《 Original Article 》

Future Issues for Pre-Agreement Protocols in Prescription Inquiries

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Based on pre-agreements between the pharmacy and the hospital/clinic, protocols that can simplify prescription Inquiries and proceed with the dispensing of medications are practised. The aim of this study is to survey the protocols published on the Internet and to assess their spread based on the number of protocols. The study also aimed to explore future issues for expanding the protocol, based on the gap between the data summarising the items in the protocol and the actual prescription inquiries. As of September 2023, protocols for which an internet search could be performed and the defined items could be verified were included in this study.

The survey found that 178 protocols were published by medical institutions, and 11 were comprehensive protocols initiated by regional pharmaceutical associations and other organisations. Among all items, "Change of specifications, dosage forms, and brand names of oral drugs with the same ingredients" showed the highest adoption ratio. We found that applying the protocol for some prescription inquiries was possible. We concluded that protocols should be utilised to optimise pharmacist operations and enhance the interpersonal services provided by pharmacists.

Key words; Prescription inquiries, Protocols, Pre-agreement, Pharmacist work

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1. Introduction

A Ministry of Health, Labour and Welfare notice[1)] issued on 30 April 2010 stated that from the perspective of improving the quality of medical care and ensuring medical safety, it is beneficial for pharmacists, who are experts in pharmaceuticals, to proactively participate in pharmacotherapy in a team approach to medical care. Furthermore, as a specific example of work that pharmacists can perform, it states that pharmacists "collaborate with physicians and other professionals to change the type of drug, dosage, administration method, administration period, etc., and order tests based on a pre-agreement protocol prepared by physicians

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and pharmacists and through the use of their specialised knowledge." In addition, the Japanese Society of Hospital Pharmacists[2] and the Japanese Society of Pharmaceutical Health Care and Sciences[3] have both released guidance on "Protocol-Based Pharmacotherapy Management." We believe that pharmacists are expected to contribute to the development of medical care teams in the future by improving the quality and safety of pharmacotherapy and reducing the burden on physicians and other specialists through pharmacists' expertise. The Japan Pharmaceutical Association and the Japanese Society of Hospital Pharmacists document[4], the simplification of inquiries between doctors and pharmacists on prescription details is mentioned as a task that could be transferred to pharmacists among the tasks currently performed by doctors and non-physician professionals.

Prescription inquiries to physicians regarding the content of prescriptions are a fundamental task, as defined in Article 24 of the Pharmacists' Act. On the other hand, Uchida et al.[5] pointed out that many minor details are only formally confirmed by the physician and that these queries interrupt outpatient consultations and procedures, increasing the workload for the physician. Prescriptions with prescription inquiries have also been reported to increase dispensing, audit, and patient waiting time significantly[6]. Longer patient waiting times can lead to errors in dispensing operations[7], and improving operations related to such prescription inquiries is critical.

Actually, initiatives have been reported to utilise protocols (hereinafter referred to as 'protocols') that allow dispensing to proceed by simplifying prescription inquiries for formal changes and other defined matters based on pre-agreements between pharmacies and medical institutions[8,9]. Hagiwara et al.[10] reported that Fukuoka University Nishijin Hospital agreed to collaborate with one nearby pharmacy and reported a significant decrease in prescription inquiries from 760 to 336 per year. In addition, as the introduction of protocols has been mentioned to reduce patient waiting times[11] and the burden on physicians[12], we consider protocols to be one of the measures to solve the problems associated with prescription inquiries.

There have been no previous reports summarising the items adopted in each protocol, although the items specified in each protocol are considered different. Summarised data on publicly available protocols would be useful when introducing new protocols or updating the items adopted. There is also a report of a comprehensive regional protocol in the Gifu City Pharmaceutical Association and a regional core hospital[11], and we believe that pre-agreed protocols are essential for single and multiple medical institutions.

The aim of this study is to survey the protocols published on the Internet and to assess their spread based on the number of protocols. The study also aimed to explore future issues for expanding the protocol, based on the gap between the data summarising the items in the protocol and the actual prescription inquiries.

2. Methods

1. Search Method

As of September 2023, a Google search of the internet was conducted using the keywords 'prescription inquiries and protocols' and 'prescription inquiries and pre-agreement.' A search

for 'prescription inquiries and protocols' returned 243 web pages. A search for 'prescription inquiries and pre-agreement.' returned 208 web pages. After merging the two searches, excluding duplicate pages, academic articles and news articles, the result was 221 protocols. Of these, 189 protocols were included in this study, excluding 32 that required a log-in or an enquiry to a medical institution or the pharmacy association to obtain the content of the protocol. All identified protocols were included in the study without any exclusions based on content checks.

2. Evaluation Method

The protocols under investigation were divided into two categories: protocols published by medical institutions, such as hospitals and clinics, and comprehensive prescription enquiry protocols published by regional pharmacists associations. Basic information was obtained from the information published online, and the items specified in the protocol were classified.

The basic information for the protocols of medical institutions included the region where the institution was located, the number of beds, and the year the protocol became operational or the first edition was prepared. For protocols of regional pharmacists' associations, the following information was used: prefecture, relevant organisation, number of participating institutions, number of participating pharmacies, and year the protocol was operational or the first edition was prepared.

The information on the protocols obtained was classified into five categories, with reference to previous reports[13,14], including 'Items related to drug changes,' 'Items related to dispensing methods,' 'Items related to dosage and administration,' 'Items related to the number of prescription days' and 'others.' The ratio of the items adopted in the protocols was also calculated. In addition, we compared the content of prescription inquiries in the Prescription Inquiries Survey[15] with the items and ratio of items adopted for the protocols classified in this survey. Microsoft Excel 2021 was used for tabulation. Few studies report on the content of prescription inquiries. In this study, we have adopted the Prescription Inquiries Survey[15] mentioned above because it is the most recent and because it reports on a nationwide pharmacy sample.

3. Results

1. Basic information on protocols

The survey revealed 178 protocols published by healthcare organisations whose content could be verified and 11 comprehensive protocols published by regional pharmacists associations, all of which were included in this study. The largest number of beds in the medical institutions included in this survey was '100–499' with 129 (72.5%) facilities in this category. This was followed by 40 (22.5%) facilities with '500≥', 6 (3.4%) with '20–99', and 3 (1.7%) with '<19.' The locations are listed in Table 1-1.

Table 1-1 Region of Hospital/Clinic

Region	n=178 (%)
Hokkaido	6 (3.4)
Tohoku	21 (11.8)
Kanto	43 (24.2)
Chubu	32 (18.0)
Kinki	46 (25.8)
Chugoku	11 (6.2)
Shikoku	8 (4.5)
Kyushu	10 (5.6)
Okinawa	1 (0.6)

Table 1-2 Protocols for regional pharmacy associations, etc.

Prefecture	Related Associations	Number of participating medical facilities	Number of participating pharmacies
Kanagawa	Kawasaki Pharmaceutical Association	19	332
Gifu	Gifu City Pharmaceutical Association	12	204
Gifu	Motosu Pharmaceutical Association	3	28
Shiga	Kohoku Pharmaceutical Association	3	-
Nara	Nanwa Regional Medical Organization	3	-
Osaka	Matsubara City Pharmaceutical Association	71	32
Osaka	Toyono-Mishima Area Collaboration between Hospital and Community Pharmacists Council	18	-
Osaka	Yao City Pharmaceutical Association	5	-
Fukuoka	Kurume-mii Pharmaceutical Association	6	-
Fukuoka	Chikushi Pharmaceutical Association	8	-
Yamaguchi	Tokuyama Pharmaceutical Association	3	-

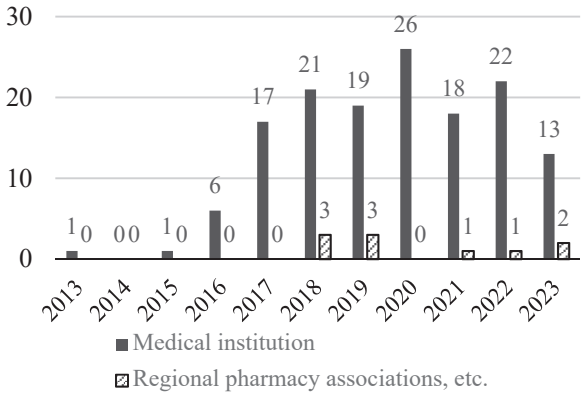

Figure 1 Year of protocol operation or year first edited

Table 1-2 shows prefectures, relevant organisations, number of participating institutions, and number of participating pharmacies for protocols of regional pharmacists associations, etc.

Regarding the year the protocol was operational, or the first edition was prepared, 144 protocols were mentioned by medical institutions and 10 by protocols of regional pharmacists associations. The Kyoto University Hospital protocol was the oldest in 2013 and has increased recently. The details are shown in Figure 1.

2. Items in the protocol

2.1. Items related to drug changes

Regarding items related to drug changes, the highest ratio of items adopted was a change of specifications ('oral') with the same ingredients, which was adopted by 166 (93.3%) medical institutions, including Kyoto University Hospital, and 11 (100%) in protocols of regional pharmacists associations. Brand name and formulation changes were highly prevalent. The classified items and the ratio of adopted items are listed in Table 2.

2.2. Items related to dispensing methods

The largest number of items related to dispensing methods were related to one-dose package instructions: 162 (91.0%) in medical institutions and nine (81.8%) in regional pharmacist associations. Of these, in 27 medical institutions and one regional pharmacists association, the protocol was only applicable to free one-dose package dispensing. Prescription inquiries are required when calculating the additional fee for a one-dose package.

Table 2 Classification of Items and Adoption

Classification Items	Medical institutions n=178 (%)	Regional pharmacist associations, etc. n=11 (%)
Items related to drug changes		
Change of specifications with the same ingredients (oral)	166 (93.3)	11 (100.0)
Change of formulation of the same ingredient (oral)	163 (91.6)	11 (100.0)
Change of brand name with the same ingredients (oral)	158 (88.8)	11 (100.0)
Change of specifications in poultices and ointments (topical)	115 (64.6)	7 (63.6)
Change in formulation of anti-inflammatory analgesic topical application	50 (28.1)	3 (30.0)
Change to compounded drugs	38 (21.3)	0 (0.0)
Change in lactobacillus formulation	32 (18.0)	0 (0.0)
Flavor changes in enteral feeding products	22 (12.4)	2 (18.2)
Change of brand name in case of drug name change, etc.	8 (4.5)	1(9.1)
Items related to dispensing methods		
Change to a one-dose package	162 (91.0)	9 (81.8)
Split in half/pulverised dispensing/mixed dispensing	116 (65.2)	9 (81.8)
Simple Suspension Method	2 (1.1)	0 (0.0)
Items related to dosage and administration		
Change of prescription when weekly or monthly formulations were prescribed on consecutive days	134 (75.3)	7 (63.6)
Description of dosage and administration of abortive medications/description of the site of topical medications	119 (66.9)	6 (54.5)
Change to proper usage in the package insert.	81 (45.5)	2 (18.2)
Usage prescribed with physician's consent	55 (30.9)	2 (18.2)
Items related to the number of prescription days		
Adjustment of the number of days for leftover medicine	149 (83.7)	10 (90.9)
Addition of prescription days	29 (16.3)	2 (18.2)
Change in the number of insulin needle prescriptions	8 (4.5)	1 (9.1)

Table 3 Other items and adoption ratios

Classification Items	Medical institutions n=178 (%)
Removal of duplicate prescriptions from different departments within the same medical institution	6 (3.4)
Other Agreements	7 (3.9)
Addition of instructions for inhalation guidance	3 (1.7)
drug dispensing by instalments	2 (1.1)
The following items are excerpts from some of the protocols	
Prescribing PPIs for more than 8 weeks is considered "maintenance therapy for reflux esophagitis with repeated relapses and recurrences."	1 (0.6)
Change of dosage for compliance reasons only in paediatrics EX: Change from after every meal to after breakfast and dinner when the child attends nursery school or kindergarten and cannot take the medicine after lunch.	1 (0.6)
Optimisation of dosage for topical application when the dosage is clearly erroneous EX: Cravit ophthalmic solution three times daily application to three times daily Ophthalmic	1 (0.6)

2.3. Items related to dosage and administration

Among items related to dosage and administration, 'change of prescription when weekly or monthly formulations were prescribed on consecutive days' accounted for the highest ratio of 134 (75.3%) for medical institutions and seven (63.6%) for regional pharmacist associations, etc. The second most common was additional dosage for abortive medication when verbally instructed by a physician, which was 119 (66.9%) in medical institutions and six (54.5%) in regional pharmacist associations.

2.4. Items related to the number of prescription days

The most common item related to the number of days prescribed was 'adjustment of the number of days associated with remaining drugs,' with 149 (83.7%) for medical institutions and 10 (90.9%) for regional pharmacist associations, etc. Extended prescription days were adopted by 29 (16.3%) medical institutions and two (18.2%) by regional pharmacy associations. However, there were also protocols with their own conditions, such as when medicines were in short supply after confirmation of the next visit date, prescriptions for chronic diseases, and prescriptions for eye drops.

2.5. Other items

Items not adopted by regional pharmacist associations and others but classified as 'other' in some medical facilities. The items were applied under detailed conditions, such as deleting duplicate prescriptions from different departments within the same facility at six (3.4%) facilities and adding instructions for inhalation guidance at three (1.7%) facilities. The details are provided in Table 3, along with the items extracted from some protocols.

3. Comparison of the prescription enquiry survey with the protocol items

Table 4 Comparison of the prescription inquiries survey with the protocol items
(Filled in area. Adapted from reference 15)

Category	n=6,350 (%)	Classification Items	Medical institutions n=178 (%)	Regional pharmacist associations, etc. n=11 (%)
Dosing method of oral medicine	953 (15.0)			
Adjustment of the number of days and pieces due to residual drugs	792 (12.5)	Adjustment of the number of days for leftover medicine	149 (83.7)	10 (90.9)
Checking the purpose of prescription (including question about insurance applications)	606 (9.5)			
Cases other than those listed	480 (7.6)			
Excess/shortage of number of days	464 (7.3)	Addition of prescription days	29 (16.3)	2 (18.2)
Question about dosing methods to facilitate ingestion or application of drugs (including change in formulation, single-pack dispensing, tablet crushing, and capsule opening)	442 (7.0)	Change of formulation of the same ingredient (oral)	163 (91.6)	11 (100.0)
		Change to a one-dose package	162 (91.0)	9 (81.8)
		Split in half/pulverised dispensing/mixed dispensing	116 (65.2)	9 (81.8)
Incomplete entry in the prescription (compared with previous prescription)	390 (6.1)			
Duplication with other drugs for same indications	388 (6.1)	Removal of duplicate prescriptions from different departments within the same medical institution	6 (3.4)	
Shortage of dosage	362 (5.7)			
Excessive dosage	315 (5.0)			
Excess/shortage of the total number of pieces (topical drug, injection, etc.)	240 (3.8)			
Dosing method of topical drug	196 (3.1)	Description of dosage and administration of abortive medications/description of the site of topical medications	119 (66.9)	6 (54.5)
Patient's request for selection of original/ generic drugs	116 (1.8)	Change of brand name with the same ingredients (oral)	158 (88.8)	11 (100.0)
Question about site of use	100 (1.6)	Description of dosage and administration of abortive medications/description of the site of topical medications	119 (66.9)	6 (54.5)
Prescription of drugs for which long-term use is prohibited	96 (1.5)			
Contraindication	71 (1.1)			
History of adverse reactions	65 (1.0)			
Interactions	39 (0.6)			
Excess/shortage of frequency of dosing (potion)	37 (0.6)			
Suspicion of adverse reactions	36 (0.6)			
Dosing (application) interval	33 (0.5)	Change of prescription when weekly or monthly formulations were prescribed on consecutive days	134 (75.3)	7 (63.6)
Question about lifestyle and occupation of a Patient	21 (0.3)			
Prohibited combination/Inadequate combination	20 (0.3)			
Careful administration	19 (0.3)			
Single-pack dispensing is not allowed	19 (0.3)			
Dosing method of injection	18 (0.3)			
Tablet crushing, capsule opening, and other dosing methods are not allowed	12 (0.2)	Split in half/pulverised dispensing/mixed dispensing	116 (65.2)	9 (81.8)
History of allergy	10 (0.2)			
Influence on lactation	6 (0.1)			
Influence on pregnancy	3 (0.0)			
Administration by simple suspension method is not allowed	1 (0.0)			

We compared prescription inquiries from the Prescription Inquiries Survey[15] with the protocol adoption items in this survey. Some of the contents of the prescription inquiries survey matched the protocol items, such as 'adjustment of the number of days and pieces due to residual drugs' and 'questions about dosing methods to facilitate ingestion or application of drugs.' Among the protocol items, items such as 'Change of prescription when weekly or monthly formulations were prescribed on consecutive days' and 'Addition of prescription days' were partially included in the content of the prescription inquiries.

4. Discussion

Among all items, "Change of specifications, dosage forms, and brand names of oral medicines with the same ingredient names" had a high ratio in protocols of medical institutions and regional pharmacists associations, etc. This item was also included in the adopted items of the protocol of Kyoto University Hospital[13], the hospital with the oldest year of operation, and the first edition of the survey. Since there are many identical items when preparing a new protocol, the protocols of other hospitals were used as references. Therefore, we conclude that the results of this survey, which systematically categorised the items to be recruited, are valuable. It is crucial to publish protocol items so that other institutions can view them to enhance this initiative in the future. Table 1-1 shows that the survey was conducted in hospitals throughout Japan, although most target hospitals were in the Kanto and Kinki regions. We also found that the protocols of regional pharmacists associations and other organisations were few and not well addressed. Regional bias and the fact that only publicly available protocols were surveyed are limitations of this study.

According to the survey on the actual status of prescription inquiries[15,16], there is a need for the adoption of protocol items, as evidenced by a certain number of prescription inquiries, although the ratios of "change to a dosage form that is easier to take" and "questionable inquiries regarding patient preference for the choice of brand-name or generic drug" are small. The ratio of items adopted for the one-dose package was also relatively high in all the protocols for medical institutions and regional pharmacist associations; however, there were protocols in which the applicable scope was only for free one-dose package dispensing. There seems to be no problem in calculating the appropriate management fee when the change contributes to improving adherence, and the patient's consent was obtained for an increase in the copayment amount. This point needs to be discussed based on the opinions of the medical institutions and pharmacies at their respective sites.

Comparing the protocols of medical institutions and regional pharmacist associations, items with low ratios of adoption in medical institutions, as shown in Table 3, were not adopted in the protocols of regional pharmacist associations, suggesting that items with individual elements may be more likely to be adopted in the protocols of each medical institution. The Takatsuki City Pharmacy Association's document points out that when protocols are signed individually at pharmacies that accept prescriptions from multiple medical institutions, there is also a risk[17] of mixing up protocols due to the different individual protocols handled and the possibility of dispensing them

without the necessary prescription inquiries being observed. According to a report[11] on the agreement between the Gifu City Pharmaceutical Association and the regional flagship hospital, the standard protocol made by the regional pharmaceutical association is easy to understand for physicians working at multiple facilities and pharmacists in dispensing pharmacies that widely accept prescriptions, with significant operational advantages leading to more efficient operations. To function as a family pharmacy/pharmacist[18], it is necessary to collaborate with single and multiple medical institutions with the patient at the centre. While specific benefits are received from protocols with individual elements in pharmacies close to medical institutions, we believe that progress in community-wide efforts is needed based on the future of pharmacies.

Comparing the content of prescription inquiries in the survey[15] with the protocols, items most likely to be inquired about, such as "Adjustment of the number of days and pieces due to residual drugs (12.5%)" and "Question concerning dosing methods to facilitate ingestion or application of drugs (7.0%)", were generally consistent with the items ranked highest in protocol adoption. Items, such as " Dosing method of oral medicine " and " Checking the purpose of prescription (including question about insurance applications)", were not adopted into the protocol. We think this is because these prescription inquiries cannot be adopted, as a standardised protocol, due to the wide variety of ways to respond to them.

Among the protocol items, items such as "Change of prescription when weekly or monthly formulations were prescribed on consecutive days" and "Addition of prescription days" were included, in part, in the content of the enquiry. Although the percentage of these protocols' adoption was partial, we believe these items are essential for the active utilisation by pharmacists. Various factors, such as the evaluation of pharmacists and the relationship between community pharmacy associations and medical institutions, will likely influence the introduction of new protocols and adoption items. Clarifying the relationship between the adopted items and pharmaceutical and drug collaborations is an issue that needs to be addressed in the future expansion of this initiative. By utilising protocols and optimising pharmacist operations, we believe there should be increased high-quality pharmaceutical prescription inquiries[19] based on information obtained through conversations with patients at the counter and at home. It is also necessary for pharmacists to provide more interpersonal services, such as patient follow-up during the drug medication period[20] and handling refill prescriptions[21].

This study indicates that the protocol is not widespread enough. We think that a one-to-one protocol is less beneficial for pharmacies located far away from a medical institution, or medical institutions that receive prescription inquiries from several pharmacies, to introduce a protocol. We believe that it is important to increase the number of regional pharmacists associations protocols in order for these pharmacies and medical institutions to introduce protocols. We concluded that we needed to establish a nationwide common protocol. A comparison of actual prescription inquiries and protocols also showed that protocols are less likely to be adopted when they cannot be responded to in a standardised way. We suggest that adjustments of dosing method of oral medicine and correction of

incomplete prescriptions should be adapted in the protocol in a comprehensive item, in collaboration with the prescribing physician. We believed that the quality of community healthcare could be improved with more facilities adopting the protocol and making better use of pharmacists.

Conflict of Interest

We have no conflict of interest.

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