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Patient safety in long-term care in Japan

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Abstract

As Japan progresses toward a “super-aging society,” long-term care facilities will become increasingly important, as they will be needed to provide effective long-term healthcare services to elderly people in need. In promoting patient safety initiatives, “reporting first” is essential to address accidents in a timely manner. In Japan, a national accident reporting system, the Project to Collect Medical Near-Miss/Adverse Event Information, was launched in 2004, and the Medical Accident Investigation System was launched in 2015. Meanwhile, the information on accidents that local governments gather from long-term care facilities is not necessarily utilized for safety among the affected population. For this reason, efforts are being made to standardize reporting forms and strengthen the safety management system at these facilities, with a view to establishing a system to utilize this information at the national level in the future. Further, from interview data on the status of efforts at long-term care facilities, it is clear that more initiatives are needed at both the facility and municipal levels to develop a coordinated system to prevent accidents (reporting, analysis, planning of countermeasures, implementation, evaluation, etc.). There is a need for training multiple professionals, including users and their families, for collaboration in long-term care patient safety. This paper offers an overview of the current state of patient safety undertakings in long-term care settings in Japan today.

keywords: long-term care, patient safety, reporting system, lawsuits, training

(accepted for publication, January 29, 2024)

I. Introduction

As Japan becomes a “super-aging society,” long-term care (LTC) facilities to provide safe long-term healthcare services to elderly people in need have become increasingly important. In promoting patient safety initiatives, “reporting first,” that is, voluntary incident reporting, is necessary to identify accidents that have occurred. The Project to Collect Medical Near-Miss/Adverse Event Information by the Japan Council for Quality Health Care (JQ) was launched in 2004 as a national accident reporting system for patient safety[1], [2]. Additionally, in 2015, the Japan Medical Safety Research Organization launched the Medical Accidents Investigation System, which focuses on fatal accidents[3]. Each reporting system has helped improve patient safety through learning from many accidents that have occurred in the medical field and by proposing systems to prevent recurrence.

The collection of information on accidents in long-term care facilities is the responsibility of local governments, but the data collected are not always utilized for further safety improvement in such facilities. For this reason, efforts are being made to standardize reporting forms and strengthen the patient safety management system at long-term care facilities, with a view to establishing a system to utilize this information at the national level in the future. This paper will introduce past and current patient safety efforts related to long-term care in Japan.

II. Changes in the system for promoting patient safety in long-term care

In 1999, Article 31 of the “Standards for Facilities and Operation of Special Nursing Home for the Elderly,” a

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Ministry of Health and Welfare [currently the Ministry of Health, Labour and Welfare (MHLW)] ordinance, stipulated the following items regarding prevention of and response to accidents [4]:

- Guidelines shall be established for responding to accidents and preventing accidents from occurring.
- When an accident occurs or a situation arises that could lead to an accident, a system shall be established to ensure that the relevant facts are reported and that staff members are informed of remedial measures to be taken through fact-based analysis.
- Committee meetings to prevent the occurrence of accidents and training for staff members shall be held regularly.
- A person shall be appointed to supervise and ensure the appropriate implementation of the measures listed in the preceding item.
(*If a nursing home does not meet the facility standards for the above four items, it is subject to exclusion from long-term care insurance from 2021 onward.)
- If an accident occurs during the treatment of a resident, the special nursing home must promptly notify the municipality, the resident's family, etc., and take necessary measures.
- A special nursing home for the elderly shall record the circumstances of the accident set forth in the preceding paragraph and the measures taken after the accident.
- In the event that an accident occurs that should be compensated for because of the treatment of residents, the special nursing home for the elderly shall promptly compensate for the damages.

Long-term care welfare facilities for the elderly (special nursing homes for the elderly) [5] accept residents who require long-term care and provide daily living support services such as assistance with bathing and eating, functional therapy/exercises, and medical care, to enable as many residents as possible to return to their homes after care.

In 2001–2002, the “Study Group on Risk Management in Welfare Services” discussed approaches to risk management in welfare services. The use of welfare services has shifted from being implemented in accordance with public policy measures to a private contract-based system. Traditionally, welfare services were provided as administrative measures, and the administrative organs determined whether a service was necessary or not, the service contents, and the service providers. Under the contract-based system, mutual rights and obligations are clarified and services must be provided appropriately. It was pointed out that with welfare services, ensuring the safety and security of users is fundamental, and that there is an urgent need to establish a risk management system in welfare services that is cen-

tered on accident prevention measures. The “Guidelines for Risk Management in Welfare Services: Seeking the Smiles and Satisfaction of Users” were then compiled. [6]

Overview of guidelines

(1) General overview

- Basic perspectives on risk management in social services
 - Many accidents can be prevented by providing higher-quality services (quality improvement).
 - As each facility has highly individualized needs, adequate considerations and adaptations are required at each facility.
- Roles and responsibilities of management
 - Importance of management's leadership and determination

(2) Development of a system to promote risk management

- Points to consider when developing a risk management system and promoting initiatives
 - Improvement of organizational culture
 - Organization-wide efforts
 - Continuous efforts

(3) Guidelines for accident prevention measures

- Perspectives and specific measures based on the characteristics of welfare services
 - Importance of communication
 - Measures to resolve complaints
 - Importance of reviewing operations and taking initiatives from a risk management perspective

(4) Guideline for handling accidents when they occur

- Basic consideration of the preferences of users and their families, and thinking from the other party's perspective
 - Importance of daily efforts from the basic perspective of improving the quality of services
 - Organizational response, based on facts, and a single point of contact are the best general practice
 - Grasping the facts and fully explaining the situation to the family, etc., considering and implementing remedial measures, and responding with sincerity
 - Necessity of preparedness and awareness for prompt response immediately after an accident

In 2006, as a part of the revision of the LTC compensation system, it became mandatory to prevent LTC accidents by improving the system in facilities in the course of efforts to improve the quality of services, and some revisions were made to the above standards as follows:

Prevention of Accidents and Response to the Occurrence of Accidents (Article 31 of the Standards)

(1) Guidelines for the prevention of accidents

The “guidelines for the prevention of accidents” to be maintained by special nursing homes for the elderly shall

include the following items.

Basic policy regarding the prevention of LTC accidents at facilities

- 1) Matters related to committees and other organizations within the facility for the prevention of LTC accidents
 - 2) Basic policy on staff training for the prevention of LTC accidents
 - 3) Basic policy on measures for improvement aimed at ensuring safety in LTC, including reporting methods for LTC accidents that have occurred at a given facility and near-miss cases that did not lead to LTC accidents but are likely to lead to an LTC accident if left unchecked (hereafter referred to as "LTC accidents, etc.")
 - 4) Basic policy on measures to be taken in the event of an LTC accident, etc.
 - 5) Basic policy regarding residents' access to these guidelines
 - 6) Other basic policies necessary to advance LTC accident prevention measures
- (2) Informing staff of remedial measures to be implemented through fact reporting/analysis

It should be noted that the purpose of a special nursing home to establish and disseminate reporting and improvement measures is to share information about LTC accidents, etc. throughout the facility and prevent future recurrence; it is never for the purpose of punishing staff.

The following concrete steps are envisioned.

- 1) Forms for reporting LTC accidents, etc., shall be prepared.
 - 2) LTC staff and other staff shall record the circumstances, background, etc. of each LTC accident, etc., and report on LTC accidents, etc., according to the form in 1).
 - 3) The committee for the prevention of accidents mentioned in item 3) below shall compile and analyze the cases reported in item 2) above.
 - 4) In analyzing the cases, the situation at the time of the LTC accident, etc. shall be analyzed, the causes and results of the LTC accident, etc. shall be summarized, and preventive measures shall be discussed.
 - 5) The reported cases and the results of the analysis shall be made known to the staff.
 - 6) Evaluate the effectiveness of preventive measures after implementation.
- (3) Accident prevention committee

The "Accident Prevention Committee" at special nursing homes for the elderly is a committee that evaluates measures to prevent the occurrence of LTC accidents as well as their recurrence, and is composed of a wide range of personnel (e.g., facility director (manager), office manag-

er, doctors, nurses, LTC staff, and lifestyle consultation staff). It is necessary to clarify the responsibilities and division of roles among the members of the committee, as well as determine a dedicated supervisor to oversee safety measures.

The Accident Prevention Review Committee should be established and operated independently from other committees such as the Steering Committee. However, the Infection Control Committee may be established and operated together with the Accident Prevention Review Committee, since it is recognized that the positions involved and matters handled are closely related. The person in charge of the Accident Prevention Review Committee should preferably be the individual responsible for overall care. It is also desirable to utilize safety experts outside the facility as members of the Accident Prevention Review Committee.

- (4) Staff training for purposes of accident prevention

The content of training for the prevention of accidents for LTC and other staff shall include the dissemination and cultivation of suitable knowledge regarding fundamental aspects of accident prevention, etc., as well as thorough safety management capacities based on the guidelines at the relevant special nursing home for the elderly.

To ensure thorough staff education in an organized manner, the relevant special nursing care facility should prepare a training program based on the guidelines, hold regular education sessions (at least twice a year), and always conduct training in the prevention of accidents when newly hired.

It is also necessary to record the details of the training conducted, which may be conducted on-site at the staff's own facility.

- (5) Compensation for damages

If a special nursing home is required to compensate a user for damages, it must do so promptly. Therefore, it is desirable to have indemnity insurance or the capacity to compensate for damages.

The 17th Long-term Care Remuneration Revision Verification and Research Committee meeting was held in March 2019. In the "Survey and Research Project on the Safety and Sanitation Management System in LTC Geriatric Welfare Facilities," a project to verify the revision of LTC remuneration in FY 2008[7], the types of accidents reported to the municipalities were "falls due to physiological weakness" (91.2%), "falls due to environmental hazards" (84.6%), "accidental medication" (72.5%), "aspiration" (72.1%), and "pica" (68.9%). In addition, 46.7% of the municipalities "do not compile or analyze" the reported LTC accident information, and 30.7% "do not utilize" this information. The

results suggest that there are limitations in the ability of municipalities to analyze and utilize accident information. The survey also revealed variations in the standard of the reports regarding the scope of accidents that municipalities require of establishments, and the need to establish rules, including the scope of reportable content regarding accidents that occurred at LTC facilities.

In the report summarizing the deliberations on the revision of LTC fees for FY2021 held in February 2020, it was stated that “in light of the fact that accident reporting standards vary from municipality to municipality, the national government will prepare and disseminate a reporting format from the perspective of contributing to information accumulation and effective utilization of such information through the standardization of accident reporting in the future.” Because of the need for the standardization of accident reporting, in March 2021, the MHLW issued the Reporting Forms for Accidents at Long-term Care Insured Facilities, etc.,” which presented standardized reporting forms for the utilization of LTC accident information reported to local governments,. In principle, all accidents that should be reported should fall under the following two categories: (1) accidents that resulted in death, and (2) accidents that were diagnosed by a physician and required some form of medical treatment or medication

The reporting of other accidents should be handled by each municipality. In addition, as a reporting procedure, the “submission of accident reports to the municipality by e-mail is preferred,” which also promotes efficient operation.

III. Current state of the long-term care safety management framework

A survey of LTC facilities and municipalities was conducted from October to November 2022 as part of a research project on risk management for LTC-insured facilities (Table 1). The purpose of the survey was to gain an understanding

of the actual situation regarding the utilization of the new accident reporting form and the content of reported accident information, as well as to obtain basic data that would contribute to the analysis of reported accident information and the study of how the data should be utilized.

Long-term care welfare facilities for the elderly (special nursing homes for the elderly) accept residents who require long-term care and provide daily living support services such as assistance with bathing and eating, functional therapy/exercises, and medical care, with the aim of enabling as many residents as possible to return to their homes.

Long-term care health facilities for the elderly/Rehabilitation facilities for the elderly[8] accept residents who will eventually return home, and provide rehabilitation, necessary medical care, LTC, and other services to enable them to live as independently as possible.

Integrated Facilities for Medical and Long-term Care / Nursing Care Medical Clinics[9] are facilities that combine medical functions such as “routine medical management” and “end-of-life care and terminal care” with “assisted living” functions, geared toward the elderly who have both long-term medical and LTC needs.

III-1. Summary of results of a survey of LTC facilities

(1) Percentage of full-time employees who had attended training courses

Of full-time employees, 56.7% responded that “80% or more” had attended training courses during FY2021, and 18.8% responded that “60-80%” had attended training courses during the same period.

(2) Percentage of full-time employees who received training

Of full-time employees, 56.7% responded that “80% or more” had attended training courses during FY2021, and 18.8% responded that “60-80%” had attended training courses during the same period.

(3) Challenges regarding training implementation

An overall 60.5% of the respondents said that “it is difficult to find time for training and to adjust to the date

Table 1 Target facilities and collection status

Target facility/organization	Total number	Number of surveys issued	Number of surveys collected	Survey collection rate	Valid survey collection rate
Long-term care welfare facilities for the elderly	8,340	3,800 (Random selection)	1,600	42.10%	42.10%
Long-term care health facilities for the elderly/Rehabilitation facilities for the elderly	4,226	1,550 (Random selection)	540	34.80%	34.80%
Integrated Facilities for medical and long-term care/Nursing Care Medical Clinic	671	653	253	38.70%	38.70%
Municipalities	1,718	1,630	801	49.10%	49.10%
Prefectures	47	47	47	100%	100%

and time” and 52.3% said that “the level of understanding training by staff members varies.”

(4) Forms for reporting LTC accident information

Overall, 78.7% of the respondents answered that information on LTC accidents occurring in their facilities was recorded in the facility’s own accident report form, and 61.0% said that it was recorded in the accident report form prescribed by the municipality.

(5) Methods of analyzing information on LTC accidents and near-misses

Regarding the method of analyzing information on LTC accidents and near-misses, 89.4% of the respondents answered that they report the “Total the number of LTC accidents and near-misses” and 69.9% answered that they “Organize the number of LTC accidents and near-misses by type of accident (falls, aspiration, etc.) to identify trends.”

(6) Effective measures and initiatives to prevent LTC accidents

According to respondents, the most effective measures to prevent LTC accidents were “Investigation of the causes of LTC accidents and consideration of measures to prevent recurrence” (72.6%), “Investigation of the causes of near-misses and consideration of measures to prevent recurrence” (52.1%), and “Implementation of facility-wide training on LTC accidents” (40.7%).

(7) Accident prevention challenges for facilities

An overall 39.6% of the respondents answered “Difficulty in ensuring user safety due to lack of manpower” and 38.7% answered “Inability to find time to study organizational measures due to busy work schedule” as challenges for facilities in preventing LTC accidents.

(8) Format of accident reports to the local municipal government

Overall, 72.6% of the facilities selected “Yes” for the standard accident report form provided by the MHLW for submitting accident reports to the municipality.

(9) Method of accident report submission to the local municipal government

In all, 43.2% of the facilities submitted accident reports to the municipality by hand delivery, 35.2% by mail, and 32.1% by e-mail.

(10) Support obtained from the local municipal government

Regarding support from municipalities for the prevention of LTC accidents and their recurrence, 59.0% of the respondents answered that they “do not receive any support from municipalities.” The support received from the municipality was “Advice on how to respond to LTC accidents occurring at the facility (e.g., handling of family members)” at 14.6%.

(11) Potentially beneficial support from the local municipal

government

A total of 56.2% of respondents answered “Provision of information on case studies and efforts to prevent recurrence of LTC accidents at other facilities” and 34.6% answered “Information on external training programs appropriate to the situation of LTC accidents at their facilities” as the most useful support they could receive from their municipalities in terms of LTC accident prevention and recurrence prevention.

III-2. Summary of survey results targeting municipalities

(1) Establishment of reporting formats and forms from facilities to the local municipal government

Of the respondents, 64.5% answered that they use the “Standard Accident Report Form (Ministry of Health, Labour and Welfare),” and 20.2% answered that they use a form separately prescribed by the municipality.

(2) Utilization of “4. Summary of Accident” entries

Regarding the status of utilization of responses to “4. Summary of Accident” in the Standard Form for Accident Reports (Ministry of Health, Labour and Welfare), 45.8% of the municipalities responded that they “tabulate and analyze” the responses.

(3) Status of utilization of responses to “5. Response to Accident Occurrence” entries

Regarding the status of utilization of responses to “5. Response to Accident Occurrence” entries in the Standard Form for Accident Reports (Ministry of Health, Labour and Welfare), 36.2% of municipalities responded that they “tabulate and analyze” such information.

(4) Utilization of “6. Situation at the time of accident” entries

Regarding the status of utilization of responses to “6. Situation at the time of the accident” in the Standard Form for Accident Reports (Ministry of Health, Labour and Welfare), 36.8% of the municipalities answered that they “do not utilize” the form, while 24.0% answered that they “tabulate and analyze” such information.

(5) Status of utilization of “7. Factor Analysis of Accidents” entries

Regarding the status of utilization of responses to “7. Factor Analysis of Accidents” in the Standard Form for Accident Reports (Ministry of Health, Labour and Welfare), 34.4% of the municipalities answered that they “do not utilize” such information, and 24.0% answered that they “tabulate/analyze” such information.

(6) Status of utilization of “8. Preventive measures against recurrence” entries

Regarding the utilization status of “8. Preventive measures against recurrence” responses in the Standard

Form for Reporting Accidents (Ministry of Health, Labour and Welfare), 36.0% of municipalities answered that they do not utilize them, and 23.4% answered that they utilize individual information on LTC accidents that occurred at each facility to provide support to the affected facility.

- (7) Scope of reportable accidents
Of the municipalities that responded “Yes,” 95.9% stated “accidents resulting in death” and 96.6% stated “accidents requiring some kind of treatment such as medication or treatment after being diagnosed by a doctor (including doctors working at the facility and doctors assigned to the facility)” as the scope of LTC accidents to be reported.
- (8) Specification of reporting method
Regarding the reporting method of LTC accidents from facilities to municipalities, 42.8% of first reports were made by “e-mail” and 40.7% by “telephone.” In the second report, 43.4% of the respondents chose “hand delivery at the relevant office,” and 43.1% chose “e-mail.” In the final report, 51.7% of respondents chose “hand delivery at the counter,” and 47.9% chose “postal mail.”
- (9) Whether reported LTC accidents are tabulated/analyzed
Regarding the tabulation/analysis conducted, 59.3% of respondents simply tabulated the number of LTC accidents, and 32.2% identified trends by organizing the number of LTC accidents that occurred by type (falls, aspiration, etc.).
- (10) Status of utilization of LTC accident information
Regarding the utilization of LTC accident information, 49.6% of the respondents indicated that this information was “used to provide guidance and support to the facility that submitted the LTC accident report” and 28.6% selected “used to provide on-site guidance and advice to facilities other than those that submitted LTC accident reports (e.g., case studies). An overall 5.2% of respondents selected “to be used in regular training sessions for facilities in the municipality.”
- (11) Challenges in tabulating, analyzing, and utilizing LTC accident information
Regarding issues in the compilation, analysis, and utilization of LTC accident information, 57.6% of respondents answered that they “do not have the manpower to perform the tabulation and analysis” and 47.9% answered that they “do not have the know-how to perform the tabulation and analysis.”
- (12) Requests to the municipality regarding risk management at local LTC facilities
Regarding requests to the municipal government regarding risk management of local LTC facilities, 40.9% of the respondents requested “distribution of a format/

tool for tabulating LTC accident information” and 37.7% requested “preparation of a manual on how to tabulate and analyze LTC accident information.”

III-3. Summary of prefectural-level survey results

- (1) Status of accident information collection
Regarding the collection of information on accidents occurring at facilities throughout prefectures, 48.9% of respondents answered that they “require municipalities to report” and 44.7% answered that they “require the LTC facilities to report.”
- (2) Reporting forms and formats from LTC facilities to prefectures
Regarding the reporting format/forms used by offices to prefectural authorities, 57.1% of the respondents said that they use the “Standard Accident Report Form (Ministry of Health, Labour and Welfare)” and 33.3% said that they use the form prescribed by prefectures.
- (3) Items requiring reporting
Regarding items not included in the forms separately prescribed by prefectural governments, 71.4% of the respondents answered “No items not included” and 28.6% answered “Root cause analysis of the accident.”
- (4) Whether information on reported LTC accidents is tabulated and analyzed
Regarding whether the reported LTC accident information is tabulated and analyzed, 57.5% of respondents answered that they “organize the number of LTC accidents by type (falls, aspiration, etc.) to identify trends,” and 52.5% answered that they “organize the number of LTC accidents by facility type to identify trends.”
- (5) Status of utilization of LTC accident information
Regarding the utilization of LTC accident information, 70.0% of respondents answered that they “use the information to provide guidance and support to the facility that submitted the LTC accident reports,” and 47.5% answered that they “use the information to provide on-site guidance and advice to facilities other than those that submitted a given LTC accident report” (e.g., to offer case studies).
- (6) Challenges in tabulating, analyzing, and utilizing LTC accident information
With regard to challenges in tabulating, analyzing, and utilizing LTC accident information, 65.0% of respondents indicated they “do not have the manpower to tabulate and analyze” and 40.0% responded that “municipal employees do not have the opportunity to learn how to compile and analyze LTC accidents.”
- (7) Support for municipalities
Regarding support for municipalities in preventing LTC accidents and their recurrence, 46.8% of respon-

dents answered that they “do not provide support to municipalities” and 40.4% answered that they “provide advice on how to receive LTC accident reports from facilities.”

(8) Requests to the prefectural government regarding risk management at local LTC facilities

Regarding requests concerning risk management measures in nursing homes, 59.6% of respondents wanted “dissemination of best practices in the use of nursing home accident information” and 51.1% wanted “distribution of a format/tool for compiling nursing home accident information.”

At the 26th meeting of the Verification and Research Committee for Revision of LTC Compensation, LTC Benefit Cost Subcommittee of the Social Security Council, it was decided that the number of accident reports from LTC-insured facilities should first be disclosed after careful discussion and organization of the following issues, which should be clarified prior to disclosure:

- The appropriateness of the term “LTC accident” and its definition
- Comparison of the occurrence of LTC accidents in non-facility settings and in the facility
- Consideration of an appropriate denominator to enable verification of the incidence rate
- Methods to disclose the number of incidents, analysis of causes, and integrated preventative measures
- Methods of publication that contribute to the promotion of risk management at the facility, such as figures that can be compared with LTC facilities’ own figures
- The significance of widely publicizing the number of reported cases

IV. Review of legal precedent relevant to long-term care and other facilities and categorization of response modalities

Litigation has a significant impact on safety efforts in long-term care facilities. A review of legal precedent related to LTC shows that there are many cases involving falls, aspiration, and choking. However, accidents involving medication, such as accidental ingestion or dropping of medication on the floor or somewhere, occur frequently in the LTC setting, but few cases have resulted in litigation. This is thought to be because the accidents are addressed and resolved before they become life-threatening events. The following is a survey of the number of cases involving falls (caused by frailty or environmental hazards), aspiration, and choking, which are the most frequently litigated types of LTC accidents, as well as the most current case law.

(1) Cases involving falls

[Period and number of cases]

Date of last judgment: December 26, 1988, to November 1, 2022

- Legal precedents for falls (Number of cases: 54)
 - 1988 to 2000: 9 cases
 - 2001 to 2010: 17 cases
 - 2011 to 2022: 28 cases

[Place of occurrence]

During commuting (outpatient): 21 cases; hospitalization (inpatient): 37 cases; other (home, recreation center): 5 cases

[Recent judicial rulings]

- A case in which the court found that it was “sufficiently foreseeable” that an 87-year-old man with dementia was likely to leave the bathroom on his own and suffer a fall if he was unattended, and ordered financial compensation to be paid (Kobe District Court, November 1, 2022, decision)
- A case in which an LTC employee briefly left a resident with dementia seated on a toilet seat unattended and the resident suffered a fall and died from related injuries 72 days later, and the court found that there was a causal relationship between the LTC employee’s negligence and the incident (Tsu District Court, March 14, 2019, decision)

(2) Court precedents involving aspiration and choking

[Period and number of cases]

Date of last judgment: December 23, 2000, to December 21, 2020

- Judicial rulings related to aspiration cases (Number of cases: 30)
 - 2000 to 2010: 12 cases
 - 2011 to 2020: 18 cases

[Place of occurrence]

During commuting: 8 cases; During admission (hospitalization): 20 cases; Home-visit nursing care: 2 cases

[Recent judicial rulings]

- A case in which the defendant facility was acquitted on the grounds that the defendant did not have a duty of care to serve the victim a small meal in a suitable manner after confirming its mode of preparation before being served to the victim-plaintiff. (Tokyo High Court (Appeals Court), July 28, 2020, decision)

(3) Accidents other than falls, aspiration, and choking

From the review of precedents, there were 31 cases of accidents other than falls and aspiration/choking. The breakdown is as follows: 2 cases during bathing, 8 cases of decubitus ulcers, 6 cases of wandering, and 15 other cases.

(4) Categorization of responses

Based on precedents and overseas efforts, the following seven perspectives were considered as typologies of responses to adverse events that should be considered. Fall cases are used as an example. Ultimately, it is not the fall itself that should be prevented but the disability (adverse event) caused by the fall:

1) Identification of and response to fall susceptibility (patient's condition and environment):

(Example ruling in a case involving a fall incident)

A case in which the operator was found liable for damages for failing to install a bed release sensor in an accident in which a patient fell while trying to go to the bathroom late at night and developed an acute subdural hematoma, on the grounds that the operator violated their duty of care for safety.

(Example ruling in a case involving a fall incident)

In a case in which a resident fell from a window in her room and suffered multiple fractures and later died, the stopper of the window was found to be defective because it could be removed by pulling hard on it by hand even when it was locked.

- In the examples of countermeasures taken in the UK, there are references to "identification of elderly people at high risk for falling," "multifactorial fall risk assessment of elderly people at high risk for falling," and "strength and balance training for high-risk individuals."

2) Early detection of behavior that could lead to a fall:

(Example ruling in a case involving a fall incident)

A case in which an LTC worker left a resident with dementia seated on a toilet seat and the resident fell, suffering an acute subdural hematoma injury, and death, and the LTC worker was found to be negligent and causally related.

- If it is not possible to prevent behaviors that could lead to falls, adverse events can be prevented by promptly discovering that the behavior has occurred and responding in a timely manner.

3) Prevention of injuries when falls do occur:

LTC facilities should also take steps to prevent injuries and other adverse events from occurring even if a fall does occur. Examples include the use of hip protectors/cushion pants and protective caps to absorb the impact of a fall on the femur and reduce the risk for fractures, and the use of flooring materials (shock-absorbing mats) to reduce the impact of a fall on the floor.

4) Early detection of adverse events (injury/disability after a fall event)

(Example ruling in a case involving a fall incident)

A hospitalized patient with multiple cerebral infarctions

fell and died in the hospital room. The hospital was found liable for damages on the grounds that the nurse was negligent in failing to escort the patient.

- Even if a patient falls, early detection of the fall increases the possibility of minimizing the damage to the patient.

- In an example of a countermeasure taken in the UK, there is a reference to "confirming fractures and other injuries caused by falls."

- A statement by a working group of the Japan Geriatrics Society and the National Association of Geriatric Health Care Facilities, "To make people aware of falls in LTC facilities - a message to the public" (July 2021)[10], includes a description of "example procedures for responding to falls"

5) Early treatment of adverse events (injury/disability after a fall event)

(Example ruling in a case involving a fall incident)

An elderly person contracted with a day-care facility to receive LTC services. When the elderly individual left his seat to exit the facility's shuttle, they fell. The operator of the LTC facility was found to have not violated their duty of care to ensure safety but was found to have violated the duty to have the patient promptly examined by a physician.

- Not only the early detection of a fall but also the subsequent diagnosis of the presence or absence of adverse events and timely treatment is required.

- In the example of the UK's efforts, there are references to "safety manuals for falls/response after a fall" and "examination after a fall incident."

6) Cooperation between LTC facilities and medical institutions:

- Cooperation is especially necessary in cases such as 4) and 5) above.

7) Efforts to prevent legal action:

- Even though various measures have been taken, some adverse events due to falls have occurred that could not be avoided. Sharing safety-related risks with users and their families and cooperative efforts is required.

- The statement by a working group of the Japan Geriatrics Society and the National Association of Geriatric Health Care Facilities, "To make people aware of falls in LTC facilities - a message to the public" (July 2021) indicates that "the existence of falls that cannot be prevented" is considered a contributing factor in this regard. "Appendix 1. Information that should be shared between facility staff and residents and their families in relation to falls, etc." included in this document is also a useful reference[10].

- In the example of the UK initiative, there is a reference to “risk assessment and intervention in the home,” reminding all that falls can occur in the home as well.

V. Hearing on the status of measures taken by LTC facilities

(1) Efforts and issues

Interviews were conducted with LTC safety personnel from about 20 corporations and organizations involved in LTC from 2019 to 2021, and the following items were raised regarding LTC safety initiatives and issues, etc.:

Reference measures

- (Facilities affiliated with hospitals)
Facility directors participate in the safety management committee of the affiliated hospitals and work together to position elder care facilities, group homes, and visiting nurse stations as a department within the hospital
- (An elder care facility attached to a psychiatric hospital)
The safety management committee of the elder care facility collaborates with the hospital on cases that are difficult to handle or cases that should be shared with the hospital
- Once a week, a case study meeting is held: committee members go to the site of the case study meeting and conduct a detailed study, such as considering the bed direction

Issues related to fall risk

- Even if there is a high risk for falling due to wandering, the care manager’s permission is required for the use of sensors
- Residents’ physical functions (vision and hearing) are deteriorating, but they are unable to receive medical examinations because of restraints posed by the COVID-19 pandemic. As such, the status of these residents’ remaining capacities remains unclear, and they are at high risk for falling
- LTC staff members’ ages are relatively advanced. This may be why LTC staff are sometimes unable to notice changes in these residents
- Measures to prevent falls are being taken in the form of physical restraints
- Inability to confirm with residents with dementia the cause(s) of fall incidents

Issues related to medication

- Many residents drop their medicine on the floor or somewhere
- There are many incidents of dropped medication, but it is often difficult to identify who is supposed to take that medication found on the floor

- After giving medication, the resident spits it out
- There is a set procedure for giving medication, but the extent to which its proper execution is confirmed is not clear

Challenges of working together as a team

- LTC staff maintain records only for the leader
- Difficulty in collaboration between nurses and LTC staff
- Difficulty in giving attention to each other
- Can not do without reservation
- No time to attend training due to lack of staff
- Unclear who will lead conferences
- Little opportunity for discussion
- The need for collaboration with multiple professions is recognized, but there are no opportunities to learn how to work together systematically, and there are many accidents due to poor communication
- LTC staff may find it difficult to understand the contents of reports from medical care staff and the proposed countermeasures, and may feel alienated from them

Reporting system issues

- Reporting culture has not taken root
- Examples of reports: falls, accidental medication, skin peeling, aspiration, different foods, trauma inside and outside the facility, and complaints
- Reporting varies considerably from facility to facility
- Kiken Yochi (Risk Prediction) Training (KYT) is conducted, but a systematic root cause analysis is not
- Incident reports are difficult to share
- Differences in the way near-misses and incidents are perceived
- No review of near-misses and incidents
- Results of the “why-why” analysis are used as a means of seeking individual responsibility
- Nurses and LTC staff differ in how they receive cases
- Even if there is a report, it does not lead to effective prevention of recurrence because there is no system to analyze the reported incidents
- Mandatory reports are made to the local government, but there is no actionable feedback

Challenges related to learning opportunities

- Lack of education on LTC safety
- There are few opportunities to learn about safety in a systematic manner. As a result, there is resistance to reporting accidents and fear of punishment, and few incidents are reported.
- There is little content on safety measures, as the focus is on “understanding the elderly” and responding to patients in a more personal manner
- Few people have received training in patient safety

Patient safety in long-term care in Japan

- There is a strong awareness of abuse prevention and complaint handling, with guidance on abuse being the main focus
- There is a strong perception that “accidents will not happen if individuals just stay vigilant”

Issues related to infection

- Every year, various infectious diseases tend to spread in specialized dementia wards (norovirus, scabies, COVID-19/influenza, etc.)
- (2) Training: Example of the approach taken at a certain social welfare corporation (team training)
- Background of training implementation and outline of training content
When incidents and COVID-19 cases occurred, on-site interviews revealed many communication problems. Therefore, they conducted a participatory training (2 hours) using materials from TeamSTEPPS®[11], an evidence-based team training.
 - Participants: 14 LTC workers, nurses, rehabilitation professionals, and others who wished to participate.
 - Over 80% with more than 10 years of occupational experience
 - Offices where they work: Residential/in-facility services (LTC elder care facilities, special nursing homes, etc.), commuting LTC (day-care service centers, etc.), and others (home-visit rehabilitation, etc.)
 - Findings from the post-training questionnaire
 - 90% responded that they enjoyed learning and found it useful for their work.
 - From watching the video materials and exchanging opinions, staff realized the importance of mutual support, communication, leadership, and situation monitoring of people, objects, etc. Staff felt particularly strongly about the video materials on rehabili-

tation in LTC facilities, and said, “Yes, situations like this occur.”

- Significance of TeamTEPPS® training in LTC facilities
TeamTEPPS® training could be used in LTC facilities and offices with diverse functions to learn about teamwork for enjoyable and successful outcomes. The fact that all participants mentioned the tools they learned as safety measures and said, “I’m going to try this,” was considered an effect of the training. A factor contributing to incidents in LTC facilities is the team collaboration problem, just as in hospitals. The participants expressed a desire to continue actively incorporating TeamTEPPS® training into safety and infection control training.

(3) Need for systematic efforts

Based on the interviews regarding the status of initiatives at LTC facilities, we inferred that there are a variety of issues that need to be addressed in order to report incidents, consider countermeasures, and put them into practice. Specifically, there are few opportunities to learn about safety in a systematic and continuous manner. As a result, the significance of reporting is not well understood, and reports tend to be sporadic. Moreover, even when there are reports, there is no mechanism to systematically analyze accidents and effectively prevent recurrence, not only in LTC facilities but also in local governments. Another factor contributing to many accidents is poor communication. In examining these issues, the “Ten Essentials for Providing Safe Medical Care” and the “Overall Structure of Patient Safety” prepared on September 11, 2001, by the Human Error Subcommittee of the Medical Care Safety Measures Study Council, Medical Policy Bureau, Ministry of Health, Labour and Welfare,

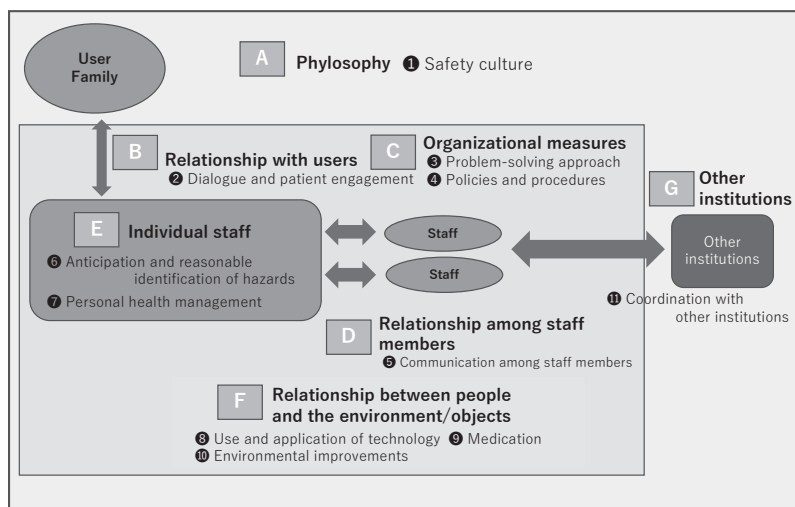


Figure 1 Overall Structure of Patient Safety in Long-term Care

can be consulted[12]. Taking this into consideration, the overall structure of patient safety in LTC (Figure 1), which shows the overall picture of various issues at LTC sites, and a system to learn systematically as a team (team training such as TeamSTEPPS®) and work better together with colleagues, users, and their families is necessary to prevent accidents.

In the overall structure of patient safety LTC (Figure 1), first, it is essential to foster a “① Safety Culture” at each facility as “A. Philosophy” An organizational culture that prioritizes the safety of users rather than business operations is necessary. In “B. Relationship with users,” “② Dialogue and patient engagement” is required, and this will also help avoid unnecessary lawsuits, etc. in the event of unavoidable accidents. “C. Organizational measures” require a “③ Problem-solving approach” and “④ Policies and procedures.” Regarding “D. Relationships among staff members,” “⑤ Communication among staff” is essential in providing safe care. Conversely, “⑥ Anticipation and reasonable identification of hazards” and “⑦ Personal health management” are required for “E. Individual staff.” In “F. Relationships between people and the environment/objects,” “⑧ Use and application of technology,” “⑨ Medication,” and “⑩ Environmental improvements” are also useful perspectives. In “G. Other institutions,” based on many cases, it is considered essential to “⑪ Cooperate with other institutions” such as medical institutions outside the facility in a timely manner to respond to events that are difficult to resolve through measures taken by the affected facility alone.

VI. Economic incentives to promote safety

Starting in 2021, LTC insurance will establish an additional reimbursement for safety measures, which will increase the income of LTC facilities if the following items are met

- Development of guidelines for accident prevention
- Establishment of a system to ensure that all staff members are aware of the details of accidents and measures to prevent recurrence, including posting of information regarding the accident
- Organization of committees and training on accident prevention
- Assignment of a manager who has attended external training

If these systems are not implemented, a deduction will be applied in the reimbursement, resulting in a decrease in revenue for the LTC facility. The content of the above items to be included in external training is left to each facility or-

ganization and has not been standardized. In the area of patient safety, the MHLW has provided information describing the content of patient safety training that managers should undergo[13].

VII. Conclusion

Safe LTC practices are required at LTC facilities. The first step necessary for safe LTC is the identification of accidents and other incidents through voluntary reporting from the field and analysis to prevent their recurrence. However, many LTC facilities and municipalities that receive reports lack the reporting and learning mechanisms to make this happen. Based on the extracted precedents and domestic and international efforts, the following seven perspectives were considered as a classification (systematic approach) of measures to prevent adverse events (e.g., injuries due to falls, aspiration, etc.) and recurrence of adverse events:

(1) Understanding the likelihood of adverse events and the mode of response

- The elderly are at high risk for falls, aspiration, and choking as they age, and it is necessary to understand the likelihood of adverse events for each individual and respond accordingly (depending on the size and function of the facility), considering various individual factors. Sharing with users and their families the risks to users and the limitations of the facility’s response to these risks will help avoid unnecessary lawsuits, etc., in relation to item (7) **Measures to prevent cases involving unavoidable incidents from developing into lawsuits** below.

(2) Early detection of behaviors leading to adverse events (3) Prevention of injury less likely to occur even in the presence of behaviors leading to adverse events

(4) Early detection of adverse events

(5) Early treatment of adverse events

(6) Cooperation between LTC facilities and medical institutions

- Collaboration is especially necessary for items (4) **Early detection of adverse events** and (5) **Early treatment of adverse events** above
- For smooth determination of the degree of injury and response, consider establishing a cooperative system during normal operation and a system that can be consulted even during emergencies

(7) Measures to prevent cases involving unavoidable incidents from developing into lawsuits

- While it is necessary to share safety-related risks, etc., with users and their families and to work in collaboration with them, in relation to item (1) **Understanding the likelihood of adverse events and the mode of response** above, the likelihood of adverse events

identified for each individual user and how to respond to them (including limitations due to the size and function of the facility) should be shared with users and their families by preparing case descriptions and other information for each facility. At this point, seek understanding and cooperation from users and their families that excessive preventive measures can limit their autonomy, quality of life, and functional recovery, and also collaborate with them.

On the basis of these results, further efforts are expected at both the facility and municipal levels to develop and promote a system for systematically addressing accident prevention (reporting, analysis, planning countermeasures, implementation, evaluation, etc.) and training for collaboration among multiple professions, including users and their families, using the overall structure of LTC safety (Figure 1) as a reference.

Reference

- [1] 日本医療機能評価機構. 医療事故情報収集等事業 Japan Council for Quality Health Care. [Project to Collect Medical Near-Miss/Adverse Event Information] <https://www.med-safe.jp/contents/english/index.html> (in Japanese) (accessed 2024-01-23)
- [2] Taneda K. Patient safety: History and recent updates in Japan. *J Natl Inst Public Health*. 2019;68(1):55-60.
- [3] Japan Medical Safety Research Organization. Medical Accidents Investigation System. https://www.medsafe.or.jp/modules/en/index.php?content_id=1 (accessed 2024-01-23)
- [4] 平成十一年厚生省令第四十六号 特別養護老人ホームの設備及び運営に関する基準 [Heisei 11 nen Koseishorei dai 46 go Standards for Facilities and Operation of Special Nursing Home for the Elderly] <https://elaws.e-gov.go.jp/document?lawid=411M50000100046> (in Japanese) (accessed 2024-01-23)
- [5] 厚生労働省. 介護老人福祉施設 (特別養護老人ホーム) Ministry of Health, Labour and Welfare. [Long-term care welfare facilities for the elderly (special nursing homes for the elderly)] <https://www.kaigokensaku.mhlw.go.jp/publish/group14.html> (in Japanese) (accessed 2024-01-23)
- [6] 厚生労働省. 福祉サービスにおける危機管理 (リスクマネジメント) に関する取り組み指針 Ministry of Health, Labour and Welfare. [Fukushi service ni okeru kiki kanri (risk management) ni kansuru torikumi shishin)] <https://www.mhlw.go.jp/houdou/2002/04/h0422-2.html> (in Japanese) (accessed 2024-01-23)
- [7] 平成 30 年度介護報酬改定検証事業「介護老人福祉施設における安全・衛生管理体制等の在り方についての調査研究事業」(結果概要) (案) Heisei 30 nendo Kaigo Hoshu Kaitei Kensho Jigyō. [Survey and Research Project on the Safety and Sanitation Management System in LTC Geriatric Welfare Facilities kekka gaiyoan] <https://www.mhlw.go.jp/content/12601000/000488392.pdf> (in Japanese) (accessed 2024-01-23)
- [8] 厚生労働省. どんなサービスがあるの? 介護老人保健施設 (老健) Ministry of Health, Labour and Welfare. [Long-term care health facilities for the elderly/Rehabilitation facilities for the elderly (roken)] <https://www.kaigokensaku.mhlw.go.jp/publish/group15.html> (in Japanese) (accessed 2024-01-23)
- [9] 厚生労働省. 介護医療院とは? Ministry of Health, Labour and Welfare. [Integrated Facility for Medical and Long-term Care towa?] <https://www.mhlw.go.jp/kaigoiryuin/about/> (in Japanese) (accessed 2024-01-23)
- [10] 日本老年医学会, 全国老人保健施設協会. 介護施設内での転倒を知っていただくために～国民の皆様へのメッセージ～ The Japan Geriatrics Society, Japan Association of Geriatrics Health Services Facilities. [To make people aware of falls in LTC facilities: a message to the public] https://www.jpn-geriat-soc.or.jp/info/important_info/pdf/20210803_01_02.pdf (in Japanese) (accessed 2024-01-23)
- [11] TeamSTEPS® <https://www.ahrq.gov/teamsteps-program/index.html>
- [12] 厚生労働省. 医療安全の全体構成. (安全な医療を提供するための10の要点) Ministry of Health, Labour and Welfare. [Overall structure of patient safety (Anzen na iryo o teikyosuru tameno 10 no yoten)] <https://www.mhlw.go.jp/topics/2001/0110/tp1030-1f.html> (in Japanese) (accessed 2024-01-23)
- [13] 厚生労働省医政局総務課医療安全推進室. 医療安全管理者の業務指針および養成のための研修プログラム作成指針. 令和2年3月改定. Iryo Anzen Suishinshitsu, Health Policy Bureau, Ministry of Health, Labour and Welfare. [Guidelines for operations and training of patient safety managers. Reiwa 2 nen revised.] <https://www.mhlw.go.jp/content/10800000/000898761.pdf> (in Japanese) (accessed 2024-01-23)

< 総説 >

我が国における介護現場の安全の取り組み

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抄録

超高齢社会を迎えて、介護施設の果たす役割は益々大きくなり、介護施設において、安全な介護の実施が求められている。医療安全の取り組みの推進において、まず起きている事故を把握することの必要性から、「Reporting first」と言われる。本邦においては、国レベルの事故報告システムとして、2004年から医療事故情報収集等事業、2015年から医療事故調査制度が開始されている。一方で介護における事故情報収集に関しては、地方公共団体にまかされているが、必ずしも介護の安全に活かされていない。このため介護現場の事故情報収集においても、将来、国レベルでの活用の仕組みの構築を視野にいれた、報告様式の標準化、介護現場の安全管理体制の強化などが取り組まれつつある。さらに介護現場の取り組み状況についてのヒアリングなどからは、介護安全の全体構成（案）を参考に、事故予防に体系的に取り組むための仕組み（報告、分析、対策立案、実施、評価など）と利用者・家族も含めて多職種で協働する訓練を整備・推進する取り組みが、各施設レベルでも各自治体レベルでもさらに期待される。この論文では、本邦における介護現場における安全の取り組みの現状について紹介する。

キーワード：介護，医療安全，報告制度，訴訟，研修