

Medication incidents associated with the provision of medication assistance by non-medical care staff in residential care facilities

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SUMMARY The shift towards community-based care in Japan has led to increased medication assistance for older people by non-medical care staff. These staff members help take pre-packaged medications, apply patches, and administer eye drops. This study assessed the risks associated with such assistance by reviewing medication-related incidents across 106 residential care facilities between April 1, 2015, and March 31, 2016. An analysis of incident reports showed that all incidents were minor, with no serious outcomes. The incidents were categorized into four types: dropped drugs, misdelivery/misuse of medicines, forgetting to take medicines, and loss of medicines, with dropped drugs being the most frequent. Most incidents occurred in the morning and primarily involved residents with intermediate nursing care needs. These findings indicate a low risk of serious incidents because of medication assistance from non-medical staff. However, the frequency and nature of the incidents were influenced by the timing of medication administration and the care needs of the residents. These insights highlight the need for customized approaches to medication assistance, considering the residents' care levels and potentially optimizing medication administration times to improve safety in residential care settings.

Keywords risk management, medication-related incidents, home care services, residential facilities

1. Introduction

Recently, there has been an increase in the population of older people, leading to a shift from hospital-based to community-based care in Japan because of the inability of hospitals to accommodate long stays for elderly patients. The "community-based integrated care system," which offers comprehensive services, including health care provision, nursing care, prevention, housing, and livelihood support, has emerged in response (1). Non-medical care staff without a license as nurses or doctors are increasingly involved in providing medical care and daily lifestyle support to individuals in homes or residential care facilities. For instance, care staff in these facilities may assist older people with pre-packaged medications prepared by pharmacists. According to the interpretation of the Medical Practitioners' Act Article 17, the Dental Practitioners' Act Article 17, and the Public Health Nurse, Midwife, and Nurse Act Article 31 issued by the Ministry of Health, Labour and Welfare, while care

staff is not authorized to perform "medical services," assisting with pre-packaged medications, applying patches, or administering eye drops is not considered a "medical service," thus, can be performed by care staff. This clarification allows non-medical staff to provide certain care services under specific conditions.

Under these conditions, the potential for incidents arising from medication assistance by non-medical staff raises concerns. A considerable number of elderly residents in such facilities receive pharmacotherapy for chronic conditions, with data indicating that approximately 40% of nursing home residents in the USA are prescribed nine or more medications (2). Despite the presumed lower risk of incidents in Japanese residential care settings compared to hospitals, evidence from our previous survey suggests that care staff find providing medication assistance challenging (3).

While past research has addressed medication incidents in hospitals (4-7) or primary care (8,9) and nursing homes (10), there has been little focus on incidents involving non-medical staff. Our previous

studies examined the factors contributing to certain types of incidents by non-medical staff in residential care facilities (11). However, a comprehensive investigation of all incident types by non-medical staff in such settings has not been conducted.

This study aimed to assess the risks associated with medication assistance by non-licensed care staff by analyzing medication-related incidents in residential care facilities where integrated care is provided.

2. Materials and Methods

2.1. Design

This multicenter retrospective study analyzed incident reports related to medication assistance by non-medical care staff in 106 long-term residential care facilities operated by a single company. These facilities shared characteristics, such as having at least one staff member present 24 hours a day, one caregiver or one nurse for every three persons requiring nursing care, or one caregiver or one nurse for every ten persons requiring support, and private living quarters for all residents. The residents of these facilities underwent routine physician visits. An incident was defined as any event leading to a resident's failure to take their prescribed medication accurately.

2.2. Data collection

This study included incidents from April 1, 2015, to March 31, 2016, focusing only on those involving non-medical care staff who were not medical professionals. Medical staff incidents were excluded. Most residents in the participating facilities received medication assistance, forming the study's basis.

Following any incident, a detailed incident report was filled out, covering the following points: conditions at the time of the incident, nature of the incident, time, place, and basic information about the resident who experienced the incident, such as age, sex, and nursing care requirement level. The responsibility for completing these reports was not confined to the care staff directly involved in the incident; facility managers or nurses were also authorized to document incidents. Policies at these facilities encourage the reporting of minor incidents.

An identifying code was assigned to the facility name, care staff name, and resident name in the incident report, anonymized to maintain confidentiality.

2.3. Data analysis

These incidents were classified into four distinct categories: dropped drugs, misdelivery/misuse of medicines, forgetting to take medicines and loss of medicines. The "taking medicines" scope included

eye drops, patches, or ointments. These categories are defined as follows. Dropped drugs: Finding drugs in an unexpected location in an unwrapped state. Misdelivery/misuse of medicines: providing support in a manner different from the standard procedures for residents taking medicines. Forgetting to take medicines: failure to take medicines at the prescribed time. Loss of medicines: inability to find medicines.

The number of incidents was calculated for each category, and the correlation coefficient between the number of incidents per facility and the facility population size was calculated. The significance of this correlation was evaluated at the 5% level. Additionally, the impact of the timing of incidents and residents' care needs, represented by their nursing care requirement levels, on incident rates was analyzed. The nursing care requirement level measures the extent of residents' care needs, ranging from support level 1 to long-term care level 5, with increasing levels indicating a greater need for care. The grading system is shown in Table 1.

The statistical analysis was conducted using Microsoft Excel version 16.28.

2.4. Ethical approval

All the procedures were performed according to the principles of the Declaration of Helsinki. This study was approved by the Research Ethics Review Committee of the Faculty of Pharmaceutical Sciences, University of Tokyo (accession number 28-15, approved on November 1, 2016) and the Research Ethics Review Committee of the Faculty of Pharmacy, Keio University (accession number 180731-7, approved on July 31, 2018).

3. Results and Discussion

This study included 2,142 incidents from 106 facilities, with an average of 20.4 incidents per facility (median, 18). The correlation coefficient between the number of residents and the incidents in each facility was 0.33 ($P < 0.05$), indicating a weak but significant correlation.

The most common incident type was "dropped drugs," comprising 55.0% of all reported incidents (Table 2). Within this category, incidents were split between "discovery of dropped drugs" and "spitting up/falling while taking medicines." Additionally, the category of "mis-delivery/misuse of medicines" was divided into "wrong person," "wrong dose," "wrong time," "forgetting to remove medicines," and "other mis-delivery/misuse" (Table 2). Cases of forgetting to remove medications were related to forgetting to remove patches. The outcome of all incidents was either "there is no change about residents' conditions" or "we conduct a follow-up for residents' conditions," and none required residents to undergo additional procedures such as emergency medical examination. More than half the incidents

Table 1. Nursing care requirement levels

a. Requiring Support, Requiring Care, Independence	
Requiring Support	They can perform basic activities of daily living, such as walking and getting up on their own, but need some support with daily living instrumental activities.
Requiring Care	Unable to perform basic activities of daily living, such as walking and getting up on their own, they need some support.
Independence	They can perform basic activities of daily living, such as walking and getting up on their own, and daily living activities, such as taking medicine and using the telephone.
b. Status of persons requiring care at each nursing care requirement level	
Long-Term Care Level 1	The ability to perform instrumental activities of daily living is further impaired compared with persons whose status is "requiring help," and partial nursing care is required.
Long-Term Care Level 2	In addition to the condition with long-term care level 1, partial care is also needed for basic activities of daily living.
Long-Term Care Level 3	The ability to perform basic and instrumental activities of daily living is markedly lower compared with persons whose status is long-term care level 2, and almost total support is required.
Long-Term Care Level 4	In addition to long-term care level 3 conditions, the ability to move is further decreased, and it is difficult to perform daily living without care.
Long-Term Care Level 5	The ability to move is further decreased compared with persons whose status is long-term care level 4, and it is almost impossible to perform daily living without care.

This table is available at <https://www.mhlw.go.jp/topics/kaigo/kentou/15kourei/sankou3.html> (Japanese website).

Table 2. Types of incidents with medication support involved by care staff

Category of Incidents	Cases (%)
Dropped drugs	
Spitting up/falling while taking medicines	160 (7.5)
Discovery of dropped drugs	1017 (47.5)
Mis-delivery/misuse of medicines	
Wrong person	139 (6.5)
Wrong dose	23 (1.1)
Wrong timing	85 (4.0)
Forgetting to remove medicines	30 (1.4)
Other mis-delivery/misuse	31 (1.5)
Forgetting to take medicines	639 (29.8)
Loss of medicines	18 (0.8)

occurred in the communal setting of a restaurant facility, highlighting the complexity of managing medication assistance in shared spaces. This finding suggests that communal areas present challenges to medication safety, necessitating strategies that consider the unique dynamics of these environments.

Each day, the number of incidents per type was calculated (Table 3). Overall, the highest number of incidents occurred in the morning, followed by the evening. While incidents of "forgetting to take medicines" tended to occur more frequently right after waking, incidents of "dropped drugs" were more common during the morning hours. This pattern suggests a potential risk concentration at specific times of day, particularly when medication administration coincides with other care activities. In the case of "dropped drugs" and "loss of medicines," many of the

incidents where the time of incident occurrence could not be determined were classified as unidentified.

The incidence rate was examined by nursing care requirement level which indicates residents' need for nursing care (Figure 1). One hundred and forty-two incidents were excluded from the analysis because the residents involved could not be identified. The total number of included incidents were 1,998. The number of incidents corrected for the number of residents in each care requirement level tended to be higher for residents at long-term care levels 2, 3, or 4 and lower for residents at support level 1 or long-term care level 5. There was little shifting in the number of incidents of "forgetting to take medicines" or "mis-delivery/misuse of medicines" according to the nursing care requirement level. However, the number of incidents of "dropped drugs" tended to be especially lower among residents at long-term care level 5. These distributions underscore the influence of resident care needs on the likelihood of medication-related incidents, with a particular vulnerability observed among those with intermediate care requirements.

Our results suggest that the medication support provided by non-medical care staff in residential care settings involves a low risk of serious incidents and that the outcomes of incidents were not serious. In the systematic review, Ferrah *et al.* reported that the serious effects of medication errors were low in nursing home settings (12), which is consistent with our research. However, most of the previous studies in their systematic reviews focused on medication errors involving medical professionals, and few focused on

Table 3. Timing of the incidents

Timing	Category of Incidents			
	Dropped drugs	Mis-delivery/misuse of medicines	Forgetting to take medicines	Loss of medicines
Right after waking	4 (0.3)	3 (1.0)	49 (7.7)	0 (0.0)
In the morning	346 (29.4)	85 (27.6)	182 (28.5)	1 (5.6)
In the afternoon	71 (6.0)	47 (15.3)	58 (9.1)	1 (5.6)
In the evening	165 (14.0)	73 (23.7)	155 (24.3)	1 (5.6)
At bedtime	88 (7.5)	25 (8.1)	70 (11.0)	3 (16.7)
Other time	6 (0.5)	74 (24.0)	118 (18.5)	1 (5.6)
Unidentified	497 (42.2)	1 (0.3)	7 (1.1)	11 (61.1)
total	1177	308	639	18

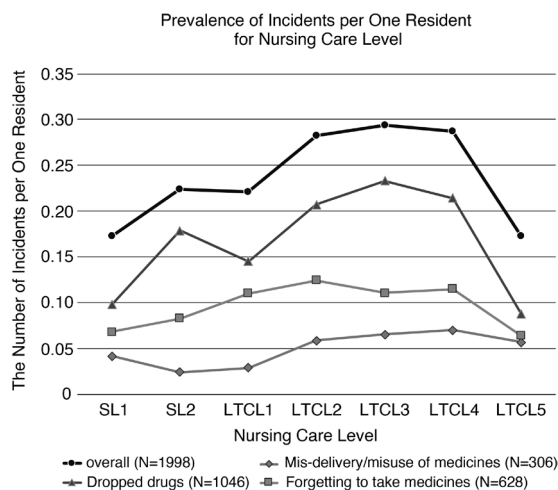


Figure 1. Prevalence of incidents per one resident according to nursing care requirement level. The number of incidents at each nursing care requirement level was divided by the number of persons in all facilities to obtain the number of incidents experienced per person. Plots show the total number of incidents and each incident type. The loss of medicines is not shown because the number was too small. LTCL: Long-term care level. SL: Support level.

incidents involving non-medical staff assisting patients with their medications. Our study is the first to focus on care staff who are not medical professionals and to investigate the prevalence of medication incidents involving non-medical care staff in a residential care setting.

This study identified four primary medication-related factors in residential care facilities. Incidents of "forgetting to take medicines" and "mis-delivery/misuse of medicines" reflect patterns that are also observed in hospital settings (4,13). The most common type of incident was "dropped drugs" in our study. Notably, this study quantitatively showed that "dropped drugs" are a common incident in residential care facilities in Japan, highlighting operational challenges in residential care facilities.

None of the 2,142 medication-related incidents documented yearly required emergency medical care. This finding indicates a minimal risk of severe incidents from medication assistance by non-medical staff in residential care, likely because of the limited scope

of such assistance. In addition, incidents like "wrong person" or "wrong dose" seen in this study have also been reported as medication errors in hospital settings (4-6,13,14) or in care home settings (11,15,16), and some of these incidents have been harmful reportedly (13,16). Although no harmful incidents were observed in our study, efforts to prevent even minor incidents are important for risk management in residential care settings.

Some incidents occurred at unknown times of the day, and most were cases in which dropped drugs, which accounted for the largest number of incidents, were discovered later. This category may include cases of "refusal," in which the patient pretended to take medicines on the spot but intentionally did not ingest them, or "leftover," in which the medicine was not completely swallowed and remained in the mouth, even if medication assistance was provided properly at the time. The highest number of incidents occurred in the morning, possibly because many residents take their medications in the morning, thus concentrating the staff's workload. A study conducted in residential facilities in Japan showed that residents consume more medicines in the morning (17). Therefore, the dispersion of drug administration times could be a method for preventing such incidents.

In this study, residents' conditions were evaluated based on the nursing care requirement level, as this could be a factor in the occurrence of incidents. Notably, the frequency of "dropped drugs" incidents varied significantly with the nursing care requirement level. Incidents were less common among residents classified as requiring long-term care level 5. Since it is impossible for residents requiring long-term care level 5 to lead their daily lives without nursing care, it is possible that the care staff more strongly recognized the need for care, including assistance in taking medicines. However, the number of incidents tended to be higher among residents with requirements for long-term care levels 2, 3, or 4 (intermediate care level). These levels represent a gradual decline in the ability to conduct activities of daily living, and the care staff did not adequately recognize this decline when providing medicines. It may be necessary to appropriately assess

the status of residents' activities of daily living and provide additional support for taking medication.

There may be potential for pharmacists to improve these residential facility conditions. Community pharmacists generally dispense and deliver pre-packaged medicines to residents. Our previous research highlighted the need for pharmacists to be involved in medication support by care staff (3). Thus, there may be room for pharmacists to improve medical safety in residential care facilities in Japan through comprehensive medical reviews.

Most of the facilities examined in this study were situated around urban areas in Japan, thereby indicating a high degree of generalizability for urban facilities. However, basic information regarding the care staff involved in the incidents, such as sex, age, and work experience, could not be analyzed because they were not identified in the incident reports used in this analysis. As our previous study showed that the mental burden of caregivers contributes to the occurrence of incidents (11), further analysis of incident occurrence situations, considering staff background information, should be conducted. Furthermore, the period of the incidents covered in this study was one year, from April 2015 to March 2016, and the possibility that the situation changed cannot be ruled out. However, since there are no major updates to the section on medication assistance not related to medical services in the notice issued by the Ministry of Health, Labour and Welfare in 2022, and there seems to be no major changes in medication-related tasks that can be performed by non-medical staff. Thus, it can be assumed that the trend of incidents will not change significantly.

In summary, many minor medication-related incidents were observed, and the outcomes were not serious, indicating that the risk of serious incidents occurring with medication support by non-medical staff, who are not doctors or nurses, should be low. Among them, dropped drugs occurred most frequently, and because their occurrence was related to the residents' nursing care requirement level, it is important to develop countermeasures that consider this factor. In addition, most of the incidents occurred in the morning. Thus, from the pharmacological management perspective, improving medical safety in residential care facilities may be effective by dispersing the administration time of medicines.

Acknowledgements

We want to thank all residents and care staff in the residential facilities operated by SOMPO Care.

Funding: None.

Conflict of Interest: KH and HS declare no competing financial interests. YD, MK, MH, and KY are

employees of SOMPO Care, Inc. SH and SY are researchers in a laboratory that received grants from SOMPO Care, Inc. The authors declare that they have no non-financial interests.

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- Received September 13, 2024; Revised February 19, 2024; Accepted February 21, 2024.
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- Released online in J-STAGE as advance publication February 28, 2024.