สถานการณ์การจัดการของเสียจากเภสัชภัณฑ์ในร้านขายยาจังหวัดสงขลา
The Situation of Pharmaceutical Waste Management in Community Pharmacies in Songkhla Province, Thailand

นิพนธ์ต้นฉบับ

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Original Article

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บทคัดย่อ

วัตถุประสงค์: เพื่อสำรวจสถานการณ์และปัญหาอุปสรรคในการจัดการของเสียจากเภสัชภัณฑ์ในร้านขายยาจังหวัดสงขลา และเสนอแนะแนวทางการปรับปรุงเกณฑ์ Good Pharmacy Practice (GPP) **วิธีการศึกษา:** การศึกษาแบบภาคตัดขวางโดยมีประชากรเป็นร้านขายยาจังหวัดสงขลาจำนวน 432 แห่ง ต้องใช้ตัวอย่างร้านยา 217 แห่ง เลือกตัวอย่างตามสะดวก ผู้วิจัยพัฒนาแบบสอบถามจากแนวปฏิบัติการจัดการของเสียทางการแพทย์ที่เป็นสารเคมี พ.ศ. 2559 ร่วมกับหลักวิธีปฏิบัติทางเภสัชกรรมชุมชน GPP เก็บข้อมูลโดยแจกแบบสอบถามด้วยตนเอง แสดงผลการวิเคราะห์สถานการณ์และปัญหาอุปสรรคด้วยสถิติเชิงพรรณนา และประเมินความรู้และการจัดการของเสียจากเภสัชภัณฑ์ของผู้ประกอบการร้านขายยา **ผลการศึกษา:** จากร้านขายยา 217 แห่ง พบว่าร้อยละ 31.31 คัดแยกของเสียฯ ด้วยถุงสีเดียวกับมูลฝอยทั่วไป และไม่มีข้อความกำกับ ร้านขายยาร้อยละ 79.26 กำจัดของเสียฯโดยไม่ได้คัดแยกประเภทยา และใช้วิธีการทิ้งรวมกับมูลฝอยทั่วไป (ร้อยละ 54.07) คะแนนเฉลี่ยของความรู้และการปฏิบัติงานตามเกณฑ์ GPP และแนวปฏิบัติฯพ.ศ.2559 เท่ากับ 55.67 คะแนน และ 21.28 คะแนนตามลำดับ จากคะแนนเต็ม 100 ปัญหาและอุปสรรคหลัก ได้แก่ การไม่ทราบแนวทาง/ไม่มีความรู้ในการกำจัดของเสียฯ (ร้อยละ 32.56) **สรุป:** ร้านขายยาหลายแห่งในจังหวัดสงขลายังจัดการของเสียจากเภสัชภัณฑ์ไม่ถูกต้อง สำนักงานคณะกรรมการอาหารและยาควรเพิ่มการสื่อสารแนวปฏิบัติที่ถูกต้องไปยังร้านขายยา รวมถึงกำกับติดตามการจัดการของเสียฯอย่างสม่ำเสมอ นอกจากนี้ใน GPP ควรเพิ่มรายละเอียดการจัดการของเสียจากเภสัชภัณฑ์

คำสำคัญ: ของเสียจากเภสัชภัณฑ์; ยาหมดอายุ; การจัดการมูลฝอย; ร้านขายยา; หลักวิธีปฏิบัติทางเภสัชกรรมชุมชน

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Abstract

Objective: To explore challenges and obstacles of pharmaceutical waste management practices in community pharmacies in Songkhla Province, Thailand and suggest improvement in good pharmacy practice (GPP) criteria. **Methods:** This cross-sectional study was conducted in population of 432 community pharmacies in Songkhla Province. A total of 217 community pharmacies was needed and recruited by convenience sampling at the pharmacies. The questionnaire was developed based on the 2016 chemical medical waste management guidelines and the GPP for community pharmacy. Pharmaceutical waste management practices, challenges and obstacles and knowledge were presented using descriptive statistics. **Results:** Of the 217 pharmacies, 31.31% separated pharmaceutical waste using bags with colors similar to the regular trash bags, without any labeling. 79.26% disposed the waste without sorting types of medications and discarded it together with general waste (54.07%). The average knowledge and practice score were 55.67 and 21.28, respectively, out of 100 points. Lack of knowledge was the main challenge (32.56%). **Conclusion:** Many community pharmacies in Songkhla province improperly managed pharmaceutical waste. Thai Food and Drug Administration could enhance communication, supervision and regular monitoring on waste management. More details of pharmaceutical waste management should be added to the GPP criteria.

Keywords: pharmaceutical waste; expired drug; waste management; community pharmacy; good pharmacy practice (GPP)

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Introduction

Pharmaceutical waste is defined as drugs or pharmaceutical products that are unused or discarded and may be left over, deteriorated, expired, or contaminated, including the packaging of them.[1] Pharmaceutical waste is classified as hazardous waste due to its negative impact on living organisms and the environment, so proper management of pharmaceutical waste, including segregation, collection, transportation and disposal, is required to prevent negative environmental impacts.

Incorrect management of pharmaceutical waste, such as disposal as general waste or flushing down toilets, leads to drug contamination in the environment and causes long-term effects, including the accumulation of drugs in living organisms and the food chain. This results in mutagenicity, genotoxicity, and antimicrobial resistance.[2] A study of Sanchez et al in 2011 found severe intersex conditions in fish living in the Dore River, which is connected to the wastewater discharge of a steroid manufacturing company in France.[3] Meanwhile,

pharmaceutical waste management surveys in many countries worldwide have revealed improper disposal practices, particularly in developing countries. Studies in Saudi Arabia (79.15%)[4], Kuwait (76.5%)[5], and Ghana (75%)[6] showed that most people dispose of pharmaceutical waste as general waste. Similarly, a 2014 study in Thailand found that 90% of people improperly disposed of pharmaceutical waste. [7]

In Thailand, community pharmacies are recognized as healthcare facilities stockpiling medications to provide drug and health services. They play a key role in distributing medicines to communities.[8] In 2014, the Thailand Food and Drug Administration (Thai FDA) established the Community Pharmacy Practice Guidelines: Good Pharmacy Practice (GPP) to standardize the quality of services provided by pharmacies,[9] which specified quality control of medicines within pharmacies, as well as the management of expired drugs, which are classified as pharmaceutical waste.

Community pharmacy operators are required to adhere to the GPP standards as a guideline for managing pharmaceutical waste. The GPP standards unfortunately provide only general guidance on handling expired drugs or pharmaceutical waste. It does not specify clear methods for waste segregation and disposal. On the other hand, the 2016 Guidelines for chemical medical waste management which serves as the national standard provide more detail in pharmaceutical waste management in healthcare facilities.

Knowledge about pharmaceutical waste management among community pharmacy operators should be adequate to correctly adhere to the GPP. Such knowledge could help prevent long-term environmental impacts on communities. Nevertheless, in Thailand, there is still a lack of research on pharmaceutical waste management in community pharmacies regarding compliance with the GPP criteria and the 2016 chemical medical waste management guidelines among pharmacy operators. This gap has led to the initiation of this study, which aimed to investigate the current situation and identify challenges in pharmaceutical waste management in community pharmacies in Songkhla Province, Thailand. Additionally, the study proposed recommendations to enhance the GPP guidelines by incorporating more detailed provisions on pharmaceutical waste management. The findings could serve as valuable input for national regulatory agencies overseeing pharmaceutical waste management, aiding in the improvement of policies and the development of effective measures to enhance pharmaceutical waste management in community pharmacies.

Methods

This cross-sectional survey study was approved by the Human Research Ethics Committee in Health Sciences, Prince of Songkla University (approvale number: Hsc-HREC-64-001-1-3). The researcher explored the situation of pharmaceutical waste management in community pharmacies, identified challenges, and proposed improvements to GPP guidelines, as outlined in the research framework (Figure 1). The study was divided into three steps as follows.

Step 1: Development of tools for surveying pharmaceutical waste management practices in community pharmacies.

1.1 Reviews of guidelines for pharmaceutical waste management

A review of Thailand's guidelines related to pharmaceutical waste management in healthcare facilities revealed two relevant guidelines.

The **first guideline** was the **GPP criteria**.[9] The GPP is a standard used to regulate pharmacies, covering all aspects of pharmacy quality assurance. However, these criteria do not place significant emphasis on pharmaceutical waste management. They provide only broad guidance on pharmaceutical waste management and lack detailed instructions on waste disposal methods.

The **second guideline** was the **chemical medical waste management guidelines (2016)**.[10] This national guideline offers more detailed recommendations on pharmaceutical waste management compared to the GPP criteria. However, this guideline is designed for healthcare facilities in general, and some practices may not be appropriate for community pharmacies. This is because pharmacies handle a smaller variety of medications compared to larger healthcare facilities, such as hospitals.

We compared the approaches to pharmaceutical waste management, which were categorized into four steps, including segregation, collection, transportation, and disposal, as outlined in the two aforementioned guidelines. The two guidelines classify pharmaceutical waste as hazardous waste

and do not provide specific procedures for waste transportation. Nevertheless, the 2016 chemical medical waste management guidelines offer more comprehensive information on segregation and disposal compared to the GPP criteria (Table 1). Therefore, the sole use of the GPP to assess pharmaceutical waste management practices in community pharmacies may result in an incomplete assessment of the situation. As a result, we deemed it necessary to develop a new tool for assessing pharmaceutical waste management in community pharmacies, incorporating evaluation criteria of the 2016 chemical medical waste management guidelines and those of the GPP.

1.2 Developing questionnaire

We developed a questionnaire to survey pharmaceutical waste management practices in community pharmacies. The content was based on the 2016 chemical medical waste management guidelines and the GPP criteria. It consisted of 41 questions assessing situation and challenges in pharmaceutical waste management in community pharmacies.

1.3 Instrument validation

The content validity, language, and completeness of the questionnaire were evaluated by a panel of five experts specifically two faculty members specialized in pharmaceutical sciences, one faculty member specialized in environmental management, one pharmaceutical waste management specialist from the Food and Drug Administration, and one senior policy and planning analyst from the Department of Health, Ministry of Public Health, Thailand. The experts assessed the alignment between the questionnaire items and the research objectives using the Item Congruence Index (IOC). The evaluation criterion was set at IOC $\geq$ 0.5. The questions were found to have a high content validity with the overall IOC of 0.94.

Step 2: Surveying current pharmaceutical waste management practices in community pharmacies.

2.1 Population and sample group

The study population consisted of 432 community pharmacies licensed by the Songkhla Provincial Public Health Office. These included (i) modern medicine pharmacies, (ii) pre-packaged modern medicine pharmacies, (iii) pre-packaged modern medicine pharmacies for animals, and (iv) modern medicine wholesale pharmacies.

The sample was selected from those in the study population whose operators were willing to provide the information. The sample size was calculated using Cochran's formula of $n_0 = z^2.p.q / e^2$ and $n = n_0 / (1 + (n_0 - 1)/N)$[11], where N was the total number of pharmacies in Songkhla Province (432 pharmacies), e was the sampling error of 0.05, Z was the z-score at a significance level of 0.05 equal to 1.96, and p is the proportion of proper pharmaceutical waste management, based on a 2019 study by Michael et al., which found that 23.4% of pharmacies managed pharmaceutical waste correctly according to the Nigerian Food and Drug Administration guidelines,[12] and q was 1 – p. With the known finite sampling frame n_0 of 432, the sample size (n) of 167 pharmacies was required.[11] To account for a potential 30% dropout rate and/or incomplete data, the target sample size was 217 pharmacies.

2.2 Variables and their definitions

In this study, pharmaceutical waste referred to unused, deteriorated, or expired drugs or pharmaceutical products, including packaging that has been in contact with the medications.[10] Pharmaceutical waste management referred to the processes of segregation, collection, transportation, and disposal of pharmaceutical waste.[13] This study evaluates the knowledge and waste management practices of pharmacies in only three stages: segregation, collection, and disposal. Segregation meant the classification of pharmaceutical waste.[13] Collection referred to the gathering of segregated pharmaceutical waste for subsequent disposal.[13] Transportation meant the movement of pharmaceutical waste to disposal sites.[13] Disposal was defined as the process of destroying pharmaceutical waste through incineration or other standardized methods for hazardous waste disposal.[13] Hazardous drugs were antibiotics, hormones, drugs prohibited for use in pregnant women, immunosuppressants, antivirals, and cancer medications.[10] General drugs refer to modern medicines with low levels of danger, which are not classified as hazardous drugs. This term also includes traditional medicines and herbal remedies drug.[10]

2.3 Research instruments

The questionnaire developed by the researcher was divided into two parts as follows. **Part 1** collected **general**

information about the community pharmacy operators consisting of six items specifically gender, age, position, job tenure, type of pharmacy, and types of drugs available in the pharmacy. **Part 2** consisted of 41 multiple-choice questions regarding pharmaceutical waste management. These questions covered **four steps of current waste management practice** (i.e., segregation, collection, transportation, and disposal). Open-ended questions on challenges, obstacles, and suggestions were also included.

2.4 Data collection

We recruited the sample group using the convenience sampling method. Additionally, due to the impact of the COVID-19 pandemic, we adjusted the data collection approach. Originally, we distributed questionnaires through Line groups, provincial-level meetings, and postal mail, which resulted in a response rate of less than 15%. We then changed the data collection method to in-person questionnaire distribution, conducted between May 1, 2021, and July 31, 2022, ultimately achieving a total of 217 sample sites as targeted. The respondents self-completed the questionnaires; however, in cases where participants were unable to do so, the researchers conducted interviews and recorded the data on their behalf.

2.5 Data analysis

Descriptive statistics, including frequency and percentage, were used for the analysis of quantitative data, such as the number of respondents, methods of segregation, and pharmaceutical waste disposal methods. For the analysis of qualitative data regarding challenges and obstacles in waste management, such as problematic steps, causes of issues, and recommendations for pharmaceutical waste management, the researcher employed thematic analysis. This method was used to compile data obtained from open-ended questions and organize responses into groups based on relevant themes. Additionally, the frequency of each theme was categorized.

Step 3: Assessing the severity of pharmaceutical waste management situation in community pharmacies and recommendations for improving GPP criteria

3.1 Development of guidelines for assessing severity of situation

The development of these questions was as follows. The questions were based on a comparison of the survey results of pharmacy behaviors obtained in Step 2 with the guidelines for pharmaceutical waste management specified in Thailand's manuals. This comparison aimed to evaluate the extent to which current behaviors reflect the knowledge and practices of pharmacy operators in managing waste correctly according to the aforementioned criteria.

The standard guidelines, such as the 2016 Guidelines for the Management of Chemical Medical Waste, are designed for healthcare facilities in general. The GPP criteria also do not provide clear guidelines for pharmaceutical waste management. Therefore, we developed the GPP-Waste (GPP-W) criteria by integrating information from these two guidelines. The goal was to create the assessment criteria that were comprehensive and more suitable for the context of community pharmacies, enabling effective evaluation of pharmacy operators' knowledge and practices regarding pharmaceutical waste management. The development process was as follows.

The criteria specific community pharmacy were developed to assess only three steps in waste management specifically segregation, collection, and disposal. The criteria did not include waste transportation since the guidelines for transportation are specifically outlined in ‘The standards for hospital sanitation and safety’[13], which are for managing various types of waste in hospitals. In contrast, the 2016 chemical medical waste management guideline and GPP criteria do not provide any details regarding waste transportation.

For assessment issues where the GPP criteria have already specified details, we used such criteria. This included, for example, the pharmaceutical waste segregation, which we evaluated whether the pharmacy correctly follows the guidelines by segregating waste into red trash bags labeled with the words "hazardous waste," as stipulated by the GPP.

Regarding issues where the GPP criteria lack detailed specifications, we added criteria stated in the 2016 guidelines. For example, the GPP criteria do not provide clear details on packaging separation (Table 2). We added criteria from the 2016 guidelines, which require the separation of drugs from their packaging and disposal as hazardous waste.

3.2 Assessing the severity of pharmaceutical waste management situation in community pharmacies

We assessed the severity of the situation by evaluating the knowledge and proper management of pharmaceutical waste among pharmacy operators. The steps involved are as follows.

We compared the responses from the survey on pharmacy behaviors obtained from Step 2 with the three evaluation criteria specifically 1) the 2016 chemical medical waste management guidelines 2) the GPP criteria, and 3) GPP-W criteria (Table 2).

We assessed the knowledge and proper pharmaceutical waste management practices according to the criteria by converting survey responses into scores for knowledge and correct practices based on the criteria. Scores were calculated only for questions that could evaluate the accuracy of knowledge and practices (Table 5). In contrast, questions that merely requested information and could not assess accuracy were not included in the scoring. Examples of questions excluded from scoring include those asking for reasons why pharmaceutical waste was not segregated from other types of waste or was occasionally segregated. Answers that agreed with the criteria were given 1 point while those not agreeing with the criteria were given 0 points.

We converted the scores for knowledge and practice scores into a standardized 100-point scale, where a score of 100 indicates that the pharmacy fully complied with all criteria for proper pharmaceutical waste management. Subsequently, the average scores obtained from the GPP criteria, the GPP-W criteria, and the 2016 chemical medical waste management guidelines were compared. The purpose of this step was to reflect the severity of the pharmaceutical waste management situation when using assessment tools with varying degrees of strictness. Furthermore, it provided valuable insights to determine whether the GPP criteria need to be revised to better suit the operational context of community pharmacies moving forward.

3.3 Data collection procedure

We recruited the participants using the convenience sampling method. Additionally, due to the impact of the COVID-19 pandemic, we adjusted the data collection approach. Originally, we distributed questionnaires through Line groups, provincial-level meetings, and postal mail, which resulted in a response rate of less than 15%. We then changed the data collection method to in-person questionnaire distribution, conducted between May 1, 2021, and July 31, 2022, ultimately achieving a total of 217 sample sites as targeted. The participants self-administered the questionnaires. However, in cases where participants were unable to do so, the researchers conducted interviews and recorded the data on their behalf.

3.4 Data analysis

Descriptive statistics including frequency and percentage and mean with standard deviation were used to summary demographic characteristics and data of methods of segregation, and pharmaceutical waste disposal. For qualitative data regarding challenges and obstacles in waste management, such as problematic steps, causes of issues, and recommendations for pharmaceutical waste management, the researcher employed thematic analysis to obtain relevant themes. Additionally, the frequency of each theme was categorized.

Results

Of the 217 participating community pharmacies, pharmacists accounted for 80.65% of the respondents, with the majority (90.78%) operating as modern drugstores (Type 1). More than half of these pharmacies (54.84%) were in Hat Yai district (Table 3).

Situation and challenges in pharmaceutical waste management in community pharmacies (Table 4)

For **segregation**, 65.90% of 217 pharmacies reported segregating pharmaceutical waste from other types of waste every time, and 79.26% classified pharmaceutical waste as hazardous waste. However, most community pharmacies used segregation methods that do not comply with GPP, the gold standard for practice in community pharmacies in Thailand. For example, 31.31% of community pharmacies used waste bags of the same color as general waste for pharmaceutical waste and did not label them accordingly. Moreover, 79.26% of community pharmacies stored all types of pharmaceutical waste together without categorizing them into subcategories based on the level of drug hazard before disposal. In contrast, only 27.27% of community pharmacies adhered to the GPP criteria by using properly labeled bags marked as "hazardous waste."

Regarding **collection and transportation**, **t**he majority of community pharmacies (48.85%) properly collected pharmaceutical waste in compliance with the GPP criteria by

storing expired drugs separately in tightly sealed containers with clear labels. Most community pharmacies transport pharmaceutical waste for disposal every month (32.26%), followed by every six months (24.88%).

In terms of **disposal**, 67.44% of community pharmacies disposed of pharmaceutical waste by returning it to the manufacturer, which is compliant with the GPP criteria. However, 172 pharmacies (79.26%) disposed of pharmaceutical waste without sorting it by type. Additionally, some community pharmacies used methods for disposing of pharmaceutical waste as general waste, such as disposing of it with general waste (54.07%) and sending it to local administrative organizations for landfill disposal (7.21%). These practices did not comply with GPP criteria, which require expired drugs to be treated as hazardous waste. Furthermore, most community pharmacies (94.01%) did not serve as collection points for unused community medications to be properly destroyed, primarily due to the complexity of the process (67.59%) (Table 4).

Lastly, for **challenges and suggestions**, the most problematic step in managing pharmaceutical waste was disposal (79.26%). The main reasons for this included lack of knowledge on proper management (32.56%), complicated procedures (25.00%), and the lack of community collection points for pharmaceutical waste (13.95%). Additionally, community pharmacies provided suggestions for improving pharmaceutical waste management, including establishing a responsible agency (36.41%), setting community collecting points (21.20%), providing education on pharmaceutical waste management (18.89%), creating clear guidelines (10.60%), and having government agencies providing waste collection services directly to pharmacies (6.45%).

Discussions and Conclusion

A survey on pharmaceutical waste management situation in community pharmacies in Songkhla province found that many pharmacies managed pharmaceutical waste improperly, with an average score of knowledge and compliance with GPP criteria of 55.67 out of 100 points. Most community pharmacies (79.26%) did not categorize medications before disposal. A significant portion (54.07%) disposed of pharmaceutical waste by mixing it with general waste, which may lead to environmental contamination. Pharmacy operators revealed that the disposal step was the most significant challenge (79.26%) due to a lack of knowledge in proper guidelines (32.56%). One contributing factor to the improper pharmaceutical waste management may be the GPP criteria, which currently do not provide clear or comprehensive guidelines for pharmaceutical waste management, especially when compared to the chemical medical waste management guideline, 2016. Specifically, the GPP criteria lack detailed guidance on waste segregation and disposal. To address this issue, this study proposed the introduction of GPP-Waste (GPP-W) criteria as a tool to promote more effective pharmaceutical waste management in community pharmacies. The GPP-W criteria integrated the chemical medical waste management guideline, 2016 with the existing GPP framework.

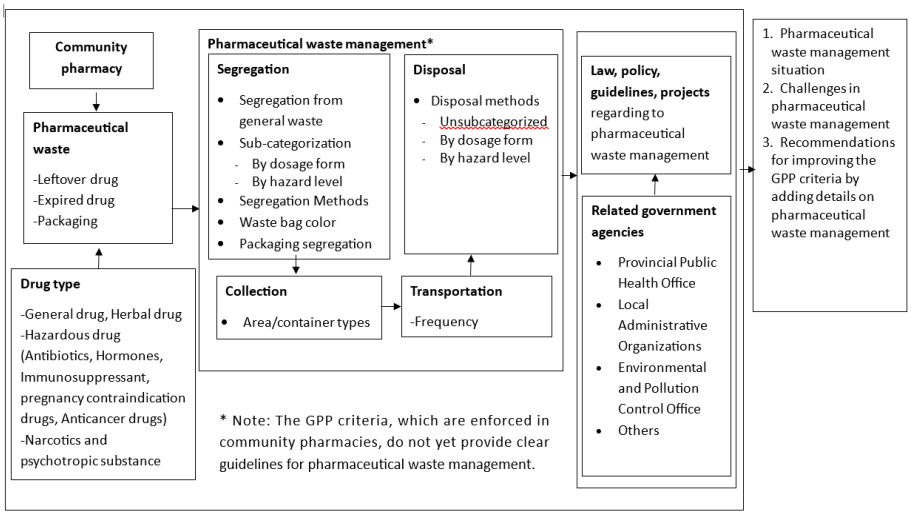

Figure 1 Study conceptual framework.

Table 1 Comparison of waste management guidelines between 1.) Guideline for the management of chemical medical waste, 201610 and 2.) GPP Criteria.[9]

Steps	Assessed issues	Details specified in the criteria		Conclusion by the researcher
		Chemical medical waste management guidelines, 2016[10]	GPP[9]	
Segregation	Waste classification การคัดแยกยาทั่วไป General drug segregation	- Hazardous waste - Grey waste bags with 'Hazardous waste' labeled - Red bin	- Hazardous waste - Red waste bags with 'Hazardous waste' labeled	- GPP criteria using the same guideline to manages all types of drugs, without based on the level of drug hazard, and does not prioritize the packaging segregation.
	Hazardous drug segregation (e.g. antibiotics, hormone drugs, drugs contraindicated in pregnancy)	- Purple waste bags with 'Hazardous waste' labeled - Purple bin	- Red waste bags with 'Hazardous waste' labeled	
	Packaging segregation	- Removed the outer packaging from the pharmaceuticals - Inner packaging that contacts pharmaceuticals such as blister packs are considered as hazardous waste	- Not specified	
Collection	Waste container	- Red bin or purple bin up to type of drug	- Designated area or container (e.g. a crate or plastic box with a tight lid) for storing expired or degraded drug with a clear sign to wait for return to manufacturer or disposal	- GPP criteria does not specify that community pharmacies must collect pharmaceutical waste in waste bins and color-coded according to the level of drug hazard, but allows for the waste to be stored in a clearly designated area or any container, with clearly labeled.
Disposal	Goal of waste disposal	- Dispose as hazardous waste and categorized hazardous level of drug	- In case of unable return medicine to manufacturer, managed as hazardous waste - There are measures to prevent the reuse of awaiting return or expired drug	- GPP criteria only specify the goal of waste disposal but do not provide details of disposal method and the prevention of expired drug reuse. GPP also does not clearly specify environmentally friendly procedures. This may lead community pharmacies to use improper practices to prevent expired drug reuse such as flushing down the toilet or sink.
	Disposal method for hazardous drugs	- Return to manufacturer - Dispose as hazardous waste by incineration at least 850 °C	- Return to manufacturer or managed as hazardous waste	
	Disposal method for general drugs	- Return to manufacturer - Dispose as hazardous waste by incineration at least 1200 °C	- Return to manufacturer or managed as hazardous waste	

Table 2 Comparison of criteria for assessing knowledge and practices regarding pharmaceutical waste management of pharmacy operators.

Steps	Assessment issues	Chemical medical waste management guidelines, 2016[10]	GPP[9]	GPP-W	
				Details	Ref.
Segregation	Waste classification	- Hazardous waste	- Hazardous waste	- Hazardous waste	GPP and Chemical medical waste management guidelines, 2016
	General drug segregation	- Grey waste bags with 'Hazardous waste' labeled - Red bin	- Red waste bags with 'Hazardous waste' labeled	- Red waste bags with 'Hazardous waste' labeled	GPP
	Hazardous drug segregation (e.g. antibiotics, hormone drugs, drugs contraindicated in pregnancy)	- Purple waste bags with 'Hazardous waste' labeled - Purple bin	- Red waste bags with 'Hazardous waste' labeled	- Red waste bags with 'Hazardous waste' labeled	
	Packaging segregation	- Removed the outer packaging from the pharmaceuticals - Inner packaging that contacts pharmaceuticals such as blister packs are considered as hazardous waste	- Not specified	- Removed the outer packaging from the pharmaceuticals - Inner packaging that contacts pharmaceuticals as blister packs is considered as hazardous waste	Chemical medical waste management guidelines, 2016
Collection	Waste container	- Red bin or purple bin up to type of drug	- Designated area or container for storing expired or degraded drug with a clear sign	- Designated Area or container for storing expired or degraded drug with a clear sign	GPP
Disposal	Disposal method for general drugs	- Return to manufacturer - Dispose as hazardous waste by incineration at least 850 °C	- Return to manufacturer or managed as hazardous waste	- Return to manufacturer - Dispose as hazardous waste by incineration at least 850 °C	Chemical medical waste management guidelines, 2016
	Disposal method for Hazardous drugs	- Return to manufacturer - Dispose as hazardous waste by incineration at least 1200 °C	- Return to manufacturer or managed as hazardous waste	- Return to manufacturer - Dispose as hazardous waste by incineration at least 1200 °C	

Table 3 Socio-demographic characteristics of respondents (N = 217).

Characteristics	N (%)
1. Age (years)	
- 20 - 29	25 (11.52)
- 30 - 39	100 (46.08)
- 40 - 49	44 (20.28)
- 50 - 59	32 (14.75)
- ≥ 60	16 (7.37)
2. Duration of working (years)	
- 1-5	87 (40.09)
- 6 - 10	47 (21.66)
- 11 - 15	39 (17.97)
- 16 - 20	9 (4.15)
- 21 - 25	3 (1.38)
- ≥ 25	21 (14.75)
3. The role of respondents	
- Pharmacists	175 (80.65)
- Owner of pharmacy (non-health care professional)	21 (9.68)
- Pharmacist assistant	18 (8.29)
- Others	2 (1.38)
4. Type of pharmacy	
- Modern medicine pharmacy (Type 1)	197 (90.78)
- Pre-packaged modern medicine pharmacies (Type 2)	16 (7.37)
- Modern medicine pharmacy (Type 1) with a license to sell narcotics or psychotropic substance schedule 3 or schedule 4	2 (0.92)
- Pre-packaged modern medicine pharmacies for animals (Type 3)	2 (0.92)

Table 4 Situations and challenges in managing pharmaceutical waste in community pharmacies categorized by steps.

Items	Number of respondents (N = 217)	Number (%)
Pharmaceutical waste segregation		
1. Segregation from other wastes	217	
- Every time*		143 (65.90)
- Sometimes		55 (25.35)
- Never segregated		19 (8.76)
2. Reason for not segregation or segregation sometimes	74	
- Lack of knowledge on waste segregation		41 (88.97)
- Complicated procedure		20 (43.4)
- Don't know that the segregation is necessary		8 (17.36)
- Others		5 (10.85)
3. Classification of pharmaceutical waste	217	
- Hazardous waste*		172 (79.26)
- General waste		41 (18.89)
- Infectious waste		4 (1.84)
4. 4. Segregation methods (if answer segregation every time or sometimes)	198	
- Placed in bags of the same color as general waste, without any labeling		62 (31.31)
- Separately bagged and labeled as "Hazardous Waste."		54 (27.27)
- Others		82 (41.41)
5. 5. Waste bag colors	198	
- Not specified color		100 (50.51)
- Red*		65 (32.83)
- Black		22 (11.11)
- Others		11 (5.56)
6. Sub-classification of pharmaceutical waste	217	
- Not sub-classified (all types collected)		172 (79.26)
- Sub-classified		
- By dosage forms		38 (17.51)
- By hazardous level of drugs		5 (2.30)
- By dosage forms and hazardous level of drugs		2 (0.92)
		(Contd.)

Table 4 Situations and challenges in managing pharmaceutical waste in community pharmacies categorized by steps. **(Contd.)**

Items	Number of respondents (N = 217)	Number (%)
7. Packaging segregations		
7.1 Blister packs	144	
- General waste		87 (60.42)
- Hazardous waste		50 (34.72)
- Others		7 (4.86)
7.2 Glass Bottles	89	
- General waste		59 (66.29)
- Hazardous waste		41 (46.07)
- Others		28 (21.46)
Pharmaceutical waste collection		
1. Collection methods	217	
- Separately keeps in tightly closed containers with labeled*		106 (48.85)
- Separately keeps in designated area with labeled*		90 (41.47)
- Keeps together with other types of waste in the store		19 (8.76)
- No area or container for separate storage		2 (0.92)
Pharmaceutical waste transportation		
1. Frequency of transport pharmaceutical waste to disposal	217	
- Monthly		70 (32.26)
- Every 6 months		54 (24.88)
- Every 1 year		28 (12.90)
- Others		65 (29.95)
Pharmaceutical waste disposal		
1. Disposal methods if not sub-classification (Multiple responses allowed)	172	
- Return to manufacturer*		116 (67.44)
- Dispose together with general waste		93 (54.07)
- Return to drug wholesaler*		80 (46.51)
- Flushing down the toilet or sink		31 (18.02)
- Sent to local administrative organizations for disposal as general waste		12 (6.98)
- Sent to hospital*		10 (5.81)
- Others		8 (4.65)
2. Disposal methods if sub-classified by dosage form (Multiple responses allowed)	38	
2.1 Solids	38	
- Return to manufacturer*		22 (57.89)
- Dispose together with general waste		17 (44.74)
- Return to drug wholesaler*		14 (36.84)
- Others		19 (50.00)
2.2 Liquids	38	
- Flushing down the toilet or sink		19 (50.00)
- Return to manufacturer*		18 (47.37)
- Return to drug wholesaler*		4 (10.53)
- Others		6 (15.79)
2.3 Semi-solids	38	
- Dispose together with general waste		19 (50.00)
- Return to manufacturer*		19 (50.00)
- Return to drug wholesaler*		10 (26.32)
- Others		8 (21.05)
3. Unused medication collection points in community	217	
- No collection service for unused medications		204 (4.01)
- Unused medications are only accepted if patients bring them in themselves		12 (5.53)
- There is a service point for collecting unused medications		1 (0.46)
4. Reasons for not providing a community unused medication collection point	216	
- Complicated procedure		146 (67.59)
- No inquiries or returns from citizens		35 (16.20)
- The local administrative organization already has a system for managing and disposing of unused medications		14 (6.48)
- Lack of knowledge on proper management		5 (2.30)
- Others		16 (7.41)
		(Contd.)

Table 4 Situations and challenges in managing pharmaceutical waste in community pharmacies categorized by steps. **(Contd.)**

Items	Number of respondents (N = 217)	Number (%)
Challenges and suggestions		
1. The most challenging step in pharmaceutical waste management	217	
- Disposal		172 (79.26)
- Segregation		32 (14.75)
- Collection		7 (3.23)
- Transportation		6 (2.76)
2. The reasons why disposal is considered the most problematic step (Multiple responses allowed)	172	
- Lack of knowledge/guidelines on proper management		56 (32.56)
- Complicated procedure		44 (25.38)
- Lack of community collecting points		30 (17.44)
- Unclear guideline		16 (9.30)
- Improper disposal methods would affect the environment		8 (4.65)
- High cost		6 (3.49)
- The manufacturer does not accept returned medicines for disposal		6 (3.49)
- Others		11 (6.40)
- Nonresponse		16 (9.30)
3. Suggestions (Multiple responses allowed)	217	
- Establishing responsible agency		79 (36.41)
- Setting up community pharmaceutical waste collecting points		46 (21.20)
- Providing education in pharmaceutical waste management guideline		41 (18.89)
- Creating clear pharmaceutical waste management guidelines		23 (10.60)
- Offering pharmaceutical waste collection services directly at community pharmacies		14 (6.45)
- Managing to reduce expired drug		10 (4.61)
- Establishing law regarding pharmaceutical waste management		6 (2.76)
- The manufacturer should take drug back for disposal		4 (1.84)
- Others		8 (3.69)
- Nonresponse		30 (13.82)

Note: * Correct methods according to GPP criteria.[9]

Table 5 Knowledge and practices scores in pharmaceutical waste management of pharmacy operators categorized by steps and criteria.

Steps	Knowledge and practices scores according to criteria*, points (full score of 100)					
	Chemical medical waste management guidelines, 2016[10]		GPP[9]		GPP-W	
	No. of questions	Average score (SD)	No. of questions	Average score (SD)	No. of questions	Average score (SD)
Segregation	12	21.47 (22.22)	4	50.00 (30.43)	12	30.84 (23.46)
Collection	1	0.00	1	90.32 (29.63)	1	90.32 (29.63)
Disposal	18	31.00 (43.19)	4	46.15 (47.19)	18	31.00 (43.19)
Sum	31	21.28 (19.72)	9	55.67 (24.43)	31	36.08 (21.00)

Note * Shows only scores from questions that must evaluate the accuracy of knowledge and practices. A score of 100 means the pharmacy has managed pharmaceutical waste correctly in all assessment questions.

Community pharmacy stores still exhibited improper management of pharmaceutical waste. Based on the GPP criteria, pharmacies scored only 55.67 out of 100 points in the assessment of knowledge and practices in pharmaceutical waste management. The scores for waste segregation and disposal did not exceed 50 points. The study also found that only 27.27% of pharmacies complied correctly with the GPP criteria, which require the segregation of pharmaceutical waste into red bags labeled "hazardous waste." These findings are consistent with international research that found improper pharmaceutical waste management in community pharmacies. For example, in Palestine, 48.3% of community pharmacies disposed of pharmaceutical waste by discarding it in trash bins, while only 5.8% disposed of it correctly by incineration.[14] Furthermore, these results are consistent with a 2014 study in Thailand by Arkaravichien et al which investigated pharmaceutical waste management among the general public. The study found that over 90% of the individuals managed pharmaceutical waste improperly by discarding it in general trash bins, flushing it into sewage systems, or storing it at home without proper disposal.[7]

The current GPP criteria enforced for community pharmacies in Thailand do not place significant emphasis on the management of pharmaceutical waste. A comparison of relevant guidelines, including the GPP criteria and the 2016 Guideline, shows that the GPP criteria lack detailed provision for the segregation of hazardous drugs such as antibiotics, the segregation of drugs from their packaging, and proper pharmaceutical waste disposal methods. Meanwhile, the study results also revealed that community pharmacies scored an average of no more than 50 points in assessment of their knowledge and capability in managing pharmaceutical waste, particularly in the steps of segregation and disposal, whether evaluated using the GPP standards, GPP-W standards, or the 2016 Guidelines. This demonstrates that community pharmacies lacked knowledge, leading to improper practices in these steps (segregation and disposal), which are areas where the GPP standards do not provide clear details. These findings align with research conducted in Nigeria which found that the unclear guidelines for pharmaceutical waste management resulted in only 23.40% of community pharmacies managing pharmaceutical waste correctly, in accordance with the guidelines of the Food and Drug Administration.[12]

The GPP criteria should include more detailed guidelines on pharmaceutical waste management tailored to the context of retail pharmacies. Based on an assessment of relevant knowledge and practice of pharmaceutical waste management according to the GPP criteria, the GPP-W criteria, and the chemical medical waste management guideline, 2016, it was

found that the scores obtained aligned with the level of strictness of the criteria, from the least to the most stringent. Specifically, the GPP criteria currently lack detail to adequately assess the situation of pharmaceutical waste management in community pharmacies. On the other hand, the chemical medical waste management guideline, 2016, which is more detailed, is still not entirely suitable for the context of community pharmacies, as they are designed to address waste management in hospitals, which handle a wider variety of drugs. Therefore, improving the GPP criteria by adding details on pharmaceutical waste management is crucial for pharmacy operators, officers who regulate community pharmacies, and the Ministry of Public Health. This will enable better monitoring of pharmaceutical waste management, which is classified as hazardous waste, and help reduce long-term environmental impacts within communities.

The lack of knowledge in pharmaceutical waste disposal methods may be another major reason why community pharmacies manage pharmaceutical waste incorrectly. The study results revealed that 79.26% of community pharmacies identified the disposal process as a significant challenge in pharmaceutical waste management, with 32.56% attributing this to a lack of awareness of proper practice. These findings align with a study conducted in India which found that the lack of knowledge among staff led to improper practices.[15] Similarly, a 2011 study in Nigeria by Ngwuluka et al recommended promoting knowledge to enhance staff compliance with guidelines.[16] Further literature review highlighted a 2023 study by Bou-Saba et al in Lebanon which proposed various strategies to enhance compliance with the GPP standards in pharmacies including increasing knowledge and awareness among pharmacists and implementing regular monitoring.[17]

Improper management of pharmaceutical waste in drugstores may lead to long-term environmental impacts. We found that 172 out of 217 community pharmacies (79.29%) disposed of pharmaceutical waste by dumping it together with general waste which is an incorrect method according to the chemical medical waste management guideline, 2016. The guideline recommends classifying pharmaceutical waste as hazardous waste and segregating it based on the drug hazard level. General drugs should be incinerated at temperatures exceeding 850 degrees Celsius. Hazardous drugs, such as antibiotics, should be incinerated at temperatures above 1200 degrees Celsius.[10] These findings are consistent with a 2020 study in Pakistan where 61.9% of drugstores disposed of pharmaceutical waste as general waste.[17] Additionally, a 2018 study by Velpandian et al in India found that burying pharmaceutical waste with general waste led to the accumulation of drugs in the environment, especially antibiotics, which could exacerbate the issue of antimicrobial resistance.[18]

Pharmacy operators need a convenient and environmentally compliant method for disposing of pharmaceutical waste. Survey results revealed that, aside from a lack of knowledge about proper management, the next major issues in pharmaceutical waste disposal for pharmacies were the complexity of the methods or procedures (25.38%) and the absence of community collection points for such waste (17.44%). Pharmacies suggested that there should be a responsible agency for managing pharmaceutical waste (36.41%) and that collection points should be established in communities (21.20%). These findings align with a 2023 study by Nairat et al in Palestine which identified multiple challenges in pharmaceutical waste management in pharmacies including a lack of knowledge and awareness (84.80%), difficulties in sending pharmaceutical waste for disposal due to unclear policies (59.50%), and the absence of designated disposal facilities (34.80%). Pharmacists recommended that Palestine establish an accessible pharmaceutical waste disposal system for citizens through community pharmacies (97.3%) and the government support the costs of pharmaceutical waste disposal (77.50%).[14]

This study has certain limitations. We had to adjust the data collection method to on-site fieldwork due to the impact of the COVID-19 situation, which significantly reduced cooperation with the original data collection plan. Excluding the findings and challenges of pharmaceutical waste management from the perspectives of other healthcare facilities and the general public, we planned to publish these findings at a later stage. The study was conducted only in the Songkhla province, so the findings may not fully represent the situation in community pharmacies across Thailand. This research did not investigate the quantity of pharmaceutical waste generated in community pharmacy. The GPP-W criteria, which propose improvements to the GPP criteria, should undergo validity testing before being applied in practice.

Based on study findings and conduct, some recommendations for practice, policy and future research are

made. Regulatory agencies overseeing pharmaceutical waste management, such as Provincial Public Health Offices and the Food and Drug Administration (FDA), can use the findings from this study to improve policies and implement measures to enhance pharmaceutical waste management in community pharmacies. These include information dissemination of guidelines to pharmacy operators, revision of GPP criteria, and enforcement of legal measures requiring community pharmacies to take responsibility for their own pharmaceutical waste.

The Food and Drug Administration should revise GPP criteria to include pharmaceutical waste management. The suggestion from this study can be applied as a preliminary framework to improve GPP criteria, alongside a review to ensure alignment with current hazardous waste regulations. For example, improper disposal methods, such as flushing down toilets, should be classified as a critical defect. However, the proposed GPP-W criteria are preliminary and have limitations; their application should be reviewed by experts and validated for accuracy.

Many pharmacy operators still lack proper knowledge about pharmaceutical waste management. In the future, education should be provided through various channels, such as continuing pharmacy education articles, integrating content into pharmacy undergraduate curricula, and public relations information via Provincial Public Health Offices.

The Ministry of Public Health and relevant government agencies, such as local administrative organizations, should further discuss appropriate and environmentally safe pharmaceutical waste disposal methods tailored to community pharmacy contexts. For example, municipalities could offer waste collection services for community pharmacies or establish hazardous waste collection points in the community, as stipulated in the Ministerial Regulation Management of Toxic and Hazardous Waste from Communities (2020).[19] This regulation mandates local administrative organizations to manage hazardous waste in communities, including pharmaceuticals and medical supplies. In the future, a survey to quantify the amount of pharmaceutical waste generated could be beneficial for calculating the costs associated with pharmaceutical waste management in community pharmacies.

In conclusion, community pharmacies in Songkhla province managed pharmaceutical waste incorrectly, especially in segregation and disposal steps. Most community pharmacies lacked knowledge of proper pharmaceutical waste management practices. Furthermore, the GPP criteria, which is the standard guidelines for regulating community pharmacies, provided only broad recommendations for pharmaceutical waste management. Therefore, the Food and Drug Administration (FDA) should support proper waste management through various measures, such as revising the GPP criteria to include more detailed guidelines on pharmaceutical waste management, communicating correct pharmaceutical waste management practices to licensed community pharmacies, and implementing regular monitoring and enforcement to ensure compliance. These steps would promote proper pharmaceutical waste management in community pharmacies, reduce pharmaceutical contamination in the environment, and prevent long-term environmental impacts on communities.

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