

Annotation Guidelines for Incident Reports of Medication Errors (Japanese Reports)

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1 INTRODUCTION

These are the guidelines for annotating incident reports of medication errors. The ultimate goal of these guidelines is to improve patient safety. To do so, these guidelines establish a framework for retrieving information from incident reports. This document aims to instruct others on how to manually annotate incident reports for the creation of training or gold standard data for automated annotation. Using recent advances in named entity recognition (NER) and artificial intelligence (AI) [1], our study provides a framework for annotating the information in incident reports in a way that allows medication errors to be extracted automatically. We envision that the entire approach could revolutionise the way we collect, utilise, and retrieve information from incident reports.

These guidelines demonstrate how to extract explicit properties of medication errors, organise abstract incident information into meaningful entities associated with incident reporting and illustrate the methods for annotating named entities of interest in incident reports. This report begins with an introduction to the various named entities (hereafter NEs, also called concepts) with examples of how they can be annotated. Each NE is associated with certain characteristics; these are presented as attributes. These guidelines provide plenty of examples of how to apply the correct attribute to the correct NE. Certain combinations of annotation tags within an incident can be interpreted systematically; these are presented as incident types and are grouped into processes of care. We also illustrate situation-specific methods of annotation with several examples.

This study was developed based on a rich body of literature. Using state-of-the-art incident reporting guidelines, we conducted an extensive narrative review of medication errors, classification schemes and annotation methods (as shown in Figure 1). Literature from the WHO International Classification of Patient Safety [2], WHO Minimal Information Model for Patient Safety (MIMPS) [3], National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) [4], Agency for Health Research and Quality (AHRQ) Common Formats Version 2.0 [5] and European Medicines Agency Good Practice Guide [6], as well as other relevant studies [4, 5, 7-10], were carefully reviewed, referenced and synthesised. We also referred to guidelines for the development of a classification scheme suitable for information extraction in general [11, 12] and clinical contexts [13, 14].

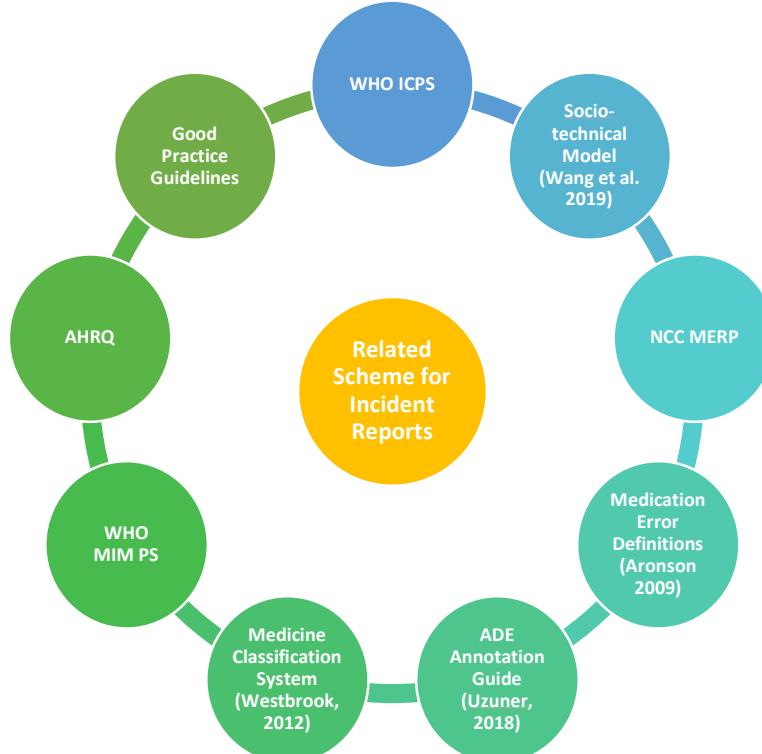


Figure 1. Literature review on annotation.

In these guidelines, we first explain the details of the annotation procedure (Chapter 2). How to annotate named entities is presented in Chapter 3 and attributes are presented in Chapter 4. Chapter 5 describes how to identify incident types based on the annotated medication errors. Throughout these guidelines, we provide sample incident reports to illustrate how to annotate named entities that are likely to be found in the narrative text of incident reports.

2 THE ANNOTATION TASK

2.1 GENERAL

The annotation procedure aims to extract a set of NEs from incident reports and identify their associated properties. The task consists of three subtasks:

- Identifying NEs, as described in Chapter 3.
- Applying attributes to specify the type and properties of each NE that has been annotated (details are provided in Chapter 4).
- Interpreting the incident type of each incident report by analysing the identified NEs and their attributes (details are provided in Chapter 5).

2.2 RATIONALE

Several basic philosophies, principles and rules apply to the annotation procedure. They are as follows:

- Annotating based on content. Annotation is based on only what is written in the incident report. Nothing should be left to the annotator's interpretation or imagination regarding incident progression. One notable exception is that misspellings are annotated as their intended entity, so long as the intended meaning is obvious from the context.
- Annotating when it fits. It is essential to follow the methods detailed in the annotation guidelines to ensure NEs are annotated appropriately. If in doubt, annotation is not done.
- Annotating everything applicable. In order to ensure the optimal prediction outcome, all NEs should be annotated, whether they correspond to medication errors or not.
- Annotating repeated items. Sometimes terminology that can be tagged as an NE is used repeatedly. As long as there is no difference in text properties, we annotate all repeated items the same way.
- Annotating only some aspects of speech. Only nouns are annotated, not verbs or adverbs.
- Acknowledging that quality and style of writing varies across authors.
- Balancing annotation complexity and patient safety impact. We have designed these annotation guidelines to be as simple as possible while still being capable of distinguishing between a variety of incident types. Simpler and more intuitive annotation rules minimise annotation errors.

2.3 THE ANNOTATION TOOL 'BRAT'

Annotation can be carried out using software such as BRAT, Oxygen XML, Prodigy and Doccane. In these annotation guidelines, we use BRAT: the 'brat rapid annotation tool' (<http://brat.nlplab.org>); all annotation examples are demonstrated with this platform. BRAT is a web-based tool for text annotation; that is, for adding notes to an existing text document. Two types of annotation can be done on BRAT: text-span annotation and relation annotation. Additionally, attributes can be applied to each annotation, which allows labelling of specific characteristics belonging to a group or individual. The BRAT manual can be accessed here: <http://brat.nlplab.org/manual.html>; the BRAT interface is shown in Figure 2.



Figure 2. A screenshot of Brat.

2.4 A NOTE ON WHAT KIND OF LANGUAGE IS CONSIDERED

The current state of NER can only capture variables of nouns, proper nouns, compound nouns and numbers. The nominalisation of verbs, adjectives and adverbs is not considered in this annotation scheme. Examples of how words are categorised follow:

- Common nouns: antibiotics, sedative, doctor, etc.
- Proper nouns: Penicillin, Patient A, Diazepam, etc.
- Numerals: 50, 1/2, 16:00, etc.
- Compound nouns: pain killer, food poisoning, etc.

Terms that are embedded within an inappropriate string of text are not annotated. For example, '38203, warfarin bag' is not annotated as the NE 'drug' (for warfarin).

2.5 MARKING THE RELEVANT SPAN OF TEXT

After the information to be extracted has been identified, the next step in the annotation process is to mark the span of text needed to correctly register the variable. In general, text spans should be as short as possible and marked consistently. Some examples follow.

Table 1. Examples of relevant spans of text.

Example Text	Correct text span	Incorrect text span
doctor prescribed diltiazem instead of diazepam	doctor prescribed <u>diltiazem instead of diazepam</u> <i>Explanation: each drug name should be tagged separately in a minimal span.</i>	doctor prescribed <u>diltiazem instead of diazepam</u> doctor prescribed <u>diltiazem instead of diazepam</u>
pharmacist dispensed a 5-mg prednisone tablet instead of a 1-mg prednisone tablet	pharmacist dispensed a 5-mg prednisone tablet instead of a 1-mg prednisone tablet <i>Explanation: different NEs should be tagged separately even these are corresponding to the same event.</i>	pharmacist dispensed a 5-mg prednisone tablet instead of a 1-mg prednisone tablet pharmacist dispensed a 5-mg prednisone tablet instead of a 1-mg prednisone tablet
nurse forgot to give oxycodone to patient at 8 am. After discovery, the nurse administrated oxycodone at 11 am	nurse forgot to give oxycodone to patient at 8 am. After discovery, the nurse administrated oxycodone at 11 am. <i>Explanation: numbers and units should be tagged together.</i>	nurse forgot to give oxycodone to patient at 8 am. After discovery, the nurse administrated oxycodone at 11 am. nurse forgot to give oxycodone to patient at 8 am. After discovery, the nurse administrated oxycodone at 11 am.

3 NAMED ENTITIES

This chapter provides practical guidelines for identifying NEs in incident reports. For illustrative purposes, some examples are provided in English. Most examples, however, use actual, Japanese-language incident reports.

3.1 DRUG

This type of NE is selected to specify the drug. All recognised drug names should be identified in the report.

Example 1:

[◀](#) [▶](#) /txt_format/Pilot_sample_30cases/39470

1 [[事故の内容]]

2 1 7時頃、病棟看護師よりセファメジン^a静注用1gを実施のところセフメタゾン静注用1gを実施したとの連絡が入り、
 3 払い出しの際にセフメタゾンを調剤してしまったことが判明した。
 4 調剤時は多忙であったため、注射調剤担当の事務員が取り揃えた薬剤を薬剤師が1名で調剤・監査しており、間違いに気がつかなかった。
 5 また、看護補助の受け取り、看護師による投与の際にも間違いが発見されず、
 6 1日2回の用法のうち1回目をセフメタゾン1gで患者に投与したことを担当看護師より説明を受けた。
 7 発見後は直ちに病棟にて事実確認と謝罪を行い、2回目の薬剤を正しいものと交換した。

Example 1 illustrates how different drugs are typically tagged. Cefamezina is the drug intended for delivery but the drug that was actually prescribed is Cefmetazon. In this case, both are recognised as NEs.

Example 2: *Normal Saline* was stopped when *Red Blood Cell (RBC)* was given to the patient.

Incident reports related to blood products are not the target of this classification scheme. However, blood products should be annotated as a drug if they are involved in an incident. Thus, in Example 2, Red Blood Cell (RBC) is annotated, despite not being the main drug associated with the error. Enteral nutrients can also be prescribed as drugs. Drug names and drug family names that are listed on lists of common medication should be regarded as drug NEs. Both product names and generic names should be annotated.

Example 3:

[◀](#) [▶](#) /txt_format/Pilot_sample_30cases/10748

1 [[事故の内容]]

2 17時準夜勤点滴確認にて夜間抗生素投与できていないことを発見する。
 3 指示簿には抗生素投与時間記載あったが、点滴には時間指示がなかった。
 4 整形外科医師へ報告し、点滴処方分で終了指示あり。

6 [[事故の背景要因の概要]]

7 点滴の時間指示が入っていないかった。指示簿には記載しているが見落としてしまった。

9 [[改善策]]

10 指示簿の確認を確実に実施する。主治医へ点滴時間指示を入れてもらえるように依頼する。指示簿だけでなく、掲示板にも抗生素時間を記載する。

In incident reports, classes of drugs (e.g., antibiotics, maintenance fluids, total parenteral nutrition), types of medication (e.g., oral medication) or medication for specific situations (e.g., daily medication, discharge prescriptions) are sometimes annotated as a drug NE. In Example 3, 'Antibiotics' is annotated, which describes the class of the drug; the specific drug name is absent in the report.

Example 4: Oral medication before breakfast was missed.

Sometimes the names of drugs are left unspecified. In Example 4, a drug name is not specified; the drug is identified simply as oral medication instead.

Example 5:

/txt_format/Pilot_sample_30cases/17607

- | | |
|----|--|
| 1 | [[[事故の内容]]] |
| | Drug * |
| 2 | 朝食後の内服を服用しなかった。 |
| 4 | [[[事故の背景要因の概要]]] |
| 5 | ・BOX管理（看護師が患者に渡して患者が1日分セットする）。 |
| 6 | ・起床時に服用する薬剤のことが気になっており、朝食後に服用することを忘れてしまった。 |
| 7 | ・昼に患者がBOXに準備する時に薬剤を持参して気が付いた。 |
| 9 | [[[改善策]]] |
| 10 | ・服薬指導。・服薬確認。 |

Similar to Example 4, no specific drug name is given.

Example 6:

/txt_format/Pilot_sample_30cases/31926

- | | |
|---|---|
| 1 | [[[事故の内容]]] |
| | Drug * |
| 2 | 18時にデュロテップパッチの貼り替え指示があつたが、指示を見落とし、貼り替え忘れた。 |
| | Drug * |
| 3 | 2日後12:30頃ラウンドした日勤看護師がデュロテップパッチを貼り替えていないことに気づいた。 |
| 5 | [[[事故の背景要因の概要]]] |
| 6 | 不明 |
| 8 | [[[改善策]]] |
| 9 | 不明 |

Patches are also annotated as drugs.

When unspecified, drugs are typically described using the terms below. Common classes of drug are also listed.

Unspecified drug
薬剤、内服、内用薬、注射薬、外用薬、静注薬、点滴、定期薬、退院時処方、吸入薬、外用塗布薬、点眼薬、点鼻薬、前投薬 etc

Drug classes
抗生剤、解熱剤、鎮痛・消炎薬、精神・神経用薬、アレルギー薬、呼吸器疾患治療薬、糖尿病治療薬、電解質製剤、輸液製剤等

When the drug name is uncertain, refer to the complete list of Japanese drug names:

<https://www.mhlw.go.jp/topics/2018/04/tp20180401-01.html>. If the variable closely resembles a drug name but the exact name cannot be found in the list, or the spelling is different or wrong, the variable should still be annotated as a drug.

What else should be known about drug names?

NEs such as drug, strength, form, timing, duration, frequency, dosage and route mainly contain sequences of nouns, compound nouns and numbers. Sometimes the official commercial name of a drug contains information about form and strength. These need to be annotated separately as their corresponding NEs. Incident reporters may refer to a drug in different ways. Such variations are still considered as the same drug and therefore share the same relation number (refer to the attributes part of Chapter 4.1). Examples of the various ways drug names might be reported are shown below.

Ways the drug might appear in incident reports	Corresponding annotation method (see Chapter Error! Reference source not found.)
Warfarin	
ワーファリン	ワーファリン[NE: drug]
ワーファリン錠	ワーファリン[NE: drug] 錠[NE: form]
ワーファリン5mg錠	ワーファリン[NE: drug] 5mg[NE: strength-amount]錠[NE: form]
Precedex	
プレセデックス	プレセデックス[NE: drug]
プレセデックス静注液	プレセデックス[NE: drug] 静注液[NE: form]
プレセデックス静注液200 μg	プレセデックス[NE: drug] 静注液[NE: form] 200 μg[NE: strength – amount]
プレセデックス静注液200 μg/2ml	プレセデックス[NE: drug] 静注液[NE: form] 200 μg/2ml[NE: strength – concentration]
プレセデックス静注液200 μg[マルイシ][200 μg/2ml]	プレセデックス[NE: drug] 静注液[NE: form] 200 μg[NE: strength] [マルイシ]•[200 μg/2ml[NE: strength – concentration]]

3.2 FORM

This entity type should be selected to specify the form of the drug or its mode of action.

3.2.1 FORM – FORM

Form is the physical form of the drug, such as a tablet.

3.2.2 FORM – MODE

The mode is the drug's mode of action, which is associated with its pharmacodynamic action. Consider the following example:

Sodium valproate was prescribed, but sodium valproate ER [extended release] was dispensed by the pharmacist.

Common types of form – mode, found in sublingual tablets, lozenges and enteric dissolving tablets, include the following:

- OD: Orally disintegrating
- D: Disintegrating
- RPD: Rapidly disintegrating
- RM: Rapidly melting, rapid dissolution
- ER: Extended release

It is important to be cautious of the differences between form – mode, form – form, dosage and route. These NEs can be misannotated if labelled based on the terms alone instead of the content of the whole incident report.

3.3 STRENGTH

Strength is the amount of drug associated with a particular dosage.

3.3.1 STRENGTH – AMOUNT

This type of NE specifies the amount of drug per unit. Note that if the number of units are described as a total dose per day, this is categorised as strength – amount.

Example 7: A doctor ordered vancomycin 500 mg diluted in 100 ml normal saline, but the nurse used vancomycin 500 mg diluted in 10 ml normal saline.

Error! Reference source not found. demonstrates how amounts of drug are typically described. 500 mg, 100 ml and 10 ml are all grouped as strength – amount.

Typically, strength – amount is presented as amount per unit, as shown above. However, the amount presented in the incident report can sometimes be in the form of amount per consumption (a one-time dose), total amount per day (or other unit of frequency, e.g., week) or total amount for the whole course of medication.

3.3.2 STRENGTH – RATE

This entity type should be selected to specify the speed with which a drug is administered. Strength – rate is typically represented with one measure compared to another measure. For instance, the flow rate of solution is represented as millilitres per hour.

Example 8: Soldem3A 200 ml was set on a pump and started at 100 ml/hr.

Note that in Example 8, ‘200 ml’ is not categorised as strength – amount because ‘100 ml/hr’ indicates a rate; this example is categorised as strength – rate instead.

Example 9: A doctor ordered a change in the rate of fentanyl to 0.5 ml/hr but the nurse missed the order.

In Example 9, 0.5 ml/hr is the flow rate of fentanyl and it should be grouped as NE strength – rate.

3.3.3 STRENGTH – CONCENTRATION

This entity type should be selected to specify the relative amount of a substance within a solution or mixture. This NE can be applied to existing drugs or mixtures.

Example 10: 20% glucose was injected.

Example 10 demonstrates strength – concentration as a percentage: 20% glucose.

3.4 DURATION

This entity type should be selected to specify the period for which a drug is administered to the patient. If the unit is in days, we can annotate either the number or the number and the days. We annotate other durations described in the incident report using the relation attribute, which is described in Chapter 4.1.2. E.g., if the patient is supposed to revisit the facility in seven days, then ‘seven days’ is tagged as the duration NE. However, it would be indexed as whichever relation number is remaining.

Duration can sometimes be presented in hours or minutes when referring to how long it takes to deliver medication. This information is also registered under the duration attribute.

Example 11: A doctor ordered the administration of 100 units/kg intravenous heparin sodium injection for the treatment of deep vein thrombosis for 7 days.

Example 12: 14 days' worth of inhalants were finished within 5 days.

In Example 11 and Example 12, either the number alone or the number and the day can be tagged because the unit of duration is days. Most incident reports use days as the unit of duration.

日数	件数	日数	件数
14日分	29	x14days	1
14TD	8	g14TM	1
14T	5	g14TH	1
/14T	5	D14T	1
14日	4(14)		1
×14日分	4	14N	1
(14)	4	14/T	1
/14TD	3	×14TD	1
X14日分	2	×(14)	1
g14TD	2	/14ds	1
×14T	3	/14	1
/14日分	2	空欄	1
x14日			1

Figure 3. Various ways to indicate an order for 14 days [31].

shows various descriptions for a duration of 14 days [31]. Under such circumstances, the unit is assumed to be days and only 14 can be annotated.

日数	件数	日数	件数
14日分	29	x14days	1
14TD	8	g14TM	1
14T	5	g14TH	1
/14T	5	D14T	1
14日	4(14)		1
×14日分	4	14N	1
(14)	4	14/T	1
/14TD	3	×14TD	1
X14日分	2	×(14)	1
g14TD	2	/14ds	1
×14T	3	/14	1
/14日分	2	空欄	1
x14日			1

Figure 3. Various ways to indicate an order for 14 days [31].

Example 13: A doctor prescribed antibiotics for 1 week.

Sometimes, a week, month or other unit of time is used to describe periods of drug administration. In these cases we annotate both the number and the unit, as seen in Example 13.

Example 14: 5 ml of antibiotics were injected into the patient over the course of 1 hour instead of 30 mins.

In this example, 5 ml is indicated as the NE strength – amount and we annotate both 30 minutes and 1 hour as the NE duration. By combining the NE strength – amount and the NE time, we know the strength – rate is 5 ml/30 minutes and 5 ml/1 hour. However, the report specifies a period of time and does not compare one measure against another. Therefore, 30 minutes and 1 hour are categorised as the NE duration.

3.5 TIMING

This type of entity is selected to specify the time at which a drug is given. Time is typically described as clock time or as a noun description, such as 'before breakfast', 'lunch', or 'bedtime'. The time to administer a drug is sometimes not specified (e.g., only information related to frequency is given). In such cases, time is not annotated. The date is also treated as time.

Example 15: The nurse forgot to give oxycodone to a patient at 8 am. After discovery, the nurse administered oxycodone at 11 am.

In Example 15, clock time is used to describe at what moment the drug is or should be taken. Therefore, 8 am and 11 am are tagged as time.

Example 16:

[◀](#) [▶](#) /txt_format/Pilot_sample_30cases/6179

1	[[[事故の内容]]
	Drug Timing
2	プロスタリンを日に与薬するのを忘れた。
3	指示簿の確認を忘れていた。昼は1剤のみ。
4	しっかり確認することが必要だと思った。準夜勤務者が見つけてくれて、教えてくれたので医師に確認しその時点で投与した。
6	[[[事故の背景要因の概要]]]
7	同室者がおらず、その病室はこの患者のみだった。病室ごと指示簿確認をしていない可能性。
9	[[[改善策]]]
10	確実な投薬の手順を守る。

In Example 16, a noun is used to indicate the time.

3.6 FREQUENCY

This entity type should be selected to specify the frequency at which a drug is given. Frequency is defined as how many times a drug is given per unit of time.

Example 17: A doctor ordered heparin calcium 3 times/day for the prevention of deep thrombosis after myoma operation. Nurse administered it 1 time/day.

In Example 17, 3 times/day and 1 time/day refer to how often the patient takes medicine; these are tagged as the NE frequency.

A study by the Ministry of Health, Labor and Welfare [31] has demonstrated common ways to describe taking a drug 3 times a day, as illustrated in **Error! Reference source not found..**

Table 3. Various prescription orders for taking a drug 3 times a day [31].

3xN	分 3
3x	分 x3 每食後
分 3 每食後	3 回:朝.昼.夕食後
3xndE	3x 朝、昼、夕食後
1 日 3 回 每食後	3x 各食後
分 3 后	3x 后
分 3 後	3x1 每食後
分 3 各食後	3 ? (unreadable)
3x 每食後	[分 3] 1 日 3 回 每食後
3x 食後	/每食後
3x1	/分 3 後
1 日 3 回 朝・昼・夕食後	/分 3 nde

/分 3 食後	/分 3
/3xnde	/Nx
/3xn	/N3x 1
/3x	/3 食後
每食後すぐ	/3x 每食後
分 3 每食後	/3nde
分 3: 朝昼夕食後 30 分	

3.7 DATE

This entity type is used to indicate any mentions of a specific time point that are at least one day in length, e.g., ‘the 7th’ or ‘Tuesday’.

3.8 DOSAGE

This entity type should be selected to specify a drug dosage. Dosage is defined as the number of units (e.g., tablets, bottles or ampules) given to the patient for a single consumption. If dosages are described in units, both the dosage and unit should be annotated. Information pertaining to form only, e.g., tablet, should not be annotated as dosage.

The relationship between NEs changes depending on how strength – amount is expressed. For example, if strength – amount is expressed in amount per unit, other NEs would be understood as follows:

- Dosage with strength – amount is equivalent to amount per consumption (i.e., a one-time dosage)
- Dosage with strength – amount with frequency (in days) is equivalent to the total amount per day
- Dosage with strength – amount with frequency (in days) with duration is equivalent to the total amount of medication taken throughout the course

However, if strength – amount is presented in per consumption, per day or per medication course, the above relationships would change accordingly.

According to the MEXT standard prescription guide, the amount per consumption is ideally prescribed by physicians. Annotators need to be aware that incident reports vary and the relationship between NEs may depend on the report.

Example 18: A doctor ordered 3 [dosage] *100 mg [strength – amount] aspirin [drug] tablets [form] 2 times/day [frequency], but the nurse gave 1 [dosage]* 100 mg [strength – amount] aspirin [drug] tablet [form].

In **Error! Reference source not found.**, dosages are described with a number and are annotated accordingly.

Example 19: A doctor ordered 1 tablet 2 times/day.

In Example 19, ‘1 tablet’ is annotated as the NE dosage, instead of ‘1’ being tagged as dosage and ‘tablet’ being tagged as form.

Example 20:

[◀](#) [▶](#) /txt_format/Pilot_sample_30cases/6817

1 [[事故の内容]]
2 マグラックス錠 2 5 0 mg 3錠、レバミビド錠 3錠分 3 4日のところ、マグラックスのかわりにロキソニンを調剤し、
3 鑑査も見落として払い出し、病棟看護師が間違いを発見した。再調剤を行い払い出した。患者には処方どおりに配薬した。
5 [[事故の背景要因の概要]]
6 日頃から数多く、レバミビド+ロキソニンの処方を調剤しており、今回も同じであると思い込み、処方箋を正確に読まなかった。
8 [[改善策]]
9 マニアル通りに調剤、鑑査を行う。

In Example 20, ‘3’ would be tagged as the dosage and ‘four days’ would be treated as the duration.

3.9 ROUTE

This entity type is selected to specify the drug route. Route is defined as the way the drug is administered to the patient, including infusion sites, routes and pumps. Annotators may find it difficult to distinguish between form and route.

Example 21: Incremin syrup 5 ml was prepared for oral administration in a syringe but was administered by intravenous infusion.

In **Error! Reference source not found.**, oral and intravenous are the way the drug is administrated to the patient, i.e., route.

Example 22: Doctor ordered oral furosemide to be stopped but the nurse mistakenly stopped intravenous furosemide.

In **Error! Reference source not found.**, oral and intravenous are the way the drug is administrated, although one might interpret oral and intravenous as the form of furosemide. Under such occasions, we can annotate oral and intravenous as form or route.

Other examples of the NE route include:

- Cutaneous, topical application, including ointments, sprays and patches
- Subcutaneous
- Ophthalmic
- Oral, including sublingual or buccal
- Optic
- Nasal – spray type
- Inhalation
- Intravenous
- Intramuscular
- Intrathecal
- Epidural
- Gastric
- Rectal
- Vaginal
- Intra-arterial
- Intra-peritoneal
- Intra-osseous

4 ATTRIBUTES

To be able to classify medical incidents according to their type and what kinds of errors contribute to them, it is not enough to label the NEs alone; the properties and characteristics of each NE should also be annotated. Distinguishing between types of incident, and knowing which errors are associated with each type, would provide an opportunity to compare incident reports from different institutions and ultimately enhance patient safety improvement. In this chapter we introduce intention and factuality analysis to identify error occurred within incident reports (which is a generic attributes (that apply to all NEs). Figure 4 outlines all attributes utilised in our annotation method. When assigning an attribute to an annotation, it is crucial that the annotator reads the entire incident report in order to understand the context and assign the appropriate attribute.

Generic attributes		Entity specific attributes			Entity specific attribute for strength, timing, duration, frequency, and dosage
Index 1 (default) 2 3 10 00 (general) 01 (patient_back) 02 (amelioration)	Sub-index 0 (general) 1 (default) 2 3 . . 10	Status Both (default) Intended Actual Neither	Drug Specific (default) Unspecified Classes mentioned Uncertain	Strength amount per unit (default) per consumption per day per whole course	Duration Drug period (default) Delivery length
Error occurred No error (default) Error Uncertain					
Entity specific relations Drug → Drug-drug interaction → Same drug name relation					

Figure 4. Overview of attributes.

4.1 GENERIC ATTRIBUTES

Generic attributes allow us to register essential information associated with each annotation. These attributes apply to every NE described in Chapter 2.5. Generic attributes include ‘relations’, ‘status’ and ‘error occurred’.

4.1.1 INTENTION AND FACTUALITY STATUS

To understand the use of the status attribute, annotators should first understand some fundamental things about medication incidents. An incident or near miss occurs due to a discrepancy between what is supposed to be delivered from upstream operations and what is actually delivered to downstream operations. A medication error might occur due to such a discrepancy happening across different phases of medication or different aspects of medication, such as drug, strength, etc. Using our NE framework, we wish to capture these discrepancies or the absence of such discrepancies for each annotation. Having this information will enable us to evaluate what type of incident the annotated incident report belongs to.

It is essential to identify what should have been delivered and what is actually delivered. Therefore, all NEs should be identified as either intended (what was supposed to be delivered) or actual (what was actually delivered). If the intended medication was the same as the actual one, i.e., no error occurred, then the NE should be classified as ‘intended and actual’, which indicates that there is no problem. Only when there is a discrepancy should ‘intended’ and ‘actual’ be used separately. ‘Intended and actual’ is the default.

To summarise, the possible options under the status attribute are as follows:

- Intended & actual (default) - IA
- Intended - IN
- Actual - NA

Example 24:

 /zoielab/supervisor/prof_wong/examples/19856

1	[[[事故の内容]]]
	
2	ファモチジンD錠 10 mg を調剤ところを 20 mg 調剤してしまい患者が 2 回服用してしまう。
4	[[[事故の背景要因の概要]]]
5	時間的に緊急処方箋や臨時処方箋の調剤を大量に処理しなくてはならず非常に繁忙であった。
6	確認したつもりであったがよく使用される薬剤で 20 mg もあるので間違えてピッキングしてしまった。

Named entity	Intended	Actual	Incident type
Drug	Famotidine D	-	
Form – mode	D	-	
Form – form	tablets	-	
Strength – amount	10 mg	20mg	Wrong amount

In this case, there is no discrepancy between the intended drug and the actual drug delivered. They are both Famotidine. There are no discrepancies for form – mode and form – form as well. However, the intended strength is 10 mg and the actual strength is 20 mg. Through correct identification of the status attribute, we are able to determine the type of incident: a wrong amount incident. The details are shown in the above attribute summary table. Annotations are listed in order of appearance.

5 INCIDENT TYPES

The incident type, i.e., what kind of medication error occurred, can be determined through an assessment of which named entities were intended and which actually occurred, as well as whether they belong to the primary event. One report might contain more than one incident type. Our pre-defined incidents are as follows: 'wrong drug', 'wrong form', 'wrong mode', 'wrong strength_amount', 'wrong strength_rate', 'wrong strength_concentration', 'wrong timing', 'wrong date', 'wrong duration', 'wrong frequency', 'wrong dosage' and 'wrong route'.

Figure 5 summarises the entire conceptual framework of the annotation scheme, including structured items.

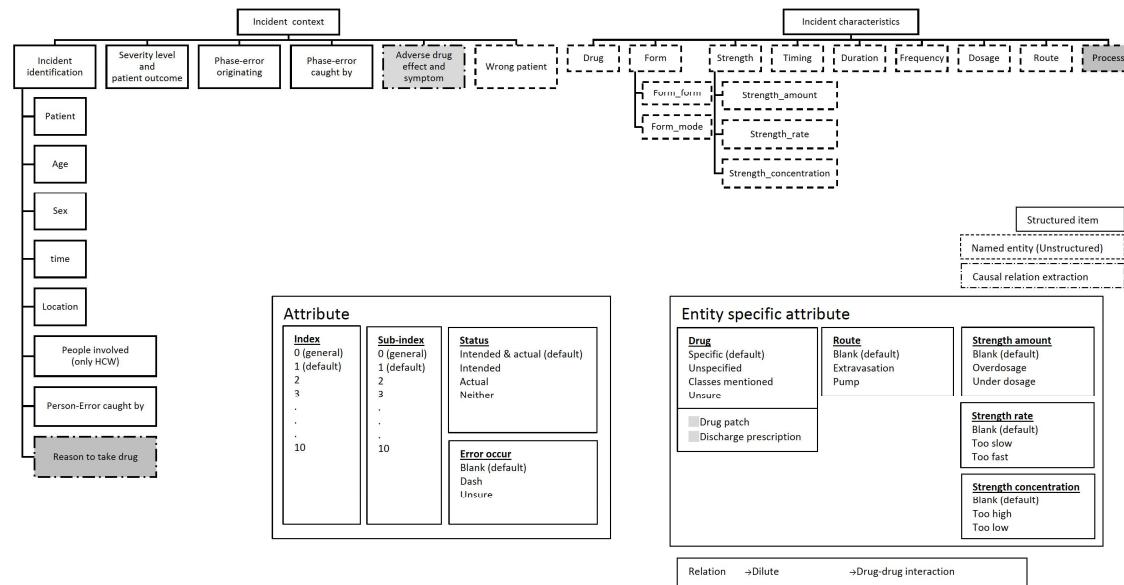


Figure 5. Conceptual framework for the classification theme.

The incident type can be determined by a comparison of the attributes 'intended' and 'actual'. One report might contain multiple incidents.

Table 3. Incident types resulting from combinations of NEs.

Named entity	Intended	Actual	Incident type
Drug	A	B	Wrong drug
Form – form	A	B	Wrong form
Form – mode	A	B	Wrong mode
Strength – amount	A	B	Wrong amount
Strength – rate	A	B	Wrong rate
Strength – concentration	A	B	Wrong concentration
Timing	A	B	Wrong timing
Duration	A	B	Wrong duration
Frequency	A	B	Wrong frequency
Dosage	A	B	Wrong dosage
Route	A	B	Wrong route

*NA = not applicable

5.1 WRONG DRUG

Wrong drug occurs when inappropriate medication or IV fluid is prescribed, dispensed, prepared or administered [10]. Wrong drug applies when the intended drug and the actual drug are different. A generic substitution is not considered as a wrong drug [10].

Example 25:

[/txt_format/JQ/JQ50/1](#)

1 [[事故の内容]]

 2 胃切術後の患者。本日昼からインスリン再開の指示あり。
 3 注射係から専用ノートで送りを受けていた。

 4 ノボリンR2単位と書かれた札をバットの中に準備し、この時点でヒューマリンRと思い込んでいたのでインスリン用の注射器で2単位を準備した。

 5 施行前別看護師と一緒にれど「2単位」の確認を行い施行した。
 6 しかし本体の確認をしていなかった。

 7 カルテに入力する際、ヒューマリンRではなくノボリンRの指示であったことに気付いた。
 9 [[事故の背景要因の概要]]

 10 本日夕食前からヒューマリンRが開始となる別患者があり、2人ともヒューマリンRと思い込んでいた。

 11 術前にノボリンRを使用していたことを看護師2人とも把握していなかった。
 12 血糖に変更がある場合は血糖測定一覧表に新規の指示書を添付するルールとしていたが、それがされていなかった。
 14 [[改善策]]
 15 ダブルチェックをする際には単位数だけでなく、本体の確認もする。
 16 思い込んで行動せず、指示簿を見て行動する。
 17 決めているルールは徹底して守る。

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Noborin	Humulin	Wrong drug
1	Mode	R	R	
1	Amount	2 doses	2 doses	

We can see that Humulin was delivered to the patient instead of Noborin, so the incident is tagged as ‘wrong drug’. The mode and amount information are not marked as wrong because ‘wrong drug’ has already been applied and it is an incident of a higher level.

Example 26:

[/txt_format/JQ/JQ50/16](#)

1 [[事故の内容]]

 2 麻酔準備において、シリングポンプにエスラックスをつなぐべきところをネオシネジンをつないでいた。

 3 上級医がエスラックスを使用しようとした際に気付き、修正した。
 4 実際には薬剤は使用されなかった。
 6 [[事故の背景要因の概要]]
 7 麻酔準備を上級医と二人で準備しており、狭い空間に二人で入っていたため目視が不十分で取り違えてしまった。
 9 [[改善策]]
 10 つなぐ前にしっかり確認する

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Esrax	Neosynergyn	Wrong drug

In this example, wrong drug is indicated by the discrepancy between ‘intended’ and ‘actual’.

Example 27:

[◀](#) [▶](#) /txt_format/JQ/JQ50/20

1	[[事故の内容]]
2	ラミクタール錠の処方であったがラミシール錠を調剤して病棟へあげてしまった。
3	看護師も気づかず家族が間違いに気づく
5	[[事故の背景要因の概要]]
6	名称が類似しており、同じ引き出しに入っていた
8	[[改善策]]
9	置く位置を変更する
10	処方箋の名称の前に薬効を記載し確認漏れがないようにした（例）抗痙攣薬 ラミクタール

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Lamotrigine	Lamisil	Wrong drug
1	Form	tablet	tablet	

In this example, form is not connected to any incident type because ‘wrong drug’ has already been applied.

5.2 WRONG FORM

Wrong form occurs when the wrong form of drug is ordered, dispensed or administered.

Example 28:

3	【事故の内容】
4	患者は継続してジルチアゼム塩酸塩錠30mg 2錠分2、朝夕 食後で内服していた。
5	その後、脈拍低下、徐脈、低血圧等の症状が出現。
6	主治医よりジルチアゼム塩酸塩錠30mgの抜き取り再調剤指示があった。
7	病棟看護師は1包化調剤のジルチアゼム塩酸塩錠30mgと再調剤依頼伝票を薬剤部に提出した。
8	薬剤師が夕食後の1包化にジルチアゼム塩酸塩Rカプセル100mgが入っているのに気づく。
9	調剤時の規格間違いと判断。服用期間は13日間と1回分と思われた。
10	直ちに主治医に報告、主治医と薬剤部長、病棟師長で患者への謝罪と説明を行った。
11	ジルチアゼム塩酸塩錠30mgを1日休薬、2日後より内服再開、症状は改善した。
12	【事故の背景要因の概要】
13	ジルチアゼム塩酸塩は錠剤30mgとカプセル100mgの2規格採用あり。

Relation	Named entity	Intended	Actual	Incident type
1	Drug	diltiazem hydrochloride	diltiazem hydrochloride	
1	Form – form	tablets	capsules	Wrong form

In this example, an agent that has a different form is dispensed.

5.3 WRONG MODE

Wrong mode occurs when the wrong mode of a medication is ordered, dispensed or administered.

Example 29:

◀ ▶ /txt_format/JQ/extrajQ/a2				
1 【事例の内容】				
   				
2 「デバケン錠 200mg」を取り揃え、調剤・鑑査するべきところ、徐放錠の「デバケンR錠 200mg」を取り揃え、調剤・鑑査してしまった。				
3 薬服直前に患者家族により発見された。病棟より連絡を受けて速やかに謝罪して、現物を交換した。				
4 本人・家族には事情は特に憤慨の様子は無かった、と思われる。				
5 【事例の背景要因の概要】				
6 【類似名称】と【複数規格】に対して処方箋印字上のルールで運用されていたが（※マークで強調）、【複数規格】のみ気にして【類似名称】の再確認を失念した。				
7 【改善策】				
8 例えば、現状「デバケン R錠 ※ 200mg※」であるが、「デバケン ※ R錠※ ※ 200mg※」のように【類似名称】と【複数規格】共に※マークを付けたい。				
Relation	Named entity	Intended	Actual	Incident type
1	Drug	sodium valproate	sodium valproate	
1	Mode		R	Wrong mode

In this example, the drug mode is wrong even though the form is the same. Only the mode for the drug actually given, 'R', is specified (in the drug name). The mode of the drug intended for administration is left blank. This is a 'wrong mode' incident.

5.4 WRONG AMOUNT

Wrong amount is defined as a dose of medication or volume of IV fluid over or under the intended amount, taking into account the patient's age, weight, renal and liver function [10].

Example 30:

◀ ▶ /txt_format/JQ/JQ400/16369				
1 [[事故の内容]]				
    				
2 他院処方にて入院前よりオキシコンチン20mg（朝・夕食後に1錠ずつ）内服されていた。				
3 入院中に持参薬がなくなり、当院にて新たに処方したが処方入力が「オキシコンチン5mg」になっていた。				
4 内服薬が病棟に上がってからの看護師同士の確認で「mg」の確認を怠ってしまい、本日の朝分のオキシコンチンも5mg1錠のみ内服させてしまった。				
6 [[事故の背景要因の概要]]				
7 不明				
9 [[改善策]]				
10 不明				

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Oxycontin	Oxycontin	
1	Amount	20 mg	5 mg	Wrong amount
1	Timing	morning	morning	
1	Timing	after dinner	after dinner	
1	Dosage	one tablet	one tablet	

In this example, amount is the titre of the drug.

Example 31:

[◀](#) [▶](#) /txt_format/JQ/JQ400/18326

1	[[[事故の内容]]]
2	昨日16時半からドルミカム0.5ml/Hでセデーション開始していた。
3	患者の状態により、一時間分早送りをするという指示があり、早送りを行ったが、早押しボタンを長押ししづぎて0.7ml静注してしまった。
5	[[[事故の背景要因の概要]]]
6	・4ヶ月ぶりにシリンジポンプを使用し、早送りの方法が不十分であった。・手技が未熟であった。
8	[[[改善策]]]
9	・シリンジポンプの練習をし、使いこなせるようにする。・できるようになるまで先輩に見ていただく。

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Dolmicam	Dolmicam	
1	Rate	0.5ml/H	0.5ml/H	
1	Amount		0.7ml	Wrong amount

In this example, a medication rate (0.5ml/h) is annotated. Later, a strength – amount that was mistakenly given to the patient (0.7 ml) is mentioned, but without note of what the intended amount was.

5.5 WRONG RATE

Wrong rate is defined as a rate, e.g., IV rate, being slower or faster than intended [10].

Example 32:

[◀](#) [▶](#) /txt_format/JQ/JQ50/23

1	[[[事故の内容]]]
2	医師は患児にソルデム200mLを2時間、側管から生食50mL+ソルメルコート0.5Vを30分の指示があり
3	看護師はそれぞれに輸液ポンプをつけ共に100mL/hでセットしたつもりだったが、ソルデム200mLの輸液ポンプは200mL/hになっており、指示より早く滴下してしまった
5	[[[事故の背景要因の概要]]]
6	・小児の点滴が多く多忙だった
7	・輸液ポンプ設置後、ダブルチェックを行わなかった
8	・指さし呼称を行わなかった
10	[[[改善策]]]
11	・輸液ポンプ施行時は、再度確認を行う
12	・指さし確認を行う

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Soldem	Soldem	
1	Amount	200ml	200ml	
1	Rate	100ml/h	200ml/h	Wrong rate
1	Drug	food	food	
1	Amount	50 ml	50 ml	
1	Drug	Solu-Medrol	Solu-Medrol	
1	Dosage	0.5 V	0.5 V	

Intravenous drugs are generally prescribed as a single dose, 'food 50 ml' and 'Solu-Medrol 0.5 v' indicate a single dose and are annotated using 'dosage'. A rate of '200ml/H' was mistakenly used.

Example 33:

[◀](#) [▶](#) /txt_format/JQ/JQ50-2/70

1	[[事故の内容]]
2	シスプラチン3クール投与1日目の患者。
3	輸液ポンプを使用し点滴投与していた。
4	当日、当事者は当該患者の担当ではなかった。
5	当事者は当該患者のナースコールで訪室し20%マンニットール注射液を400mL／時間での投与が終了していることに気付いた。
6	20%マンニットール注射液を400mL／時間での投与終了後、シスプラチニを250mL／時間で投与する指示であった。
7	しかし、シスプラチニに切り替えた後に投与速度を変更せず、シスプラチニを400mL／時間で投与してしまった。
8	シスプラチニ投与開始して5分以内に当事者以外の看護師が発見し直ぐに中止した。
9	医師に報告し、残りのシスプラチニを250mL／時間で投与した。
11	[[事故の背景要因の概要]]
12	点滴切り替え時に点滴の指示を確認していなかった。
13	抗悪性腫瘍薬の適切な投与速度、投与速度が速いことによる有害事象に関する知識が不足していた。
15	[[改善策]]
16	点滴投与前に点滴の指示やクレンメの開封の有無、ラインの破損の有無等の確認を指差し呼称で行う。
17	抗悪性腫瘍薬に関する知識を充足させる。
18	担当以外の患者のナースコールに対する対応で分からることは担当の看護師に確認する。

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Cisplatin	Cisplatin	
1	Concentration	20%	20%	
1	Drug	Mannitol	Mannitol	
1	Form	injection	Injection	
1	Rate	400ml/hr	400ml/hr	
1	Rate	250ml/hr	400ml/hr	Wrong rate
1	Drug	Cisplatin		
1	Rate	250ml/hr		

In this example, cisplatin was mistakenly administrated at 400ml/hr instead of 250ml/r.

Example 34:

[◀](#) [▶](#) /txt_format/JQ/extrajQ/a4

1	【事例の内容】
2	100ml以上の尿流出があり、11時の採血結果でK値2.9meqと低下。 →Diluted
3	Drug Drug? Strength.concentration Strength.amount Strength.amount Form.form Form.form Strength.rate Frequency
4	医師よりKCL注20meq 20ml+生理食塩液80ml 計100mlを1時間での投与を3回実施するように指示があった。
5	薬剤を準備し輸液セットもポンプ用セットを付け他看護師が準備した。
6	Drug Drug Strength.amount ***
7	約15分後、患者の所へ行くと、KCL+生理食塩液が輸液ポンプを使用せず、手動で約50ml投与されているところを発見。
8	Strength.rate***
9	倍速投与となった。直ちに投与を中止し状態観察を実施。
10	致死性不整脈がないことを確認し、以後は輸液ポンプを使用し投与した。
11	その後、患者のバイタルの異常なく経過。医師へ報告し経過観察となった。
12	【事例の背景要因の概要】 ・他看護師は担当看護師が投与経験があると回答したため、側で確認・指導することなくその場を離れた。 ・担当看護師はKCLについての知識が不足していた。

Relation	Named entity	Intended	Actual	Incident type
1	Drug	KCL	KCL	
1	Form	Injection	injection	
1	Amount	20mEq/20ml	20mEq/20ml	
1	Drug	saline	saline	
1	Amount	80ml	80ml	
1	Amount	100ml	100ml	
1	Rate	1 hour		Wrong rate (Too fast)
1	Frequency	3 times	3 times	
1	Amount		50 ml	Wrong amount (Overdosage)

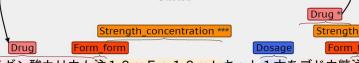
Multiple incidents are captured in this example. Rate is closely related to amount, so sometimes ‘wrong rate’ and ‘wrong amount’ occur together. Sometimes the exact amount, rate or concentration are not mentioned in the incident report. In such cases, ‘entity-specific attributes’ can be used to indicate the incident type. In this example, while the actual rate is not explicitly mentioned, within the free text ‘too fast’ indicates that the rate is faster than intended, therefore it is a wrong rate incident. Similarly, while amount was not clearly mentioned, within the free text ‘overdosage’ indicates that an amount larger than intended was administered. Note that while the amount 50 ml is less than what was planned, we used wrong amount to indicate such overdose situation.

5.6 WRONG CONCENTRATION

Wrong concentration is defined as the concentration of a medication being higher or lower than intended [10]. Concentration is also closely related to amount and rate; most cases of ‘wrong concentration’ co-occur with ‘wrong rate’ or ‘wrong amount’. A wrong concentration might be reported as a wrong amount.

Example 35:

[/txt_format/JQ/extrajQ/a3](#)

1 【事例の内容】

 Drug Form form Strength concentration *** Drug Strength amount *
 Form form Dosage Strength concentration *** Dosage Strength rate ***

2 アスパラギン酸カリウム注10mEq10mlキット1本をブドウ糖注5%100ml1瓶に溶解し1時間で投与するオーダにおいて、
 Strength concentration Strength rate

3 添付文書では「濃度は40mEq/L以下として1分間8mLを超えない速度で点滴静脈内注射する」とされているが疑義照会せず、オーダを通した。
 4 その後、病棟看護師にて病棟薬剤師に問い合わせがあり、発覚した。
 5 【事例の背景要因の概要】

6 カリウム製剤において「濃度40mEq/L以下、速度20mEq/h以下で投与」という認識はあったが、
 Strength rate Strength concentration

7 速度20mEq/h以下であれば濃度40mEq/L以上であっても許容してよいというような指導を受けていたため、誤った認識により判断を誤ってしまった。

8 【改善策】
 9 不明

Relation	Named entity	Intended	Actual	Incident type
1	Drug	potassium aspartate	potassium aspartate	
1	Form	Injection	Injection	
1	Strength-amount	10mEq10ml	10mEq10ml	
1	Dosage	one bottle	one bottle	
1	Drug	glucose	glucose	
1	Concentration	5%	5%	
1	Strength-amount	100ml	100ml	
1	Dosage	one kit	one kit	
1	Rate	8ml/min		Wrong rate
	Duration		one hour	
1	Concentration	40mEq/L		Wrong concentration (Positive – more than expected)

As mentioned before, an intravenous infusion is generally prescribed as a single dose, which is why ‘one bottle’ and ‘one kit’ are annotated as a single dose using ‘dosage’. As was the case previously, the actual rate is also not explicitly mentioned, but within the free text, it appears that intended rate is <8ml/min and intended concentration is <40mEq/L, i.e. it is a wrong rate and wrong concentration incident. While there is no ‘actual’ concentration mentioned, it is possible to deduce from the amount that the concentration is higher than recommended.

5.7 WRONG TIMING

Timing-related errors are defined as administration too early or too late, relative to the time designated by the healthcare facility [22]. There are three scenarios associated with wrong timing:

- 1) No 'omission' or 'extra drug' results from wrong timing (Example 54)
- 2) 'Omission' results from wrong timing (Example 56)
- 3) 'Extra drug' results from wrong timing (Example 57)

Example 36:

[/txt_format/Pilot_sample_30cases/39978](#)

```

1 [[[事故の内容]]]
2 12:30帰くて昼食が食べられないと訴えあり。
3 Timing Drug
4 9:00内服予定であったオキシコンチン錠を内服していないことに気付く。すぐに内服していただく。
5 [[[事故の背景要因の概要]]]
6 Timing
7 朝の申し送り時、確認不足であった。看護指示から、指示うけできず、9:00に内服があることを確認できていなかった。
8 [[[改善策]]]
9 申し送り時、受持ち患者の麻薬は、自分で確認し、注意を促す。申し送り前に患者情報を取り、確認する。

```

Relation	Named entity	Intended	Actual	Incident type
1	Timing	9:00		Wrong timing
1	Drug	Oxycontin	Oxycontin	
1	Form	tablets	tablets	

Example 37:

[/txt_format/JQ/JQ50/21](#)

```

1 [[[事故の内容]]]
2 Drug
3 持参薬で薬袋に記入されている用法を鑑別書に入力し鑑別書を作成した。
4 Timing Timing Timing Timing Timing Timing
5 [[[事故の背景要因の概要]]]
6 多忙で確認が疎かになってしまった
7 鑑別後に最終確認を怠ってしまった
8 Drug Frequency
9 ステロイドは1日3回の服用はあまりなく、考えなしに行っていた
10 [[[改善策]]]
11 鑑別書と薬剤を確認する
12 多忙でも冷静に対応する
13 自分の目できちんと情報を取る
14 持参薬の内容を見て適切か考えて作成する

```

Relation	Named entity	Intended	Actual	Incident type
1	Drug	medication	medication	
1	Timing	after breakfast	after breakfast	
1	Timing	lunch	lunch	
1	Timing		dinner	Wrong timing
1	Frequency	2 times a day	3 times a day	Wrong frequency

Example 38:

⬅ ➡ /txt_format/JQ/JQ50/19				
1 [[事故の内容]]				
2 本日、2時、10時、18時にフィニパックスの指示が出されていたが看護師は指示を見落とし2時の点滴を施行しなかった				
4 [[事故の背景要因の概要]]				
5 患者の注射処方箋が3枚あり、3枚目に抗生剤の指示が記載されていた。指示内容を見たつもりであったが見落としていた				
7 [[改善策]]				
8 ワークシートを活用する				
9 処方箋は最後のページまで目を通す				

Relation	Named entity	Intended	Actual	Incident type
1	Timing	2:00		Wrong timing
1	Timing	10:00	10:00	
1	Timing	18:00	18:00	
1	Drug	Finibax	Finibax	

In this case, wrong timing led to the drug administration being skipped. If the drug is administered after detecting the delay, then it is not an omission error but an error of wrong timing. However, this was not explicitly described in the text. Therefore, an omission error is registered.

Example 39:

⬅ ➡ /txt_format/JQ/JQ50/10				
1 [[事故の内容]]				
2 朝のラウンド時に朝の内服を準備するよう声かけし、食後内服の確認に行くと、昼食後のエペリゾンを内服してしまっていることを発見する。				
3 朝食後の内服（一包化）の中にも同じ薬が入っており重複内服となつた。医師報告し様子観察となる。				
5 [[事故の背景要因の概要]]				
6 内服自己管理中の患者。看護師は食前薬の準備と服薬確認を実施していたが、朝、患者が寝ていたこと、				
7 また、本日退院でもあったため、食後薬の準備しておいてくださいと声かけをしただけで、実際に準備するところを確認しなかつた。				
9 [[改善策]]				
10 本日退院予定のため薬包をしっかり確認するよう説明した。				

Relation	Named entity	Intended	Actual	Incident type
1	Timing	Morning	after lunch	Wrong timing
1	Drug	Eperisone	Eperisone	

In this example, a drug is administered at the wrong timing, but the intended timing is unclear.

5.8 WRONG DATE

Wrong date refers to the medication being administered for a different date compared to the intended date.

5.9 WRONG DURATION

Wrong duration refers to the medication being administered for a longer or shorter period than intended.

Example 40:

[/txt_format/JQ/JQ50/12](#)

1	[[事故の内容]]
2	患者より次の吸入薬をくださいと希望あり。
3	吸入薬を確認すると11／17処方のスピオルトレスピマット（28吸入分）が空になっている。
4	1日1回2吸入のため、10日分以上はあるはずだが、5日間でなくなってしまった。
5	本人に吸入について確認すると「1日1回、1回2吸入だよ」と吸入回数理解されている。
6	以前吸入手技確認した際も問題はなかった。
7	主治医に上記報告。そのまま吸入継続でよいと指示あり。
9	[[事故の背景要因の概要]]
10	吸入を重ねて実施してしまった可能性や空打ちを何度も実施していた可能性があるが、
11	退院後自己管理になるため吸入薬を患者管理にしてしまい、毎日残量を確認できていなかった。
13	[[改善策]]
14	吸入手技だけでなく、残量も確認する。
15	管理が不十分である場合は看護師管理とする。

Relation	Named entity	Intended	Actual	Incident type
1	Drug	inhalant Spiriva Respimat	inhalant Spiriva Respimat	
1	Amount	28 inhalations	28 inhalations	
1	Frequency	once a day	once a day	
1	Dosage	two puffs	two puffs	
1	Duration	10 days	5 days	Wrong duration

In this example, based on the drugs remaining, the prescribed duration didn't match the actual duration. Here, drug is expressed using both a generic description of form and a specific name. Both represent the same drug and so share the same relation number.

5.10 WRONG FREQUENCY

A wrong frequency occurs when the prescribed or administered frequency of delivery for a drug or an IV rate falls outside of the recommended range or planned number [10]. If the frequency is larger, it is often also labelled as an extra drug. If the frequency is smaller, then 'omission' is applicable. Wrong timing is also relevant in such cases.

Example 41:

[/txt_format/JQ/JQ400/11891](#)

1	[[事故の内容]]
2	ロキソプロフェン 1日2回朝、夕のところ、1日3回にセットし最も投与した。患者より服用後に報告があった。
4	[[事故の背景要因の概要]]
5	確認不足。
7	[[改善策]]
8	1回配薬の患者の内服薬をセットする際に全ての内服薬に残数と、セット者、配薬者を記載した紙を作り、内服薬の袋に貼り、ダブルチェックを徹底する。

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Loxoprofen	Loxoprofen	
1	Frequency	twice a day	three times a day	Wrong frequency
1	Timing	morning	morning	
1	Timing	evening	evening	
1	Timing		afternoon	Wrong timing

In this example, both frequency and timing are wrong.

5.11 WRONG DOSAGE

Patients may be subject to excessive or insufficient amounts of a drug.

Example 42:

[◀](#) [▶](#) /txt_format/JQ/JQ400/14659

1	[[[事故の内容]]]
2	疼痛の訴えあり、指示薬のカルノールを1錠与薬した。
3	カルテに記載時、前日と量が異なるため確認したところ、指示は2錠であり、過少与薬が発覚した。
4	気が付いた際患者は入眠中であり、起床時に疼痛の訴えがなかったため経過観察とした。
6	[[[事故の背景要因の概要]]]
7	一般指示、処方箋の確認が不十分であった。
9	[[[改善策]]]
10	ダブルチェック時、与薬時に5 Rでの確認を行う。

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Calonal	Calonal	
1	Dosage	2 tablets	1 tablet	Wrong dosage

In this example, the actual dosage is smaller than the intended amount.

Example 43:

[◀](#) [▶](#) /txt_format/JQ/JQ50/28

1	[[[事故の内容]]]
2	27日からセレコックス(100) 2錠2×1の指示あり。15時頃、内服薬が薬剤部から届いたため、本日の分を内服させた。
3	16時30分、準夜勤務看護師に、本日の夕分は時間がずれることを申し送っている際に、1回一錠ではなく、2錠内服させたことに気付いた
5	[[[事故の背景要因の概要]]]
6	・「2錠2×1は朝1錠・夕1錠」内服することは知っていたが、1回2錠と思いこんだ。 ・5R確認の怠り。
9	[[[改善策]]]
10	・5Rの徹底。
11	・指差し、呼称で確認する。

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Celecoxib	Celecoxib	
1	Amount	100	100	
1	Amount	2 tablets	2 tablets	
1	Frequency	2x	2x	
1	Dosage	one tablet	two tablets	Wrong dosage

In this example, '2 tablets' is annotated as 'amount' because it is the total amount of tablets for a day. Also '2 tablets' is annotated as 'dosage, actual' because it is a single unit that was wrongly given to the patient. Dosage is defined as the number of units (e.g., tablets, bottles and ampules) given to the patient as a single dose. However, sometimes the total amount of units is described instead of single dose. In such a situation, the total amount of units is annotated as amount.

5.12 WRONG ROUTE

Wrong route occurs when a medication is prescribed or administered via an incorrect route of administration, e.g., a drug that creates strong vascular irritation and should be given via the central line is administered via the peripheral line.

Example 44:

[/txt_format/JQ/extra_JQ/a6](#)

1 【実施した医療行為の目的】
2 薬剤の投与経路間違い
3 【事故の内容】

4 看護師Aは、処方指示画面を確認し、**インクレミンシロップ5cc**を透明シリングに準備し、看護師Bへ他の錠剤と一緒に手渡した。
Drug **Form form** **Strength amount** **Drug ***

5 看護師Bは患者の病室を訪室し、最初に錠剤を内服してもらった。
Drug

6 その後、左正中皮静脈に留置（生食ロック）されていた末梢ルートから透明シリングに入った液体（インクレミンシロップ）5ccを注入した。
Route ** **Drug** **Form form**

7 その直後、嘔気・嘔吐が出現。
Drug

8 同じ頃、ナースステーションのモニター上頻脈を確認し看護師Cが訪室し、状況を確認したところ、誤ってインクレミンシロップを静脈内注射したことが分かった。
Drug **Form form** **Route ****

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Incremin	Incremin	
1	Form	syrup	syrup	
1	Amount	5 ml	5 ml	
1	Route	oral	intravenous	Wrong route

5.13 OTHERS

We may find other errors that are not covered by the current scope of this annotation guide, e.g., procedural errors such as forgetting to fill out a questionnaire before administrating a vaccine to a patient. For errors that are out of the scope of the above or the free text inputs does not present any error, the incident type is registered as "Others".

6 CONCLUSION

These guidelines demonstrated how to manually annotate medical incident reports for the creation of gold-standard data, which is used for training artificial intelligence to conduct automated annotation.

The named entities found within reports, and their attributes, were introduced and explained with examples. Incident types, certain combinations of annotations that can be interpreted systematically, were also described.

Together with recent advances in named entity recognition, these guidelines provide a framework for extracting actionable data from unstructured textual reports. We anticipate this approach could revolutionise the collection, utilisation and retrieval of information from incident reports – an exciting prospect for the future of patient safety.

7 REFERENCES

1. Liu Z, Yang M, Wang X, Chen Q, Tang B, Wang Z, et al. Entity recognition from clinical texts via recurrent neural network. *BMC Med Inform Decis Mak*. 2017;17(Suppl 2):67.
2. Conceptual Framework for the International Classification for Patient Safety: WHO; 2009 [Available from: https://apps.who.int/iris/bitstream/handle/10665/70882/WHO_IER_PSP_2010.2_eng.pdf?sequence=1.
3. Anonymous. Minimal information model for patient safety incident reporting and learning systems: user guide Geneva: World Health Organization; 2016 [Available from: <http://www.who.int/iris/handle/10665/255642>.
4. Anonymous. National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy of Medication Errors. US: National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) 1998. Contract No.: 5 March.
5. Yao B, Kang H, Wang J, Zhou S, Gong Y. Toward Reporting Support and Quality Assessment for Learning from Reporting: A Necessary Data Elements Model for Narrative Medication Error Reports. *AMIA Annu Symp Proc*. 2018;2018:1581-90.
6. Althaus CL, Low N, Musa EO, Shuaib F, Gsteiger S. Ebola virus disease outbreak in Nigeria: Transmission dynamics and rapid control. *Epidemics*. 2015;11:80-4.
7. Aronson JK. Medication errors: definitions and classification. *British journal of clinical pharmacology*. 2009;67(6):599-604.
8. Zhou S, Kang H, Yao B, Gong Y. An automated pipeline for analyzing medication event reports in clinical settings. *BMC medical informatics and decision making*. 2018;18(5):113.
9. Wang J, Liang H, Kang H, Gong Y. Understanding Health Information Technology Induced Medication Safety Events by Two Conceptual Frameworks. *Appl Clin Inform*. 2019;10(1):158-67.
10. Westbrook JI, Reckmann M, Li L, Runciman WB, Burke R, Lo C, et al. Effects of two commercial electronic prescribing systems on prescribing error rates in hospital in-patients: a before and after study. *PLoS Med*. 2012;9(1):e1001164.
11. Denise B. Evaluating classification schema and classification decisions. *Bull Am Soc Inf Sci*. 2013;39(2):13-21.
12. Nadeau D, Sekine S. A survey of named entity recognition and classification. *Lingvisticae Investigationes*. 2007;30(1):3-26.
13. Uzuner Ö, South BR, Shen S, DuVall SL. 2010 i2b2/VA challenge on concepts, assertions, and relations in clinical text. *J Am Med Inform Assoc*. 2011;18(5):552-6.
14. Carson-Stevens A, Hibbert P, Williams H, Evans HP, Cooper A, Rees P, et al. Health services and delivery research. Characterising the nature of primary care patient safety incident reports in the England and Wales National Reporting and Learning System: a mixed-methods agenda-setting study for general practice. Southampton (UK)2016.
15. Shiima Y, Wong Z. Classification Scheme for Incident Reports of Medication Errors. *Studies in Health Technology and Informatics*. 2019;265:113 - 8.
16. Minimal information model for patient safety incident reporting and learning systems: user guide: WHO; 2016 [Available from: <http://www.who.int/iris/handle/10665/255642>.
17. Goedecke T, Ord K, Newbould V, Brosch S, Arlett P. Medication Errors: New EU Good Practice Guide on Risk Minimisation and Error Prevention. *Drug safety*. 2016;39(6):491-500.
18. Working paper Preliminary version of minimal information model for patient safety: WHO; 2014 [Available from: https://www.who.int/patientsafety/implementation/IMPS_working-paper.pdf?ua=1.
19. Anonymous. The Conceptual Framework for the International Classification for Patient Safety (ICPS). Geneva: World Health Organization; 2009. Contract No.: 14 Feb.
20. Good practice guide on recording, coding, reporting and assessment of medication errors: EUROPEAN MEDICINES AGENCY; 2015 [Available from: https://www.ema.europa.eu/documents/regulatory-procedural-guideline/good-practice-guide-recording-coding-reporting-assessment-medication-errors_en.pdf.
21. Guidelines for publication of medical accidents at National University Hospitals: National University Hospital Medical Safety Management Council, Japan; 2012 [Available from: http://www.univ-hosp.net/guide_cat_04_15.pdf.
22. NCC MERP Taxonomy of Medication Errors 1998 [Available from: <https://www.nccmerp.org/sites/default/files/taxonomy2001-07-31.pdf>.
23. AHRQ Common Formats for Event Reporting-Hospital Version 2.0a IMPLEMENTATION GUIDE 2018 [Available from: https://www.psoppc.org/psoppc_web/publicpages/commonFormatsHV2.0.

24. Good practice guide on risk minimisation and prevention of medication errors: EUROPEAN MEDICINES AGENCY; 2015 [Available from: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guide-risk-minimisation-prevention-medication-errors_en.pdf].
25. Morimoto T, Gandhi TK, Seger AC, Hsieh TC, Bates DW. Adverse drug events and medication errors: detection and classification methods. *Quality & safety in health care*. 2004;13(4):306-14.
26. Annie Yang MG. Wrong-Patient Medication Errors: An Analysis of Event Reports in Pennsylvania and Strategies for Prevention. *Pennsylvania Patient Safety Advisory*. 2013;10(2):41-9.
27. Buchan K. Annotation Guidelines for the Adverse Drug Event (ADE) and Medication Extraction Challenge 2018 [Available from: https://n2c2.dbmi.hms.harvard.edu/files/ADE_annotation_Guideline_final.pdf].
28. AHRQ Common Formats for Event Reporting-Hospital 2.0a Medication or Other Substance 2018 [Available from: https://www.psoppc.org/psoppc_web/publicpages/commonFormatsHV2.0].
29. Classification for Drug related problems 2016 [Available from: https://www.pcne.org/upload/files/152_PCNE_classification_V7-0.pdf].
30. Claeys C, Neve J, Tulkens PM, Spinewine A. Content validity and inter-rater reliability of an instrument to characterize unintentional medication discrepancies. *Drugs Aging*. 2012;29(7):577-91.
31. Department of Health, Government of South Australia. 2011. [Available from: <https://www.sahealth.sa.gov.au/wps/wcm/connect/dd45b8804390a6f58bc3dfbc736a4e18/Spell+it+out+Guidelines+2011.pdf>]