



National Survey to Establish Guidance on Open Disclosure and Clinically Significant Radiation Safety Events

Introduction

Disclosing errors of clinical significance incurred during the course of a medical procedure is a legal requirement under the Patient Safety (Notifiable Incidents and Open Disclosure) Act (2023). Protective provisions for open disclosure are set out in the Civil Liability Amendment Act (2017) to support the process. In addition to this legislation, statutory instrument 256 (2018) requires practitioners to disclose clinically significant adverse events involving medical ionising radiation.

However, there is limited guidance available to support practitioners in defining an inadvertent exposure to radiation that is clinically significant. The risk to a person from radiation exposure is dependent on many factors, such as the dose received, the age of that person and their previous medical history of radiation exposures.

The HSE Open Disclosure (OD) Policy outlines the process to be followed when disclosing an adverse event to a patient and requires that the level of response is determined by an assessment of harm to the patient against the HSE risk impact table. Although HIQA have provided guidance on the identification of notifiable events which must be reported to them, HIQA have advised that these notifiable incidents may not necessarily be considered clinically significant or require the OD conversation with the patient. Additionally, a clinically significant inadvertent radiation exposure may only be discovered sometime after the patient has left the department which could potentially lead to confusion when it comes to informing the patient or the event.

Survey

This survey was proposed by the National Radiation Safety Committee to establish current practice in relation to OD in radiological services and to determine how clinically significant unintended radiation exposures were identified.

The survey was developed using the HSE OD policy and associated guidance. Respondents were given the opportunity to include additional comments or suggestions which could potentially be used to standardise and improve practice nationally.

The survey was issued to the acute hospital and community services in February 2024. 30 locations (27 acute hospital and three community services) returned completed surveys within the one month timeframe and their collated responses are presented herein.

Findings

1. Obligations in relation to disclosing clinically significant errors to patients

The majority of returns confirmed that the HSE OD policy was endorsed by the local Radiation Safety Committee. One respondent noted *“A clinically significant radiation event would be a relatively rare occurrence. Should one occur, hospital policy will be followed. Open Disclosure is in place for all occurrences but would be proportionate to the level of harm.”*

Three respondents said that the local Radiation Safety Committee did not use the HSE OD policy – one noted that the OD policy had no guidance on what constitutes a clinically significant radiation incident; one advised that a local OD policy tailored to radiation incidents was used; and one answered no but did not elaborate.

Six respondents confirmed that there was a lead for OD in their radiological service, however in two cases, these individuals were not officially nominated and did not interact with local or national OD leads. The remaining 24 locations did not have a lead for OD working within the department however five of these respondents acknowledged the invaluable support provided by the local Quality and Risk Manager.

The majority of respondents confirmed that guidance on the OD process had been, or was in the process of being incorporated into the local radiation safety procedures. One respondent said *“For any inadvertent exposure in the future, a form is being developed to include in the patient record.”*

The facilitation of a recent webinar on OD was highlighted, together with the mandatory online OD training available on the HSEland platform.

Three respondents advised that there were no processes in place to support OD in their radiological service.

2. OD practices in the radiological service

The importance of OD when managing an incident and of documenting that the conversation with the patient had occurred was acknowledged by the majority of respondents.

The general consensus was that either the referrer or the practitioner had responsibility for informing the patient when an error had occurred; and that the level of radiation exposure would determine if a formal OD meeting was required.

One respondent stated that *“OD in relation to clinically significant radiation incidents is performed under leadership of the referring consultant team +/- the QPS manager. Relevant dose information is provided to the referring team. OD re other non-clinically significant events may be performed ideally by the Radiographer Services Manager / other radiology personnel.”*

A large number of respondents advised that when an incident happened within the department, it was typically the radiographer who reported the event and informed the patient. If the inadvertent exposure was considered significant at that time, then it would typically fall to the Radiographer Services Manager and/or Consultant Radiologist / Radiation Oncologist to converse with the patient.

One respondent advised that in interventional radiology and cardiology suites, responsibility for OD lay with the operator.

If the failure in care was discovered after the patient had left the department, respondents advised that the lead clinician responsible for the patient's care would initiate the OD conversation. Other suggestions in this regard included nursing staff if the patient was admitted on a ward and clerical staff if the patient was an outpatient and was to be contacted with a new appointment.

15 respondents confirmed that the patient was informed of an error within 48 hours of discovery; 11 advised that the 48 hour timeline was either not met or that they did not know if it had been; and the remaining 4 declined to answer the question. Various comments were received, for example, one respondent stated that when an error had occurred, the patient's *"Consultant was in the CT department. Said he would let the patient know. It was one of his patients."*

16 Respondents advised that the OD discussion with the patient was typically recorded in the medical record if available at the time; on the National Incident Management System when reporting the incident; and sometimes by the radiographer on the Radiology Information System. Two respondents confirmed that the Radiation Protection Officer recorded the discussion in a file held separate to the patient's medical record. One respondent advised that the referring clinician was asked to record details in the medical notes when the radiation incident was categorised as notifiable to the regulator. Seven respondents said that the OD conversation with the patient was not recorded locally, one stated that they did not know and three declined to answer the question.

The majority of returns confirmed that the patient was advised to contact the hospital patient services department or the radiological department if they had any additional questions or concerns. The contact person identified varied across sites and included the Quality and Risk Manager, Radiology Services Manager, Consultant Radiologist, Consultant's secretary and the patient's referring clinician. One respondent stated that they did not know and two declined to answer the question.

In two locations, it was confirmed that there was a process in place whereby a letter was issued to the patient following the OD conversation which explained the event and whom they should contact if they had any concerns or questions. One respondent wrote *"The idea of talking initially to the patient, then issuing a letter and finally meeting with the Radiologist was agreed on at the Radiation Safety Meeting and incorporated into our incident policy. In my own personal experience I find that if patients are told that an error has occurred and given reassurance, then they tend never to request further information (in a letter) nor following on from that, seek a meeting with a Radiologist."*

Another respondent suggested that a *"Written leaflet could be distributed to patients after such incidents to further explain radiation risks and clear contact details (e.g. email of RSO) if they have any further queries. At present it is verbalised only to the patient in most cases in the department."*

3. The requirements of an OD conversation

To meet the statutory requirements of OD, the conversation with the patient must include an acknowledgement of the error; an apology or expression of regret; details of the circumstances of the incident; information on the supports available to the patient; and where possible, information on the quality improvement measures put in place to prevent the error happening again.

Two respondents declined to complete this section of the survey. In the remaining 28 returns, it was confirmed that when conversing with the patient, there was an acknowledgement that an error had occurred. Most said that there was an apology or expression of regret for the incident and that the patient was given information on the details of the event. They also confirmed that the patient was advised of available supports and of the immediate changes that were made to prevent recurrence of the event. It was acknowledged by a number of respondents that identifying potential quality improvement initiatives at the time of the incident was unlikely however patients would be informed of same after a review had been completed.

4. OD training for staff

OD training is mandatory and available online to all staff via the HSELand platform. 26 returns confirmed that staff who should attend OD training were identified and facilitated. One respondent noted that there were often difficulties in facilitating this training during working hours due to staff shortages. Three respondents declined to answer the question.

The HSE OD department incorporates the 'train-the-trainer' approach to delivering OD training nationally however the majority of respondents advised that there were no staff in their radiological service trained as OD trainers. A number of respondents acknowledged the local Quality and Risk Manager for providing support and for managing the OD conversation with the patient.

Most respondents advised that staff records of attendance at OD training were maintained locally and many also confirmed that annual targets were set for same.

It is the ethos of the HSE to support both patients and staff when there is a failure in care and this was evident in the majority of returns. Many respondents promoted the culture of 'no blame' whereby staff are encouraged to report errors with a focus on investigation and improving practice. Many cited the benefits of a de-briefing session with the radiation protection team immediately after an event. Respondents also identified as important staff 'huddles' within the department where the event could be discussed and experiences shared. The respondents noted the benefits of the After Action Review and in many cases, the availability and willingness of line management to give advice and reassurance. Respondents also highlighted the importance of the Employee Assistance Programme and the HSE ASSIST Model.

Two respondents declined to answer this section of the survey.

5. Clinically significant unintended exposures to radiation

There is currently no nationally agreed definition of a clinically significant exposure to radiation. Respondents confirmed that when there is an inadvertent exposure to radiation, the medical physicist team is informed promptly and their assessment determines the dose involved and the direction of subsequent investigations and reporting.

The majority of respondents identified the HIQA guidance '*Statutory notifications for accidental or unintended medical exposures to ionising radiation*' as an important tool to determine if a radiation exposure was clinically significant.

Three respondents acknowledged relevant UK guidance for defining an exposure that is clinically significant and one highlighted an article written by Kotre and Walker, entitled '*Duty of Candour and the definition of moderate harm for radiation overexposure and exposures much greater than intended in diagnostic radiology*' published in the *British Journal of Radiology* in 2014.

One respondent noted that the UK guidance advises that "*open disclosure is mandatory where accidental or inadvertent exposure to ionising radiation results in an effective dose in excess of 20mSv. Although this approach is used to determine when mandatory open disclosure is required, it would seem a rational approach to deciding when an exposure can be considered "clinically significant", under the terms set out by HIQA and Statutory Instrument 256 of 2018.*"

Whilst another respondent observed that the "*UK guidance defines clinically significant as a service user receiving greater than 20 millisieverts. There has never been an incident which qualifies as clinically significant using this definition in this hospital.*"

In the majority of returns, it was confirmed that the referring clinician was informed of the inadvertent exposure to radiation and that a record of the OD conversation had been given to them with the medical report. Three respondents said that the referrer was not informed, two advised that they did not know if the information had been given to the referrer and two declined to answer the question.

Almost half of respondents advised that they had a recent experience of managing a clinically significant event in their department that required an OD conversation with a patient. One respondent observed that there had been issues surrounding which regulator the incident should have been reported to and why.

Another stated "*It was difficult and time consuming to locate pertinent information to explain a comparison of dose received to background radiation. Since then our RPO has designed a very clear poster with infographics explaining comparative doses received to background radiation. This is displayed in all areas where ionizing radiation is utilized. Leaflets are available also with this information.*"

Conclusion

There will always be a potential risk of inadvertent exposure when working with medical ionising radiation and there is a legal requirement to ensure that the patient is informed when there are failures in care.

This national survey reflects the various measures in place to facilitate the OD conversation with the patient in radiological services and it highlights the important supports available to staff when errors do occur.

The survey also identifies an opportunity for the NRPC to develop guidance on what constitutes a clinically significant radiation safety event.