal practices or implementing a pharmacy-led take-back system in Kerala?

12 APPENDIX 2: PARTICIPANT INFORMATION PARAGRAPH



Participant Information Paragraph

ASSESSING THE FEASIBILITY OF IMPLEMENTING A PHARMACY-LED MEDICATION TAKE-BACK SYSTEM IN KERALA: A COMPARATIVE ANALYSIS OF FRANCE'S CYCLAMED MODEL.

I invite you to take part in a research study assessing the feasibility of a pharmacy-led medication take-back system in Kerala, inspired by France's CYCLAMED model. My name is Madhuralekshmi Pankey Sadanam Omanakuttan, and I am pursuing a Master's in Pharmaceutical Business and Technology at Griffith College Dublin. This study aims to explore the regulatory, infrastructural, and public awareness challenges associated with medication disposal in Kerala.

If you choose to participate, you will be asked to complete an anonymous online survey, which will take approximately 10–15 minutes. The survey includes questions about your current medication disposal practices, awareness of take-back programs, and willingness to engage in such initiatives. Participation is voluntary, and you can skip any questions or withdraw at any time without consequences. No personal identifiers will be linked to your responses, ensuring confidentiality.

You have been invited because you are a licensed pharmacist in Kerala, and your insights are crucial in evaluating the feasibility of a pharmacy-led take-back system. Your experience with medication dispensing and waste management will provide valuable input on implementation challenges and opportunities.

There are no significant risks to participation, aside from a minimal confidentiality risk, which will be mitigated through anonymization and secure data storage. The study complies with all relevant data protection regulations, and your responses will be stored securely. The findings will contribute to my Master's dissertation, which will be submitted to Griffith College Dublin and made available for academic reference.

Your participation is highly valued and will help shape strategies for improving pharmaceutical waste management in Kerala. If you have any questions, please feel free to ask before deciding whether to participate.

THANK YOU

13 APPENDIX 3: ETHICS APPLICATION AND DECLARATION FORM

Innopharma
education



GRIFFITH COLLEGE

Ethics Application & Declaration Form

14 DISSERTATION TITLE: ASSESSING THE FEASIBILITY OF IMPLEMENTING A PHARMACY-LED MEDICATION TAKE-BACK SYSTEM IN KERALA: A COMPARATIVE ANALYSIS OF FRANCE'S CYCLAMED MODEL.

RESEARCHER'S NAME: **MADHURALEKSHMI PANKEY SADANAM OMANAKUTTAN**

PROGRAMME OF STUDY: **MSc IN PHARMACEUTICAL BUSINESS AND TECHNOLOGY**

SUPERVISOR'S NAME: **PHILIP BYRNE**

DECLARATION:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE:

DATE: 28/02/2025

The research contained within this research dissertation proposal has been approved.

For Supervisor:

ETHICS COMMITTEE APPROVAL GIVEN:

Yes No

SUPERVISOR SIGNATURE:

For Ethics Committee (if required):

Ethics Committee Approval Given:

Yes No

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

15 SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

16 AIM

To assess the feasibility of adapting France's CYCLAMED pharmacy-led medication take-back system to Kerala's context, focusing on the regulatory, infrastructural, and public awareness challenges.

17 RESEARCH OBJECTIVES

Primary Objective:

To evaluate the feasibility of implementing a pharmacy-led medication take-back system in Kerala based on France's CYCLAMED model.

18 Specific Objectives:

1. Assess the current medication disposal practices in Kerala.
2. Analyse the operational structure, success factors, and impact of France's CYCLAMED model.
3. Compare regulatory policies, pharmacy involvement, and public participation in both regions.
4. Identify barriers and opportunities for implementing a similar system in Kerala.
5. Recommend policy and operational strategies for Kerala's government and pharmacies

1.2 Research methodology:

In this primary research design, an online survey will be administered to a stratified sample of 50 licensed pharmacists in Kerala to collect quantitative and qualitative data on their current practices for pharmaceutical waste management and their perceptions of a pharmacy-led medication take-back system. The survey instrument will include structured sections to capture demographic information (such as age, years of practice, and type of pharmacy), current waste disposal methods, awareness of models like France's CYCLAMED, and willingness to participate in a take-back program. Likert-scale items will measure the degree of readiness and perceived benefits or barriers, while open-ended questions will allow respondents to provide detailed suggestions and highlight specific challenges. The study will also incorporate a comparative component by mapping the key operational features of the CYCLAMED model against the practices currently in place in Kerala, thus enabling a SWOT analysis to identify strengths, weaknesses, opportunities, and threats associated with implementing a similar system locally.

The selection of 50 licensed pharmacists as the study's sample size is justified using the finite population correction formula, which ensures statistical validity while maintaining feasibility. Given that Kerala has an estimated 50,000 licensed pharmacists, a representative sample was determined using a 95% confidence level, a conservative population proportion of 50% (0.5), and a 14% margin of error. Applying the finite population correction formula, the required sample size was calculated to be approximately 48, which rounds up to 50 participants for practical purposes. This sample size is statistically adequate for capturing pharmacists' awareness, practices, and willingness to engage in a take-back system while allowing for meaningful quantitative analysis. Additionally, for the qualitative aspect of the study, data saturation is a key consideration, ensuring that new responses do not introduce significant new insights. Research in qualitative methodology suggests that 20–50 participants are typically sufficient for obtaining diverse perspectives in thematic analysis. By incorporating open-ended questions alongside structured survey items, the study aims to balance depth and breadth in data collection. Moreover, a sample size of 50 is manageable within the research's time and resource constraints, ensuring efficient data analysis while maintaining representativeness. Thus, this sample size effectively supports the study's mixed-methods approach, providing robust insights into the feasibility of implementing a pharmacy-led medication take-back system in Kerala.

19 SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

20 SUBJECT MATTER

21 Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

22 RESEARCH PROCEDURES**23 Does the research proposal involve:**

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

24 PARTICIPANTS**25 Does the research proposal involve:**

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups (Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)	No

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

26 SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

- 3.1. If your ethics relates to **Subject Matter**, outline your action plan to work around any sensitive issues.
- 3.2. If your ethics relates to **Research Procedures**, outline your action plan to deal with possible ethical issues in your research procedures.
- 3.3. If your ethics relates to **Participants**, outline how you will protect vulnerable persons or those that do not have English as their first language.

27 SECTION 4: ABOUT YOUR PARTICIPANTS

- 4.1. Outline your participant profile and why you have chosen them for this study

This study selects licensed pharmacists in Kerala as participants due to their key role in medication dispensing, disposal, and regulatory compliance. As primary stakeholders in a pharmacy-led take-back system, their insights on current disposal practices, legal challenges, and willingness to participate are crucial for assessing feasibility. A stratified sample of 50 pharmacists ensures diverse representation across practice settings and locations, balancing statistical reliability with practical feasibility.

- 4.2 How do you plan to gain access to/contact/approach your participant(s).

To gain access to and contact participants, I will use a multi-channel recruitment approach targeting licensed pharmacists across Kerala. First, I will collaborate with professional pharmacy associations such as the Kerala State Pharmacy Council and local pharmacist networks to distribute the survey. Additionally, I will reach out to community, hospital, and chain pharmacies via email, and phone calls, seeking permission from pharmacy owners or managers where necessary. Social media and professional platforms (e.g., WhatsApp pharmacist groups, LinkedIn) will also be utilized to enhance reach. A clear informed consent process will be followed, ensuring participants understand the study's purpose, confidentiality, and voluntary nature before participation.

28 SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 Participant Information Letter (PIL) for participants

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

29 Please confirm below that your information letter covers:

Description of the research topic and method	NO
Details of what participation will involve	NO
Rights to anonymity	NO
Confidentiality	NO
Rights to withdraw from the research	NO
The contact details of the researcher and supervisor (if necessary)	NO

5.2 Informed Consent Form (ICF) for participants

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research e.g. interviews, phonecalls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only: NO

No: my research study involves an online survey only and/or does not require signed consent

30 SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws <https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/>].

*The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on moodle. The rationale is to keep data **as long as it is still useful** and there is an intention to use it further **for research** so if this is not the case then this can be stipulated here and a shorter retention period given.]*

6.1. How will you store the research data and for how long? How will you manage data protection issues?

All research data will be stored in password-protected digital files on a secure institutional server or encrypted cloud storage. Data will be retained for two years after the study's completion, following ethical guidelines, and will then be permanently deleted or securely destroyed after two years. To ensure privacy, all responses will be anonymized, with access restricted to the researcher and authorized supervisors. The study will comply with GDPR and local data protection laws, ensuring participants are fully informed about how their data will be used, stored, and protected through the Participant Information Letter (PIL) and consent form.

31 SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 Non-Disclosure Agreement (NDA)

Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non- Disclosure Agreement (NDA) e.g. industry-based research? **NO**

7.2 Student consent

If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College? **YES**

32 SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA**8.1 Viva Recording**

The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

33 SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

34 Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	Yes
9.3 Questions/survey for interviewees/focus groups etc (<i>can be in draft form</i>)	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE:



DATE: 28/02/2025

SECTION 10:**35 APPENDIX 1-
SAMPLE SURVEY QUESTIONNAIRE****DEMOGRAPHIC INFORMATION****Type of Pharmacy:**

- a) Independent
- b) Chain Pharmacy
- c) Hospital Pharmacy
- d) Online Pharmacy
- e) Other [Please specify]

Location of Pharmacy:

- a) Urban
- b) Suburban
- b) Rural

Which of the following best describes your pharmacy's size?

- a) Very small (1-2 employees)
- b) Small (3-5 employees)
- c) Medium (6-10 employees)
- d) Large (11-20 employees)
- e) Very large (20+ employees)

CURRENT MEDICATION DISPOSAL PRACTICES

1. **How often do you receive unused or expired medications from patients for disposal?**
 - a) Never
 - b) Occasionally
 - c) Sometimes
 - d) Often
 - e) Always
2. **How often do you provide patients with guidance on safe medication disposal?**
 - a) Never
 - b) Occasionally
 - c) Sometimes
 - d) Often
 - e) Always
3. **How effective do you think your current disposal methods are in preventing environmental harm?**
 - a) Not effective at all
 - b) Slightly effective
 - c) Neutral
 - d) Effective
 - e) Very effective
4. **To what extent do you rely on each of the following methods for disposing of unused or expired medications?**

(Mark each method on a scale of 1 to 5, where 1 = Never and 5 = Always)

4.a) Returning to the manufacturer

1 2 3 4 5

4.b) Disposing of in household trash

1 2 3 4 5

4.c) Disposing of in designated waste bins

1 2 3 4 5

4.d) Collected by a waste disposal company

1 2 3 4 5

4.e) Other (please specify in comments)

1 2 3 4 5

5. How challenging do you find each of the following aspects of current medication disposal practices?

(Rate each factor on a scale of 1 to 5, where 1 = Not challenging at all and 5 = Very challenging)

5.a) Lack of proper disposal facilities

1 2 3 4 5

5.b) Lack of awareness among patients

1 2 3 4 5

5.c) High cost of waste disposal

1 2 3 4 5

5.d) Regulatory confusion

1 2 3 4 5

5.e) Other (please specify in comments)

1 2 3 4 5

Comment:

6. How important do you think patient education is in improving medication disposal practices?

- a) Not important at all
- b) Slightly important
- c) Neutral
- d) Important
- e) Very important

AWARENESS OF CURRENT REGULATIONS IN KERALA

1. How familiar are you with Kerala's medication waste management regulations?

- a) Not at all familiar
- b) Slightly familiar
- c) Neutral
- d) Moderately familiar
- e) Very familiar

2. How clear do you find the existing regulations on medication disposal in Kerala?

- a) Not clear at all
- b) Slightly clear
- c) Neutral
- d) Clear
- e) Very clear

3. How easy is it for your pharmacy to comply with the current regulations on medication disposal?

- a) Very difficult
- b) Difficult
- c) Neutral
- d) Easy
- e) Very easy

4. Do you believe the current regulations are sufficient to ensure safe medication disposal in Kerala?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

5. Have you received adequate training on pharmaceutical waste disposal regulations in Kerala?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

6. How supportive do you think regulatory authorities are in helping pharmacists manage pharmaceutical waste?

- a) Not supportive at all
- b) Slightly supportive
- c) Neutral
- d) Supportive
- e) Very supportive

AWARENESS OF CYCLAMED OR SIMILAR PROGRAMS

1. How aware are you of the CYCLAMED model (pharmacy-led medication take-back system) implemented in France?

- a) Not aware at all
- b) Slightly aware
- c) Moderately aware
- d) Well aware
- e) Very well aware

2. How familiar are you with the structure and operation of the CYCLAMED model?

- a) Not familiar at all
- b) Slightly familiar
- c) Somewhat familiar
- d) Moderately familiar
- e) Very familiar

3. To what extent do you think a pharmacy-led medication take-back program could work in Kerala?

- a) Not feasible at all
- b) Slightly feasible

- c) Neutral
- d) Feasible
- e) Highly feasible

4. How beneficial do you think a pharmacy-led medication take-back system would be in Kerala for the following aspects?

(Rate each on a scale of 1 to 5, where 1 = Not beneficial at all and 5 = Highly beneficial)

4.a) Reducing environmental impact

1 2 3 4 5

4.b) Preventing misuse or abuse of medications

1 2 3 4 5

4.c) Cost-effectiveness for pharmacies

1 2 3 4 5

4.d) Public health improvement

1 2 3 4 5

4.e) Compliance with regulations

1 2 3 4 5

5. To what extent do you believe implementing a pharmacy-led take-back program would improve medication disposal practices in Kerala?

- a) Not at all
- b) Slightly
- c) Neutral
- d) Somewhat
- e) Significantly

WILLINGNESS TO PARTICIPATE IN A TAKE-BACK PROGRAM

1. Willingness to Participate in a Pharmacy-led Take-back Program

How willing are you to participate in a pharmacy-led medication take-back program?

- a) Not willing at all
- b) Slightly willing
- c) Neutral
- d) Willing

- e) Very willing

2. How prepared do you believe your pharmacy is to implement a pharmacy-led medication take-back program?

- a) Not prepared at all
- b) Slightly prepared
- c) Neutral
- d) Prepared
- e) Very prepared

3. To what extent do you believe that patients would be willing to return unused medications to pharmacies if a take-back program were implemented?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

BARRIERS TO IMPLEMENTATION

1. To what extent do you think lack of public awareness is a major barrier to implementing a pharmacy-led medication take-back program?

- a) Not a barrier at all
- b) Slight barrier
- c) Neutral
- d) Moderate barrier
- e) Major barrier

2. How much do you think insufficient infrastructure is a major barrier to implementing a pharmacy-led medication take-back program?

- a) Not a barrier at all
- b) Slight barrier
- c) Neutral
- d) Moderate barrier
- e) Major barrier

3. To what extent do you believe regulatory hurdles are a barrier to implementing a pharmacy-led medication take-back program?

- a) Not a barrier at all
- b) Slight barrier
- c) Neutral
- d) Moderate barrier
- e) Major barrier

SUPPORT FOR IMPLEMENTATION

1. Do you agree that financial support or subsidies would help in implementing a pharmacy-led medication take-back program?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

2. Do you agree that clear regulatory guidelines would be necessary for implementing a pharmacy-led medication take-back program?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

3. How much do you agree that public awareness campaigns would be essential for the success of a pharmacy-led medication take-back program?

- a) Strongly disagree
- b) Disagree
- c) Neutral
- d) Agree
- e) Strongly agree

PUBLIC AWARENESS AND ENGAGEMENT

1. How important do you think public education is for improving medication disposal practices?

- a) Not important at all
- b) Slightly important

- c) Neutral
- d) Important
- e) Very important

2. How effective do you think pharmacy-based educational campaigns would be in increasing public awareness about safe medication disposal?

- a) Not effective at all
- b) Slightly effective
- c) Neutral
- d) Effective
- e) Very effective

3. How important do you think government support is for the success of a pharmacy-led medication take-back program?

- a) Not important at all
- b) Slightly important
- c) Neutral
- d) Important
- e) Very important

4. How do you think the public's awareness of safe medication disposal practices can be increased?

- a) Through pharmacy-based educational campaigns
- b) Through social media campaigns
- c) By government regulations or campaigns
- d) Other [Please specify]

5. Do you believe that a government-led initiative could play a role in promoting medication take-back programs?

- a) Yes
- b) No
- c) Maybe

6. What kind of outreach or educational materials would you find useful in promoting a pharmacy-led take-back program?

- a) Flyers and brochures
- b) Training sessions for pharmacists
- c) Online resources
- d) Social media campaigns
- e) Other [Please specify]

FINAL FEEDBACK AND SUGGESTIONS

Do you have any additional suggestions for improving medication disposal practices or implementing a pharmacy-led take-back system in Kerala?

[Open-ended response]



Participant Information Paragraph

36 ASSESSING THE FEASIBILITY OF IMPLEMENTING A PHARMACY- LED MEDICATION TAKE-BACK SYSTEM IN KERALA: A COMPARATIVE ANALYSIS OF FRANCE'S CYCLAMED MODEL.

I invite you to take part in a research study assessing the feasibility of a pharmacy-led medication take-back system in Kerala, inspired by France's CYCLAMED model. My name is Madhuralekshmi Pankey Sadanam Omanakuttan, and I am pursuing a Master's in Pharmaceutical Business and Technology at Griffith College Dublin. This study aims to explore the regulatory, infrastructural, and public awareness challenges associated with medication disposal in Kerala.

If you choose to participate, you will be asked to complete an anonymous online survey, which will take approximately 10–15 minutes. The survey includes questions about your current medication disposal practices, awareness of take-back programs, and willingness to engage in such initiatives. Participation is voluntary, and you can skip any questions or withdraw at any time without consequences. No personal identifiers will be linked to your responses, ensuring confidentiality.

You have been invited because you are a licensed pharmacist in Kerala, and your insights are crucial in evaluating the feasibility of a pharmacy-led take-back system. Your experience with medication dispensing and waste management will provide valuable input on implementation challenges and opportunities.

There are no significant risks to participation, aside from a minimal confidentiality risk, which will be mitigated through anonymization and secure data storage. The study complies with all relevant data protection regulations, and your responses will be stored securely. The findings will contribute to my Master's dissertation, which will be submitted to Griffith College Dublin and made available for academic reference.

Your participation is highly valued and will help shape strategies for improving pharmaceutical waste management in Kerala. If you have any questions, please feel free to ask before deciding whether to participate.

THANK YOU