Recommendations for the prevention of recurrence of medical accidents

Number 15

Analysis of Deaths Related to "Erroneous Administration of Medicine"

January 2022

Medical Accident Investigation and Support Center
Japan Medical Safety Research Organization

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The Purpose of “Recommendations for the Prevention of Recurrence”

These recommendations are provided as information based on the medical accident investigation reports from the concerned medical institutions. Among those reports, the Medical Accident Investigation and Support Center accumulates similar cases, investigates and analyzes their common or similar points, and provides them as recommendations.

These recommendations should be regarded as recurrence prevention measures focusing on the importance of avoiding accidents that may result in death, and should be distinguished from the “Guidelines” issued by the government and academic societies. So, this leads to the fact that the recommendations do not set any limit to the discretion of health-care professionals, nor impose any new obligations or responsibilities.

Based on these considerations, we hope these recommendations will be widely used, taking into account comprehensively various situations such as the user’s medical decision-making, each patient's condition and age, the wishes of the patient and family, as well as the medical institution’s practice systems and size.

In addition, these recommendations are to provide information to avoid similar deaths, to prevent recurrence, and to ensure medical safety. It is based on the provisions of Medical Care Act, and is not intended to be used as a means for resolving disputes.

In Publishing the Recommendations for the Prevention of Recurrence of Medical Accidents (Number 15)

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Based on the Medical Accident Investigation System enforced in October 2015, the Medical Accident Investigation and Support Center [ISC] of the Japan Medical Safety Research Organization [Medsafe Japan] has been working with every effort to promote medical safety and to prevent recurrences of medical accidents. Along with the advancement and diversification of the current medical surroundings, medical institutions are supposed to have taken preventive measures against medical accidents, accumulating reports of near-miss incident cases so as not to allow serious accidents to occur. In practice, however, serious events do occur in fact, at times resulting in the death of the patient. Such cases have been reported to ISC. I believe that the mission of the Medical Accident Investigation System is to accumulate these reports, to investigate and analyze each case and to provide information for preventing recurrence of serious events.

Six years and three months have elapsed since the enforcement of the Medical Accident Investigation System, and we, ISC, have published our fifteenth report compiled in our Expert Analysis Subcommittee to prevent recurrence of medical accidents. The number of “In-Hospital Investigations” completed and reported to ISC was 1,539 cases in total during the five years from the start of the system to September 2020. As the fifteenth theme of analysis, we decided to take up the cases of death related to erroneous administration of medicine. The number of target cases that were reported under the Medical Accident Investigation System was 36. The recommendations in this report have been compiled in view of the seriousness of deaths resulting from erroneous administration of medicine.

ISC’s measures to prevent recurrences of accidents are based on the analyses of “death” cases and are focusing on “how to avoid accidents that may result in death”. “Guidelines” issued by the government and academic societies were examined from broad knowledge. We believe that our measures should be distinguished from such guidelines.

These recommendations do not limit or oblige the discretion of health-care workers, because each medical institution may have different environments and circumstances, such as size and system. With this in mind, we sincerely hope that the recommendations in this report will be widely utilized in each medical institution to avoid deaths resulting from erroneous administration of medicine.

Finally, we would like to express our sincere gratitude to the medical institutions and bereaved families who cooperated in providing in-hospital investigation reports and offering additional information, as well as to the experts of the analysis subcommittee who analyzed the cases in detail and explored the measures to prevent the recurrence, for their understanding and cooperation.

Recommendations for the Prevention of Recurrence of Medical Accidents (Number 15)

Analysis of Deaths Related to "Erroneous Administration of Medicine"

< Characteristics of target cases>

- In 35 out of the 36 cases, the cause of erroneous administration was insufficient confirmation.
- Looking at the 35 cases by drug administration process, 17 errors occurred during "Prescribing," 2 during "Compounding," and 16 during "Drug administration." All of those errors were not detected as errors throughout the series of processes.
- Of the 36 cases, 10 used the "medications placed in hospital wards" and 4 continuously prescribed their own "brought-in medication", which resulted in erroneous administration.
- Twenty-nine of the 36 patients were on high-risk medications.

[Confirmation in the processes of drug administration]	
Recommendation 1	The position of each person in charge in the process of prescribing and administering medicine should be clarified, and the "validity check" to confirm the indication of the medicine to the patient and the "collation type check" to check the prescription with the actual medicine, patient name, etc. should be reconfirmed. (See Figure 1 on P23).
[Manuals for confirmation]	
Recommendation 2	The in-hospital manuals for confirmation should be specific so that any staff member can clearly understand what and how to be reconfirmed in the "validity check" and the "collation type check" procedure, assuming that it will be used during busy times.
[Handling of unfamiliar medications]	
Recommendation 3	Medical institutions need to create an environment where drug information can be easily searched, and when dealing with unfamiliar medication, health-care professionals should utilize accurate information about the medication and have a good understanding of it before using it.
[Support for patients in checking their own medication]	
Recommendation 4	Medical institutions should establish a system that enables patients themselves to check their own medications, for example, by providing them with a "Medicine Information Form" so that they can check the name and appearance of the medicine as well as the number of tablets at the time when they take them.
["Medications placed in hospital wards" and their management]	
Recommendation 5	Considering the risk that placed medications are used without a pharmacist compounding process, the pharmacy division and the patient safety management division should also participate in determining medicines to be placed in the ward.
[Identification of "brought-in medicines" and audits in the continuous prescription]	
Recommendation 6	Medical institutions should establish a system whereby the pharmacy division identifies medicines brought-in by patients and proposes alternative prescriptions when necessary, and should also build a mechanism which enables pharmacists to check prescription and medication history again at a later date when differentiation and inspection cannot be performed timely.
[Response against "erroneous administration of medicine"]	
Recommendation 7	Overdosage of high-risk or antihypertensive medications should be interpreted as drug intoxication and patient monitoring should be initiated immediately even if there is no change just after administration, and at the same time consultation with a consultation service or physician specializing in drug intoxication should be sought.

〈 Characteristics of the target cases related to insulin 〉

・In all four cases related to insulin, “Insulin in vial preparation” was used.
・In two of the four cases, an excess amount was sucked up without using a dedicated insulin syringe.

[Instruction and confirmation of “Insulin”]

Recommendation 8	Insulin instructions must use “units” instead of “volume” [ml]. If you cannot suck up insulin with a dedicated insulin syringe, you should suspect that the instruction must be incorrect and check with the physician who ordered the instruction.

[Use “Dedicated insulin syringe”]

Recommendation 9	When you suck up insulin from “Insulin in vial preparation”, always use a dedicated insulin syringe and do not use any other syringe.

The full text of Recommendations No. 15, "The Analysis of Deaths Related to Erroneous Administration of Medicine", as well as the training material "To Prevent Accidents Related to Insulin in Vial Preparations" are available on the website of the Medical Accident Investigation and Support Center.
Please click on the QR code on the right to view the materials.

January 2022
The Expert Analysis Subcommittee and the Committee for Prevention of Recurrence
Medical Accident Investigation and Support Center.

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[Technical terms]

High-risk medicines:

① Pharmaceutical products that require careful attention to their dosage, etc.
② Pharmaceutical products that have a withdrawal period or require careful management to the duration of the medication.
③ Pharmaceutical products that are contraindicated for coadministration or those require careful attention to the interaction.
④ Pharmaceutical products that are contraindicated for specified diseases or pregnant women, etc.
⑤ Pharmaceutical products that require regularly scheduled examination to avoid serious side effects
⑥ Pharmaceutical products that require careful attention to cardiac arrest, etc.
⑦ Injections that require attention to respiratory depression
⑧ Injections whose dosage is measured in “Unit”.
⑨ Injections that cause skin disorder due to leakage

Quoted from / General Incorporated Association Japanese Society of Hospital Pharmacists: Work Guidelines for High-Risk Medicines [Ver.2.2.]. June 2016

1. Introduction

1) About erroneous administration of medicines

Health-care professionals recognize in general terms that drugs may cause harm and to lead to death. However, the accidents dealt with in this recommendations are deaths caused by “Erroneous Administration of Drugs” and must be distinguished from general risk management (measures for adverse reactions) by medications. Patient death due to erroneous administration of medicines should never occur.

In order never to occur the erroneous administration, it is necessary to understand that “human makes a mistake” is inevitable and then we should consider countermeasures. However, the competence for the medication therapy varies among the health-care professionals, and also there is a limit to aim at improving the knowledge of each individual. Therefore, in this recommendations, we put emphasis on the system countermeasures, such as process management from the point of prevention and monitoring system after the occurrence of erroneous administration. Also, the electronic medical record system is difficult to reform in a single medical institution, which is related to the measures against the erroneous administration of medicines such as similar appearance or the name of the drug [Error on object] or from patient identification or dosage / usage verification [Error on patient and dosage / usage verification], we would like to recommend correspond the countermeasures under a nationwide scale. However, these protections is still not perfect. It is possible to pass through multiple layers of protection, leading to erroneous administration. Therefore, It is important to create a mechanism which prevents death ever even if the drug is erroneously administered. So it was included in the recommendations that each medical institution should establish a superior patient monitoring and responding system for a sudden worsening situation at erroneous administration.

The Manual for preparing "Operating Procedure for Safe Use of Pharmaceutical Products", [2)] revised in December 2018, requires that the “Procedure Manual” should be arranged for each division and each process which covers from the adoption of pharmaceutical products to their administration. In addition, the promotion of patient participation in medical care has been regarded as one of the important measures, such as patient compliance instruction or drug administration guidance. By all means, in each medical institution refer to the cases presented in this recommendations when making “Procedure Manual” to prevent erroneous administration. Furthermore, in addition to the measures on system, the awareness of each health-care professional is also important. It should also be confirmed that the system alone cannot prevent accidents caused by erroneous administration.

In issuing this recommendations, we would like to draw special attention to the erroneous administration of “Insulin”, for which warning cases have been repeatedly reported in the past. Therefore, the “Insulin Vial” product was taken up separately as items of Recommendation 8 and Recommendation 9.

We sincerely wish that the nine recommendations contained in this issue could be one step toward the decrease of deaths from erroneous drug administration.

2) The circumstances and its evaluation of establishing the “Expert Analysis Subcommittee”

In order to prevent recurrence, the Committee for Prevention of Recurrence (see P41) in the Medical Accident Investigation and Support Center (hereinafter referred to as "the Center") compares and examines similar cases among the reported accidents to determine the subjects (themes) to be analyzed, and then establishes the Expert Analysis Subcommittee (see P40) which consists of specialists for each theme and prepares recommendations.

The environment surrounding medicines has greatly changed with advancement and sophistication in medical care. As a basis of preventing erroneous administration of medicine, the confirmation of “6Rs” is generally recommended: 1) Right Patient, 2) Right Drug, 3) Right Purpose, 4) Right Dose, 5) Right Route, and 6) Right Time.

Regarding medical safety information on medicines, a variety of warning notices have been provided by the “Project to Collect and Analyze Pharmaceutical Near-Miss Event Information” of the Japan Council for Quality Health Care (JQ) and by the Pharmaceuticals and Medical Devices Agency (PMDA), etc. Near-miss events included “overdose” due to incorrect input into medical record or wrong units, etc., “drug errors” due to similar drug names or mix-up of drugs placed side by side, etc., and “patient identification mistakes”, etc.

Under such circumstances, the manual for the preparation of "Operating Procedure for Safe Use of Pharmaceutical Products" [2] was revised in December 2018, and it is expected that each medical institution will also revise its own operating procedure.

Because multiple cases related to erroneous administration of medicines had been reported to the Center, we were convinced that it was an urgent task to analyze the cases of death related to the erroneous administration of medicines and to take measures to prevent recurrence, and then selected it as a theme and established the Expert Analysis Subcommittee under this theme.

3) Past initiative approach of patient-safety related to the recommendations

The following items have been published as a patient-safety approach to prevent the erroneous administration of medicines.

○ Japan Council for Quality Health Care

The Japan Council for Quality Health Care has published 61 items on drug-related medical safety information, of which 46 cases are related to our recommendations (as of October 2021).

Title of information	Year of publication	Title of information	Year of publication
No.1 Misidentification of Insulin content	2006	No.18 Mistakes in drug dosage due to wrong interpretation of prescription	2008
No.2 Bone marrow depression associated with overdose of antirheumatics (Methotrexate)	2007	No.22 Mistakes in the prescription of chemotherapy plan	
No.4 Mix-up of medicines		No.23 Mistakes in “units” when entering prescritions	
No.6 Misunderstanding of insulin “unit”		No.27 Medicine dosage mistakes in oral instruction	2009
No.9 Overdose due to misidentification of the total amount of prescribed drug product as the amount of active ingredient		No.29 Mistake in administrating 10 times the proper dose of medicine to a child	
No.13 Forgetting to check the flow rate of drip infusion pump, etc		No.30 Administrating a known medicine with positive allergic history	
No.15 Mix-up of medicines prepared in syringes	2008	No.38 Mix-up of medicines prepared in syringes in a clean field	2010

Title of information	Year of publication	Title of information	Year of publication
No.39 Insufficient identification of brought-in medicines	2010	No.108 Incorrect concentration of adrenaline	2015
No.41 Mistakes in drug dosage due to wrong interpretation of prescription [part2]		No.114 Forgetting to restart anticoagulants / anti-platelets	2016
No.45 Bone marrow depression associated with overdose of antirheumatics (Methotrexate) [part 2]		No.116 Patient mix-up when giving medication	
No.61 Administration of contraindicated medicines for coadministration	2011	No.118 Mix-up of medicines that are similar in appearance	
No.65 Mix-up of medicines placed in the emergency cart	2012	No.119 Mistakes in setting the drug volume or solution amount for a syringe pump	
No.66 Misidentification of insulin content [part 2]		No.120 Erroneous administration of medicine in a syringe with no name labelled on it	
No.68 Mix-up of medicines [part 2]		No.129 Administration of contraindicated medicines for coadministration [part 2]	2017
No.75 Mistakes in setting flow rates and scheduled volume for infusion pumps, etc.	2013	No.131 Misunderstanding of insulin “unit” [part 2]	
No.78 Mistakes in prescription quantities when switching from brought-in medicines to in-hospital prescription		No.140 Overdose exceeding the upper limit of the total dosage as an antineoplastic medicine	2018
No.84 Insufficient reconfirmation of incorrect prescription		No.143 Mistakes in re-prescription due to uncorrected previous prescription	
No.86 Administration of contraindicated medicine	2014	No.145 Administration of normal range dose of medicine to patients with decreased kidney functions	
No.89 Mix-up of syringe pumps		No.156 Erroneous administration of injectable medicine used for sedation	2019
No.96 Mix-up of insulin injectors		No.165 Administration of allergic medicine because of ineffective alert function	2020
No.98 Mistakes in administration method of potassium preparation	2015	No.167 Bone marrow depression associated with overdose of antirheumatics (Methotrexate) [part 3]	
No.101 Mistakes in the route of medicine administration		No.169 Inadequate prescriptions / instructions when continuing prescriptions of brought-in medicines	
No.106 Mistakes in dispensing medicines for children (dispensing pediatric medicines)		No.173 Mistakes of setting the flow rate to 10x speed at infusion pump, etc	2021

○ Pharmaceuticals and Medical Devices Agency (PMDA)

PMDA has published 15 drug-related medical safety information items, of which nine cases are related to our recommendations (as of October 2021).

Title of patient safety information	Publication year
No. 6 Information regarding erroneous administration (overdose) of antirheumatic methotrexate	2008
No.19 Information on erroneous administration of potassium (K) preparations	2010
No.21 Precautions when setting-flow rates for infusion pumps	2011
No.23 Precautions in handling “insulin vial” preparations (Exclusive use of “insulin syringe”)	2011 Revised in 2020
No.27 Information on handling of pharmaceutical products with a solvent attached	2011
No.31 Precautions when handling radiopharmaceuticals for injection	2012 Revised in 2020
No.44 Mistakes in drug selection when ordering a medicinal prescription	2014
No.49 Information on erroneous administration (overdose) of antirheumatic methotrexate [2nd report]	2016
No.51 Information on drug mix-up due to generic name similarity	2017

2. Methods of analysis

1) Extraction of target cases

Of the 1,539 in-hospital investigation reports on medical accidents submitted to the Center during the five years (October 2015 - September 2020), 273 cases were medicine-related deaths and deaths for which the relation between medicine and death could not be denied.

The Expert Analysis Subcommittee decided to analyze 36 cases, in which erroneous administration of medicine without confirming the "6Rs" may have been the cause of death. Of these 36 cases, 29 were high-risk medicines (see P4) and the remaining 7 cases were not high-risk medicines, but required alerting as high-risk medicine.

Other than the above, the death cases included anaphylactic shock, drug side effects, and bleeding due to disconnection of an intravenous infusion line.

2) Collecting and sorting of information from target cases

Based on the information provided in the in-hospital investigation reports submitted to the ISC, the cases were analyzed in the Expert Analysis Subcommittee. With regard to the areas that require confirmation, additional information was collected with cooperation of the reporting facilities as far as possible. The information was organized according to the investigation items checklist (see 7. "Materials")

3) Meetings of the Expert Analysis Subcommittee

○ First meeting	June 25, 2020
○ Second meeting	August 19, 2020
○ Third meeting	October 6, 2020
○ Fourth meeting	December 1, 2020
○ Fifth meeting	February 10, 2021
○ Sixth meeting	April 22, 2021
○ Seventh meeting	August 4, 2021
○ Eighth meeting	October 12, 2021

・In addition, opinions were exchanged through electronic media and other means.

3. Overview of target cases

The case overview was prepared by the Expert Analysis Subcommittee based on the in-hospital investigation reports and additional information. Regarding the notation of drug names, the product names (brand names) and generic name were listed together, and the registered trademark signs were omitted.

[Explanatory Note]

Case #:

Each Case number lists the "process" in which the error occurred, the "accident" that resulted from the error, the "medicine name" that was administered, and its "category".

1) Patient's age and disease(s) (diseases to be treated and related diseases).
2) Process leading to administration of the medicine.
3) Process after administration.
4) The cause of death. Presence or absence of autopsy images. Presence or absence of autopsy.

Case 1: Due to an "error in prescribing", contraindicated medicine was administered. Sulbacillin IV infusion 1.5g (Ampicillin sodium. + Sulbactam sodium) / Antimicrobials.

1) 70s, with lung cancer
2) At the time of the out-patient visit, the patient declared the anaphylaxis towards penicillin and it was confirmed in the patient referral document. After the admission, inflammation in the lung was observed, and Sulbacillin 1.5 g x 2 + Physiological saline 100 mL was prescribed. Allergy medicines had been registered, but there was no warning from the system, and then an intravenous infusion was administered without any opportunity to reconfirm allergy information at any point in the process.
3) Two minutes after the start of infusion, dyspnea appeared. The infusion was stopped immediately, but the patient fell into shock symptoms, and died two days after administration.
4) Cause of death: Anaphylactic shock. Ai (Autopsy imaging): absent. Autopsy: present.

Case 2: Due to an "error in prescribing", contraindicated medicine was administered. Wystal (Cefoperazone sodium + Sulbactam sodium). / Antimicrobials.

1) 70s, with cholangitis
2) Because of fever the patient visited emergency outpatient. Although information about allergies on Sulperazon and Wystal was described in the medical paper chart, an intravenous infusion containing Wystal was prescribed without checking the medical chart, and the intravenous infusion was administered without reconfirming allergy information at any point in the process.
3) Immediately after the start of intravenous infusion, the patient complained of throat itching and lost consciousness, and died on the day.
4) Cause of death: anaphylactic shock. Ai: absent. Autopsy: present

Case 3: Due to an "error in prescribing", contraindicated medicine was administered. Midazolam Injection 10 mg (Midazolam). / Sedative hypnotics.

1) 80s, with myasthenia gravis and cholangitis
2) For the endoscopic retrograde cholangiopancreatography, Midazolam 10 mg + Physiological saline 18 mL, which is a contraindicated drug for the patient with myasthenia gravis, was prescribed under the critical pass system. The drugs applied in the examination procedure were not the subject to prescription/drug inspection. Midazolam 1.25 mg was injected two times intravenously during the procedure, and the examination was completed.
3) Four and a half hours after the start of administration, percutaneous arterial oxygen saturation (hereinafter referred to as "SpO_2") decreased to 90%. Noninvasive positive pressure ventilation was performed but the patient died on the day.
4) The cause of death: Crisis of myasthenia gravis. Ai: absent. Autopsy: absent.

Case 4: Due to an "error in prescribing", a high concentration of medicine was administered. Meylon (8.4%) (sodium hydrogen carbonate) intravenous infusion. / Acidosis therapeutics.

1) 60s, with atrial fibrillation. The patient was taking anticoagulant oral administration, had decreased renal function, and was after cardiac operation.

2) At the site of contrast-enhanced CT examination, the radiologist suggested to the attending physician that sodium hydrogen carbonate should be used for renal protection (The drug concentration was not confirmed). While he should have prescribed 1.26% sodium hydrogen carbonate 1000 ml, the attending physician prescribed Meylon 8.4% 1000 ml. The nurse, having had doubts about the prescription, received this instruction after reconfirming it with the attending physician. Meyon was compounded as instructed and infused intravenously at a drip speed of 180 ml/h.
3) Approximately four hours after the start of infusion, a ventricular fibrillation appeared, and resulted in cardiac arrest. Angiography and hemostasis were performed due to pulmonary hemorrhage caused by chest compression but the patient died about one week later.
4) The cause of death: Fatal arrhythmia due to hypokalemia, hemorrhagic shock. Ai: absent. Autopsy: present.

Case 5: Due to an "error in prescribing", a high concentration of medicine was administered. "Fulcaliq type 3" infusion (high calorie infusion: multivitamin, glucose, amino acid, electrolyte solution). / Intravenous hyperalimentation (IVH) kit.

1) 80s, with diabetes mellitus
2) The prescription was changed from "Bfluid" two bottles a day (total 420 kcal/day) to "Fulcaliq type 3" two bottles a day (total 2,320 kcal/day) by the physician who had experienced prescribing only "Fulcaliq" as the high calorie infusion. The physician was unaware that the in-hospital adopted high calorie infusions were type 1 and type 2 (low calorie) for "Elneopa", type 3(high calorie) for "Fulcaliq", and type 1,2 "Fulcaliq" was not adopted. The pharmacist questioned the prescription in the electronic medical record, but was unable to get the physician's attention. However, the pharmacist compounded as prescribed, thinking the suspicions had been resolved, and the nurse administered the infusion.
3) On the fourth day after the start of high calorie infusion, urine output increased, and on the fifth day the consciousness level decreased and hyperglycemia became clear. The patient died on the day.
4) The cause of death: Diabetic ketoacidosis. Ai: absent. Autopsy: absent.

Case 6: Due to an "error in prescribing", an excessive dose of medicine was administered. Lidocaine drip infusion 1%. / Antiarrhythmics.

1) 50s, with fatal arrhythmia.
2) The physician who was inexperienced in Lidocaine administration, after checking the drug package insert, prescribed 200ml of Lidocaine 1% drip infusion for 30 minutes. At the pharmacist inspection step, the drip infusion rate was not checked. The nursing team was unfamiliar with handling the Lidocaine drip bag, and started the infusion with natural dripping at instructed speed.
3) About 15 minutes after the start of infusion, convulsions appeared and followed by cardiopulmonary arrest. The patient died on the day.
4) The cause of death: Lidocaine intoxication. Ai: absent. Autopsy: absent.

Case 7: Due to an "error in prescribing", an excessive dose of medicine was administered. Temodal capsules 100mg (temozolomide). / Antineoplastics

1) 70s, with Brain tumor (under chemotherapy)
2) The patient referral document from the attending neurosurgeon had not arrived at the hospital where the patient was urgently admitted due to the fracture. The orthopedic surgeon continued to prescribe 3 capsules of Temodal (100mg)/day for about one month. During that time, both prescribing audits and drug inspections overlooked multiple times that they should have included a drug withdrawal periods, and the medicine was administered.
3) Approximately one and a half months later, pancytopenia and bone marrow suppression occurred. After that It became clear that the medicine had been administered every day during the period that should have been a withdrawal period. The patient was treated, but died in about 4 months later.
4) The cause of death: Exacerbation of general condition due to bone marrow suppression. Ai: absent. Autopsy: absent.

Case 8: Due to an "error in prescribing", an excessive dose of medicine was administered. Rheumatrex capsules 2 mg (methotrexate). / Immunosuppressant.

1) 80s, with Rheumatoid arthritis, Pneumonia, and Cerebral infarction
2) The patient had been taking Rheumatrex capsules 4 mg once a week prior to admission, but Rheumatrex was not included in the brought-in medicines. From the point of not discontinuing medication, the neurosurgeon who did not recognize Rheumatrex required a withdrawal period, prescribed as everyday medication, 4 mg on the first and second day, and 2 mg on the third day. Since it was a holiday, and only one pharmacist was

on duty, and the same person conducted prescription audits and drug inspections, and compounded as instructed. Then the nurse administered it daily.
3) Three days after the start of administration, pneumonia worsened, and a prescription error became clear. The patient recovered temporarily, but died about four weeks later.
4) The cause of death: Exacerbation of pneumonia. Ai: present. Autopsy: absent.

Case 9: Due to an "error in prescribing", an underdose of medicine was administered. Predonisolone tablets 1 mg (predonisolone). / Corticosteroids

1) 80s, with Interstitial pneumonia.
2) When switching from "brought-in" prednisolone powder 1% 1.2 g/day to "in-hospital adopted medicines", the physician prescribed 1.25 prednisolone (1 mg) tablets/day. The prescription audit noticed that the dosage was different from that of the brought-in medicine, and reported it in writing to the pharmacist in the ward, but no reconfirmation or correction was made. A few days later, the medication was compounded as prescribed and administrated to the patient by a nurse.
3) Approximately one week after the start of the administration, a pharmacist who rechecked the prescription reported the underdose to the physician. Steroid pulse therapy was started the patient died about two weeks later.
4) The cause of death: Acute exacerbation of interstitial pneumonia. Ai: present. Autopsy: present.

Case 10: Due to an "error in prescribing", an excessive dose of medicine was administered. Digoxin KY tablets 0.25 (Digoxin). / Cardiac failure therapeutics

1) 70s, with Atrial fibrillation and Chronic renal failure.
2) The patient had been taking orally Digoxin 0.5 tablets of (0.25 mg) once a week. After the patient was transferred to the long-term care beds, the physician prescribed "Digoxin" along with the other regular 14-day medications, using an electronic medical record system with batch conversion on the duration. At the same time, the physician entered "once a week" for digoxin in the comments section, but the pharmacist did not notice this inconsistency in the prescription and compounded it in a single package with other medicines, and the nurse administered it daily.
3) After the start of administration, loss of appetite and slurred speech and indistinct behavior were observed. About two weeks later, the blood digoxin concentration level became abnormally high value and oral administration was discontinued. The patient died two days after the discontinuation.
4) The cause of death: Digoxin poisoning (suspected). Ai: absent. Autopsy: absent.

Case 11: Due to an "error in prescribing", Duplicated amount of medicine was administered. Xeloda tablets 300 (Capecitabine), *and* TS-1 combination OD tablets T 25 (Tegafur/ Gimeracil/Oteracil potassium). / Antineoplastics

1) 80s, with Gastric cancer (under XELOX therapy)
2) Because of the side effects, Xeloda should have been changed to TS-1, but the physician did not discontinue Xeloda. As a result, two medicines were prescribed in duplicate. They were compounded at an out-of-hospital pharmacy, and the patient started taking these two medicines.
3) Approximately two weeks after the start of administration, the patient fell ill and emergently transported, where duplicate administration was revealed, but the patient died 4 days after the duplicate administration.
4) The cause of death: Exacerbation of general condition due to bone marrow suppression.
Ai: absent. Autopsy: absent.

Case 12: Due to an "error in prescribing", medication was interrupted. Clopidogrel 75 mg tablets (Clopidogrel sulfate) / Antiplatelet agent.

1) 60s, with Old myocardial infarction
2) After the coronary angiography examination, Clopidogrel tablets 75 mg were prescribed at the time of discharge. At the first visit as an outpatient, the physician forgot to prescribe Clopidogrel and the administration was interrupted.
3) Approximately a month and a half later, the patient was readmitted for the purpose of percutaneous coronary intervention (hereinafter referred as "PCI"). After the PCI, it was revealed that Clopidogrel had not been administrated. After PCI, Prasugrel tablets 3.75 mg (antithrombotics) was administrated, but about one hour later, chest pain occurred, resulting in cardiac arrest. The patient died about two weeks later.
4) The cause of death: Acute myocardial infarction due to stent occlusion. Ai: absent. Autopsy: absent.

Case 13: Due to an “error in prescribing”, an excessive dose of medicine was administered. Bosmin injection 1mg (Adrenaline). / Cardiotonic agent.

1) 10s, with Anaphylaxis due to food.
2) The patient was diagnosed as the immediate type allergy at the emergency visit. and the physician instructed intravenous injection of Bosmin 1mg/1mL. The nurse recited back to the physician and confirmed the instruction, picked up the medicine from the medications placed in the emergency visit, and injected it intravenously.
3) Immediately after administration, the patient complained of headache and dyspnea, and turned pale. Loss of consciousness and cardiopulmonary arrest occurred. The patient died on the day.
4) The cause of death: Food-induced anaphylactic shock (suspected) and fatal arrhythmia due to the overdose intravenous injection of Bosmin (suspected). Ai: absent. Autopsy: present.

Case 14: Due to an “error in prescribing”, an excessive dose of medicine was administered. Fostoin intravenous infusion 750mg (Fosphenytoin sodium hydrate). / Anticonvulsants.

1) 40s, with Symptomatic epilepsy, Severe pneumonia, and Adult respiratory distress syndrome.
2) When switching the brought-in medication “Aleviatin powder 10% 1.5g orally administered” to in-hospital medication, the physician misread it as "Phenytoin 1.5g/day as drug substance" and prescribed “Fostoin 2.25g/day for intravenous administration”. The nurse picked up the medication from the medicines placed in the hospital ward and injected it intravenously.
3) Three days after the start of administration, the heart rate suddenly dropped to a 50s and SpO_2 80s%. The patient went into cardiopulmonary arrest and died on the day. After death, the blood concentration level of phenytoin was high, and a conversion error was revealed.
4) The cause of death: Cardiac conduction disorder. Exacerbation of adult respiratory distress syndrome. Ai: present. Autopsy: present.

Case 15 Due to “patient misidentification in prescribing”, unnecessary medicine was administered. Bosmin injection 1 mg (Adrenaline). / Cardiotonic agent.

1) 80s, with Interstitial pneumonia.
2) An ex post facto prescription for “Bosmin 1 mg” that had already been administered to another patient at the time of the emergency was prepared to be returned to the emergency cart. In doing so, the physician accidentally misidentified and wrote down the said patient's name. The Bosmin was delivered to the very patient from the pharmacy department. The newcomer nurse placed it in the storage area for the medication to be administered the next day. The next day, another nurse intravenously injected Bosmin 1 mg + Physiological saline 20 ml through the side tube of patient's intravenous infusion line.
3) After administering 15 ml, the nurse noticed the date on the injection slip was different and discontinued the infusion. Immediately thereafter, pallor of the face, respiratory distress, and decreased blood pressure occurred. After that, the condition did not improve, so the patient was transported emergently to another hospital. The patient died the next day.
4) The cause of death: Acute exacerbation of interstitial pneumonia. Ai: absent. Autopsy: absent.

Case 16: Due to an “error in compounding”, a different kind of medicine was administered. Dezolam tablets 0.5 mg (Ethizolam). / Anxiolytics.

1) 80s, with Breast cancer. Metastases to the liver and the brain.
2) Decadron (0.5 mg) four tablets/day was prescribed to continue the same medication as the “brought-in medicines” after switching to the “in-hospital medicines”. The pharmacist compounded Dezolam 0.5 mg after taking a look at the first two letters "De-" and "0.5 mg" on the prescription. It was overlooked through the drug inspection and the drug was delivered. When putting the drug in the distribution box, the nurse did not collate the name of the drug in the prescription with the drug itself in the box. The nurse in charge thought that the drug and the prescription had already been collated and reconfirmed only the patient's name and administered the oral medication.
3) On the day following the start of administration, drowsiness occurred, and the oral administration was discontinued (a total of 4 tablets had already been administered). On the fourth day after administration, it became clear that the dispensed drug was Dezolam 0.5 mg, which was different from that prescribed. The patient died about one week after administration.
4) The cause of death: Exacerbation of liver function and renal function. Ai: absent. Autopsy: absent.

Case 17: Due to an “error in compounding”, a different kind of medicine was administered.
Lixiana tablets (Edoxaban tosilate hydrate). / Anticoagulants

1) 70s, with Liver cell cancer and Hepatic encephalopathy.
2) Rifxima (hepatic encephalopathy therapeutics) was prescribed. The pharmacy assistant misidentified “Lixiana” as “Rifxima”, and compounded Lixiana. Then, the pharmacist overlooked the name of the drug through the drug inspection and dispensed it. The nurse did not collate the drug name on the drug envelope with the name in the prescription and administered it. The pharmacy was in a very busy situation at that time, with frequent interruptions in dispensing operations.
3) Nine hours after administration, hematemesis with a clot occurred. Heart rate rose up to 150s temporarily and remained around 80s. On the third day, bleeding of the palpebral conjunctiva and tarry stool appeared, and blood transfusion was started and upper gastrointestinal endoscopy were performed. Subsequently, blood pressure decreased. The patient died four days after administration. On the following day after the death, it was revealed that Lixiana tablets had been misidentified as Rifxima tablets.
4) The cause of death: Hemorrhagic shock due to gastrointestinal bleeding (suspected).
Ai: absent. Autopsy: absent.

Case 18: Due to “dosage error when preparing for administration”, an excessive dose of medicine was administered.
Morphine hydrochloride injection 50 mg (Morphine hydrochloride hydrate). / Narcotics

1) 60s, with Obstructive hypertrophic cardiomyopathy.
2) For the intended use in the cardiac catheter treatment and postoperative pain management, the attending doctor prescribed 50 mg/5 ml of morphine, which was a higher dose than the standard use (10 mg/1 ml). During the operation, the operator instructed "Inject ‘*morphi*’ 2.5", and then the nurse reiterated "It's a half of 50 mg of morphine hydrochloride, right?", but the doctors there did not show a reaction to it. Just before administering the dose, the nurse repeated to confirm, "I can inject ‘*morphi*‘ 2.5, right?" The operator responded, "OK, inject 2.5," and so the nurse injected 2.5 ml (25 mg) intravenously.
3) Immediately after administration, the patient respiration arrested, and chest compressions and electrical defibrillation and others were performed against the ventricular fibrillation. Spontaneous circulation returned once but the patient died in about two weeks later.
4) The cause of death: Respiratory arrest and ventricular fibrillation due to the overdose of morphine administration. Ai: absent. Autopsy: present.

Case 19: Due to “dosage error when preparing for administration”, an excessive dose of medicine was administered.
Oxifast injection 10 mg (oxycodone hydrochloride hydrate). / Narcotics

1) 60s, with Urinary bladder cancer. Multiple lung metastases.
2) The newly-appointed physician prescribed "Oxifast injection (10 mg/1 ml/A) 2 mg subcutaneous injection" on the narcotic prescription. The physician did not know the in-hospital rule that the prescriptions should be given in "ml" not “mg”. The nurse assumed that she would administer “one ampule” and overlooked the dose on the injection worksheet. During the double check, she was asked "One ampule is too much, isn't it?" But she answered, "I have heard one ampule," and gave a subcutaneous injection. Oxifast Injection Solution was infrequently used in the ward.
3) Approximately one and a half hours after administration, the consciousness level decreased and respiratory arrest occurred. The patient died on the day. Three days after the death, an overdose of Oxifast became apparent when the pharmacy department checked the remaining amount of narcotics.
4) The cause of death: Respiratory arrest. Ai: absent. Autopsy: absent.

Case 20: Due to “mix-up of medicines when preparing for administration”, medicine different from the instruction was administered.
OLIVES for intravenous infusion 1% (Lidocaine). / Antiarrhythmics.

1) 60s, with Ascending colon cancer. Peritoneal metastasis.
2) For the purpose of pain relief, Acelio 1000 mg/100 ml three times a day and OLIVES 4 ml/h had been administered daily. A nurse misidentified “OLIVES” as “Acelio”, and without collating the drug names, put an Acelio injection label on an OLIVES intravenous infusion bag. After patient identification, the intravenous infusion prescription was displayed on the screen and the label display was confirmed, and then the infusion was intravenously administered in 15 minutes.
3) Approximately one hour after administration, another nurse noticed the patient was in a state of cardio-pulmonary arrest and confirmed that the empty intravenous infusion bag was OLIVES. Assisted circulation using an artificial heart lung machine was performed, but the patient died on the day.

4) The cause of death: Lidocaine intoxication. Ai: absent. Autopsy: absent.

Case 21: Due to "patient misidentification when preparing for administration", unnecessary medicine which was ordered to be discontinued was administered.
Diltiazem hydrochloride injection 50 mg (Diltiazem hydrochloride). / Antihypertensives.

1) 80s, with Post-pleuritis pleural adhesion, Small cell lung cancer and Multiple rectal ulcer. Sepsis.
2) Diltiazem had been continuously administered as drip infusion for tachycardiac atrial fibrillation, but the patient's general condition worsened, and the infusion was discontinued under verbal instruction. The patient was transported to ICU with the notification to discontinue diltiazem cancellation. In this situation, an injection confirmation slip of another patient was slipped into, and the nurse misidentified the patient because the names were similar. The nurse collated with the wrong injection confirmation slip, being under the impression that the discontinuation had been instructed temporarily. In addition, there was a message saying "Completed" on the bar code, the nurse assumed that the data was misinput to the electronic medical record system, and administered intravenous infusion.
3) Thirty minutes after the start of infusion, blood pressure and heart rate were decreased, and diltiazem was discontinued, but the patient died on the day. (There was little possibility that diltiazem had reached into the body.)
4) The cause of death: Sepsis. Ai: absent. Autopsy: Present.

Case 22: Due to "patient misidentification when preparing for administration", a medicine different from the instruction was administered.
Amlodipine OD tablets 5 mg (Amlodipine besilate), Olmetec OD tablets 20 mg (Olmesartan medoxomil) / Antihypertensives (and five other drugs).

1) 80s, with Cerebral infarction and Nasogastric tube inserted.
2) Two patients with similar names were in the ward. The nurse prepared the oral medication alone without performing a double-check, and misidentified the patient's name. A total of seven drugs, including Amlodipine and Olmetec for another patient, were dissolved and prepared in one bottle. During the preparation, the work was interrupted by a nurse call. The patient's name label on that bottle was checked by another nurse, and the drugs were administered through a nasogastric tube.
3) Four hours after administration, it was discovered that the medication that should have been taken by the patient remained, and revealed that the oral drugs for another patient had been mistakenly administered. Drip infusion for supplement fluid was started, but vomiting, decreased blood pressure, and respiratory distress occurred, and the patient was emergently transported to the medical center. Contrast CT showed a thrombus in the aortic arch and ischemic changes in the abdominal organs. The patient died four days after the misadministration.
4) The cause of death: Prolonged hypotension. Cerebral ischemia due to shower embolism.
Ai: absent. Autopsy: absent.

Case 23: Due to "mix-up of medicines when preparing for administration", a medicine different from the instruction was administered.
Popscaine 0.25% injection bag 250 mg/100 ml (Levobupivacaine hydrochloride) / Local anesthetics

1) 60s, with Breast cancer.
2) A nurse prepared Acelio for relief of pain. A 100 ml medicine bag was taken out of the basket labeled "Acelio" which was one of the medications placed in hospital wards, but the medicine name was not checked. Another nurse sticked on the injection label "Acelio" on the intravenous infusion bag without collating the medicine name. In addition, intravenous infusion was started without bar code authentication at the time of administration.
3) Thirty minutes after the start of administration, the patient was found in a state of cardio-respiratory arrest. It became clear that "Popscaine" had been picked out from the basket placed next to "Acelio". Furthermore, the infused dose could have been a lethal level. The patient died on the day.
4) The cause of death: Acute right heart failure. Ai: absent. Autopsy: present.

Case 24: Due to "mix-up of medicines when preparing for administration", a medicine different from the instruction was administered.
Osvan disinfectant solution 10% (benzalkonium chloride) / Antiseptics

1) 90s, with Aspiration pneumonia.
2) The patient was receiving nebulized inhalation for sputum aspiration. The nurse took out a bottle among the medicines placed in hospital ward, assuming it was a bottle of purified water, and infused it into the inhaler,

and started inhaling. Purified water and Osvan were stored in the same storage cabinet.

3) Approximately two hours after the start of inhalation, the patient was found in a state of cardiopulmonary arrest, resulting in death on the day. Because of irritating odor in the room, investigation was performed, and it became clear that Osvan which was placed adjacent to the purified water, had been used instead of the purified water.
4) The cause of death: An exacerbation of pneumonia (suspected to the inhalation of Osvan).
   Ai: absent. Autopsy: present.

Case 25: Due to "mishandling of color syringes when preparing for administration", a medicine different from the instruction was administered. Nitorol injection 5 mg (isosorbide dinitrate) / Antianginals

1) 70s, with Effort angina.
2) For PCI (Percutaneous Catheter Intervention) treatment, the physician instructed a clinical engineer to fill heparin sodium and Nitorol in different colored syringes respectively. The engineer felt uncomfortable because the color of each syringe was the opposite of the operational rules, but prepared them as instructed and left the place. There were no drug names on the syringes. During the operation, another physician judged the drug to be "Heparin sodium" by the color of the syringe and, while saying "8,000 units of heparin will be administered," actually administered "Nitorol 8 ml" intraarterially.
3) Approximately 20 minutes after administration, thrombus adhesion was found on the PCI guide, revealing that Nitorol was administered instead of heparin. Although 8,000 units of heparin was injected intravenously to remove the thrombus, the right coronary artery occluded. Balloon dilatation was performed but cardio-respiratory arrest occurred. The patient died four days later.
4) The cause of death: Acute myocardial infarction. Acute subdural hematoma.
   Ai: absent. Autopsy: present.

Case 26: Due to an "error in setting the speed of the infusion pump" when preparing for administration, excessive dose of medicine was administered. Onoact intravenous Infusion (landiolol hydrochloride) / Antiarrythmics, Noradrenaline injection 1 mg (noradrenaline) / Vasopressors

1) 80s, with Aortic stenosis & regurgitation. Mitral regurgitation and Tricuspid regurgitation.
2) For valve replacement and valvuloplasty, the nurse prepared drugs on the syringe pumps for Onoact and noradrenaline. In setting the syringe pump speed, the nurse mixed up the unit "μg/kg/h" with "mg/kg/h". During the operation, the physician assumed that dosage unit had been set according to the in-hospital rule of "μg/kg/h" and administered intravenous infusion without reconfirming the set unit.
3) Approximately one hour after the start of infusion, the hemodynamics became unstable and the drug administration route was confirmed. An excessive dose administration was found, and the settings of Onoact and noradrenaline were changed, but acute right heart failure occurred. Extracorporeal circulation assist was performed. The patient died about one week later.
4) The cause of death: Acute right heart failure. Ai: present. Autopsy: present.

Case 27 Due to an "error in setting the speed of the infusion pump" when preparing for administration, excessive dose of medicine was administered. Catabon Hi 600 mg injection (dopamine hydrochloride) / Cardiac failure therapeutics

1) 90s, with Pneumonia and Congestive heart failure.
2) For the purpose of diuresis due to pleural effusion, "Catabon 2.0 ml/h" was instructed. The nurse misunderstood the smallest set unit of the flow rate in the infusion pump, mistakenly set it to "20 ml/h" when it should have been "2.0 ml/h", and started intravenous infusion without double checking.
3) Eight and a half hours after the start of infusion, the next nurse on duty noticed that the dose was different from the instruction and immediately lowered the flow rate to 2.0 mL/h. After that, vomiting appeared, blood pressure and SpO_2 decreased. The patient died on the day.
4) The cause of death: Acute exacerbation of congestive heart failure. Ai: absent. Autopsy: absent.

Case 28: Due to an "error in setting the speed of the infusion pump" during administration, excessive dose of medicine was administered. Fentanyl infusion 0.1 mg (Fentanyl citrate) / Narcotics

1) 70s, with Malignant lymphoma.
2) For the relief of pain, fentanyl 0.1 mg 4A + physiological saline 100 ml with the drip speed of 5 ml/h and intravenous feeding infusion at a speed of 43 ml/h were continuously administered with two infusion pumps in parallel, but the flow rate of intravenous feeding infusion was re-set to 10 ml/h in order that the remaining

volume would last until the infusion renewal time. When renewing the intravenous feeding infusion, the nurse misidentified the fentanyl infusion pump as an intravenous feeding infusion pump, and changed the rate of fentanyl infusion to 43 ml/h. The nurse signed the checklist of the infusion pump, but did not double check it, considering that the other nurses were busy.

3) Approximately one hour after the change of infusion rate, another nurse noticed that the fentanyl dosing rate had been set to 43 ml/h. Infusion of fentanyl was discontinued, and because the blood pressure decreased transiently, steroids and antagonists were administered. After that, renal function decreased. The patient died on the day.
4) The cause of death: Decreased blood pressure. Deterioration of malignant lymphoma.
   Ai: absent. Autopsy: absent.

Case 29: Due to "patient misidentification" during administration, excessive dose of medicine was administered.
Oxycontin TR tablets 40 mg (oxycodone hydrochloride hydrate) / Narcotics

1) 60s, with Paget's disease and Liver metastasis.
2) For the relief of pain, Oxycontin 5 mg orally twice a day was started. There were four patients who needed narcotics at the same time, and the nurse put four medication bags in one tray. While checking the patient's name on the medication bag at the bedside, she was interrupted due to a brief meeting. When she resumed her work, the nurse took out one medication packet from another patient's medication bag and handed it to the patient, which contained four tablets of Oxycontin 40 mg. The patient said, "Three tablets, right?" but the nurse replied, "Four tablets," without collating the medication bag or the medication history list and administered.
3) Approximately 20 minutes after the administration, it was discovered that another patient's oral medication had been administered. Subsequently, decreased urine volume and pyrexia (fever) were observed, and the condition worsened. The patient died three days later.
4) The cause of death: Acute renal failure. Progression of Paget's disease. Ai: absent. Autopsy: absent.

Case 30: Due to "patient misidentification" at the time of administration, a medicine different from the prescription was administered.
Maintate tablets 2.5 mg (bisoprolol fumarate), Norvasc 5 mg (amlodipine besilate), Artist tablets 2.5 mg (carvedilol), Olmetec OD tablets 20 mg (olmesartan medoxomil) / Antihypertensives and six other drugs.

1) 80s, with Severe combined valvular disease, Heart failure and Chronic kidney disease.
2) A nurse entered the patient room with two medication tray boxes for two patients. Having asked the patient for his/her name, the nurse handed the patient a total of 10 medications including four antihypertensives taken from the other patient's medication tray box. The patient pointed out that there were more tablets than usual, but the tablets were finally administered. In the next room, when the drug was distributed to the other patient, who pointed out that the medicines were less than usual, and it became clear that the medication for this patient had been administered to the previous patient in the next room.
3) Approximately two and a half hours after administration, blood pressure decreased. Fluid replacement, administration of vasopressors, continuous dialysis, etc. were performed. The patient died about three weeks later.
4) The cause of death: Exacerbation of cardiac failure triggered by hypotension.
   Ai: absent. Autopsy: absent.

Case 31: Due to misunderstanding, the infusion pump was not used and excessive dose of medicine was administered
OLIVES for intravenous infusion 1% (Lidocaine injection solution) / Antiarrhythmics

1) 70s, with Non persistent ventricular tachycardia.
2) OLIVES 1% 200 ml at 4 ml/h intravenous injection was instructed verbally. The nurse did not know that this medicine was to be controlled by an infusion pump, and administered intravenous infusion as slowly as possible under manual control.
3) Intermittent convulsions appeared 15 minutes after the start of administration. After about one hour, respiration decreased and cardiopulmonary arrest occurred. It was found that the blood concentration of Lidocaine was high. Hypothermia therapy was performed. The patient died about three weeks after administration.
4) The cause of death: Lidocaine poisoning (suspected). Ai: absent. Autopsy: absent.

Case 32: Overdosed medication due to medication mix-up during self-administration
Nesina tablets 12.5 mg (alogliptin benzoate) / Antidiabetics

1) 70s, with Diabetes mellitus, Renal disfunction and Hypoalbuminemia. (Self-administration of oral medications was underway for home care.)
2) The patient was managing his own medication, a total of 11 medicines including Gliclazide (antidiabetics) for pre-breakfast and Nesina for post-breakfast. When the nurse checked the medication after dinner, it was found that the post-breakfast medicine had been mixed-up with post-dinner medicine (including antidiabetics) and Nesina was also taken after dinner.
3) Blood glucose levels were checked approximately two hours after taking the medicine and no change was observed. The next morning, the patient was found in a state of cardiopulmonary arrest. The blood glucose was at a level of 50 mg/dl. The patient died about 12 hours after administration.
4) The cause of death: Brain disorder due to hypoglycemia. Acute coronary syndrome (suspected).
Ai: present. Autopsy: absent.

Case 33: When the unit (unit) should have been used, medicine was mistakenly measured in volume (ml) and was overdosed.
Humalin (insulin human) / Antidiabetics (hyperkalemia treatment)

1) 60s, with Chronic cardiac failure, Hepatic cirrhosis and Hepatic cell cancer.
2) GI (Glucose Insulin) therapy was performed for the hyperkalemia. Instead of "Humalin 10 units", "Humalin 10 ml" (1000 units) + "7% glucose solution 100 ml" was mistakenly prescribed. The nurse did not use a dedicated syringe for insulin but prepared using a 10 ml syringe for general use and administered a continuous infusion.
3) Approximately one hour after the start of infusion, tachycardia, marked cold sweat, depressed levels of consciousness appeared, and blood glucose levels were measured but showed undetectably low. GI therapy was discontinued, and 20% glucose solution, 50% glucose solution 40 ml + physiological saline were injected intravenously. The blood glucose level rose up to 160 mg/dl, and consciousness was temporarily returned. However, the level of consciousness gradually decreased, and melena followed by state of shock was seen. The patient died about two weeks later.
4) The cause of death: Hepatic failure triggered by hypoglycemia. DIC (Disseminated intravascular coagulation syndrome). Ai: absent. Autopsy: present.

Case 34: Due to an error in prescribing, a required medication was under-dosed.
Humalin R injection 100 units/ml (insulin human) / Antidiabetics

1) 30s, with Type Ⅰ diabetes mellitus and Diabetic ketoacidosis.
2) Although the intention was to prescribe "Humalin R 50 units + physiological saline 49.5 ml with dripping speed at 4 ml/h", actually prescribed was "Humalin R 5 units + physiological saline 49.5 ml at 0.4 ml/h". The nurse prepared and performed continuous infusion as instructed.
3) Approximately one hour after the start of infusion, hyperglycemia and hyperkalemia were not improved, and the flow rate was set to 0.6 ml/h but blood pressure decreased and cardiac arrest occurred. The patient died on the day.
4) The cause of death: Acidosis due to the under-dose of insulin and hyperkalemia.
Ai: absent. Autopsy: absent.

Case 35: During preparation for administration, there was an error in dosage measurement (measuring in "ml" when units should have been measured in "units"), resulting in an overdose of medication.
Humalin R injection 100 units/ml (insulin human) / Antidiabetics

1) 60s, with Septic shock and Type Ⅱ Diabetes mellitus.
2) During daily dosing, "Fulcaliq type 2 + Humalin R 10 units" had been prescribed. The nurse prepared the insulin co-injection bottle by herself, being unaware that there was a dedicated syringe for insulin, and used a syringe for general use to measure and mix "Humalin R 1 ml (100 units)" from the insulin vial to perform a continuous infusion.
3) Approximately nine hours after renewing the bottle, the patient was found in a state of cardio-respiratory arrest. Since it had been agreed not to perform resuscitation treatment, cardiopulmonary resuscitation was not performed, and the patient was confirmed dead.
4) The cause of death: Arrhythmia due to severe hypoglycemia and ischemic heart disease (suspected).
Ai: absent. Autopsy: absent.

Case 36: An overdose of medication at the time of administration is suspected, but details are unknown.
Humalin R injection 100 units/ml (insulin human) / Antidiabetics

1) 80s, with Pancreatic cancer and Type Ⅱ diabetes mellitus.
2) Elneopa NF type 2 1000 ml + Furosemide 10 mg + NaCl 2 g + Humalin R 6 units had been administered daily with an infusion pump. Prepared by two nurses, Humalin R 6 units were co-injected with a dedicated insulin syringe when intravenous infusion was renewed, and the dosing rate was set at 42 ml/h as usual.
3) Approximately 19 hours after the renewal, there was a response to the call from nurse, but 22 and a half hours later, the patient was found in a state of consciousness level of JCS 300. Since the blood glucose level was 9 mg/dl, 50% glucose 40 ml was injected intravenously and the blood glucose level became 80 mg/dl or higher, but the consciousness was disturbed and prolonged. The patient died about three weeks after administration. The remaining amount of the insulin vial preparation was checked and found to be 0.32 ml less than the used amount calculated.
4) The cause of death: Hypoglycemic encephalopathy. Ai: present. Autopsy: present.

4. Recommendations and explanations to prevent recurrence

These recommendations analyze cases reported by medical institutions based on the Medical Accident Investigation System and describes measures to prevent recurrence. Many safety measures have been taken to prevent erroneous administration of medicine. Therefore, before going into the recommendations and explanations, we would first like to mention below the current status of the series of medication processes and the roles expected of each profession.

● Administration of medicine is a practice that cross-sectional involves multiple professions

Administration of medicine is a medical practice that requires three professionally different procedures: physicians/dentists prescribe, pharmacists compound and in a hospital setting mostly nurses administer. Administration of medicine cannot be completed by a single profession, but is characterized by involving cross-sectional multiple professions, and it is required to fulfill their roles and responsibilities in safe administration of medicine in each work procedure.

Compounding medicine before administration is performed by both pharmacists and nurses, but in recent years with the progress of task shifting, it is gradually increasing in the medical institutions that the pharmacists are responsible especially for the compounding of anticancer drugs and central venous nutrition.

● Risks related to the work process with the three professions

At present, the actual situation is that the three professions have not reached a common understanding of what work process each of the three professions contributes to complete medicine administration.
Each work process has its own mistakes that are likely to occur. It is necessary to clarify the risks and share them as common knowledge. In the process of passing the baton from physicians/dentists to pharmacists, and from pharmacists to nurses, it is important to keep in mind and play their respective roles in the involved work process, so as not to make mistakes. Their specific roles are, first, to take measures in advance to prevent mistakes, second, to detect errors made by other professions recognizing that human error cannot be eliminated.

It is important for each person to take responsibility for his or her own role, to recognize what kinds of potential risks of erroneous administration exist before and after the work process involved, and to take measures in advance to avoid those risks. If you have any questions or a feeling of wrongness during the work process, it is important to take actions such as reconfirming even immediately prior to administration or checking with health-care professionals who can respond appropriately.

Among them, pharmacists are specialists in medicine. However, in the current situation, even with in-hospital prescriptions, pharmacists do not intervene in most cases while medications placed in the ward are used. This could be a major problem to secure the safety in medication. Therefore, pharmacists should be expected to be key personnel for the safe administration of medicine.

● Patient participation in preventing erroneous administration of medicine

The work in the process of administration is completed when the medicine is correctly administered to the patient. Although we have stated that there are three steps in which three professions are involved in the administration process, it is also desirable for patients themselves to participate in the final confirmation of their medication to be taken immediately prior to administration. Even in the reported cases, there were seven cases where the patients took distributed drugs without any doubt about the difference from the usual contents, or dosage. This suggests that the patients did not check the medicine they were taking on their own. In addition, among 36 target medical institutions in this report, only 20 of them handed out “medicine information documents” to patients for confirmation of their drugs.

Therefore, it is necessary to be aware that it is important for patients themselves to be interested in the medication from the early stage of starting the medication, and to create an approach and a system that involves the patient as a member of the medical care team in the prevention of erroneous administration. These will be described in “Recommendation 4”.

[Confirmation in the processes of drug administration]

Recommendation 1	The position of each person in charge in the process of drug prescribing and administering medicine should be clarified, and the "validity check" to confirm the indication of the medicine to the patient and the "collation type check" to check the prescription with the actual medicine, patient name, etc. should be reconfirmed. (See Figure 1 on P23)

● Two types of confirmation measures and its details in the three procedures

Of the 36 target cases, 35 cases led to erroneous administration due to insufficient confirmation, and the one exception was a case in which the administration of oral medications was left with self-management.

The meaning of confirmation in drug administration process is to detect and correct errors, and it is classified into two measures from an ergonomic point of view, a "validity check" and a "collation type check". “Validity check” is to confirm whether the prescription for the patient's condition is medically and pharmacologically appropriate. “Collation type check” is to confirm by collating the drugs to be administered with definite information (prescriptions, etc.). These two confirmation measures are taken in the whole process of prescribing/compounding/administering of medicine. It is important to recognize which confirmation measures you focus on. (see Figure 1 on P23).

However, there are the cases in which an irregular process of drug administration, such as consecutively prescribing brought-in medications or using medications placed in hospital ward, etc. need to be taken without tracing a normal drug administration process. In these cases, it is necessary to check by two measures, after recognizing the difference from the usual administration process.

<Validity check>

In 16 cases, the errors were in the prescription process, and contraindicated drugs, dosage/dose, and withdrawal period were wrongly prescribed. In 11 of the 16 cases, prescription mistakes were not pointed out in the validity check of prescription audit / drug inspection. Five other cases did not receive a pharmacist's audit / inspection, in such cases medications placed in hospital wards, etc. were used.

First, the physician should decide the medicine itself and the dosage/dose for the appropriate prescription, considering the patient's condition and treatment strategy, medication history, body weight, contraindicated drugs, etc. Among the target cases, contraindicated drugs and withdrawal period were entered incorrectly, but resulted in a prescription because there was no alerting system there.

Second, pharmacists need to review the medication history, contraindications for co-administration, contraindicated drugs, withdrawal period, etc., and confirm the validity of the prescription (prescription audit). The pharmacists should recognize that this is an important time to identify, to detect prescription errors and to improve the precision of the audit. It is necessary to establish a system that permits pharmacists to intervene in even irregular drug administration processes, such as continuing brought-in medication and using medications placed in hospital wards.

Third (finally), it is desirable for nurses to check the validity in the administration process, such as whether the drug is appropriate for the patient's condition, whether there are injection medicine which present composition changes at the time of co-administration, whether the duration of administration is appropriate, and whether there are any contraindicated drugs at the time of administration. Among the target cases, the drugs that were not appropriate to the patient's disease condition, or for which allergies or dosage had not been confirmed, were administered.

<Collation type check>

For the inspection of medicine, the set-up for administration, and the execution of administration, it is required the collation type check should be certainly performed, which is to confirm by collating the medicine with the reliable information from the prescription or the electronic medical record.

Among the target cases, 18 cases resulted in erroneous administration due to insufficient collation type check on the items of the drug name, dosage/dose, patient name, and an infusion pump flow rate setting, etc.

In the cases of insufficient confirmation in the drug inspection procedure, a wrong drug with a similar name was manually prepared, but it was not checked by drug inspection. In the collation type check in drug inspection, the 3Rs of patient name (Right patient), drug name (Right drug), and dose (Right dose) of prepared drugs are mainly collated with definite information such as prescriptions. In addition, for the collation type check, it is advisable to introduce the use of a machine such as a barcode reader, because the collation type check can be performed more accurately and quickly by machines than by humans.

In the cases of insufficient confirmation at the time of set-up for drug administration, there were cases in which a wrong label was applied without collating the drug name, and cases in which an administration drug was prepared while there was no description of the drug name on the label. In each case, the drug name of the prepared drug was not collated and as a result, leading to erroneous administration. In the collation type check at the time of preparation, definite information such as a prescription is mainly collated with the patient name, drug name, and single dose of the prepared drug. In the case in which an injection label was mistakenly applied, the wrong label was used for subsequent confirmation, resulted in erroneous administration. In addition, if the collation type check is not performed at the time of set-up for the administration, it is difficult to detect an error such as drug mix-up from the external appearance in the later process, because the injection drug is mixed into an intravenous infusion bag or the powder dissolved in water for administration through a feeding tube. As described above, an error in set-up for administration preparation and a subsequent failure to detect it greatly affect the success or failure of confirmation at the time of administration, therefore collation type check at this point should be very important.

There were cases of insufficient confirmation at the time of administration by a nurse, including: a case in which another patient's drug was administered without identifying the patient's name just before the administration; a case of drug overdose caused by setting wrong numerical values without confirming the dose unit of the infusion pump; a case in which an unscheduled infusion pump setting was renewed accidentally because two infusion pumps were placed side by side. Check and confirmation in the process of administration is the last important chance in which an error can be detected prior to administration of medicine. In the collation type check, definite information such as a prescription should be collated with the patient name, drug name, single dose, dosage form and duration, and in case an infusion pump is used, the flow rate and dosage unit on the setting window should also be collated. Usually, the same nurse does the set-up procedures and the final administration. Therefore, the nurse needs to be aware that he or she is the final checker and confirmer prior to administration.

The information and the hour-arrangement of confirmation for validity check and collation type check are different individually, depending on the scale of medical institution, the business outline, the resources it uses, and others. Information required for the two checking measures and the hour-arrangement of confirmation should be considered and clarified in each medical institution (see Recommendation 2).

<Self-check of prescription>

There were two cases of erroneous prescriptions about the continuous infusion of insulin. The physicians themselves actually entered a value different from the intended one into an electronic medical record and prescribed. Before finalizing a prescription in the electronic medical record, it is important for the physician to confirm that the intended detail is correctly entered. However, since physicians are in the position of prescribing for themselves and do not have definitive information (prescriptions) for confirmation, it is necessary for them to confirm with a method different from the collation type checks by pharmacists or nurses. Concretely, it is necessary to collate the actually entered contents with the intended contents regarding drug name, units (mg, mL, etc.), number of tablets, number of days prescribed, duration, and presence or absence of any drug allergy. Physicians need to recognize that the time immediately prior to finalizing the prescription is an important confirmation chance to detect errors before going to the compounding and administering procedures.

● Points of communication in executing the two types of confirmation measures

In eight of the target cases, there were communication errors among health-care professionals.

<Smooth communication methods>

In 5 of the 8 cases in which communication errors occurred, the errors could have been identified if a two-way communication had been done between the persons in charge. Specific reasons for the lack of communication include: the person in charge was hesitant to tell others when a suspicion arose, and the person in charge told about the suspicion, but was then too busy to confirm.

When doubt arises, it is important to resolve the question in one's own work process. For that purpose, it is important to create an environment for personal "two-way" communication, and strategies (such as the "Two challenges rule" that is one of the tools of Team STEPPS®, and consultation with other physicians, etc.). In order to make these strategies effective, it is important to create a favorable in-hospital cultural climate, and it is necessary that the entire organization works on it, including hospital executives.

< Proper use of confirmation conversation>

“Confirmation conversation” is not to repeat simply the received instructions, but to rephrase them in other words or to specifically convey the doubt or something they noticed.

Of the 8 cases in which there were communication errors, in one case the drug concentration was not confirmed in requesting a prescription between physicians, and in two cases a nurse simply repeated the oral instruction of the physician and did not confirm the dosage/dose. In one of these cases, when instructing the administration of morphine hydrochloride, the physician instructed "Inject Mohi 2.5", then the nurse asked, "I inject ‘Mohi 2.5’, right?" In this case, if she replies, "Does ‘morphine hydrochloride 2.5’ mean ‘2.5 mg?’" the question should have become clear, and it is regarded as a confirmed conversation. Thus, in the confirmation conversation, it is important to concretely convey and resolve any questions that have arisen.

Validity check: To confirm whether the prescription for the patient's condition is medically and pharmacologically appropriate.

Collation type check: To confirm by collating the drugs to be administered with definite information (prescription, etc.).

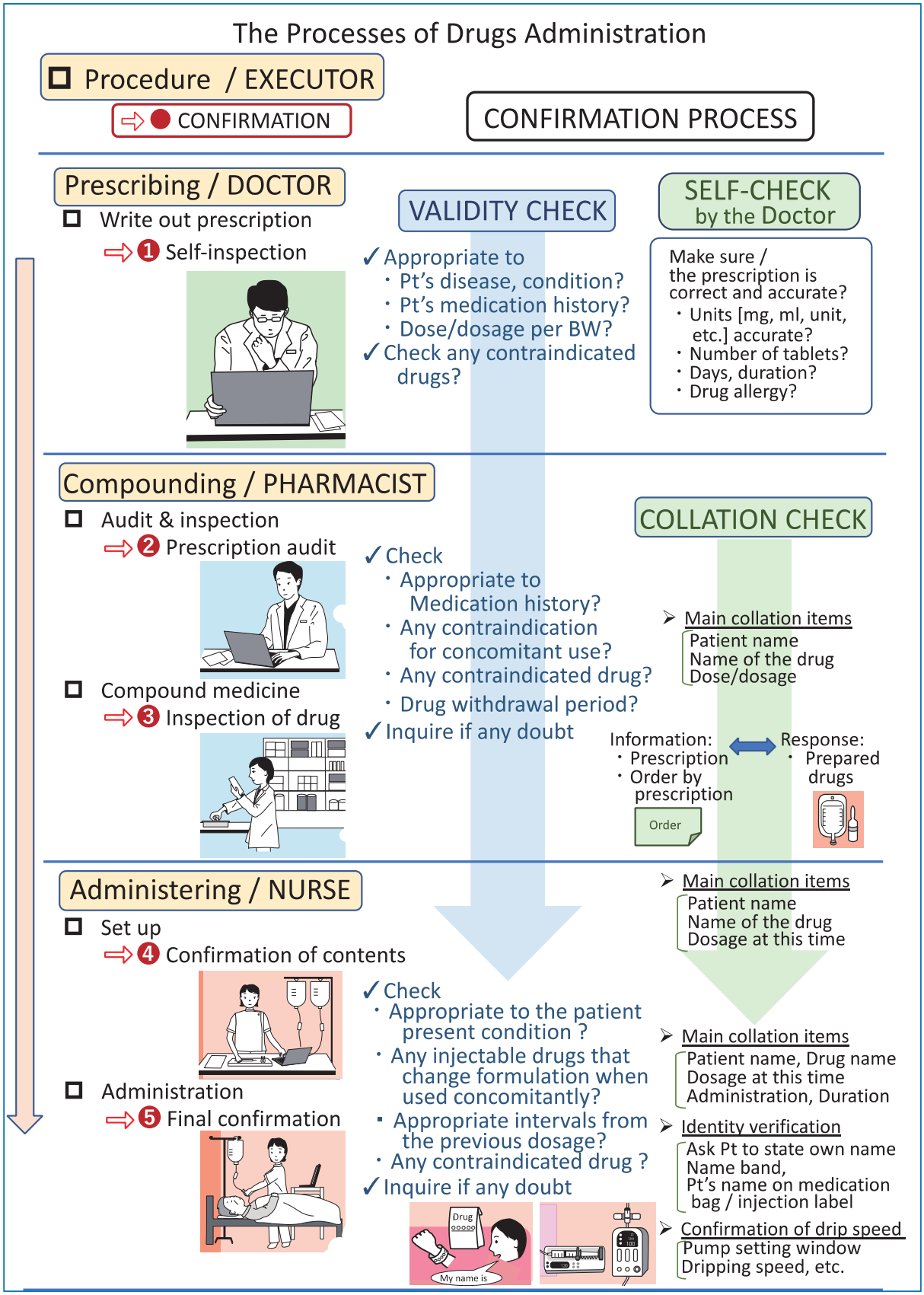

Figure 1 Two confirmation measures <Validity check> / <Collation type check>

[Manuals for confirmation]

Recommendation 2	In-hospital manuals for confirmation should be specific so that any staff member can clearly understand what and how to be reconfirmed in the “validity check” and the “collation type check” procedure, assuming that it will be used during busy times.

● In-hospital confirmation procedures assuming the busy times that are unique to each hospital

Twenty-five of the 36 target cases did not undergo validity checks or collation type checks which were agreed upon in the in-hospital manual. As self-assessment of the situation at the time of the accident, busyness was pointed out in 12 of the 25 cases, and in 7 of these cases accidents occurred during the night shift hours or on holidays. It may be difficult to carry out the prescribed checks at times, such as during work hours or busy hours when there is staff shortage. Furthermore, there is a concern that the accuracy of confirmation may be reduced because work may be interrupted under these circumstances. In 3 cases of the above 12 cases in which busyness was pointed out, work was actually interrupted, and error detection failed.

If the procedure for confirmation work is complicated or its steps are too numerous, the workload of the confirmation practitioner would increase, which may lead to a decline in the error detection rate and a failure of compliance with procedures.

The procedure for confirmation work needs to be determined with an emphasis on feasibility, taking into consideration the work contents and the number of personnel. Therefore, it is advisable to set the confirmation procedure on the premise of busy times and emergency response as an inherent procedure. Additionally, in order to avoid those works during busy times, it is recommended to review the work schedule, staff distribution, and work contents, and evaluate and improve regularly for the defined procedures.

● In-hospital manual possessing the information specifically and emphatically summarized for these two confirmation measures

In the manuals of the 21 target medical institutions where the validity check and collation type check were not conducted, the confirmation items and confirmation means were clearly described. However, in fact, the information necessary for the validity check was overlooked at the time of prescription audit, or in the collation type check, the method of matching patient name, drug name, and drug amount did not follow the manual, or the collation type check was omitted.

In addition to the information required for the validity check and the definite information /collation items required for the collation type check, the in-hospital manual is expected to include a specific description of the timing of those checks and confirmations, and descriptive expressions which draw attention to important check points for confirmation to prevent errors.

Many of the in-hospital manuals of those 36 institutions, the important points and the timing for confirmation were not concretely specified.

In some of the target cases, a wrong injection label was applied without checking the drug name on the intravenous infusion bag at the preparation stage of administration, and the intravenous infusion that was different from the prescription was administered. The manual of the concerned institution described that "On preparing for intravenous infusion, collate the contents written on the injection drug and injection drug label". However, it did not describe what on the injection drug should be checked. In this case, it is advisable to describe more specifically in the manual the items to be collated with the definite information, such as "Collate the drug name written on the injection label with the drug name of the intravenous infusion bag". There is also a method of description using illustrations to make the manual easier to understand.

However, if the manual is described in too much detail, there is a risk of oversight. It is also important to have descriptions tailored to the health-care professionals who use the manual. Because health-care professionals who are accustomed to their work tend to have less chance to confirm on the manuals, there is another method to provide them with a checklist to review regularly. It is also necessary to educate and to evaluate abilities so that the work can be practiced in compliance with the prescribed procedure.

COLUMN 1: Viewpoints of reviewing the manual. [Must, Better, Nice]

We introduce how to describe the manual. It is divided into three categories: "Must", "Better", and "Nice", according to the content of the items in the manual. When reviewing the manual, it is advisable to be aware of these three stages.

- "Must" (matters which should be absolutely executed)

  There are the matters which inevitably contribute to accidents if the prescribed procedure is violated, or which leads to accidents if it is not implemented. They must be implemented in any situation, including busy times.

- "Better" (matters to be conformed in principle)

  There are the matters that can surely reduce the probability of errors or problems if the procedure is followed. For example, they correspond to basic work procedure that cause confusion, if not decided in advance, and to basic safety motions such as "pointing and calling".

- "Nice" (matters to be referred to)

  There are the matters that should be referred to, and are used as a recommendations, standard strategies and lessons. If the procedure and response method are not uniform depending on the situation, success or failure cases are indicated as response required cases that should be referred to.

[Handling of unfamiliar medications]

Recommendation 3	Medical institutions need to create an environment where drug information can be easily searched, and when dealing with unfamiliar medication, health-care professionals should utilize accurate information about the medication and have a good understanding of it before using it.

● Ingenuity of the method of providing drug information and promotion of utilization of consultation service

In twelve of the 36 target cases, the health-care professionals had little experience with the concerned medicine, and mishandling of unfamiliar medicine resulted in erroneous administration.

In thirty of the 36 target cases, the consultation systems or the inquiry counters were provided for checking medicine information, and in 27 cases, the systems for checking medicine information were in place. However, in 12 cases in which unfamiliar medications were handled, erroneous prescribing and administration occurred. Possible reasons include: the healthcare professionals were unable to check the information themselves due to their busy situations such as night shifts or holidays, or the confirmation system was difficult for them to use and they were unable to master it. Therefore, it is desirable for the pharmacy division to evaluate whether the current browsing environment is being utilized on the job site and whether necessary information can be easily viewed and confirmed, and to devise an information provision method, and to encourage other professions to utilize the consultation service.

In addition, in five of the 12 cases in which unfamiliar medications were handled, the medications were prescribed at night or on a holiday. Two of these cases had a consultation reception system provided only for daytime. It is desirable to introduce a system in which pharmacists can receive consultations 24 hours a day at medical institutions that provide clinical practice for patients even at night or on holidays, if possible. It is advisable to consider this in accordance with the scale and system of each medical institution.

It is recommended to create an environment where information can be easily accessed when needed, such as posting in in-hospital manuals or electronic medical records the method to refer to and inquire about in-hospital drug information (information edited and organized through the use of package inserts and in pharmacy divisions).

● Acquisition of the knowledge necessary for handling high-risk medications

Of the 12 cases in which unfamiliar medications were handled, seven cases were prescribing mistakes, and four cases revealed a discrepancy between the field of medicine prescribed and the physician's specialty, for example, therapeutics for brain tumors being prescribed by an orthopedic surgeon. In some case, a physician recalled that consultation to a relevant clinical department was inadequate.

The attending physician may prescribe to an inpatient outside of his specialty drugs consecutively which were prescribed in other departments or other hospitals before admission. If you prescribe an unfamiliar medication, you must consider that you are unfamiliar with it, and before prescribing, you must identify the medicine by contacting the relevant clinical department for consultation or the consultation service of the pharmacy division, and must investigate the drug by using the system to check drug information in the hospital. In addition, there was a case of an overdose due to a mistake about the "withdrawal period", so when prescribing medications of outside specialty, it is important to check with the relevant clinical department or pharmacy division regarding drug usage, dosage, withdrawal period, etc.

In addition, in order to handle high-risk drugs, it is essential to obtain the knowledge and information that is particularly necessary for using high-risk drugs. In two of the seven cases in which mistakes occurred in the prescribing procedure, high-risk drugs for the circulatory system (Lidocaine, Bosmin) were administered in abnormal dose/dosage. Health-care professionals who may handle high-risk drugs should regularly learn and acquire the knowledge about the normal and maximum dosage, prohibited matters, etc. To this end, it is important for each medical institution to establish a system that enables health-care professionals to learn, such as patient safety trainings as stipulated in the Medical Care Act and seminars on the use of high-risk drugs on each department basis, etc.

COLUMN 2: "Unfamiliarity", the situations, human errors are likely to occur

Unfamiliarity refers to work or situations that falls under the 3Hs (in Japanese): "for the first time (*hajimete*)", "change (*henko*)", and "after a long time (*hisashiburi)*" in the safety work slogan. It is said that human errors are more likely to occur in unfamiliar work or situations.

In work that you experience for the first time, in work as a newcomer, in work under–different conditions or irregular operations, or in work that you seldom perform, it is important for practitioners to be aware that they are in a situation where human errors are likely to occur, and to take measures in advance to prevent errors.

[Support for patients in checking their own medications]

Recommendation 4	Medical institutions should establish a system that enables patients themselves to check their own medications, for example, by providing them with a “Medicine Information Form” so that they can check the name and appearance of the medicine as well as the number of tablets at the time when they take them.

● Medication check conducted by patients themselves

Twelve of the 36 target cases were related to oral medicine. Among these cases, mistakes in prescribing procedure were found in 6 cases, mistakes in compounding procedure in 2 cases, a mistake at the time of administration set up in 1 case, mistakes during administration in 2 cases, and a mistake during the self-management in 1 case. Oral medicines are handed to patients at the time of administration, but the patients may not notice even if the dosage/dose is different from the previous ones. As a reason, it is assumed that patients tend to believe that physicians and nurses would never make mistakes and that their prescriptions may probably have been changed after hospitalization. On the other hand, there was a case that even though the patient pointed out that the number of tablets was different from usual, the health-care professionals recognized the patients were mistaken.

Even if a patient asks a question about the provided medicine, it does not result in preventing erroneous administration unless the health-care professionals reconfirm it. If a patient expresses doubt, health-care professionals should be required to suspend administration of the medicine and countercheck it. It might be said that patients are the last bastion to confirm the drug being properly prepared. Especially for patients who have no problem with cognitive function and can manage medication by themselves, it is important to explain to patients that they themselves are the last persons who can check their medications to prevent erroneous administration, and to make patients aware that they themselves are also participants in receiving safe medicine therapies.

● A mechanism for patients to confirm their own drugs and instructions on medication

For patients to be the last bastion in confirmation at the time of administration, it is necessary to check their own medications before administering them. Therefore, it is advisable to consider a mechanism that allows the health-care professionals who distributed medicines and patients to share information. At present, it is not common for patients to recheck their medications by themselves even if they received the medicine information form or instructions.

Three measures could be designed as countermeasures to encourage patients participation in taking their medications: 1) Information (such as a medicine information form) should be provided to patients so that they themselves can collate their own prescriptions with medications; 2) Patients should inform healthcare professionals if they feel that the prescribed or distributed medications are different from usual; and 3) Patients should not take medicines until health-care professionals confirm the contents. It is desirable to create a mechanism which encourages patients to participate in medication checking by providing them with instructions on medication. Specific examples include: "Check the medications before taking them using a medicine information form, etc." or "Whenever the prescription changes, an explanation will be made. So, if the medicines prescribed have a different type or dose/dosage from your usual ones without any explanation, please feel that something is wrong and voice your concerns."

● Efforts to minimize the consequence of erroneous medication by the elderly themselves

In target cases, there was a case in which an elderly patient duplicatedly took antidiabetics during the self-management training of medication, resulting in hypoglycemia. In elderly patients, there is a potential of making a mistake in medication in association with the concomitant use of multiple drugs, and contributing to unexpected situations because of deterioration of the internal organ function with aging. Since many elderly patients manage their own medication after leaving the hospital, and at the same time, their managing ability declines, it would be difficult to completely prevent erroneous management of medication.

Sharing information among the health-care professionals around patients and also with their families, and considering the patient's cognitive function and ADL, it is desirable to consider a prescription which minimizes the consequence of erroneous medication, even if it should occur. It would be one of the methods to unify the safety management of medicine for the elderly, such as compiling the medication notebook into one book and instructing patients to have one family pharmacy. In addition, it is desirable to engage with the family to obtain their cooperation in medication management as necessary.

[“Medications placed in hospital wards” and their management]

Recommendation 5	Considering the risk that placed medications are used without a pharmacist compounding process, the pharmacy division and the patient safety management division should also participate in determining medicines to be placed in the ward.

● Risk of using medications placed in hospital ward in which the pharmacists are not involved in the administration process

The risk of using medications placed in hospital ward is that a pharmacist cannot check the validity of the prescription because they are not involved in compounding.

In ten out of the 36 target cases, the use of medications placed in hospital ward resulted in erroneous administration. Four of these 10 cases were caused by prescription mistakes, of which 3 cases indicated dosage/dose mistakes and 1 case was due to dosage conversion error.

In using medications placed in hospital ward, if a physician prescribes a medication, a nurse who receives the instruction performs a validity check, but it is difficult to do it at the same level as a prescription audit by a pharmacist. Therefore, this increases the risk of administering it to patients without noticing the erroneous dosage/dose. In fact, in one case, the nurse who received the instruction did not notice the erroneous dosage/dose or dose conversion mistake and administered it as prescribed.

When using medications placed in hospital ward, it is advisable for a physician to keep in mind that there is no prescription audit and to reinforce the level of self-checking. A nurse who receives the instructions should perform a validity check to ensure that the instructions are correct. If unsure, consult with a physician other than the one who ordered, a pharmacist, or a nurse who is accustomed to handling the medications.

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● Consideration on the safety of medication placement

Nine of the above 10 institutions looked into the “safety” when deciding on or changing the medications placed in hospital ward. However, only three institutions considered whether physicians and nurses were familiar with the handling of those medications.

Based on that there is no prescription audit by pharmacists, it is desirable to minimize the number of medicines and consider whether it is appropriate to place them in that ward, in determining medications placed in hospital ward. For this purpose, consider the past usage of the drug, and whether the physicians and nurses who handle them have an understanding of the dosage/dose and are not unfamiliar with it. In addition, when the placement is finally decided, it is important that the administrative departments related to patient safety and pharmaceuticals as well should be involved and consider the safety management precautions associated with the placement.

● Ingenuity for safe placement of medications

While medications are available immediately if they are placed in hospital ward, there is a risk of confusing medications in case they have similar shapes.

In three of the 10 cases in which medications placed in hospital ward were used, they were found to have been misidentified. Among them, in one case where Acerio and Popscaine were misidentified each other, Popscaine was placed separately from other medicines as a preventive measure against misidentification, and the drug name was labeled in large red letters since it is a “powerful drug”. However, a misidentification occurred because the two drugs were in similarly shaped intravenous infusion bags, being placed side by side. In other case where an inhalant was misidentified, disinfectants and purified water were stored on the same shelf.

As for medications placed in hospital ward, it is common that both the drug for being administered into the patient's body and the disinfectants are placed together. Medications which should never enter the patient's body (disinfectants, etc.) must be stored separately from medications to be administered into the body. It is important that the storage locations should be determined in a specified place and be indicated clearly and visually standing out by applying labels, etc. and that fixed number of placed medications should be determined. Further, it is advisable to discuss placement rules within the hospital so that the location of placed medications is constantly the same in each department.

Because “powerful drugs” carry a high risk of being life-threatening in case the method or dose/dosage is incorrect, it is also necessary to limit the number of drugs placed in a department to one type if they are similar in form, taking into consideration the misidentifying risk and its frequency of use.

[Identification of "brought-in medicines" and audits in continuous prescription]

Recommendation 6	Medical institutions should establish a system whereby the pharmacy division identifies medications brought-in by patients and proposes alternative prescriptions when necessary, and should also build a mechanism which enables pharmacists to check prescription and medication history again at a later date when differentiation and inspection cannot be performed timely.

In four of the 36 cases, prescription mistakes occurred when switching from "brought-in medication" to "in-hospital medication" in order to keep medications uninterrupted. In two cases, medicines requiring a rest period were prescribed daily, and in the other two cases there were conversion mistakes in dosage.

● The structure of prescription proposals when switching from brought-in medication to in-hospital adopted medication

In one of the two cases with erroneous conversion, when "predonisolone powder 1% 1.2 g" was switched to in-hospital prescription, there was no standardized version of the same medicine in the hospital, and a conversion mistake occurred with "predonisolone 1 mg 1.25 tablets", resulting in under-dose prescription of the medicine. The pharmacists' report on brought-in medication investigation presented caution for the conversion and alternative proposals, but these proposals were not communicated to the physician, and the physician prescribed the drug with the erroneous conversion. Therefore, when making a prescription proposal, it is necessary to have a system to ensure that the prescription proposal is definitely communicated to the physician after clarifying important information such as precautions, and to know that the physician has confirmed it.

In another case, when switching from brought-in oral medicine to in-hospital injection medicine, "Aleviatin powder 10% 1.5 g" was misread as "Phenytoin bulk drug 1.5 g", and it was erroneously converted and prescribed. Furthermore, because it was one of the medications placed in hospital ward and there was no pharmacist's prescription audit, an overdose administration occurred without noticing the conversion mistake.

In regards to brought-in medication, medicines under the same standard are not always adopted in the hospital. Pharmacists have information and expertise about the medicines adopted in the hospital and the standard of the drugs. It is ideal to introduce a system where, at the time of distinguishing the brought-in medications, pharmacists provide information on whether there are drugs under the same standard adopted in the hospital, and where pharmacists make proposal of prescriptions when switching from a brought-in medicine to an in-hospital one. Physicians should not make decisions on their own, but consult with a pharmacist so that they can receive information from the pharmacist and reconfirm that there are no conversion errors before prescribing. In particular, when switching from a brought-in medicine to an in-hospital adopted one, it is better to have a system in which a pharmacist reconfirms the prescription even when using medications placed in hospital wards.

● Prescription audit and drug inspection system for consecutive prescriptions of brought-in medications

There were two cases in which medications were prescribed without considering the "washout interval", and it was overlooked in the prescription audit and also drug inspection. In one of these cases, it was on holiday when "Rheumatrex" prescribed by another hospital was switched to the in-hospital prescription, and the pharmacist worked on it alone. Therefore, prescription audit and drug inspection normally performed by different pharmacists, had to be performed by one pharmacist, resulting in inadequate medication history review and resulting in daily prescription, though the washout interval was necessary. In other case, when prescribing the brought-in medicine continuously, the physician prescribed the antineoplastic daily, without recognizing that the drug required a washout interval because the drug was outside of the physician's area of expertise. The physician prescribed and compounded the drug without a washout interval, believing that the medication history would have been confirmed in the subsequent prescription audit.

Among the target cases, there were medical institutions that actually performed prescription audit and medication check on weekdays converted from Saturdays, Sundays and holidays, or institutions where pharmacists re-check on weekdays what physicians and nurses checked once. Assuming the possibility of continuously prescribing medicines switching from brought-in medications on holidays with different staffing situation, it is advisable to establish a system that enables pharmacists to recheck prescriptions and medication histories as quickly as possible.

Pharmacists are required not only to identify the actual brought-in medications but also to check whether the contents of the brought-in medicines are appropriate, whether their continuous use is valid, and how the drugs that require a washout interval should be handled; and to discuss with the physicians in charge if there is any doubt [3)].

COLUMN 3: Recommendation of “Pharmacy-pharmacy cooperation” approaches at the time of admission and discharge

In the 36 target cases, only six institutions received the summary of medication management history, etc. from the pharmacies which compounded the brought-in medications at the time of admission.

The Japanese Society of Hospital Pharmacists has drawn up the "Guide for Regional Medical Care Collaboration Ver.1" [4] with the main purpose that the pharmacists of the medical institution under national insurance system share the information with pharmacy pharmacists or healthcare professionals at other institution at the time of outpatient visit or admission and discharge.

Some prefectural pharmacist associations are exchanging information between medical institutions and pharmacies using the "Medicine notebook" and "Information communication form between facilities for the proper use of drugs" (co-created by the Japan Pharmaceutical Association and the Japanese Society of Hospital Pharmacists) with the aim of providing more secure and continuous drug therapies for patients [5].

As the regional comprehensive care system is being promoted, it is expected that the expansion of such nationwide approaches will lead to the continuation of drug therapy based on patient safety.

[Response against "erroneous administration of medicine"]

Recommendation 7	Overdosage of high-risk or antihypertensive medications should be interpreted as drug intoxication and patient monitoring should be initiated immediately even if there is no change just after the administration, and at the same time consultation with a consultation service or a physician specializing in drug intoxication should be sought.

● Saving the Patient lives

Twenty of the 36 target cases had relations to overdose. Among them, 8 cases were related to circulatory system drugs such as Lidocaine, Digoxin and Bosmin, 4 cases were narcotics, 4 cases were antidiabetics, 2 cases were antineoplastics, and 2 other cases were immunosuppressants and anticonvulsants.

In case such drugs are overdosed, vital signs may appear to remain normal immediately after administration due to the compensatory function of homeostasis. It is important to take action as soon as possible rather than just to observe the progress because there is no change for the time being.

An overdose of drugs should be considered as drug poisoning. Treatment varies depending on the type and amount of the drug and the patient's situation. Therefore, it is important to start monitoring the patient immediately, as well as to share the patient's condition with the pharmacy division, to consult with a physician who specializes in drug addiction or specializes in addiction treatment on how to deal with overdosed drugs, and to take a prompt action. Particularly, in the case of erroneous administration of Bosmin, which is a cardiac stimulant, a more rapid response is required because the effect is large on hemodynamics.

If an overdose (or suspected overdose) is found, the patient should be transferred to the intensive care unit for real-time monitoring and close observation, depending on the patient's condition. In addition, the patient's vital signs, laboratory findings and clinical findings should be constantly monitored so as not to overlook a sudden deterioration in the course of addiction treatment, and a system should be established where an immediate response to any change is possible.

«Reference»

Table 1 shows clinical parameters related to the patient's survival rate, signs observed in patients at the hospital prior (within 6 hours) to cardiac arrest. If these signs had been reported to the physician, the survival rate should have been higher. It is advisable to observe and report using these warning signs as references and consider how to deal with the situation. It is also important to consider these warning indicators individually, depending on the type and amount of the erroneously administered drug and the patient's condition.

Table 1 Remarkable warning signs of sudden deterioration [6)]

・Mean arterial pressure:	≦ 70 mm Hg	or	≧ 130 mm Hg
・Pulse rate:	≦ 45 /min	or	≧ 125 /min
・Respiratory rate:	≦ 10 /min	or	≧ 30 /min
・Chest pain			
・Changing condition of consciousness (Threatening, Confusion, Lethargy)			

● System for responding against sudden deterioration

Since there have been cases of sudden deterioration due to medications provided in the hospital, it is important to establish an in-hospital system to deal with sudden worsening due to erroneous administration of medicine. Specifically, the system includes: ① Education and dissemination of emergency response to adverse events due to erroneous administration of medicine; ② Education and instruction of Cardiopulmonary resuscitation to staff through regular training in the hospital; and ③ Establishing an in-hospital emergency program and structure, including clarification of the staff (e.g., physicians in the Patient Safety Department) who will respond as soon as possible and determine a treatment plan, in response to an accidental administration of an erroneous dose. In the event of an actually applicable case, they should decide immediately whether or not their hospital or department is capable of responding to the drug poisoning, and if it seems to be impossible, transport the patient to a medical institution that is capable of handling the case. For that purpose, local medical institutions should collaborate with each other on a daily basis and establish a system for transferring patients to other hospitals.

It is useful to establish a consulting system for the erroneous administration of high-risk as well as common medications, or a system to keep in touch constantly with the specialized professionals on a daily basis can be effective in quickly responding to sudden deterioration of patient. For a quick response, it will be needed to prepare in advance a consultation service specialized in drug poisoning and to inform a method and procedure for making inquiries to the physicians.

[Instruction and confirmation of “Insulin”]

Recommendation 8	Insulin instructions must use “units” instead of “volume” [ml]. If you cannot suck up insulin with a dedicated insulin syringe, you should suspect that the instruction must be incorrect and check with the physician who ordered the instruction.

Four of the 36 target cases were related to “insulin vial preparations”. Not only overdose due to erroneous dose conversion, but also underdose occurred in the cases of death.

● Enhance awareness that for insulin vial preparation, “1 ml = 100 units”

All of the four target cases were under continuous drip infusion using the insulin vial preparation.

In the case of GI therapy (glucose/insulin therapy: A treatment that lowers the potassium level in the blood rapidly by co-administering glucose and insulin), the amount of insulin was prescribed at 100 times the correct level, resulting in an overdose. In the case where “Intravenous hyperalimentation + Humulin R 10 units” was instructed, the nurse used a general syringe to prepare 100 units, resulting in an overdose.

An overdose of insulin preparations leads immediately to life-threatening conditions. Healthcare professionals should be aware that “1 ml = 100 units”, when handling insulin vial preparations.

● Instructions on the premise of using a dedicated insulin syringe

In two of the 4 target cases, weighing out (sucking up) without using a dedicated insulin syringe led to an overdose. In one of them, to use a dedicated insulin syringe was already known, but a general syringe was used because the instruction prescribed was “insulin 10 ml/1000 units". In this hospital, a study session on GI therapy had not been held, and no one noticed that the instruction “10 ml/1000 units” was generally impossible.

When instructing the use of an insulin vial preparation, physicians should use “units” for the dose, assuming that a dedicated insulin syringe is used. If a nurse (an administering staff) receives an instruction for a dose that cannot be weighed with a dedicated insulin syringe, checking with the physician is necessary, suspecting a mistake in the instruction.

● Potential risks of insulin vial preparations

The volume of all insulin vial preparations approved in Japan is 10 ml (equivalent to 1000 units of insulin). The vial preparation has a mechanism in which, despite the risky amount, you can easily weigh out a large amount of insulin without discomfort, even if you accidentally use a general syringe. From this reason, you should recognize once again that vial preparation is likely to cause human errors.

In order to prevent the occurrence of human error, it is also important to reconsider the handling methods of the vial at your own institute, such as restricting the handling of insulin vial preparations as much as possible and limiting its types adopted in the hospital as much as possible, etc.

In addition, since the vial preparation does not have a function that prevents weighing more than enough amount (foolproof function), it is not protected against an error such as erroneous conversion. It is required to enhance awareness that the insulin vial preparation is a drug product that does not have a foolproof function.

● Standardization of continuous infusion of insulin and registration of predetermined prescription

Continuous infusion of insulin is often urgently required, and GI therapy in particular is a method of application which has a different purpose from the common use of insulin. Therefore, in each medical institution, it is recommended that standard administration method for GI therapy and for continuous insulin infusion should be established in their own drug administration manuals, and should be disseminated throughout the hospital. Another method is to register the prescriptions in advance in the electronic medical record, in which fixed amount of insulin and amount of drug for dilution are determined.

[Use of a “Dedicated insulin syringe”]

Recommendation 9	When you suck up insulin from “Insulin in vial preparation”, always use a dedicated insulin syringe and do not use any other syringe.

● Use of a dedicated insulin syringe

In two of the four target cases, sucking up insulin with a general syringe instead of using a dedicated insulin syringe, led to an overdose.

Also, in the medical safety information from the Japan Council for Quality Health Care, cases of erroneous administration of insulin by mistaking the unit of insulin content (UNITS) for the unit of fluid volume (ml) has been repeatedly reported. In addition, in the revised instruction of "Precautions for Use" Notification No. 0519-1 of PSEHB (dated May 19, 2020) [7], "When preparing or administering (...) use a syringe dedicated to insulin vials" is specifically described in the "Important basic precautions" section of the package insert. In light of the above, it is necessary to carry out the use of a dedicated insulin syringe thoroughly.

● Education for thorough awareness of the use of dedicated insulin syringe

In one of the two cases, the nurse (as an administering staff) did not know that a dedicated syringe had to be used. In order to make the use of a dedicated insulin syringes thoroughly known in each medical institution, it is necessary to educate healthcare professionals repeatedly on the necessity (the reason) of using dedicated syringes.

Dedicated insulin syringes are sold by multiple companies under different brand trade names. One way to provide information at training sessions is, instead of simply calling them "dedicated insulin syringes", to present specifically the brand name which the medical institution has adopted, or to show pictures of the dedicated syringes in a creative way.

● Devices to encourage healthcare professionals to use dedicated syringes

It is also necessary to devise an environment where a dedicated insulin syringes should always be used. So far, examples have been presented, such as fastening a card stating "Use a dedicated insulin syringe" on the insulin vial preparation with a rubber band [8]. It is advisable for each medical institution to devise displays whose alert encourages healthcare professionals to always pick up a dedicated syringe, taking into consideration their work flow lines and the placement of the materials (see Figure 2).

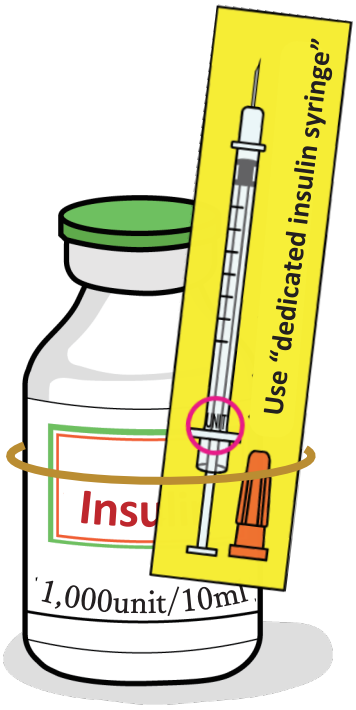

Figure 2

5. What we expect of (or what we want to propose to) academic societies and companies

We expect that academic societies and companies will challenge the following problems, that will develop further improvement of patient safety.

(1) National standardization of “electronic ordering system”

As for the ordering system, it is basically desirable that the united organization of government, academic societies and industries should work together unitedly to deal with the risks associated with the system, rather than each medical institution does.

"Study Group Report on the Method of Describing Prescriptions for Oral Medicine" (Ministry of Health, Labour and Welfare, January 2010) [9] recommends advising standardized input methods rather than methods that differ by system vendors. Therefore, in consideration of the subsequent changes in the environment, we expect the Japan Association for Medical Informatics and companies to discuss the following three issues to be standardized.

A management-enhanced system that automatically checks the validity of the withdrawal period and the doses when you enter the name of the disease and the medicine which requires a special direction for use, and raises the alert if there is a problem.
A system which automatically excludes the medicine which requires a special dosage when prescribing multiple drugs with a batch conversion method (e.g., a function that can prescribe multiple drugs for the same number of days at the same time). In other words, an automatic conversion does not occur equally even if a batch conversion system is used.
A system that the contraindicated medicines can be collated in conjunction with the patient information, etc.

(2) Use of ICT to prevent misidentification

Due to the rules of "Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices" (Pharmaceuticals and Medical Devices Law) and issues such as securing space, there are limits to the ingenuity of pharmaceutical containers and labels. Therefore, we hope that companies will consider a function (like QR code for the URL) that alerts the user with a display (visual) or voice (auditory) when the user holds up a cellular phone to read the label of the medicine, rather than the precaution displays on the label to prevent accidents.

(3) Regarding insulin vial preparations

We expect companies to introduce small-volume preparations such as “3 ml vial preparations” (100 units/ml) that are already distributed overseas.

In addition, although insulin vial preparations are “pharmaceutical products”, and dedicated insulin syringes are “medical devices”, it is hoped that they will be sold as a set beyond company boundaries (even in the form of a sample with a dedicated syringe attached).

Furthermore, as for the structure, it is expected that insulin vial preparations which incorporated a fool-proof mechanism will be developed, such as an excess amount cannot be sucked up or only a dedicated syringe can be used.

(4) Standardization of “logo marks” regarding precautions for use of medicines

Use of precaution logos is also one method for the special pharmaceutical products such as disinfectants that should not enter the body. However, in the current situation for a logo mark, it is left to each company to determine the design of its logo and whether or not it should be attached, if it meets the standards stipulated in the Pharmaceuticals and Medical Devices Law. Therefore, we expect companies to standardize those medicines which should have a logo attached and also their designs.

6. Conclusion

In these recommendations, the cases of death related to erroneous administration of medicines were analyzed in the specialists from muti-disciplinary field. Specific and concrete recommendations were made with awareness of the roles of the three occupational executor involved in the process of drug administration.

Through the analysis of the 36 cases, it was clarified again that errors can be made in any procedure of prescribing, compounding, and administering, in other words, the errors are not caused only by the final actors (administering executors). In these recommendations, from the quality control point of view, we have kept in mind a creation of mechanism in which errors in your own process are not passed on to the next process (post-process). It is important for each occupation to be aware of their own role and take specific actions to prevent accidents. In addition, healthcare professionals are not the only persons who can prevent accidents. In some cases, the patient perceived something wrong and tried to inform and complain of it, but the health-care professional was unable to recognize the erroneous administration of medicine. Listening to the patient's doubt and to stop and consider will lead to avoid medical accidents. As part of information sharing with patients, it is important to consider and also practice medication verification support.

It is also necessary to recognize that errors cannot perfectly be eliminated. When getting into the event of erroneous administration, immediate response is necessary to prevent a path to death. From some analyzed examples, it has been revealed that appearance of abnormal vital signs is already too late. It is not always primary physicians who give direction to the response after erroneous administration. It is important that those who have the knowledge of pharmacological effect of the medicine should participate in the response.

Based on the above mentioned, Recommendation 1 is "Confirmation in the processes of drug administration", Recommendation 2 is "Manuals for confirmation", Recommendation 3 is "Handling unfamiliar medicines", Recommendation 4 is "Support for patients in checking their own medication", Recommendation 5 is "'Medications placed in hospital wards' and their management", Recommendation 6 is "Identification of 'brought-in medicines' and audit for the 'consecutive medication'", and Recommendation 7 is "Response against 'erroneous administration of medicine'".

Each medical institution differs in the names of medicine themselves being handled, its organizational frameworks including the distribution of personnel, and the degree of utilization of ICT such as electronic medical record. From the results of validation and analysis of the target cases, we have compiled these Recommendations considering it in mind that each medical institution would interpret these Recommendations and apply them to measures at each medical institution. On the other hand, Recommendation 8 "Instruction and confirmation of 'Insulin'" and Recommendation 9 "Use 'Dedicated insulin syringe'" are conveyed the traditionally transmitted message in direct expression without any interpretation, because they are based on repeated fatal accidents due to erroneous administration of insulin.

In addition, another material has been prepared separately from this Recommendations. The purpose is to establish knowledge to eliminate fatal accidents due to erroneous administration of medicine. We aim for the Recommendations to be used as material for training on medical safety at each medical institution. We hope that the provision of material will lead to supporting the activities of the drug safety management division.

Finally, we would like to express our deepest condolences to the patients who died due to the accident and to the bereaved families, as well as to express our sincere gratitude to the medical institutions that contributed to the investigation of the causes of accidents and the prevention of recurrence, and cooperated in sharing the in-hospital investigation reports. We hope that the Recommendations will be useful to healthcare professionals as a step toward improving patient safety.

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7. Materials

This material lists the viewpoints and specific items for collecting necessary information when analyzing cases of erroneous administration of medicine.

Erroneous administration of medicine / Items of information collection

Items		Viewpoints		Concrete items
Basic information	Patient information	Age/Sex		Age: Sex:
		Clinical department		
		Primary disease		
		Medical history		
		Body height/Weight		Height: cm Body weight: kg
		General condition		
		Cognitive function		□ Interfered medication: □ Not interfered
		Allergy history		□ Present: □ Absent □ Unknown
		Contraindicated drugs		□ Present: □ Absent
	Medicines to be administered	Drug names/High-risk drugs		Drug names: High-risk drugs (Present/Absent)
		Dosage/dose	Administration route	Dosage:
			Daily dose	Dose: * For insulin vial preparations (use of dedicated syringe: Yes/No)
		Use of instruments		□ Present (Infusion pump/Syringe pump) □ Absent
	Erroneously administered medicines	Drug names/High-risk drugs		Drug names: High-risk drugs (Present/Absent)
		Dosage/dose	Administration route	Dosage:
			Daily dose	Dose: * For insulin vial preparations (use of dedicated syringe: Yes/No)
		Use of instruments		□ Present (Infusion pump/Syringe pump) □ Absent
Cause of death	Autopsy Ai	Autopsy results		
		Ai results		
	Other	Specimen findings, etc.		
Process of Drugs administration	Prescribing	Prescribing methods		□ Electronic medical charts □ Ordering systems □ Prescriptions (paper medical charts) □ Other:
		Items confirmed regarding validity check of prescription		□ Disease condition □ Medication history □ Dosage/dose per body weight □ Withdrawal period □ Other:
		Information confirmed before the prescribing		□ Presence or absence of contraindicated drugs □ Unit □ Number of tablets □ Prescription days □ Duration □ Other:
	Compounding	Prescription audit	Validity check	□ Medication history □ Presence or absence of contraindications for coadministration □ Presence or absence of contraindicated drugs □ Withdrawal period □ Other:
		Inquiry of suspicion		□ Present: □ Absent

		Method of suspicion inquiry		
		Inspection of drug	Validity check	□ Presence or absence of contraindications for coadministration of drugs □ Presence or absence of contraindicated drugs □ Withdrawal period □ Other:
			Items of Collation check	□ Patient name □ Drug name □ Dosage/dose □ Medication history □ Other:
			Those used as definite information	□ Prescription order □ Prescriptions □ Other:
	Administering	Confirmation of contents at the time of preparation	Items of Collation check	□ Patient name □ Drug name □ Single dose □ Other:
			Information used as definite items	□ Electronic medical charts □ Prescriptions □ Injection labels □ Other:
			Confirmation of suspicions	□ Present (Contents:) □ Absent
		Final confirmation immediately before administration	Validity check	□ Disease condition □ Contraindicated drugs □ Treatment duration □ Composition changes caused by coadministration □ Other:
			Items of Collation check	□ Patient name □ Drug name □ Dosage/Single dose □ Other:
			Information used as definite items	□ Electronic medical charts □ Prescriptions □ Injection labels □ Other:
			Patient confirmation	□ Name band □ Verbal confirmation to the patient □ Bar code authentication □ Patient names on medicine envelopes and injection labels, etc. □ Other:
			Confirmation of suspicions	□ Present (Contents:) □ Absent

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Conflict of interests:
Medical Accident Investigation and Support Center confirmed the status of conflicts of interest on the contents of this report self-declared by Expert Analysis Subcommittee members.

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Recommendations for the prevention of recurrence of medical accidents (Number 15)

Analysis of Deaths Related to “Erroneous Administration of Medicine”

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