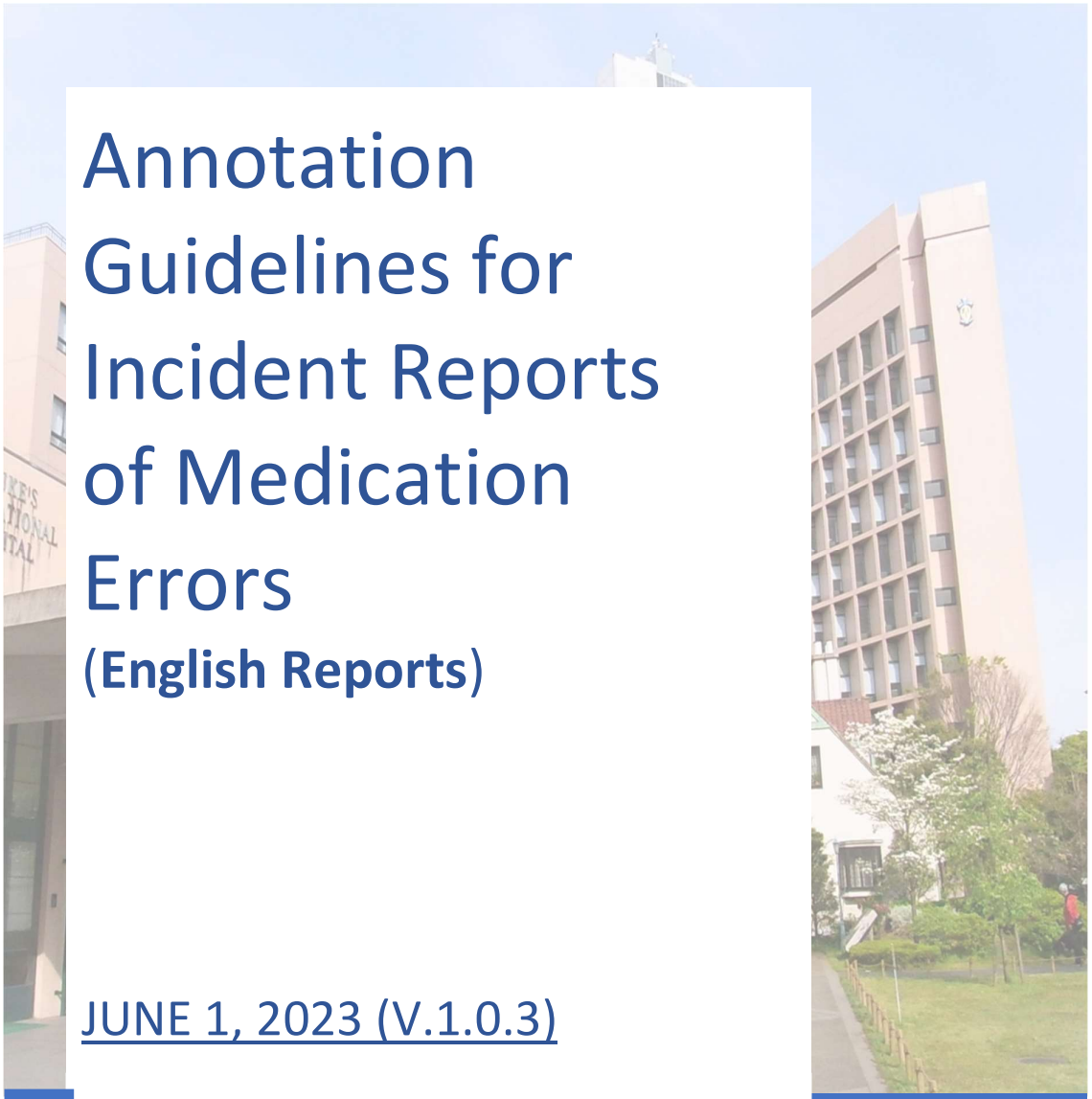

Annotation Guidelines for Incident Reports of Medication Errors

(**English Reports**)

JUNE 1, 2023 (V.1.0.3)

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Table of Contents

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].

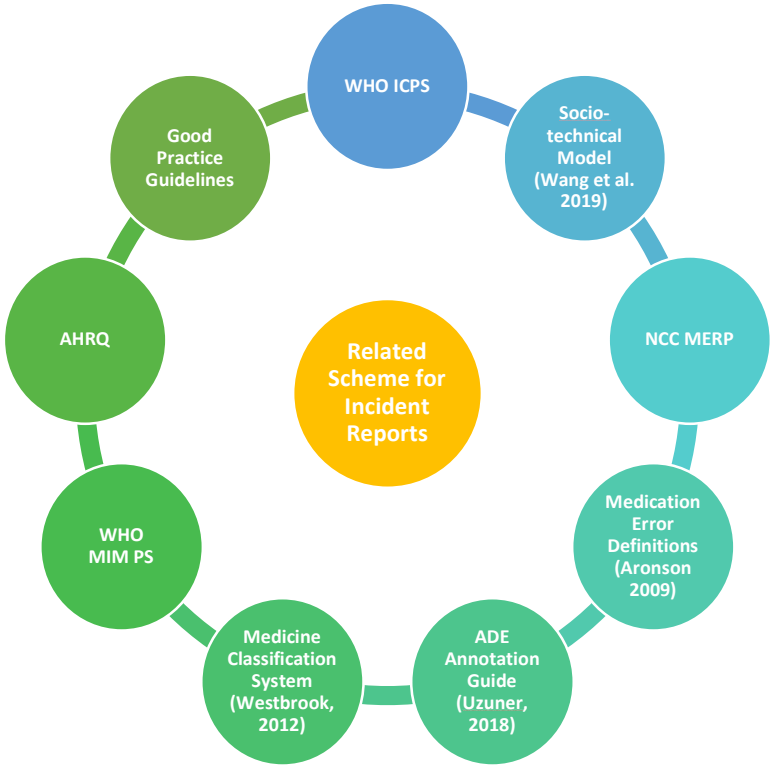


Figure 1. Literature review on annotation.

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 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 Figure 2.

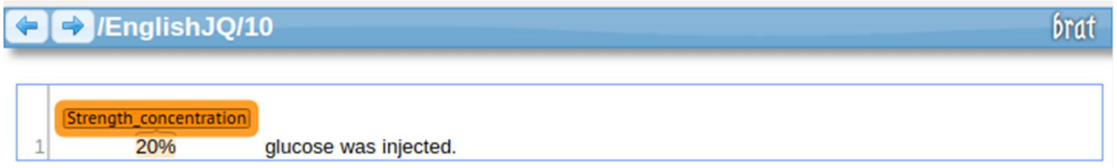


Figure 2. A screenshot of Brat.

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 diltiazem instead of diazepam *Explanation: each drug name should be tagged separately in a minimal span.*	doctor prescribed diltiazem instead of diazepam doctor prescribed diltiazem instead of diazepam
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 *Explanation: different NEs should be tagged separately even these are corresponding to the same event.*	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. *Explanation: numbers and units should be tagged together.*	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.

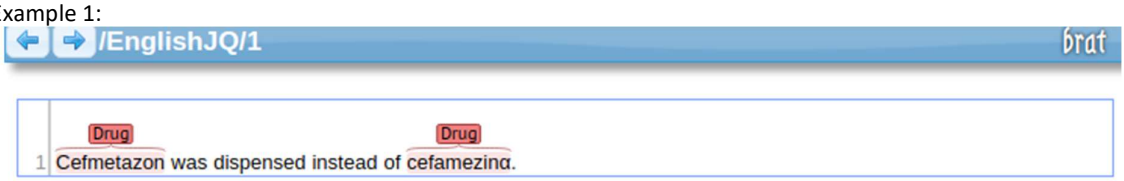
3 NAMED ENTITIES

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:

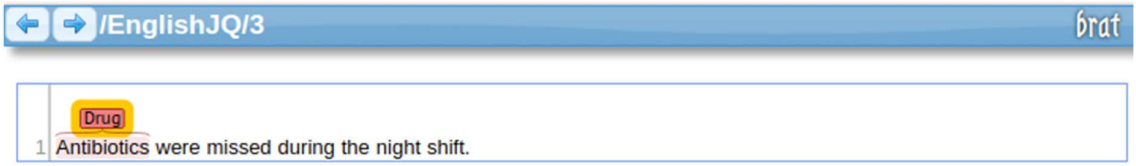


Example 1 illustrates how different drugs are typically tagged. Cefamezinα is the drug intended for delivery but the drug that was actually prescribed is Cefmetazon. In this case, both are recognised as NEs.

Example 2:

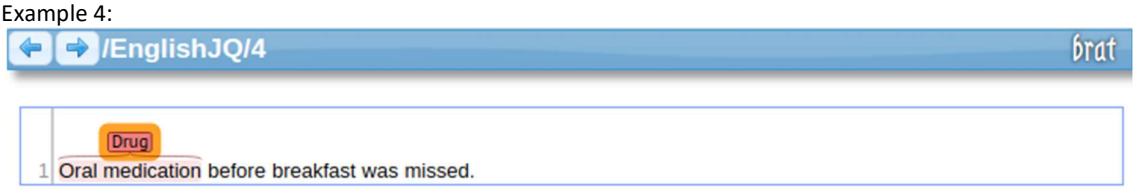
Incident reports related to blood products are not the target of this classification scheme. However, blood products should be annotated as a drug if they are involved in an incident. Thus, in Example 2, Red Blood Cell (RBC) is annotated, despite not being the main drug associated with the error. Enteral 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:



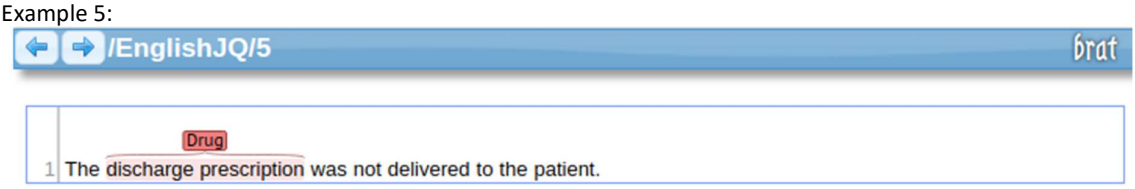
In incident reports, classes of drugs (e.g., antibiotics, maintenance fluids, total parenteral nutrition), types of medication (e.g., oral medication) or medication for specific situations (e.g., daily medication, discharge prescriptions) are sometimes annotated as a drug NE. In Example 3, 'Antibiotics'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

Example 4:



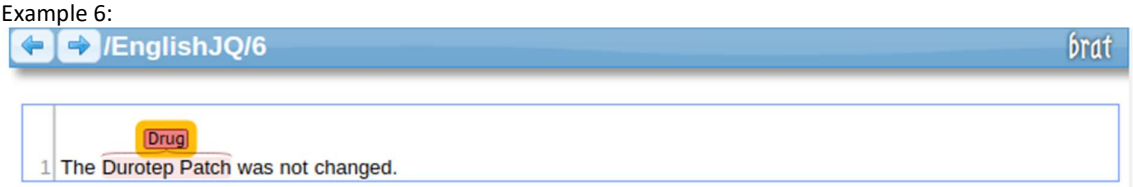
Sometimes the names of drugs are left unspecified. In Example 4, a drug name is not specified; the drug is identified simply as oral medication instead.

Example 5:



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

Example 6:



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.

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

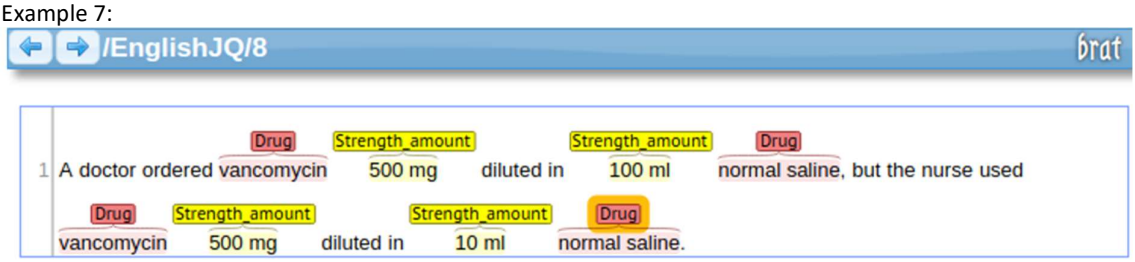
3.3 STRENGTH

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:



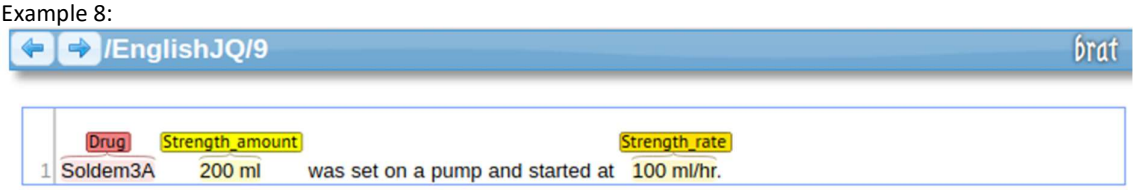
Example 7 demonstrates how amounts of drug are typically described. 500 mg, 100 ml and 10 ml are all grouped as strength – amount.

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.

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:



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.

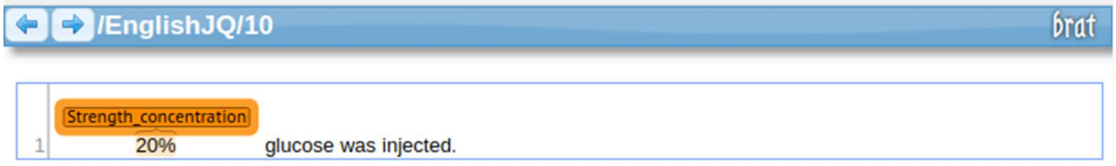
Example 9: A doctor ordered a change in the rate of fentanyl to 0.5 ml/hr but the nurse missed the order.

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:



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:

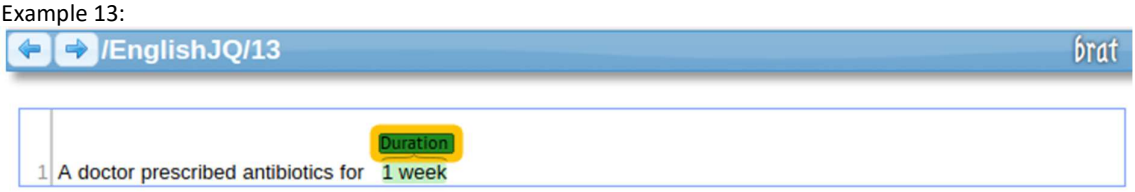
In Example 11 and Example 12, either the number alone or the number and the day can be tagged because the unit of duration is days. Most incident reports use days as the unit of duration.

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	× 14 D
14 days' worth	(14)
14 days' dose	14
/14 days	14N
/14D	14/D
/14DD	× (14)

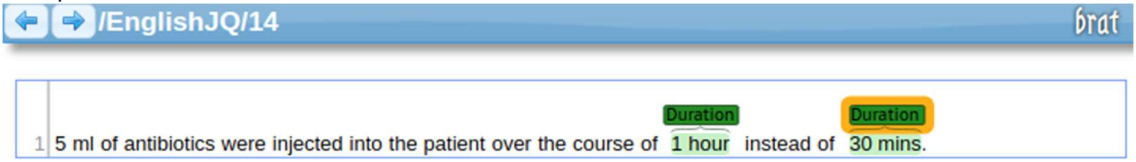
Figure 3. Various ways to indicate an order for 14 days [31].

Example 13:



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:

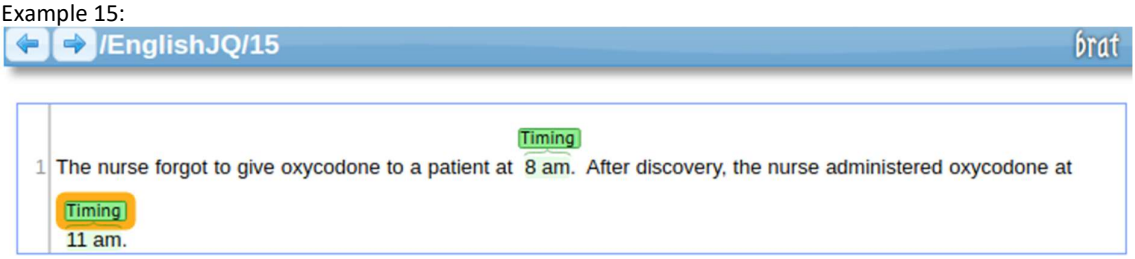


In this example, 5 ml is indicated as the NE strength – amount and we annotate both 30 minutes and 1 hour as the NE duration. By combining the NE strength – amount and the NE time, we know the strength – rate is 5 ml/30 minutes and 5 ml/1 hour. However, the report specifies a period of time and does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

3.5 TIMING

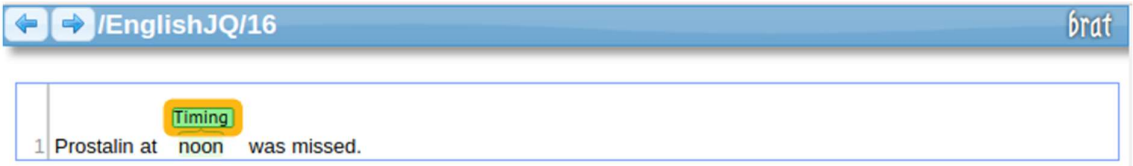
This type of entity is selected to specify the time at which a drug is given. Time is typically described as clock time or as a noun description, such as 'before breakfast', 'lunch', or 'bedtime'. The time to administer a drug is sometimes not specified (e.g., only information related to frequency is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

Example 15:



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:

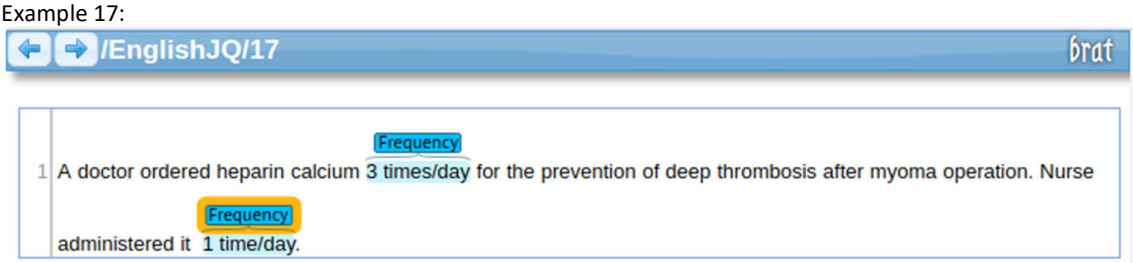


In Example 16, a noun is used.

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:



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.

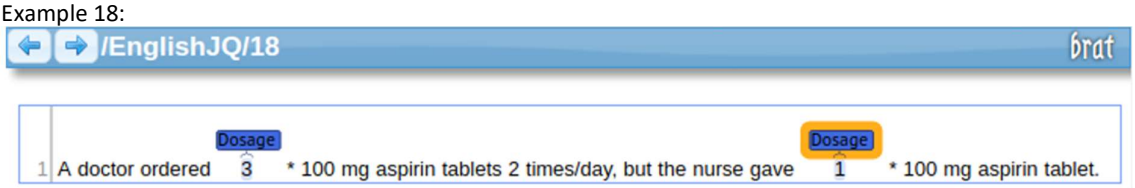
The relationship between NEs changes depending on how strength – amount is expressed. For example, if strength – amount is expressed in amount per unit, other NEs would be understood as follows:

- 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.

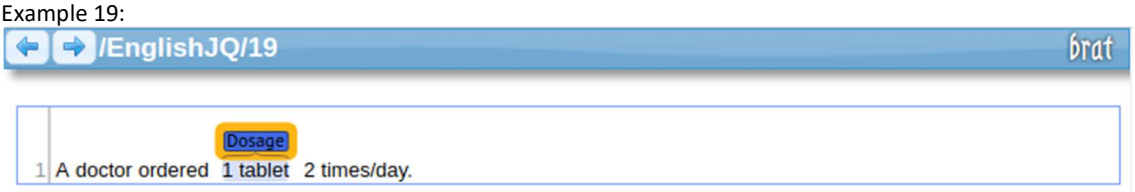
According to the MEXT standard prescription guide, the amount per consumption is ideally prescribed by physicians. Annotators need to be aware that incident reports vary and the relationship between NEs may depend on the report.

Example 18:



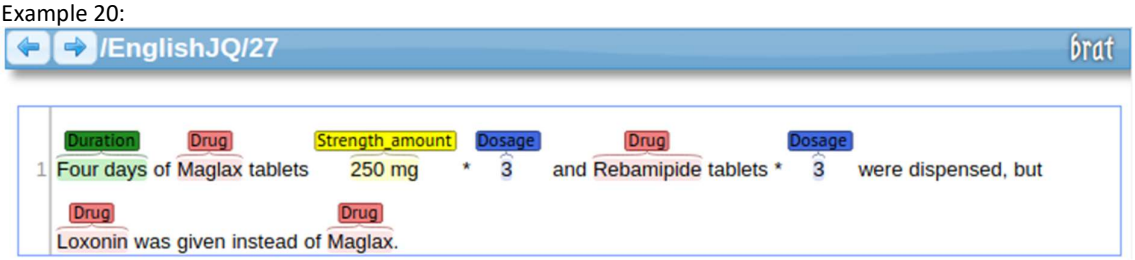
In Example 18, dosages are described with a number and are annotated accordingly.

Example 19:



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:

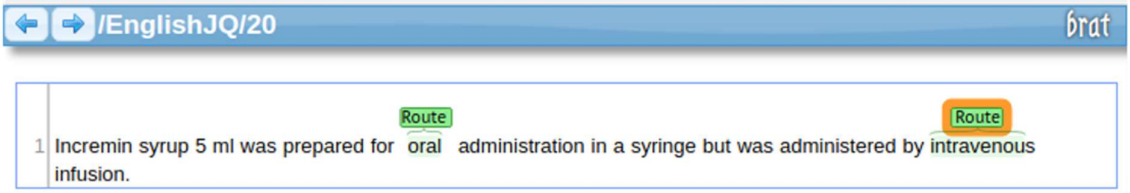


In Example 20, '3' is tagged as the dosage and 'four days' is treated as the duration.

3.9 ROUTE

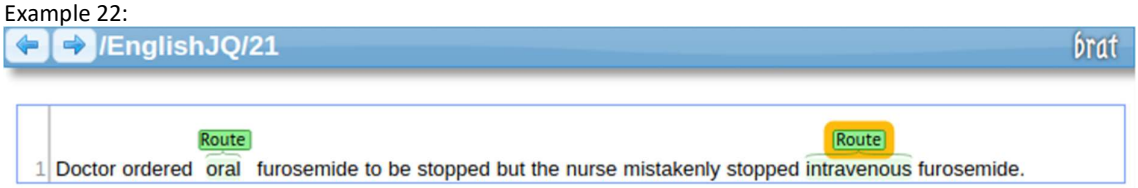
This entity type is selected to specify the drug route. Route is defined as the way the drug is administered to the patient, including infusion sites, routes and pumps. Annotators may find it difficult to distinguish between form and route.

Example 21:



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

Example 22:



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

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.

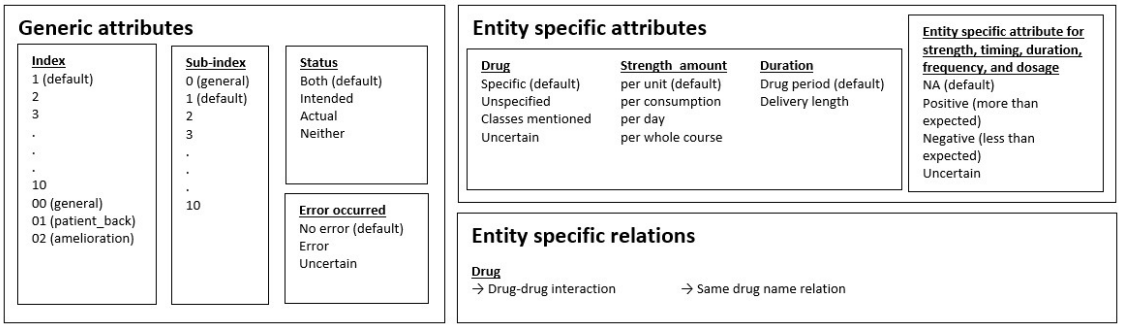


Figure 4. Overview of attributes.

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’.

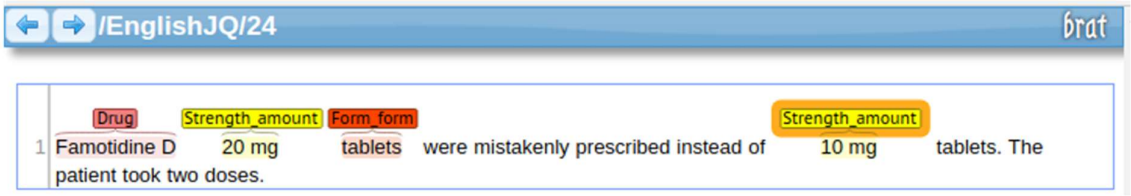
4.1.1 INTENTION AND FACTUALITY STATUS

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:



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.

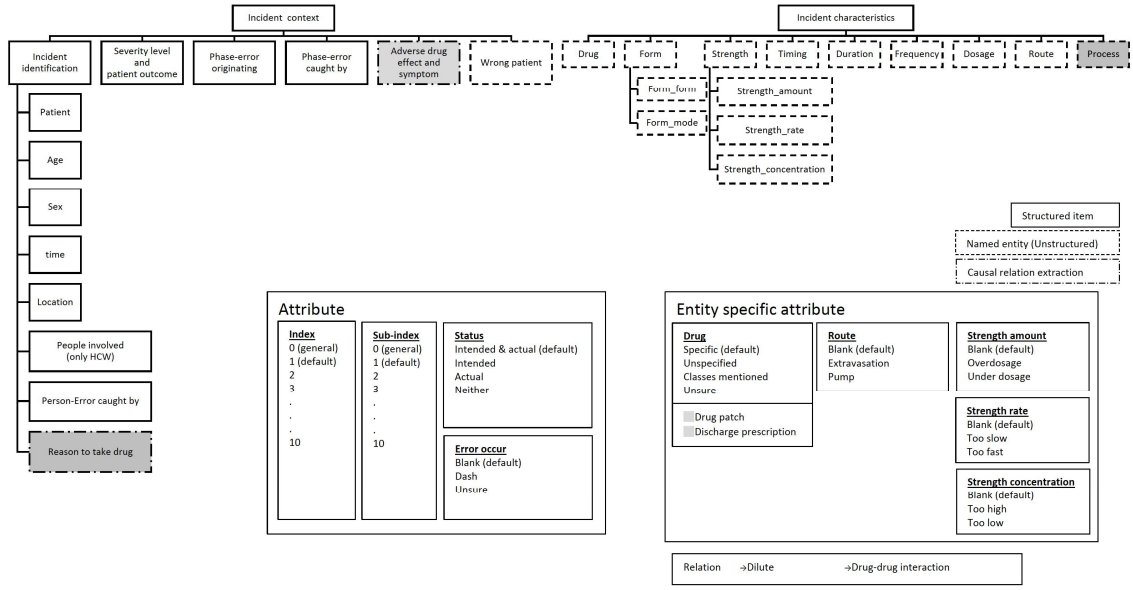


Figure 5. Conceptual framework for the classification theme.

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.

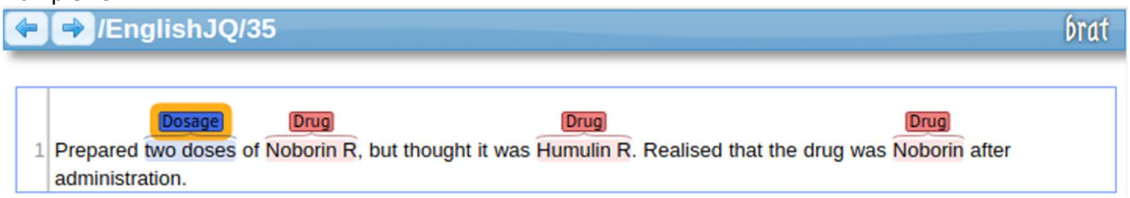
Named entity	Intended	Actual	Incident type
Drug	A	B	Wrong drug
Form – form	A	B	Wrong form
Form – mode	A	B	Wrong mode
Strength – amount	A	B	Wrong amount
Strength – rate	A	B	Wrong rate
Strength – concentration	A	B	Wrong concentration
Timing	A	B	Wrong timing
Duration	A	B	Wrong duration
Frequency	A	B	Wrong 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].

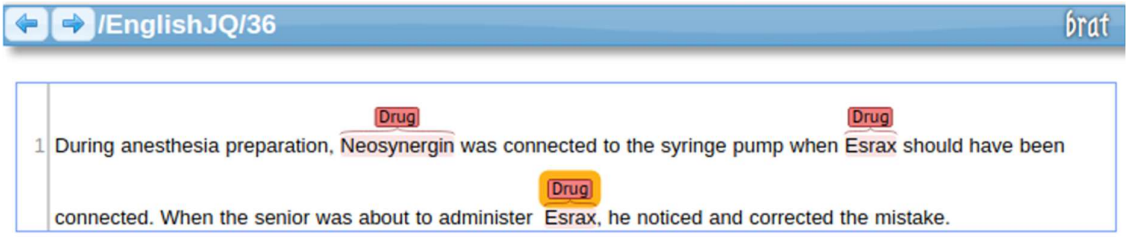
Example 25:



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.

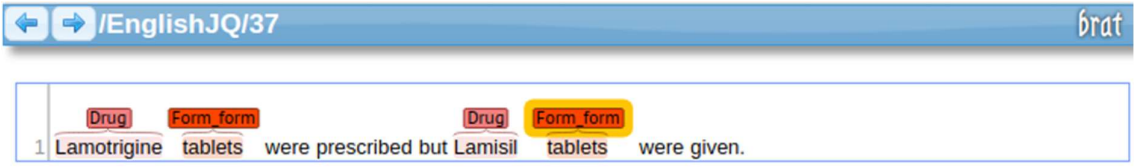
Example 26:



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

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

Example 27:



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

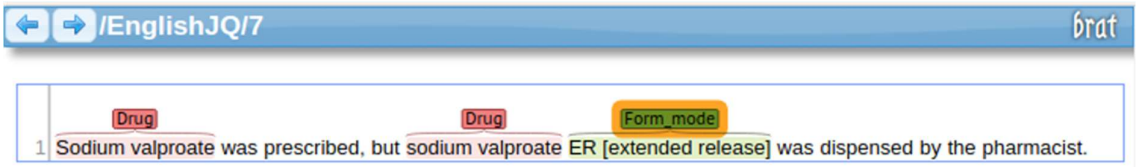
Relation	Named entity	Intended	Actual	Incident type
1	Drug	ibuprofen	ibuprofen	
1	Form – form	tablets	topical gel	Wrong form

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:



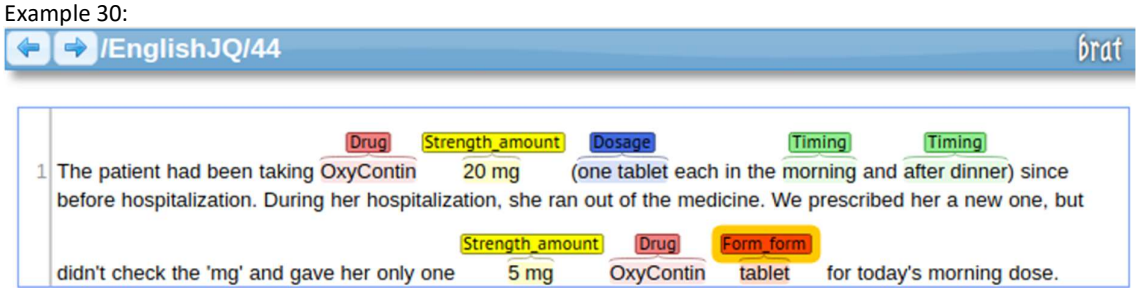
Relation	Named entity	Intended	Actual	Incident type
1	Drug	sodium valproate	sodium valproate	
1	Mode		ER	Wrong mode

In this example, the drug mode is wrong even though the form is the same. Only the mode for the drug actually given, 'ER', 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].

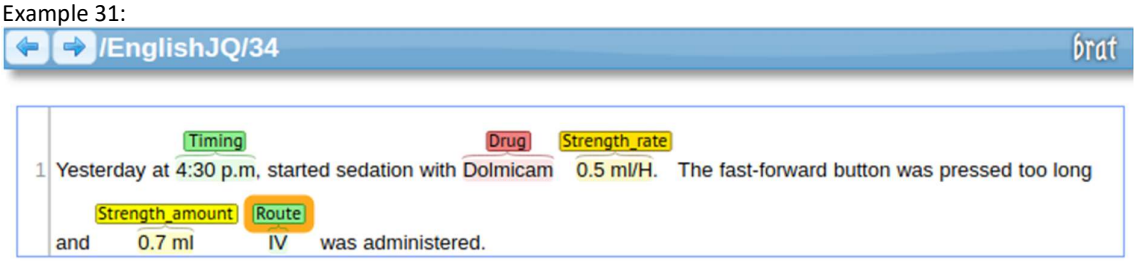
Example 30:



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:



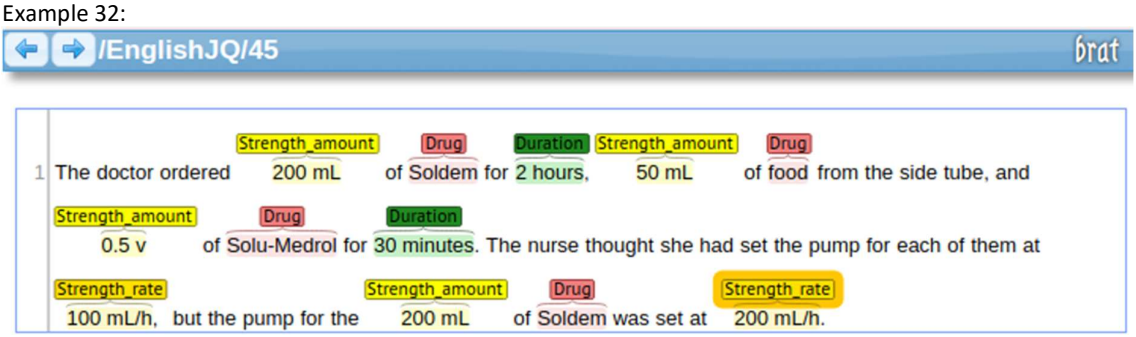
Relation	Named entity	Intended	Actual	Incident type
1	Drug	Dolmicam	Dolmicam	
1	Rate	0.5ml/H	0.5ml/H	
1	Amount		0.7ml	Wrong amount

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].

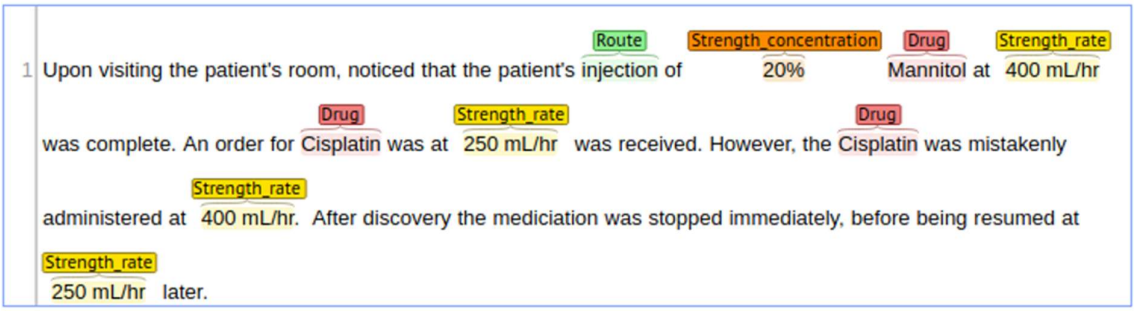
Example 32:



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:



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:
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.

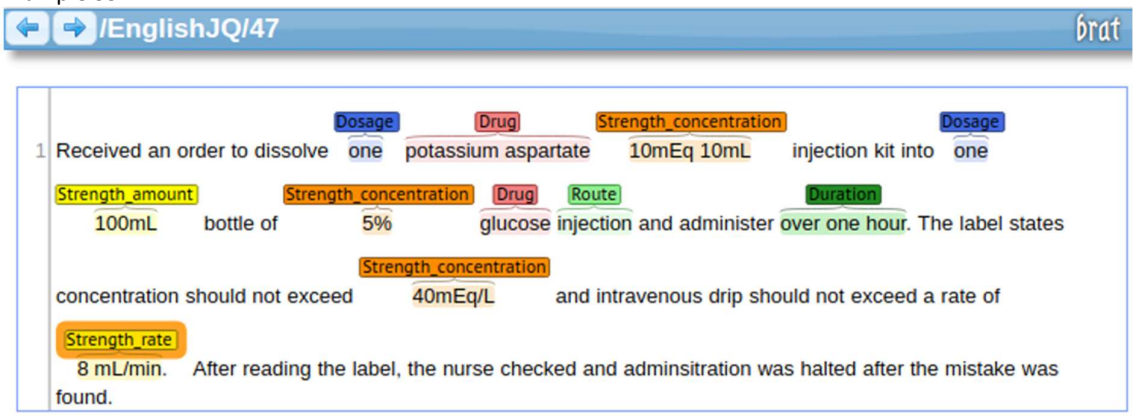
Relation	Named entity	Intended	Actual	Incident type
1	Drug	KCL	KCL	
1	Form	Injection	injection	
1	Amount	20mEq/20ml	20mEq/20ml	
1	Drug	saline	saline	
1	Amount	80ml	80ml	
1	Amount	100ml	100ml	
1	Rate	1 hour	Too fast	Wrong rate (Too fast)
1	Frequency	3 times	3 times	
1	Amount		50 ml	Wrong amount (Overdosage)

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 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:



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.

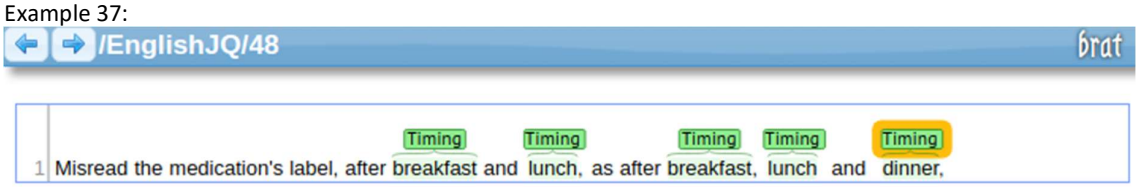
5.7 WRONG TIMING

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

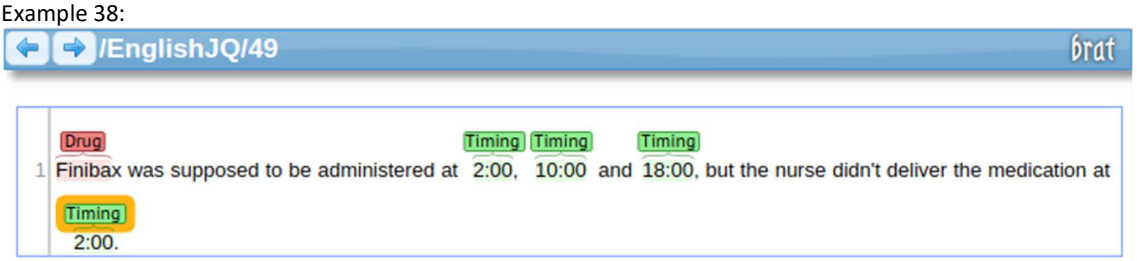
Relation	Named entity	Intended	Actual	Incident type
1	Timing	9:00		Wrong timing
1	Drug	Oxycontin	Oxycontin	
1	Form	tablets	tablets	

Example 37:



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

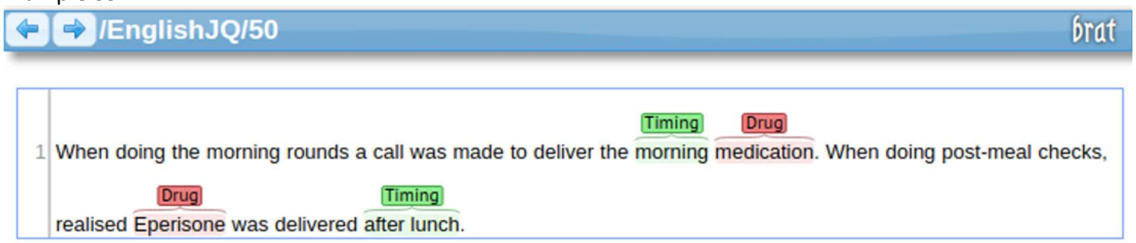
Example 38:



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:



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.

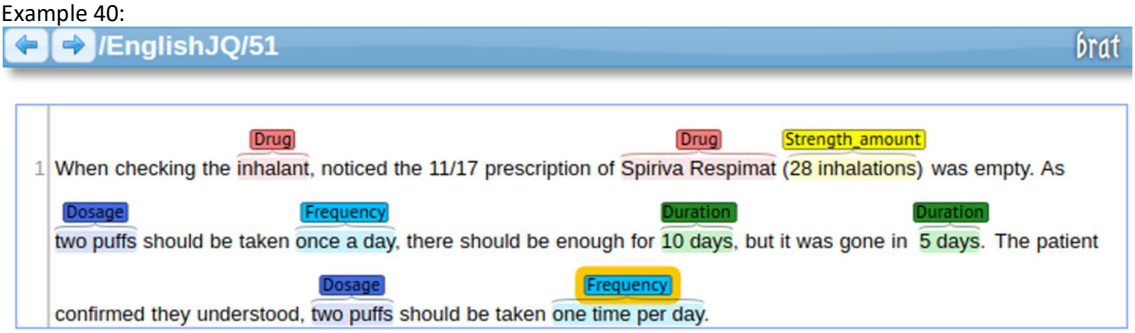
5.8 WRONG DATE

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:



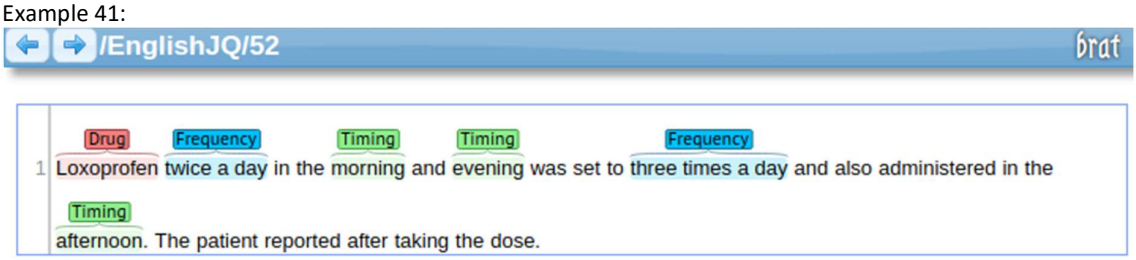
Relation	Named entity	Intended	Actual	Incident type
1	Drug	inhalant Spiriva Respimat	inhalant Spiriva Respimat	
1	Amount	28 inhalations	28 inhalations	
1	Frequency	once a day	once a day	
1	Dosage	two puffs	two puffs	
1	Duration	10 days	5 days	Wrong duration

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:



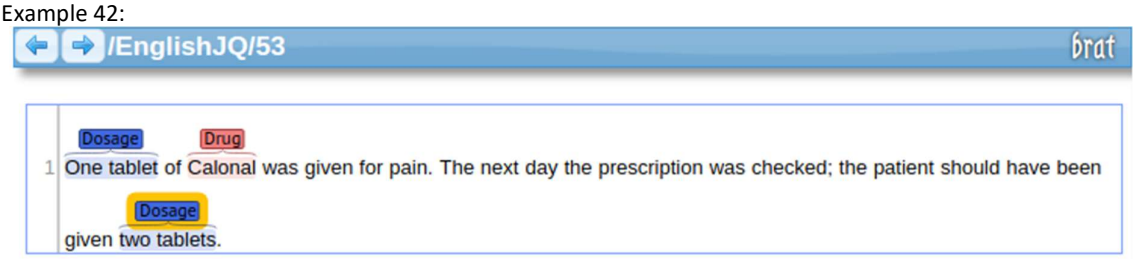
Relation	Named entity	Intended	Actual	Incident type
1	Drug	Loxoprofen	Loxoprofen	
1	Frequency	twice a day	three times a day	Wrong frequency
1	Timing	morning	morning	
1	Timing	evening	evening	
1	Timing		afternoon	Wrong timing

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.

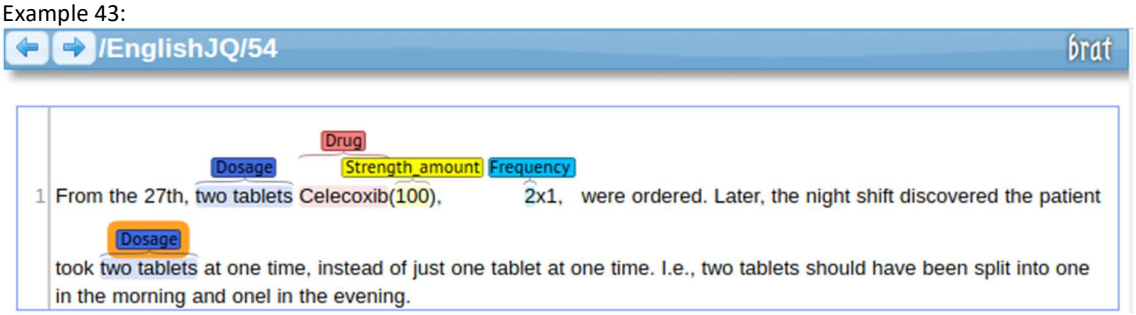
Example 42:



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:



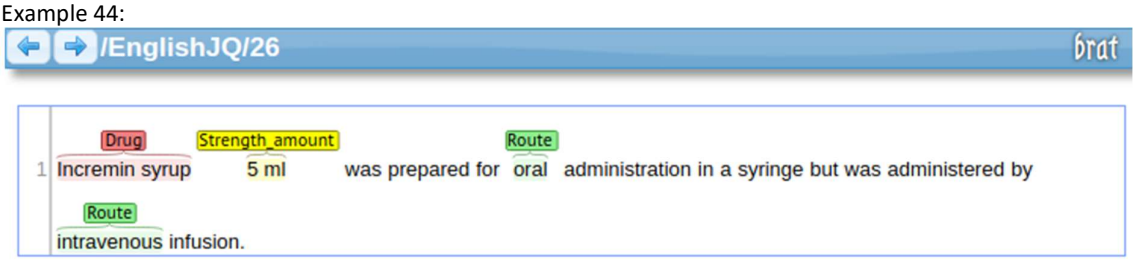
Relation	Named entity	Intended	Actual	Incident type
1	Drug	Celecoxib	Celecoxib	
1	Amount	100	100	
1	Amount	2 tablets	2 tablets	
1	Frequency	2x	2x	
1	Dosage	one tablet	two tablets	Wrong dosage

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:



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.

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