Design Guidance

Displaying Adverse Drug Reaction Risks

Wednesday, 28 January 2009
Version 1.0.0.0

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 – Date Display	2.0
Design Guidance – Medication Line	2.0
Design Guidance – Displaying Graphs and Tables	2.0
Design Guidance – Terminology – Display Standards for Coded Information	1.0

TABLE OF CONTENTS

1 INTRODUCTION

> **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.

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). The report quotes a study which found that an estimated 6.5% of hospital admissions are due to an adverse drug reaction.

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 healthcare systems, which could result in its ambiguous or incomplete communication.

This guidance aims to support clear and unambiguous communication of the known ADR risks for a patient which could be 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). Therefore, 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.

Another important issue associated with the recording and subsequent display of adverse drug reactions is that of maintaining data quality. In writing this guidance, attempts have been made to ensure that data display requirements do not encourage poor data quality at the point of entry. For example, this guidance does not require the display of data that is unavailable to the clinician who enters the risk. Also, this guidance mandates that the application faithfully reflects certain key data, such as the causative agent of the reaction risk, in the form in which it was entered. The issue of maintaining ADR risk data quality is a theme which will be usefully addressed in any future work addressing user interface design for entering ADR risks.

> **Important**
>
> 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}**.

[1] NHS National Patient Safety Agency, National Reporting and Learning Service, Safety in Doses **{R1}**: http://www.npsa.nhs.uk/nrls/alerts-and-directives/directives-guidance/safety-in-doses/

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 adverse drug reaction, there are many sub-definitions and opposing classifications.

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

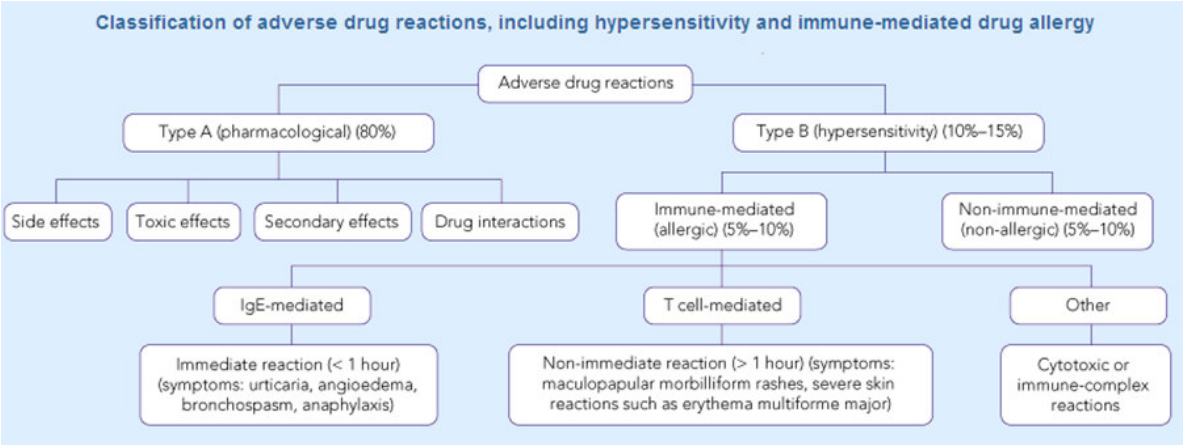


Figure 1: Classification of Adverse Drug Reactions

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 drug reactions 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.

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

[3] Riedl, M. and Casillas, A. American Family Physician™, November 1, 2003, Adverse Drug Reactions: Types and Treatment Options **{R4}**: http://www.aafp.org/afp/20031101/1781.html

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.

1.2 Risks Versus Events

This guidance will take the approach that an adverse drug reaction 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 '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.

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:

- Check if the patient is believed to be at risk of suffering adverse reactions if they are administered one or more drugs, or if there is a stated absence of risks for that patient
- Decide if one or more adverse drug reactions should influence the current clinical decision
- Predict what additional actions should be taken in response to the risk of one or more adverse drug reactions

In order to prevent the administration of drugs known to be dangerous to a patient, care must be taken to ensure that clinicians are provided with sufficient information to:

- Identify the presence or confirm the positive absence of adverse drug reactions
- 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
Structure of list	Guidance on how the list is structured and ordered.
Content of risk phrase	Guidance on the information that needs to be included in the expression of an adverse drug reaction risk. The information is prioritised: some information must be immediately visible, whereas other information can be available upon interrogation by the user (for example, a click away).
Content of supporting events, including previous adverse reaction events (high level)	Guidance on the supporting information that may be featured to justify the risk phrases, including adverse reaction events. This guidance addresses content at a high level rather than at a detailed level.
Format of list	Guidance on how to format the words and phrases within the list, including tabular arrangement, punctuation and text formatting.
Justification of risks	Guidance on how to display justification of risks. This information may be encoded or may be free text, and may include details of the reaction events that support the expression of a risk. The guidance outlines the types of information that should be available, but without specifying the precise structure or content of the information.
Displaying dates and times	Guidance on which dates and times to display, where and how to display them.
Displaying source of risk	Guidance on how to communicate the source of the risk, such as whether a clinician witnessed a reaction or the patient recounted a risk or event.
Displaying authorship of risk	Guidance on communicating the author of a risk, including their name, role and location.
Communicating absence of risks	Guidance on communicating where no risks have been recorded, including: ▪ Where a positive absence has been recorded (for example, 'no known drug allergies') ▪ Where the patient has not been asked ▪ Where information is simply not available
No Decision Support	Guidance on communicating where a risk will not trigger Decision Support mechanisms, including alerts, because the risk is either not encoded (that is, it is free text) or because the causative agent in the risk is not included in the Decision Support reference list.
Displaying risks in narrative text	Guidance on how to display risk phrases as part of narrative text, as opposed to in a list/table.

Table 1: In Scope

1.4.2 Out of Scope

Guidance Area	Details
Content and structure of adverse drug reaction event details	Guidance does not cover the content or structure of the adverse drug reaction events that support the risk phrases. It will not specify what detailed information must be included in the description of a reaction event. However, the guidance will cover how to show reaction event summaries and will use examples of detailed reaction event descriptions to show how events may be displayed as justification for the risks that they support.
System-initiated adverse drug reaction warning and alert messages	Guidance does not cover adverse drug reaction warnings and alerts.
Dealing with long lists of adverse drug reaction risks	Guidance does not cover how to deal with long lists of adverse drug reaction risks.

Guidance Area	Details
Displaying an abbreviated status of a patient's ADR risks	Guidance does not cover how to display an abbreviated status of a patient's ADR risks, such as an entry on a patient's identification banner.

Table 2: Out of Scope

1.5 Assumptions

ID	Assumption
A1	The structured terminology used as exemplars for this guidance will be SNOMED CT®[4] and the NHS Dictionary of Medicines + Devices (dm+d)[5].
A2	Appropriate subsets within SNOMED CT **{R5}** and dm+d **{R6}** are available.
A3	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'.

Table 3: Assumptions

1.6 Dependencies

ID	Dependency
D1	The availability of appropriate data sets, for example, SNOMED CT **{R5}** subsets.
D2	The following design guidance documents (changes in these documents may affect the current design guidance given for displaying adverse drug reaction risks): ▪ Design Guidance – Date Display **{R7}** ▪ Design Guidance – Medication Line **{R8}** ▪ Design Guidance – Displaying Graphs and Tables **{R9}** ▪ Design Guidance – Terminology – Display Standards for Coded Information **{R10}**
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 **{R6}**.

Table 4: Dependencies

[4] SNOMED CT® **{R5}**: http://ihtsdo.org/

[5] NHS Dictionary of Medicines and Devices (dm+d) **{R6}**: http://195.97.218.30/dmd_download.htm

2 GUIDANCE OVERVIEW

2.1 Visual Summary of the Guidance

The following section provides a diagrammatic representation of the design guidance, emphasising the process flow and introducing where in the flow the various guidance areas apply.

Figure 2 provides an overview of the ADR display, in this case shown as a list (views are discussed later in this document):

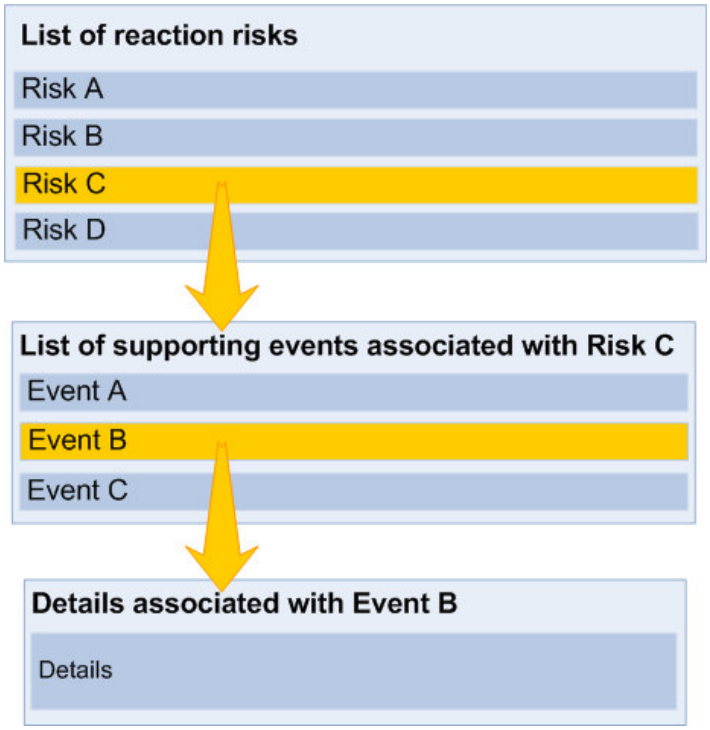
Visual Summary	Areas of Guidance
	3.3.1 Structure of Adverse Drug Reaction Risk List 3.3.2 Content of Adverse Drug Reaction Risk Phrases 3.3.4 Format of List 3.3.8 Displaying Absence of Risk 3.3.9 Displaying that no Decision Support is Available for a Specific Risk 3.3.1 Structure of Adverse Drug Reaction Risk List 3.3.3 Content of Supporting Data (High-Level Guidance) 3.3.5 Displaying Dates and Times 3.3.6 Displaying Source of Risk 3.3.7 Displaying Authorship of Risk and Event Phrases 3.3.1 Structure of Adverse Drug Reaction Risk List

Figure 2: Diagrammatic Overview of the Structure of the Adverse Drug Reaction Risk Display

> **Note**
>
> Section 3.3.10, Displaying Risks in Narrative Text, is not featured in this diagram. That section shows how to apply the guidelines to a narrative text format.

3 GUIDANCE DETAILS

3.1 Introduction

The guidance in this document covers the structure of the list used to display the adverse drug reaction risks, the content of the risk phrases, the display of supporting event phrases and the display of sufficient provenance information and appropriate formatting.

The guidance in this document is based upon a programme of research, including:

- A Web-based survey of clinicians
- One-to-one interviews with a range of healthcare professionals
- An opening risk assessment with clinicians
- A closing risk assessment with clinicians

3.2 Principles

The following key principles inform the guidance in this document:

- Display sufficient content to allow users to act appropriately
- Minimise content in order to reduce the risk of misleading the user:
  - Where the meaning of content is ambiguous
  - Where the content is irrelevant to the users' decision-making needs
- Distinguish different types of clinical phrases, where they have radically different meanings, for example:
  - Distinguish expressions of future risk from expressions of past events
  - Distinguish different types of phrase by distinct styles of content, labelling and location
- Distinguish individual clinical phrases from one another, for example, through visual format
- Describe substances in a common, unambiguous terminology (where possible)
- Describe substances at an appropriate level, in order to help the user act appropriately
- Order lists appropriately
- User must be able to easily access justification for expressions of future risk, where justifying information is available
- User must be able to easily return to high-level information after viewing detailed information
- Clearly communicate the provenance of clinical phrases, where appropriate

3.3 Guidelines

3.3.1 Structure of Adverse Drug Reaction Risk List

This section relates to the structure of the list that communicates the risk of adverse drug reactions if the patient is administered certain drugs, or a stated absence of known risks. The main principle is that there are multiple levels of information which are revealed sequentially, upon request by the clinician.

The initial view (‘Level 1’) contains the core information that is required by a clinician in order to identify the causative agent (namely, what medication to avoid) and what reactions the patient has had in the past.

The second view (‘Level 2’) contains information that supports the core information, primarily providing the justification and provenance of the core information. The second level view could also provide a repository for other links to relevant entries elsewhere in the patient's record.

ID	Description	Conformance	Evidence Rating
ADR-0001	Feature multiple levels of display: an immediate view (‘Level 1’) containing the risk phrase (comprising the causative agent and any past reactions) and a set of other views (‘Level 2’) that are not immediately visible and contain supporting events data, if such event data and linkages exist.	Mandatory	High
ADR-0002	Feature a mechanism that allows the user to access relevant items within the ‘Level 2’ view from individual risks in the ‘Level 1’ view, if such event data and linkages exist.	Mandatory	High
ADR-0003	Feature a mechanism that allows the user to return to the ‘Level 1’ list.	Mandatory	High
ADR-0004	Link each risk phrase in the ‘Level 1’ view to one or more related event phrases in the ‘Level 2’ view, if such event data and linkages exist.	Mandatory	High
ADR-0005	In the ‘Level 1’ view, the causative agent column should be displayed at the far left-hand side of the table.	Mandatory	Medium
ADR-0006	In the ‘Level 1’ view, the past reactions column should be displayed to the right of the causative agent column.	Mandatory	Medium
ADR-0007	Feature a mechanism that allows the user to access further details from the ‘Level 2’ line items, if such event data and linkages exist.	Recommended	Low
ADR-0008	Arrange the list according to a consistent (default) order.	Mandatory	High
ADR-0009	Order the list alphabetically on the generic medication name (causative agent).	Recommended	Low

Usage Examples

This figure shows the various levels of information required to express a set of adverse drug reaction risks for a single patient. Level 1 is the initial view, and the one that clinicians use to check if a given medication could cause an adverse drug reaction. At this point, they may not decide to view any further information.

However, they may indeed wish to view further information that justifies the risk, possibly to find out more details about the reaction, to discover the form or route of the medication that caused the reaction or to identify the provenance of the risk. In which case, they would select the risk in question and activate a control which reveals detailed information about the risk, including links to appropriate data in the wider record (Level 2).

They can then choose to view further details about any of those Level 2 entries.

Figure 3: Diagrammatic Overview Showing Structure of ADR Risk List

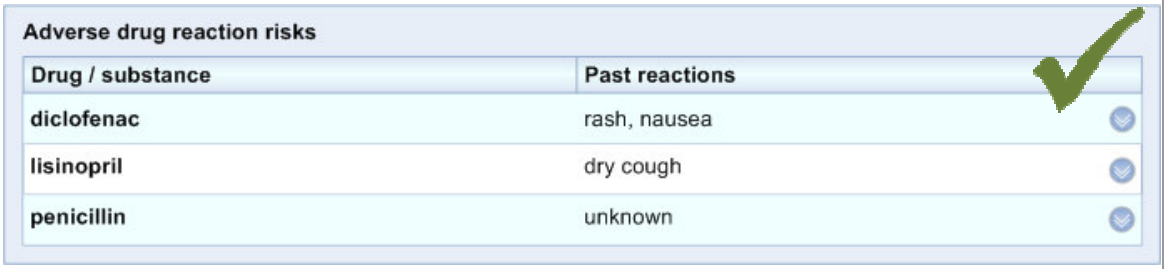


Figure 4: Example of Level 1 View

Figure 5: Example of Level 2 View

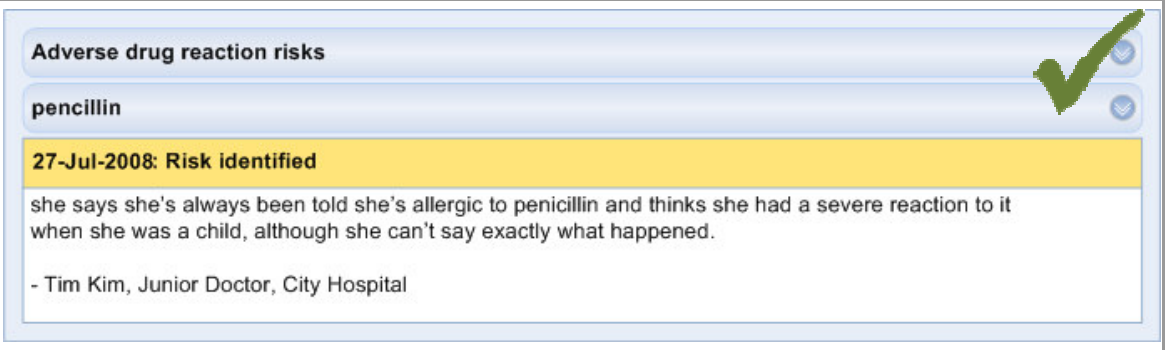


Figure 6: Example of Level 2 Details View

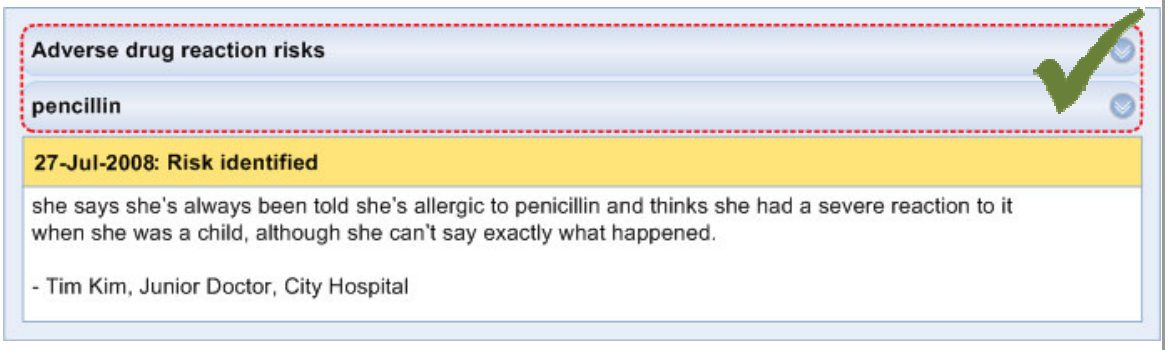


Figure 7: Provide Clear and Appropriate Navigation Back to the List (Highlighted in this Diagram by the Red Outline)

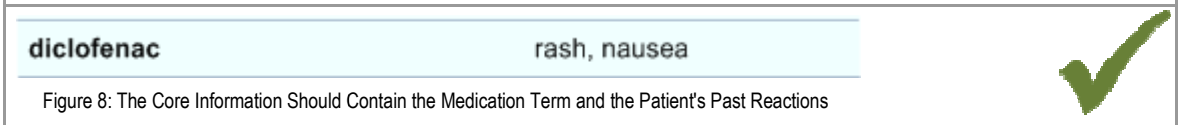


Figure 8: The Core Information Should Contain the Medication Term and the Patient's Past Reactions

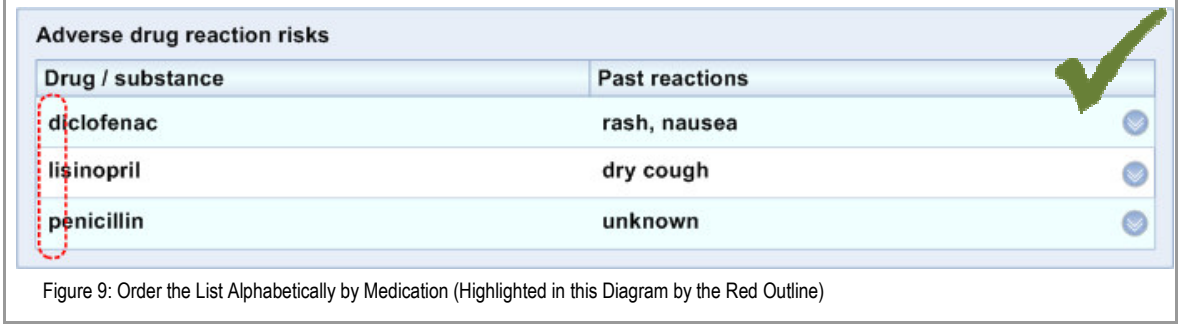
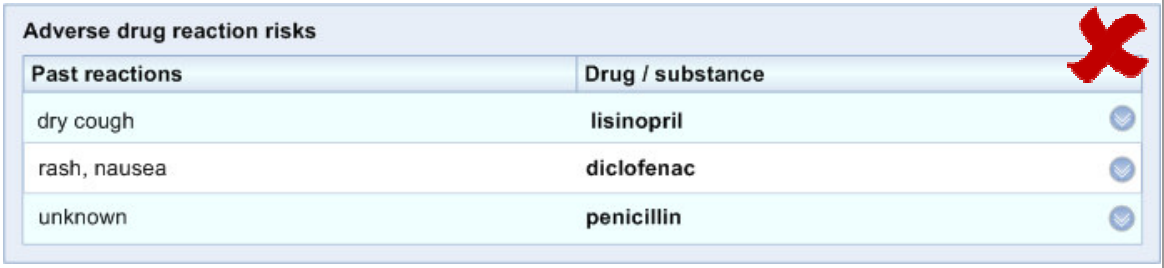


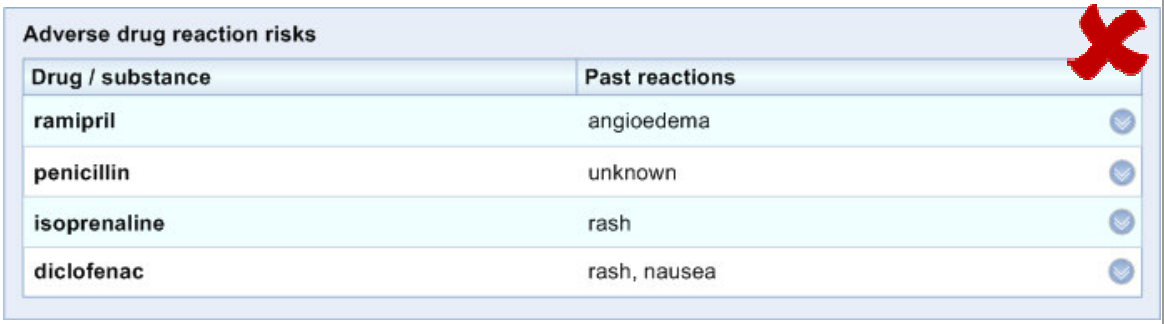
Figure 9: Order the List Alphabetically by Medication (Highlighted in this Diagram by the Red Outline)



Adverse drug reaction risks

Past reactions	Drug / substance
dry cough	**lisinopril**
rash, nausea	**diclofenac**
unknown	**penicillin**

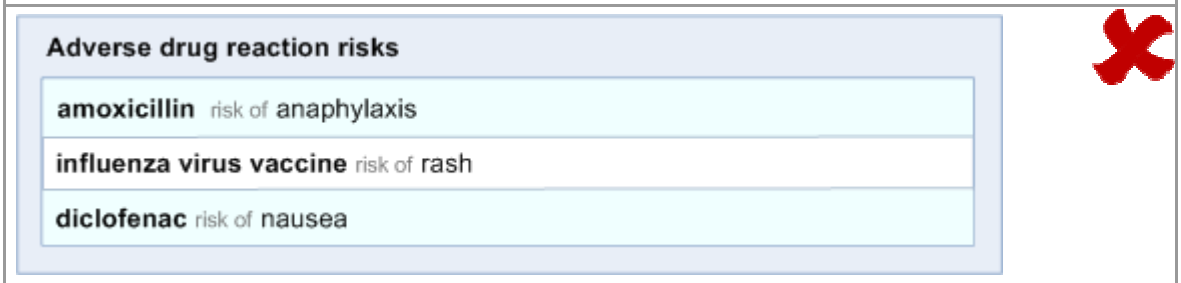
Figure 10: Do Not Feature the Causative Agent in the Right-Hand Column



Adverse drug reaction risks

Drug / substance	Past reactions
ramipril	angioedema
penicillin	unknown
isoprenaline	rash
diclofenac	rash, nausea

Figure 11: Do Not List the Risks in a Non-Alphabetical Fashion (that is, Randomly or by Date)



Adverse drug reaction risks

amoxicillin risk of anaphylaxis

influenza virus vaccine risk of rash

diclofenac risk of nausea

Figure 12: Do Not Merge Data Types in the Line

Rationale

Desk research:

Secondary research has led to the conclusion that:

- Logically, events (such as reaction events and risks) must be kept as separate phrases. For example, this is demonstrated in the NHS Connecting for Health (NHS CFH) SCG Guidance paper *Representation of Allergies and Adverse Reaction Information Using NHS Message Templates*[6]. A risk could exist without a reaction event, such as when a patient knows that they are allergic to a drug but cannot remember any details of the reaction they had experienced (if they had indeed experienced a reaction). Conversely, a reaction event could be recorded, but without the clinician feeling the need to indicate that there is an accompanying future risk, although this would be out of the current design scope. Also, there can be multiple past reactions to a single risk and, potentially, multiple risks associated with a single event. The risk phrase is a terse summary to alert future prescribers, whereas the recording of a reaction event will take a whole clinical encounter to record, including elements such as history, examination, diagnosis and plan. In all, this evidence suggests the need to separate clinical risk phrases from clinical event phrases.

[6] NHS Connecting for Health document SCG Guidance on the Representation of Allergies and Adverse Reaction Information Using NHS Message Templates **{R11}**: http://www.connectingforhealth.nhs.uk/systemsandservices/data/scg/publications/SCG0001.pdf

- The severity of the risk and the certainty that the patient suffers from this risk can be misleading when relating to future risks, as opposed to actual reaction events. For example, this is demonstrated in the NHS CFH paper on adverse drug reaction propensity **{R11}.** However, it also suggested that legacy data may feature phrases about adverse drug reactions and their associated risks which include the expression of severity and/or certainty. In these cases, it may be necessary to communicate this information in relation to the risk phrase, but not to hinder the key risk. By separating the risk phrases from the supporting events phrases, we can allow the expression of severity and/or certainty to remain as details in an event phrase, such as a 'Risk identified' event (displayed in Level 2 details), but without affecting the headline risk phrase.
- If a patient's record has a reaction event phrase, then it should, in most cases, also have one corresponding risk phrase. However, if a patient's record has a risk phrase, a corresponding reaction event phrase is not required. For example, this is expressed in the NHS CFH paper on adverse drug reaction propensity **{R11}.**

User research:

- Clinicians felt the categorisation of adverse drug risks, in this case 'allergy', 'intolerance' and 'adverse drug reaction', are misleading and confusing. Indeed, when asked to categorise risks, based upon reaction evidence, there was clear variation between clinicians' categorisations, further supporting the notion that these categories are too ambiguous and open to misinterpretation to be used in a meaningful way.
- The research showed that certain attributes that could be used to order the list, such as severity, certainty or adverse reaction type were open to subjective interpretation to such a degree as to be misleading. Given that currently there does not tend to be electronic lists of ADR risks, there is also no recognised convention on ordering these risks (see APPENDIX B).

  Therefore, in the absence of any priorities, alphabetical ordering by medication is an arbitrary, but not misleading order. Also, it makes it easier to search against risks for a medication, as the user can match the first letters of the target medication against the first letters of the medications in the list. This would also help to check for risky medications during prescribing (see APPENDIX C).

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 there is no single source in the record for adverse drug reaction risk information, the clinician may miss reaction risks	The structure allows for a single list of adverse drug reaction risk information, which could link events from various parts of the record
If a clinician only has access to the risk phrase, but does not understand why it has been recorded (that is, its justification), there is a risk that the clinician cannot fully interpret it	Provide access from the risk phrase to a second level of supporting event information
If finding the detail about reaction events involves hunting in the notes certain details may be missed	The structure links the risk phrase to justificatory phrases, such as event details (where available) in order to provide the clinician with easy access to the details that support the phrase
If the allergic reaction varied in severity between events, any severity associated with the risk phrase could be misleading	The structure allows multiple reactions of varying severities to be linked to a single risk phrase

3.3.2 Content of Adverse Drug Reaction Risk Phrases

> **Note**
>
> It is intended that guidance on the entry of the causative agent will be addressed in future research.

ID	Description	Conformance	Evidence Rating
ADR-0010	Display the causative agent, which comprises a single medication, excipient or drug class.	Mandatory	High
ADR-0011	Display the causative agent in the immediate view (‘Level 1’).	Mandatory	High
ADR-0012	The causative agent should be displayed in the same text in which it was recorded. This may be typically the Virtual Therapeutic Moiety (VTM) or drug class name, or, less commonly, the Trade Family (TF) name or the name of a medication excipient.	Recommended	Medium
ADR-0013	Do not feature two or more risk phrases that contain the same causative agent.	Mandatory	High
ADR-0014	The display must be able to handle both encoded and unencoded data relating to the causative agent.	Mandatory	High
ADR-0015	Where possible, the causative agent should be displayed as encoded data.	Recommended	High
ADR-0016	Do not display information about the form, route or dosage of the medication in the Level 1 view.	Recommended	Medium
ADR-0017	In Level 1 view, display a description of any linked past reactions, if available.	Mandatory	Medium
ADR-0018	Communicate descriptions of past reactions as key words, ideally only one or two per reaction, although this will depend upon the available data.	Recommended	Medium
ADR-0019	Where information about the past reactions for a given ADR risk is not known, communicate that this information is not known.	Recommended	Low
ADR-0020	The display must be able to handle multiple past reactions for a single causative agent.	Mandatory	Medium
ADR-0021	For a given risk, the display should be able to distinguish between those reactions which occurred simultaneously and those which occurred on different occasions, that is, in separate clinical episodes.	Recommended	Medium
ADR-0022	Where multiple reactions occurred for the same reaction event (that is, simultaneously), display the character ‘+’ in between them or the word ‘AND’ in capital letters. For example, if the patient experienced a rash and nausea at the same time, the words ‘rash + nausea’ would be displayed, or ‘rash AND nausea’.	Recommended	Low
ADR-0023	Where multiple reactions occurred for different reaction events (that is, separated in time), punctuate them with a comma.	Recommended	Medium
ADR-0024	Clearly label the causative agents.	Mandatory	High
ADR-0025	Label the causative agents ‘Drug / substance’ for example, as a column header.	Recommended	Medium
ADR-0026	Clearly label the past reactions.	Mandatory	High
ADR-0027	Label the past reactions ‘Past reactions’.	Recommended	High
ADR-0028	Clearly label the whole list.	Mandatory	High
ADR-0029	Label the list ‘Adverse drug reaction risks’.	Recommended	Medium

Usage Examples

The examples in this section demonstrate how to arrange and format the adverse drug reaction risk phrase (Level 1).

diclofenac	rash, nausea

Figure 13: Feature the Medication Term plus Summary Descriptions of Past Reaction Events

Adverse drug reaction risks

Drug / substance	Past reactions
diclofenac	rash, nausea
lisinopril	dry cough
penicillin	unknown

Figure 14: Display the Risk Phrases Vertically Stacked in a List View

Adverse drug reaction risks

Drug / substance	Past reactions
Norpramin	nausea

Figure 15: Where Medication is Expressed as Unencoded Text, Feature it in Normal Weight Text

Adverse drug reaction risks

Drug / substance	Past reactions
diclofenac	rash, nausea
lisinopril	dry cough
penicillin	unknown

Figure 16: Display a Summary of Past Reactions in the Level 1 View

Adverse drug reaction risks

Drug / substance	Past reactions
diclofenac	rash, nausea
lisinopril	dry cough
penicillin	unknown

Figure 17: Provide a Clear Label for Overall Risk List

Adverse drug reaction risks

Drug / substance	Past reactions
diclofenac	rash, nausea
lisinopril	dry cough
penicillin	unknown

Figure 18: Provide Clear Labels for Data Columns

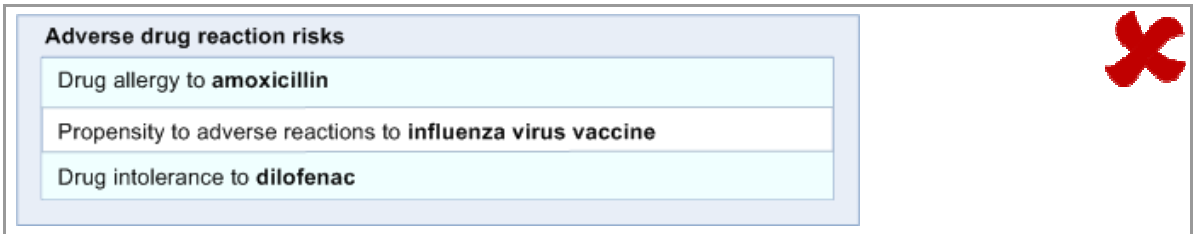


Figure 19: Do Not Categorise Adverse Drug Reaction Risks in the Level 1 View of the Risk Phrases

Rationale

General:

- Research outlined in this Rationale section showed that categorisations of adverse drug reaction risks should be eschewed in favour of displaying a summary of past reactions (see APPENDIX B and APPENDIX C).
- Gradings of severity, risk or certainty should also be avoided. In the absence of a universally defined scale, gradings of severity are subjective and open to misinterpretation. Also, the severity of a reaction can vary over time, meaning that the current severity grading may not hold for future reactions. The level of risk posed by a medication is even more difficult for a clinician to calculate: not only can the reaction severity change between exposures, but also the probability that a patient will react or not on subsequent exposures is incalculable, given that subsequent reactions to a drug allergy are idiosyncratic and therefore no one can calculate the probability of their recurrence. Also, expressions such as 'Low risk' can imply that the patient is unlikely to react, when in fact this is not meant by the author.
- The causative agent of an ADR risk will typically be an active agent or an excipient of a medication. In the majority of cases, the causative agent will be expressed either as a generic drug name (VTM) or a drug class. However, in addition to being able to record a risk in terms of an excipient, there are some cases where a VTM cannot be specified and the drug risk must be expressed as a Trade Family (TF) name, such as in the cases of Gaviscon and dioralyte.

Desk research:

Secondary research has led to the conclusion that:

- Categorisations of adverse drug reactions are done in a variety of ways and that there is little consistency throughout the healthcare industry (see APPENDIX B).
- Clinicians find it very hard to determine the precise aetiology of a reaction. For example, a pseudo allergic reaction may be clinically indistinguishable from Type 1 (allergic) reactions **{R4}**.
- Reactions to a given medication can vary over time in a single patient. They could have a mild reaction one time and the next time suffer a heavy reaction, or vice versa. Also ratings of severity are highly dependent upon context, so much so that they could be used quite inconsistently between different clinical situations or between different clinical authors (see APPENDIX B).
- Analysis of paper artefacts, such as drug charts and other forms, in addition to documentation about hospital policies, has revealed that clinicians are often required to record a summary of the nature of the reaction in visually prominent places, such as on the front of a drug chart or at the front of clinical notes.
- Displaying risk phrases indicates that causative agent codes should not be duplicated. For example, this is demonstrated in the NHS CFH paper on adverse drug reaction propensity **{R11}.**
- Ideally, risk phrases should not be modified with certainty or severity. For example, this is demonstrated in the NHS CFH paper on adverse drug reaction propensity **{R11}.** However, this article does recognise the fact that there may be legacy data in which certainty and/or severity has been recorded. Also, the problem with legacy data is that it may not be clear whether it refers to an event or a risk. Therefore, in these cases, the safest option is to bring this data forward unchanged, but as an event (in the Level 2 view), with the medication displayed as the risk phrase. In this way, the expression of certainty or severity is not displayed at the Level 1, risk phrase, view.
- If the required drug cannot be found in the appropriate terminology, then systems should be able to record ADR risks as free text, although free text should never be the default setting**.** For example, this is demonstrated in the NHS CFH paper on adverse drug reaction propensity **{R11}**.

User research:

- The majority of clinicians interviewed and surveyed, after being shown a variety of alternatives, indicated that the safest information to display is the causative agent, usually the medication, and a brief summary of past reactions. Any further information they deemed to be more likely to cause confusion, be misread or be misinterpreted (see APPENDIX C).Clinicians indicated that the categorisation of adverse drug risks ('allergy', 'intolerance' and 'adverse drug reaction') is misleading and confusing. Indeed, when asked to categorise risks, based upon reaction evidence, there was clear variation between clinicians, further supporting the notion that these categories are too ambiguous and open to misinterpretation to be used in a meaningful way (see APPENDIX C). User research showed a lack of consistency between clinicians regarding what constitutes an 'intolerance' as opposed to an 'adverse drug reaction' or a 'drug allergy' (see APPENDIX C).Clinicians indicated that it was important to display the reaction. This information they felt was 'crucial' to the interpretation of the risk. Indeed, this notion is supported by further workshops we conducted in which clinicians indicated that they would expect key reaction words, such as 'anaphylaxis' to be immediately visible and prominent. A number of clinicians indicated that whenever they hear or read phrases regarding allergies, they will initially enquire about the nature of the past reaction(s). Also, seeing the reaction may be helpful in ways that the author may not have anticipated. For example, a vasovagal response to an injection may be more likely to be attributed to needle anxiety than to an actual adverse drug reaction (see APPENDIX C). Given a variety of choices, including displaying the past reactions in the 'Level 2' view, clinicians deemed it safer to display a summary of past reactions in the immediately visible 'Level 1' view (see APPENDIX C).
- Given a choice of a largely unstructured narrative description of past reactions or a terser 'key words' summary of past reactions, clinicians chose the latter, for reasons of readability and lack of distracting clutter (see APPENDIX C).
- It was suggested in the study that the system should indicate where reactions occurred simultaneously. The use of the word 'AND' in uppercase is used by a number of concepts in SNOMED CT **{R5}** to denote multiple independent concepts occurring simultaneously (see APPENDIX C).

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:	Design mitigation:
▪ Given the variety of interpretations of their meaning, categorising adverse drug reactions into types, such as 'allergy' and 'intolerance', may negatively influence the clinicians' interpretation of the risk	▪ Avoid categorising adverse drug reactions at the level of risk expression. If known (or suspected), categorisations can be made in the event description, such as observation or diagnosis events
▪ Severity of risk is often subjective and can be misleading as reactions may vary, even for a single patient ▪ Severity of a risk may be missing, which could lead to incorrect assumptions about its severity	▪ Avoid displaying a severity for the risk. However, severity of a past reaction can be communicated when describing a past reaction
▪ In the absence of indications of severity relating to the risk phrase, there is a risk that the clinician cannot understand the potential impact of administering a drug	▪ Provide a high-level summary of the patient's past reactions to a medication (if known)
▪ If only the generic drug name is displayed, the clinician may not be able to identify that the patient is allergic to an excipient of particular brand	▪ Allow the system to display excipients of drugs in addition to VTM (generic) and TF (brand) names

3.3.3 Content of Supporting Data (High-Level Guidance)

ID	Description	Conformance	Evidence Rating
ADR-0030	In Level 2, feature at least one event phrase, preferably an encoded expression, if such event data is available and has been linked to the risk data.	Mandatory	High
ADR-0031	In those instances where information about a reaction event is not known, feature an entry comprising other justification, such as reference to a patient's assertion of their ADR condition. This may comprise free text.	Recommended	Medium
ADR-0032	Supporting data may comprise information which is not directly associated with a recorded reaction event, such as a patient's account of their allergy history.	Recommended	Medium

Usage Examples

The figures below show the progression of possible table views which show how the user could access supporting data. The supporting data shown here includes the entry of the risk information, an entry outlining the actual reaction which led to the clinician deciding that the drug was a risk and an entry relating to a clinician confirming the risk after asking the patient. All these entries include details of when and where the data was entered, and by whom.

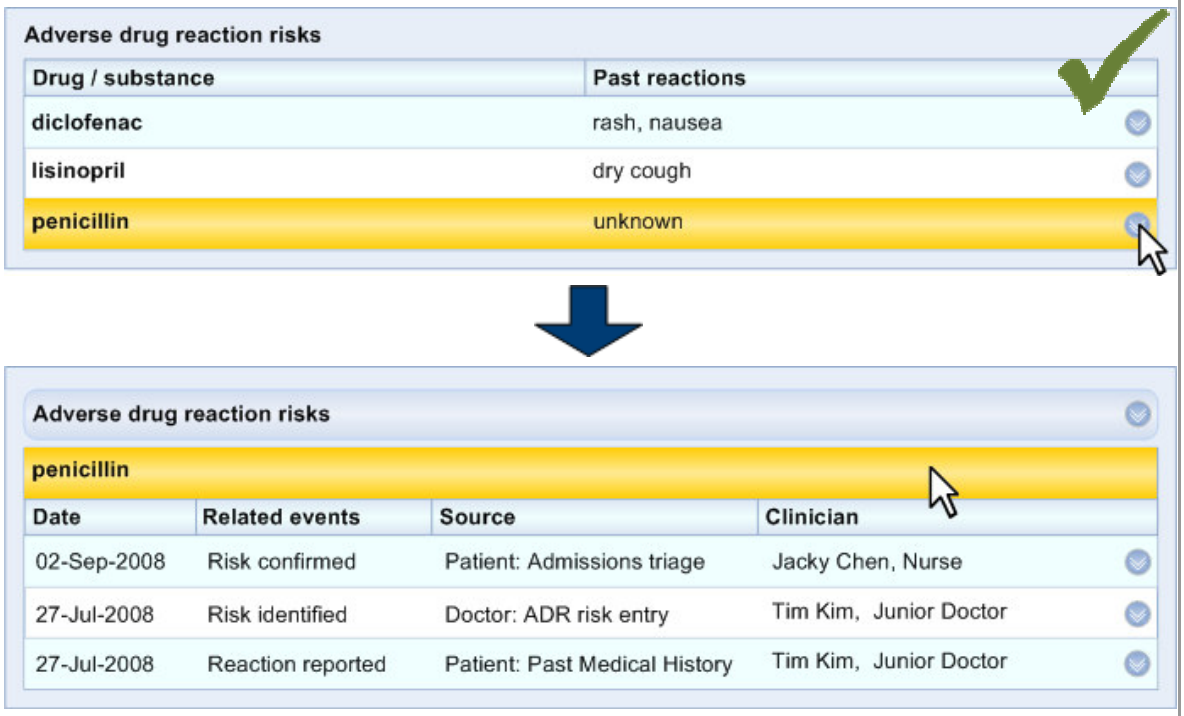


Figure 20: Allow the Clinician to Quickly and Easily Access Supporting Justification Event Information in the Level 2 View

In this example, clicking on the risk phrase (Level 1) reveals the supporting event phrases (Level 2).

The figures below show the sequence of possible table designs which allow the user to view further information about a given supporting data entry, in this case the identification of the risk. In this case, this further information comprises free text describing the patient's account of the history of their penicillin allergy. This is an example of supporting information that is not relating to a direct account of a recorded event.

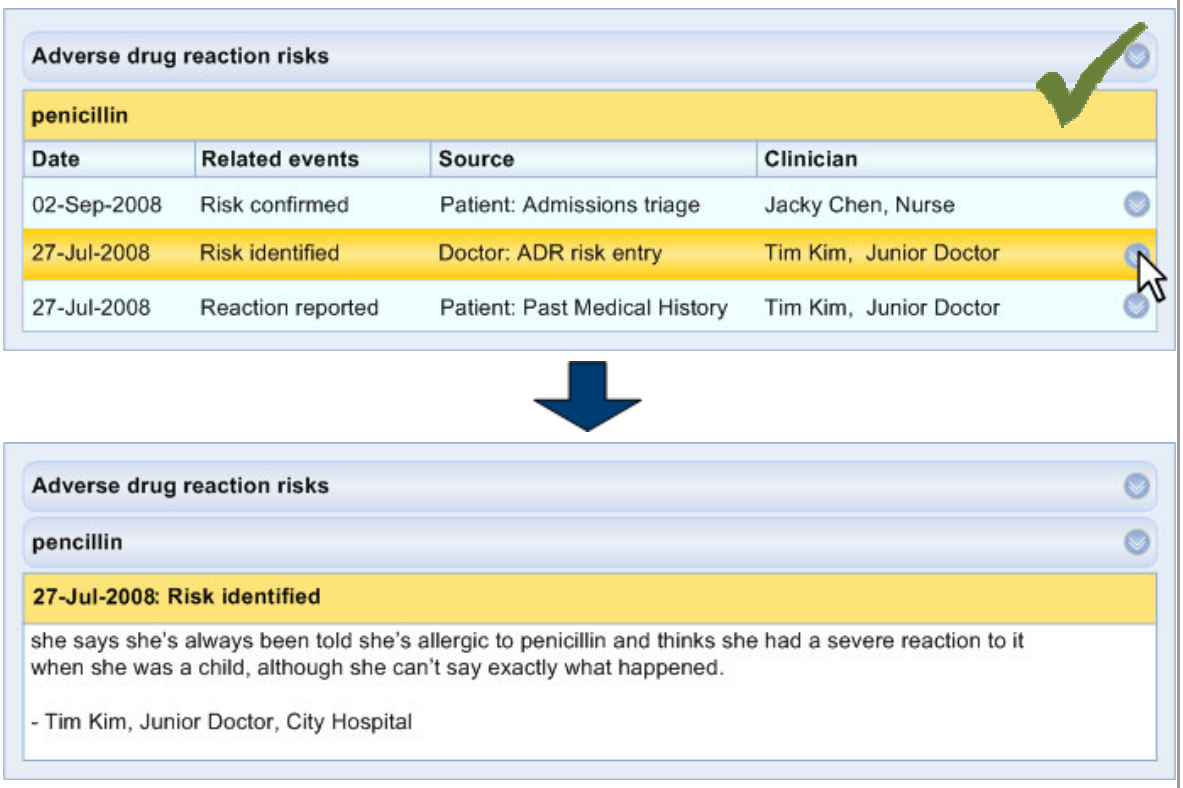


Figure 21: Display of Further Details , Where Appropriate, such as a Description of an Account Given by the Patient about their Allergy History

Rationale

General:

- It is important that justification which does not relate to a past reaction event is also accessible from the adverse drug reaction risk as this can be important as well. This information will typically be entered at the point of identifying and recording the risk. The clinician may have identified a risk based upon a patient's testimony, but the patient cannot remember the reaction event; they simply know that they have an allergy. In this case it will be important that the clinician can record that they believe that the patient has an ADR because of what the patient has told them. A justification entry will also be important if the clinician has edited an existing risk. For example, they may have modified the causative agent for a given risk after the patient had been exposed to it with no harmful effects. In this case, the clinician may now believe that the original reaction was caused by another agent (or possibly a more specific instance of the listed agent) and must also record why they are modifying the risk.
- Possibly there is a need to visually distinguish event items (such as diagnosis of a reaction) from non-event items (such as identification of a risk). There may also be a need to be able to filter out certain events, depending on how many are linked with the risk. However, this is not covered by the current guidance, but could be usefully addressed by further research

User research:

- Clinicians indicated that, in certain cases, they need to be able to access the details of the supporting evidence for a given risk phrase if they are to be able to properly interpret it (see APPENDIX C).

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 hazard:	Design mitigation:
▪ In the absence of indications of severity relating to the risk phrase, there is a risk that the clinician cannot understand the potential impact of administering a drug	▪ Provide access from the risk phrase to a second level of supporting event information, in which the patient's past reactions (and associated severities) are described

- If the only the generic drug name is displayed, the clinician may not be able to identify factors which could have influenced the nature of the reaction, such as the dose and other excipients of the specific drug the patient had taken
- If information about the route of the drug is not available the clinician may not be able to identify (i) if the severity of the reaction has been mediated by the route; or (ii) that the patient is in fact allergic to a constituent of a drug rather than the active ingredient
- Provide access from the risk phrase to a second level of supporting event information, which may include fuller details about the medication which caused the reaction, including brand name, dosage and route
- Provide access from the risk phrase to a second level of supporting event information, which may include fuller details about the medication which caused the reaction, including brand name, dosage and route

3.3.4 Format of List

ID	Description	Conformance	Evidence Rating
ADR-0033	In the 'Level 1' view the medication column must be able to expand to a default width of at least 44 characters, allowing for a maximum two-line wrap. **Note** Where a medication wraps onto a second row, it should not split any words. The new row should occur at a space in the phrase.	Mandatory	High
ADR-0034	In the 'Level 1' view, the data should be displayed in a tabular format.	Recommended	High
ADR-0035	Feature the 'Level 2' supporting events data in a tabular format.	Recommended	Low
ADR-0036	Follow the guidance featured in the Medication Line design guidance **{R8}** which addresses how to format medication names.	Mandatory	High
ADR-0037	In the 'Level 1' view, feature all encoded medication names (causative agent) in bold and in lower case.	Mandatory	High
ADR-0038	Feature all unencoded (that is, written in free text) medication names in normal weight and in lower case.	Recommended	Low
ADR-0039	Feature light shading on alternate rows in the tables.	Recommended	High
ADR-0040	Feature a highlight colour for hover-over of lines.	Mandatory	High
ADR-0041	Do not feature black triangles as navigation controls.	Mandatory	High

Usage Examples

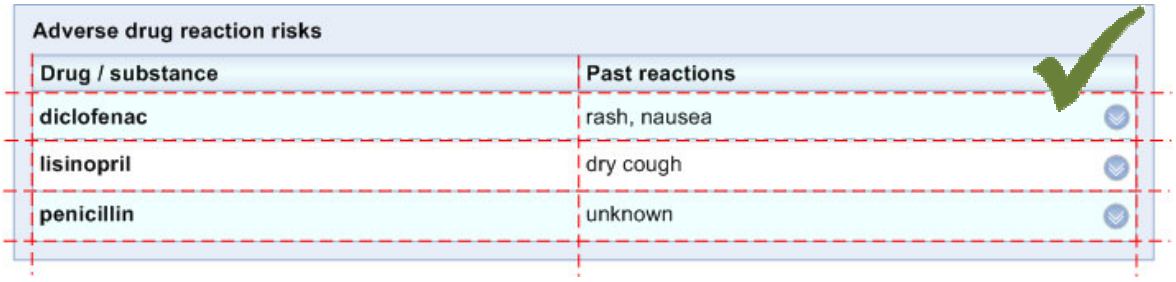


Figure 22: Feature the Risk Phrases in a Tabular Format (Emphasised in this Diagram by the Red Lines)

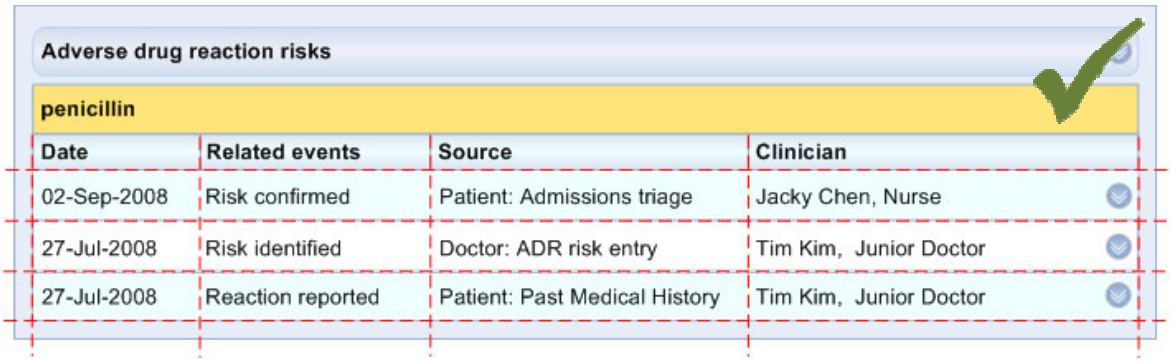


Figure 23: Feature the Supporting Event Phrases in a Tabular Format (Emphasised in this Diagram by the Red Lines)

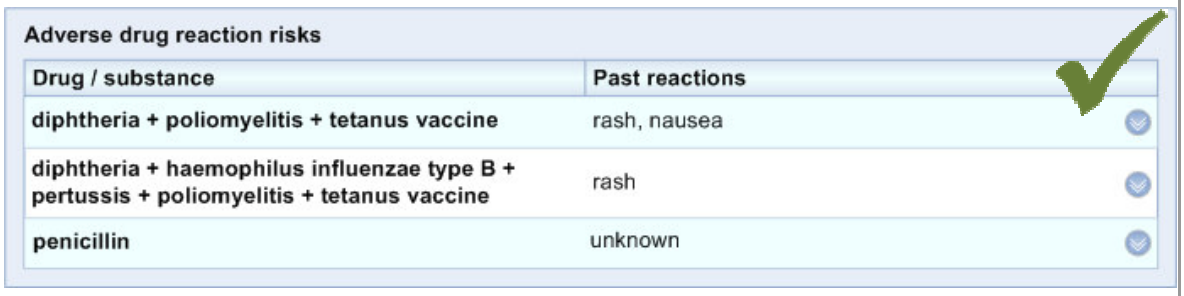


Figure 24: Allow for a Width of at Least 44 Characters in the Medication List, with a Single Line of Wrapping also Allowed

Figure 25: Do Not Split a Word when Wrapping

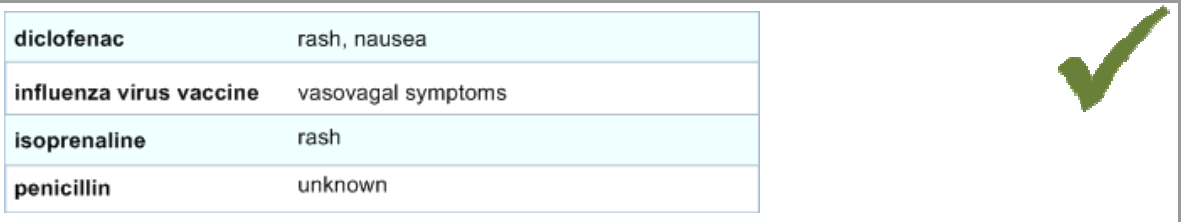


Figure 26: Alternate Lines with a Faint Banding and Lines

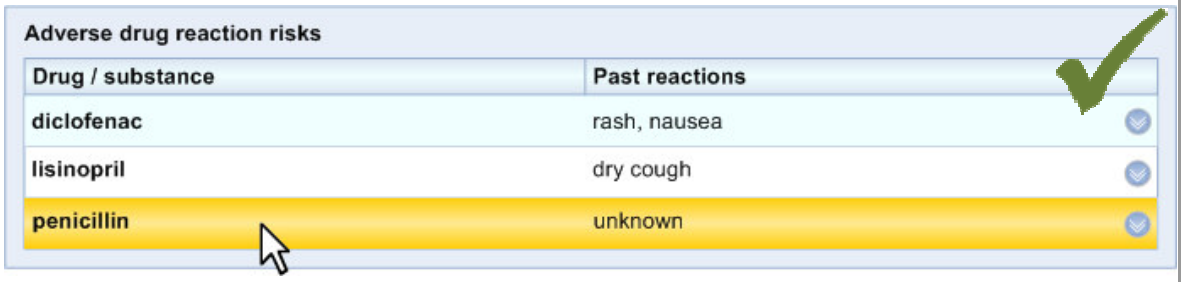


Figure 27: Display Selected Line with a Coloured Highlight

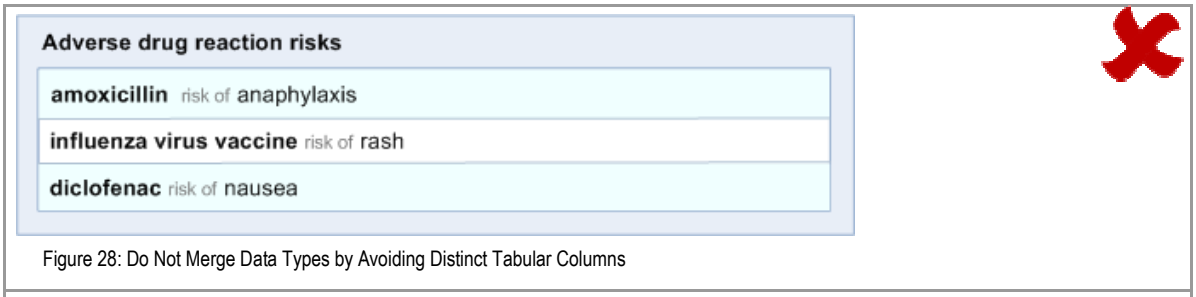


Figure 28: Do Not Merge Data Types by Avoiding Distinct Tabular Columns

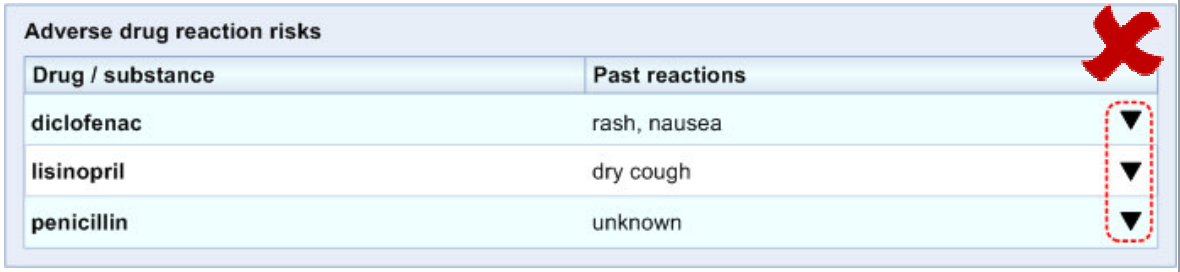


Figure 29: Do Not Feature Black Triangles as Navigation Controls (Highlighted in this Diagram by a Red Outline)

Rationale

Desk research

- Research into the lengths of drug names (in terms of characters) has shown that the maximum length of medication labels (specifically VTM and TF labels) is 88 characters long. Just over 98% have 44 characters or less, whereas 95% have 34 characters or less. There may names which are not VTM or TF which have longer length labels, such as for drug excipients, but not only will the expression of these be much rarer it will be less critical to have their full labels in view; in the case of VTM, often it is the last few letters of the label which indicate the family to which the drug belongs, but we have no evidence to suggest that this is true of drug excipients or drug classes.
- Other design guidance has indicated that one must display generic medication labels, comprising dm+d terms, in bold, lower case text **{R8}**.
- Other design guidance has indicated that SNOMED CT encoded text must be displayed in bold, and that un-encoded text can be left in normal weight. **{R10}.**
- Other design guidance has indicated that it is easier to read along rows if they feature alternate light banding. **{R9}**.
- Inverted black triangles are used to indicate when new drugs and vaccines are first marketed and healthcare professionals should report ('Yellowcard') all suspected ADRs which occur as a result of drugs marked with the black triangle, regardless of the severity of the reaction. For this reason, this symbol should not be used for other purposes, such as to indicate a 'reveal' or 'drop-down' action **{R12}**.

User research

- User research showed that clinicians found it clearer and safer to read risks arranged into a tabular rather than sentence-based structure. Reasons included that the data was easier to scan, simpler, less likely to be misread and key information, such as the medication and critical data, such as anaphylaxis, stands out more prominently (see APPENDIX C).

3.3.5 Displaying Dates and Times

ID	Description	Conformance	Evidence Rating
ADR-0042	Feature a date for each discrete event item in the 'Level 2' view. This includes record-entry events, such as 'risk identified' or 'risk confirmed'.	Mandatory	Medium
ADR-0043	Do not feature dates in the 'Level 1' view.	Mandatory	Medium
ADR-0044	For each event item listed in Level 2, display, as a default, the date of entry, unless, at the point of entry, a different date has been specified (such as the actual date on an event).	Recommended	Medium
ADR-0045	Allow for the display of partial dates, where appropriate (in Level 2).	Recommended	Medium/

Usage Examples

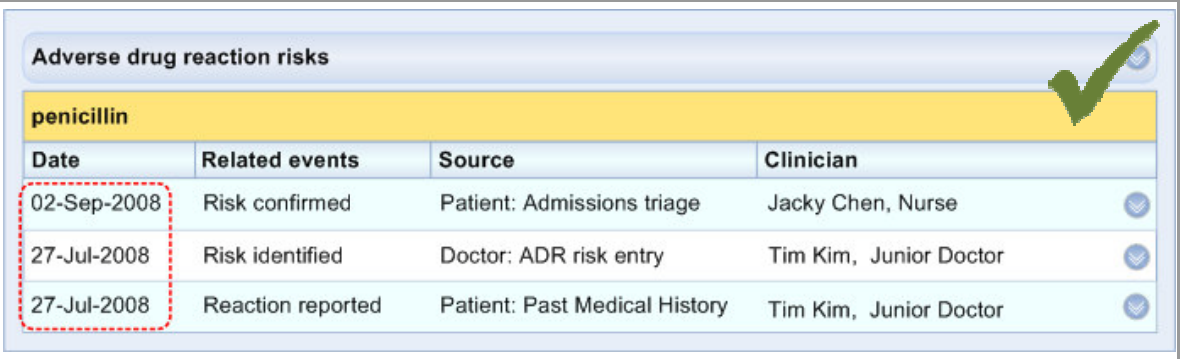


Figure 30: Display a Date, or a Time if Appropriate, for each of the Supporting Event List Items (Highlighted in this Diagram by a Red Outline)

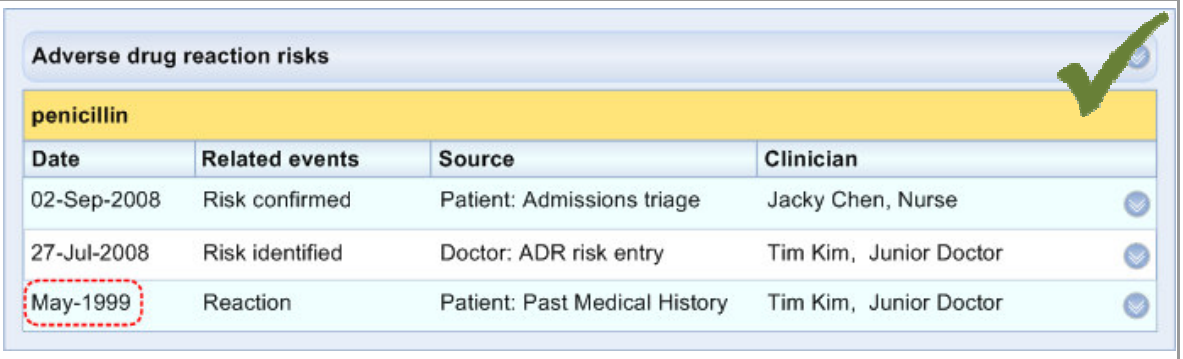


Figure 31: Display a Partial Date, if that Is What Has Been Entered (Highlighted in this Diagram by a Red Outline)

Rationale

General:

There may be a number of dates associated with any given risk phrase. Indeed, there may be multiple reaction event dates associated with a single risk phrase. Providing any single date at the level of risk phrase, even if it is well labelled, can lead to misinterpretation and incorrect assumptions. For example, if the date were 'risk identified' or 'last confirmed' the clinician could wrongly assume that that was also the date of the reaction event. If the date was the date of the reaction, the clinician could think that this was also the date that the risk was first identified, which could also be incorrect. When displaying dates, it would be safer to display all the key dates simultaneously, in order to reduce the risk of misinterpretation. Therefore, we recommend that a single date should not be displayed at the risk phrase level. Dates should be shown at the 'event' level, including the event of identifying the risk.

User research:

- Research found that simply providing a date in the risk phrase level view (Level 1) can be problematic, as clinicians may interpret it in a number of ways, and the predominant understanding is that it means the date of last reaction, rather than when the risk was first identified or last confirmed (see APPENDIX B and APPENDIX C).
- In tests, clinicians indicated that they thought that displaying multiple dates at Level 2 was safer than showing one or more dates at Level 1. It should be pointed out that, although this solution was most popular, there was some mixed opinion (see APPENDIX B).

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 hazard:	Design mitigation:
▪ Featuring a date next to the risk phrase can be misleading as clinicians may assume it is the date of a reaction taking place, whereas, in fact, it is the date when the risk has been identified	▪ Do not feature the date in the risk phrase level (Level 1)

3.3.6 Displaying Source of Risk

ID	Description	Conformance	Evidence Rating
ADR-0046	For each 'source' description, feature the 'source' who first articulated the information (for example, 'Patient', 'Doctor', 'Carer')	Mandatory	Medium
ADR-0047	For each 'source' description, feature the encounter or situation in which the event took place (for example, 'Past Medical History', 'Admissions Triage')	Recommended	Low

Usage Examples

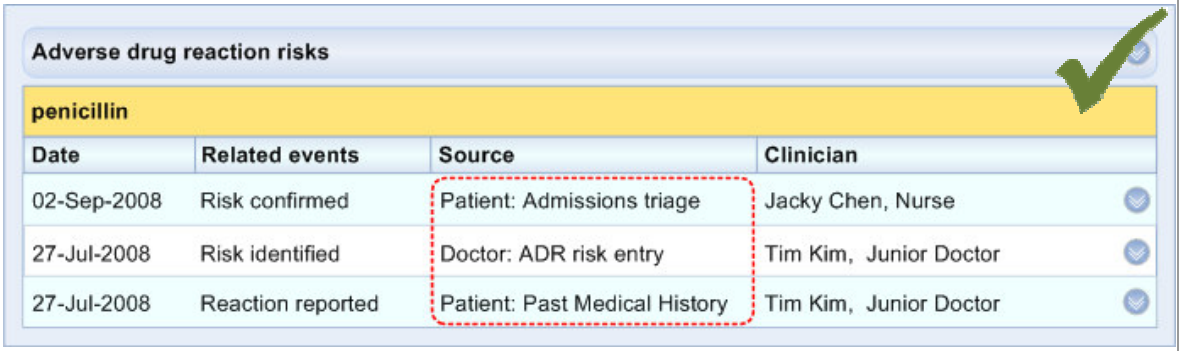


Figure 32: Display the Source of the Information for each Event Phrase (Level 2) (Highlighted in this Diagram by the Red Outline)

Rationale

User research:

Clinicians will look for the source of the risk information as this may influence their interpretation of the risk. For example, they will assign greater confidence if the source of the risk is an allergist or pharmacist (see APPENDIX B).

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 hazard:	Design mitigation:
▪ If the source of the risk is not known, the clinician may give it undue credibility or inversely may underestimate the legitimacy of the phrase	▪ Indicate the source of the risk phrase

3.3.7 Displaying Authorship of Risk and Event Phrases

ID	Description	Conformance	Evidence Rating
ADR-0048	For each event phrase, feature the name of the clinician who recorded the event.	Mandatory	High
ADR-0049	For each event phrase, feature the role of the clinician who recorded the event (for example, 'Nurse', 'F2', 'Registrar').	Mandatory	Medium
ADR-0050	For each event phrase, feature the location in which the event was recorded (for example, 'City Hospital'). This may be included in the 'further details' sections.	Recommended	High

Usage Examples

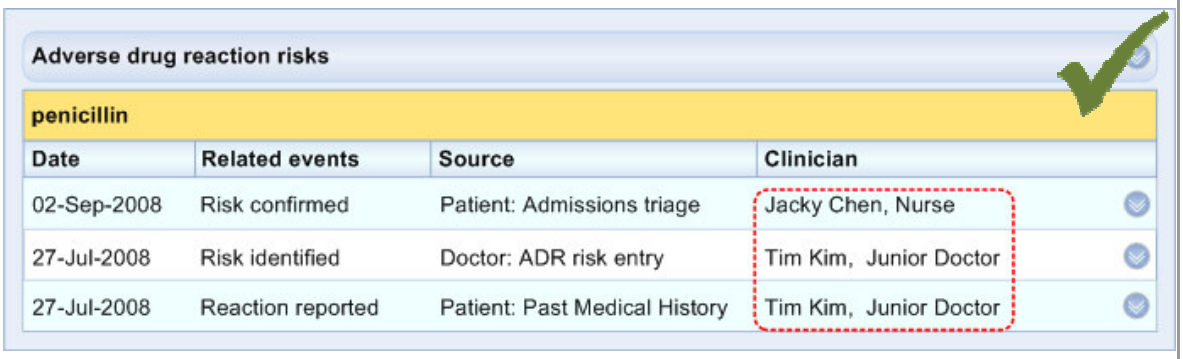


Figure 33: Display the Authors of the Event Information, Including the Event of Identifying the Risk

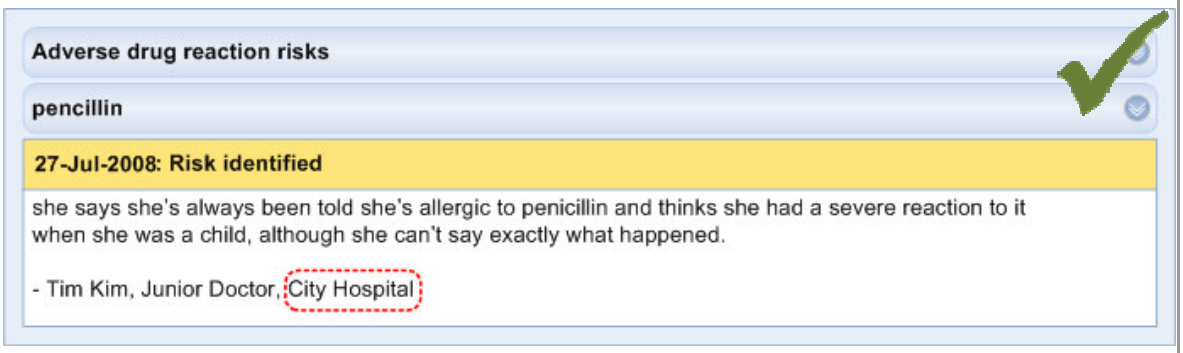


Figure 34: Allow the Clinician to Access Information about the Location in which the Event Took Place (Highlighted in this Diagram by the Red Outline)

Rationale

General:

Displaying the authors of the event phrases, including the author s of the risk phrase (that is, the clinician involved in the 'event' of identifying the risk) both adds legitimacy and accountability for the information and also allows the reader to contact the author if there is a question about the risk.

3.3.8 Displaying Absence of Risk

ID	Description	Conformance	Evidence Rating
ADR-0051	Where the clinician has checked if the patient has any adverse drug reaction risks and has concluded that there are none, the system should display 'No known adverse drug reaction risks'.	Mandatory	Medium
ADR-0052	Where the system displays 'No known adverse drug reaction risks', it should also display the date and time when this phrase was recorded.	Mandatory	Medium
ADR-0053	Where the system displays 'No known adverse drug reaction risks', it should also display provenance information relating to the author of the phrase, such as the name, role and, possibly, location of the author.	Recommended	Medium
ADR-0054	Where no clinician has checked if the patient has any adverse drug risks, the system should display 'Risk status unknown'.	Mandatory	Low

Usage Examples

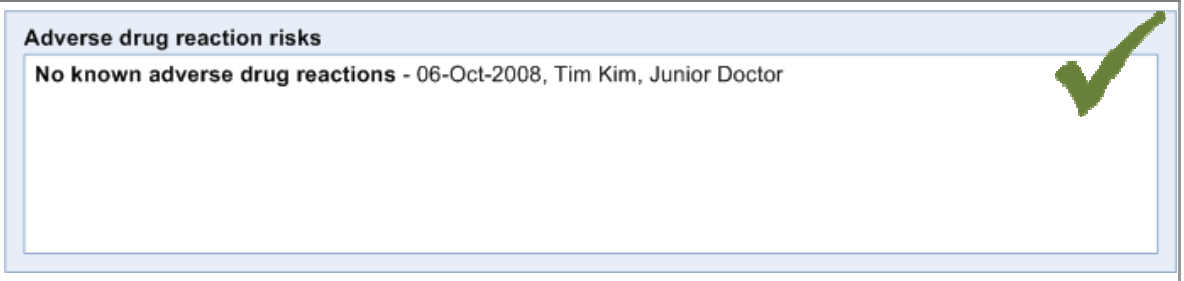


Figure 35: Display the Message 'No known adverse drug reaction risks' Where Appropriate

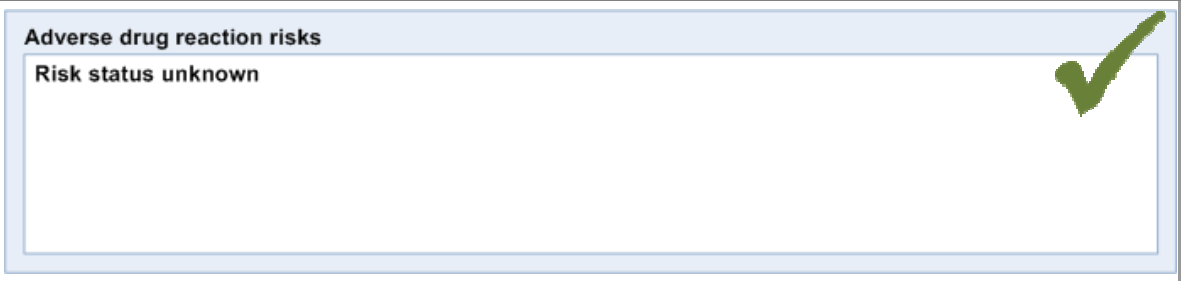


Figure 36: Display the Message 'Risk status unknown' Where Appropriate

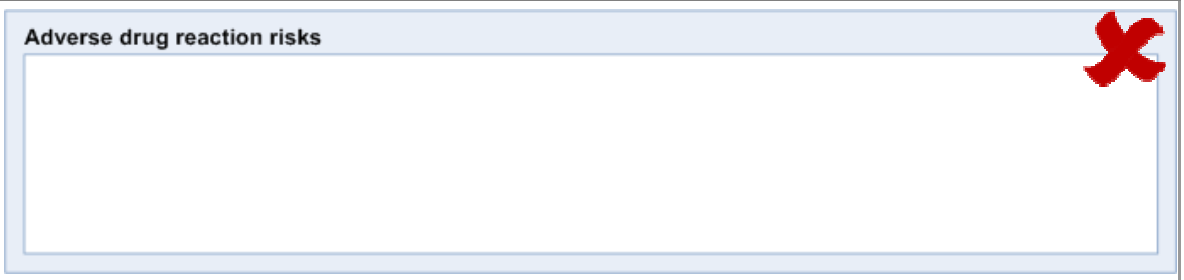


Figure 37: Do Not Feature Just a Blank Box

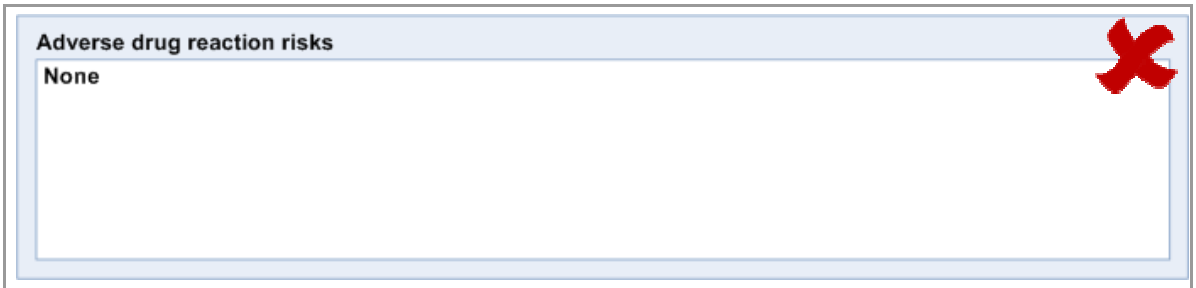


Figure 38: Do Not Feature the Text 'None'

Rationale

General:

Arguably, the definite indication of no adverse drug reactions is less reliable where a clinician does not see a patient often. Clinicians, though, do see a need to indicate no adverse drug reactions. However, this view is held more strongly in hospital and acute care rather than general practice. The general opinion is that the communication of 'no known adverse drug reactions' does not obviate the need to regularly ask the patient if they have any such risks. Yet, seeing such an entry authored by a pharmacist a few hours earlier may be useful for someone who is about to administer a medication. This suggests the need for a distinction between positive absence and unknown statuses, and for the display of provenance, including the date and time and the author's name and role.

Desk research:

Secondary research has led to the conclusion that:

- Within the healthcare industry, often the positive absence of ADR risks is expressed with the words "No Known Drug Allergy", which gives us confidence that the similar "No Known Adverse Drug Reaction risks" will be understood (see the documents *Audit of Drug Allergy Documentation*[7], *Policy for the Documentation of Allergy Status*[8], *Accuracy of drug allergy document: have we improved our practice?* **{R15}**, and *Strategies to Improve medical Record Documentation of Allergies and Adverse Reaction* [9]). However, the exact use of this term varies between different parts of the organisation, and so there is a strong need to provide common guidance for its usage (see APPENDIX B).

User research:

- Clinicians indicated that the distinction between positive absence and unknown absence needs to be explicit (see APPENDIX C)
- Clinicians indicated that the message 'No known adverse drug reaction' is clearer and safer than displaying a blank field. However, it must be noted that most of the clinicians came from a UK hospital and acute care culture where it they are expected to record positive absence of ADR risks(see APPENDIX C).
- Clinicians indicated that the author of the 'No known adverse drug reaction' and the date of this phrase are important. For example, if a pharmacist made the phrase recently, the message carries more weight than a less recent assertion made by a less qualified person (see APPENDIX C).
- When presented with 'null state' conditions, clinicians misinterpreted the phrase 'Risk status unknown' significantly less than 'No recorded adverse drug reactions', and also felt that the former phrase was safer than the latter (see APPENDIX C)

[7] Bedford General Hospital, Audit of Drug Allergy Documentation **{R13}**: http://www.londonpharmacy.nhs.uk/educationandtraining/prereg/pfizerProjectAwards2008/Rupam%20Purohit%20Bedford%20general%20Hospital.doc

[8] Department of Health, Social Services and Public Safety (Northern Ireland), Policy for the Documentation of Allergy Status **{R14}**: http://www.dhsspsni.gov.uk/policy_allergy.pdf

[9] Harvard Pilgrim Health Care, Strategies to Improve medical Record Documentation of Allergies and Adverse Reactions **{R16}**: https://www.harvardpilgrim.org/pls/portal/docs/PAGE/PROVIDERS/MEDMGMT/MEDICALRECORDS/IMPROVEMENT_STRATEGIES.PDF

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:	Design mitigation:
▪ If the clinician mistakes an expression of unknown presence or absence with an expression of known absence, they may wrongly assume that the patient does not have any adverse drug reaction risks, and may be less inclined to check	▪ Explicitly distinguish positive absence with unknown presence or absence

3.3.9 Displaying that no Decision Support is Available for a Specific Risk

The list mechanism described in this document is one way of communicating adverse drug reaction risks in a clinical software system. However, we envisage that it will be supplemented by a decision support service, which monitors medications being entered during the process of prescription or medications administration. If the medication matches a medication featured in the ADR list, the decision support service will trigger an alert message, warning the clinician that they are about to give the patient a drug to which they have a risk of ADR.

However, there may be circumstances where a medication that has been entered as a risk does not trigger decision support alerts. It could be that the medication name does not match anything in the structured terminology upon which the decision support is based (for example, obsolete or foreign drug names may not trigger an alert).

Also, even when using a structured terminology such as SNOMED CT **{R5}** and dm+d **{R6}** for recording causative agents, not all substances may be checked as part of a decision support system; any given decision support system will typically only check against a subset of the whole list.

In these cases, it is important that:

1. The clinician habitually checks the ADR risk list prior to prescription.
2. The system highlights to the clinician that the medication risk will not trigger an alert.

If the clinician is expecting decision support, in the absence of an alert, they may assume that a medication is not a risk, even if they see it in the list. Therefore it is imperative to indicate where decision support does not apply.

Providing such a feature can also educate the clinicians more generally about the limits of decision support and how they should only use it in conjunction with a high level of human vigilance. Currently the use and role of decision support is an unfamiliar concept to many working with the healthcare industry, and especially in hospital and acute care, primarily because it is not widely implemented at the moment.

ID	Description	Conformance	Evidence Rating
ADR-0055	If, upon displaying the risks, the term describing the medication will not trigger decision support the system should communicate this (for example, if the term is not expressed in structured terminology or if the term is not in the decision support system subset).	Mandatory	Medium
ADR-0056	Communicate the fact that a medication will not trigger decision support next to the medication label.	Recommended	Medium
ADR-0057	Communicate the potential lack of a decision support service by displaying either an icon with a hover-over message and/or appropriate text (depending upon space constraints).	Recommended	Low

Usage Examples

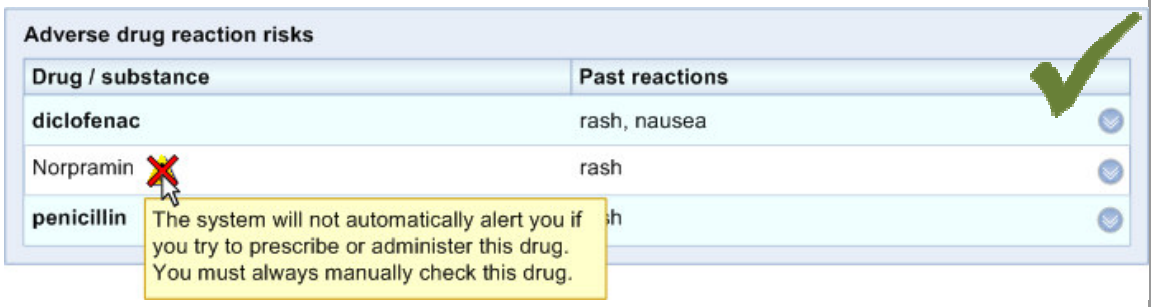


Figure 39: Example Icon with Hover-Over which Communicates that an Alert will not be Triggered for that Medication

> **Note**
>
> The guidance does not extend to specifying the actual icon, which has been chosen here for illustration and not instruction.

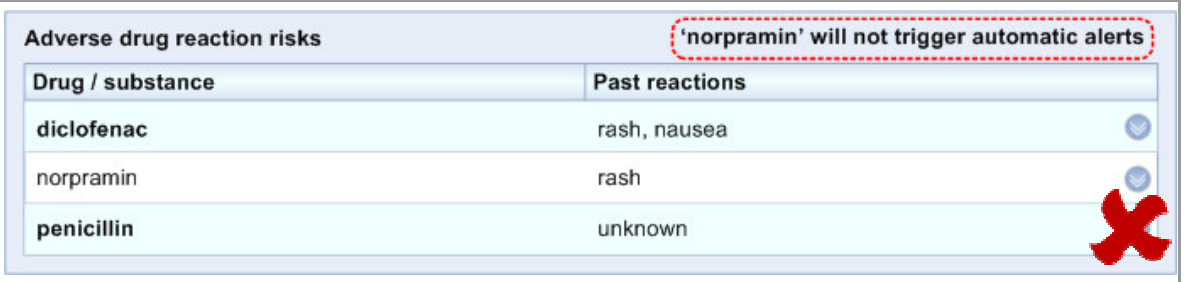


Figure 40: Do not Provide a General Message about the Non-Availability of Decision Support Outside the List Area

Rationale

Desk research:

There is a concern that that decision support may not be fully supported by a standardised ADR risk representation, potentially because the causative agent chosen by the user may not always be one which has the capability to trigger the Decision Support. For example, this is outlined by the NHS in the document *Representation in Electronic Patient Records of Allergic Reactions, Adverse Reactions, and Intolerance of Pharmaceutical Products* **{R17}.**

User research:

In the research, we explored alternative designs, such as groupings and subheadings within the list, but participants indicated that a warning, either in text or as an icon, might be the safest option (see APPENDIX C).

Other research:

Discussions in workshops with clinicians revealed that there could be many instances where the clinician will need to record the name of a foreign drug or a drug that may now be obsolete, hence where the clinician may not know the generic ingredients for these drugs. It could be that the patient half-remembers the name of a drug to which they report having had a reaction, and the clinician decides to note the name of the drug, even though it does not exactly match an encoded term, such as a term in SNOMED CT or dm+d.

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 hazard:	Design mitigations:
▪ If foreign or obsolete drug names do not match a common structured terminology, decision support systems will not be able to raise an alert if the clinician tries to administer the risky drug. The clinician may incorrectly assume that they can go ahead with the administration	▪ Medications expressed in unencoded text should be formatted differently to encoded terminology: normal weight rather than bold weight Medications expressed in unencoded terminology should carry a warning that decision support will not be triggered

3.3.10 Displaying Risks in Narrative Text

This section addresses the display of adverse drug reaction risk information outside of a highly structured format. There may be a number of situations where a full table is not appropriate, for example, because there is not sufficient room or because a table would break the flow of the text. Examples of such situations include where the risks are expressed in a referral letter or as part of a clinical summary.

Although 'narrative text' describes text which is not arranged in a table, this type of text does share a number of common guidelines with the tabular text.

ID	Description	Conformance	Evidence Rating
ADR-0058	Maintain a structured format to the display of risk phrases in narrative text, as opposed to in a list.	Recommended	Medium
ADR-0059	Display risk phrases on successive lines rather than displaying them in a continuous line.	Recommended	Medium
ADR-0060	Provide information about the causative agent (medication) in a narrative text expression of an adverse drug reaction risk.	Mandatory	High
ADR-0061	Provide information about the past reactions in the narrative text.	Mandatory	High
ADR-0062	Ensure that the text indicates that the medication relates a risk of adverse drug reaction.	Mandatory	High

Usage Examples

Risk of adverse drug reactions to the following:

- **codeine,** has caused nausea
- **penicillin**, has caused rash

Figure 41: Feature Some Structure in the Narrative Text

Risk of adverse drug reactions to the following: **influenza virus vaccine,** has caused vasovagal symptoms; **penicillin**, has caused unknown reaction

Figure 42: Do Not Display Risks as Part of a Block of Text

Rationale
Desk research: In our desk research, which included a look at a range of artefacts that contained reference to adverse drug reaction risks, we discovered a number of instances in which these risks are documented, including discharge forms and referral letters. Our solution should have some flexibility, given the variety of space available and the way in which the surrounding text is written. However, we identified a small set of guidelines, based upon the list view, which need to be followed in order to preserve a clear and consistent message (see APPENDIX B). **User research:** We compared the relative clarity and associated patient safety of displaying the risks as a long continuous block of text or in more structured solutions. Participants indicated that the structured formatting is clearer and safer (see APPENDIX C).

3.4 Rationale Summary

User research provided most of the rationale for this design guidance. Importantly, it revealed that:

- Display risk categorisations are misleading and confusing
- Past reactions must be displayed with the risk phrases

Design guidance work done prior to the creation of this document also provided rationale for the guidance, including the specification of the causative agent and the split between risk and event.

4 Document Information

4.1 Terms and Abbreviations

Abbreviation	Definition
ADR	Adverse Drug Reaction
CUI	Common User Interface
dm+d	dictionary of medicines + devices (NHS)
DSS	Decision Support Systems
NPSA	National Patient Safety Agency
NHS	National Health Service
NHS CFH	NHS Connecting for Health
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
TF	Trade Family
VTM	Virtual Therapeutic Moiety
WHO	World Health Organisation

Table 5: Terms and Abbreviations

4.2 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.

Table 6: Definitions

4.3 Nomenclature

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

4.3.1 Body Text

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

Table 7: Body Text Styles

4.3.2 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 8: Cross Reference Styles

4.4 References

Reference	Document	Version
R1.	Safety in doses: medication safety incidents in the NHS, NHS National Patient Safety Agency, National Reporting and Learning Service www.npsa.nhs.uk/nrls/alerts-and-directives/directives-guidance/safety-in-doses/	2007
R2.	Requirements for adverse reaction reporting. Geneva: Author, World Health Organization	1975
R3.	Thien, F., Practice Essentials, Allergy: Drug hypersensitivity, Medical Journal of Australia http://www.mja.com.au/public/issues/185_06_180906/thi10282_fm.html	2006
R4.	Riedl, M. and Casillas, Adverse Drug Reactions: Types and Treatment Options, A. American Family Physician http://www.aafp.org/afp/20031101/1781.html	01 Nov 2003
R5.	SNOMED CT http://www.ihtsdo.org/	
R6.	NHS Dictionary of Medicines and Devices (dm+d) http://195.97.218.30/dmd_download.htm	2.3
R7.	Design Guidance – Date Display	2.0
R8.	Design Guidance – Medication Line	2.0
R9.	Design Guidance – Displaying Graphs and Tables	2.0
R10.	Design Guidance – Terminology – Display Standards for Coded Information	1.0
R11.	Rae Long and Steve Bentley, SCG Guidance on the Representation of Allergies and Adverse Reaction Information Using NHS Message Templates, NHS Connecting for Health http://www.connectingforhealth.nhs.uk/systemsandservices/data/scg/publications/SCG0001.pdf	1.0
R12.	Reporting Adverse Drug Reactions: A guide for healthcare professionals, British Medical Association http://www.bma.org.uk/health_promotion_ethics/drugs_prescribing/AdverseDrugReactions.jsp	04 May 2006
R13.	Audit of Drug Allergy Documentation, Bedford General Hospital http://www.londonpharmacy.nhs.uk/educationandtraining/prereg/pfizerProjectAwards2008/Rupam%20Purohit%20Bedford%20general%20Hospital.doc	
R14.	Policy for the Documentation of Allergy Status, Department of Health, Social Services and Public Safety (Northern Ireland) http://www.dhsspsni.gov.uk/policy_allergy.pdf	
R15.	Nzuma, F.S., Accuracy of drug allergy document: have we improved our practice? Royal Brompton & Harefield NHS Trust http://www.londonpharmacy.nhs.uk/educationandtraining/prereg/pfizerProjectAwards2007/Farirai%20Sally%20Nzuma%20Royal%20Brompton%20and%20Harefield%20NHS%20Trust.pdf	Mar 2007

Reference	Document	Version
R16.	Strategies to Improve medical Record Documentation of Allergies and Adverse Reactions, Harvard Pilgram Health Care https://www.harvardpilgrim.org/pls/portal/docs/PAGE/PROVIDERS/MEDMGMT/MEDICALRECORDS/IMPROVEMENT_STRATEGIES.PDF	
R17.	Peter Horsfield, Representation in Electronic Patient Records of Allergic Reactions, Adverse Reactions, and Intolerance of Pharmaceutical Products, NHS	

Table 9: References

APPENDIX A REFERENCE SUMMARY OF GUIDANCE

Reference	Section	Description
ADR-0001	3.3.1	Feature multiple levels of display: an immediate view ('Level 1') containing the risk phrase (comprising the causative agent and any past reactions) and a set of other views ('Level 2') that are not immediately visible and contain supporting events data, if such event data and linkages exist.
ADR-0002	3.3.1	Feature a mechanism that allows the user to access relevant items within the 'Level 2' view from individual risks in the 'Level 1' view, if such event data and linkages exist.
ADR-0003	3.3.1	Feature a mechanism that allows the user to return to the 'Level 1' list.
ADR-0004	3.3.1	Link each risk phrase in the 'Level 1' view to one or more related event phrases in the 'Level 2' view, if such event data and linkages exist.
ADR-0005	3.3.1	In the 'Level 1' view, the causative agent column should be displayed at the far left-hand side of the table.
ADR-0006	3.3.1	In the 'Level 1' view, the past reactions column should be displayed to the right of the causative agent column.
ADR-0007	3.3.1	Feature a mechanism that allows the user to access further details from the 'Level 2' line items, if such event data and linkages exist.
ADR-0008	3.3.1	Arrange the list according to a consistent (default) order.
ADR-0009	3.3.1	Order the list alphabetically on the generic medication name (causative agent).
ADR-0010	3.3.2	Display the causative agent, which comprises a single medication, excipient or drug class.
ADR-0011	3.3.2	Display the causative agent in the immediate view ('Level 1').
ADR-0012	3.3.2	The causative agent should be displayed in the same text in which it was recorded. This may be typically the Virtual Therapeutic Moiety (VTM) or drug class name, or, less commonly, the Trade Family (TF) name or the name of a medication excipient.
ADR-0013	3.3.2	Do not feature two or more risk phrases that contain the same causative agent.
ADR-0014	3.3.2	The display must be able to handle both encoded and unencoded data relating to the causative agent.
ADR-0015	3.3.2	Where possible, the causative agent should be displayed as encoded data.
ADR-0016	3.3.2	Do not display information about the form, route or dosage of the medication in the Level 1 view.
ADR-0017	3.3.2	In Level 1 view, display a description of any linked past reactions, if available.
ADR-0018	3.3.2	Communicate descriptions of past reactions as key words, ideally only one or two per reaction, although this will depend upon the available data.
ADR-0019	3.3.2	Where information about the past reactions for a given ADR risk is not known, communicate that this information is not known.
ADR-0020	3.3.2	The display must be able to handle multiple past reactions for a single causative agent.
ADR-0021	3.3.2	For a given risk, the display should be able to distinguish between those reactions which occurred simultaneously and those which occurred on different occasions, that is, in separate clinical episodes.
ADR-0022	3.3.2	Where multiple reactions occurred for the same reaction event (that is, simultaneously), display the character '+' in between them or the word 'AND' in capital letters. For example, if the patient experienced a rash and nausea at the same time, the words 'rash + nausea' would be displayed, or 'rash AND nausea'.
ADR-0023	3.3.2	Where multiple reactions occurred for different reaction events (that is, separated in time), punctuate them with a comma.
ADR-0024	3.3.2	Clearly label the causative agents.

Reference	Section	Description
ADR-0025	3.3.2	Label the causative agents 'Drug / substance' for example, as a column header.
ADR-0026	3.3.2	Clearly label the past reactions.
ADR-0027	3.3.2	Label the past reactions 'Past reactions'.
ADR-0028	3.3.2	Clearly label the whole list.
ADR-0029	3.3.2	Label the list 'Adverse drug reaction risks'.
ADR-0030	3.3.3	In Level 2, feature at least one event phrase, preferably an encoded expression, if such event data is available and has been linked to the risk data.
ADR-0031	3.3.3	In those instances where information about a reaction event is not known, feature an entry comprising other justification, such as reference to a patient's assertion of their ADR condition. This may comprise free text.
ADR-0032	3.3.3	Supporting data may comprise information which is not directly associated with a recorded reaction event, such as a patient's account of their allergy history.
ADR-0033	3.3.4	In the 'Level 1' view the medication column must be able to expand to a default width of at least 44 characters, allowing for a maximum two-line wrap. **Note** Where a medication wraps onto a second row, it should not split any words. The new row should occur at a space in the phrase.
ADR-0034	3.3.4	In the 'Level 1' view, the data should be displayed in a tabular format.
ADR-0035	3.3.4	Feature the 'Level 2' supporting events data in a tabular format.
ADR-0036	3.3.4	Follow the guidance featured in the document *Design Guidance – Medication Line* **{R8}** which addresses how to format medication names.
ADR-0037	3.3.4	In the 'Level 1' view, feature all encoded medication names (causative agent) in bold and in lower case.
ADR-0038	3.3.4	Feature all unencoded (that is, written in free text) medication names in normal weight and in lower case.
ADR-0039	3.3.4	Feature light shading on alternate rows in the tables.
ADR-0040	3.3.4	Feature a highlight colour for hover-over of lines.
ADR-0041	3.3.4	Do not feature black triangles as navigation controls.
ADR-0042	3.3.5	Feature a date for each discrete event item in the 'Level 2' view. This includes record-entry events, such as 'risk identified' or 'risk confirmed'.
ADR-0043	3.3.5	Do not feature dates in the 'Level 1' view.
ADR-0044	3.3.5	For each event item listed in Level 2, display, as a default, the date of entry, unless, at the point of entry, a different date has been specified (such the actual date on an event).
ADR-0045	3.3.5	Allow for the display of partial dates, where appropriate (in Level 2).
ADR-0046	3.3.6	For each 'source' description, feature the 'source' who first articulated the information (for example, 'Patient', 'Doctor', 'Carer').
ADR-0047	3.3.6	For each 'source' description, feature the encounter or situation in which the event took place (for example, 'Past Medical History', 'Admissions Triage').
ADR-0048	3.3.7	For each event phrase, feature the name of the clinician who recorded the event.
ADR-0049	3.3.7	For each event phrase, feature the role of the clinician who recorded the event (for example, 'Nurse', 'F2', 'Registrar').

Reference	Section	Description
ADR-0050	3.3.7	For each event phrase, feature the location in which the event was recorded (for example, 'City Hospital'). This may be included in the 'further details' sections.
ADR-0051	3.3.8	Where the clinician has checked if the patient has any adverse drug reaction risks and has concluded that there are none, the system should display 'No known adverse drug reaction risks'.
ADR-0052	3.3.8	Where the system displays 'No known adverse drug reaction risks', it should also display the date and time when this phrase was recorded.
ADR-0053	3.3.8	Where the system displays 'No known adverse drug reaction risks', it should also display provenance information relating to the author of the phrase, such as the name, role and, possibly, location of the author.
ADR-0054	3.3.8	Where no clinician has checked if the patient has any adverse drug risks, the system should display 'Risk status unknown'.
ADR-0055	3.3.9	If, upon displaying the risks, the term describing the medication will not trigger decision support the system should communicate this (for example, if the term is not expressed in structured terminology or if the term is not in the decision support system subset).
ADR-0056	3.3.9	Communicate the fact that a medication will not trigger decision support next to the medication label.
ADR-0057	3.3.9	Communicate the potential lack of a decision support service by displaying either an icon with a hover-over message and/or appropriate text (depending upon space constraints).
ADR-0058	3.3.10	Maintain a structured format to the display of risk phrases in narrative text, as opposed to in a list.
ADR-0059	3.3.10	Display risk phrases on successive lines rather than displaying them in a continuous line.
ADR-0060	3.3.10	Provide information about the causative agent (medication) in a narrative text expression of an adverse drug reaction risk.
ADR-0061	3.3.10	Provide information about the past reactions in the narrative text.
ADR-0062	3.3.10	Ensure that the text indicates that the medication relates a risk of adverse drug reaction.

Table 10: Reference Summary of Guidance

APPENDIX B STUDY ID 42: 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 key findings from initial qualitative research carried out in August 2008 by the CUI CAPS team on Adverse Drug Reaction Risks (ADR Risks). These findings are a subset from a larger internal report prepared for the CUI CAPS ADR Risks team.

Purpose:

To understand current practice and hazards for ADR Risk display, to understand the purpose behind ADR Risk display in clinical contexts, and to gain clinical feedback on early design concepts. With the overall aim of providing design requirements for ADR Risk display.

Method:

Interviews: semi-structured telephone interviews with 12 Healthcare Professionals (HCPs), incorporating wireframe illustrations of early design concepts. Literature search: analysis of existing NHS CFH documentation on Allergies / ADR Risks and external references on Allergy / ADR Risk documentation.

B.2 Research Objectives

To gain an understanding of:

1. Current paper and electronic practices for documenting ADR Risks (such as allergies) in a variety of clinical contexts
2. Current advantages and disadvantages with these practices, in particular known and potential patient safety hazards with electronic display of ADR Risks
3. What purpose the documentation of ADR Risks has in clinical contexts
4. The potential impact of, and hazards associated with, implementing the existing NHS CFH recommendations on ADR Risk data structure for electronic records, such as by the categorisation of ADR Risks
5. Clinical feedback on specific design areas of ADR Risk display, such as the display of the nature of reaction and stating positive absence

B.3 Research Design

Interviews were semi-structured and incorporated early design concepts for ADR Risk display. These concepts were wireframe designs based on existing NHS CFH and CUI work, and were used as a means to stimulate discussion around key areas. Interviews were carried out by telephone and lasted one hour. Detailed notes from the interviews were qualitatively analysed using thematic coding.

The literature analysis was based on:

- NHS CFH documentation on Allergy / ADR data structures provided by the CUI NHS CFH Specific Audience
- Previous ADR Risks groundwork done by the CUI project and NHS CFH
- Material collected during previous CUI research – not specific to ADR Risks
- External literature found through the internet

B.4 Results

B.4.1 Participant Description

12 participants were interviewed separately. Each had either volunteered through the NHS CFH Event Management System signup (EMS) or had been contacted by the CUI having taken part in previous CUI work. Five out of 12 respondents had previously taken part in CUI clinical engagement for other work areas. Table 12: Interview Participants shows a summary of the participants' profiles:

Session	Job Role	Speciality	Level	Site	Computer Experience
303	Nurse	Renal (outpatients)	Consultant	Teaching hospital	Med
304	Pharmacist	Management	Assc Director	Teaching hospital	Med / High
305	Pharmacist	Research	Junior	Teaching hospital	Med
306	Doctor	On rotation	F2	DGH	Med / High
307	General Practitioner (GP)	GP	Senior	GP	High
308	Doctor	Paediatrics	Assc Specialist	DGH (Foundation)	Med
309	Pharmacist	EPR	Senior	Teaching Hospital	Med
310	Doctor	Care of the Elderly	ST3	DGH (Foundation)	Med
311	Nurse / Change Facilitator	Critical Care / change management	Sister	Teaching Hospital	Low / Med
312	Pharmacist	Research	Senior (Prof)	Teaching Hospital	High
313	Doctor	Accident and Emergency (A&E / on rotation	F2	Teaching Hospital	Med
314	Doctor	A&E / on rotation	F1	Teaching Hospital	High

Table 11: Interview Participants

All participants were clinical staff who had experience of viewing and recording ADR Risks as part of their work (usually as 'drug allergies'). The majority of participants were from acute secondary care, with one participant from general practice and none from community care. The 11 secondary care participants were from eight different trusts, with diverse geographical locations.

Most participants had used some kind of electronic patient record, which meant they had experience of electronic display of some kind of ADR Risk list. The majority also had medium-to-high computer experience, where high experience included items such as being familiar with spreadsheet calculation functions and having an understanding of databases.

B.4.2 Example Current Practice

- Many kinds of clinical staff will be viewing and recording patient's ADR Risk status and details
- ADR Risks currently may be recorded on a large range of documents: drug charts, the body of the medical notes, warning sticker on front of medical notes, wristbands, bed notices, handover sheets, discharge forms, and so on
- The proximal reasons for a clinician viewing / recording ADR Risks are that they are trying to understand now OR document so that someone else (or themselves) can understand later:
  - What caused the reaction?
  - Exactly what reaction did it cause?
  - What was the mechanism that linked the agent to the reaction?
- The ultimate reasons a clinician may be viewing or recording ADR Risks are to:
  - Know what you or someone else should not be prescribing / dispensing / administering now or in the future
  - Know what you CAN prescribe / dispense / administer now or in the future
  - Know whether the potential risk of giving the agent again is outweighed by the benefit
  - Know what other treatment might be required if the supposed causative agent were to be given again (for example, increased monitoring)

B.4.3 Example Known and Potential Hazards

- Currently, finding the detail about a patient's allergies (ADR Risks) involves hunting in the notes, which is time consuming and error-prone, meaning information that would support, refute or add detail to a risk is missed
- Over cautious marking of a patient as allergic to an agent limits future therapeutic choice, which can have negative consequences for the patient and the healthcare organisation
- Excessive false positive ADR Risk documenting can lead clinicians to ignore allergy documentation
- Summaries of the nature of reaction may hide important detail and lead staff to make incorrect assumptions. 'Rash' in particular is problematic
- The nature of reaction is often not documented for a risk
- The nature of past reactions may not be a good predicator of the nature of future reactions, especially when surrounding contextual information is not available
- Staff may incorrectly assume that a previous administration of an agent without an adverse reaction means that the agent could not be the cause of a subsequent reaction. Whereas the initial administration could have been when sensitization to the agent occurred

B.4.4 Key Findings per Design Area

Categorisation of Risk

Participants did not have a shared understanding of the terms: ADR, intolerance and allergy.

Participants were not familiar with having to categorise a reaction into allergy / intolerance / ADR. 10 out of 12 participants had concerns about the validity and safety of being forced to categorise when documenting ADR Risks or about seeing these categories when subsequently viewing the risks.

Causative Agent

The most useful piece of information in an ADR Risk is the causative agent.

When trying to determine the causative agent for a reaction, clinicians would usually require access to a large range of information, much of which is not often available to them.

Nature of Reaction

Currently it is good practice to document the nature of reaction with the ADR Risk.

Participants differed over whether it was possible to summarise the nature of reaction safely in a word or short phrase. They also differed over whether in an electronic display it was necessary to always display the nature of reaction when viewing the ADR Risk.

The nature of reaction was generally used to interpret the ‘severity’ of the reaction. However some participants pointed out problems with assuming a ‘severity’ of future risk based on short descriptions and past reactions.

Threshold of Documentation

Though the majority of participants would document all reactions possibly caused by drugs, some felt that what you documented would vary due to factors such as: ‘significance’ of reaction, seniority of staff and where you were documenting the risk.

Generalising Risks

The generalising of risks is seen as currently problematic as staff may not know what class a drug belongs to, or how the reaction may generalise. Therefore there is the danger of mistakenly generalising, or mistakenly not generalising, a reaction.

Positive Absence

Though a variety of terms were currently used (NKDA, NKA, nil known), all secondary care participants were familiar with the concept of documenting positive absence.

Modification

All participants felt it should be possible to ‘remove’ or deprecate a risk from the active ADR Risk List in certain situations. However, all felt that subsequent readers of the ADR Risk List should be aware of these ‘removed’ items.

Event / Risk Propensity Distinction

Participants who had used GP systems were familiar with the distinction between events and risk propensity, and felt it was useful. Other participants were less clear about the distinction, but felt it was similar to structures sometimes used in paper notes.

Dates

Many participants were confused by the dates presented in the design concepts, which could be interpreted as the date of: first reaction, diagnosis, documentation or review / confirmation.

Certainty that Agent Caused Reaction

All participants understood the concept ‘probably caused by’, most found it familiar, but only some felt it was useful, as only in a minority of cases would the causative agent be certain.

APPENDIX C STUDY ID 45: 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 key findings from user research carried out in September 2008 by the CUI CAPS team on the display of Adverse Drug Reaction Risks (ADR Risks). These findings are a subset from a larger internal report prepared for the CUI CAPS ADR Risks team.

Purpose:

To gain clinical feedback on design concepts for displaying ADR Risks in electronic systems.

Method:

Interviews: structured interviews with 13 Healthcare Professionals (HCPs) eliciting HCP preferences and qualitative feedback on design alternatives. Online survey: survey with 56 HCPs eliciting HCP preferences and qualitative feedback on a subset of the design alternatives used in interview.

Key Results:

Based on clinician preference and rationale:

- Do not categorise risks into allergy / ADR / intolerance
- Display a succinct summary of past reactions in the risk statement, clarifying that they are past reactions
- Position the causative agent first in the risk statement
- Do not display dates at the top level, as long as they are easily accessible
- Allow immediate access to the information on supporting events

C.2 Research Objectives

To gather HCP design preferences, qualitative feedback and possible patient safety hazards of CUI ADR Risk display designs.

Focusing on the areas of:

- Risk categorisation
- Displaying the nature of reaction
- Inclusion criteria of an ADR Risk List
- Sort orders
- Headings
- Dates
- Layout

- Positive absence and null states
- Levels below the risk statement
- Drug class
- Representing an ADR Risk as narrative
- Decision Support absence

C.3 Research Design

Interviews were structured, lasted one hour and carried out in person or by telephone. Participants were taken through wireframe design alternatives for each area of investigation and asked for preference based on patient safety criteria. Other qualitative feedback was elicited covering rationale for preference, design fit with current and best practice, design understandability and any potential hazards resulting from the designs. Detailed notes from the interviews were qualitatively analysed using thematic coding.

Online surveys covered a subset of the interview's design areas and similarly elicited HCP preferences for design alternatives, with the option to record rationale for preference and other qualitative feedback. The survey was distributed by NHS CFH to NHS employees who had signed-up to participate through the NHS CFH Events Management System (NHS CFH EMS) or who had provided their contact details as part of previous CUI work. Recipients were able to forward the survey to colleagues. No remuneration was supplied for completing the survey. The survey took 20-40 minutes to complete.

C.4 Results

C.4.1 Participant Description

Interviews

13 participants were interviewed separately. Each had either volunteered through the NHS CFH EMS signup or had been recruited by an HCP who had volunteered. Three out of 13 respondents had previously taken part in CUI clinical engagement for other work areas.

Table 12: Interview Participants shows a summary of the participants' profiles:

Session	Job Role	Specialty	Level	Site	Computer Experience
329	Nurse Practitioner	Emergency	Senior	Walk-in centre	Low / Med
330	Nurse Practitioner	Emergency	Senior	Walk-in centre	Med / High
331	Nurse Practitioner	Emergency	Senior	Walk-in centre	Low / Med
332	Nurse Practitioner	Emergency	Senior	Walk-in centre	Low / Med
333	Nurse Practitioner	Emergency	Senior	Walk-in centre	Med / High
334	Nurse Practitioner / IT Lead	Emergency	Senior	Teaching Hospital	High
335	Nurse Practitioner	Emergency	Senior	Teaching Hospital	Med

Session	Job Role	Specialty	Level	Site	Computer Experience
341	Doctor	Emergency	SpR	Teaching Hospital	Med / High
336	Doctor	GP	7 years GP	GP	Med / High
337	Doctor	GP trainee	SpR	GP / Hospital	Med / High
338	Research Nurse	Renal	Senior	Teaching Hospital	Med
339	Doctor	Palliative care / GP trainee	SpR	DGH / Hospice	Med
340	Doctor	GP	17 years GP	GP	Med / High

Table 12: Interview Participants

All participants were clinical staff who had experience of viewing and recording ADR Risks as part of their work (usually as 'drug allergies'). The majority of participants were from acute secondary care, with three participants from general practice and none from community care. The 10 secondary care participants were from four different trusts, with diverse geographical locations.

All participants had used some kind of electronic patient record, which meant they had experience of electronic display of some kind of ADR Risk List. The majority had medium computer experience, where high experience includes items such as being familiar with spreadsheet calculation functions and having an understanding of databases.

Online Survey

56 respondents completed the survey during the seven days that it was live. Table 13: Survey Respondents shows a summary of the respondents' profiles:

Role	Respondents n=56
Ward Manager	2%
Midwife	2%
Other Nurse	7%
Junior Doctor	19%
General Practitioner	12%
Medical Consultant	9%
Other Doctor	2%
Anaesthetist	2%
Physiotherapist	2%
Allied Health Professional	2%
Pharmacist	25%
Healthcare Informatician	2%
Healthcare Manager	5%
Software - Manager	1%
Other	9%

Table 13: Survey Respondents

Roles that were not represented by survey respondents have been removed from the table.

Other respondent descriptions:

- 40% had not taken part in Microsoft Health CUI clinical engagement before
- 76% had worked in NHS for more than five years
- 71% worked in secondary care, 16% worked in general practice
- 75% had created or modified a spreadsheet calculation function, implying a high familiarity with computer use
- Respondents were from diverse geographical locations

C.4.2 Design Areas

Categorising Risks

- Survey respondents were not able to consistently categorise a reaction into: ADR / allergy / intolerance based on short reaction statements, many also described problems in performing the task
- Many interviewees struggled to describe the difference between ADR and intolerance
- Though some interviewees felt risk categorisation might be useful, they felt it was likely to be unreliable
- The majority of survey respondents and interviewees preferred a design that did not display risk categories. Rationale for preference was that the categorisation was not useful or at least less useful (and familiar) than the nature of reaction

Displaying the Nature of Reaction

- The majority of survey respondents and interviewees preferred a design with a reaction shown at the 'top level'. The presence of reaction information was given as the key reason for preference
- A succinct summary of the reaction was preferred to longer free-text. However, some concerns were raised about summarising reactions in several words – however this is already widespread current practice and no participants felt it was impossible
- Showing 'severe' reactions only was seen to be problematic. But if a universal distinction can be found, it might be useful to indicate it in some way

Inclusion Criteria of ADR Risk List

- There are likely to be differences of opinion about whether an item should be included on a risk list. Issues that therefore need to be addressed are:
  - Dealing with long ADR Risk Lists
  - Dealing with list management where HCPs using the list have diverse perspectives
  - Clear indication about what kinds of item the list does and should contain
- Some clinical applications are likely to use risk lists that are not limited to ADR Risks

Sort Order of ADR Risk List

- Though sorting risk statements by 'most potential for harm' might be desirable, objectively determining this for all items would be difficult and possibly misleading

Causative Agent Headings

- All of the design alternatives for a causative agent column heading were seen as problematic. Alternative suggestions included those often seen on drug charts, for example, 'Medication / Substance'

Dates

- Date labels 'Last Confirmed' and 'Risk Identified' were seen as confusing. Clarification of the risk propensity / event distinction may be necessary with whatever labels are used for dates
- The majority of survey respondents and interviewees preferred dates to be on-demand rather than continuously displayed at the top level of the risk display, though this was not a strong preference

List Layout

- Preference and rationale showed that the causative agent should be positioned first in a row, so that it is read first and stands out
- Preference and rationale showed that the risks should be displayed in columns rather than 'sentences'

Positive Absence and Null States

- At least in acute secondary care, stating positive absence was expected, and could include these elements:
  - 'no known' (rather than 'no')
  - An indication of what is not known
  - Date of risk status last checked
  - Clear access to details of how this was checked
- Six of 12 interviewees misinterpreted 'no recorded adverse drug reactions' as a label for a null state – instead believing it to indicate a positive absence

Levels

- All interviewees felt that information about supporting events should be immediately accessible from the risk statement. For example, not hidden behind a tab

The Term 'Risk'

- Several interviewees misunderstood the term 'Risk' believing it to be generic knowledge support information. In addition, reactions based on past events should be clarified as past, rather than statements of the nature of future risk

Drug Class

- Automatic display of drug class with the risk statement was felt to be unnecessary and potentially misleading as risks with specific medications may not necessarily generalise to the familiar drug categories such as 'NSAID'
- Most interviewees did not understand a description of the chemical classification 'Heteroaryl acid'

Displaying Risks as Narrative Text

- Interviewees preferred risks expressed in narrative as structured text (such as bullet points) rather than as prose in a paragraph