



Once for Wales Concerns Management System

Datix Cymru

Community Pharmacy Patient Safety Incident Reporting and Management

Quick Reference User Guide

V3A April 2023

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Introduction

Community pharmacies are required under the Clinical Governance requirements for community pharmacies in Wales to report appropriate patient safety incidents.

From the 1st of April 2023, as part of the Health and Social Care (Quality and Engagement) (Wales) Act 2020, Primary Care Contractors are also required to capture and report on occasions where the Duty of Candour is triggered. Primary Care Contractors must notify the relevant Health Board of occurrences where the Duty of Candour is triggered in respect of the health care they provide under a contract or other arrangement.

Website access: [Pharmacy - NHS Wales Shared Services Partnership](#)

The Once for Wales Concerns Management System (Datix Cymru) provides a consistent Cloud based solution for incident reporting across NHS Wales and was launched on 1 April 2021. This revised approach to incident reporting has been agreed by Welsh Government, supported by the Once for Wales Concerns Management Central Team based in NHS Wales Shared Services Partnership (NWSSP).

Help with Reporting

The Once for Wales Concerns Management Central Team are based in NHS Wales Shared Services Partnership (NWSSP) and will host the website. If you have any queries regarding the reporting process or any technical issues, please contact:

OnceForWales.CMS@wales.nhs.uk – this inbox is monitored Monday to Friday 0900-1700.

User Feedback

We would be pleased to receive any feedback on the reporting process to inform improvements please email the Once for Wales Concerns Management Central Team:

OnceForWales.CMS@wales.nhs.uk

Aspects of the Form

-  This icon indicates that a field is mandatory, and you are required to complete it before saving or submitting the form.

-  This icon indicates that the field you are completing is a dropdown list. Clicking this icon will allow you to select the relevant option(s).

-  This icon indicates a date field. Clicking the icon will allow you to select a date from a calendar, or you can simply type the date in using the dd/mm/yyyy format.

-  Any field that shows this icon next to it indicates that there is additional information available to help you complete it correctly. Click the icon to view the additional guidance.

-  In a multi-select field, where you can choose more than one option from a dropdown, clicking this icon will remove the currently selected value(s)

-  Save button

Accessing the Form

The website contains links to the Health Boards Datix Cymru reporting systems. The bespoke Incident Reporting Form can be accessed by a URL link via Nadex or a logged-out form.

Link to logged out access

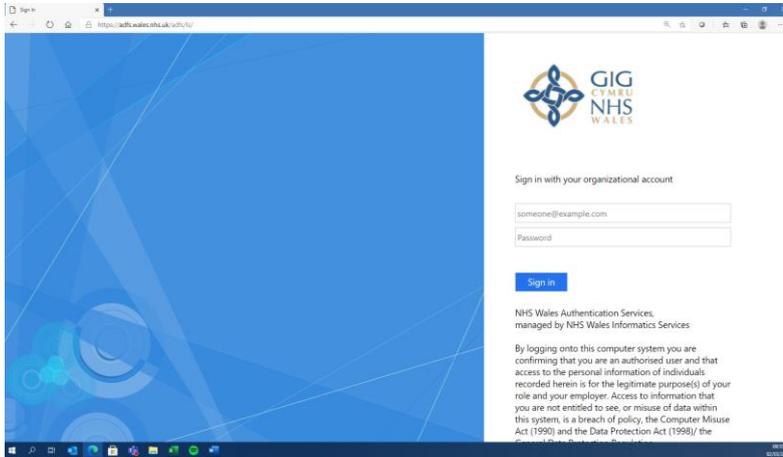
Access for colleagues with no login details/ Nadex is also via the website and link to the logged-out form. Incidents can still be reported and submitted but there is reduced functionality via this route e.g., the Master Patient Index (MPI) is not searchable, and the reporter will not be able to go back in the system and view the submitted report.



The screenshot shows the Datix web interface. At the top left is the 'RLDatix' logo. At the top right are 'COVID-19 Resources' and 'Login' buttons. The main content area is titled 'Incidents' and contains a form titled 'OFW Community Pharmacy Patient Safety Incident Reporting Form'. The form has a 'Pharmacy Details' section with the following fields:

- * Location of Incident**: A text input field with a search icon on the right.
- Exact location**: A text input field.
- Branch Number (if applicable)**: A text input field.
- Reference Number**: A text input field.

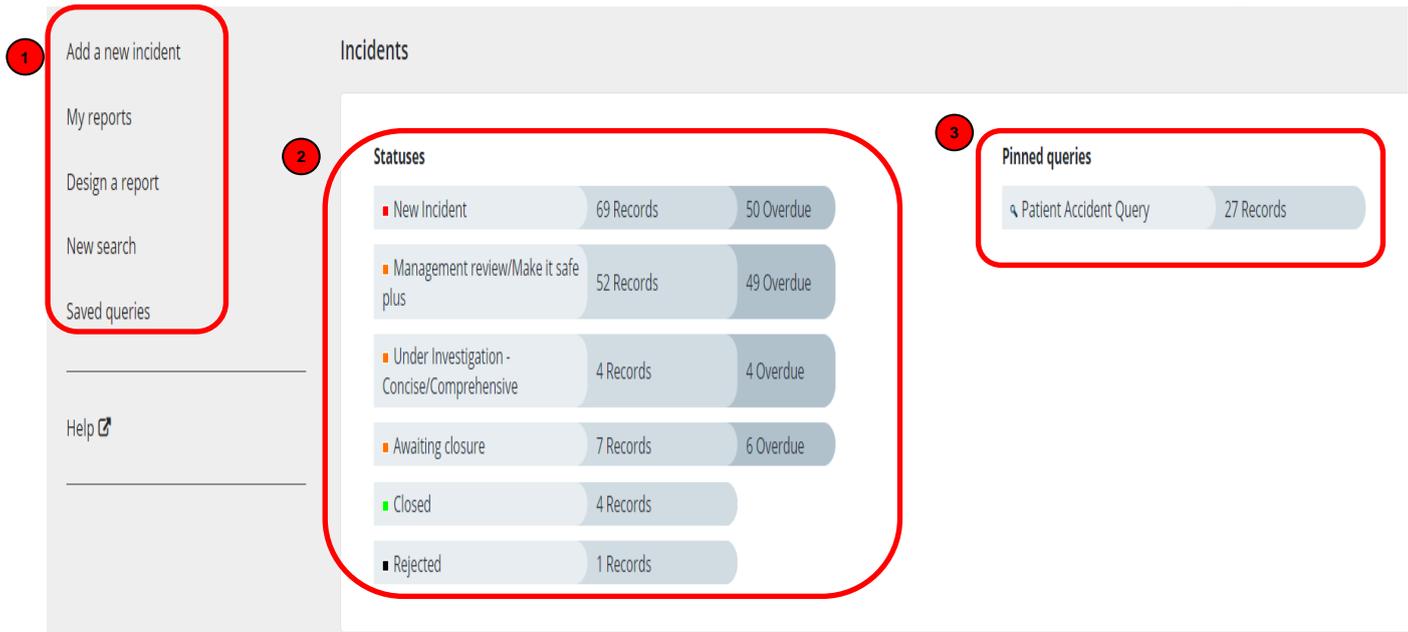
Logged in Form



Landing Page

When you login to the Incident Reporting and Management functionality you will be presented with the landing page below, the status area contains all the tools necessary to add a new record, manage a record and produce statistical and listing reports.

1. The left-hand navigation panel contains all the tools necessary to add a new incident, manage a record and produce statistical and listing reports.
2. The status area records where the incident record sits within the workflow.
3. Pinned queries allow instant access to the most frequently used searches.



The below table provides the information that is displayed on the landing page:

Left -hand navigation panel	Field name	Explanation
	Add new Incident	If you click on this, you can add a new Incident record
	My reports	If you click on this, you can run saved custom reports
	Design a report	If you click on this, you can create a custom report
	New Search	If you click on this, you can search for records
	Saved queries	If you click on this, you can use saved queries for re-use
Statuses	New incident	This is a holding area when a new incident is reported
	Management Review/Make it safe plus	These records are awaiting a review and make it safe actions by a manager within 2 working days
	Under investigation	This status indicates that the incident has undergone a management review and initial make it safe actions and has been identified for further investigation within 25 working days
	Awaiting Closure	This status indicates that all appropriate actions have been taken and the incident is awaiting final review before closure within 30 working days
	Closed	All actions are complete, and record has been closed
	Rejected	This status is used for any rejected incidents, these can be duplicate incidents or those not identified as incidents
Pinned Queries	Pinned Queries	Pinned queries allow instant access to the most frequently used searches. If you click on any of the pinned queries it will open the records within the query

If you click on any of the status areas, it will take you to a listing page. The records displayed can be sorted by clicking on any column heading. Select the record you wish to view by clicking on any of the numbers/words.

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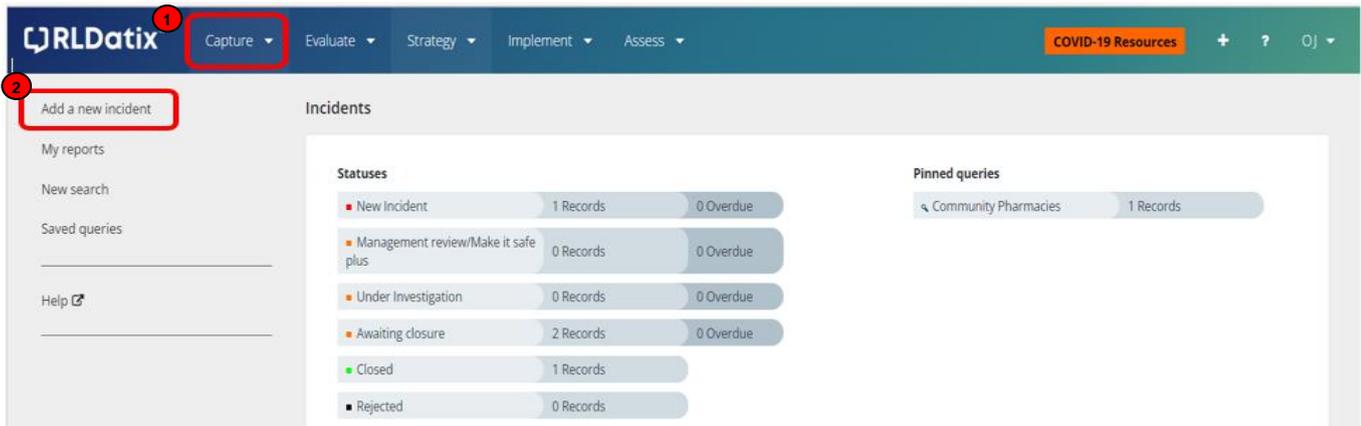
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How to add a new incident Record

If you logged out of the system you can click on the link to the reporting form.

If you are logged into the system, please:

1. Click Capture > Incidents in the top application menu.
2. Click Add new Incident in the left-hand navigation menu.



Enter the information for the incident record ensuring all mandatory fields are completed.

The fields that you are required to complete to add a new Incident record are described in the table below, this includes the section names, field names, descriptors and what type of incident information will display what fields within the reporting form:

Section	Field	Description
Incident Affecting?	Who was affected	Select the relevant field form the drop-down menu.
People Affected	Contact Type	If the contact type is anything other than Service User/Relative/Public, a search of the contact module can be undertaken by entering the forename and surname of the person affected. If no record is found, complete all fields relating to the person involved in the incident
	NHS/ID Number	If the contact type is a Patient/Service User, the search function will trigger. You can select to search via NHS number. If Patient/Service User is selected the initial trigger field for Duty of Candour will be visible in the Incident Severity section of the form
	ID Number	Enter the appropriate number and search
	Was the person injured in the incident?	If yes, this will trigger an Injury Details section

Section	Field	Description
When did the incident happen	Incident date (dd/mm/yyyy)	The date the incident occurred
	Time (hh:mm)	The time the incident occurred
	Reported Date	This record auto populated at time of reporting
Where did the Incident happen?	Location of incident	The Location the incident took place
	Exact Location	Please enter the exact location the incident took place if not available in Location field.
Incident Details/What Happened	Description	Enter details of the incident, enter only the facts not personal opinions and do not enter any personal identifiable information. i.e., names
	Immediate action taken	Enter details of actions taken at the time of the incident.
	Vehicle registration number	Enter details as appropriate e.g., vehicle involved.
	Booking/CAS number if applicable (WAST)	Enter details as appropriate. This is a WAST reference number
Incident Type (Entries in this section may trigger additional questions for completion by the reporter)	Laboratory specimen number	Enter details as appropriate e.g., specimen involved
	Incident Type	Select the Type of Incident that has occurred from the options in the drop-down menu
	Sub Type	Enter the Sub type of incident that has occurred from the drop-down menu
Additional Information	Sub Subtype	Enter the Sub subtype of incident that has occurred form the drop-down menu
	Was any equipment involved in the incident?	Select yes if there are any equipment involved in the incident
	Was there any medication involved?	Select yes if there are any medication involved in the incident. A controlled drug field will be visible if yes is selected
	Was a Controlled Drug involved?	Select yes if there are any controlled drugs involved in the incident
	Does the incident have Information Governance considerations?	Select yes if there are any information governance considerations related to the incident, If yes is selected an Information Governance section will be visible
	Does this incident have any safeguarding elements?	Select yes if there are any safeguarding elements related to the incident
	Is this related to Coronavirus/Covid 19?	Select yes if the incident is related to Covid 19
	Is this related to Industrial Action?	Please select Yes/No If Yes is selected, the below industrial action questions appear
	Date of Industrial Action	Please enter date of the industrial action
	Further information pertinent to Industrial Action	Please type in any information pertinent to the industrial action
	Is this incident connected to the nursing care?	Select yes if the incident is related to nursing care
	Are there any documents to be attached to this record	Select yes if you have any documents to attach on submission, this will trigger fields at the bottom of the form. You will also be able to attach documents after submission
Was any other contact involved in the incident	If there were other contacts involved complete the other contact fields that will be triggered by answering yes to this question	

Section	Field	Description
Incident Severity	Reporter's view on level of harm	Enter the level of harm from a drop-down menu options
	Potential Harm/Priority	Enter the potential harm of the incident from a drop-down menu
	Does this Incident need external reporting?	Select yes if it needs to be reported externally
	If the patient took/used the medicine/medical device, what symptoms did they experience?	Please enter details of symptoms in narrative box
	Following the Initial/Management review, what level of adverse outcome was considered?	Please select appropriate level from options in drop-down menu. If Moderate, Severe or Catastrophic/Death is entered further Duty of Candour questions are visible in this section and a Duty of Candour section is visible to complete
	Following the initial review, has the grading changed	Please select Yes or No as appropriate. If Yes is chosen the following narrative box is visible
	Please explain why the grading has changed since the record was submitted	Complete narrative box with full explanation to cover the reason for change
Communication	Incident Manager	Reporters should select their Line Manager or Departmental Manager
	Who have you informed of the incident?	Select who you have informed about the incident from the drop-down list. If 'Police' is selected, a further section 'Police Officer details' is triggered
	Is this incident highly confidential (not for circulation)?	Select yes if this incident is not for wide circulation. This field should also be used in "Freedom to Speak Up Safely" cases

Medication Incidents

You can record incidents that involve medication in two ways. Either via incident type or by indicating medication was involved.

Incident Type

* Who was affected?

Patient/Service User

* Incident Type

Medication, IV Fluids

* Sub Type

Medication prescribing error

* Sub Subtype

Duplication of medication

Additional Information

* Were there any medications involved?

Yes

When medication has been indicated in the incident a medication form triggers on the reporting form (overleaf).

Administered	Intended / Suspected
<input type="button" value="Clear"/> <input type="button" value="Duplicate"/>	<input type="button" value="Clear"/>
<p>*Search for drug administered or omitted</p> <input type="text"/>	<p>*Search for intended / suspected drug</p> <input type="text"/>
<p>Brand name of drug administered</p> <input type="text"/>	<p>Brand name of drug intended / suspected</p> <input type="text"/>
<p>Manufacturer of drug administered</p> <input type="text"/>	<p>Manufacturer of drug intended / suspected</p> <input type="text"/>
<p>Class of drug administered</p> <input type="text"/>	<p>Class of drug intended / suspected</p> <input type="text"/>
<p>Type of drug administered, prescribed, dispensed or omitted</p> <input type="text"/>	<p>Type of drug intended / suspected</p> <input type="text"/>
<p>Route administered, prescribed, dispensed or omitted</p> <input type="text"/>	<p>Route intended / suspected</p> <input type="text"/>
<p>Dose administered, prescribed, dispensed or omitted</p> <input type="text"/>	<p>Dose intended / suspected</p> <input type="text"/>
<p>Form administered, prescribed, dispensed or omitted</p> <input type="text"/>	<p>Form intended / suspected</p> <input type="text"/>
<p>Drug administered or omitted BNF classification (1-15)</p> <input type="text"/>	<p>Drug intended BNF classification (1-15)</p> <input type="text"/>
<p>Drug administered or omitted batch number</p> <input type="text"/>	<p>Intended drug batch number</p> <input type="text"/>
<p>Drug administered or omitted ethics committee name and reference</p> <input type="text"/>	<p>Drug intended ethics committee name and reference</p> <input type="text"/>
<p>Is the drug administered or omitted under clinical trial?</p> <input type="text"/>	<p>Is the drug intended under clinical trial?</p> <input type="text"/>
<p>Is the drug administered or omitted a manufactured special?</p> <input type="text"/>	<p>Is the drug intended a manufactured special?</p> <input type="text"/>
<p>Is the drug administered or omitted a parallel import?</p> <input type="text"/>	<p>Is the drug intended a parallel import?</p> <input type="text"/>
<p>Stage at which error occurred</p> <input type="text"/>	
<p>Type of error</p> <input type="text"/>	

You can search for the administered medication and the intended.

If you are unable to find the medication you require to report, please complete the section below the medication table:

* Other Important Factors

New Medication

Please add medication below, if you are unable to find name in medication section

A radio button allows the Reporter to indicate if the medication involved is a controlled drug.

Openness and Transparency

	Field	Description
Openness and Transparency (Triggered for incidents graded Moderate and above)	Was the patient/appropriate person informed that an incident occurred?	Yes/No drop down
	When was the Patient/Service User /appropriate person informed? (dd/mm/yyyy)	Enter date the discussion took place
	Were the members of staff involved in the incident involved in informing the Patient/Service User/appropriate person?	Yes/No drop down
	Please provide details of staff members who informed the Patient/Service User/appropriate person.	Enter details of staff who were involved
	Please provide details of the Patient/Service User/appropriate person who was informed.	Enter details of the Patient/Service User/appropriate person who was informed
	Was an apology provided to the Patient/Service User/appropriate person?	Yes/No drop down
	Was a truthful account of the facts known at the time shared with the Patient/Service User/appropriate person?	Yes/No drop down
	Was the Patient/Service User/appropriate person advised about next investigative steps to be undertaken?	Yes/No drop down
Details of Person reporting the Incident	Reporter	If you are logged in your details will automatically populate. If you are not logged in, you will need to add your details in this field and then submit the Incident record
Additional Reporter Details	Reporters Location	Please enter the Location of the Reporter at the time the Incident took place
	Reporters Service	Please enter the Service the Reporter was under at the time the Incident took place

Yorkshire Contributory Factors Framework

What were the apparent contributing factors? The form contains the Yorkshire Contributory Classification Framework* in 5 domains with a conclusion for completion. If Yes or Maybe is selection a further narrative box will be visible to capture more detail for each question.

Further investigations following management review?

Management Actions Sufficient-Close



Yorkshire Contributory Factors Framework

Domain 1: Situational Factors

★ Team Factors: Was there any failure or team function?

For example; Conflicting Team Goals, Poor Delegation, Lack of respect for colleagues, Absence of feedback

- Yes
 No
 Maybe

★ Individual Staff Factors: Were there any reasons this incident was more likely to occur with the particular staff involved?

For example; fatigue, stress, rushed, distraction, inexperience

- Yes
 No
 Maybe

★ Task characteristics: Did the task features make the incident more likely?

For example; unfamiliar task, monotonous task, difficult task

- Yes

* Acknowledgement to the Yorkshire and Humber Improvement Academy*

Section	Field	Description
Conclusion	Is this incident related to the five harms of Covid 19?	Select from drop-down menu
	Severity of incident post investigation	Enter severity of incident following investigation
	Result	Enter the outcome of the incident following investigation
	Lessons learned	Enter any lessons for learning