Profile and Determinants of Compounding Services among Pharmacists in Indonesia

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Abstract

Introduction: Compounding practice in pharmacy is common, especially in the developing countries. However, the practice of compounding has not been well standardized, as it may lead to cross-contamination or low-quality products. Compounding practice may be influenced by many factors such as patient, health system, and economic issues. The purpose of this study was to determine the extent of compounding practice by pharmacists and to explore factors that influence pharmacists' reasons to provide compounding services. Materials and Methods: The study was a cross-sectional survey using a self-administered questionnaire. Participants were pharmacists in charge in Yogyakarta Province area, working at pharmacies, hospitals, or clinics which provide pharmacy services. An anonymous questionnaire was sent door to door in practice sites. Data were analyzed descriptively. Findings: Among the 425 pharmacists who were contacted, 305 agreed to participate in the survey, giving a response rate of 71%. Overall, 286 (94.08%) pharmacists provided compounding services. Compounded prescriptions accounted for 155 (11.55%) of the 1342 total prescriptions dispensed per month. About 265 (40.4%) pharmacists reported that their aim to provide full pharmaceutical care to patients was one of the most important reasons for providing compounding service. About one-third of compounded prescriptions, 208 (30.1%), were general practitioners, while the remaining were specialized physicians. The three most commonly prescribed dosage forms were powder (32.1%), capsule (25.3%), and syrup (21.9%). The most frequent drug compounded was paracetamol (28.1%), chlorpheniramine maleate (11.4%), and ambroxol (10.6%). Regarding the pharmacists' perception to control the quality of compounded products, most of the pharmacists answered that they feel confident in the quality of compounding because of the guideline provided (80.26%), documenting all procedure in compounding (73%), and the availability of special room for compounding (56.58%). Conclusion: Compounding service remains a core component of pharmacy practice. There is a need to develop evidence-based regulations for compounding practice by pharmacists.

Key words: Compounding, cross-sectional, Indonesia, pharmaceutical care, pharmacist, practice

INTRODUCTION

ompounding practice in pharmacy is defined as combining or mixing of ingredients into a different drug product to provide a customized medication for an individual patient. Usually, the extemporaneously prepared product uses traditional compounding technique by crushing manufactured tablets or opening capsules. Compounding practice likely reflects patients' customized needs. Prescribers request to a pharmacist to provide a medication requiring compounding for a patient with special health needs. It is also pharmacists' effort in assisting the patients by providing customized dosage forms that are suitable for the patient.

Compounding was both traditional and current competence of pharmacists. Compounded products usually prepared for special situations and can contribute to patient medication regimens. However, regarding the systematic review conducted by Kristina *et al.* 2017,it is revealed that the prevalence of compounding practice in community pharmacy was very low, <5% of total prescription.^[3] It has been found

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Received: 22-06-2018 **Revised:** 08-08-2018 **Accepted:** 27-08-2018 that stability of the compounded products and accuracy in dose strength still become an important issue. Little is known about the possible pharmaceutical and clinical drug problems resulted from this type of practice. Errors in preparation, some of them with potentially serious consequences, have been noted. [2,4] Compounding medications are individualized; therefore, there are only a few reports related to this study as highlighted potential issues related to compounding practice by the Food and Drug Administration study (FDA). [5]

In Indonesia, many of medicines are administered in the compounded dosage forms. [6] The practice of compounding has not been well standardized. Consequently, it may lead to either contamination or products which did not possess high quality. Prescription of the compounded medicine may be influenced by many factors, i.e., patient, health system, and economic issues. [7] Budget shortages cause the limited availability of formulas and dosage forms suitable for pediatric outpatients. [7]

According to the Indonesian Pharmacists Association (IPA) statistics in 2015, there are about 1800 registered pharmacists in the Yogyakarta Province, and the majority of them work in the area of pharmacy services. There are 850 pharmacists in the Yogyakarta that they are allowed to perform pharmaceutical compounding. [8] Data on the current status of compounding in pharmacy practice are unavailable in Indonesia. Understanding of the current prevalence of compounding in pharmacies is needed.

The objectives of this study were to determine the extent of prescription compounding by pharmacists in the Yogyakarta Province and to explore factors that influence the practice of compounding services among pharmacists.

MATERIALS AND METHODS

The study was a cross-sectional survey, employed a twopage self-administered questionnaire. Pharmacists from five districts of the Yogyakarta Province were selected conveniently.

Registered pharmacists' list was obtained from IPA of Yogyakarta Province. The respondent was selected based on their name and working site. We found 425 pharmacists who work related to compounding services (hospital, community pharmacies, and clinics) that received our invitation to join the project, presented around 50% of the registered pharmacists. The questionnaire was delivered door-to-door visit to pharmacies in an attempt to optimize the participation rate. Only pharmacists who are responsible for compounding practice have to complete the questionnaire. Responses were fully anonymous and voluntary non-incentive task.

The questionnaire was developed from the previous systematic review conducted by Kristina *et al.*^[3] and focused a group

discussion employed among the selected pharmacists. Pilot testing of the questionnaire was conducted on 20 randomly selected community pharmacists, and several reasons for providing or not providing compounding services were added to the questionnaire based on their recommendations.

The demographical data, whether compounding services were provided or not and number of total and compounded medications dispensed in a typical month, were asked. Respondents who provide compounding services were asked to consider six statements, representing their reasons for providing compounding services, and to give their three most important reasons

Responses were entered into the Statistical Package for the Social Sciences (SPSS), version 16 (SPSS, Chicago, IL, USA). Data were analyzed using descriptive analysis including frequency distribution and percentage.

RESULTS

The basic characteristics of the participating pharmacists are presented in Table 1. A response rate of 71% was achieved, obtained from the 425 pharmacists who were contacted, and 305 agreed to participate in the survey. The majority of pharmacists were female, 278 (91.1%), and had been practicing in pharmacy service for 5.8 years (range 1–20 years) 291 (95.7%) respondents held pharmacist degree as their highest education degree.

Of the 305 pharmacists' responses, 286 (94.08%) provided daily compounding services. Prescription-required compounding accounted for 155 (11.55%) of the 1342 total prescriptions dispensed per month. General practitioner

Pharmacists' demographics (n=305)	n (%)
Sex	
Male	27 (8.9)
Female	278 (91.1)
Age (years, mean)	30.2
Work	
Drug store	186 (61)
Primary health center	20 (6.6)
Hospital	70 (23)
Private clinic	28 (9.2)
Others	1 (0.3)
Practice in community pharmacy (years, mean)	5.8
Education level	
Pharmacist degree	291 (95.72)
Master degree	13 (4.28)

was the most frequent in asking a pharmacist to dispense compounded medications (30.8%) [Table 2].

When pharmacists were asked to rank the most important reasons for their decision to provide compounding services, 265 (40.4%) of them reported that their aim to provide full pharmaceutical care to patients was one of the most important reasons for providing compounding service. The second most common reason for providing compounded prescriptions was as part of pharmacist's competence, indicated by 221 (33.7%) pharmacists. Compounding is performed because of the adequate equipment in practice site which was the third most frequent reason for compounded prescription, which was chosen by 95 (14.48%) pharmacists.

About one-third of compounded prescriptions, 208 (30.1%), were general practitioners, while the remaining were specialized physicians (pediatrician, dermatologist, internist, psychiatrist, and neurologist). The three most commonly prescribed dosage forms were powder (32.1%), capsule (25.3%), and syrup (21.9%).

The pharmacists were also asked to choose a list of drugs frequently compounded. This part was resulting in 612 responses. The majority of all dispensed compounded medicines were paracetamol (28.1%), chlorpheniramine maleate (11.4%), and ambroxol (10.6%). Regarding the pharmacists' perception to control the quality of compounded products, most of the pharmacists answered that they feel confident in the quality of compounding because of the guideline provided (80.26%), documenting all procedure in compounding (73%), and providing the room for compounding (56.58%), as described in Table 2.

DISCUSSION

This is the first study investigated pharmaceutical compounding practice in Indonesia. The main findings of this study revealed that most community pharmacists (94%) dispensed prescriptions with compounding. Prescription-required compounding accounted for 11.55% of prescriptions dispensed within 1 month. The most frequent reason for pharmacists' decision to compound the medicines was the intention of pharmacists in providing full pharmaceutical practice for the patients, due to the unavailability of the required dosage forms.

The second-most given reasons by pharmacists were generally considered as a component of pharmaceutical care. Pharmaceutical care has evolved the process around a patient and other professionals in designing, implementing, and monitoring therapeutic plans that will result in a higher quality of life for a patient. [9] Other studies have shown that pharmacists were described as having a closer relationship with patients receiving compounded preparations than with patients receiving only manufactured products. They perceived

Table 2: Characteristics of compounding practice by pharmacists

pharmacists	
Characteristics of compounding (305)	n (%)
Provide compounding services	286 (94.08)
Compounded prescriptions (mean per month)	155 (11.55)
Reasons for providing compounding service	
Provide the pharmaceutical care for patients	265 (40.40)
Part of pharmacist's competence	221 (33.69)
Have equipment for compounding	95 (14.48)
Have adequate skills for compounding	25 (3.81)
Enjoy compounding	19 (2.90)
Compounding is profitable	31 (4.37)
Specialty of doctor served for compounding (301)	
General doctor	208 (30.50)
Pediatrician	179 (26.25)
Dermatologist	128 (18.77)
Internist	71 (10.41)
Psychiatrist	59 (8.65)
Neurologist	27 (3.96)
Others (pulmonologist, surgeon, and gynecologist)	10 (1.47)
Dosage form prescribed (780)	
Powder	250 (32.05)
Capsule	197 (25.26)
Syrup	171 (21.92)
Cream	162 (20.77)
Most frequent drug compounded (612)	
Paracetamol	172 (28.10)
Chlorpheniramine maleate	70 (11.44)
Ambroxol	65 (10.62)
Salicylic acid	62 (10.13)
Salbutamol	59 (9.64)
Glyceryl guaiacolate	44 (7.19)
Others (corticosteroids, antibiotics, antiallergy)	40 (6.70)
Quality control (304)	
Availability of guideline	244 (80.26)
Documentation	222 (73.03)
Room with special requirements	172 (56.58)
Training	157 (51.64)
Beyond use date	133 (43.75)

a greater responsibility in providing patient-centered care when dispensing a compounded medication compared to a manufactured product. In addition, there was greater follow-up

with patients and physicians regarding therapy with the compounded medications than the manufactured products.^[10,11] This idea was also reported in this study when pharmacists considered compounding as a factor that reinforces trust between patients and pharmacists. This trust may encourage patients to take their medications which may possibly result in increased patient compliance. The enjoyment that pharmacists felt when they prepare compounded preparations was reported as a third reason for providing a compounded prescription. This reason was interpreted by McPherson et al.[12] as a decision by the pharmacist to serve patients' own needs or desires. McPherson et al. reported that "my compounding service is a response to demand by prescribers" as a second reason for providing compounding, which indicated that cooperation between physicians and pharmacists should be considered as an essential part of a successful therapy.^[12]

Our study revealed that compounding was a critical part of providing care to patients with special and individualized needs who might be underserved by industrial-made products. However, pharmacists were obligated to ensure that the medications they compound were safe, effective, and of exceptional quality. Unlike a registered pharmaceutical product, compounded medicines have not been tested for safety and efficacy. Their use is generally based on empirical experiences and derived from the component ingredients.[13] Therefore, it is suggested that pharmacy graduates provided with relevant compounding experience would be better equipped with training to optimize patient outcomes than graduates who were not trained in compounding.[14,15] In addition, developing collaborative interprofessional pharmaceutical services with other health professional students would be beneficial for improving patient care.[16] Efforts to improve training and education of pharmacy staff, environmental control, quality assurance, and sterilization practices would generate safe compounded medications as recommended by the FDA.[17] Furthermore, adoption of the standardized United States Pharmacopeia guidelines or any other suitable guidelines by regulatory bodies such as the Ministry of Health and IPA had the potential to be a significant step forward in improving compounding pharmacy practices and ensuring the quality and safety of the compounded products.

This study gives basic information regarding the value of compounding for the Indonesian pharmacists. The limitations of this study include lack of in-depth analysis about the perspective of patients and physicians regarding the compounding practices. Broadening the survey by presenting representative samples will give the detail information of cases of this study. The quality of compounded products prepared by pharmacists is also still unobserved. From this study, we are able to provide baseline data about pharmaceutical compounding in Yogyakarta Province which can be helpful in the development and regulating this practice.

Compounding service remains a core component of pharmacy practice. This practice is currently necessary to ensure

patient' needs with customized medicines. Pharmacists could do much to improve the quality of practice through continuous training. Development of some evidence-based regulations for compounding practice by pharmacists need to be addressed.

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