

Once for Wales Concerns Management System

Datix Cymru

Community Pharmacy

Patient Safety Incident Reporting and Management

Quick Reference User Guide

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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.

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

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.


Incident Affecting?

* Who was affected?

Branch Number (if applicable)

Reference Number

When did the incident happen

* Incident date (dd/mm/yyyy) 

* Time (hh:mm)

Reported Date

Logged in Form

Enter your email address and password when prompted



Sign in

Email, phone, or Skype

[Can't access your account?](#)

Next

Enter password

Password

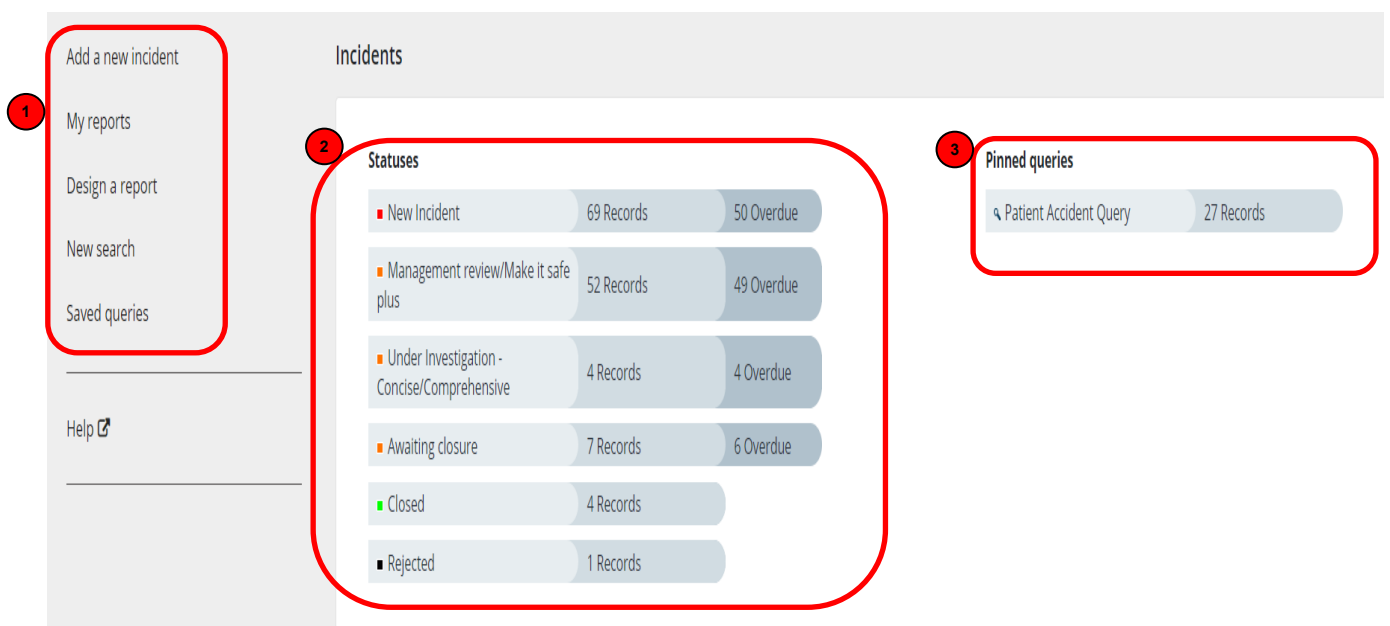
[Forgot my password](#)

Sign in

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.



Incidents

1. Navigation Panel:

- Add a new incident
- My reports
- Design a report
- New search
- Saved queries
- Help

2. Statuses:

Status	Records	Overdue
New Incident	69 Records	50 Overdue
Management review/Make it safe plus	52 Records	49 Overdue
Under Investigation - Concise/Comprehensive	4 Records	4 Overdue
Awaiting closure	7 Records	6 Overdue
Closed	4 Records	
Rejected	1 Records	

3. Pinned queries:

- Patient Accident Query (27 Records)

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

	Field name	Explanation
Left -hand navigation panel	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

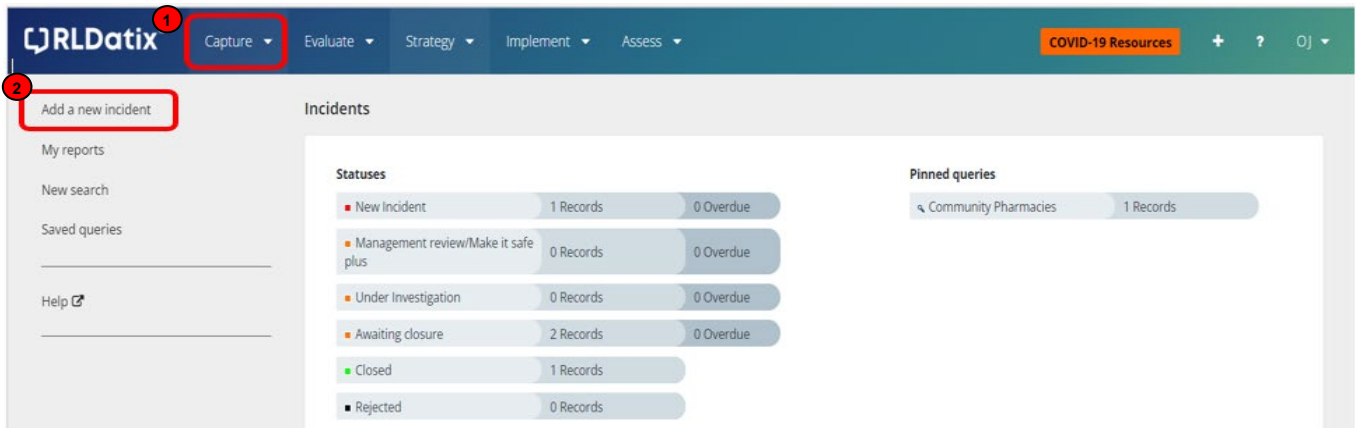
If you click on any of the status areas, it will take you to a listing page. The records displayed can be sorted by clicking on any column heading. Select the record you wish to view by clicking on any of the numbers/words.

How to add a new incident Record

If you are 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 from the drop-down menu. If any option is selected, other than 'organisation' the People Affected section is displayed. If 'organisation' is selected, the People Affected section is not displayed If Patient/Service User is selected the Openness and Transparency section will be visible on the reporting form.
	Branch Number (if applicable)	Optional fields which can be used by Community Pharmacies for internal data use
	Reference Number	
People Affected	Contact Type	A search* of the contact module can be undertaken by entering the forename and surname of the person affected. If the NHS number is available, a search using the ID Number can be undertaken. Select NHS Number in the ID number Type field and enter the 10 digit NHS number (with no spaces) in the ID number field. Click 'Search'

Section	Field	Description
		If no record is found, complete all fields relating to the person involved in the incident *The search function is disabled in the logged-out form.
	Was the person injured in the incident?	If yes, this will trigger an Injury Details section
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 Severity	Reporter's initial harm assessment	Enter the level of harm that you, as the reporter, feel is appropriate from a drop-down menu options
	Does this Incident need external reporting?	Select yes if it needs to be reported externally eg COSHH, RIDDOR
	If the patient took/used the medicine/ medical device, what symptoms did they experience?	Please enter details of symptoms in narrative box
	Managers Interim Harm Assessment	Following an interim review of the incident, the interim harm assessment must be recorded here
	Following the initial review, has the grading changed?	Yes / No options Has the Reporters view on harm (grading) been changed following the manager's interim harm assessment? If yes, the following text box will be disclosed
	Please explain why the grading has changed since the record was submitted	Complete narrative box with full explanation to cover the reason for change
	Was the healthcare provided a factor or may it have been a factor in a Patient/Service user suffering harm?	Please select Yes or No from the drop down. If Yes is selected, the Duty of Candour section becomes available.
Incident Details/What Happened	Description	Enter details of the incident, enter only the facts not personal opinions and <u>do not enter</u> any personal identifiable information. i.e., names
	Brief Description of actions 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

Section	Field	Description
	Laboratory specimen number	Enter details as appropriate e.g., specimen involved
Incident Type (Entries in this section may trigger additional questions for completion by the reporter)	Classification	Select the Type of Incident that has occurred from the options in the drop-down menu
	Category	Enter the Sub type of incident that has occurred from the drop-down menu
	Sub Category	Enter the Sub subtype of incident that has occurred from the drop-down menu
	Fire Additional Options	Please select all appropriate options if this field has been made visible.
	Fire alarm activation: Additional Options	Please select all appropriate options if this field has been made visible.
	Was a ligature used?	Please select Yes or No as appropriate if this field has been made visible.
	Method violence and aggression was received by	Please select appropriate option if this field has been made visible.
	Was absconder detained under the Mental Health Act?	Please select Yes or No as appropriate if this field has been made visible.
	Has a Perpetrator been identified?	Select 'Yes' to make the Perpetrator form visible or 'No' if you haven't got specific details and text field will be visible to capture any known details
Please provide as much information that is known about the perpetrator	Please provide as much detail as possible in this text field to assist the case manager.	
Restrictive Practice (Triggered for Physical Restraint event – Care planned and Physical restraint event – Not care planned incidents).	What model of physical intervention (training) used?	Please select all appropriate options from list.
	What technique was used?	Please select appropriate option from list.
	Who took the lead in the intervention	Please select appropriate staff from options from list.
	What other staff were involved in intervention?	Please select appropriate staff from options from list.
	Time physical intervention commenced	Please end the time in the physical intervention commenced.
	Time physical intervention concluded	Please end the time in the physical intervention concluded.
	Legal status of patient / service user?	Please select appropriate option from list.
	Why was intervention used?	Please select appropriate option from list.

Section	Field	Description
	Was medication used?	Please select Yes or No from drop down
	Who administered the medication?	Please enter the information of the person who administered the medication in this field.
	Was any other person injured during the intervention?	Please select appropriate option from list.
	What was the outcome for the patient / service user	Please select appropriate option from list.
	Was there a post incident welfare debrief with staff?	Please select Yes or No from drop down
Additional Information	Was any equipment involved in the incident?	Select yes if there are any equipment involved in the incident
	Did medication have a direct impact on this incident?	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
	Is this Incident related to EPMA (Electronic Prescribing and Medicines Administration)?	Please select Yes or No from the drop down menu
	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
	Are there any Additional Factors relating to this Incident?	Please select options relating to Emergency Planning. If Industrial action is selected, further fields will be visible to complete.
	Is this incident about nursing care?	Select yes if the incident is related to nursing care
	IPC Antigens	If visible please select appropriate option
	Were temporary staff involved in the incident?	Select Yes or No from the drop down menu
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	
Information Governance	Has personal data been disclosed outside of the organisation?	Please select Yes / No / Don't Know from the coded options If 'Yes' is selected, the question: What type of personal data is included? appears
	What type of personal data is included?	Please select all options that apply from the coded field
	Has there been (or is there likely to be) any impact to individuals as a result of the	Please select all options that apply from the coded field If 'Other adverse effects' is selected, the question:

Section	Field	Description
	incident?	Other adverse effects please specify appears
	Other adverse effects please specify	Please enter any relevant information
Communication	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
	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.
	Please select which 'Other NHS Body' has been informed	Select from drop down which other NHS body has been informed.
	Other NHS Body, please provide more detail	If 'other' is selected, please provide further details
Openness and Transparency (only disclosed if Patient/service user selected as the person affected)	Was the patient/appropriate person informed that an incident occurred?	If yes, this discloses additional questions relating to this subject (further details below)
	When was the patient/appropriate person informed? (dd/mm/yyyy)	Enter date the discussion took place
	Name and job role of staff that informed Patient/appropriate person'	Enter details of staff who were involved
	Name of person(s) who was informed	Enter details of the Patient/Service User/appropriate person who was informed
Documents	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

Medication Incidents

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 section triggers on the reporting form:

Drug administered / prescribed / omitted / supplied	Intended drug to be administered / prescribed / supplied
<input type="text" value="Clear"/> <input type="button" value="Duplicate"/>	<input type="text" value="Clear"/>
Search for Drug administered / prescribed / omitted / supplied <input type="text"/> <input type="button" value="Q"/>	Search for Intended drug to be administered / prescribed / supplied <input type="text"/> <input type="button" value="Q"/>
★ Drug administered or omitted <input type="text" value="Alclometasone"/>	★ Intended / Suspected drug <input type="text"/>
Brand name of drug administered <input type="text" value="Alclometasone 0.05% cream"/>	Brand name of drug intended / suspected <input type="text"/>
Manufacturer of drug administered <input type="text" value="Aspire Pharma Ltd"/>	Manufacturer of drug intended / suspected <input type="text"/>
Class of drug administered <input type="text"/>	Class of drug intended / suspected <input type="text"/>
Type of drug administered,prescribed, dispensed or omitted <input type="text"/>	Type of drug intended / suspected <input type="text"/>
★ Route administered, prescribed, dispensed or omitted <input type="text"/> <input type="button" value="v"/>	★ Route intended / suspected <input type="text"/> <input type="button" value="v"/>
★ Dose administered, prescribed, dispensed or omitted <input type="text"/> <input type="button" value="v"/>	★ Dose intended / suspected <input type="text"/> <input type="button" value="v"/>
★ Form administered, prescribed, dispensed or omitted <input type="text"/> <input type="button" value="v"/>	★ Form intended / suspected <input type="text"/> <input type="button" value="v"/>
Drug administered or omitted BNF classification <input type="text"/>	Drug intended BNF classification <input type="text"/>
Drug administered or omitted batch number <input type="text"/>	Intended drug batch number <input type="text"/>
Drug administered or omitted ethics committee name and reference <input type="text"/>	Drug intended ethics committee name and reference <input type="text"/>
★ Is the drug administered or omitted under clinical trial? <input type="text"/> <input type="button" value="v"/>	★ Is the drug intended under clinical trial? <input type="text"/> <input type="button" value="v"/>
Is the drug administered or omitted a manufactured special? <input type="text"/>	Is the drug intended a manufactured special? <input type="text"/>
Is the drug administered or omitted a parallel import? <input type="text"/>	Is the drug intended a parallel import? <input type="text"/>
Stage at which error occurred <input type="text"/>	
Type of error <input type="text"/>	
Notes <input type="text"/>	
Other Important Factors <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:

Medication – Additional Information

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

★ Did an earlier prescribing error contribute to this incident?

★ Did a medication supply error contribute to this incident?

★ Did the medication incident involve any of the following:

★ Other important factors relating to the medication incident

★ Please provide further information (Medication)

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

Duty of Candour (DOC)

The Duty of Candour panel is triggered when Moderate, Severe or Catastrophic/Death is selected in the field 'Manager's Interim Harm Assessment' and 'Yes' is selected in the field 'Was the healthcare provided a factor, or may it have been a factor in a Patient/Service user suffering harm?'

Section	Field	Description
Duty of Candour (DoC)	Who is the Duty of Candour Point of Contact for this case?	Select the Duty of Candour Point of contact from the list of staff available
	Brief description of the circumstances in which the duty came into effect	Free text box – Please type the brief description of the circumstances in which the duty came into effect
	Has the Duty of Candour Point of Contact for this case made initial 'in person' contact with the Service User or the person acting on their behalf?	Please select from the drop-down options available No / Unable to make in person notification / Unable to obtain contact details. All 3 codes trigger text box 'Please provide further details on attempts made to contact the service user or the person acting on their behalf'.
	Please provide further details on attempts made to contact the service user or person acting on their behalf or the reasons why a decision was made not to make contact	Enter the details of further attempts made to contact the service user or person acting on their behalf.
Duty of Candour - Initial Notification	Date of 'in person' initial notification (dd/mm/yyyy)	Enter the date of 'in person' initial notification
	Was the 'in person notification' made within 30 working days of the Date the	Please select Yes or No as appropriate

	NHS Body first became aware that DoC was triggered	
	Please explain why the 'in person notification' was made after 30 working days of the Date the NHS Body first became aware that DoC was triggered	Text field to be completed if visible giving reason why 'in person' notification was made after 30 working days of the Date the NHS Body first became aware that DoC was triggered
	Method of initial notification	<p>Please select the method of how the initial notification was conveyed to the Service user or the person acting on their behalf.</p> <p>If 'Other Method' is selected, the below question appears.</p>
	Other method (further details)	Free text box – Please describe how the initial notification was conveyed if this option has been selected
	Following the 'in person' initial notification, has written correspondence been sent to the Service User or person acting on their behalf	<p>Please select Yes/No/Patient did not want to receive written correspondence' from the drop down</p> <p>If 'Yes' is selected, the question 'Was the written correspondence sent to the service user or the person acting on their behalf in Welsh?' appears</p> <p>If 'No' or "Patient did not want to receive written correspondence" is selected, the question 'Please explain why written correspondence has not been sent' appears</p> <p>If 'Yes' is selected, the next Duty of Candour section also appears.</p> <p>If 'Yes' is selected 'Date written notification sent' is visible</p>
	Was the written correspondence sent to the service user or the person acting on their behalf in Welsh?	Please select 'Yes' or 'No' from the drop down
	Date written notification sent (dd/mm/yyyy)	Enter Date written notification sent
	Please explain why written correspondence has not been sent	Please enter further details explaining why written correspondence has not been sent
	Was the 'written notification' sent within 5 working days following the in-person contact being made	Please select Yes or No as appropriate
	Please explain why the 'written notification' was sent after 5 working days following the in-person contact being made	Text field to be completed if visible giving reason why the 'written notification' was sent after 5 working days following the in-person contact being made
Duty of Candour - Investigation response	Has the investigation response been sent to the Service User or person acting on their behalf?	<p>Please select 'Yes' or 'No' from the drop down</p> <p>If 'Yes' is selected, a date field will be visible to capture the date.</p> <p>If, 'No' is selected, a text field is visible to capture explanation of why final response has not been sent.</p>

	Final response done date (dd/mm/yyyy)	Enter Date Final response sent
	Please explain, why no final response has been sent	Please enter explanation of why a final response has not been sent
	Type of response	Please select the type of response sent to the service user of the person acting on their behalf.
Time Chain Welsh Duty of Candour	The time chain is not a mandatory section; however, this could be used to support calculation of the essential criteria regarding the in-person contact being made within 30 working days of the organisation becoming aware that the Duty was triggered, and 5 working days to complete the written notification. This will only be triggered if the question: Was Healthcare provided a factor or may it have been a factor in a patient/service user suffering harm and answered Yes.	

Yorkshire Contributory Factors Framework

* Acknowledgement to the Yorkshire and Humber Improvement Academy*

The form contains the Yorkshire Contributory Classification Framework in 5 domains.

	Field	Description
Yorkshire Contributory Factors Framework	Domain 1 : Situational Factors	Each domain has a series of 'yes/no/maybe' questions for completion. A further narrative box will be visible to capture more detail for each question.
	Domain 2 : Local Working Conditions	
	Domain 3 : Organisational Factors	
	Domain 4 : External Factors	
	Domain 5 : Communication and Culture	
Causal Factors Framework Summary	Which are the most important contributory factors for this incident?	Text box to free type the most important contributory factors for the incident

Conclusion

Section	Field	Description
Conclusion	Is this incident related to the five harms of Covid 19?	Select from drop-down menu
	Post investigation Harm Assessment	Enter severity of incident following investigation
	Result	Enter the outcome of the incident following investigation
	Recommendations	Enter all relevant recommendations

	Conclusion	Enter text as applicable to the conclusion following investigation
	Lessons learned	Enter any lessons for learning

Details of Person reporting the incident

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