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Implementation of Standards for Managing Pharmaceutical, Medical Devices and Disposable Medical Materials in Community Pharmacy in Medan City

Wiryanto Wiryanto[1], Harri Tanjung[1*], Reski Rumonda[2]

[1]Pharmacists Education Program of Pharmacy Faculty, Universitas Sumatera Utara, Medan, Indonesia; [2]Bachelor of Pharmacy Program of Pharmacy Faculty, Universitas Sumatera Utara, Medan, Indonesia

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***Correspondence:** Harri Tanjung. Pharmacists Education Program of Pharmacy Faculty, Universitas Sumatera Utara, Medan, Indonesia. E-mail: harri@usu.ac.id

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Abstract

BACKGROUND: The implementation of pharmacy service standards is a way to implement the practice philosophy, which in essence aims to protect the public from unprofessional pharmaceutical services. The Indonesians standard of pharmacy services has been updated several times according to the development of legal requirements in the community pharmacy setting.

AIM: This study aimed to evaluate the implementation of pharmacy service standards for managing pharmaceuticals, medical devices and disposable medical materials at pharmacies.

METHODS: The study was conducted with a descriptive method using a cross sectional survey research design, with a checklist as an instrument for retrieving variable data on pharmaceutical services at pharmacies in the city of Medan, Indonesia. The study was conducted from July to November 2018.

RESULTS: The overall standard implementation from 99 pharmacies showed that 72 pharmacies were at a good level (72.72%), fair level as many as 26 pharmacies (26.26%) and 1 pharmacy in bad level (1.02%).

CONCLUSION: The study result revealed that even though the level of implementation was good but there were some elements that have high level of "done but not documented" (especially in planning and destruction/withdrawal standards). There were many aspects that must be improved especially the documentation aspect and require cooperation from all relevant parties.

Introduction

The standards of pharmaceutical services of community pharmacies No.73 / 2017 consists of two areas; standards of pharmacy management and clinical pharmacy services. All of the regulations were the government policies to support the implementation of pharmaceutical care practice in Indonesia [1], [2].

Clinical pharmacy is the practice of pharmacy as part of a multidisciplinary healthcare team directed at achieving quality use of medicines. By working with other professionals, healthcare or otherwise, pharmacists can lend their drug knowledge expertise to help identify and solve medication related problems and increase patient safety [3], [4], [5], [6].

After a prescription prescribed, pharmacists perform medication review of prescription to assess the medication appropriateness and identify drug therapy problems that may be actual or potential to occur. Pharmacist ensures that patients receives the most appropriate medicine for their medical condition / disease state, the most appropriate dose and dosage form, that timing of dosage and the duration of therapy is appropriate and that medicine-related problems are minimized. Pharmacists contact the prescriber if there are any discrepancies / errors. Pharmacists also have a responsibility to provide patients with information and education to encourage the safe and appropriate use of medicines [7], [8], [9], [10].

The implementation of clinical pharmacy services can only be carried out if the pharmacy can provide medicines in the right type, quantity and quality. This requires the application of standard pharmacy management in managing medicines at the

pharmacy [11].

However, there was no data about the implementation of pharmacy management standards for community pharmacies especially in Medan city even though the regulations were already published by the Indonesian ministry of health years ago. This study aimed to describe the level of implementation of standards for managing pharmaceutical, medical devices and disposable medical materials for community pharmacy in the city of Medan, Indonesia.

Material and Methods

This study was a descriptive research that used a cross-sectional survey methodology. The level of implementation of standards for managing pharmaceutical, medical devices and disposable medical materials in community pharmacies obtained by direct survey to the selected community pharmacy at Medan city. The selection of community pharmacy was done by purposive random sampling method. Researcher was offered the pharmacists joined the study by a *whatsapp* and *facebook* apps groups and until the date line time there were 99 pharmacists that joined the study. The study was conducted on July to November 2018.

The pharmacists in selected community pharmacy was asked to fill the questioners that developed according to the standards for managing pharmaceutical, medical devices and disposable medical materials in community pharmacies that stated in the Indonesian ministry of health regulation No. 73 / 2017. The questioners consist of 17 (seventeen) element of management standard. The pharmacists were asked to choose the answer about the implementation of the 7 (seven) main elements in 3 (three) levels implementation; done and documented (score 2), done but not documented (score 1), not implemented (score 0).

The maximum questionnaire score was 34 and the pharmacy categorized into 3 categories based on the total score (total score of 17 standard items) of each pharmacy. Pharmacy categories based on scores were as follows: good (score 24-34), fair (score 12-23) and bad (score 0-11).

Results

The evaluation results of the implementation of the standards for managing pharmaceutical, medical devices and disposable medical materials in 99 community pharmacies showed that the overall level of application of standards was at a good level with an average score of 27.07 ± 5.54. The number of pharmacies included in the good category were 72 pharmacies (72.72%). Distribution of respondents by category revealed in table 1.

Table 1: Pharmacies category distribution based on implementation of pharmacy management standards.

No	Category	No	(%)
1	Good	72	72.72
2	Fair	26	26.26
3	Bad	1	1.02
	Total	99	100.0

Implementation of pharmaceutical service standards for managing pharmaceuticals, medical devices and disposable medical materials in community pharmacies measured in accordance with the Indonesian ministry of health regulation No. 73 / 2017 includes; planning, procurement, admission, storage, destruction and withdrawal, controlling, recording and reporting.

Planning

Forty-seven-point five percent respondents stated they planned to procure pharmaceuticals, medical devices and disposable medical materials by taking into account disease patterns, consumption patterns, culture and capabilities of the community but were not well documented. Distribution of respondents based on planning standards stated in Table 2.

Table 2: Distribution of pharmacies planning management standards implementation

Planning	Done and documented		Done but not documented		No implementation		Total	
	N	%	N	%	N	%	N	%
Make plans to procure pharmaceuticals, medical devices and disposable medical materials by taking into account disease patterns, consumption patterns, culture and capabilities of the community	43	43.4	47	47.5	9	9.1	99	100.0

Procurement

84.8% of respondents stated that they had procured pharmaceutical preparations through official chains of pharmaceutical distributors in accordance with statutory provisions and were well-documented. Distribution of respondents based on procurement can be seen in Table 3.

Table 3: Pharmacies distribution based on implementation of procurement standard

Procurement	Done and documented		Done but not documented		No implementation		Total	
	N	%	N	%	N	%	N	%
Procurement of pharmaceutical preparations through official chains of pharmaceutical distributors in accordance with statutory provisions	84	84.8	14	14.2	1	1.0	99	100.0

Pharmaceutical admission

Seventy-nine-point eight percent respondents stated that pharmaceutical admission process guarantees the suitability of the type of specifications, quantity, quality, time of submission and the price stated in the order letter with physical conditions that are well received and documented. Distribution of respondents based on pharmaceuticals admission can be seen in Table 4.

Table 4: Pharmacies distribution based on pharmaceuticals admission standards

Pharmaceuticals admission	Done and documented		Done but not documented		No implementation		Total	
	N	%	N	%	N	%	N	%
Pharmaceuticals admission process guarantees the suitability of the type of specification, quantity, quality, time of delivery and the price stated in the order letter with the physical condition received	79	79.8	18	18.2	2	2.0	99	100.0

Storage

Seventy-three-point eight percent respondents stated that the medicines were storage in the original container from the factory were well-documented. A total of 71 respondents stated that they did the storage conditions appropriately so that the security and stability of the medicines were well-documented and as many as 55 respondents stated that storage was not used for storing other items that could cause contamination and well-documented.

Table 5: Pharmacies distribution based on implementation of storage standards

No	Storage	Done and documented		Done but not documented		No implementation		Total	
		N	%	N	%	N	%	N	%
1	Storage of drugs / medicinal ingredients in the original container from the factory	73	73.8	23	23.2	3	3.0	99	100.0
2	Storage conditions are appropriate so that the safety and stability of the drug / medicinal ingredients is guaranteed	71	71.7	25	25.3	3	3.0	99	100.0
3	Storage is not used for storing other items that cause contamination	55	55.6	40	40.4	4	4.0	99	100.0
4	Paying attention to dosage forms and drug therapy classes and arranged alphabetically	69	69.7	25	25.3	5	5.0	99	100.0
5	Drug Expenditures use the FEFO (First Expire First Out) and FIFO (First In First Out) system	66	66.7	31	31.3	2	2.0	99	100.0

A total of 69.7% respondents stated that they pay attention to dosage forms and drug therapy classes and were arranged alphabetically and well-documented and as many as 66.7% respondents stated that drug expenditure uses FEFO (First Expire First Out) system and FIFO (First In First Out) and well documented. Meanwhile, there were about 23.2% to 40.4% of pharmacies that not documented the storage process.

Destruction and Withdrawal

50.5% respondents stated that expired or damaged drugs were destroyed according to the type and dosage form. A total of 48 people (48.5%) respondents said that prescriptions that have been stored for more than 5 (five) years can be destroyed, and as many as 56.6% respondents stated that storage is not used for storing other items that cause contamination. All of these activities were well documented.

Table 6: Pharmacies distribution based on implementation of destruction and withdrawal standard

No	Destruction and Withdrawal	Done and documented		Done but not documented		No implementation		Total	
		N	%	N	%	N	%	N	%
1	Expired or damaged drugs are destroyed according to the type and dosage form	50	50.5	42	42.4	7	7.1	99	100.0
2	Prescriptions that have been stored for more than 5 (five) years can be destroyed	48	48.5	38	38.4	13	13.1	99	100.0
3	Storage is not used for storing other items that cause contamination	56	56.6	39	39.4	4	4.0	99	100.0
4	Withdrawal of pharmaceutical preparations, medical devices and BMHP that do not meet statutory standards / provisions	54	54.5	36	36.4	9	9.1	99	100.0

Thirty-six-point four percent to 42.4% respondents were not documented the destruction and withdrawal process. Furthermore, there were 4% to 13.1% of respondents that not implemented the standards.

Controlling

Sixty-six-point seven percent respondents stated that they arranged the order system or procurement, storage and expenditure and as many as 55 people (53.5%) respondents stated that inventory control was done using 2 methods, stock cards manually or electronics, and these activities were well documented.

Table 7: Pharmacies distribution based on controlling standards implementation

No	Controlling	Done and documented		Done but not documented		No implementation		Total	
		N	%	N	%	N	%	N	%
1	Arrangement of order systems or procurement, storage and expenditure	66	66.7	28	28.3	5	5.0	99	100.0
2	Inventory control is done using 2 stock cards by manual or electronic method	53	53.5	31	31.3	15	15.2	99	100.0

Documentation and Report

Seventy-point seven percent respondents stated that records were carried out in each process of managing pharmaceutical preparations, medical devices, and disposable medical materials including procurement (order letters, invoices), storage (stock cards), delivery (receipts or sales receipts) and other records were adjusted to the needs of well-documented. 75.8% respondents stated that

pharmacies reporting the internal and external report.

Table 8: Pharmacies distribution based on documentation and report standard

No	Documentation and Report	Done and documented		Done but not documented		No implementation		Total	
		N	%	N	%	N	%	N	%
1	Recording is carried out in every process of managing Pharmaceutical Preparations, Medical Devices, covering procurement (order letters, invoices), storage (stock cards), delivery (notes or sales receipts) and other records according to needs.	70	70.7	25	25.3	4	4.0	99	100.0
2	Reporting consists of internal and external reporting. Internal reporting is reporting that is used for pharmacy management needs, including finance, goods and other reports.	75	75.8	20	20.2	4	4.0	99	100.0
3	External reporting is a report made to fulfill obligations in accordance with the provisions of legislation, including reporting of narcotics, psychotropics and other reporting	79	79.8	11	11.1	9	9.1	99	100.0

The results also revealed 11% to 25% pharmacies were not documented the reporting process and 4% to 9% pharmacies were not implemented the reporting standards.

Discussion

The implementation of management standards of pharmaceuticals, medical devices and disposable medical materials in the planning aspects are mostly already done, but more are not well-documented, which is as much as 47.5%. This showed that the pharmacies had not fully implemented the Indonesian ministry of health regulation No. 73 / 2017 concerning the standard of pharmacy service planning stage.

It can generally be seen that the procurement of pharmaceutical preparations through official channels in accordance with the provisions of more legislation has been carried out and was well documented, which is as much as 84.8%. Meanwhile, there were 14.2% pharmacies not documented the procurement process. This showed that the pharmacy has implemented the current regulation concerning the standard of pharmacy procurement services but need to improve the documentation of procurement process.

The results of this study were in line with the results of a research in Ketapang City [12] that concluded all pharmacies procure pharmaceutical preparations through official chain of pharmaceuticals distributors. All pharmacies always include proof / purchase invoices for each medicine they bought and were always recorded in the receipt book.

The study also revealed 28% to 31% pharmacies were not documented the controlling process and 5% to 15% pharmacies were not implement the controlling standards. The results of this study were different with the results of the study in Ketapang City [12] that stated from the 6 pharmacies studied, only 1 pharmacy has an electronic stock card, namely computerized, and 5 other pharmacies have a stock card manually. However, the results of this study were also different from the results of the research conducted by Somi [13] concluded 91.33% pharmacies have carried out the control phase well in East Flores Regency, Indonesia.

Overall, the study result revealed that even though the level of implementation was good but there are some elements that have high level of “done but not documented” (especially in planning and destruction / withdrawal standards). Good documentation constitutes an essential part of the quality assurance system. The purpose of documentation: proof of fact, record, regulatory requirements, quality maintenance and improvement, and controlling the process [14], [15].

This condition was becoming important problem to improve the implementation of the standards that must resolved together by the government, pharmacist’s professional organization, and other part of society in order to ensure the providing of the safe, qualified, and effective pharmaceutical services to the society. If not, we leaved ourselves and our society in danger.

In conclusion, the study result revealed that even though the level of management standards implementation was good but there were some elements that have high level of “done but not documented” (especially in planning and destruction/withdrawal standards). There were many aspects that must be improved especially the documentation aspect and require cooperation from all relevant parties.

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