

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

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Table of Contents

1	INTRODUCTION.....	4
2	THE ANNOTATION TASK.....	6
2.1	GENERAL.....	6
2.2	RATIONALE.....	6
2.3	THE ANNOTATION TOOL 'BRAT'	6
2.4	A NOTE ON WHAT KIND OF LANGUAGE IS CONSIDERED.....	7
2.5	MARKING THE RELEVANT SPAN OF TEXT.....	7
3	NAMED ENTITIES.....	8
3.1	DRUG.....	8
3.2	FORM.....	10
3.2.1	<i>Form – form</i>	10
3.2.2	<i>Form – mode</i>	10
3.3	STRENGTH.....	10
3.3.1	<i>Strength – amount</i>	10
3.3.2	<i>Strength – rate</i>	11
3.3.3	<i>Strength – concentration</i>	11
3.4	DURATION.....	12
3.5	TIMING.....	13
3.6	FREQUENCY.....	13
3.7	DATE.....	14
3.8	DOSAGE.....	14
3.9	ROUTE.....	15
3.10	WRONG PATIENT.....	16
4	ATTRIBUTES	16
4.1	GENERIC ATTRIBUTES.....	17
4.1.1	<i>Status</i>	17
4.1.2	<i>Relations</i>	18
4.1.3	<i>Error occurred</i>	20
4.2	ENTITY-SPECIFIC ATTRIBUTES.....	20
4.2.1	<i>Drug-related attributes</i>	20
4.2.2	<i>Attributes for strength – amount</i>	20
4.2.3	<i>Attributes for duration</i>	21
4.2.4	<i>Attributes for strength, timing, duration, frequency and dosage</i>	22
4.3	DRUG-SPECIFIC RELATIONSHIPS.....	23
4.3.1	<i>Drug–drug interactions</i>	23
4.3.2	<i>Drug name contains other NEs</i>	23
4.4	CHAPTER SUMMARY.....	24
5	INCIDENT TYPES	25
5.1	WRONG DRUG	26
5.2	DRUG OMISSION	27
5.3	EXTRA DRUG	28
5.4	DRUG—DRUG INTERACTION	29
5.5	WRONG FORM	29
5.6	WRONG MODE.....	30
5.7	WRONG AMOUNT.....	30
5.8	WRONG RATE	31
5.9	WRONG CONCENTRATION	33
5.10	WRONG TIMING	34
5.11	WRONG DURATION.....	35

5.12	WRONG FREQUENCY	36
5.13	WRONG DOSAGE	37
5.14	WRONG ROUTE	38
5.15	WRONG PATIENT	38
6	CONCLUSION.....	39
7	REFERENCES.....	40

List of Tables

TABLE 1.	EXAMPLES OF RELEVANT SPANS OF TEXT.....	7
TABLE 2.	VARIOUS DESCRIPTIONS AND ABBREVIATIONS FOR FREQUENCIES [31].	14
TABLE 3.	THE USE OF ATTRIBUTES ACROSS NES.	24
TABLE 4.	INCIDENT TYPES RESULTING FROM COMBINATIONS OF NES.....	25

List of Figures

FIGURE 1.	LITERATURE REVIEW ON ANNOTATION.....	4
FIGURE 2.	A SCREENSHOT OF BRAT.	6
FIGURE 3.	VARIOUS WAYS TO INDICATE AN ORDER FOR 14 DAYS [31].	12
FIGURE 4.	OVERVIEW OF ATTRIBUTES.	16
FIGURE 5.	CONCEPTUAL FRAMEWORK FOR THE CLASSIFICATION THEME.....	25

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 **Error! Reference source not found.**). 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].

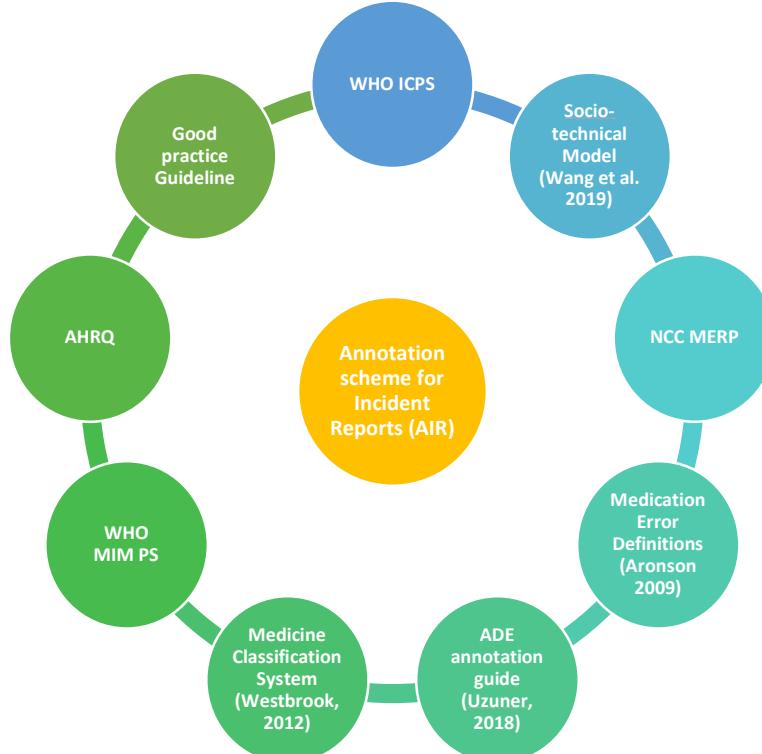


Figure 1. Literature review on annotation.

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 Doccano. 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 **Error! Reference source not found..**

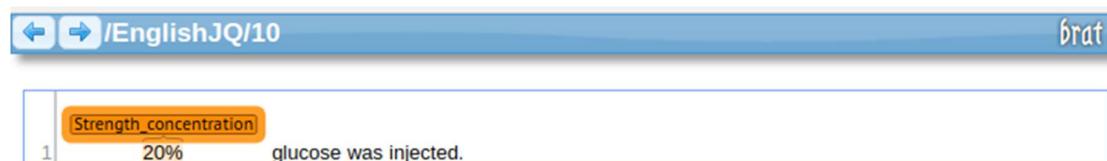


Figure 2. A screenshot of Brat.

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, with examples using actual 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:

The screenshot shows a software interface with a blue header bar containing icons for back, forward, and search, followed by the text '/EnglishJQ/1'. On the right side of the header is a small logo with the letters 'brat'. Below the header is a list item. The first word 'Cefmetazon' has a red rectangular box with the word 'Drug' written in it above it. The second word 'cefamezina' also has a similar red box with 'Drug' above it. The list item itself reads: '1 Cefmetazon was dispensed instead of cefamezina.'

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:

The screenshot shows a software interface with a blue header bar containing icons for back, forward, and search, followed by the text '/EnglishJQ/2'. On the right side of the header is a small logo with the letters 'brat'. Below the header is a list item. The first word 'Normal' has a red rectangular box with the word 'Drug' written in it above it. The second word 'saline' has a yellow rectangular box with the word 'Drug' written in it above it. The list item itself reads: '1 Normal saline was stopped when red blood cells (RBC) were 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:

The screenshot shows a software interface with a blue header bar containing icons for back, forward, and search, followed by the text '/EnglishJQ/3'. On the right side of the header is a small logo with the letters 'brat'. Below the header is a list item. The word 'Antibiotics' has a yellow rectangular box with the word 'Drug' written in it above it. The list item itself reads: '1 Antibiotics were missed during the night shift.'

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. While this is acceptable, we need to indicate the properties of the drug by applying attributes. For details on attributes, please refer to Chapter 4.2.1. In Example 3, 'Antibiotics' is annotated, which describes the class of the drug; the specific drug name is absent in the report.

Example 4:

1 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:

1 The discharge prescription was not delivered to the patient.

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

Example 6:

1 The Durotect Patch was not changed.

Patches are also annotated as drugs.

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

Some nonspecific terms used to describe drugs
Oral, internal, injectable, topical, intravenous, regular, discharge prescription, inhalant, topical, nasal, pre-medication, eye drops, nasal drops, etc.
Some terms used to describe classes of drug
Antibiotics, antipyretics, analgesics and anti-inflammatory drugs, psychiatric and neurological drugs, allergy drugs, respiratory drugs, anti-diabetic drugs, electrolytes, infusion preparations, etc.

When the drug name is uncertain, refer to a list of English drug names: <https://www.rxlist.com/>. 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. However, the attribute ‘uncertain’ would be applied to the drug (for details, please refer to Chapter 4.2.1).

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 annotations (see Chapter 0)
Warfarin	
Warfarin	Warfarin [NE: drug]
Warfarin tablets	Warfarin [NE: drug] tablets [NE: form]
Warfarin 5mg tablets	Warfarin [NE: drug] 5mg [NE: strength-amount] tablets [NE: form]
Precedex	Precedex [NE: drug]
Precedex intravenous solution	Precedex [NE: drug] intravenous solution [NE: form]
Precedex intravenous solution 200 µg	Precedex [NE: drug] intravenous solution [NE: form] 200 µg [NE: strength – amount]
Precedex intravenous solution 200 µg/2ml	Precedex [NE: drug] intravenous solution [NE: form] 200 µg/2ml [NE: strength – concentration]
Precedex intravenous solution 200 µg [Maruishi] [200µg/2ml]	Precedex [NE: drug] intravenous solution [NE: form] 200 µg [NE: strength] [Maruishi] [200µg/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:

/EnglishJQ/8

1 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.

Example 7 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. All of these cases would be registered as the NE strength – amount, but such properties are registered as entity-specific attributes (see Chapter 4.2.2)

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:

/EnglishJQ/9

1 Sodem3A 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:

/EnglishJQ/10

1 Strength concentration 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:

The screenshot shows a blue header bar with navigation icons and the text '/EnglishJQ/12'. Below is a white text area containing the following sentence:

1 | 14 days' worth of inhalants were finished within 5 days.

Annotations are shown as colored boxes: 'Duration' in green over '14', 'Duration' in green over 'days', and 'Duration' in yellow over '5'.

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.

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.

for 14 days	$\times 14$ D
14 days' worth	(14)
14 days' dose	14
/14 days	14N
/14D	14/D
/14DD	$\times (14)$

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

Example 13:

The screenshot shows a blue header bar with navigation icons and the text '/EnglishJQ/13'. Below is a white text area containing the following sentence:

1 | A doctor prescribed antibiotics for 1 week

Annotations are shown as colored boxes: 'Duration' in green over '1' and 'Duration' in green over '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:

The screenshot shows a blue header bar with navigation icons and the text '/EnglishJQ/14'. Below is a white text area containing the following sentence:

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

Annotations are shown as colored boxes: 'Duration' in green over '1', 'Duration' in green over 'hour', and 'Duration' in green over '30'.

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 screenshot shows a blue header bar with navigation icons and the text '/EnglishJQ/15'. Below is a white text area with a blue border. Inside, a sentence is displayed: '1 The nurse forgot to give oxycodone to a patient at 8 am. After discovery, the nurse administered oxycodone at 11 am.' A green box labeled 'Timing' is placed above the word '8 am'. An orange box labeled 'Timing' is placed above the word '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:

The screenshot shows a blue header bar with navigation icons and the text '/EnglishJQ/16'. Below is a white text area with a blue border. Inside, a sentence is displayed: '1 Prostalgin at noon was missed.' An orange box labeled 'Timing' is placed above the word 'noon'.

In Example 16, a noun is used.

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:

The screenshot shows a blue header bar with navigation icons and the text '/EnglishJQ/17'. Below is a white text area with a blue border. Inside, a sentence is displayed: '1 A doctor ordered heparin calcium 3 times/day for the prevention of deep thrombosis after myoma operation. Nurse administered it 1 time/day.' A blue box labeled 'Frequency' is placed above the word '3 times/day'. An orange box labeled 'Frequency' is placed above the word '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.

Guidelines from the Government of South Australia [31] demonstrate the diversity of abbreviations used for common frequencies.

Table 2. Various descriptions and abbreviations for frequencies [31].

Intended Meaning	Recommended Abbreviation	Not Recommended Abbreviation
Twice a day	bd	bid
Three times a day	tds	
Four times a day	qid	
Every four hours	4 hrly, 4 hourly, every 4 hrs	
As required	prn	
Bedtime	bedtime	bed
Mornings	Mornings	M
Once a week	weekly	OW
Every day	daily	QD, qd
Every hour	Hourly	QH, qh
Every night at 6pm	6pm daily, every night at 18:00	Q6PM, etc.

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:

1 A doctor ordered 3 * 100 mg aspirin tablets 2 times/day, but the nurse gave 1 * 100 mg aspirin tablet.

In Example 18, dosages are described with a number and are annotated accordingly.

Example 19:

1 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:

The screenshot shows a sentence from EnglishJQ/27: "1 Four days of Maglax tablets 250 mg * 3 and Rebamipide tablets * 3 were dispensed, but Loxonin was given instead of Maglax." Various tokens are highlighted with colored boxes: "Duration" (green) over "Four days", "Drug" (red) over "Maglax", "Strength_amount" (yellow) over "250 mg", "Dosage" (blue) over "* 3", "Drug" (red) over "Rebamipide", and "Dosage" (blue) over "* 3". Below the sentence, it says "Loxonin was given instead of Maglax."

In Example 20, '3' is tagged as the dosage and 'four days' is 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:

The screenshot shows a sentence from EnglishJQ/20: "1 Incremin syrup 5 ml was prepared for oral administration in a syringe but was administered by intravenous infusion." The word "oral" is annotated with a green "Route" box, and "intravenous" is annotated with an orange "Route" box.

In Example 21, oral and intravenous are the way the drug is administrated to the patient, i.e., route.

Example 22:

The screenshot shows a sentence from EnglishJQ/21: "1 Doctor ordered oral furosemide to be stopped but the nurse mistakenly stopped intravenous furosemide." The word "oral" is annotated with a green "Route" box, and "intravenous" is annotated with an orange "Route" box.

In Example 22, 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

3.10 WRONG PATIENT

This entity type involves two patients: one who received the dose by mistake and one who suffered from an omission error. This NE is used only when two different hospital subjects are involved. If the incident does not involve a mistake related to patient identity, we do not annotate any patient identities within the incident report (unlike other NEs). If the incident involves a mistake related to patient identity, we annotate all patient identities within the incident report. In most cases, identifiers of the patients involved (e.g., name, ID, etc.) are de-identified before annotation or analysis for ethical reasons. However, the reports may still be able to indicate differences in identity through terms such as patient A and patient B, patient 001 and patient 002, etc.

The screenshot shows a blue header bar with navigation icons and the text '/EnglishJQ/23'. Below is a white text area containing a sentence: '1 The proton pump inhibitor (PPI) was mistakenly administered to patient A instead of patient B.' Two spans are highlighted with orange boxes: 'patient A' and 'patient B', both labeled 'Wrong_patient'.

In **Error! Reference source not found.**, patient A mistakenly received PPI instead of patient B; both patient A and patient B should be tagged.

When we register the attributes for ‘wrong patient’, note that ‘wrong patient’ also indicates a missed dose to the ‘intended’ patient and an extra dose to the ‘actual’ patient. We use ‘status: NE’ to describe the attributes of other NEs, e.g., drug, time, strength, etc.

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 different types of attribute are introduced: generic attributes (that apply to all NEs), entity-specific attributes (that only apply to specific NEs), and entity-specific relations. **Error! Reference source not found.** 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	Sub-index	Drug Specific (default) Unspecified Classes mentioned Uncertain	Status Both (default) Intended Actual Neither	Strength_amount per unit (default) per consumption per day per whole course	Duration Drug period (default) Delivery length
1 (default) 2 3 10 00 (general) 01 (patient_back) 02 (amelioration)	0 (general) 1 (default) 10	Error occurred No error (default) Error Uncertain			NA (default) Positive (more than expected) Negative (less than expected) 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 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)
- Intended
- Actual

Example 24:

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.

4.1.2 RELATIONS

When assigning relations, we need to consider whether the tagged variables belong to any particular event. If tags belong to the same event, they will share the same relation number.

The relation number is either 1 (default) or 2. One number represents the primary event, which might involve multiple NEs. The relation number itself is not important and is generally assigned in order of appearance. If a medical incident is described by a single event, only the relation number '1' is used. If an incident is described by multiple events, all events outside of the primary event share a relation number. When two events are independent of each other, then they should be labelled with distinct relation numbers.

Example 26:

The screenshot shows the brat NER interface with the URL /EnglishJQ/20. A single event is highlighted with a blue border. Inside the event, there are two annotations: 'oral' with a green 'Route' label and 'intravenous' with an orange 'Route' label. Both annotations are underlined in their respective colors.

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

In Example 26, all annotations belong to one event. Therefore, we assign the same relation, 1, for all of these annotations.

Example 27:

The screenshot shows the brat NER interface with the URL /EnglishJQ/27. A single event is highlighted with a blue border. It contains several annotations with different relation numbers: 'Duration' (green), 'Drug' (red), 'Strength_amount' (yellow), 'Dosage' (blue), 'Drug' (red), and 'Dosage' (blue). The annotations are distributed across different parts of the sentence, indicating multiple events.

1 Four days of Maglax tablets 250 mg * 3 and Rebamipide tablets * 3 were dispensed, but Loxonin was given instead of Maglax.

In Example 27, the relation number '1' is applied to indicate the administration of Maglax and Loxonin, including the NEs form – form, strength – amount, dosage and duration. Relation '2' corresponds to the delivery of Rebamipide and related NEs. In this report, both relation numbers '1' and '2' apply to '3 times' and '4 days'.

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Maglax	Loxonin	Wrong drug
1	Form	tablet		-
1	Strength – amount	250 mg		-
1	Dosage	3		-
1	Frequency	* 3		Note: '* 3' indicates the frequency for both drugs, therefore relation '1' and '2' are applied.
1	Duration	Four days		Note: 'Four days' indicates the duration for both drugs, therefore relation '1' and '2' are applied.
2	Drug	Rebamipide		-
2	Form	tablets		-
2	Dosage	3		-
2	Frequency	* 3		Note: '* 3' indicates the frequency for both drugs, therefore relation '1' and '2' are applied.
2	Duration	Four days		Note: 'Four days' indicates the duration for both drugs, therefore relation '1' and '2' are applied.

Example 28:

← → /EnglishJQ/28 brat

1 The patient was taking Persantin capsules for AF. However, the patient was later told to discontinue Persantin (permanently). The patient ceased medication until 9/12, but was found to have taken from 9/13 - 9/15. The capsules were removed from their medicine box.

Relation	Named entity	Intended	Actual	Incident type
2	Drug	Persantin		Note: patient background info
2	Form	capsule		Note: patient background info
1	Drug	-	Persantin	Extra drug
1	Form	capsule		-
1	Timing	9/12		-
1	Duration	9/13 - 9/15		-

In this example, 'Persantin' and 'capsule' have been annotated two times. The relation number '2' is applied to the first occurrence because the description is about the patient's daily medication and is not related to this event. When relation '1' is applied, it is not necessary to distinguish between intended or actual – therefore the default is selected. The second occurrence of Persantin refers to an event where the drug was given to the patient without such intention and is therefore considered an extra drug case.

4.1.3 ERROR OCCURRED

'Error occurred' is an attribute for indicating whether an error occurred under a particular NE label. After tagging all NEs as 'intended and actual', 'intended' or 'actual', a comparison of these tags will allow the incident type to be determined automatically (as detailed in Chapter 5).

When it is unclear whether an error occurred, the 'Uncertain' option can be used. It is important to remember that these annotation guidelines are for content-based annotation; annotation is not done when an entity or attribute is not clearly described in an incident report.

The possible options for the error occurred attribute are as follows:

No error (default)

Error

Uncertain

4.2 ENTITY-SPECIFIC ATTRIBUTES

4.2.1 DRUG-RELATED ATTRIBUTES

Drug-related attributes allow us to register information relevant to annotations under the NE 'drug'. The drug-related attributes are as follows:

- Specific (default)
- Class mentioned
- Uncertain
- Unspecified

Example 1 in Chapter 3.1, the drugs Cefmetazon and Cefamezina were annotated. As these annotations indicate specific, identifiable drug names, we select 'Specific' (the default).

If the drug is not specified but the class of drug is mentioned (e.g., Example 3 in Chapter 3.1), the entity-specific attribute for the drug NE is 'Class mentioned'.

In Example 4 of Chapter 3.1, the drug's attribute is labelled as 'unspecified' because neither a specific name nor a drug class are indicated. For a list of terms commonly used when drugs are unspecified, see Chapter 3.1.

The attribute 'uncertain' is selected when the name of the drug is uncertain due to misspellings, etc.

4.2.2 ATTRIBUTES FOR STRENGTH – AMOUNT

As addressed in Chapter 3.3.1, strength – amount may be presented as an amount per unit, amount per consumption (i.e., a one-time dosage), amount per day (or other unit of frequency, e.g., week), or total amount for the whole medication course. We register such properties as specific attributes. The possible options for attributes under strength – amount are as follows:

- | | |
|----------------------|----------------------------|
| • Per unit (default) | • Per day or other unit |
| • Per consumption | • Per course of medication |

Example 31:

The screenshot shows the brat NLP tool interface with a blue header bar containing navigation icons and the text '/EnglishJQ/27'. Below the header is a light blue toolbar with a magnifying glass icon. The main area contains a text document with annotations. The text reads: '1 Four days of Maglax tablets 250 mg * 3 and Rebamipide tablets * 3 were dispensed, but Loxonin was given instead of Maglax.' Annotations are shown as colored boxes: 'Duration' (green) covers 'Four days'; 'Drug' (red) covers 'Maglax', 'Rebamipide', and 'Loxonin'; 'Strength_amount' (yellow) covers '250 mg'; 'Dosage' (blue) covers the multipliers '* 3' and the word 'and'; another 'Drug' (red) box covers 'Rebamipide tablets'; and another 'Dosage' (blue) box covers the second multiplier '3'. A 'brat' watermark is visible in the bottom right corner of the main window.

Example 31 demonstrates how the amount of drug can be described by its basic unit, e.g., a 250 mg tablet of Maglax.

Example 32:

The screenshot shows a sentence: "1 Incremin syrup 5 ml was prepared for oral administration in a syringe but was administered by intravenous infusion." Two annotations are present: "oral" is highlighted with a green rounded rectangle and labeled "Route", and "intravenous" is highlighted with an orange rounded rectangle and labeled "Route".

If we were to annotate this example, a total volume of 5 ml would be annotated as 'strength – amount' and the attribute would be registered as 'per consumption'.

In case the attributes cannot accurately capture the report's narrative, 'uncertain' is used.

4.2.3 ATTRIBUTES FOR DURATION

Remember that the NE 'duration' aims to specify the period for which a drug is administered to the patient. This attribute describes the different ways duration might be presented. It is usually presented in days, weeks or months. However, clock time is sometimes used, such as 30 mins, 1 hour, etc. to indicate the period of time needed to deliver the drug (for a single consumption). While these two definitions are different in nature, both fit the concept of duration. The possible attributes for duration are as follows:

- Period over which a drug is routinely taken (default)
- Time needed to deliver a single consumption

Example 33:

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

Example 34:

Inhaled medical products for 14 days were finished within 5 days.

In Example 33 and Example 34, as the unit of duration is day, tagging only the number or both the number and unit are acceptable. Most incident reports use day as the unit.

Example 35:

A doctor prescribed antibiotics for 1 week.

Sometimes, week, month or other units of time are used; in such cases both the number and unit are annotated, as seen in Example 35.

Example 36:

The screenshot shows a clinical note in the brat NLP interface. The text is as follows:

1 KCL injection 20meq 20ml + saline 80 ml, total of 100 ml over one hour to be delivered

Frequency
3 times.

Entities are highlighted with colored boxes:

- Drug**: KCL, saline
- Route**: injection
- Strength amount**: 20meq, 20ml, 80 ml, total of 100 ml
- Duration**: over one hour
- Frequency**: 3 times.

Here, the duration is registered as 1 hour. A total of 100 ml of KCL + saline solution (one consumption) was delivered for 1 hour, so '100 ml' is the strength – amount per consumption, and '1 hour' is registered as the duration, with 'Time needed to deliver a single consumption' listed as the duration-specific attribute.

4.2.4 ATTRIBUTES FOR STRENGTH, TIMING, DURATION, FREQUENCY AND DOSAGE

The NEs of strength, timing, duration, frequency, dosage and route can all be presented as numerical values. When an error has occurred but 'Intended', 'Actual' or 'Intended and actual' are not indicated, the attributes 'positive' (i.e., more than expected) and 'negative' (i.e., less than expected) are applied. 'NA' is otherwise used.

There is also an 'uncertain' attribute for strength, timing, duration, frequency and dosage. Unlike 'positive' and 'negative', which are only applied for numerical values or if an error has occurred, this option is applicable to any situation where the aforementioned NEs are presented in an unclear manner.

The possible attributes for the strength, timing, duration, frequency and dosage NEs are as follows:

- NA (default)
- Positive
- Negative
- Uncertain

Interpretations of 'more than expected' and 'less than expected' for each NE are listed as follows:

- Strength – amount (overdose and underdose)
- Strength – rate (too fast and too slow)
- Strength – concentration (too high and too low)
- Timing (too early and too late)
- Duration (too long and too short)
- Frequency (too many and too few)
- Dosage (too high and too low)

4.3 DRUG-SPECIFIC RELATIONSHIPS

There are two relationships we wish to capture for drug NEs: drug–drug interactions and when others NEs are indicated within a drug name.

4.3.1 DRUG–DRUG INTERACTIONS

This relationship only applies to when two or more drugs have been annotated (with different relation values) and are classified as ‘actual’ or ‘intended and actual’. When one drug interacts with another, the two annotated drug NEs must be paired to determine the nature of the drug–drug interaction. No directionality is implied – the interaction might be drug A to drug B or drug B to drug A.

	Drug A	Drug B	Illustrative examples
Case 1	Intended and actual	Actual	Patient has been taking drug A for a period of time and drug B is newly prescribed.
Case 2	Actual	Actual	Drug A and B are prescribed at the same time and neither has priority. Using them together is an error.

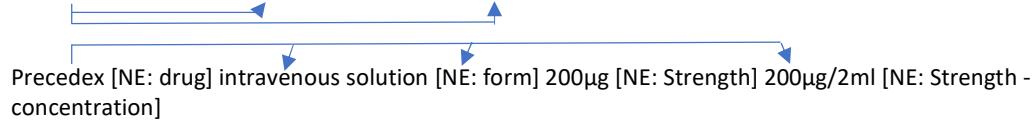
4.3.2 DRUG NAME CONTAINS OTHER NAMED ENTITIES

This relationship is used when information pertaining to other NEs is part of the drug name (as shown in Chapter 3.1). Commercial drug names often contain information about form and strength. These concepts are annotated separately as their corresponding NEs.

These annotations apply to the drug indicated by the drug name, as such all of these NEs share the same relation number. The relationships between the drug and the associated NEs are indicated by the arrow. This attribute is applied regardless of whether the NEs are labelled as intended or actual.

Example 37:

Warfarin [NE: drug] 5 mg [NE: Strength-amount] tablets[NE: Form]



4.4 CHAPTER SUMMARY

Error! Reference source not found. summarises information that has been presented on generic attributes, entity-specific attributes and drug-specific relationships in this chapter.

Table 3. The use of attributes across NEs.

Name Entities	Generic attributes				Entity-specific attributes				Drug-specific relationships	
	Index	Sub-index	Status	Error occurred	Drug-specific attributes	Attributes for strength-amount	Attributes for duration	Attributes for strength, timing, duration, frequency and dosage	Drug-drug interaction	Drug name contains other NEs
Wrong patient	○	○	○	○	×	×	×	×	×	×
Drug	○	○	○	○	○	×	×	×	○	○
Form	○	○	○	○	×	×	×	×	×	○
Strength	○	○	○	○	×	○	×	○	×	○
Timing	○	○	○	○	×	×	×	○	×	×
Duration	○	○	○	○	×	×	○	○	×	×
Frequency	○	○	○	○	×	×	×	○	×	×
Dosage	○	○	○	○	×	×	×	○	×	×
Route	○	○	○	○	×	×	×	×	×	×

5 INCIDENT TYPES

Error! Reference source not found. summarises the entire conceptual framework of the annotation scheme, including structured items.

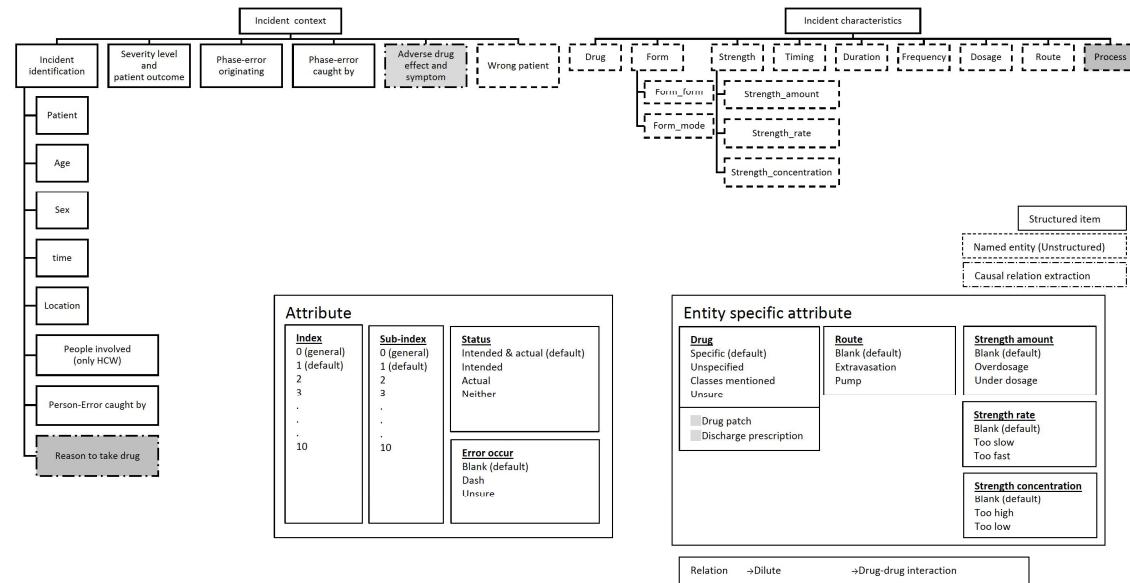


Figure 5. Conceptual framework for the classification theme.

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

Table 4. Incident types resulting from combinations of NEs.

Named entity	Intended	Actual	Incident type
Drug	A	B	Wrong drug
Drug	A	-	Omission
Drug	-	A	Extra drug
Drug (with different indices)	NA	A --> B	Drug–drug interaction
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
Wrong patient	A	B	Wrong patient

*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 38:

The screenshot shows the brat interface with the URL /EnglishJQ/35. An annotation is highlighted with four red boxes labeled 'Drug' above the entities 'Noborin R', 'Humulin R', 'Noborin', and 'Humulin'. The annotation text reads: '1 Prepared two doses of Noborin R, but thought it was Humulin R. Realised that the drug was Noborin after administration.' Below this is a table:

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 39:

The screenshot shows the brat interface with the URL /EnglishJQ/36. An annotation is highlighted with three red boxes labeled 'Drug' above the entities 'Neosynergine' and 'Esrax'. Another red box labeled 'Drug' is above the entity 'Esrax'. The annotation text reads: '1 During anesthesia preparation, Neosynergine was connected to the syringe pump when Esrax should have been connected. When the senior was about to administer Esrax, he noticed and corrected the mistake.' Below this is a table:

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

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

Example 40:

The screenshot shows the brat interface with the URL /EnglishJQ/37. An annotation is highlighted with two red boxes labeled 'Drug' above the entities 'Lamotrigine' and 'Lamisil'. Another red box labeled 'Form form' is above the entity 'tablets'. The annotation text reads: '1 Lamotrigine tablets were prescribed but Lamisil tablets were given.' Below this is a table:

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, which is a higher level in the incident hierarchy.

5.2 DRUG OMISSION

Omission is the failure to administer an ordered dose to a patient before the next scheduled dose. This excludes patients who refuse to take medication or a decision not to administer [22].

Example 41:

Humulin R was being administered regularly to a patient by subcutaneous injection. It was decided to begin administering insulin, but the night shift forgot to administer.

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Humulin		
1	Mode	R		
1	Route	subcutaneous injection		
2	Drug	Insulin		Omission

In this example, the patient's daily medication and the incident are distinct, thus two relation numbers are used.

Example 42:

1. Bisono tape and Nitroderm tape are applied to the patient daily. However, night staff found that Bisono tape and Nitroderm tape had not been applied.

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Bisono tape		Omission
2	Drug	Nitroderm tape		Omission

In this case, the issuance of two patch drugs is missed. This example is simple and can be identified from the NEs, but some cases involving patches are difficult to interpret with the current NEs. For this reason, a drug-specific attribute should be used to mark patch-related cases: 'drug patch'.

Omission is sometimes related to a case of wrong timing (see the example in Chapter 5.12). When the report used multiple NEs to indicate the situation of an omission case, e.g., with timing, duration, drug name, we indicate all as 'intended' and 'error occurred'.

5.3 EXTRA DRUG

'Extra drug' can be applied to two different situations. The first is when the drug is not called for. Examples include a drug not indicated in the report being prescribed or administered to the patient, a drug being continued despite a clinically significant adverse drug reaction, a drug no longer called for being reordered or a drug that should be discontinued being continued instead.

The second situation to which 'wrong drug' applies is the issue of duplication. For example, two orders are mistakenly prescribed for one medication and both orders are active, two orders for the same medication are active on two different charts or the same drug is prescribed or administered twice, once as a single agent and again as a combination product [10].

Example 43:

1 The patient was taking Persantin capsules for AF. However, the patient was later told to discontinue Persantin (permanently). The patient ceased medication until 9/12, but was found to have taken from 9/13 - 9/15. The capsules were removed from their medicine box.

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Persantin		
1	Form	capsules		
2	Drug	-	Persantin	Extra drug
2	Form	capsule	capsule	

In this example, the first sentence is about the patient's daily medication and is thus distinct from the event.

Example 44:

1 The patient takes one tablet of codeine in the morning, at noon, in the evening and before sleeping. Due to miscommunication, a codeine phosphate tablet was taken from tomorrow's medicine case and delivered to the patient one time too many.

Relation	Named entity	Intended	Actual	Incident type
1	Drug	codeine		
1	Timing	morning		
1	Timing	noon		
1	Timing	evening		
1	Timing	before sleeping		
1	Dosage	one tablet		
2	Drug		codeine phosphate	Extra drug
2	Form	tablet	tablet	

In this example, the same drug is administered twice as a single agent. The first sentence is about the patient's daily medication. This incident is not considered 'wrong timing' because the drug intended for tomorrow, noon is given at noon.

Example 45:

The screenshot shows a clinical note in the brat interface. The note reads: "1 Farydak is taken by the patient after breakfast on Mondays, Wednesday and Fridays. The doctor ordered Farydak to be stopped, but the nurse missed the order. Farydak was given after breakfast before the nurse discovered the order." Annotations are present: 'Drug' is highlighted in red boxes above the first and last 'Farydak' mentions; 'Timing' is highlighted in green boxes above 'Mondays', 'Wednesday', 'Fridays', and 'Timing' (referring to the order being stopped); and another 'Drug' is highlighted in a red box above the second 'Farydak' mention.

Relation	Named entity	Intended	Actual	Incident type
1	Drug	Farydak		
1	Timing	Mondays		
1	Timing	Wednesdays		
1	Timing	Fridays		
1	Timing	after breakfast		
2	Drug		Farydak	Extra drug

In this example, 'timing' has two distinct meanings: timing as it relates to the week and timing as it relates to the day. As neither of them are related to the incident they are annotated with a different relation number. If these were related to the incident, then subindices would be used. An extra drug, or an omitted drug, is sometimes related to a case of wrong timing. See, for example, Chapter 5.12.

5.4 DRUG—DRUG INTERACTION

A drug–drug interaction is a common type of incident and can be labelled as 'drug–drug interaction' (refer to Chapter 0)

5.5 WRONG FORM

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

Example 46:

Ibuprofen tablets were prescribed, but ibuprofen topical gel was mistakenly administered.

Relation	Named entity	Intended	Actual	Incident type
1	Drug	ibuprofen	ibuprofen	
1	Form – form	tablets	topical gel	Wrong mode

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

5.6 WRONG MODE

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

Example 47:

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

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.

5.7 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 48:

1 The patient had been taking OxyContin 20 mg (one tablet each in the morning and after dinner) since before hospitalization. During her hospitalization, she ran out of the medicine. We prescribed her a new one, but didn't check the 'mg' and gave her only one 5 mg OxyContin tablet for today's morning dose.

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 49:

/EnglishJQ/34

brat

	Timing	Drug	Strength_rate
1	Yesterday at 4:30 p.m. started sedation with Dolmicam	0.5 ml/H	The fast-forward button was pressed too long
	Strength_amount	Route	
	and 0.7 ml	IV	was administered.

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.

5.8 WRONG RATE

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

Example 50:

/EnglishJQ/45

brat

	Strength_amount	Drug	Duration	Strength_amount	Drug
1	200 mL	Soldem	2 hours,	50 mL	food
	Strength_amount	Drug	Duration		
	0.5 v	Solu-Medrol	30 minutes		The nurse thought she had set the pump for each of them at
	Strength_rate	Strength_amount	Drug	Strength_rate	
	100 mL/h,	200 mL	Soldem	200 mL/h.	

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

In this example, the drugs represented by relation '2' interact with each other, which is why they share a relation number. 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'. '100ml/H' is annotated twice because it is a rate for the drug of relation 1 and relation 2.

Example 51:

		Route	Strength concentration	Drug	Strength rate
1	Upon visiting the patient's room, noticed that the patient's injection of		20%	Mannitol	400 mL/hr
		Drug	Strength rate	Drug	
	was complete. An order for Cisplatin was at 250 mL/hr was received. However, the Cisplatin was mistakenly				
		Strength rate			
	administered at 400 mL/hr. After discovery the medication was stopped immediately, before being resumed at				
		Strength rate			
	250 mL/hr later.				

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

In this example, action taken after the incident is also described. This information is annotated with the relation number '2' because it is not part of the main incident.

Example 52:

KCL injection 20meq 20ml + saline 80ml total of 100 ml over one hour to be delivered 3 times. However, the medicine (50 ml total) was administered too quickly before being stopped.

Relation	Named entity	Intended	Actual	Incident type
1	Drug	KCL	KCL	
1	Form	Injection	injection	
1	Amount	20mEq/20ml	20mEq/20ml	
2	Drug	saline	saline	
2	Amount	80ml	80ml	
1	Amount	100ml	100ml	
1	Rate	1 hour	Too fast	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 rate is not explicitly mentioned, use of the 'too fast' attribute indicates that the rate is faster than intended. Similarly, while amount was not clearly mentioned, use of the 'overdosage' attribute indicates that an amount larger than intended was administered. Note that while the amount 50 ml is less than what was planned, if the amount administered over a period of time is considered, then an overdosage should be labelled.

5.9 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 53:

Received an order to dissolve one potassium aspartate 10mEq 10mL injection kit into one 100mL bottle of 5% glucose injection and administer over one hour. The label states concentration should not exceed 40mEq/L and intravenous drip should not exceed a rate of 8 mL/min. After reading the label, the nurse checked and administration was halted after the mistake was found.

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	
2	Drug	glucose	glucose	
2	Concentration	5%	5%	
2	Strength-amount	100ml	100ml	
2	Dosage	one kit	one kit	
1	Rate	8ml/min	20mEq/hr	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 rate is also not explicitly mentioned, but this time, an indication that the rate is too high or too low can also not be found. In this case, we use the label ‘unsure’ under the attribute ‘error occurred’. While there is no ‘actual’ concentration mentioned, it is possible to deduce from the amount that the concentration is higher than recommended.

5.10 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 54:

Oxycontin tablets were to be given at 09:00, but the nurse forgot.

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

Example 55:

1 Misread the medication's label, after **breakfast** and **lunch**, as after **breakfast**, **lunch** and **dinner**,

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	Extra drug

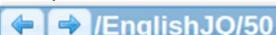
Example 56:

1 Finibax was supposed to be administered at **2:00**, **10:00** and **18:00**, but the nurse didn't deliver the medication at **2:00**.

Relation	Named entity	Intended	Actual	Incident type
1	Timing	2:00		Omission
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 57:



brat

- 1 When doing the morning rounds a call was made to deliver the **morning** **medication**. When doing post-meal checks, **Drug** **Timing**
Drug **Timing**
realised Eperisone was delivered after lunch.

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

In this example, a drug is administered at the wrong timing, but the intended timing is unclear, so the ‘unsure’ attribute could be used under the ‘error occurred’ field.

5.11 WRONG DURATION

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

Example 58:



brat

- 1 **Drug** **Drug** **Strength_amount**
When checking the **inhalant**, noticed the 11/17 prescription of Spiriva Respimat (28 inhalations) was empty. As
Dosage **Frequency** **Duration** **Duration**
two puffs should be taken once a day, there should be enough for 10 days, but it was gone in 5 days. The patient
Dosage **Frequency**
confirmed they understood, two puffs should be taken one time per day.

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.

5.12 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 59:

The screenshot shows a software interface with a blue header containing navigation icons and the text '/EnglishJQ/52'. Below the header is a patient record for 'Loxoprofen'. The record includes several colored-coded fields: 'Drug' (red), 'Frequency' (blue), 'Timing' (green), 'Timing' (green), and 'Frequency' (blue). The text in the record states: '1 Loxoprofen twice a day in the morning and evening was set to three times a day and also administered in the afternoon. The patient reported after taking the dose.'

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.

5.13 WRONG DOSAGE

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

Example 60:

/EnglishJQ/53

brat

1
 One tablet of Calonal was given for pain. The next day the prescription was checked; the patient should have been given two tablets.

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 61:

/EnglishJQ/54

brat

1
 From the 27th, two tablets Celecoxib(100), 2x1, were ordered. Later, the night shift discovered the patient took two tablets at one time, instead of just one tablet at one time. I.e., two tablets should have been split into one in the morning and one in the evening.

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.

5.14 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 61:

The screenshot shows a blue header bar with navigation icons and the text '/EnglishJQ/26'. Below it is a white text area containing a sentence with annotations. The sentence is: "1 Incremin syrup 5 ml was prepared for oral administration in a syringe but was administered by intravenous infusion." Annotations include: 'Drug' over 'Incremin', 'Strength_amount' over '5 ml', 'Route' over 'oral' and 'intravenous', and another 'Route' over 'intravenous infusion'.

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

Other errors

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. Such cases do not register as an error under any of our NEs.

5.15 WRONG PATIENT

'Wrong patient' applies to situations in which medication is prescribed or delivered to the wrong patient [10]. In these cases, all other attributes are annotated normally. Patient is typically part of incident identification and is therefore structured information; it is only annotated when a 'wrong patient' incident occurs. All patients related to the incident are annotated: 'intended' and 'wrong patient' for the patient who didn't receive the intended drug and 'actual' and 'wrong patient' for the patient who received an unintended drug.

Example 62:

The screenshot shows a blue header bar with navigation icons and the text '/EnglishJQ/56'. Below it is a white text area containing a sentence with annotations. The sentence is: "1 Patient A was ordered to receive Takepron at 11:00 p.m. Patient B was ordered to receive Takepron at 0:00 a.m. At around 11:30 p.m., Patient A's Takepron was taken to Patient B's bedside, and when the PDA was checked before administration, an 'X' was displayed, indicating a patient error." Annotations include: 'Wrong_patient' over 'Patient A', 'Drug' over 'Takepron', 'Timing' over '11:00 p.m.', 'Wrong_patient' over 'Patient B', 'Drug' over 'Takepron', 'Timing' over '0:00 a.m.', and 'Wrong_patient' over 'Patient B's'.

Index	Subindex	Named entity	Intended	Actual	Incident type
1	1	Wrong patient	Patient A	Patient B	Wrong patient
1	1	Timing	11:00 pm	11:00 pm	
1	2	Timing	00:00 am	00:00 am	
1	1	Drug	Takepron	Takepron	

The above example features both patient A and patient B equally, but patient B is tagged as the actual patient because patient B received the unintended drug. There are two moments of time mentioned here, as indicated by subindices '1' and '2', but this is not a 'wrong timing' or 'wrong drug' incident because it has already been marked as 'wrong patient'. There is nothing to suggest it is an 'omission' or 'extra drug' case.

Example 63:



Index	Subindex	Named entity	Intended	Actual	Incident type
1	1	Wrong patient	another patient	patient	Wrong patient
1	1	Drug		Alosenn	Extra drug
1	1	Strength – amount		1 g	

The above example is a ‘wrong patient’ incident, as indicated by the ‘intended’ and ‘actual’ attributes. Unlike the previous example, the drug mistakenly given to the ‘actual’ patient was not supposed to be given to the ‘intended’ patient either; this is considered ‘extra drug’. Deciding which incident type is applicable, and how many, depends on way the incident report is written. If the incident type is not apparent based on the report, we do not annotate. Timings related to Patient A or B only can be differentiated using subindices.

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. This approach could revolutionise the collection, utilisation and retrieval of information from incident reports – an exciting prospect for the future of patient safety.

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