



An Stiúrthóireacht um Ardchaighdeán  
agus Sábháilteacht Othar  
Oifig an Phríomhoifigigh Cliniciúil

National Quality and  
Patient Safety Directorate  
Office of the Chief Clinical Officer

# Recording Open Disclosure on NIMS and reporting Notifiable Incidents to the Relevant Regulator

V1 23/09/2024

## Background

The Patient Safety (Notifiable Incident and Open Disclosure) Act 2023 (referred as the Act) introduces a legal framework for patient safety, focusing on open disclosure. The Act requires health service providers to report notifiable incidents to the relevant regulator. All notifiable incidents are listed in [Schedule 1](#) of the Act.

All health service providers must report the notifiable incident to the relevant regulator using the National Incident Management System (NIMS). HSE and HSE-funded services (Section 38 organisations) will report the notifiable incident directly from the incident management record and private providers will access NIMS using a portal on the relevant regulators website pages.

### **The Patient Safety (Notifiable Incident and Open Disclosure) Act 2023**

#### **Notification to the Relevant Regulator (Part 4 of the Act):**

Where a health services provider is satisfied that a notifiable incident has occurred in the course of the provision by the health services provider of a health service to a patient, it shall notify the relevant regulator of that notifiable incident –

- (a) as soon as practicable, and
- (b) in any event, not later than 7 days from the day on which the provider was satisfied the incident had occurred.

The Act (Part 4, s. 30) states that:

For the purposes of making a notification under section 27, 28 or 29, the health services provider shall make the notification by means of the National Treasury Management Agency incident management system.

## Roles and Responsibilities

**For the purpose of reporting notifiable incidents on NIMS there are some key roles and responsibilities:**

### **All staff**

- All staff must report patient safety incidents on the National Incident Reporting Form or directly on NIMS as per their local processes and procedures.

### **Incident managers updating the incident record**

- Management staff such as senior nurses, quality and patient safety advisor/managers, senior administrators, senior clinicians, etc. within the service will have responsibilities for updating the incident record regularly

### **Manager making the notification to the regulator on NIMS**

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- Each service must determine who in their organisation will make the notification to the relevant regulator on NIMS. Only the senior manager identified by the service must make the notification to the regulator.
- The person making the notification must have access and log-in details for NIMS in line with the HSE Access and Control Policy. Access can be requested via [NIMS@hse.ie](mailto:NIMS@hse.ie)
- Once the health service provider is satisfied that a notifiable incident has occurred then the relevant manager will be instructed locally to make the notification on NIMS (this will likely be made by the SAO or their delegate at a serious incident management team SIMT meeting).
- Each health service provider may have a number of managers who are able to make the notification on their behalf.

#### Point of contact nominee in the health service for the relevant regulator

- Each service will determine who the point of contact will be for the relevant regulator.
- This will generally be the Senior Accountable Officer or registered person of a designated or registered centre.
- The manager making the notification on NIMS will include the contact details of the SAO/registered person at the time of reporting (for designated and approved centres that will be the same person listed with the regulator for other regulatory reporting requirements)

#### Relevant Regulator

- The service must report the notifiable incident to the relevant regulator (HIQA, the Chief Inspector of Social Service or the Mental Health Commission) using NIMS.
- Where a service carries out the business of a **designated centre** and it is satisfied that a notifiable incident has occurred it shall notify the **chief inspector of social services** of that notifiable incident. (Part 4, s.28)
- Where a service, which provides a health service in an **approved centre**, is satisfied that a notifiable incident has occurred it shall notify the **Mental Health Commission** of that notifiable incident (Part 4, s.29)
- Where a service **carries out the business other than that of a designated centre or an approved centre**, and it is satisfied that a notifiable incident has occurred it shall notify **HIQA** of that notifiable incident. (Part 4, s.27). That means that all service providers that are not an approved centre or designated centre will report to HIQA, i.e. primary care services
- The regulator shall acknowledge receipt in writing no later than 21 days following receipt of the notification. This will be outside of NIMS via the contact details provided.

#### Services

- This refers to the hospital/centre/community service of the HSE or section 38 Organisation accountable for reporting the notifiable incident

Further information can be found at:

HSE Open Disclosure website page [Open Disclosure - Corporate \(hse.ie\)](https://www.hse.ie/open-disclosure)

HIQA website page [www.hiqa.ie](http://www.hiqa.ie)

MHC website page <https://www.mhcirl.ie/>

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## Recording Open Disclosure on NIMS

- 1) All staff must report patient safety (and staff) incidents on NIMS either by initially reporting the incident on a National Incident Reporting Form (NIRF) which then gets transcribed or directly onto NIMS using Electronic Point of Entry [ePOE].
- 2) The NIRF (paper) includes a question on open disclosure asking if open disclosure has taken place, meaning an open disclosure conversation for lower harm incidents or the open disclosure meeting for more serious incidents, and asking for the date.
- 3) The NIMS record (electronic) will make the question visible when the person logging the incident selects that a 'service user' was involved in the incident.

The screenshot shows the 'Details of Person Affected' section of the NIMS form. The 'Category of Person' dropdown menu is open, displaying the following options: External Contractor, Member of the Public, Panel Staff/Agency/Locum, Service User, Staff Member, Volunteer, and Work Placement/Trainee. A red arrow points to the 'Service User' option.

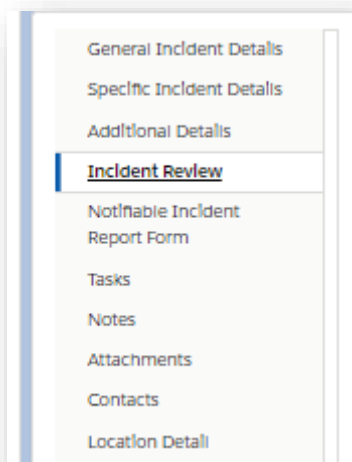
The screenshot shows the 'Has Open Disclosure taken place with the patient/their relevant person' field set to 'Yes'. Other visible fields include 'Who was involved?' (Service User), 'Category of Person' (Patient), and 'Date of Open Disclosure' (dd/MM/yyyy).

## Updating the open disclosure fields in the review screen section of an incident

- 1) As per the HSE Open Disclosure Policy all incidents where moderate harm, severe harm, permanent disability/death or notifiable incidents is reported, staff are required to initiate the 'Open Disclosure Process'. Whilst even low harm incidents require open disclosure it is only the more serious incidents where the process will apply. The open disclosure process means that there needs to be an open disclosure meeting in line with the Service Users/Relevant Person will and preference, the meeting must be followed up in writing and the review report must be shared with the patient/their relevant person.
- 2) On the review screen section of the incident record staff can enter when they had the open disclosure meeting, or if they were unable to have the meeting due to one of the two

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exemptions (drop-down), and when the follow-up letter was shared and when the review report was shared.



- Staff can log which notifiable incident it relates to and these fields are then mirrored on the 'Notifiable Incident Report Form'

Open Disclosure

Required for all Category 1 and Category 2 Patient Safety Incidents and Notifiable Incidents under the Patient Safety Act

Has Open Disclosure taken place?   Date of Open Disclosure

Open Disclosure was not possible

Has Letter been sent following Open Disc?   Date the Letter was sent

Has Incident Review Report been shared?   Date the Report was shared

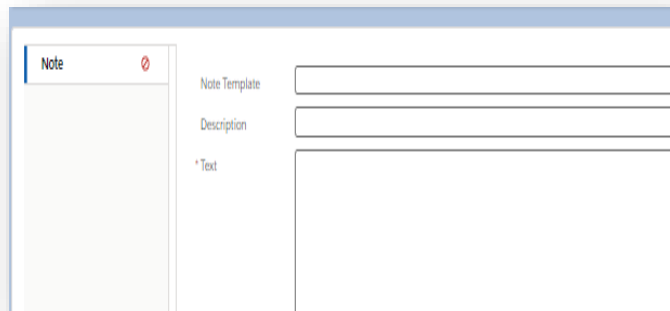
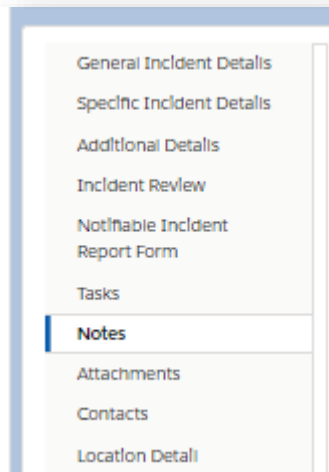
[Click here for a full description of Notifiable Incidents](#)

Is this a Notifiable Incident?

Type Of Notifiable Incident

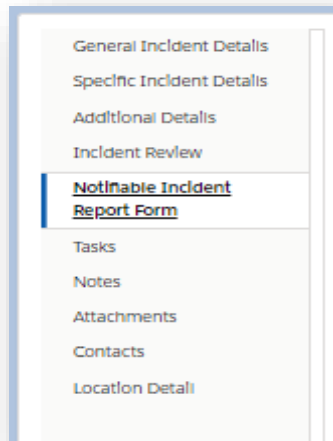
- When the record is saved, a prompt will appear to ask the person to complete some other fields on the review screen record if they have not already been completed (e.g. name of SAO, is this an SRE).
- Updates regarding the review, intermittent interactions and communications, etc. can be referenced in the 'Notes' section on the review screen. This is intended only for staff, in particular where a few staff members have oversight of incidents in a service, to help them manage the incident.

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### Notifying the relevant regulator of the notifiable incident

- Once the service is satisfied that a notifiable incident has occurred they must make the notification to the relevant regulator. This must occur not later than 7 calendar days from the day on which the provider was satisfied that there was a notifiable incident
- The manager assigned to make the notification accesses NIMS with their log-in details and searches for the incident record using the NIMS reference number. This manager will have been nominated by the local service to action this and is generally a senior QPS manager, senior operational or senior administrative manager.
- The manager clicks on the tab to the left of the screen labelled 'Notifiable Incident Report Form'.



- The questions on the form are aligned to the reporting requirements of the Act.
- The person notifying the incident will pick which regulator they are notifying from a drop-down option. If the incorrect regulator is picked and the form is submitted then this can be followed up on for correction by contacting [NIMS@hse.ie](mailto:NIMS@hse.ie)
- This is a potential data breach which needs to be considered on a case-by-case basis. There should not be identifiers shared but where there was something very sensitive in a

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notification that ended up with the wrong regulator, then this would be a breach under Article 5 (f) of GDPR concerning confidentiality and that an e-mail sent with the same data again would compound that breach. A data breach must be managed as per local requirements.

Notifiable Incident Report Form \*\* To be completed by the senior manager in your organisation assigned to report to the regulator

\*\* To be completed by the senior manager in your organisation assigned to report to the regulator

Is this a Notifiable Incident?

Please enter the name of the Health Service Provider

Name of Hospital/Centre where the Incident happened?

Yes

Description ^

- 1 - Office of the Chief Inspector (HIQA)
- 2- HIQA
- 3 - Mental Health Commission

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- Where the person completing the form is asked the name of the service and name of the Hospital/Centre where the incident happened:
  - all HSE services must add 'HSE' and then the relevant hospital or centre. For example HSE, Nenagh Hospital or HSE, Sunshine Care centre

Health Service Provider and Hospital/Centre details

Please enter the name of the Health Service Provider

Name of Hospital/Centre where the Incident happened?

HSE

- All Section 38 service providers must add the legal entity for xxx and the relevant service, for example CHI, CHI Tallaght

Health Service Provider and Hospital/Centre details

Please enter the name of the Health Service Provider

Name of Hospital/Centre where the Incident happened?

CHI

- At the end of the form, once all fields are completed, the person making the notification is asked to confirm that the details are correct and that the notification does not include personal data. To confirm that **xxx** regulator should receive the notification, the reporter chooses 'yes- submit to xxx'.

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**Acknowledgement**

I confirm that all details provided are accurate to the best of my knowledge. I also confirm that no personal data, of the parties involved has been submitted.

Confirmation

Description	Code
Yes - Submit to HIQA	002

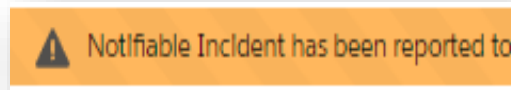
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- At the top of the form, the person making the notification presses 'save' and the form is submitted to the relevant regulator.

**Incident - 24959273**  
Notifiable Incident Report Form

Save Save and Close Print Cancel Copy Change Coverage

- A banner will appear at the top of the incident record confirming that the notifiable incidents has been submitted.



**Steps to be taken if the original notification made did not, on further review/information constitute a notifiable incident**

In the Act it states that 'where the health services provider is satisfied that a NI has occurred', then... In the spirit of the legislation (openness and transparency), the HSE is interpreting this in the following way: *Whilst there is a determination to be made if a Notifiable Incident occurred, it is not a requirement to establish this with absolute certainty in the legal sense or to determine a cause of death. Rather a reasonable clinical assessment should be made with the information available at that time on the likelihood that a Notifiable Incident occurred. Where it is deemed that a Notifiable Incident likely occurred the health care practitioner and health services provider must take the required actions*

It is a likely occurrence that an incident is reported as a notifiable incident when it later transpires not to be one. When this occurs the service must:

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- Discuss the new information at SIMT and make the determination that it is not a notifiable incident. If the incident retains the status of a patient safety incident then the review process must continue.
- It is important that the patient/relevant person is informed in a compassionate manner and any new information explained, as well as its implications. The designated person or even advocacy services can support clinical teams with the discussion.
- Inform the relevant regulator to whom notification was made originally in line with the below

➤ **HIQA**

- Should the health services provider form the view on further investigation or based on additional clinical information that the original notification did not constitute a notifiable incident, this can be addressed by the health services provider by emailing **HIQA** at [patientsafetyactincidents@hiqa.ie](mailto:patientsafetyactincidents@hiqa.ie) In line with data retention schedules, relevant additional information will be archived with original notification linked to the service however the health services provider will be communicated with by email that the notification has been deemed not a notifiable incident and will be excluded from overall notification stats against the service.

➤ **The Chief Inspector of Social Services**

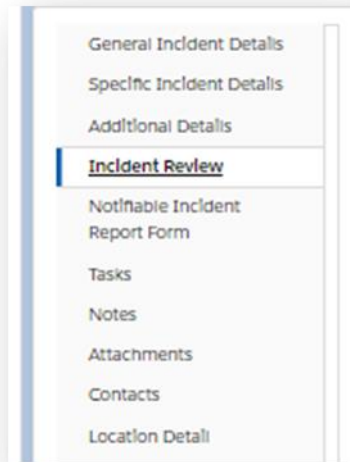
- Should the health services provider form the view on further investigation or based on additional clinical information that the original notification did not constitute a notifiable incident, this can be addressed by the health services provider by contacting the office of the chief inspector of social services. In line with data retention schedules, relevant additional information will be archived with original notification linked to the service however the health services provider will be communicated with by email that the notification has been deemed not a notifiable incident and will be excluded from overall notification stats against the service.

➤ **MHC**

- Should the health services provider form the view on further investigation or based on additional clinical information that the original notification did not constitute a notifiable incident, this can be addressed by the registered proprietor in writing by formal letter to the Director of Regulation at [compliance@mhcirl.ie](mailto:compliance@mhcirl.ie) . In line with data retention schedules, relevant additional information will be archived with the original notification linked to the service however the health services provider will be communicated with and informed that the notification has been deemed not a notifiable incident and will be excluded from overall notification stats against the service.
- In all instances, the HSE or HSE-funded service must also contact [nims@hse.ie](mailto:nims@hse.ie) who will log a request with the State Claims Agency to update the record so that that it is not logged a notifiable incident. This will ensure the data is accurate and is not included in any national KPI for the service.

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- Update the necessary NIMS fields on the review tab and add a note in the 'Notes' tab to provide context.



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## Business Continuity – paper form

Where the electronic notification function to the relevant regulator is not possible due to system down-time (local/national):

- Planned down-time – there will be prior communication with clear instructions/advice provided for the down-time and notification purposes
- Un-planned down-time - where there is an unplanned downtime without any prior communications and instructions/advice received from [nims@hse.ie](mailto:nims@hse.ie) (or local sites), then the service should contact [nims@hse.ie](mailto:nims@hse.ie) to raise the issue (it may be local/national issue). Alternative means of contacting NIMS in the HSE will be provided through operational lines if email communication will be down also.

Should there be the need to instigate the business continuity plan and paper reporting then this will be agreed with the operational service, relevant regulator, SCA and NIMS at HSE. This paper form must be completed and submitted to [NIMS@hse.ie](mailto:NIMS@hse.ie) for such reporting purposes of a notifiable incident to the relevant regulator. *It may also be used by services for their own purposes in agreeing the content of what is being reported before it is logged by the senior manager on the system.*

### Contingency Notifiable Incident Report Form

Please submit to [NIMS@hse.ie](mailto:NIMS@hse.ie) and seek confirmation email stating it had been submitted to the relevant regulator. The incident record will be updated once the system available again and the paper form scanned to the record.

NIMS reference number (where available): \_\_\_\_\_

Is this incident notifiable? \_\_\_\_\_

Regulator to be informed (HIQA, MHC, Chief Inspector)? \_\_\_\_\_

Name of the Health Service Provider (i.e. HSE or s.38) \_\_\_\_\_

Name of Hospital/Centre where the incident happened \_\_\_\_\_

Point of Contact Nominee Name and role: \_\_\_\_\_

Email contact details of the Contact Nominee: \_\_\_\_\_

Phone contact details of the Contact Nominee: \_\_\_\_\_

Type of [Notifiable Incident](#) (reference number as per Schedule 1 in the PSA): \_\_\_\_\_

Date the Notifiable Incident occurred: \_\_\_\_\_

Date the Notifiable Incident came to the notice of the health service provider: \_\_\_\_\_

Please do not enter private personal information in the next fields

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Description of the notifiable incident:

Mitigating actions taken:

Actions taken or due to be taken to share learning:

(At the time of notification) has the open disclosure meeting happened? \_\_\_\_\_

If no, please indicate the plan for open disclosure including intended timeframe:

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I confirm that all details are accurate to the best of my knowledge. I also confirm that no personal data, of the parties involved has been submitted.

Signed: \_\_\_\_\_

Name in print: \_\_\_\_\_

Date: \_\_\_\_\_

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