Design Guidance

Recording Adverse Drug Reaction Risks

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Prepared by
Microsoft

Microsoft

PREFACE

Documents replaced by this document

Document Title	Version
None	

Documents to be read in conjunction with this document

Document Title	Version
Design Guidance – Displaying Adverse Drug Reaction Risks	1.0.0.0
Design Guidance – Terminology – Matching	1.0.0.0
Design Guidance – Terminology – Elaboration	1.0.0.0
Design Guidance – Displaying Standards for Coded Information	1.0.0.0
Design Guidance – Date Display	2.0.0.0
Design Guidance – Medication Line	2.0.0.0
Design Guidance – Displaying Graphs and Tables	2.0.0.0

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1 INTRODUCTION

Adverse drug reactions (ADRs) represent a significant risk to patient safety. This is demonstrated in a recent report[1] drawn up by the National Patient Safety Agency (NPSA).

Currently, information about a patient's propensity (that is, risk) for suffering an ADR to a given drug is not recorded or displayed consistently across the healthcare systems, which could result in ambiguous or incomplete communication.

This guidance aims to support clear and unambiguous communication of the known ADR risks for a patient which is also appropriate for a wide range of settings throughout the healthcare industry.

Clinical software applications that record or display ADR risks must provide sufficient information to allow the user to make good clinical decisions, such as:

- Whether to prescribe a medication
- Whether to take additional actions (such as administering the drug in a hospital).

The users must also be able to determine whether the patient's current symptoms are attributable to an ADR.

This guidance is written with the assumption that the display of a list of ADR risks would be featured in clinical applications in addition to automatic warning alerts based upon Decision Support Systems (DSS). Accordingly, the guidance scope does not cover such DSS alerts and the reader should not assume that the designs in this document would remove the need for such alerts. However, it is the case that DSSs would be dependent upon the clear and error-free recording of ADR risks by clinicians, which is addressed by the current guidance.

Another important issue associated with the recording and subsequent display of ADRs is that of maintaining data quality. If data is entered to a poor standard, it may be interpreted incorrectly at the point of display.

> **Note**
>
> The example names of companies, organisations, people, places and events depicted in the graphical illustrations are fictitious. No association with any real company, organisation, person, place, or events is intended, or should be inferred.
>
> The visual representations used within this document to display the guidance are illustrative only. They are simplified in order to support understanding of the guidance points. Stylistic choices, such as colours, fonts or icons, are not part of the guidance and, unless otherwise specified, are therefore not mandatory requirements for compliance with the guidance in this document.

1.1 Definitions of Adverse Drug Reactions

The World Health Organisation (WHO) defines 'adverse drug reactions' as "any response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" **{R2}**. In other words, in normal cases, the drug itself is not toxic, but for some patients, the drug will provoke a negative physiological response.

However, beyond this general notion of what is an ADR, there are many sub-definitions and opposing classifications.

[1] NHS, Clinical Governance, Safety in Doses: Medication Safety Incidents in the NHS (NPSA) **{R1}**: http://www.clingov.nscsha.nhs.uk/Default.aspx?aid=4021

Many taxonomies categorise ADR risks according to whether they are immune-mediated or not. Some also make the distinction between Type A (pharmacological) and Type B (hypersensitivity). For example, Figure 1 shows a classification of ADRs from the *Medical Journal of Australia*[2]:

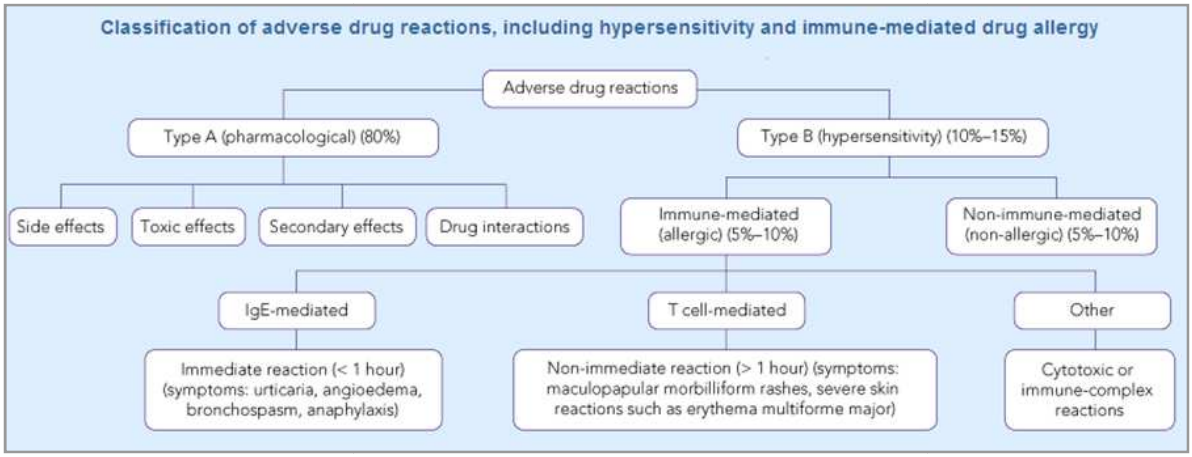


Figure 1: Classification of Adverse Drug Reactions

Another report describes how there are multiple sub-groups within the category of immunological reactions alone, the most common being Type 1, or 'allergy', and that immunological reactions only account for 5-10% of adverse reactions[3].

It would be fair to say that most clinicians would not be familiar with such a detailed classification. A national healthcare agency, focused on the delivery of IT and infrastructure in the UK, categorises adverse into three categories:

1. **Allergic drug reaction**

   A response to a pharmaceutical product to which an individual has become sensitised, in which histamine, serotonin and other vasoactive substances are released, in response to an immune system-mediated reaction.

   This causes systemic symptoms which can include pruritus, erythema, flushing, urticaria, angio-oedema, nausea, diarrhoea, vomiting, laryngeal oedema, bronchospasm, hypotension, cardiovascular collapse and death.

2. **Adverse drug reaction**

   A response to a pharmaceutical product which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.

3. **Drug intolerance**

   An undesirable effect produced by the pharmacological actions of a pharmaceutical product at therapeutic or sub-therapeutic dosages, and which prevents the patient from tolerating treatment with that product.

The goal of the current guidance is to ensure that clinicians can easily and effectively record ADR risks in order that the patient is not given the offending drug again (unless there are extenuating circumstances). This is not about recording the expected side effects of drugs; instead it is about identifying past idiosyncratic reactions in order to prevent them in the future.

[2] Thien, F. MJA Practice Essentials, 2006, Allergy: Drug hypersensitivity **{R3}**: http://www.mja.com.au/public/issues/185_06_180906/thi10282_fm

[3] Riedl, M.A. and Casillas, A.M., American Academy of Family Physicians, Adverse Drug Reactions: Types and Treatment Options **{R4}**: www.aafp.org/afp/20031101/1781.html

1.2 Risks Versus Events

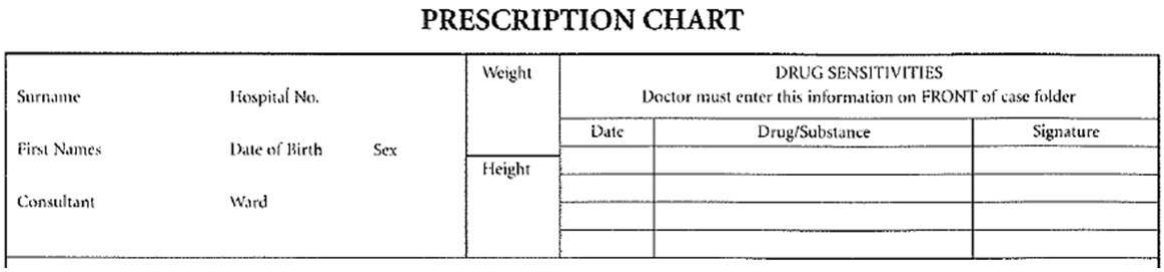
This guidance will take the approach that an ADR can be expressed in terms of an actual reaction event or in terms of a future risk to the patient. As will be shown later in the document, this is an important distinction, given that a patient can experience a reaction (event) without the clinician believing that the drug represents a serious future risk; or, conversely, the clinician may wish to record that the patient is at risk of adversely reacting to a given medication, even if the details of any past reaction are not known. For example, the patient may tell the clinician that they are allergic to penicillin, but are not able to recall any specific reaction event to justify this risk. The clinician may therefore wish to record this as a risk and not an event.

Obviously, the confusion of 'risk' and 'reaction event' at this point could be dangerous as future readers of the risk information could place undue confidence in the risk if they think that the clinician has witnessed a reaction in the patient.

Therefore, this guidance distinguishes between the risk of a future reaction and the event of past reaction, but acknowledges that these two sets of data are intimately linked and that this should be reflected in the user interface.

This notion is expressed in the *Representation in Electronic Patient Records of Allergic Reactions, Adverse Reactions, and Intolerance of Pharmaceutical Products* **{R5}**, in which it is argued that it is important to distinguish between these two kinds of ADR in the medical record: namely distinguishing discrete ADR 'events' and persisting ADR 'conditions'. In this paper, the authors talk about "recording a clinician's opinion about future risk of (or propensity to) an allergy or other ADR if the patient is exposed to a substance" . They also acknowledge the difficulties faced by interface developers in labelling the corresponding condition for an ADR event; they point out that the word "adversy" does not exist. For this reason, we refer to this condition as a 'risk' in this document.

A good example to demonstrate the need for a summary of ADR risks is the area on drug charts reserved for recording drugs which should be avoided, shown as 'Drug Sensitivities' in Figure 2:


PRESCRIPTION CHART

Surname	Hospital No.		Weight	DRUG SENSITIVITIES Doctor must enter this information on FRONT of case folder		
				Date	Drug/Substance	Signature
First Names	Date of Birth	Sex	Height			
Consultant	Ward					

Figure 2: Example of the 'ADR Risk' Area of an Existing Paper Drug Chart

Where possible, the ADR risks listed in this area must be based upon empirical evidence (such as the clinician witnessing a reaction). This area does not replace the need to write detailed examination notes about ADRs elsewhere in the record. Nor should the clinician be expected to write detailed notes about the ADRs on the drug chart, as this detailed information would obstruct the important medication information and may not be necessary on most occasions

This information relates to a 'risk' of reaction in the future. We can view it as a risk because:

- The relationship between the reaction and the drug is most often a likely probability, rather than a certainty
- If a drug has caused a reaction in the past, this does not mean that it will necessarily produce a similar reaction in the future

However, since beginning the development of this guidance, we have discovered that certain key groups of clinicians find the concept of 'risk' difficult to understand in the context of ADRs. Instead, they understood the notion of summarising past reactions. Therefore, we suggest that labelling in any user interface (UI) that is presented to the clinician employs the term 'summary'.

However, for the benefit of the readers of this guidance document, we shall still use the word 'risk' in order to distinguish it from the ADR 'event'. This should make matters clearer to those responsible for ensuring that appropriate data is recorded during clinical noting.

Figure 3 shows an example of the ADR summary proposed:

Figure 3: Example of the ADR Summary

Therefore, to the clinician who is using the user interface, the overall list is called the **Adverse drug reaction summary** (or **Adverse drug reaction summary list**), and each line in the list corresponds to an **Adverse drug reaction** that the list summarises. Accordingly, clinicians will be required to perform the action of adding an ADR to the summary. To the clinician, the ADR is still an ADR; it is just that they are summarising it for the purposes of warning other clinicians.

However, for the readers of the current guidance document, whereas the overall list is also called the **Adverse drug reaction summary**, each line in the list corresponds to an **Adverse drug reaction risk**.

Suppliers of clinical noting systems should ensure that the clinician not only records a detailed description of any ADR events that they witness the patient experiencing (for example, as part of examination notes), but also that the clinician records if they believe that the patient is at risk of suffering a future reaction if they take the drug again.

1.3 Customer Need

Avoiding known adverse reactions to drugs is a well-recognised and important goal within the healthcare industry. Communicating the risk of a drug to a specific patient is an important step in achieving this.

To achieve this communication, the user must be able to:

- Record that there is a risk of a medication causing an ADR in a patient, as part of a summary of ADRs for that patient
- Record or link to justification for the ADR risk, where appropriate, which exists elsewhere in the patient record and which includes the diagnosis of the ADRs, past reaction symptoms and medication administration or prescription events
- Record appropriate context and provenance data for the ADR risk, including date(s), authorship and location

  > **Note**
  >
  > Some of this recording may be automatic.

- Record that the patient has no known ADR risks
- Edit an existing ADR risk, including declassifying it as an active risk

These goals should be achieved whilst minimising the amount of re-entry of past details by providing intuitive entry-points in the clinical noting process, whilst not interfering with the consultation process.

The ultimate aim is to prevent the administration of drugs known to be dangerous to a particular patient by ensuring that the clinicians are provided with sufficient information to:

- Identify the presence or confirm the positive absence of ADRs
- Determine the previous outcomes (including reaction) of the drug being administered
- Form an opinion on future outcomes if the drug is again administered

1.4 Scope

1.4.1 In Scope

Guidance Area	Details
Adding new ADR risks to the ADR summary	The guidelines in this section cover when the clinician wishes to add a new drug risk (for a particular patient) to the ADR summary. This will typically occur when the clinician feels that they have seen or heard sufficient evidence to conclude that the patient is at risk of suffering an adverse reaction if they take a certain drug in future. This evidence may take the form of a patient testimony, a testimony from a third party or an account in existing clinical documentation, such as a referral letter. Additionally, it may be that the clinician has examined the patient and has concluded that they have suffered an ADR.
Editing existing ADR risks within the ADR summary	The guidelines in this section cover when the clinician wishes to edit details of an existing ADR in the summary.
Removing existing ADR risks within the ADR summary	The guidelines in this section cover when the clinician wishes to remove an existing ADR from the summary. This section covers any warning messages that are required and how to allow the clinician to view risks that have been removed from the summary list in the past. The warning messages would also communicate to the clinician that by removing the ADR risk from the summary they are not removing any corresponding notes from the rest of the patient record.
Recording 'No known ADRs'	The guidelines in this section cover how to allow the clinician to record where they have checked the patient's ADR status and are confident that the patient has no known ADRs.

Table 1: In Scope

1.4.2 Out of Scope

If the clinician examining the patient has noticed relevant symptoms and is diagnosing the patient as having experienced an ADR, he or she is expected to make detailed notes about this reaction event and the events leading up to it, as noted in *Adverse Drug Reactions: Types and Treatment Options* **{R4}**. The clinician would be expected to note all prescription and non-prescription drugs taken prior to the reaction, including dates of administration and dosage. The clinician must also document in detail the physical examination of the patient, focusing in on the reaction symptoms, which may include a detailed skin examination as the skin is the organ most frequently and prominently affected by ADRs. The execution of this detailed noting is assumed, but is **not** addressed by the current guidance.

Guidance Area	Details
Detailed documentation of ADR events	The current guidelines have been developed on the assumption that, in the event that a clinician witnesses an ADR, they enter detailed examination notes in the record. However, the **current guidelines do not cover the entry of such notes**. The assumption is that in addition to the detailed notes, the clinician should also record a summary of the ADR in a highly accessible and visible area of the record, which communicates that the patient is **at risk** of reacting to the drug if administered in future. The current guidelines **only** cover the recording of this summary, or risk, of the ADR.

Guidance Area	Details
How to communicate the link between supporting notes and ADR risk during input	The current guidelines have been developed on the assumption that, within the ADR summary list, there will be links to any detailed examination notes and/or any other relevant data, such as details of past drug administration or diagnoses of ADRs. However, the current guidelines do not cover how to create nor present these links.
Browsing up and down a terminology hierarchy structure, in order to define either the causative agent or a reaction type	In order to assist the clinician in finding the drug or substance name that they seek in attempting to define the ADR's causative agent, the UI could allow the clinician to browse the terminology hierarchy structure. For example, they could enter 'penicillin' and browse down to specific instances of penicillin, such as 'amoxicillin'. However, this feature is not covered by the current guidance. But, for a fuller discussion of how this may be achieved, refer to the document *Design Guidance – Terminology – Matching* **{R6}**.
How to trigger an automatic ADR entry dialog	The current guidelines cover some aspects of the UI that could enable the clinician to quickly and easily add an entry to the ADR summary list if they have just entered: ▪ Notes about an examination of ADR symptoms ▪ A diagnosis of an ADR However, the current guidelines do not cover how the UI identifies that the clinician has entered information about an ADR nor the criteria for triggering an 'add to summary' prompt.
Automatic linking between risk and supporting notes (and vice versa)	If the user interface (UI) can identify where notes about an ADR event have been entered, and can automatically prompt the user to enter the corresponding risk, it can ensure that these two types of note can be linked together automatically. This would facilitate the clinician's accessing of the detailed notes from the ADR summary. However, the current guidelines do not cover the process or the UI that would be involved in creating such links. Equally, the guidelines do not cover how much of the detailed notes are linked to the risk in the summary.
Manual linking between risk and supporting notes	The current guidelines also assume that, in future, it will be possible for the clinician to manually link entries in the ADR summary to entries elsewhere in the patient record that document symptoms or diagnoses relating to the corresponding ADR event. However, the current guidelines do not cover the process or the UI that would be involved in allowing the clinician to create such links.
Inputting dates, including distinguishing between recorded, reported and actual dates	The current guidelines outline a UI whereby ADRs are described in a fairly abstract and high-level manner; that is to say, the ADR is described as a risk that is not limited by date or time. This is in contrast to descriptions of the corresponding ADR events (namely occasions when the patient has actually reacted to the drug) that are firmly linked to a specific date and time (and place). Although the clinician may add some dates to the summary as part of their justification (which is captured in free text), they are not required to enter dates in a structured manner. The system may automatically capture the date and time when the clinician records the risk, but the main purpose of this is for data organisation and audit and this does not need to be visible to the clinician at the point of entering the risk. Therefore, the current guidelines do not cover when the clinician should input dates. However, for guidance on how to enter dates please refer to document *Design Guidance – Date Display* **{R7}.**
How to automatically extract reaction keywords from free text	As part of the design work, the guidance authors considered solutions whereby the clinician could type in text freely and the UI would identify word matches with the clinical terminology and would then provide a mechanism by which the clinician could encode these words. However, as this natural language parsing technology is still fairly immature and largely unavailable to suppliers of health technology, the current guidelines do not cover such a solution as the primary entry mechanism.

Guidance Area	Details
Moving links to a supporting note between risks	If links exist between an ADR risk entry (in the summary) and the detailed notes which support it, there may be a need for the clinician to be able to transfer links between risks. For example, following the attribution of a rash to an ADR to penicillin, subsequent evidence suggests that the rash was more likely in response to them taking diclofenac. In this case, the clinician may want to transfer the linked rash event from the penicillin risk to the diclofenac risk. However, the current guidelines do not cover how the clinician can transfer links.

Table 2: Out of Scope

1.5 Assumptions

ID	Assumption
A1	The structured terminology used for this guidance will be SNOMED CT®[4] and the Dictionary of Medicines and Devices (dm+d)[5]. **Note** This approach has been taken in line with a national healthcare agency, focused on the delivery of IT and infrastructure in the UK that the authors of this guidance were working with to create it (see *SNOMED CT – the language of the NHS Care Records Service*[6]). However, the requirement that clinical information technology (IT) suppliers must use SNOMED CT is not one that is specifically endorsed by Microsoft® over another provider.
A2	Appropriate subsets within SNOMED CT and dm+d are available.
A3	The user interface design correlates with the advice given in the document *Representation in Electronic Patient Records of Allergic Reactions, Adverse Reactions, and Intolerance of Pharmaceutical* Products **{R5}**, unless there are patient safety reasons not to do so.
A4	The application will be able to recognise that the encoded terms 'allergy to penicillin' and 'intolerance to penicillin' are subtypes of 'propensity to adverse reaction to penicillin'.
A5	The assumed messaging standard for allergies and ADRs, and therefore the Summary Care Record application, correlates with the guidelines given in the document *SCG Guidance on the Representation of Allergies and Adverse Reaction Information Using NHS Message Templates*[7].
A6	This guidance applies to PC-screen-based applications that allow dynamically changing screen views, linked into a database. It does not apply to mobile devices, electronic paper or voice-recognition software although some of the principles that apply in the current guidance could also apply to applications delivered by those types of mechanism.
A7	This guidance applies (although not exclusively) to server-based applications delivered over a network (for example, over the Internet).

Table 3: Assumptions

[4] SNOMED CT® **{R8}**: http://snomed.org/

[5] NHS Dictionary of Medicines and Devices (dm+d) **{R9}**: http://195.97.218.30/dmd_download.htm

[6] NHS Connecting for Health, SNOMED CT®, the language of the NHS Care Records Service, A guide for NHS staff in England **{R10}**: http://www.connectingforhealth.nhs.uk/systemsandservices/data/snomed/snomed-ct.pdf

[7] Bentely, S. And Long, R. (NPfIT Standards Consulting Group), SCG Guidance on the Representation of Allergies and Adverse Reaction Information Using NHS Message Templates {**R12**}: http://www.connectingforhealth.nhs.uk/systemsandservices/data/scg/publications/SCG0001.pdf

1.6 Dependencies

ID	Dependency
D1	The availability of appropriate data sets, for example, SNOMED CT **{R8}** subsets.
D2	The following design guidance documents (changes in these documents may affect the current guidance given for recording ADR risks): ▪ Design Guidance – Displaying Adverse Drug Reaction Risks ▪ Design Guidance – Terminology – Matching ▪ Design Guidance – Terminology – Elaboration ▪ Design Guidance – Terminology – Display Standards for Coded Information ▪ Design Guidance – Date Display ▪ Design Guidance – Medication Line ▪ Design Guidance – Displaying Graphs and Tables
D3	Certain guidelines are dependent upon the fact that the medication terminology used contains the same length terms as the current version of the dm+d **{R9}.**

Table 4: Dependencies

2 GUIDANCE OVERVIEW

2.1 Visual Summary of the Guidance

This section provides an overview of the main design elements that are referenced in the guidance. Figure 4 outlines the key elements that comprise the main entry dialog:

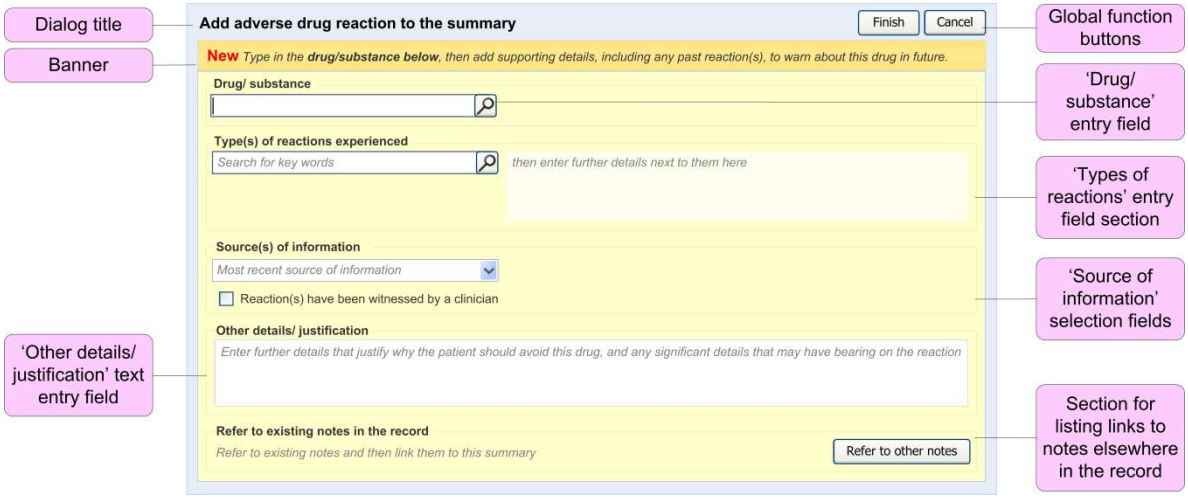
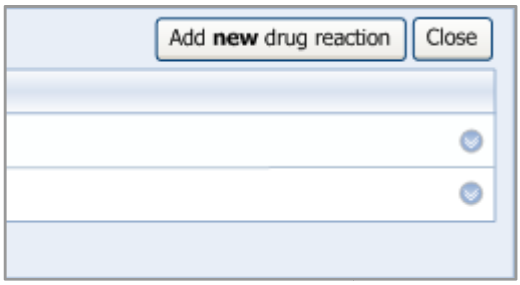
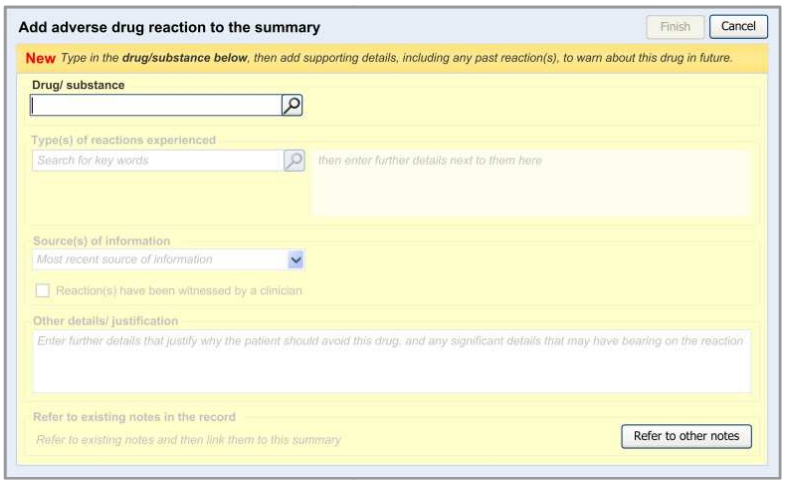
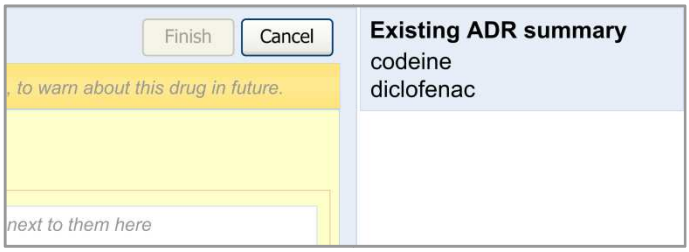
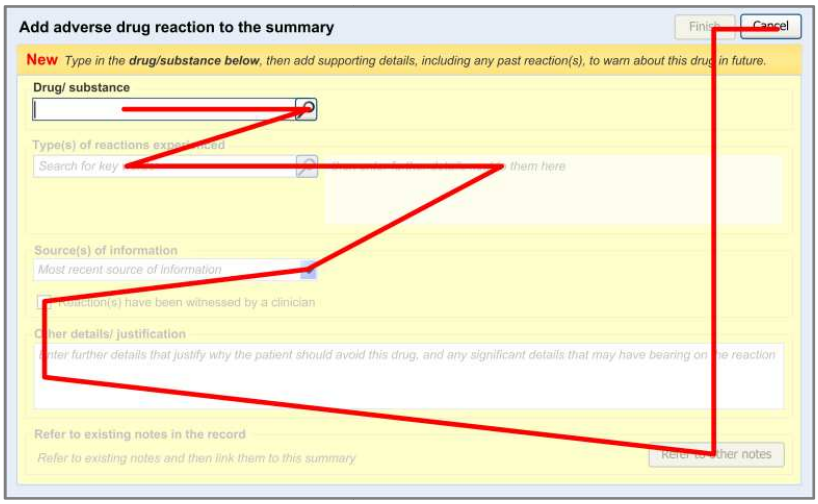
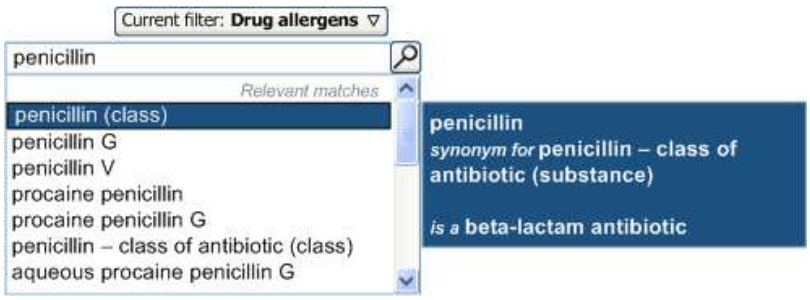
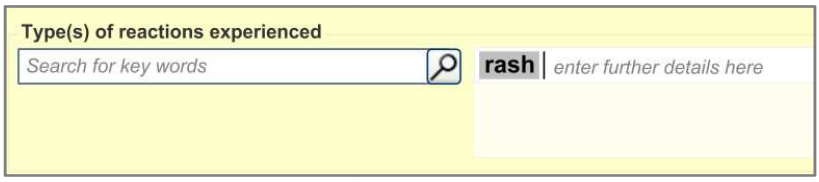
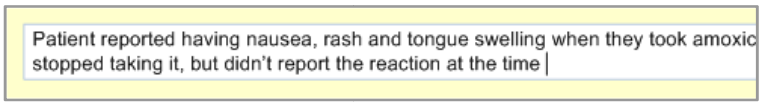
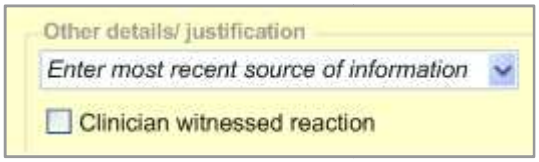
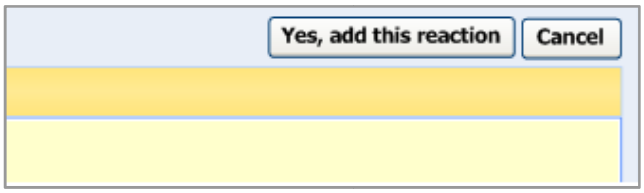
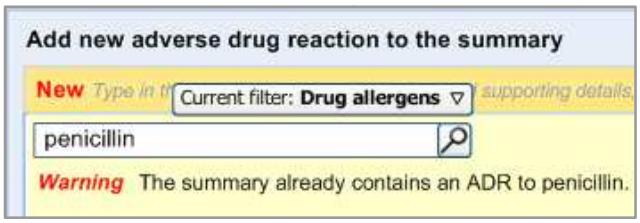
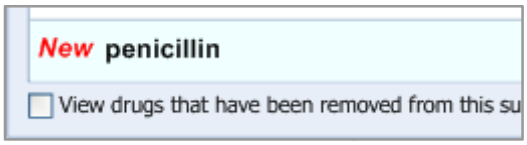
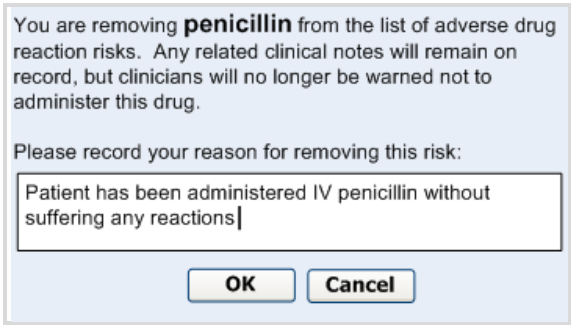
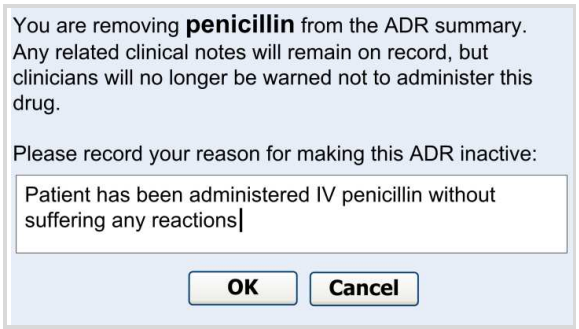
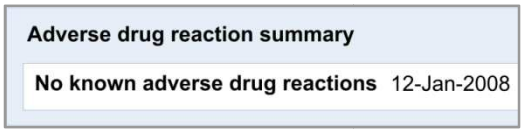


Figure 4: Key Elements in the Main Entry Dialog

Table 5 provides excerpts of the guidance illustrations and identifies where in the guidance they are found:

Visual Summary	Areas of Guidance
	3.2.1 Initiating the Addition of a New Adverse Drug Reaction Risk
	3.2.2 Dialog for Adverse Drug Reaction Risk Entry

Visual Summary	Areas of Guidance
	3.2.3 Displaying Existing Reaction Risks
	3.2.4 Entry Field Ordering and Tabbing
	3.2.5 Entering the Causative Agent
	3.2.6 Entering Reaction Types
	3.2.7 Elaborating the Encoded Reaction Type Keywords
	3.2.8 Adding Further Details and Justification

Visual Summary	Areas of Guidance
	3.2.9 Specifying the Source of Information
	3.2.10 Displaying ADR Risk Details for the Clinician to Confirm
	3.2.11 Warning About Duplicating Risks in the Summary
	3.2.12 Feedback Upon Adding, Editing or Removing a Risk
 	4.2 Guidelines – Removing an Adverse Drug Reaction Risk
	5.2 Guidelines – Recording 'No Known Adverse Drug Reactions'

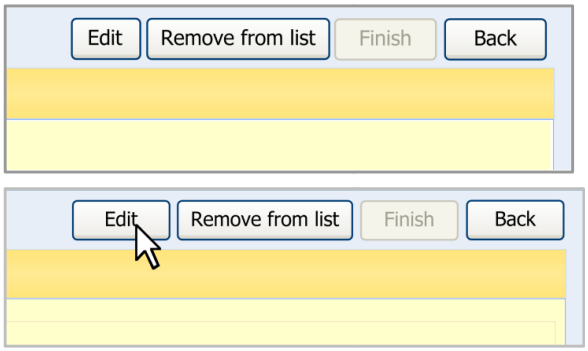
Visual Summary	Areas of Guidance
	6.2 Guidelines – Editing an Adverse Drug Reaction Risk

Table 5: Overview of the Structure of the Adverse Drug Reaction Risk Display

2.2 Clinical Statement Modelling

The user interface implied by the guidance in this document is intended to fulfil two purposes:

- Assist the clinician in creating a set of associated electronic clinical statements
- Provide an early exemplar for creating such clinical statements

The definition of a clinical statement in the current guidance corresponds with that provided in the presentation *NPfIT and the International Input into HL7*, where it is defined as "an expression of a discrete item of clinical (or clinically related) information that is recorded because of its relevance to the care of a patient"[8].

A fundamental assumption behind this guidance is that an electronic health record, which itself must support many diverse care processes, can be modelled as clinical statements. A detailed look at the various factors that contribute to this clinical statement model is not provided in this guidance, however, further information is given in the document, *SCG Guidance on the Representation of Allergies and Adverse Reaction Information using NHS Message Templates* **{R12}**.

The structure of clinical statement modelling is based in part upon Health Language Seven (HL7) v3 messaging rules (see *HL7 delivers healthcare interoperability standards*[9]**)**. The current guidance expects that clinical user interfaces that enable the recording of ADR risks should allow them to be recorded in a way that is consistent with this clinical statement message pattern.

The approach outlined in this guidance is to treat clinical statements as being the smallest piece of clinical data that has clinical meaning, irrespective of the document or application in which it is displayed. To this end, each clinical statement must have embedded within it the entire 'context of use'. For example, a 'family history' statement of 'asthma' contains the context of 'family history of asthma' and not just asthma. In this way, statements can be rearranged under different headings and within different clinical contexts, and still convey a consistent, accurate meaning.

Within the context of ADR summaries, this guidance considers the following to be the main clinical statements:

- The 'risk' statement (for example, 'Patient has a risk of adversely reacting to penicillin'):
  - In order to be meaningful alone, this statement must have at least one date associated with it (such as the date of entry, an author or the source of the information **{R12}**)

[8] Jones, T., NPfIT and the International Input into HL7, HL7 UK Annual Conference **{R13}**: www.hl7.org.uk/marketing/downloads/HL7UKConference2004/HL7UK%20NPfIT%20presentation.ppt

[9] Health Language Seven UK: HL7 delivers healthcare interoperability standards **{R14}**: http://www.hl7.org.uk/

- This statement may contain additional information relating to the justification for recording the risk
- Associated with this will be one or more ‘type of reaction’ statements and a number of statements relating to clinical events (such as high-level descriptions of the adverse reaction events).

- The ‘type of reaction’ statement (for example, ‘Patient has had a rash’):
  - This statement may contain additional information relating to the quality of the reaction (such as its severity)
  - In order to be meaningful alone, this statement must also have at least one date associated with it (such as the date of entry, an author or the source of the information). As the emphasis is not so much on the specific details of past occurrences, but rather on what has happened in the past that could potentially happen in future, the date could be the date of entry as distinct to the date of the actual event

Therefore, throughout this document, the guidance will refer to the capture of such clinical statements.

3 ADDING A NEW ADVERSE DRUG REACTION RISK

The guidelines in this section cover when the clinician wishes to add a new drug risk to the ADR summary.

This will typically occur when the clinician feels that they have seen or heard sufficient evidence to conclude that the patient is at risk of suffering an adverse reaction if they take a certain drug in future. This evidence may take the form of a patient testimony, a testimony from a third party, or an account in existing clinical documentation, such as a referral letter. Additionally, it may be that the clinician has examined the patient and has concluded that they have suffered an ADR. However, in addition to this detailed noting, the clinician would also be expected to add the drug to a high-level ADR summary so that future prescribers and administrators can be made aware of this risk, without having to read through pages of detailed notes. The clinician is effectively creating a clinical statement about the future risk to the patient of taking the drug, in addition to clinical statements about the events surrounding past reactions (that should be documented elsewhere in the record).

As far as is safely possible, and where it is technically feasible, the application should reduce the amount of duplicate information that the clinician must enter into the summary; it would be frustrating for clinician to have to retype part of their notes into the summary. To this end, the guidance covers when the system partly automates the summarisation of the detailed event notes.

However, the clinician must be aware of what they are entering into the ADR summary as this is the information that will be first viewed by future prescribers; in many cases, clinicians may not read beyond the summary.

Figure 5 shows the dialog flow for the process of adding a new ADR:

Figure 5: Screen Flow for ADR Entry

The clinician views the ADR summary list then activates a control to launch the dialog in which he or she can enter the new ADR risk. After finishing entering the necessary risk data, the clinician activates a control for finishing the adding process, which has the effect of navigating back to the ADR summary list.

3.1 Principles

The following key principles inform the guidance in this section:

- The clinician may need to add a new ADR risk to the summary at the point of viewing the existing summary
- The clinician will need to check the existing ADR summary before adding a new risk to the summary
- Clinicians work in time-pressured environments and may need to trade-off detailed reading and entry of notes against speed and efficiency

The following user interface design principles inform the guidance in this section:

- Directness: provide direct and intuitive ways for the user to accomplish their tasks
- Control: the user must control the interaction (actions should result from explicit user requests)
- Phrasing of menu items: use familiar and consistent terminology, ensure that items are distinct from one another, use consistent and concise phrasing, position the key words to the left of the text string

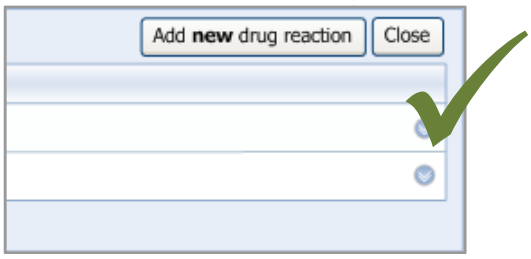
3.2 Guidelines – Adding a New Adverse Drug Reaction Risk

3.2.1 Initiating the Addition of a New Adverse Drug Reaction Risk

This guidance covers the action of initiating the 'add new reaction' dialog.

ID	Description	Conformance	Evidence Rating
RAD-0010	Provide a control in the ADR summary list that initiates the process of adding a new ADR	Mandatory	High
RAD-0010.1	Activating the control will open the ADR entry dialog	Mandatory	High
RAD-0010.2	Ensure that the control is always visible upon initially viewing the ADR summary display	Mandatory	High
RAD-0010.3	Provide a button for initiating the process of adding a new reaction risk	Recommended	High
RAD-0010.3.1	Locate the button at the top of the ADR summary display	Recommended	Medium
RAD-0010.3.2	Label the button with a phrase that refers to the action of adding the reaction risk	Mandatory	High
RAD-0010.3.3	Label the button 'Add new drug reaction'	Recommended	Medium
RAD-0010.3.4	Locate the button immediately adjacent to the other options available in the ADR summary dialog (for example, a 'Close' button)	Recommended	High

Usage Examples



Provide a control in the ADR summary list that initiates the process of adding a new ADR

Activating the control will open the ADR entry dialog

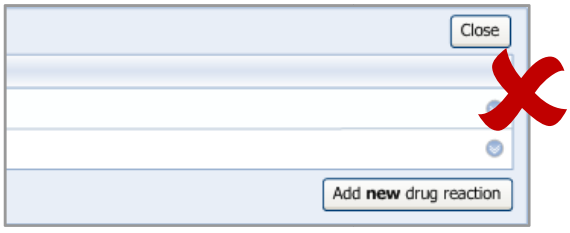
Provide a button for initiating the process of adding a new reaction risk

Locate the button at the top of the ADR summary display.

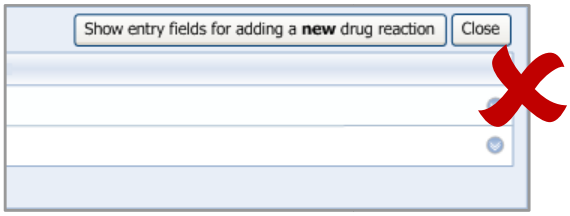
Label the button with a phrase that refers to the action of adding the reaction risk

Label the button 'Add new drug reaction'

Locate the button immediately adjacent to the other options available in the ADR summary dialog (for example, 'Close or an 'x' button in the corner of a dialog window')



Do not locate command buttons that are functionally related in distinct locations



Do not label the button with an overly complicated phrase

Rationale

Design Analysis:

The point at which the clinician views the ADR summary is also a logical point for adding a new risk. This is demonstrated, for example, in a scenario we considered regarding checking ADR risks upon admission. There are a number of elements on the ADR risk display with which the control will have to compete. The 'add' control is an important function that may be needed regularly by the clinician.

Our analysis compared different widget options and concluded that a button is the best feature, based upon this type of control's familiarity.

Our analysis compared different location options and concluded that the top of the display is the optimal location for the function buttons, as this would allow the list to be extended in length (if necessary) while keeping the 'Add new' button in view. The top right-hand location avoids competing for space with the title text.

Our analysis showed that providing labels that describe the action (to be performed by the user) that the control will execute are easier to understand than labels that contain other types of phrase. It is also good usability practice to feature consistency in the phrasing of labels and this action label is consistent with other action labels, including 'Close', 'Undo', 'Cancel' and 'Finish'.

Desk Research:

Studies that considered eyeball tracking have shown that, when viewing displays of information, the user's eyes move first to the upper-left centre of the dialog, then quickly move through the display in a clockwise direction. Streveler and Wasserman (1984) showed that users found visual targets fastest when they were located in the upper-left quadrant of a screen (quoted in *Essential Guide to User Interface Design: An Introduction to Gui Design Principles and Techniques* **{R15}**). According to their research, those targets located in the lower-right quadrant took longest to find. Given that the dialog title text is located in the top left-hand corner, the most appropriate prominent location for the 'add new' control is the top right-hand corner of the dialog. In this way, the user may read the title and then look across and see the 'add new' control.

According to the UI design expert Ben Shneiderman (*Designing the User Interface: Strategies for Effective Human-Computer Interaction* **{R16}**), the phrasing of menu items should:

1. Use familiar and consistent terminology
2. Ensure that items are distinct from one another
3. Use consistent and concise phrasing
4. Bring the keyword to the left

Our research has shown that clinicians understand the term ‘add’ when used in relation to entering new information into a summary. Also, there are no other actions in the dialog that employ the word ‘add’, so it is distinct. Finally, the word ‘add’ is located at the far left of the label.

User Research:

In testing, clinicians all identified how to add a new risk correctly using a design that followed the guidelines listed here. The mechanism for adding a new risk was consistently understood in both iterations of the testing.

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ User does not understand that they can add a new ADR risk to the summary	▪ Provide a clear control for adding a new ADR risk to the summary. Provide such a control in an intuitive location
▪ It might be easy for someone to accidentally click ‘add to the list’ without intending to	▪ If the user clicks the 'add' button, they will be presented with a dialog that is clearly titled and a button to go back to the list view

3.2.2 Dialog for Adverse Drug Reaction Risk Entry

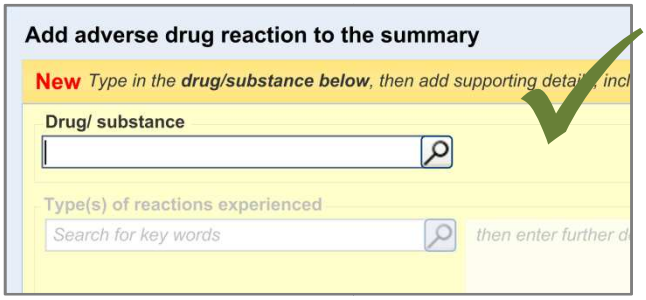
This guidance covers the layout and labelling of the dialog that contains the entry fields necessary for the clinician to enter the new reaction risk. It also outlines the main screen elements that are to be contained within this dialog.

It is worth emphasising that the term 'dialog' does not necessarily imply a pop-up modal window. In the current guidance, 'dialog' could refer to a discrete set of screen elements within a given section of a page. We are also assuming that, owing to an expected constraint on screen space, the 'ADR summary list' and the 'ADR risk entry' dialogs would not be both visible at the same time. However, if space is not constrained, there would be no reason why they should not be visible at the same time.

ID	Description	Conformance	Evidence Rating
RAD-0020	Feature a title which communicates the purpose of the dialog	Mandatory	High
RAD-0020.1	Phrase the title in terms of the action that the user can perform with the dialog	Recommended	High
RAD-0020.2	Locate the title in a sufficiently prominent position	Mandatory	High
RAD-0020.3	Locate the title in the top left-hand corner of the dialog	Recommended	High

RAD-0030	Feature all the global function buttons in a single location	Recommended	High
RAD-0030.1	Locate all the global function buttons horizontally adjacent to each other	Recommended	Medium
RAD-0030.2	Label all the global function buttons and phrase the labels in terms of the actions that the user will perform	Recommended	Medium
RAD-0040	Visually deprecate those global function buttons that cannot be activated at the time of viewing by greying them out	Mandatory	High
RAD-0040.1	Provide a common point of reference (for example, a banner) that spans both the list display and the input field set so that the clinician understands the relationship between the entry field set and the final list display	Recommended	Medium
RAD-0040.2	Within the ADR risk entry dialog clearly communicate what information will appear immediately as a line in the ADR summary list display after the new risk is saved	Recommended	High
RAD-0040.3	Provide a banner in the input field set that looks like a line in the risk list display, and in which data will populate as the user enters data into the fields below. This will emphasise what data will be visible at the top level of the display and what will be initially hidden.	Recommended	Medium
RAD-0040.4	Feature similar formatting between the banner and a selected line in the ADR summary list	Recommended	Medium
RAD-0040.5	Display the causative agent in the banner following its entry into the fields below	Recommended	Medium
RAD-0040.6	Display the reaction types in the banner following their entry into the fields below	Recommended	Medium
RAD-0040.7	Highlight the data that the user enters that will be displayed at the top level (that is, immediately visible) in the ADR list display	Recommended	Medium
RAD-0050	Communicate to the user that the fields relate to the action of adding a new risk	Mandatory	High
RAD-0060	Provide a brief prompt that outlines the instructions for entering the risk	Recommended	High
RAD-0060.1	Provide a brief prompt that communicates the purpose of recording the risk in the summary, namely that it will warn other clinicians of the risk.	Recommended	High
RAD-0060.2	The prompts that relate to the purpose of, and instructions for, recording the risk may disappear once the user starts entering the information	Recommended	Low
RAD-0060.3	The prompts that relate to the purpose of, and instructions for, recording the risk may be located in the banner	Recommended	Low
RAD-0070	The user must be able to always access the prompting information in the form of an on-screen help feature	Recommended	Low

Usage Examples



Feature a title which communicates the purpose of the dialog

Phrase the title in terms of the action that the user can perform with the dialog

Locate the title in a sufficiently prominent position

Locate the title in the top left-hand corner of the dialog

Communicate to the user that the fields relate to the action of adding a new risk

Feature all the global function buttons in a single location

Locate all the global function buttons horizontally adjacent to each other

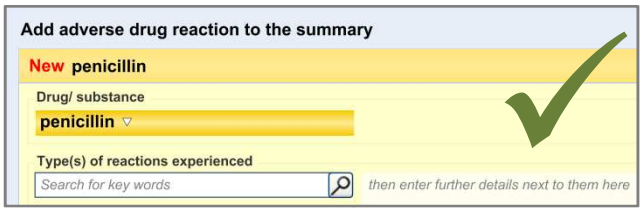
Label all the global function buttons, and phrase the labels in terms of the actions that the user will perform

Visually deprecate those global function buttons which cannot be activated at the time of viewing (grey out)

Provide a common point of reference (for example, a banner) that spans both the list display and the input field set so that the clinician understands the relationship between the entry field set and the final list display.

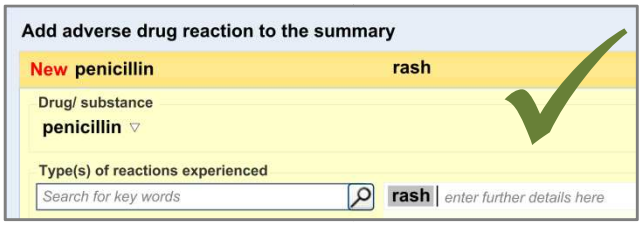
Provide a banner in the input field set that looks like a line in the risk list display and in which data will populate as the user enters data into the fields below. This will emphasise what data will be visible at the top level of the display and what will be initially hidden.

Provide a brief prompt that outlines the instructions for entering the risk. The prompts that relate to the purpose of, and instructions for, recording the risk may be located in the banner



Display the causative agent in the banner following its entry into the fields below

Within the ADR risk entry dialog clearly communicate what information will appear immediately as a line in the ADR summary list display after the new risk is saved



Display the reaction types in the banner following their entry into the fields below

Within the ADR risk entry dialog clearly communicate what information will appear immediately as a line in the ADR summary list display after the new risk is saved

Feature similar formatting between the banner and a selected line in the ADR summary list

Highlight the data that the user enters that will be displayed at the top level (that is, immediately visible) in the ADR list display

Rationale

Design Analysis:

Our analysis showed that providing a title in the dialog would orient the user in terms of what they need to do in the dialog and where they are in the clinical noting process. It also indicated that providing titles that refer to the action to be performed by the user in the dialog will be easier to understand than titles that contain other types of phrase.

Following early design exploration of the ADR entry dialog, clinicians and UI experts indicated that, owing to the fact that creating an ADR summary electronically is a new and unfamiliar concept (in secondary care), the first-time user could be confused as to what they should enter on the screen. Additionally, it was deemed appropriate to communicate to users the purpose of entering this information, in the form of prompts, as this could help the clinician to determine what information to enter. Once the risk has been (or is being) recorded, the prompts are less useful and may contribute to on-screen clutter and, in this way, may be a distraction to the main task. This is especially pertinent if the same interface will be used for displaying the details in future. Therefore, the prompts may disappear once the user starts entering the information.

Although it is good UI practice to provide a control that allows the user to 'undo' the entry or editing action that they have just performed, featuring the control in the entry dialog was considered confusing and risky: typically 'undo' is handled at a more global level in applications. Therefore, the guidance recommends that if the application features an 'undo' and 'redo' control, these controls should apply to the ADR entry dialog and the actions performed within it.

Vertical space should be used sparingly in this design, given the number of stacked fields in the body of the dialog. Therefore a horizontal arrangement of the global function buttons is more appropriate in this situation.

Our analysis showed that providing labels that describe the action (to be performed by the user) that the control will execute are easier to understand than labels which contain other types of phrase. It is also good usability practice to feature consistency in the phrasing of labels and this action label is consistent with other action labels, including 'Add', 'Close', 'Cancel' and 'Finish'.

A key concern is that the user is unsure of how what they are entering will eventually be displayed. This could lead to them entering information in a suboptimal fashion, for example, if they decide not to enter keywords describing the type of reaction associated with the risk. Also, navigationally, it is important that, if the user clicks on a row to view more details, they can see that the details in the ensuing dialog relate to the row they just clicked. Finally, although the team considered showing the whole dialog within the ADR summary list, this was not deemed practical due to space considerations and issues of clutter. Therefore, a common point of reference that links the display and the input or further details dialog should feature in the design. Our analysis showed that a banner which contains the same information as is (or will be) displayed on the first level ('LEVEL 1', according to the document *Design Guidance – Displaying Adverse Drug Reaction Risks* **{R17}**) in the ADR risk list could provide this point of reference in the simplest manner.

Desk Research:

According to the RCP Health Informatics Unit (in *Validating Clinical Requirements for information systems in secondary care (VCR): Detailed Clinical Requirements (DCR)* **{R18}** (section 2.10.1)), applications should "provide on-line help for new and experienced users". Therefore, the guidance proposes that the UI provides detailed prompts to help the user to complete the dialog. These prompts may disappear after the user has entered information into the relevant fields. The current guidance does not cover how this online help can be accessed by the user after the initial prompts have disappeared from the screen, but it is clear from the DCR that this facility should be provided.

A quick best practice review of popular applications showed that typically dialog titles are located at the top of the dialog, and left or centre-justified. Given the small amount of space available in the current dialog (a space that could shrink, given competing demands from other screen areas in the application), the default option should be to locate the title in the top left-hand corner. This is consistent with studies that have shown that users' eyes tend to direct initially to that area of the screen, described earlier in this document **{R15}**.

It is good UI practice to locate the title of a dialog in a sufficiently prominent position, but one which does not affect the fields that the user must address. This gives the user feedback that they have selected the correct option to initiate the entry process. Failure to locate the title in a sufficiently prominent position could mean that the user does not see it and assumes that they are in a different dialog.

Locating all command buttons, which comprise alternative actions, in the same area of the screen is good UI design practice, as this allows the user to quickly and easily see the options that are available to them. The Gestalt principle of 'proximity' suggests that items that are close together are perceived as belonging to a common group if they are located sufficiently close to one another in relation to the other screen elements.

User Research and Reviews:

Previous Microsoft Health CUIresearch has shown that clinicians are sometimes confused by the nature of the ADR summary list and consequently believe that it is a repository for full details about the reaction that the patient experienced. Therefore, it is important that the interface communicates that the entry fields relate to the action of adding a new risk.

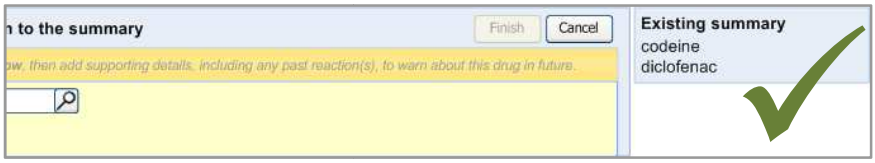
Hazard Risk Analysis Summary:

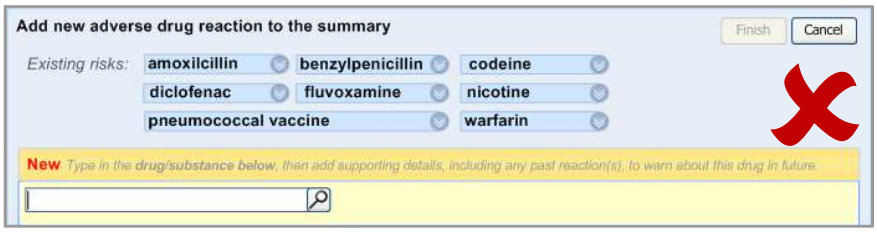
From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ What if the word 'risk' is misunderstood in the context of ADR 'Risk'?	▪ Our design avoids the use of the word 'risk'. Instead it distinguishes the 'risk' data from 'event' data by referring to the former data type as an entry in the summary
▪ Cannot record 'tests' (for example, skin-prick tests) with the reactions.	▪ The user should refer or link to notes outside of the summary (the details are out of scope) or make a note of the test in the free text field. The UI will enable this to happen. **Note** Skin-prick tests are fairly uncommon in addressing drug reactions
▪ Users interpret the ADR entry UI as conveying ADR history rather than ADR risk	▪ The dialogs now refer to the term 'adverse drug reaction summary' rather than 'adverse drug reaction risks'.

3.2.3 Displaying Existing Reaction Risks

It is important that the clinician can see the salient information from the existing ADR risk statements (namely the causative agents) before and during the entry of a new ADR risk, as knowledge of these other risks may influence how the clinician expresses the new risk. For example, if the clinician was entering an ADR to ampicillin, and they noticed that the patient has an existing ADR risk to flucloxacillin, they may decide to record a risk to Penicillins (the class of drug), taking care to justify this risk entry and refer to both the ampicillin and flucloxacillin in the associated justification field.

ID	Description	Conformance	Evidence Rating
RAD-0070	Allow the user to access the existing reaction risks without leaving the dialog	Mandatory	Medium
RAD-0070.1	Where space allows, display all existing reaction summaries simultaneously at the time of displaying the ADR input fields.	Recommended	Medium
RAD-0070.2	Provide a label or header for any list of existing ADR risks	Mandatory	High
RAD-0070.3	Display the existing ADR risks stacked vertically in any list of existing reaction summaries	Recommended	High
RAD-0070.4	Display the current drug risks immediately to the right of the ADR risk entry field set	Recommended	Low
RAD-0080	Warn the user if they are entering a drug that has already been entered	Mandatory	High
Usage Examples			
		Allow the user to access the existing reaction risks without leaving the dialog Display the existing ADR risks stacked vertically Display the current drug risks immediately to the right of the ADR risk entry field set	



Do not display the existing reactions in a tiled arrangement

Rationale

Design Analysis:

Scenario analysis has shown that it is a patient safety risk for the user to enter a new reaction risk without being aware of the existing ADR risks as the presence of an existing risk may affect the optimum choice of drug for the risk being entered. For example, if the user entered 'amoxicillin' when a risk to 'ampicillin' is already on the list this would be suboptimal compared to updating the amoxicillin risk to one of 'penicillin'.

Analysis also showed that failure to provide an appropriate label could leave open the possibility of the user misinterpreting this list. For example, if there were only a single other risk listed, they may think that the system was proposing that the user record this risk in the current encounter.

Owing to a shortage of vertical space, due to the other screen elements in the dialog, the most efficient location for the existing drug risks is immediately adjacent to the main dialog. Our analysis suggested that locating the list immediately to the left could be too distracting for the task in hand. Locating the list immediately to the right of the main dialog may be sufficiently noticeable but not too distracting.

Desk Research:

Best practice indicates that users can more quickly and effectively scan and find items that are stacked vertically than those which are arranged horizontally **{R19**, **R20}**.

User Research:

In user testing, we compared a number of designs where existing risks were arranged in a number of configurations, including vertically stacked and horizontally arranged (and wrapped). Although users showed evidence of being able to spot drugs within both arrangements, they indicated a preference for vertically stacking the risks.

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

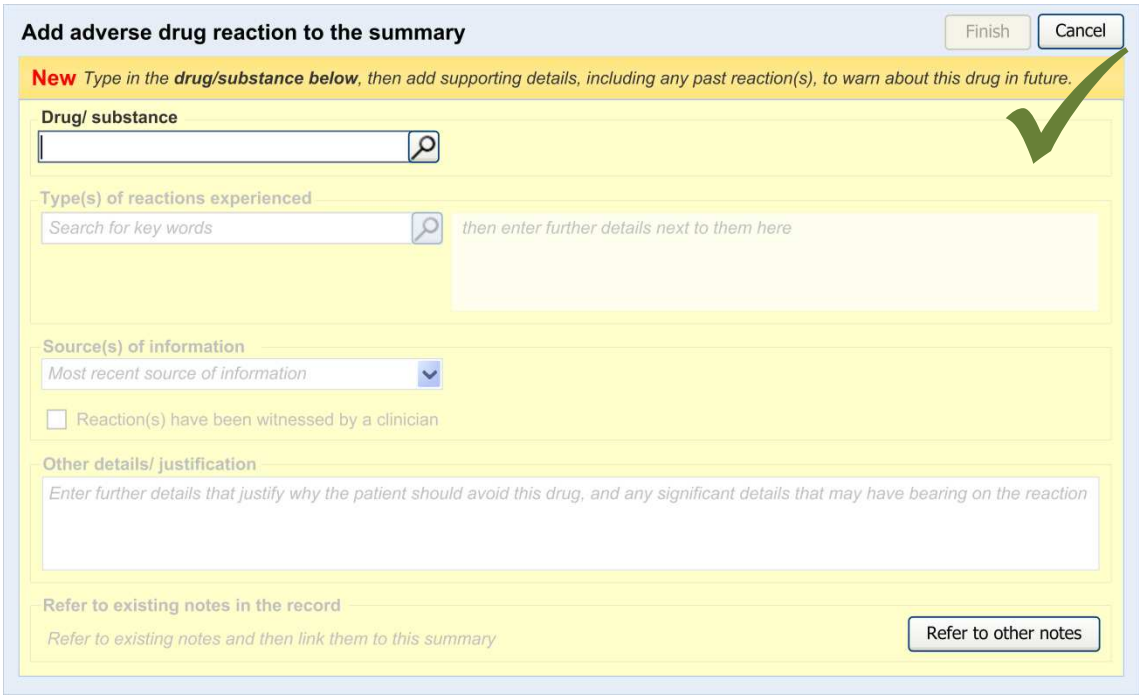
Potential Hazards:	Mitigations:
▪ Clinician enters a drug that is similar to or the same as an existing drug risk	▪ Provide a summary of existing ADR risks ▪ Provide a mechanism that identifies exact duplicates and warns the clinician that they are entering a duplicate

3.2.4 Entry Field Ordering and Tabbing

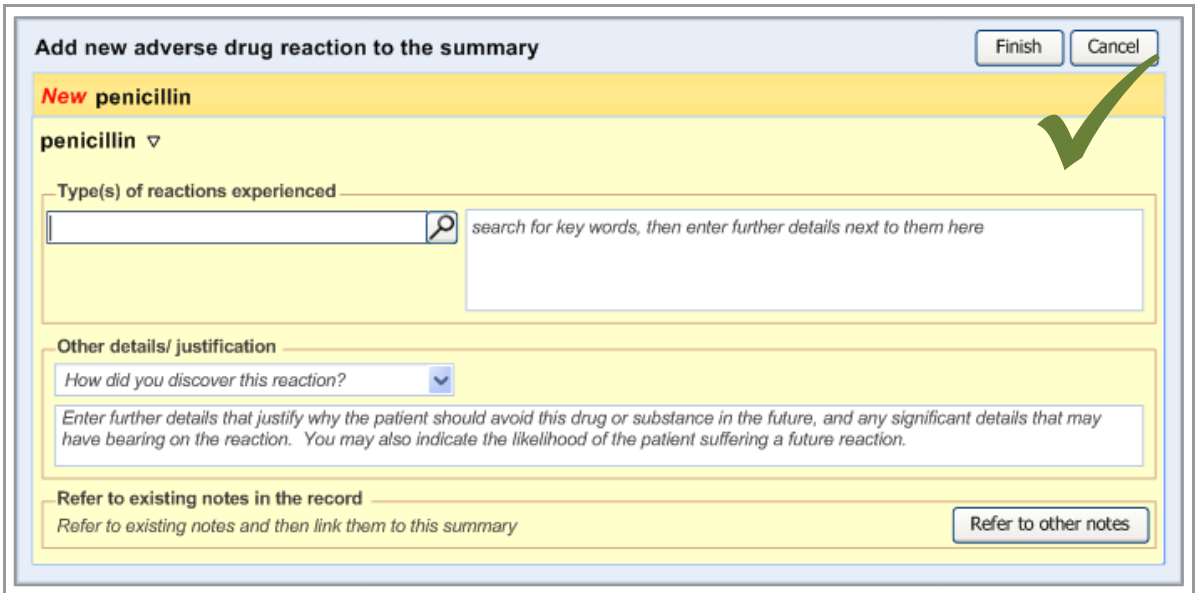
The order in which the entry fields are visually arranged, and the order in which the focus navigates through the action of keyboard tabbing, is important as it can influence whether fields are completed or not. Accordingly, this section of the guidance describes how the ordering and tabbing should be arranged to reduce such errors.

ID	Description	Conformance	Evidence Rating
RAD-0090	Disable all fields, except for the causative agent, until the causative agent field has been completed	Recommended	High
RAD-0100	After the causative agent field has been completed, enable the remaining fields	Recommended	High
RAD-0110	If the user has entered data into the causative agent field, plus any other fields, and then removes the data in the causative agent field, the user must be warned that, without a causative agent, the risk will not be saved and, accordingly, will not be displayed in the list	Mandatory	Medium
RAD-0120	Automatically move the focus into the causative agent field upon opening the dialog	Recommended	High
RAD-0130	If the causative agent field is not completed, the tab order takes the user to the 'Cancel' button (that is, the point of exit from dialog)	Recommended	Medium
RAD-0140	After the user has entered a causative agent, the system must provide a control that allows the user to leave the dialog with the risk retained by the system and/or committed to the record.	Mandatory	High
RAD-0150	Feature a consistent and logical tabbing order that is reflected in the left-to-right, top-to-bottom visual ordering	Mandatory	High
RAD-0150.1	The tabbing order will follow the order of priority: causative agent, reaction types, source of information, 'clinician witness reaction' and then justifications and details	Recommended	High

Usage Examples

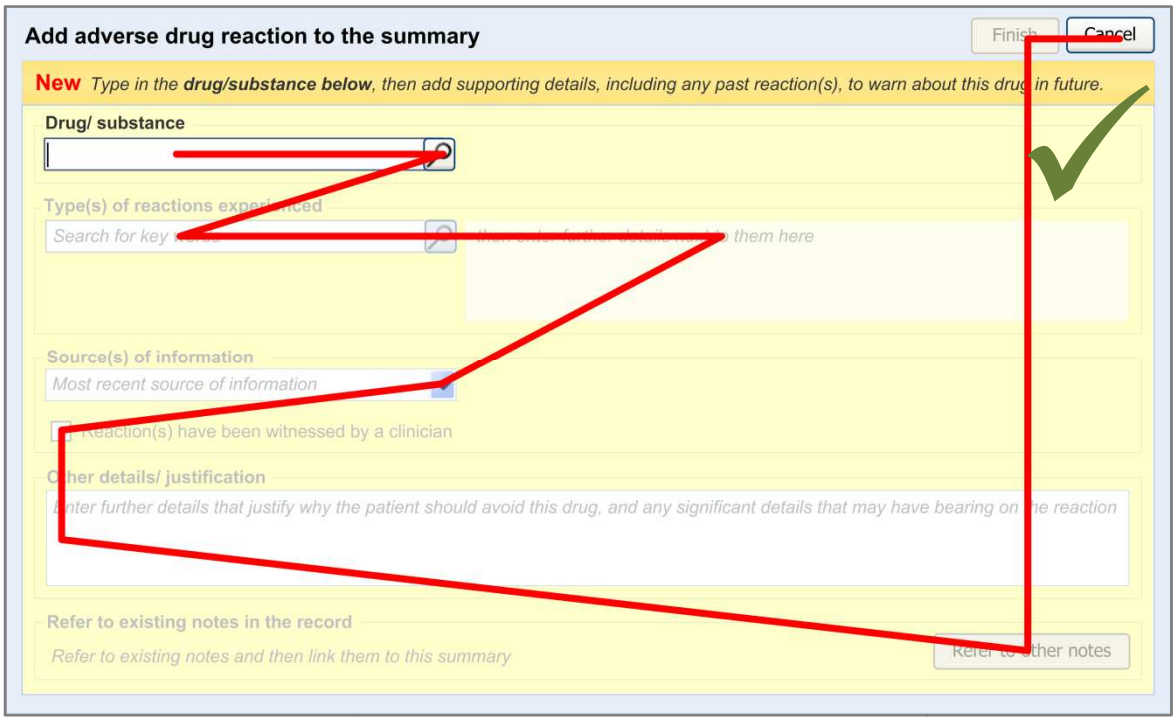


Disable all fields, except for the causative agent, until the causative agent field has been completed.



After the causative agent field has been completed, enable the remaining fields

After the user has entered a causative agent, the system must provide a control that allows the user to leave the dialog with the risk retained by the system and/or committed to the record



Feature a consistent and logical tabbing order which is reflected in the left-to-right, top-to-bottom visual ordering.

The tabbing order will follow the order of priority: causative agent, reaction types, source of information, 'clinician witness reaction' and then justifications and details.

Rationale

Design Analysis:

Following early design exploration of the ADR entry dialog, a clinical audience indicated that they found it difficult to see the focus of the dialog when all the fields have equal visual prominence. Therefore, the guidance proposes that those fields that cannot be completed at the time of viewing should be visually deprecated by being greyed-out.

Desk Research:

Best practice reviews of existing applications, both within and outside of the healthcare industry, has shown that the technique of greying out fields until they are editable is a common practice.

User Research:

In testing, users found that they could understand which fields to complete, although in early designs, where there were fields arranged horizontally, some users missed fields. Therefore, the current design arranges the fields vertically where possible.

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ User fails to record the causative agent of the ADR risk, namely the drug or substance	▪ The interface prevents the ADR risk being added to the summary if the causative agent field has not been completed
▪ User fails to record other details of the risk	▪ The tabbing order navigates the user through the other entry fields before arriving at the command buttons (including 'Finish')

3.2.5 Entering the Causative Agent

This section of the guidance covers the action of entering the causative agent of the ADR risk, namely the drug or substance that is believed to provoke a reaction in the patient. The illustrations in this section largely feature design aspects that are currently being explored (further details of these design aspects can be found in section A.2).

This section only covers those guidelines that are specific to the recording of an ADR causative agent and does not cover more general design aspects, which are currently undergoing exploration. The reader is advised to refer to section A.2 and to the document *Design Guidance – Terminology – Matching* **{R6}**.

The user is expected to type in all or part of the name of the drug that they believe provokes ADRs in the patient. The system then returns a list of matched drug names. The trigger for the return of the matches can be automatic ('progressively' matching terms as the user types in letters) or it can be user-triggered (either by clicking a button or 'Enter'). The user then selects one of the matched terms.

This causative agent term will be automatically 'post-coordinated' with the concepts 'propensity to adverse reactions to drug' (SNOMED CT ID 419511003), or 'propensity to adverse reactions to substance ', if the causative agent term is identified to fall within a non-drug subset. These concepts will be connected by the attribute concept 'has causative agent' (SNOMED CT ID 246075003)[10]. This is consistent with guidance provided by the NPfIT Standards Consulting Group **{R12}**.

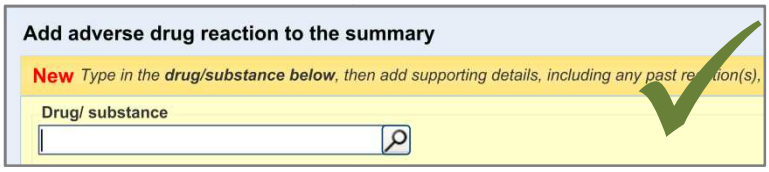
In addition to the user explicitly entering the causative agent, the system will also automatically record the time and date of the entry and the author who entered it (from their login credentials).

[10]Further details about SNOMED CT post-coordination can be found in the International Health Terminology Standards Development Organisation, SNOMED Clinical Terms User Guide **{R21}**: http://www.ihtsdo.org/fileadmin/user_upload/Docs_01/SNOMED_CT_Publications/SNOMED_CT_User_Guide_20080731.pdf

This information will combine with the causative agent and the source and justification free-text data to constitute the ADR risk statement.

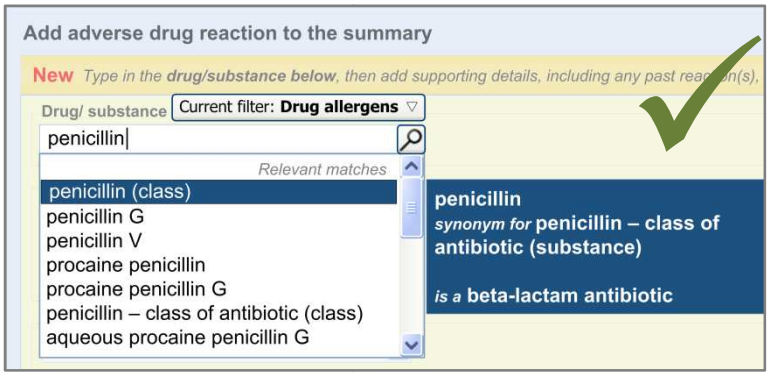
ID	Description	Conformance	Evidence Rating
RAD-0160	Ensure that any appropriate labels for the subsets that will filter the matching process are displayed as the user is entering either the causative agent or the reaction types	Mandatory	Medium
RAD-0170	Display encoded causative agent text in bold	Mandatory	Medium
RAD-0190	The system should identify whether the causative agent that the user has entered is a drug or a non-drug substance. It should post-coordinate drug concepts with concepts 419511003 : 246075003, and non-drug substance concepts with concepts 418471000 : 246075003	Recommended	High
RAD-0191	If a term is not recognised, the system will warn the clinician that the term has not been recognised, but will allow them to enter it as free text	Recommended	Medium

Usage Examples

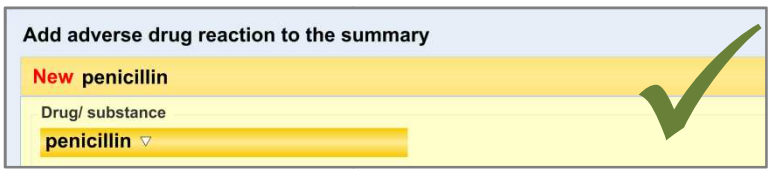


Present the user with a blank text field into which they can type the causative agent of the ADR risk. For details see the document *Design Guidance – Terminology – Matching* **{R6}**

Ensure that any appropriate labels for the subsets which will filter the matching process are displayed as the user is entering either the causative agent or the reaction types



After the user has typed three letters (or has clicked the 'search' icon) the system matches the text against terms in SNOMED CT, constrained by relevant subsets. For details see the document *Design Guidance – Terminology – Matching* {**R6**}



Display encoded causative agent text in bold

Rationale

Design Analysis:

An ADR risk (propensity) could be expressed in SNOMED CT in a number of ways. For example, an allergy to penicillin could be expressed as:

- Allergy to penicillin (91936005)
- Drug allergy (416098002): has causative agent (246075003): penicillin – class of antibiotic (6369005)

The former example shows the expression of this clinical concept as a 'pre-coordinated' term, whereas the latter example shows a 'pre-coordinated' expression. Ultimately they mean the same.

Our analysis showed that it is preferable to enter the causative agent according to the latter structure because:

- Not all drugs and substances have a corresponding pre-coordinated ADR or allergy concept in SNOMED CT. Mixing the two structures could lead to problems due to inconsistent data quality.
- The latter, 'normalised' version is easier to interpret by machine: decision-support systems have less processing to do using the SNOMED CT structure in order to identify the causative agent.

Additionally, previous Microsoft Health CUI research has shown that, for the purposes of displaying ADR risks, it is problematic to communicate whether the ADRs have been immunologically or pharmacologically mediated (that is, whether the reaction is allergic or not). Therefore, the guidance proposes that the codes that are used are:

- Propensity to adverse reactions to drug (419511003): has causative agent (246075003): + *drug concept*
- Propensity to adverse reactions to substance (418471000): has causative agent (246075003): + *substance concept*

However, given that the Microsoft Health CUI research also demonstrated that the word 'propensity' is not well understood, the guidance does not propose that the labels 'propensity to adverse reactions to…' are visible to the user. Equally, the guidance does not recommend that the label 'has causative agent' is displayed.

Desk Research:

Currently there is legacy data in existence that could contain pre-coordinated allergy or adverse reaction codes (such as "14L1. H/O Penicillin allergy" in Read 2; "Xa5sH Penicillin allergy" in CTV3; and "91936005 penicillin allergy" in SNOMED CT **{R12}**). However, the NPfIT Standards Consulting Group (SCG), recommend that "the handling of the allergy codes by systems **must** follow the post-coordinated model" **{R12}**. This would apply to the entry of new ADR risks.

The SNOMED CT codes 'propensity to adverse reactions to drug' (419511003) and 'propensity to adverse reactions to substance' (418471000) are both approved by the NPfIT SCG **{R12}**.

The post-coordination of these terms could be thus:

- Propensity to adverse reactions to drug (419511003): has causative agent (246075003): + *drug concept*
- Propensity to adverse reactions to substance (418471000): has causative agent (246075003): + *substance concept*

User Research:

In testing, users understood the process of matching a causative agent. In early designs there was some confusion as to the precise meaning of the term 'penicillin', namely whether it referred to the class of drug or a specific type of penicillin. The confusion lies in the fact that:

- Clinicians often use the term synonymously with specific types of penicillin (such as penicillin V)
- In SNOMED CT, the word 'penicillin' is a synonym for 'penicillin - class of antibiotic'

In the current design, the system identifies if the drug falls directly within a subset of 'drug class' concepts. If it does, the system will display the word 'class' in parentheses next to the term's label. Clinicians reviewing this design found it easy to understand, although they stressed that, once encoded, the word 'class' must remain next to the term.

However, a cleaner and safer approach to resolving this problem would be for the synonym to be changed within SNOMED CT, which is beyond the scope of the current guidance.

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ What if the clinician selects the wrong drug from a drop down list?	▪ The design not only automatically displays a definition for the drug at the point of its selection but also clearly displays the term back to the user in the dialog. This should mitigate against the user mistakenly selecting the wrong drug when they know the correct drug name. The design cannot mitigate against the user mistakenly choosing the wrong drug if they believe that that drug actually caused the reaction (as this is a clinical decision).
▪ What if visually or auditorily similar terms are presented or selected?	▪ The further SNOMED CT definition of a term is provided in a fly-out that automatically appears as the user is selecting the term from the list of results.
▪ What if an allergy is a non-drug substance?	▪ Users can change the subset filter to be able to choose from a set of non-drug substances. **Note** General allergy recording is out-of-scope.
▪ What if the allergy is recorded in an over specific way (for example, specific drug)?	▪ We cannot force the clinician to record the drug to a given level. The aim of the design guidance is to enable clinicians to record their notes, rather than to instruct them in the content of their notes. However, owing to the fact that the UI encourages the user to record the causative agent in encoded terminology, DSS can detect to which class a drug belongs
▪ What if the allergy is recorded in an under specific way (for example, drug class)?	▪ We cannot force the clinician to record the drug to a given level. The aim of the design guidance is to enable clinicians to record their notes, rather than to instruct them in the content of their notes. However, owing to the fact that the UI encourages the user to record the causative agent in encoded terminology, DSS can detect to which class a drug belongs
▪ What if the clinician does not recognise the generic drug from a drug brand name (or vice-versa)?	▪ Our design allows the clinician to enter a drug brand name, although it encourages users to enter the generic name, if known. The default subset does not include trade family names (brand names), but the user can expand the subset range to include them
▪ What if a term is misspelled and not recognised?	▪ The drug names and reaction types are to be encoded. We are recommending partial word matching or pre-fix matching to allow misspelled terms to be recognized. Also, if an application has the capability for progressive matching, this feature could help the user to get to the correct spelling
▪ What if a term is not recognised?	▪ If a term is not recognised, the system will still allow the user to enter it. The system will warn the clinician that the term has not been recognised, but will allow them to enter it as free text
▪ Singular and plural for penicillin have different implications	▪ Although in our design, if a drug term refers to a drug class, the word 'class' is displayed in brackets next to the term's label, we would recommend that this issue is solved by changing the terminology (SNOMED CT) in order that the synonym for 'penicillin - class of antibiotic' features the word 'class' in it or is removed
▪ Readers want to navigate to more details of specific reactions	▪ The design will allow readers to navigate to details of specific reactions, if such details have been linked to the summary

3.2.6 Entering Reaction Types

This section of the guidance covers the action of entering the types of adverse reaction that have been provoked in the patient after taking the drug or substance. It is worth emphasising that the clinician is only expected to enter brief details of the types of reaction that the patient has suffered, rather than providing a detailed account of an examination of the patient. Detailed notes of the reaction event(s) suffered by the patient will have been fully documented when the reaction occurred, and are likely to be elsewhere the patient's record, but not in the ADR summary list. Instead, the clinician is expected to summarise the most significant reactions, ideally as single words or phrases.

The illustrations in this section largely feature design aspects that are currently being explored (further details of these design aspects can be found in section A.3. This section only covers those guidelines that are specific to the recording of types of adverse reaction and will not cover guidelines for general terminology encoding, for which the reader is advised to refer to APPENDIX A and to the document *Design Guidance – Terminology – Matching* **{R6}**.

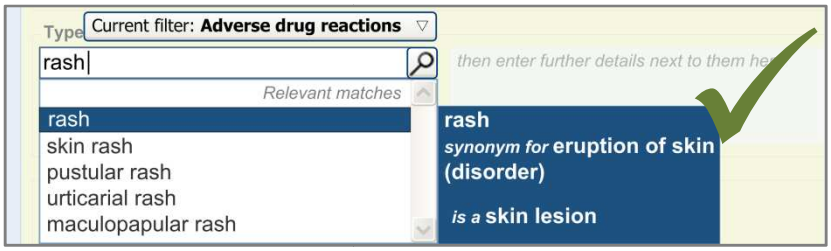
The clinician is expected to enter each reaction type in the same way as for the causative agent, except that, when the clinician selects a reaction type, the encoded term is displayed in the text box to the right of the search field and the search field becomes blank. At this point, the clinician may tab to the text field in order to add additional text to the encoded term or may enter an additional reaction type. In this way, the clinician may enter several types of reaction that the patient has suffered in response to taking the drug.

ID	Description	Conformance	Evidence Rating
RAD-0200	Provide one or more controls for entering the types of past reaction that the patient has had to the causative agent	Mandatory	Medium
RAD-0210	Provide one or more text entry fields for entering or selecting reaction keywords or key phrases that summarise the past reactions to the causative agent	Mandatory	Medium
RAD-0220	Allow for multiple reaction keywords or key phrases to be entered for a single drug	Mandatory	medium
RAD-0230	Encourage the user to enter at least one encoded SNOMED CT concept for each distinct reaction. This will be the keyword or key phrase for that reaction	Mandatory	Medium
RAD-0240	Provide one or more fields for entering elaborating or qualifying text around each reaction keyword or key phrase	Recommended	Medium
RAD-0250	Elaborating text may comprise either (i) free text or (ii) encoded text. If the text is encoded, it must be linked to the keyword or key phrase by the encoding terminology model or a clinical data model	Recommended	Medium
RAD-0260	If the system identifies any words which fundamentally change the meaning of the keyword or key phrase the system should warn the user These 'dangerous' words may include expressions of negation, expressions of reduction, or references to family history or other patients	Mandatory	High
RAD-0270	Ensure that the system sufficiently communicates to the user which elaborating text applies to which reaction keyword or key phrase	Mandatory	High
RAD-0280	Clearly and appropriately label the section for entering the reactions	Mandatory	High
RAD-0280.1	Label the reactions section 'Type(s) of reactions experienced'	Recommended	Medium
RAD-0290	Allow the entry of negation with the reaction keywords. This will post-coordinate the reaction term with 'known absent'	Recommended	High

RAD-0300	Allow the entry of severity qualifiers with the reaction keywords. This will post-coordinate the reaction term with the appropriate severity	Recommended	High
RAD-0310	Provide prompting text to instruct the clinician what to do in the fields	Recommended	High
RAD-0320	Allow the clinician to delete the reaction keyword or key phrase	Mandatory	High
RAD-0330	If the clinician clicks on the encoded reaction keyword or key phrase, reveal a button to delete the reaction	Recommended	Low

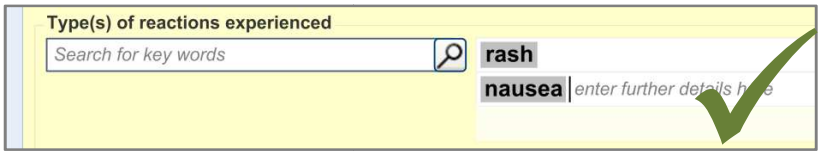
Usage Examples

Provide one or more controls for entering the types of past reaction that the patient has had to the causative agent



Encourage the user to enter at least one encoded SNOMED CT concept for each distinct reaction. This will be the keyword for that reaction

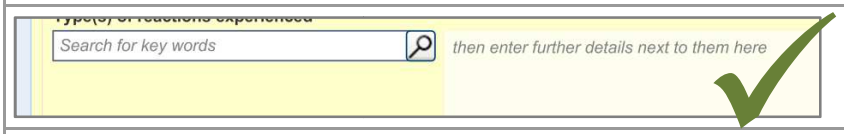
Once the term has been matched, it will appear in the right-hand field (see section A.3)



Allow for multiple reaction keywords to be entered for a single drug (see section A.3)

Allow the entry of negation with the reaction keywords. This will post-coordinate the reaction term with 'known absent'

Allow the entry of severity qualifiers with the reaction keywords. This will post-coordinate the reaction term with the appropriate severity



Provide prompting text to instruct the user what to do in the fields

If the clinician clicks on the encoded reaction keyword or key phrase, reveal a button to delete the reaction

Rationale

Design Analysis:

In the phrase 'Type(s) of reaction experienced', the word 'Type(s)' has been included in order to emphasise that, although the risk is based upon the evidence of past reactions, these reactions are not specific to a particular time as they are an ever-present risk (if the patient takes the drug in question). Also, in the unlikely event that the patient has reacted in the same way to the same drug, but on different occasions, it is not helpful to list the reaction twice in the summary. This should be avoided by using the more abstract phrase 'Type(s) of reaction experienced'. This should also emphasise the distinction between the current ADR risk statements and statements that may exist elsewhere in the record that document the actual reaction events in detail.

Desk Research:

The latest design is supported, in part, by the document *Design Guidance – Terminology – Matching* **{R6}**, which outlines how to match the text typed in by the user against SNOMED CT concepts from within a specially chosen subset.

The requirement for entering multiple past reactions is supported by the Design Guidance – *Displaying Adverse Drug Reaction Risks* **{R17}**.

User Research:

Initial designs featured a single field into which the user could enter the reaction. If users wanted to add another reaction, they had to click a button that would add another blank field into which they could enter another reaction type. However, testing showed that, although users understood the process of typing a word and selecting the matched term, they did not understand the mechanism for adding multiple reactions. The latest design has been reviewed by clinicians who did not find that the design presented any risks to patient safety. However, this design has not been fully user tested, and therefore confidence in this mechanism is low.

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ All users request reaction severity ranking that can be used to sort the ADR	▪ On balance, a structured grading of severity that relates to the drug risk as a whole has been deemed to be potentially unclear and ambiguous. The problem is that the rating of severity of a past reaction is quite subjective. Attempts to rate the severity of a future reaction is quite impossible. This is supported by a study that has shown that most fatal drug anaphylactic reactions are unpredictable: in the study, over four-fifths dying from drug anaphylaxis had no previous indication of their allergy **{R22}**. Allowing clinicians to rate either the severity of a future reaction or the likelihood of the patient will suffer it is therefore unnecessary and actually could be misleading and dangerous, if it incorrectly influences the action of another clinician. Therefore severity of reactions are (i) implied by the type of reaction and (ii) can be expressed as encoded (post-coordinated) qualifiers of the reaction term that the clinician enters (for example, 'severe rash'). This has been supported by user research conducted by the Microsoft Health CUI team (see the document *Design Guidance – Displaying Adverse Drug Reaction Risks* **{R17})**.
▪ Some users will omit to enter reaction keywords in the reactions field	▪ The fields have been located in a prominent location in order to encourage the user to enter reaction types (if known). **Note** This is not mandatory data as the reaction may be unknown.

3.2.7 Elaborating the Encoded Reaction Type Keywords

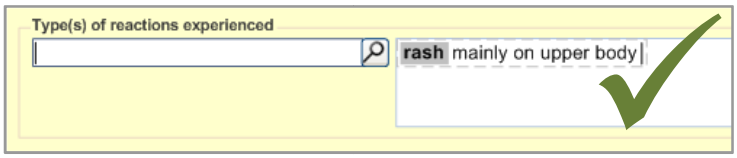
This section of the guidance covers the action of entering additional information to an encoded reaction type term. For example, the clinician may want to add some additional description to the reaction, which they feel is significant enough to include in the summary.

This text would be packaged up with the keyword to which it relates to form a clinical statement. Therefore, it is imperative that the UI clearly shows which text belongs with which keyword.

The general mechanism for this 'elaboration' action is being covered in more detail in ongoing design work (see section A.3) and, in part, by the document *Design Guidance – Terminology – Elaboration* **{R23}**.

ID	Description	Conformance	Evidence Rating
RAD-0340	Allow the user to add additional free text that elaborates on the reaction keywords	Recommended	Medium
RAD-0350	Enable the free text elaboration to be strongly visually associated with a specific reaction keyword	Recommended	Low
RAD-0360	Upon its saving and subsequent retrieval, the free text elaboration should be treated as part of a unit in conjunction with the reaction keyword or key phrase. These components can be used to populate a clinical statement message pattern (see section **2.2**).	Recommended	Medium
RAD-0370	Words corresponding to severity or certainty (and that are recognised SNOMED CT qualifiers) that are entered as free text should be highlighted and offered to the user for encoding.[11] **Note** This guideline is only recommended for applications with the technological sophistication to handle text parsing of free text (see the document *Design Guidance – Terminology – Matching* **{R6}** for details)	Recommended	Low

Usage Examples



Allow the user to add additional free text that elaborates on the reaction keywords

Enable the free text elaboration to be strongly visually associated with a specific reaction keyword

Words corresponding to severity or certainty (and that are recognised SNOMED CT qualifiers) that are entered as free text should be highlighted and offered to the user for encoding

[11] This follows the *Design Guidance – Terminology – Elaboration* **{R23}** document.

Rationale

Design Analysis:

Analysis has shown that clinicians may wish to type in more description than a single SNOMED CT concept or expression in order to express the true nature of the reaction that the patient experienced. For example, they may wish to indicate the location of a rash if they feel that is a significant detail. They may also wish to enter that they are unsure if the patient's reaction was a direct result of the drug. Although this would not be a forced structured choice, it would appear to be a valid comment that the clinician wishes to make in relation to the reaction. As this is not the proper repository for a detailed description of the patient's reaction, the clinician should not be offered prompts or dedicated fields in which to type detailed examination notes.

User Research:

Initial user research tested designs in which the user had to select an encoded term or phrase and then continue typing in the field if they had any further (free text) notes. However, users did not find this design easy to understand. Therefore, the design has been updated to feature a fixed field into which the user can insert the encoded keywords (using the search field) and then add additional free text. This action is communicated to the user by a text prompt that appears in the right-hand field until data is entered into it. As each encoded keyword is inserted only on a new line, the clinician is encouraged to enter the elaboration immediately after it (but they can carry on typing onto a new line). This new design has been reviewed by a panel of clinicians who did not deem this control to be a risk to patient safety. However, to date, it has not been fully user tested.

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

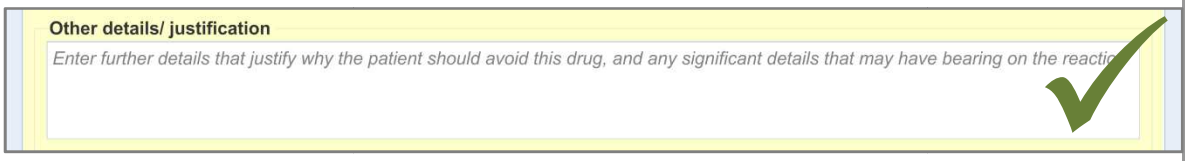
Potential Hazards:	Mitigation:
▪ The user elaborates the keyword with text that effectively negates the keyword	▪ The system should warn the user if it identifies expressions of negation in the elaboration text ▪ The elaboration text will be packaged with its associated keyword as a single clinical statement. Therefore, if the clinician decides to leave the negating free-text in, this will be partially mitigated by the fact that the accompanying text will often be accessed at the same time as the keyword (although it still constitutes a risk)

3.2.8 Adding Further Details and Justification

This section of the guidance covers the action of entering additional free text that (further) justifies the clinician's belief that the drug or substance constitutes a significant risk to the patient in the future.

ID	Description	Conformance	Evidence Rating
RAD-0380	Allow users to enter text which justifies or adds further detail to the risk and which may apply to the overall risk	Recommended	High
RAD-0380.1	The user can type in as much text as they wish into the field (the field can start scrolling when the text exceeds the visible space)	Recommended	High
RAD-0390	Provide one or more text entry fields into which the user may type justification or further details pertaining to the risk	Recommended	Medium
RAD-0400	Justification text can comprise either free text or encoded text, depending upon the data model in place	Recommended	High
RAD-0410	The UI should identify any reaction keywords or key phrases that are typed into the justification field	Recommended	Medium
RAD-0410.1	The UI should communicate to the user that a significant reaction word (or words) has been identified in the text and that the user should enter this word in the 'Type(s) of reactions experienced' section	Recommended	Medium
RAD-0410.2	The UI should highlight significant reaction words or phrases with a coloured highlight	Recommended	Medium
RAD-0410.3	The UI should not highlight any reaction words that have already been matched in the 'Type(s) of reactions experienced' section	Recommended	High
RAD-0420	When there is no text in the justification field, display instructional text prompts in the field	Recommended	Medium

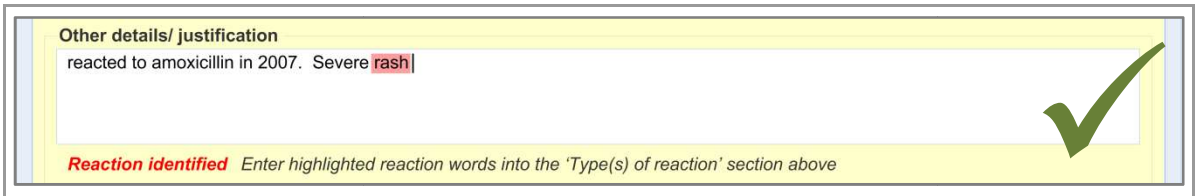
Usage Examples



Provide one or more text entry fields into which the user may type justification, or further details, pertaining to the risk.

When the field is devoid of data (or focus), the field contains prompting text.

Justification text can comprise either free text or encoded text, depending upon the data model in place.



The UI should identify any reaction keywords or key phrases that are typed into the justification field.

If the user enters text that relates to a reaction that has not already been entered in the 'type(s) of reactions experienced' section, the system warns them and instructs them to enter the term into the appropriate section. After entry in the appropriate section, the highlight and the warning disappear.

Rationale

Design Analysis:

Analyses indicated that in many situations there will be justification and details that the clinician wishes to enter that does not correspond to a reaction type. Therefore, a free text field is appropriate in this situation.

User Research:

User research showed that:

- Users felt it was clear what they could type into this field
- Users noticed the highlighted terms and why they were highlighted

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ What if vital contextual info such as route of medication, or reason for medication, is not entered?	▪ The precise details of an ADR event should be recorded elsewhere in the notes, as usual. If the clinician believes that it is a significant factor that must be flagged in a prominent location, he or she may add this as free text in the summary
▪ What if it is not clear that the justification area (text and callouts) relates to the new ADR (in dialogue box above) including 'More past reactions'?	▪ The current solution clearly indicates that the fields relate to the entry of a new ADR (that is, it is new to the summary)

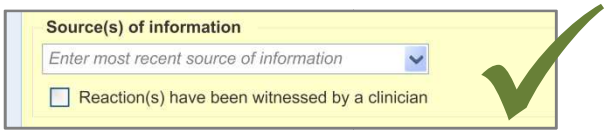
3.2.9 Specifying the Source of Information

This section of the guidance deals with how to allow the clinician to record the source of the ADR risk information.

ID	Description	Conformance	Evidence Rating
RAD-0430	Allow the user to specify a 'source' of the information displayed for the risk	Mandatory	High
RAD-0430.1	Allow the user to specify the most recent source of the risk information (namely, how they discovered the risk)	Recommended	Medium
RAD-0430.2	Provide a field for selecting the most recent source of the risk	Recommended	High
RAD-0430.3	Provide a drop-down list for selecting the source of the risk	Recommended	High
RAD-0430.4	Provide a suitable prompt in the 'source' field	Mandatory	High
RAD-0430.4.1	Provide the prompt 'Enter source of most recent information'	Recommended	Medium
RAD-0430.5	Within the drop-down list, present a set list of 'sources' of the risk (data to be determined by an appropriate clinical authority)	Mandatory	High

RAD-0430.6	Do not provide a default selection in the 'source' field	Recommended	High
RAD-0440	Provide a control that allows the clinician to specify that they know that a clinician has witnessed the patient reacting to the causative agent	Recommended	Medium
RAD-0440.1	The control that allows the clinician to specify that a clinician has witnessed a reaction should be a checkbox	Recommended	Medium
RAD-0440.2	If the user selects 'Clinician witnessed reaction' in the 'most recent source' drop-down, the corresponding checkbox becomes automatically ticked	Recommended	Low

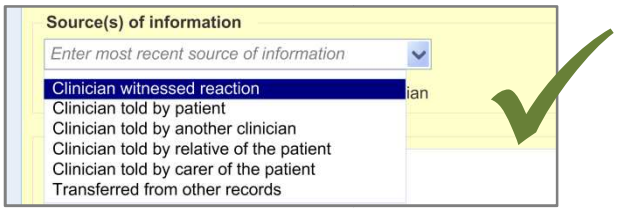
Usage Examples



Provide a control that allows the clinician to specify that they know that a clinician has witnessed the patient reacting to the causative agent

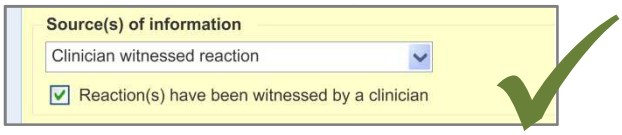
Provide a drop-down list for selecting the source of the risk. The control that allows the clinician to specify that a clinician has witnessed a reaction should be a checkbox

> **Note**
>
> By default, the 'source of information' field is blank until the clinician selects from it.



Allow the user to specify the most recent source of the risk information (namely, how they discovered the risk)

> **Note**
>
> The options displayed here are illustrative only.



If the user selects 'Clinician witnessed reaction' in the 'most recent source' drop-down, the corresponding checkbox becomes automatically ticked

Rationale

User Research:

Clinicians expressed how important it is to be able to record the source of the information. In particular, they stressed that it is important to know if a clinician actually witnessed a reaction. This is reflected in the design.

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ What if the allergy was a reported event (rather than observation)?	▪ Allow the user to enter the source of the information, such as whether it came from patient testimony or a reaction witnessed by the clinician

3.2.10 Displaying ADR Risk Details for the Clinician to Confirm

This section covers guidance relating to the system:

- Identifying where the clinician has noted details about an ADR event (for example, as part of a diagnosis)
- Presenting the clinician with a dialog that allows the clinician to create a corresponding entry in the ADR summary

This guidance assumes that a mechanism is put in place that can identify where an ADR event is being noted and then triggers a dialog accordingly. The current guidance only addresses the dialog itself (shown on the right in Figure 6), and not the triggering process.

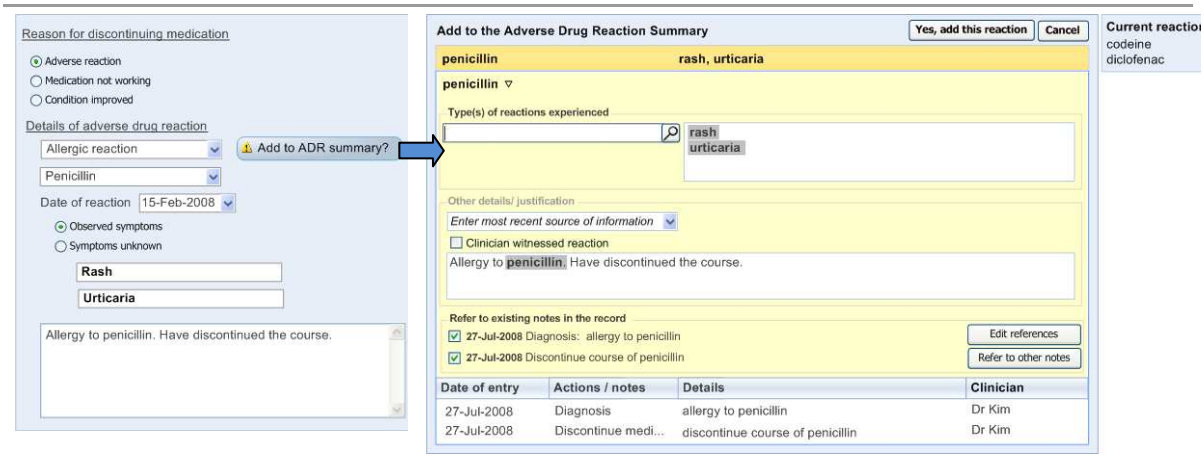
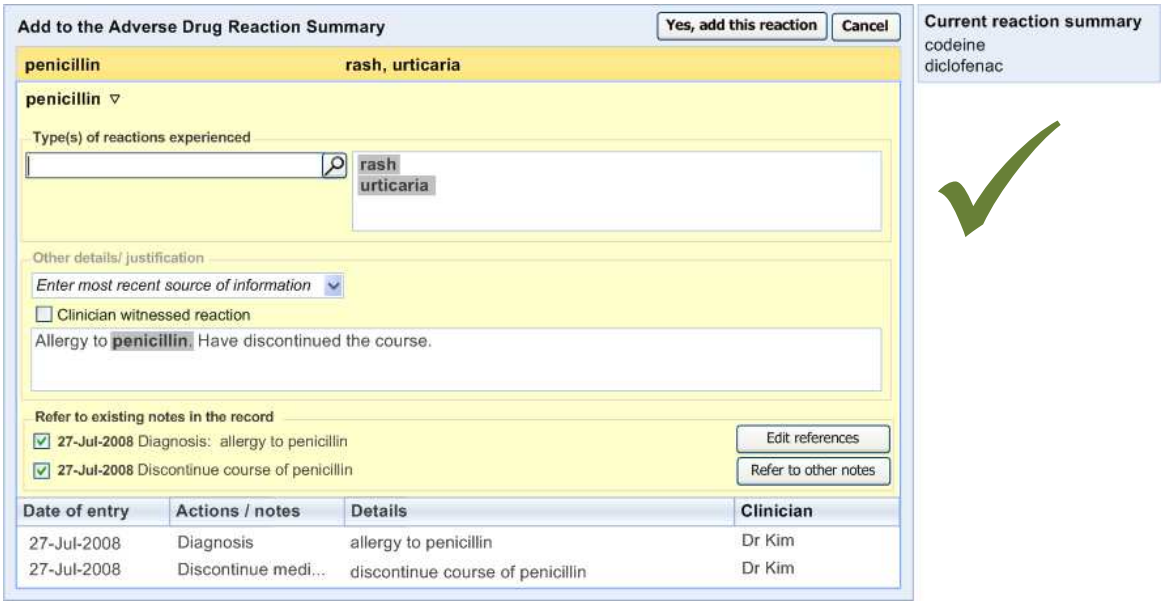


Figure 6: UI Triggers a Dialog for Entering an ADR Risk into the Summary

ID	Description	Conformance	Evidence Rating
RAD-0450	If, when the clinician is making a note entry, and the system has identified a potential ADR risk, it should display a dialog that allows the user to confirm that they believe it is a risk that should be displayed in the ADR risk list	Mandatory	High
RAD-0460	The dialog for confirming a potential ADR risk must feature an option to add the risk to the list (that is, it allows the user to confirm that they believe it to be a risk)	Mandatory	High
RAD-0470	The dialog for confirming a potential ADR risk must feature an option to ignore the risk (that is, not record the risk)	Recommended	Medium
RAD-0480	Locate the confirmation and non-confirmation options adjacent to each other	Recommended	Medium
RAD-0490	Clearly label both the 'confirm' and 'do not confirm' risk buttons	Recommended	Medium
RAD-0490.1	Label the 'confirm' button ‘Yes, record the risk’	Recommended	Medium
RAD-0490.2	Label the 'do not confirm' button ‘Cancel’	Recommended	Medium
RAD-0490.3	Ensure that the button labels are consistent with the dialog heading	Mandatory	High
RAD-0500	Locate the confirmation and non-confirmation buttons in the same area of the dialog as the function buttons in the other ADR risk dialogs (namely, the top right-hand corner)	Recommended	Medium
RAD-0510	Display all the details that will form the ADR risk to the user prior to their confirming the risk	Mandatory	Medium
RAD-0520	Display the details so that each field appears editable	Recommended	High

RAD-0530	Encourage the user to edit the displayed details if they feel that this action is appropriate	Recommended	Medium
RAD-0540	Display a 'selection' of the original notes from which the system identified the potential ADR risk (for example, the text which contained the term ‘allergy to penicillin’) These notes could be encoded or free text and could have been entered by a number of mechanisms, including by free text field or by a set of form fields	Recommended	Medium
RAD-0550	If they are known, prepopulate the fields in the 'risk confirmation' dialog with the: ■ Causative agent ■ Reaction type keywords	Recommended	Low
RAD-0560	If the 'selection' text comprises a 'narrative block', display it in the 'Justification/ Details' field and highlight the encoded text items	Recommended	Low
RAD-0570	Where data is not known by the system, feature a blank in the relevant field	Recommended	Medium
RAD-0580	Disable the ‘Yes, record the risk’ button if there is no causative agent entered into the appropriate field	Mandatory	High
RAD-0590	Following the confirmation of a risk, the dialog should provide clear feedback that the risk has been added to the ADR risk list	Recommended	High
RAD-0600	Following the confirmation of a risk, the dialog should automatically close and, in its place, reveal the ADR risk list	Recommended	High

Usage Examples



If, when the clinician is making a note entry, and the system has identified a potential ADR risk, it should display a dialog that allows the user to confirm that they believe it is a risk that should be displayed in the ADR risk list

The dialog for confirming a potential ADR risk must feature an option to add the risk to the list (that is, it allows the user to confirm that they believe it to be a risk)

Display all the details that will form the ADR risk to the user prior to their confirming the risk

Display the details so that each field appears editable

Encourage the user to edit the displayed details if they feel that this action is appropriate

Display a 'selection' of the original notes from which the system identified the potential ADR risk (for example, the text which contained the term ‘allergy to penicillin’)

These notes could be encoded or free text and could have been entered by a number of mechanisms, including by free text field or by a set of form fields

If they are known, prepopulate the fields in the 'risk confirmation' dialog with the:

- Causative agent
- Reaction type keywords

If the 'selection' text comprises a 'narrative block', display it in the 'Justification/ Details' field and highlight the encoded text items

The dialog for confirming a potential ADR risk must feature an option to ignore the risk (that is, not record the risk)

Locate the confirmation and non-confirmation options adjacent to each other

Clearly label both the 'confirm' and 'do not confirm' risk buttons

Label the 'confirm' button 'Yes, record the risk'

Label the 'do not confirm' button 'Cancel'

Ensure that the button labels are consistent with the dialog heading

Locate the confirmation and non-confirmation buttons in the same area of the dialog as the function buttons in the other ADR risk dialogs (namely, the top right-hand corner)

Rationale

Desk Research:

The NPfIT Standards Consulting Group **{R12}**, recommend that "the system **should** record an allergy event recording for each allergy event that the patient suffers"**.** In our interpretation, the term 'allergy' is being used synonymously with the more general concept of 'adverse reaction propensity'. This implies a (semi-) automatic process by which the system identifies where the clinician has documented an ADR event and then creates an accompanying ADR risk (which, in our design, could reside in the ADR summary). In the NPfIT paper, they expand this point by proposing that, if a patient's record contains an ADR event statement, then they should, in most cases, also have one corresponding allergy propensity (ADR risk), but that it may be reasonable to not have a corresponding ADR risk if the ADR event is not certain. They also propose that the existence of an ADR risk (that is, an ADR in the summary list) does not necessarily require the documentation of an ADR event. Finally, they make it clear that, although there could be multiple ADR events associated with a single ADR risk, there should be no duplicate ADR risks documented.

User Research:

Users understood this design in user testing.

Hazard Risk Analysis Summary:

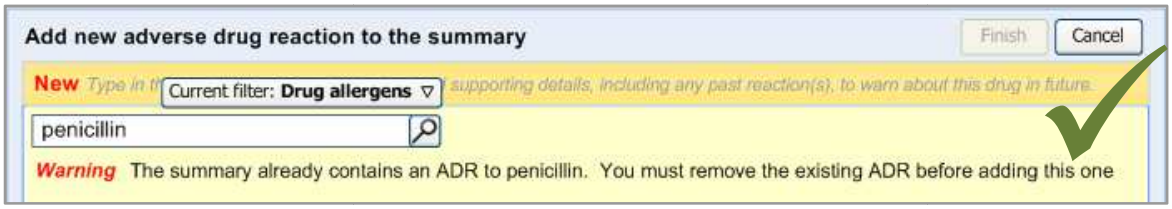
From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ Source of information cannot be known, then pre-filled, by the system	▪ The 'source of information' field is not pre-filled
▪ Confusion about 'Record ADR Risk' because it is already recorded in the clinical notes	▪ This label has been changed to indicate that the action involves adding information to the summary

3.2.11 Warning About Duplicating Risks in the Summary

ID	Description	Conformance	Evidence Rating
RAD-0610	Provide a warning if the user has entered a causative agent that is the same as the causative agent for an existing risk	Mandatory	Medium
RAD-0620	Communicate to the user that they must remove the existing risk before adding a new risk with the same causative agent	Recommended	Low

Usage Examples



Provide a warning if the user has entered a causative agent that is the same as the causative agent for an existing risk

Communicate to the user that they must remove the existing risk before adding a new risk with the same causative agent

Rationale

Desk Research:

The NPfIT Standards Consulting Group **{R12}**, recommend that, in representing allergies and adverse reactions information using messaging, the causative agent code should not be duplicated. They suggest that it is acceptable to feature entries for causative agents that are similar, such as penicillin and amoxicillin, but that they must have different causative agent codes. They go on to propose that systems "should prompt users if adding allergy propensities with duplicate causative agents" . Please note that this is **not** the same as recording instances of multiple reaction events that have occurred on different times, which is perfectly acceptable. Therefore, although we would only expect there to be a single risk to 'penicillin' recorded in the ADR summary list, within the 'Refer to existing notes' section we could see links to multiple reactions (for example, the patient experienced a rash in response to amoxicillin in 2001, then a severe rash to flucloxacillin in 2005).

Hazard Risk Analysis Summary:

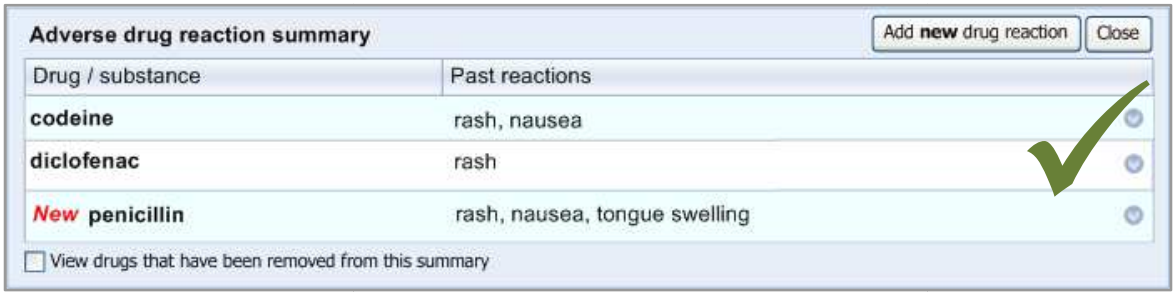
From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ What if the same risk is entered more than once?	▪ If the user attempts to enter the same risk twice, the system will warn them not to do this

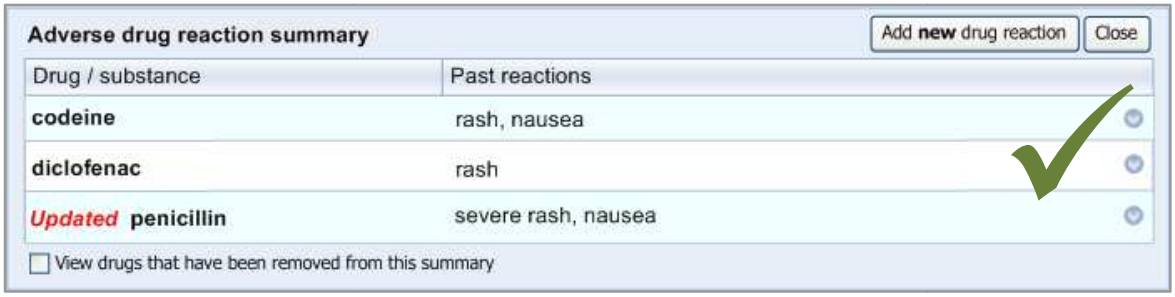
3.2.12 Feedback Upon Adding, Editing or Removing a Risk

ID	Description	Conformance	Evidence Rating
RAD-0630	Visually highlight any risks that have just been added or changed	Recommended	High
RAD-0640	Visually highlight any risks that have been newly added with the text 'New'	Recommended	Medium
RAD-0650	Visually highlight any risks that have been newly updated (edited) with the text 'Updated'	Recommended	Medium
RAD-0660	Provide the visual highlight immediately adjacent to the relevant ADR risk	Recommended	High
RAD-0670	Only display the visual highlight for the current viewing by the clinician. After the dialog has been closed and reopened, the visual highlight will no longer be presented	Recommended	Medium

Usage Examples



Visually highlight any risks that have been newly added with the text 'New'



Visually highlight any risks that have been newly updated (edited) with the text 'Updated'

Rationale

User Research:

Users noticed and understood the feedback messages, although some proposed that it was slightly unclear how long the message would remain visible and to whom.

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ It is unclear whether the new ADR has been successfully added to the ADR list without proactively navigating to it and viewing it	▪ The design currently features a feedback mechanism, whereby the ADR summary view is always shown after an ADR has been added to it. Additionally, in the immediate feedback view, a new or newly updated ADR risk is distinguished by a label ('New' or 'Updated')
▪ Text label 'New' has no clear reference point to event (new to system, new allergy) and time (when does something cease to be new)	▪ The label ('New' or 'Updated') will only appear in the immediate feedback view

4 Removing an Adverse Drug Reaction Risk from the Summary

4.1 Principles

The following key principles inform the guidance in this section:

- Clinicians should not delete notes from the record (with a few exceptions) but they can remove them from a summary
- Clinicians should explain why they believe that a particular drug no longer presents a significant risk
- Clinicians should be able to see what risks have been removed from the summary

4.2 Guidelines – Removing an Adverse Drug Reaction Risk

ID	Description	Conformance	Evidence Rating
RAD-0680	Provide a control that is easily accessible from the ADR risk list that initiates the process of removing an existing ADR risk	Mandatory	High
RAD-0680.1	Feature this removal control within the 'details' view of a risk	Recommended	Medium
RAD-0680.2	The removal control can be a button	Recommended	Medium
RAD-0690	Clicking the 'remove' button will remove all the details of the chosen risk (including medication, reaction types and justification details) from the active ADR summary list	Recommended	High
RAD-0700	Provide a hover-over message that explains to the user what will happen if they click the ‘Remove from list’ button	Recommended	Medium
RAD-0710	ADR risks that have been removed from the active ADR summary list should be accessible in a 'display deactivated summaries' mode	Mandatory	High
RAD-0720	Encourage the user to enter a reason for removing a risk	Recommended	High
RAD-0730	Upon removing a risk, the view should return to the ADR risk list	Mandatory	High
RAD-0740	Upon removing a risk, this risk will not appear in the ADR risk list	Mandatory	High
RAD-0750	Provide a confirmation message that explains the implications of removing the risk to the user and allows the user to choose whether to proceed with the removal or cancel the removal	Recommended	High
RAD-0750.1	The removal confirmation message should: ■ Outline which drug the user is about to remove and from where it will be removed (namely, the ADR risk list) ■ Explain that any related clinical notes will remain on record ■ Explain that clinicians will no longer be warned not to administer this drug by the system	Recommended	Medium
RAD-0750.2	In the removal confirmation message dialog, the options should be presented as two buttons	Mandatory	Medium
RAD-0750.3	The removal confirmation buttons should be appropriately labelled in words that are consistent with the wording of the confirmation question	Mandatory	High

Usage Examples

Provide a control that is easily accessible from the ADR risk list that initiates the process of removing an existing ADR risk

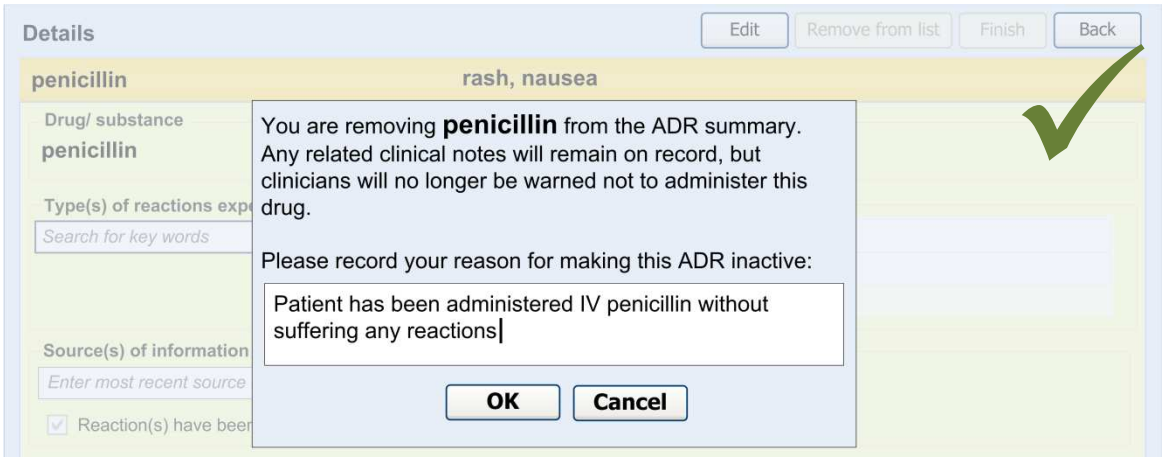
The user must open the 'details' view of a risk in the active summary list before removing it

Feature an option to remove an ADR from the active summary list within the 'details' view of a risk

The removal control can be a button

Clicking the 'remove' button will remove all the details of the chosen risk (including medication, reaction types and justification details) from the active ADR summary list

Provide a hover-over message that explains to the user what will happen if they click the 'Remove from list' button



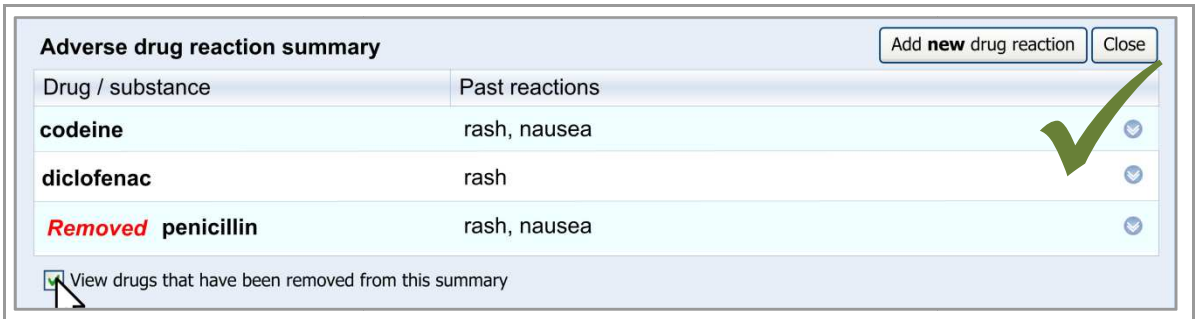
Provide a confirmation message that explains the implications of removing the risk to the user and allows the user to choose whether to proceed with the removal or cancel the removal

The removal confirmation message should:

1. Outline which drug the user is about to remove and from where it will be removed (namely, the ADR risk list)
2. Explain that any related clinical notes will remain on record
3. Explain that clinicians will no longer be warned not to administer this drug by the system

In the removal confirmation message dialog, the options should be presented as two buttons.

The removal confirmation buttons should be appropriately labelled in words that are consistent with the wording of the confirmation question.



ADR summaries that have been removed from the active ADR summary list should be accessible in a 'display deactivated summaries' mode

Rationale

User Research:

In early testing, although clinicians understood how to remove a risk, many indicated that they were reluctant to do so. Our analysis showed that this was because:

- Users were incorrectly thinking that they were deleting all references to the reaction from the record
- Users were worried about there not being a place to record why they were removing it (the 'justification for removal' text field only appears after they have clicked 'Remove'.
- Possibly the test scenario was addressing a corner case reason for removing the risk (that is, that new evidence had emerged contesting the veracity of the risk) and clinicians felt that they could not contest existing data in this way. If the scenario had addressed the removal of risk because it had been entered in error, then possibly clinicians may have been less reluctant

The current design addresses these issues by:

- Emphasising that the clinician would only be removing the reaction from the summary and not from the record entirely
- Providing a hover-over for the 'Remove' button, which informs the clinician that they will be given an opportunity to add a reason for removal

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ What if a clinician accidentally or inappropriately deactivates an ADR?	▪ The design provides sufficient warning to the user that they are deactivating a risk. The user must explicitly confirm that they are deactivating a risk
▪ What if a clinician is not aware of the existence of 'deactivated' ADRs?	▪ The design allows the user to view ADRs that have been 'deactivated' from the summary
▪ User could remove an ADR without providing a justification	▪ The user is forced to attend to a dialog that contains a text field into which they can type the justification. However, whether or not it is mandatory to enter text into that field is a matter for the appropriate clinical authority to address
▪ What if the clinician is not aware of the clinical implications (and risks) involved with removing a drug from the ADR summary list before removing it?	▪ The clinician is presented with a message that communicates the implications of removing the risk from the summary
▪ Clinicians always want to enter justification text before taking any action	▪ The design features a hover-over message that indicates to the user that clicking a button will allow the user to record a reason for removing the ADR summary before actually removing it
▪ The user does not feel that they have enough room to record sufficient useful information in the **Removing Risk** dialogue box	▪ The text field will expand (for example, by becoming a scrollable text field) if the user types in more information than will fit in the viewable area. However, the maximum data size that can be entered into the field is a matter for the appropriate clinical authority to address

5 Recording 'No Known Adverse Drug Reactions'

5.1 Principles

The following key principles inform the guidance in this section:

- Clinicians must distinguish between a lack of knowledge about the patient's ADR risk history and a knowledge that the patient does not have any ADR risks ('No known ADR risks')

5.2 Guidelines – Recording 'No Known Adverse Drug Reactions'

This section of the guidance covers the act of the clinician confirming that, as far as he or she knows, the patient has no known ADRs. This statement is distinct from not knowing the patient's ADR; instead it communicates a 'known' absence of ADRs.

ID	Description	Conformance	Evidence Rating
RAD-0760	Where the risk status is unknown or where a clinicians has recorded that there are no known ADRs, feature three action options: 1. An option to confirm that there are no known ADR risks 2. An option to add new risk 3. An option to close the dialog	Recommended	High
RAD-0760.1	Provide these controls as buttons	Recommended	High
RAD-0760.2	Locate the buttons adjacent to one another	Recommended	High
RAD-0760.3	Locate the buttons in the same location of the dialog as the function buttons in other dialogs	Recommended	High
RAD-0760.4	Locate the buttons in the top right-hand corner of the dialog	Recommended	High
RAD-0760.5	Clearly label the option buttons	Mandatory	High
RAD-0760.6	Label the button for confirming that there are no known ADR risks, 'No known adverse drug reaction risks'	Recommended	High
RAD-0770	If the user clicks 'No known adverse drug reaction risks', the phrase 'No known adverse drug reaction risks' should appear in the main area of the dialog	Mandatory	High
RAD-0780	If the user clicks 'No known adverse drug reaction risks', the date of entry and the author's name should appear next to the phrase 'No known adverse drug reaction risks'	Mandatory	Medium
RAD-0790	If the user clicks 'No known adverse drug reaction risks', a drop-down list should appear from which the user can select who or what was the source of this information	Recommended	Medium
RAD-0800	If the user clicks 'No known adverse drug reaction risks', an entry field should appear into which the user may add further details that support their belief that there are no known ADR risks	Recommended	Low
RAD-0810	If the user clicks 'No known adverse drug reaction risks', the 'Close' button label should change to 'Finish'	Recommended	High
RAD-0820	If the user clicks 'No known adverse drug reaction risks', the 'No known adverse drug reaction risks' button should become disabled. It should remain disabled while the dialog is still open	Mandatory	Medium

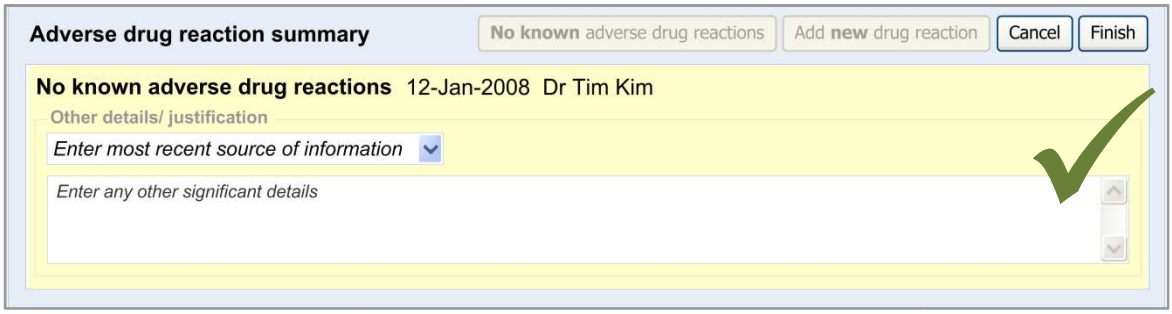
Usage Examples

Where the risk status is unknown or where a clinicians has recorded that there are no known ADRs, feature three action options:

1. An option to confirm that there are no known ADR risks
2. An option to add new risk
3. An option to close the dialog

Provide these controls as buttons

Locate the buttons adjacent to one another



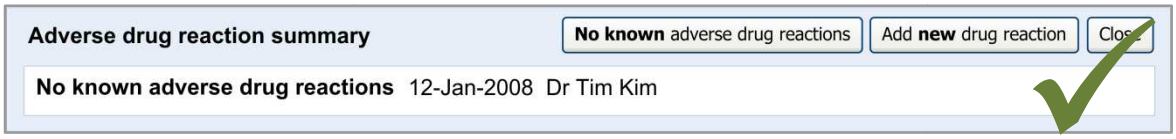
If the user clicks 'No known adverse drug reaction risks', the phrase 'No known adverse drug reaction risks' should appear in the main area of the dialog

If the user clicks 'No known adverse drug reaction risks', the date of entry and the author's name should appear next to the phrase 'No known adverse drug reaction risks'

If the user clicks 'No known adverse drug reaction risks', a drop-down list should appear from which the user can select who, or what was, the source of this information

If the user clicks 'No known adverse drug reaction risks', an entry field should appear into which the user may add further details that support their belief that there are no known ADR risks

If the user clicks 'No known adverse drug reaction risks', the 'Close' button label should change to 'Finish'



If the user clicks 'No known adverse drug reaction risks', the date of entry and the author's name should appear next to the phrase 'No known adverse drug reaction risks'

This is the view once the user has clicked 'Finish'

Rationale

User Research:

In testing, clinicians all identified how to record 'No known adverse drug risks' using the current design.

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ Unable to enter source of 'no known ADR risks' or view how previous no known ADR was established	▪ The 'no known ADR risks' dialog now contains a field for entering the source of the information

6 Editing an Adverse Drug Reaction Risk in the Summary

6.1 Principles

The following key principles inform the guidance in this section:

- Clinical summary information can be edited, given that the clinical events upon which it is based are documented elsewhere
- Clinicians may wish to add further information to a summary item as and when new information becomes available
- Changing the causative agent in an ADR risk would significantly change the meaning of the risk to the extent that all the details associated with it must be re-addressed

The following usability principles inform the guidance in this section:

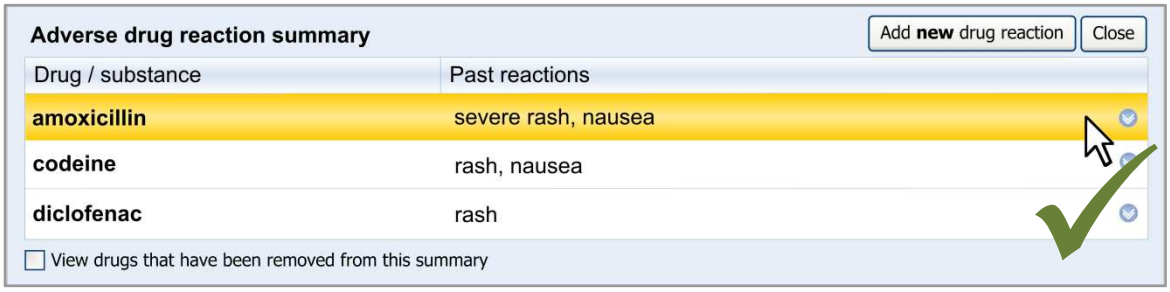
- Provide the mechanism for editing a data item as close as possible to its display ('direct editing')
- Clearly demarcate what is editable from what is not editable

6.2 Guidelines – Editing an Adverse Drug Reaction Risk

This section covers guidelines relating to the editing of and adding to an ADR risk that has already been edited and saved in the ADR summary.

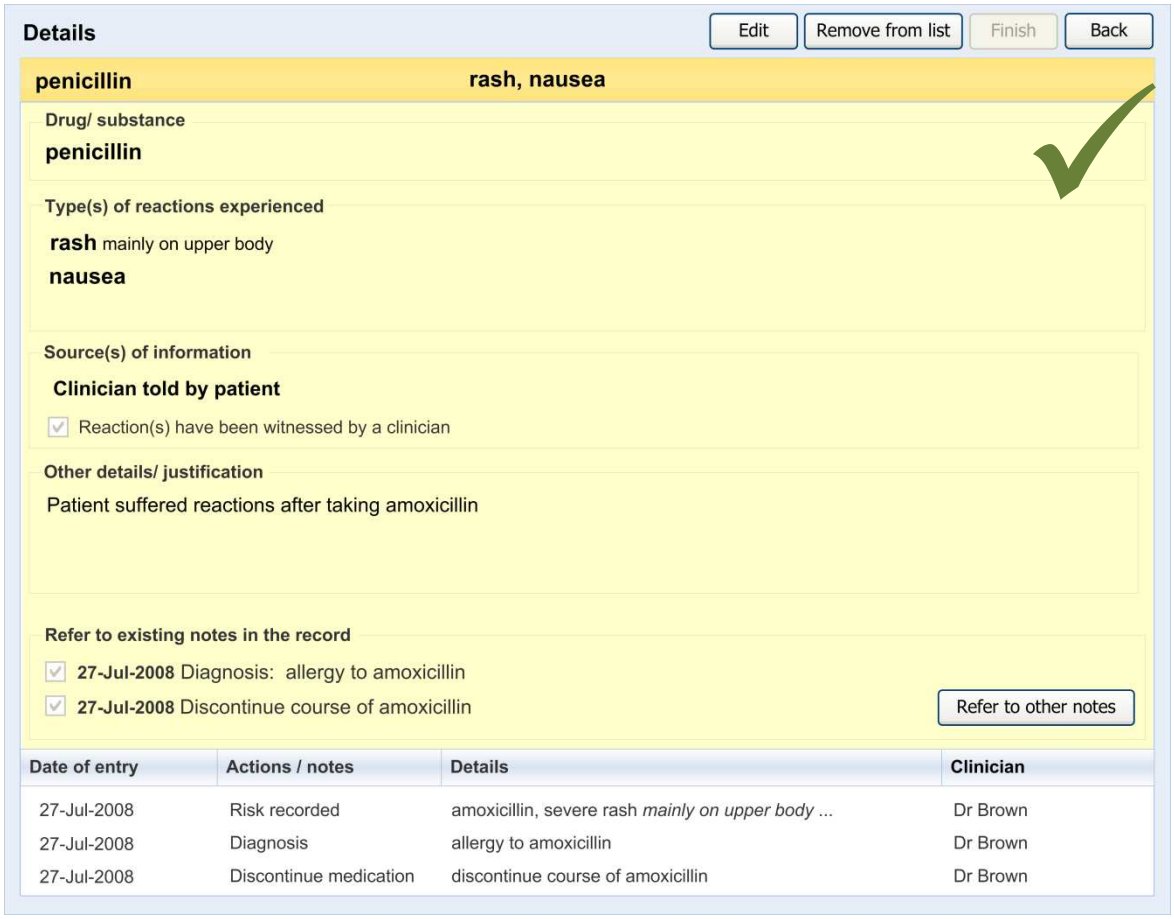
ID	Description	Conformance	Evidence Rating
RAD-0830	Feature a control that renders all of the details of an ADR risk editable (with the exception of the causative agent) and allows more details to be added	Mandatory	High
RAD-0830.1	Feature this 'editing' command button in the 'details' view of the ADR risk	Recommended	High
RAD-0830.2	Clicking on the 'editing' command button renders all the fields (except for the causative agent) in an editable format and laid out like the original entry dialog but with data pre-populating the fields	Recommend	High
RAD-0830.3	Label the 'editing' command button 'Edit'.	Recommended	High
RAD-0840	Provide an 'editing' command control that is local to each editable data item	Recommended	Medium
RAD-0840.2	Double-clicking on the data item (or right-clicking on it to reveal an 'Edit' option) will render it editable	Recommended	Medium
RAD-0850	Disable the 'Finish' button until the user has changed or added to the data	Mandatory	High
RAD-0860	Once the user has changed or added to the data, the 'Back' button changes to 'Cancel'	Mandatory	Medium
RAD-0870	The 'Cancel' button will navigate back to the ADR summary list view but without saving or retaining any changes to the data	Mandatory	High
RAD-0880	The 'Finish' button will navigate back to the ADR summary list view and will save or retain any changes to the data	Mandatory	High
RAD-0890	Provide access to an edit history, including appropriate dates, for the data visible in the 'Details' view	Recommended	High

Usage Examples

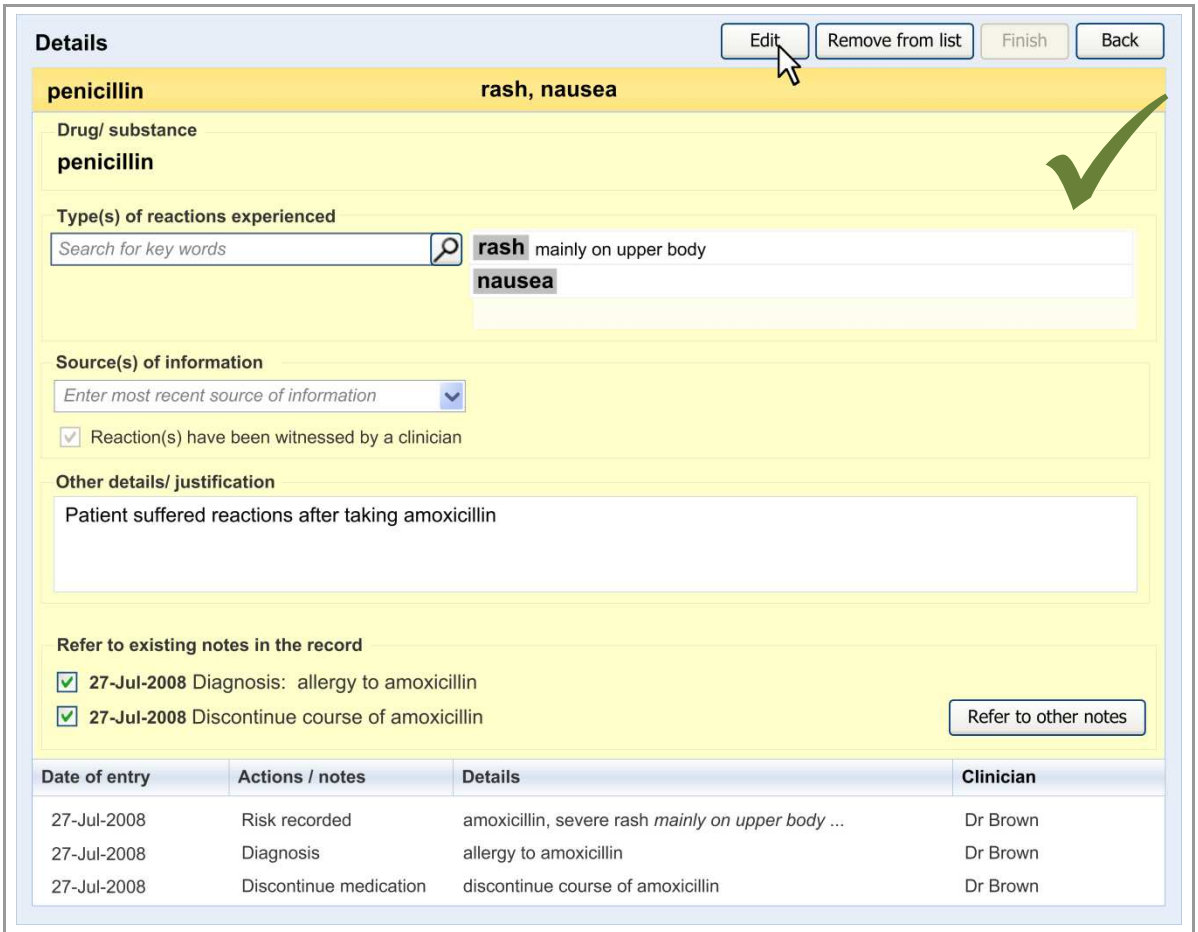


Feature an 'editing' command button in the 'details' view of the ADR risk that renders all the fields (except for the causative agent) in an editable format and laid out like the original entry dialog but with data pre-populating the fields.

The user can edit or add to an item in the ADR summary by clicking on it to reveal its 'Details' view



Label the 'editing' command button 'Edit'



Feature an 'editing' command button in the 'details' view of the ADR risk that renders all the fields (except for the causative agent) in an editable format and laid out like the original entry dialog but with data prepopulating the fields

Clicking on the 'Edit' button renders the 'Details' dialog for the ADR editable (except for the causative agent field)

Disable the 'Finish' button until the user has changed or added to the data

Rationale

User Research:

User research showed that users did not realise that they could click on a data item to edit it. Therefore the current design also features a global 'Edit' button.

Additionally, when presented with the option to edit the causative agent, clinicians were confused by why they would want to do this. It was deemed too risky to allow clinicians to do this. This opinion was raised even though the clinicians raising it were aware of the concept that this is just a summary (rather than the detailed notes).

Hazard Risk Analysis Summary:

From our Patient Safety Risk Assessment analyses, we identified a number of potential hazards, including the following key risks which are mitigated by the design:

Potential Hazards:	Mitigations:
▪ If the user edits the causative agent of a risk, the remaining details will be out-of-context. Future readers could assume, therefore, that the reactions were associated with a specific drug whereas, in fact, the patient had actually reacted to another in its class	▪ Do not allow the clinician to edit the causative agent

7 Document Information

7.1 Terms and Abbreviations

Abbreviation	Definition
ADR	Adverse Drug Reaction
CUI	Common User Interface
dm+d	dictionary of medicines + devices (NHS)
DCR	Detailed Clinical Requirements
DSS	Decision Support Systems
HL7	Health Language Seven
IT	Information Technology
NHS	National Health Service
NHS CFH	NHS Connecting for Health
NPfIT	National Programme for Information Technology
SCG	Standards Consulting Group
SNOMED CT	Systematized Nomenclature of Medical Clinical Terms
UI	User Interface
VCR	Validating Clinical Requirements:

Table 6: Terms and Abbreviations

7.2 Definitions

Term	Definition
Current best practice	Current best practice is used rather than best practice, as over time best practice guidance may change or be revised due to changes to products, changes in technology, or simply the additional field deployment experience that comes over time.
Summary Care Record	Part of the NHS Care Records Service, the Summary Care Record is centrally held patient data that can be uploaded and viewed by different NHS organizations, such as the GP practice and the hospital, and by patients themselves.
Post-coordination	Post-coordination is a process which allows the combination of concepts. For example, a focus concept may be qualified to produce a more specific clinical concept. See *SNOMED CT – the language of the NHS Care Records Service* **{R10}** for further details on post-coordination.

Table 7: Definitions

7.3 Nomenclature

This section shows how to interpret the different styles used in this document to denote various types of information.

7.3.1 Body Text

Text	Style
Code	`Monospace`
Script	
Other markup languages	
Interface dialog names	**Bold**
Field names	
Controls	
Folder names	Title Case
File names	

Table 8: Body Text Styles

7.3.2 Cross References

Reference	Style
Current document – sections	Section number only
Current document – figures/tables	Caption number only
Other project documents	*Italics* and possibly a footnote
Publicly available documents	*Italics* with a footnote
External Web-based content	*Italics* and a hyperlinked footnote

Table 9: Cross Reference Styles

7.4 References

Reference	Document	Version
R1.	Safety in Doses: Medication Safety Incidents in the NHS (NPSA) – NHS – Clinical Governance http://www.clingov.nscsha.nhs.uk/Default.aspx?aid=4021	2007
R2.	Requirements for adverse reaction reporting – World Health Organization: Geneva: Author	1975
R3.	MJA Practice Essentials – Allergy – Drug hypersensitivity – Thien, F. – Medical Journal of Australia http://www.mja.com.au/public/issues/185_06_180906/thi10282_fm	2006
R4.	Adverse Drug Reactions: Types and Treatment Options – American Academy of Family Physicians – Riedl, M.A. and Casillas, A.M. www.aafp.org/afp/20031101/1781.html	01-Nov-2003
R5.	Representation in Electronic Patient Records of Allergic Reactions, Adverse Reactions, and Intolerance of Pharmaceutical Products – Horsfield, P. and Sibeko, S. (	
R6.	Design Guidance – Terminology – Matching	1.0.0.0
R7.	Design Guidance – Date Display	2.0.0.0

Reference	Document	Version
R8.	SNOMED CT http://ihtsdo.org/	
R9.	NHS Dictionary of Medicines and Devices (dm+d) http://195.97.218.30/dmd_download.htm	
R10.	SNOMED CT – the language of the NHS Care Records Service – A guide for NHS staff in England – NHS Connecting for Health http://www.connectingforhealth.nhs.uk/systemsandservices/data/snomed/snomed-ct.pdf	2007
R11.	Representation in Electronic Patient Records of Allergic Reactions, Adverse Reactions, and Intolerance of Pharmaceutical Products – NHS Connecting for Health http://hiu.rcplondon.ac.uk/clinicalstandards/EPR-CFH-Technical-Doc.pdf	
R12.	SCG Guidance on the Representation of Allergies and Adverse Reaction Information Using NHS Message Templates – Bentley, S. and Long, R. (NPfIT Standards Consulting Group) (2008) http://www.connectingforhealth.nhs.uk/systemsandservices/data/scg/publications/SCG0001.pdf	1.0
R13.	NPfIT and the International Input into HL7 – Jones, T. – HL7 UK Annual Conference www.hl7.org.uk/marketing/downloads/HL7UKConference2004/HL7UK%20NPfIT%20presentation.ppt	2004
R14.	HL7 delivers healthcare interoperability standards – Health Language Seven UK http://www.hl7.org.uk/	
R15.	Essential Guide to User Interface Design: An Introduction to Gui Design Principles and Techniques – Galitz, W.O.	1997
R16.	Designing the User Interface: Strategies for Effective Human-Computer Interaction – Shneiderman, B. – (1998)	Third edition
R17.	Design Guidance – Displaying Adverse Drug Reaction Risks	1.0.0.0
R18.	Validating Clinical Requirements for information systems in secondary care (VCR): Detailed Clinical Requirements (DCR) – RCP Health Informatics Unit (23-Oct-2003)	
R19.	Guide to Presentation of tables and graphs – British Standards Institute – British Standard BS 7581	1992
R20.	Show me the numbers. Designing tables and graphs to enlighten – Few, Stephen (2004)	First edition
R21.	SNOMED Clinical Terms User Guide – The International Health Terminology Standards Development Organisation http://www.ihtsdo.org/fileadmin/user_upload/Docs_01/SNOMED_CT_Publications/SNOMED_CT_User_Guide_20080731.pdf	July 2008
R22.	Can We Tell Who is at Risk of a Fatal Reaction?, Current Opinion in Allergy and Clinical Immunology – Pumphrey, R. Anaphylaxis – 4(4): 285-290	2004
R23.	NHS CUI Programme – Design Guide Entry – Terminology – Elaboration	2.0.0.0
R24.	Allergy and Adverse Drug Reaction: Implementation of SNOMED CT in structured electronic records – Challen, R. – NHS Connecting for Health: SSeRP Working Document (2007)	0.1
R25.	Design Guidance – Terminology – Display Standards for Coded Information	1.0.0.0

Table 10: References

APPENDIX A DESIGN ASPECTS BEING EXPLORED

A.1 Introduction

This appendix illustrates design aspects that could assist the implementation of the guidelines outlined in the main document, but which are still undergoing development and exploration.

Future planned guidance development work aims to explore the application of these design aspects in other areas of clinical noting.

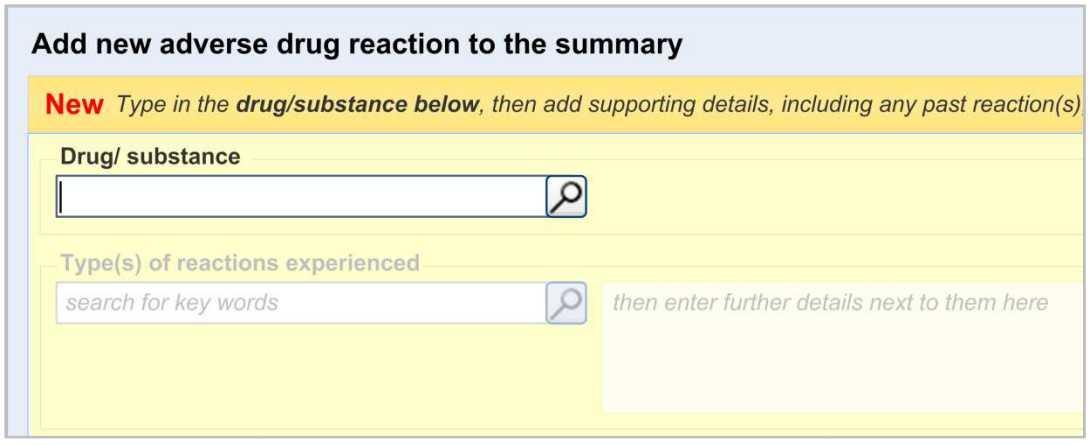
Therefore, the designs in this appendix should not be mistaken for actual guidelines: they have not been tested with clinicians to the same degree as the designs that are implied by the guidelines in the body of this document. Instead of being followed as guidelines, the designs in this appendix are intended to inspire further development. They also provide some context to help readers of this guidance understand the guidelines themselves.

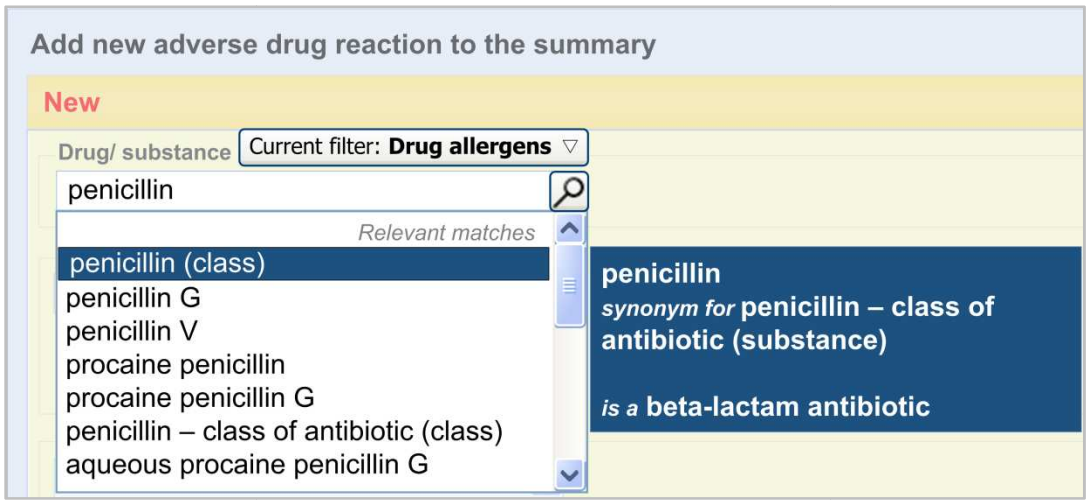
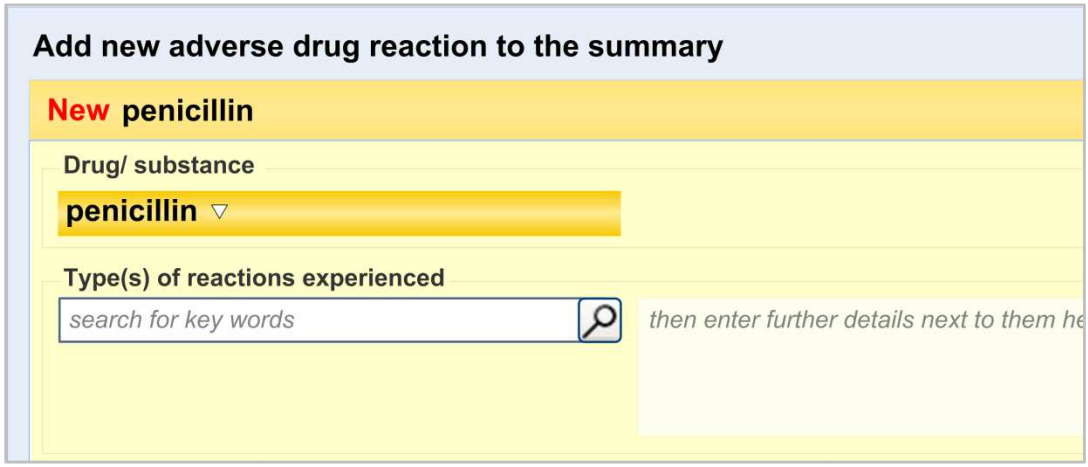
This appendix is divided into sections pertaining to different functional areas or features, each of which contains some visual illustrations and lists some UI assumptions. In some cases, there may be multiple designs that are still being considered, but those other designs are not presented here.

A.2 Adding New Clinical Terms in a Form

The process of adding new clinical terms within a form has been based largely on previous Microsoft CUI guidance (see *Design Guidance – Terminology – Matching* **{R6}**). The general assumption is that clinicians are presented with a field into which they may type the word or words that they feel expresses the clinical belief, observation, risk or plan that they wish to record. At that point, the UI invokes the matching of these words against a recognized clinical terminology, such as SNOMED CT.

Table 11 shows the possible sequence of steps taken to add new clinical terms in a form:

Step	Design Aspects Being Explored
1	

Step	Design Aspects Being Explored
2	
3	
4	

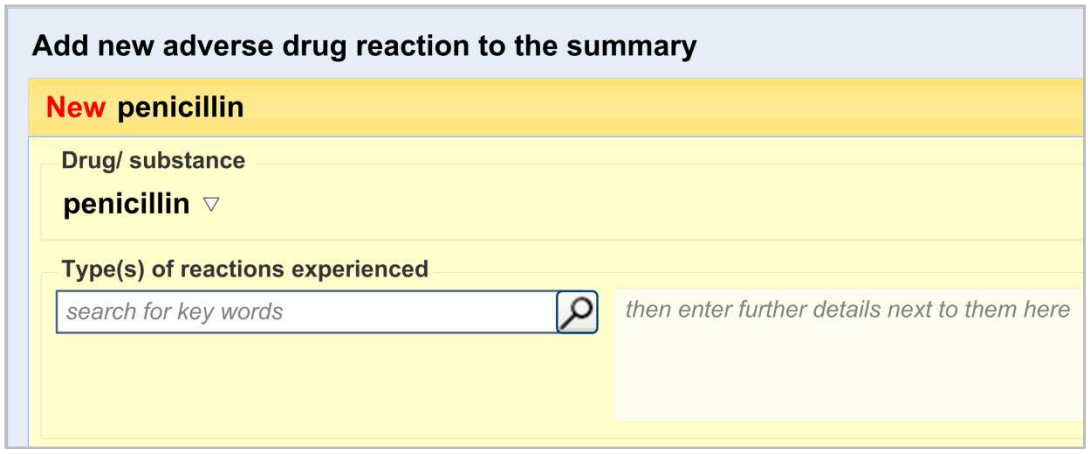
Step	Design Aspects Being Explored
5	

Table 11: Adding a New Clinical Term in a Form

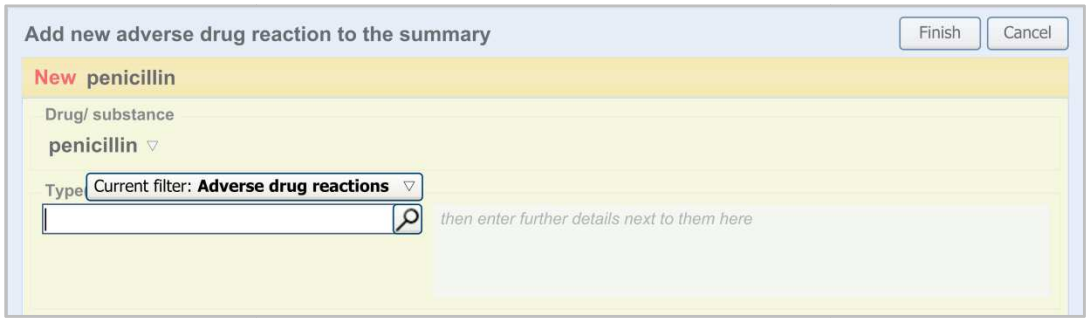
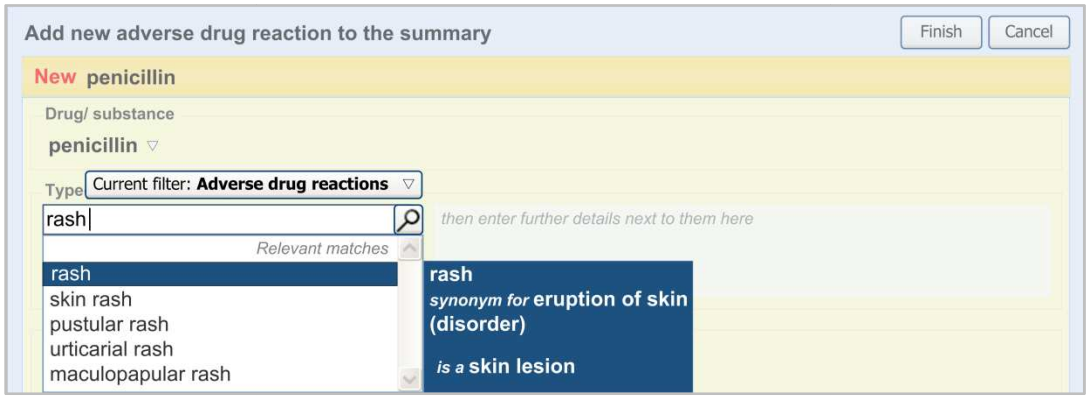
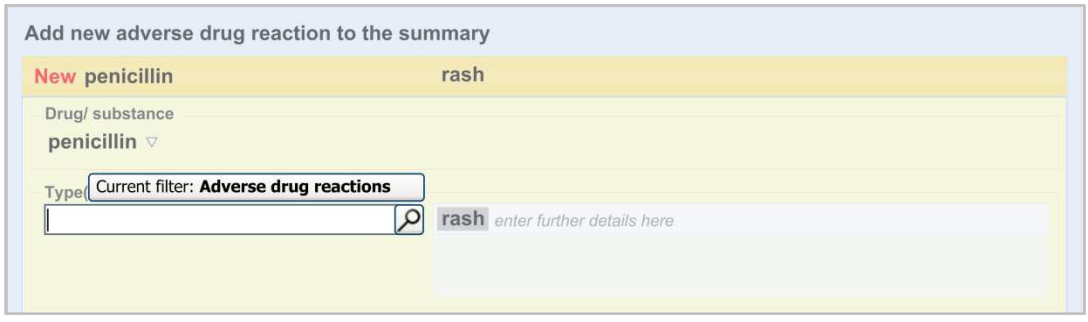
A.3 Adding Multiple Instances of Clinical Terms into a Form

Another common requirement will be to add multiple instances of a single category of clinical content. For example, the user may want to enter several types of reaction. The terms ‘rash’, ‘nausea’ and ‘anaphylaxis’ are all instances of the same clinical category, namely ‘reaction type’. In these cases, there may be no clear limit as to how many such instances of a single category of clinical content the clinician may need to enter. Therefore the control must have sufficient flexibility to allow the clinician to enter many terms but also clearly show that they are all instances of the same type of term. The control must also be efficient enough to meet the space limitations of a screen-based form.

The design being explored features a single input field and a list field into which the clinician can enter multiple instances of a clinical term (such as a type of reaction). After clinicians have matched a term to their inputted text, this term automatically populates the next available line in the list. The clinician may also then type in additional text next to the term.

Table 12 shows the possible sequence of steps taken to add multiple clinical terms in a form:

Step	Design Aspects Being Explored
1	

Step	Design Aspects Being Explored
2	
3	
4	
5	

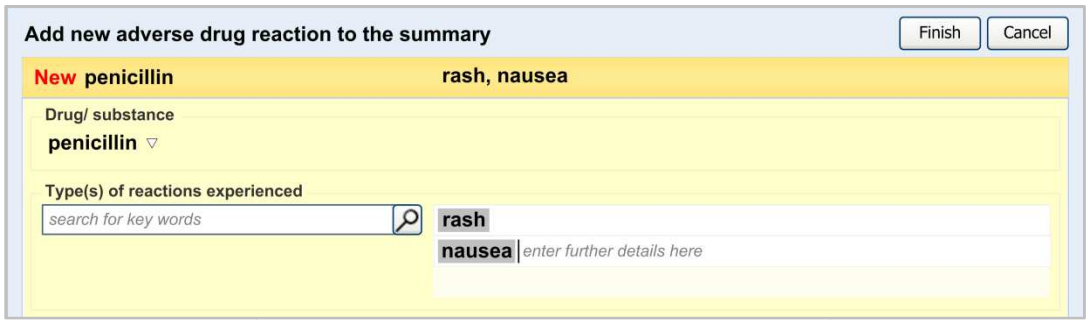
Step	Design Aspects Being Explored
6	
7	

Table 12: Example of a Sequence of Screens That Allow the Entry of Multiple Concepts

A.4 Displaying Edit History

Displaying the edit history of a data item will be very important to clinicians as it contextualises the current data. Currently, clinicians tend to view this history by paging back through the patient's record.

Figure 7 shows an example of an 'edit history' feature:

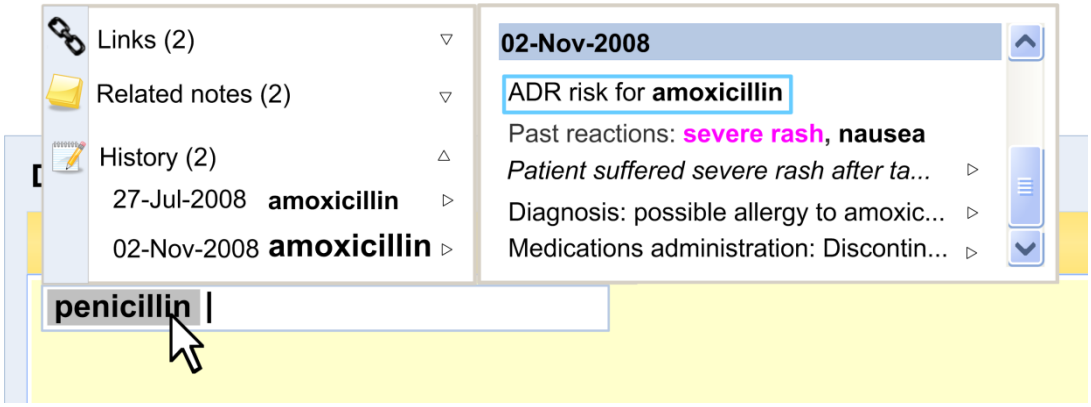


Figure 7: Example of an Edit History Feature

A.5 Match Not Found

If the clinician types in a term that is not matched against SNOMED CT, the clinician must be able to record it anyway, albeit formatted in a way that indicates that it is not encoded. The clinician should also be warned that the term has not been matched but informed that they can record it anyway.

Figure 8 shows an example of a message that could appear if a match were not found:

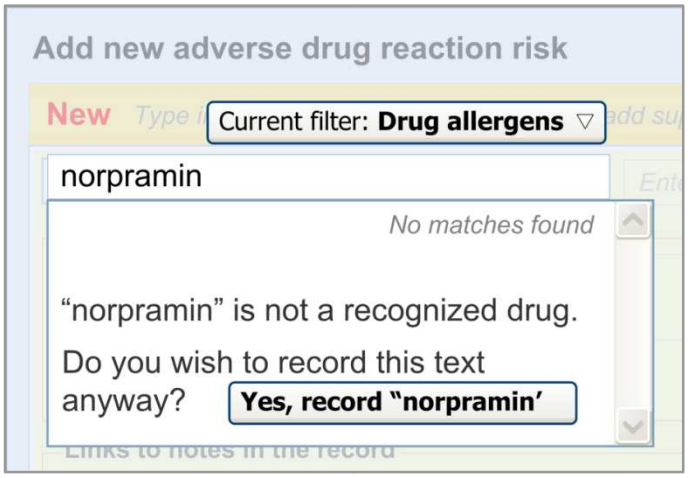


Figure 8: Example of a 'Match Not Found' Message

APPENDIX B STUDY ID 30: EXECUTIVE SUMMARY

B.1 Abstract

The UK National Health Service (NHS) Common User Interface (CUI) programme is a partnership between Microsoft® and NHS Connecting for Health (NHS CFH), which is part the NHS National Programme for Information Technology (NPfIT).

As part of CUI, the Clinical Applications and Patient Safety (CAPS) project has the goal of ensuring that software applications used by the NHS enhance patient safety. To achieve this, CAPS provides software developers with user interface design guidelines derived through a user-centric development process that includes explicit patient-safety evaluations.

This summary describes the results of interviews conducted with five NHS Health Care Professionals (HCPs) at their normal place of work.

Purpose:

To gather feedback to enhance static wireframe preliminary design options for recording information about Adverse Drug Reactions (ADRs) that will enable patient-safe prescribing decisions.

Method:

Within an audio-recorded interview, participants were presented with designs arranged in ideal click-through routes for five use scenarios and asked to describe what they saw and what they would do next.

Results:

The designs were generally very well received as a significant improvement over paper recording and prompted responses like: “This might improve the recording of allergies and have an unintended effect on the quality of care” (p1), “Excellent” (p2), “I think this is probably enough” (p3), “Perfect, a list of drugs and what they cause” (p4).

The most significant design changes suggested by the research are to enable the HCP to:

- Record and discover recorded severity of reactions. Otherwise, the existing data entry fields were acceptable with a range of information presentation and navigation changes
- View the reaction history of ADR risks before combing them within a drug class
- Avoid all those issues identified use issues that represented potential patient safety hazards

B.2 Research Objectives

This study was designed to gather HCP understandings, preferences and patient safety assessments of preliminary wireframe design flows.

The specific objectives were:

- Use the following five use scenarios to assess and refine preliminary design task flows:
  a. Recording a new ADR risk
  b. Diagnosing an ADR risk
  c. Removing an ADR risk
  d. Recording no known ADR risk
  e. Combining recorded ADR risks under a parent drug

- Identify whether the data entry format and fields are appropriate
- Identify design strengths and weaknesses with specific reference to patient-safety
- Identify new design requirements

B.3 Research Design

Click-through designs were used to provide a structure to the three interviews with individuals and the one interview with two individuals. To assess their understanding of the information represented in the design, and whether it supported progression to effectively complete the scenario, HCPs were asked two questions:

- What do you see?
- What would you do next?'

All interviews were audio recorded to facilitate analysis and to identify quotes from individual HCPs.

B.4 Results

B.4.1 Respondent Descriptions

Five people that had not previously participated in CUI studies were interviewed at their normal place of work between 08-Dec-2008 and 11-Dec-2008. Participants had worked for the NHS for a wide range of durations (from 1 to 29 years). Table 13 provides a summary of the interviewee's job roles, NHS employment, workplace and main work location:

Respondent Identifier	Job Role	Years Employed in the NHS	Workplace	Location	Accomplishments
p1	Consultant Pharmacist for safe medications practice	15 years	Hospital	London	Using Microsoft® Office Access™
p2	Consultant Pharmacist for infectious diseases	20 years	Hospital	London	Designing Web pages
p3	Prescribing Pharmacist	4 years	GP Surgery	South West	Using Microsoft® Office PowerPoint®
p4	F2 – Junior Doctor	1 year	GP Surgery	South West	Using Microsoft® Access™
p5	GP (Primary Care Trust prescribing lead)	29 years	GP Surgery	South West	Evaluating systems for use in clinical practice

Table 13: Respondent Descriptions

B.4.2 Data Entry Format and Fields

The participants:

- Requested some way to systematically indicate the severity of recorded reactions (all). This was illustrated by a request for explicit severity rating or by reference to the implications of not having this information such as: "There's a difference between anaphylaxis and a small rash on your hand .You don't want to not give someone a life saving antibiotic just because they had a tiny rash from it before" (p4), "I'd like to have 'potentially fatal, don't do this".(p5)
- Requested a way to systematically record 'Reaction Certainty' whether the reaction was suspected as an ADR (p1) or proven as an ADR (p2)
- Interpreted the 'Undo' button as acting on the main user interface component rather than on the last user-action (p2)

- Senior HCPs (p1, p2, p5) preferred the ADR process to be based on completing multiple required field selections (p1, p2) rather than open text
- Mentioned the difference between drug side-effects and drug allergies. Requested distinct recording categories for drug side-effects and drug allergies (p5)
- Indicated that the route to editing an entered ADR required too many clicks, particularly having to click two different buttons labelled 'Edit'

B.4.3 Scenario Design Flow

The participants:

- Noticed, liked and acted on the prompt to record an ADR being a notification that arrived within the clinical notes as they were being typed (all)
- Did not notice the availability of an open-text field to enter a justification for recording a new ADR (p1, p2, p5)
- Wanted to view the reaction history of an ADR before combining it with a parent drug (p1, p2, p5)
- Believed there should be a requirement to provide a justification for the addition (p1, p2, p5), or removal (all), of an ADR

B.4.4 New Requirements

New requirements that the interviews revealed include providing HCPs with the ability to:

- View the reaction history of an ADR before combining it with a parent drug
- Add and easily discover the certainty of a reaction (such as 'suspected' or 'proven')

Individual HCPs made suggestions that are being considered by the design team, for example, HCPs variously asked for:

- The ability to record the outcomes of drug reactions tests systematically using dedicated fields (for example, the outcomes of a skin-prick test).
- Completion of all data entry fields shown for recording an ADR to be made compulsory (p1)
- Explicit distinction between ADR and allergies (p3)
- Use of the term 'unknown' to refer to an ADR past reaction in the ADR risk display summary to be unacceptable (there should be some summary of what is actually recorded) (p1)

APPENDIX C STUDY ID 59: EXECUTIVE SUMMARY

C.1 Abstract

The UK National Health Service (NHS) Common User Interface (CUI) programme is a partnership between Microsoft® and NHS Connecting for Health (NHS CFH), which is part the NHS National Programme for Information Technology (NPfIT).

As part of CUI, the Clinical Applications and Patient Safety (CAPS) project has the goal of ensuring that software applications used by the NHS enhance patient safety. To achieve this, CAPS provides software developers with user interface design guidelines derived through a user-centric development process that includes explicit patient-safety evaluations.

This summary describes the results of interviews conducted with five NHS Health Care Professionals (HCPs) at their normal place of work.

Purpose:

To gather feedback to enhance static wireframe preliminary design options for recording information about ADRs that will enable patient-safe prescribing decisions.

Method:

Within an audio-recorded interview, participants were presented with designs arranged in ideal click-through routes for six use scenarios and asked to describe what they saw and what they would do next.

Results:

Feedback from 27 HCPs was gathered through two cognitive walk-throughs (one with five people and one with six people) and work-place interviews (with 16 people). The HCPs were presented with click-through screenshots of proposed design solutions to add, remove, combine, reclassify and edit ADR risks, and to record no known ADR risks.

28 use actions by the HCPs introduced issues that will lead to design changes. These use actions primarily stem from:

- HCP uncertainty about what is required in the reactions keyword and details justification text entry boxes
- Command links not recognised as actionable and command line text being interpreted in diverse ways
- An opened ADR risk did not look editable

All HCPs were able to record no known ADR risk. Many requested the ability to cite the steps they had taken to ascertain the lack of a known risk (for example, asked the patient, reviewed hospital notes, called the GP).

Most HCPs do not want to remove an ADR risk history from the summary, even when it is proven to be no longer a risk. Removed ADR risks should be available to prescribers and recorders as a listed proven non-risk.

The majority of HCPs attempted to combine ADR risks by editing an existing risk.

Most HCPs questioned the clinical validity of reclassifying a penicillin ADR risk to a Beta-Lactam ADR risk. No HCP was able to complete this task with the current design, primarily because they did not perceive the ADR fields as editable.

C.2 Research Objectives

This study was designed to gather HCP understandings, preferences and patient safety assessments of wireframe design flows.

The specific objectives were:

- Use the following five use scenarios to assess and refine design task flows:
  a. Add penicillin ADR risk
  b. Add penicillin ADR risk from clinical notes
  c. Record No Known ADR Risk
  d. Remove an ADR risk
  e. Combine ADR as class risk
  f. Edit ADR to class risk
- Identify whether the data entry format and fields are appropriate
- Identify design strengths and weaknesses with specific reference to patient-safety
- Identify new design requirements

C.3 Research Design

Two streamlined cognitive walk-throughs were completed, session one with five technically able clinical advisors and session two with six technically able clinical advisors.

In addition to the cognitive walk-throughs, on-site interviews were conducted with 16 people as individuals, pairs and one threesome in a meeting-room at their normal place of work.

During the interviews, click-through designs were used to provide a structure to the three interviews with individuals and the one interview with two individuals. To assess their understanding of the information represented in the design, and whether it supported progression to effectively complete the scenario, HCPs were asked two questions:

- What do you see?
- What would you do next?'

All interviews were audio recorded to facilitate analysis and to identify quotes from individual HCPs.

C.4 Results

C.4.1 Respondent Descriptions

Table 14 provides a summary of the interviewee's job roles, NHS employment, workplace and main work location:

Respondent Identifier	Job Role	Years Employed in the NHS	Workplace	Location	Computing Accomplishments
p1	Other Nurse	30 years or more	Hospital	West Midlands	Written Software Code
p2	Pharmacist	10–14 years	Hospital	London	Modified Microsoft® Office Access™ database
p3	Pharmacist	10–14 years	Hospital	West Midlands	Installed a program
p4	Pharmacist	10–14 years	Hospital	London	Modified Microsoft® Office Access database
p5	Pharmacist	20–24 years	Other	Other	Written Software code
p6	Pharmacist	5–9 years	Hospital	South West	Written Software code
p7	Midwife	15–19 years	Hospital	East Midlands	Modified Microsoft® Office Access database
p8	Pharmacist	5–9 years	Hospital	London	Modified Microsoft® Office Access database
p9	Surgeon	30 years or more	Hospital	London	Written Software code
p10	Pharmacist	25–29 years	Hospital	Yorkshire and Humberside	Modified Microsoft® Office Access database
p11	GP	25–29 years	General Practice	North West	Written Software code
p12	SHO Anaesthetist	3 years	General Hospital	North East	Confident with Microsoft® Office System applications
P13	ICU Ward Sister	14 years	General Hospital	North East	Microsoft® Office PowerPoint®
P14	ICU Staff Nurse	16 months	General Hospital	North East	Microsoft® Office PowerPoint
P15	Pre-Assessment Sister	25 years	General Hospital	North East	Providing clinical feedback on beta-trail software
p16	ENP	(not given)	Walk-in Hospital	London	Audits using symphony
p17	Staff nurse	(not given)	Walk-in Hospital	London	Using Microsoft® Office Excel® and Microsoft Office PowerPoint
p18	ENP	25 years	Walk-in Hospital	London	Leaning a new program with no training (.ppt)
p19	ENP	15 years	Walk-in Hospital	London	Leaning a new program with no training (.ppt)
p20	ENP	24 years	Walk-in Hospital	London	Leaning a new program with no training (.ppt)
p21	GP Partner	30 years	GP Surgery	North East	System-1
p22	GP Partner	30 years	GP Surgery	North East	System-1
p23	Practice Nurse	21 years	GP Surgery	North East	Entering data to templates
p24	Practice Nurse	23 years	GP Surgery	North East	Entering data to templates

Respondent Identifier	Job Role	Years Employed in the NHS	Workplace	Location	Computing Accomplishments
p25	GP registrar	6 years	GP Surgery	North East	Using clinical systems
p26	Principle GP	25 years	GP Surgery	North East	Using Clinical systems
p27	Pharmacist	23 years	GP Surgery	North East	Auditing

Table 14: Respondent Descriptions

C.4.2 Data Entry Format and Fields

The participants:

- Were unclear how to record ADR when more than one drug is the potential source of the reaction
- May type two or three drug names in the ADR drug field
- Were unsure what is meant by 'keyword' on first encounter of ADR form (p16, p17)
- Interpreted 'Add more reactions' as an instruction for the first reaction entry text box
- Did not recognise 'Add more reactions text' as a command-link
- May omit to enter reaction keywords in the reactions field
- May not type more text after having seen the reaction text highlighted 'grey' in the reactions field
- Interpreted blue highlighted text within the 'Details/Justification' field as a severity warning, not as actionable
- Commented that 'More keywords' pop-up is too complicated and out of context
- Questioned whether the 'More keywords' reaction entry-pop-up was a description or actionable item
- Were confused about why some reactions were grey (swollen tongue) in justification text and others were not (rash)
- Were unable to enter source of KNADR risk or view how previous no known ADR was established
- Commented that an opened ADR (including drug name) did not look editable

C.4.3 Design Comments

The participants:

- May enter a list of reactions (rash and nausea) in one reactions entry field (p13, p14, p17, p18, p19)
- Questioned whether the second reaction entry box was for entering another reaction to a different drug (p13, p14)
- Interpreted 'Link to notes' as a way to add the ADR to the clinical notes
- Were confused as to whether 'How did you discover the risk?' is a question to the patient or to the HCP
- Were unclear as to how to access notes to find if there is more relevant information before making the entry (p13, p15)
- Were unsure if cancelling a pre-filled form would remove data from clinical notes that was used to create the form

- Were unclear about the action associated with the ADR pop-up chevron (this may not indicate how to record the entry as an ADR risk)
- Were confused about the term ‘Record ADR Risk’ because it is already recorded in the clinical notes
- May be uncomfortable with the action of removing the risk
- Were unsure that the ‘Removal justification’ conveyed the clinical risk of removing this item
- Were concerned that removal of a risk is too easy
- Were unclear about the behaviour of the auto-suggestion menu and pop-up menu

C.4.4 New Requirements

New requirements that the interviews revealed include providing HCPs with the ability to:

- Arrange reactions in order of severity (swollen tongue more important than rash)
- Enter justification text before taking an action (for example, select remove, select combine)