Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Overview Report
Medical exposure to ionising radiation

September 2021

Lessons learned from receipt of statutory notifications of accidental and unintended exposures in 2020

About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Office of the Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

Contents

Executive summary

This is the second overview report from the Health Information and Quality Authority (HIQA) of lessons learned from the receipt of statutory notifications of accidental and unintended medical exposures to ionising radiation. HIQA is responsible for sharing lessons learned from significant events. This report summarises notifications reported by undertakings* in 2020 and includes the analysis of the circumstances considered by undertakings to have contributed to the causes of significant events.

In 2020, HIQA received 76 notifications of significant events of accidental or unintended exposures along with their associated investigation reports. This represented an 11% increase from notifications reported in 2019. Similar to 2019, the most common error reported to HIQA involved medical exposures to the wrong service user which accounted for 34% of all notifications reported. The majority (n=65) of notifications received were from diagnostic imaging services with the remaining 11 submitted from radiotherapy services. The majority of incidents reported were seen in computed tomography (CT) services.

In 2020, HIQA also received notifications from the imaging modalities† of interventional cardiology, mammography and fluoroscopy for the first time, suggesting a more open and positive patient safety culture in undertakings. However, it was noted that the majority of significant events reported in 2020 were received from 20% of medical facilities. This highlights the importance for each service of having the appropriate mechanisms in place to identify, track, trend, analyse and review incidents for the benefit of the service user.

Although, human error was identified as the main cause in 58% of the notifications, contributory factors were also identified in 87% of incidents. This is a positive finding and shows that undertakings have looked beyond human factors to establish what caused incidents within their services.

* An undertaking is a person or body who has a legal responsibility for carrying out, or engaging others to carry out, a medical radiological procedure, or the practical aspects of a medical radiological procedure, as defined by the regulations. For the purpose of this report, this means the person or body legally responsible for medical exposures of ionising radiation.
† Imaging modalities refers to different types of imaging used to conduct medical exposures. Examples of modalities in diagnostic imaging which are referred to in this report include CT, general radiography, interventional radiology, interventional cardiology, DXA, mammography and fluoroscopy.

Corrective actions implemented in response to significant events in 2020 were often low to medium level strategies. There was evidence that multiple measures were implemented in some cases such as education and information, reminders, checklists, double checks and updating of rules and policies. These measures are people focused and in general were proportionate with the identified risk associated with the incidents. However, higher level strategies such as automation, computerisation and forcing functions[‡] are considered more effective as they are systems focused.

The underlying theme from the notifications relates to communication processes and highlights how issues with communication can contribute to incidents. Timely communication between the undertaking and the regulator was also identified as an area for improvement. In addition, a potential contributor noted was the communication between healthcare professionals in relation to whether the procedure was justified.

Appropriate communication between healthcare professionals and service users is also essential. HIQA found that there was potential to improve service users'[§] participation in helping to prevent errors through ensuring they are informed about the procedure they are referred for. Service users should also be encouraged to actively assist in the identification or consent process, for example, with respect to establishing pregnancy status, where applicable. Service users can be assured they are informed when radiation safety incidents occur, which is a positive finding identified in the majority of incidents reported in 2020. Furthermore, subsequent investigations and preventative measures implemented following reported incidents were focused on improving the safety of the service user.

Errors that occur in healthcare settings have the potential to cause harm to people and patients using the service during the delivery of care. In general, significant events of accidental and unintended exposures submitted to HIQA in 2020 involved relatively low levels of radiation exposure. For the majority of incidents relating to diagnostic imaging, the additional dose delivered to service users due to unintended exposures was reported in the range of 1-5mSv. These doses are relatively low when compared to the radiation exposure each person in Ireland receives annually from background radiation.

[‡] Forcing functions are part of the design of a process that significantly reduces the likelihood of an error occurring.
[§] Service user is a person or persons who attends an undertaking for the purpose of undergoing a medical exposure. This includes a patient, comforters and carers and volunteers participating in research. The terms 'service user' and 'patient' are used interchangeably within this report.

In order to improve patient safety, undertakings must remain proactive with ongoing vigilance in relation to the conduct of medical exposures due to the potential harmful effects from radiation. All stakeholders must have an active role in enhancing the radiation protection of persons undergoing medical exposures in Ireland.

1. Introduction

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019 provide a framework for the regulation of medical exposure to ionising radiation in Ireland.[1] These regulations define minimum safety requirements to protect patients and service users from any potential hazards associated with medical exposure to ionising radiation, such as a risk of developing cancer and tissue injuries. In January 2019, the Health Information and Quality Authority (HIQA) became the competent authority for regulating medical exposure to ionising radiation in Ireland.

The regulations extended HIQA's role and regulatory powers to include public and private radiological, radiotherapy, nuclear medicine and dental services. The regulations also include medical exposures to ionising radiation incurred by carers and comforters, and by volunteers in medical or biomedical research.

HIQA monitors compliance with the regulations by conducting inspections and assessing information which is received through notifications and unsolicited information received from staff and members of the public.

Since January 2019, each undertaking has a responsibility to submit notifications of significant events arising from an accidental or unintended medical exposure to ionising radiation to HIQA. In addition, there is a requirement on HIQA** to share the lessons learned from the investigation and outcomes of these events. To fulfil this requirement, HIQA published its first overview report in September 2020 relating to the notifications of significant events received in 2019 and this can be accessed on the HIQA website.

This second overview report provides a summary of significant events of accidental and unintended exposures notified to HIQA between 1 January 2020 and 31 December 2020. The potential learnings we found are spread throughout this report in key findings, presentation of data, trends and case studies from the incident notifications received from medical ionising radiation services.

1.1 Competent authority work completed to date

Since becoming the competent authority for regulating medical exposure to ionising radiation in January 2019, much work has been completed through

** The regulations relate to both HIQA's role and the undertakings' role and responsibilities in relation to accidental and unintended exposures and significant events (Regulation 17).

our programme of monitoring. In addition to receiving and managing statutory notifications, this includes:

- 52 inspections of public and private medical facilities providing medical exposures to ionising radiation
- publishing guidance documentation
- implementing a national diagnostic reference level[††] (DRL) survey
- issuing self-assessment questionnaires to undertakings
- conducting a series of stakeholder engagement activities.

Further detail of work completed with respect to ionising radiation can be found in the 2020 HIQA Healthcare Annual Report available here.

1.2 Aim of the report

The aim of this report is to share learning with service users and service providers, known as undertakings, on the circumstances that may contribute to a radiation incident and how such events may be prevented from happening again. The primary focus is to protect persons using the services from the unwanted and unintended effects resulting from accidental or unintended exposures to ionising radiation.

This report is divided into three sections including the perspectives of the service provider, the regulator and the persons using the service, followed by the conclusions of this report. Specifically:

- Section 2 focuses on what undertakings found and reported to HIQA.
- Section 3 explains what HIQA found from the analysis of these incidents and the way they were managed.
- Section 4 reviews key learning from the perspective of the person receiving medical exposures as part of their diagnosis or treatment.

The underlying theme in this report relates to communication processes and highlights how communication issues can contribute to clinical incidents. The case studies presented in the report show how better communication practices could have prevented incidents from occurring. From this review, HIQA recognises the vital role the service user can play in radiation protection. Undertakings should empower people undergoing medical exposures to be active participants in their care and help improve their safety.

[††] A diagnostic reference level is a measure of the typical radiation dose levels set for common medical imaging procedures and clinical tasks. These values allow medical facilities to compare local values, which represents patient dose, to a national standard.

2. What undertakings reported to HIQA

2.1 Introduction

There is a positive association between increased incident reporting rates and a patient safety culture.[2] Therefore, high levels of incident reporting can be a good indicator of a positive patient safety culture. However, low rates of reporting does not necessarily mean that a low number of incidents or near misses are occurring. Healthcare services should aim to encourage and support individuals to report errors with the assurance that the response will be focussed on what happened, rather than who failed.[3,4]

In 2020, undertakings faced unique challenges due to the COVID-19 pandemic. The level of service activity was impacted in different ways in every medical and dental facility. The impact of these variations in activity may have potentially increased the stress and pressure placed on frontline staff during the pandemic. Indeed, this was referenced as a potential contributory factor in some incidences of accidental and unintended exposures received by HIQA.

Despite the challenges faced by undertakings, notifications of significant events continued to be reported and an increase in the level of reporting was seen between 2019 and 2020. This provided assurance to HIQA that patient safety remained a central focus for undertakings despite the challenges presented due to the pandemic.

2.2 Number of notifications reported

The total number of medical radiological procedures carried out in Ireland from both public and private practice can be conservatively estimated at over three million per year.[5]

In total, HIQA received 76 notifications between 1 January 2020 and 31 December 2020 which met the defined thresholds of reportable significant events (Appendix A). This represented an 11% increase in notifications submitted compared with notifications received in 2019.

Of the 76 notifications received, 65 related to diagnostic imaging and interventional services, while the remaining 11 were reported from radiotherapy services. Similar to 2019, dental imaging and dual-energy X-ray absorptiometry (DXA) services did not report any significant events. These services generally provide low dose medical exposures that would not typically meet the required reporting thresholds should an incident occur. However, for all undertakings there is a requirement that there are systems in place to

record and analyse events or near misses involving accidental or unintended medical exposures and incidents.

Of the 160 public and private hospitals and imaging facilities, 31 facilities reported 65 notifications in 2020. This meant that less than 20% of all medical facilities notified HIQA of a significant event in 2020. One third of these notifications were reported by five facilities, and 16 out of the 31 facilities reported at least two significant events within this time period. Many services with high levels of activity and providing complex medical exposures did not report any significant event. The lack of reporting in these services may be indicative of consistently good practice. Alternatively, it may suggest that not all errors or incidents that occur are identified or reported. All undertakings should take this opportunity to reassess the reporting culture and systems in place to determine if they can be improved.

2.3 The categories and associated circumstances of notifications

The most common error reported to HIQA related to circumstances in which radiation dose was not intended, or when an incorrect service user was exposed to greater than 1 millisievert (mSv). This accounted for 34% of the total number of reported significant events. Following this, the category of incorrect imaging procedure with a dose greater than 1 millisievert accounted for 21% of all notifications received. Of the 17 categories (listed in Appendix A), 10 categories were used in 2020 (Table 1).

Table 1: Categories of significant events used to notify HIQA in 2020

Significant event category	Percentage* (and number) of incidents reported
No dose intended or incorrect service user exposed to greater than 1 millisievert (mSv)	34% (26)
Incorrect procedure greater than 1 millisievert (mSv)	21% (16)
Incorrect anatomy greater than 1 millisievert (mSv)	12% (9)
Any other radiation exposure incident considered to have serious service user safety implications	11% (8)
Radiotherapy dose or volume variation of 20% or greater from the fraction prescribed	8% (6)
Radiotherapy dose or volume variation of 10% or greater from the total prescribed	4% (3)
Overexposure of an adult twice the exposure intended (over 10mSv) or 20 times the dose intended	3% (2)
Overexposure of a child twice the exposure intended (over 3mSv) or 15 times the dose intended	3% (2)
Inadvertent dose to a foetus greater than 1 milligray (mGy)	3% (2)
Incorrect radiopharmaceutical	3% (2)

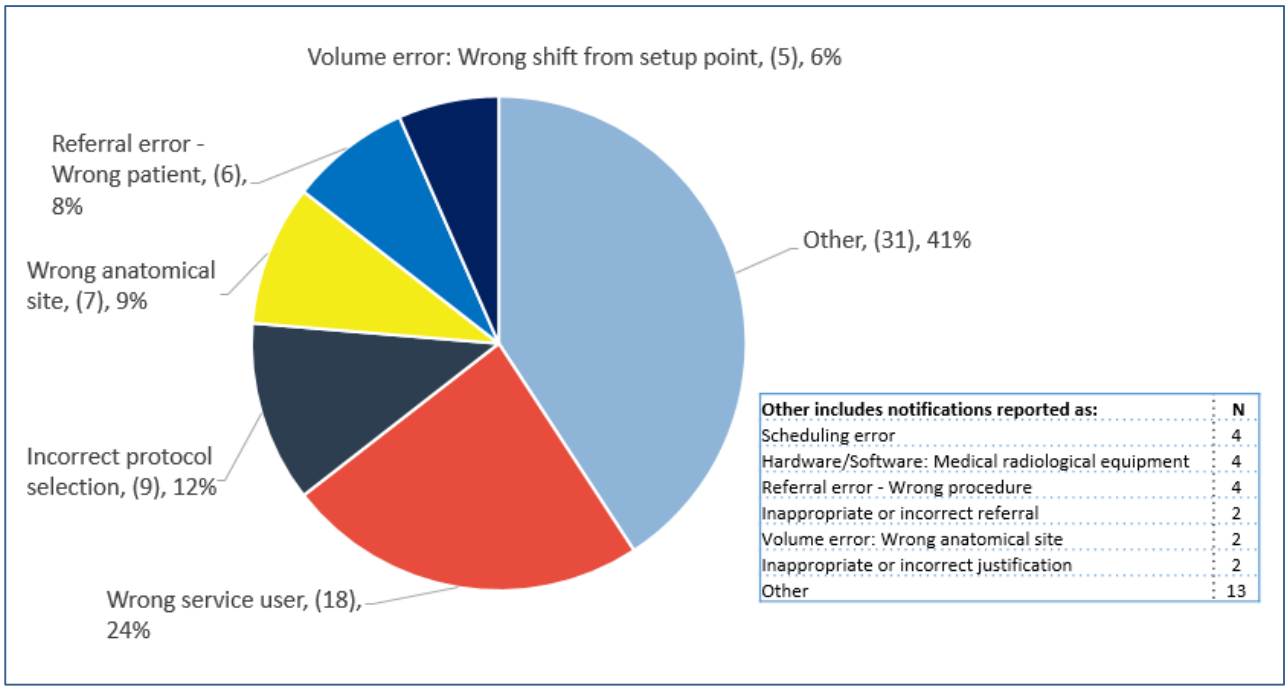
* due to rounding up of the numbers, percentages do not total to 100%

In order to better understand the nature of the incident reported, undertakings provide further information relating to circumstances of the incident when submitting a notification (Figure 1). For example, in situations where an incorrect service user received a radiation exposure or a procedure was conducted that was not intended, errors relating to the referral for the procedure contributed to 16% of notified incidents. Examples of errors included:

- inappropriate or incorrect referral
- the wrong service user was referred
- the wrong procedure was requested.

Circumstances which accounted for less than 5% of the total number of incidents are represented collectively within the category 'other' in Figure 1.

Figure 1. Circumstances associated with notifications

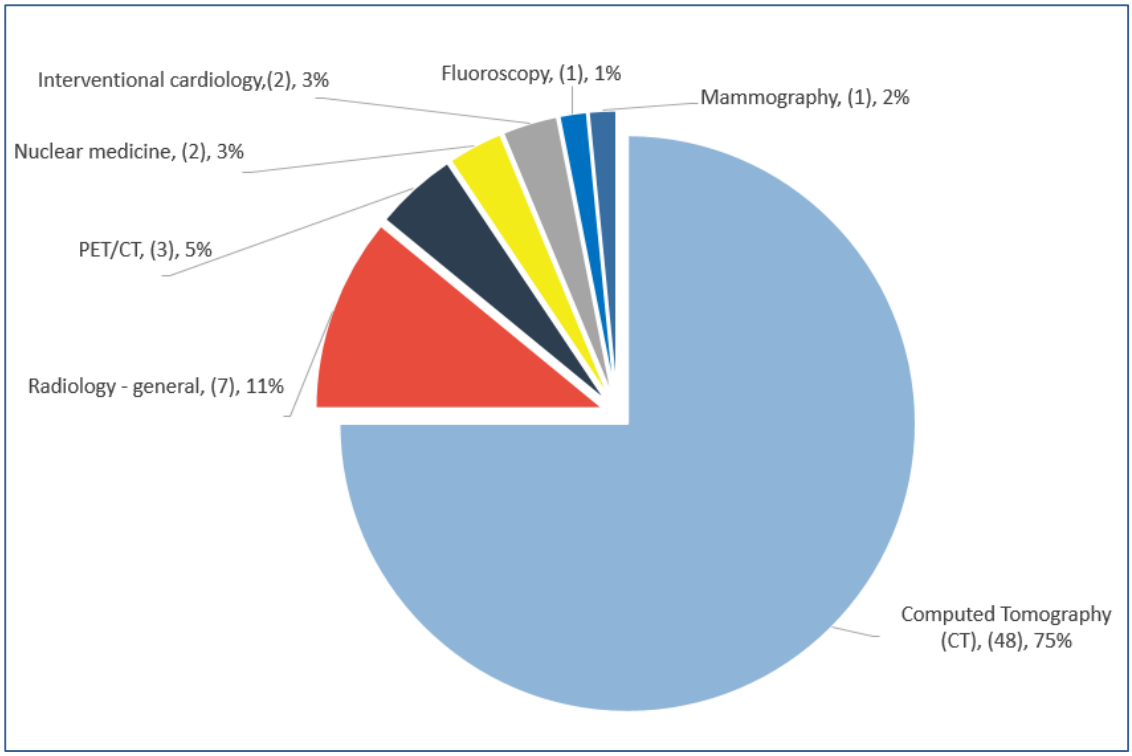


2.4 Imaging modalities where significant events occurred

Similar to 2019, notifications relating to computed tomography (CT) accounted for 75% (at least 48 of 65) of all diagnostic imaging notifications. In 2020, for the first time, HIQA received notifications from interventional cardiology which can utilise relatively high radiation doses in a number of highly complex, but essential procedures. HIQA also received the first notifications of significant events from mammography and fluoroscopy services. Receipt of notifications in these areas are particularly encouraging as there was a notable absence of reporting from these modalities in 2019. This was also identified as an area of improvement for undertakings in the 2019 report.

The breakdown of all diagnostic imaging notifications received in 2020 is outlined in Figure 2.

Figure 2: Notifications received per modality in diagnostic imaging



Similar to 2019, the number of notifications received from radiotherapy services accounted for 11 of 76 notifications received in 2020 (14% of the total number of notifications). A breakdown of these notifications is presented in Table 2. These notifications were received from 6 of the 13 facilities which provide a radiotherapy service. All notifications related to external beam radiotherapy, again similar to the findings in 2019. Radiotherapy incidents reported in 2020 related to errors occurring during the delivery of treatment. The majority of incidents were associated with volume error, with half of these caused by an error when making the required movement from the setup point to the treatment point.

Table 2 : Significant events reported in radiotherapy

Significant event category	Associated circumstances	Number
Radiotherapy dose or volume variation of 20% or greater from the fraction prescribed	Dose error: Wrong plan dose	1
	Dose error: Wrong prescription dose	1
	Volume error: Wrong anatomical site	1
	Volume error: Wrong shift from setup point	3
Radiotherapy dose or volume variation of 10% or greater from the total prescribed	Volume error: Wrong anatomical site	1
	Volume error: Wrong shift from setup point	2
No dose intended/incorrect service user exposed to greater than 1 millisievert (mSv)	Inappropriate or poorly informed decision to treat or plan	1
Any other radiation exposure incident considered to have serious service user safety implications	Hardware/software: Medical radiological equipment	1
Total number of radiotherapy incidents received in 2020		**11**

2.5 How undertakings managed significant events

In most cases, unintended and accidental exposures meeting reporting thresholds were identified quickly and reported within the three working day time frame required by HIQA. However, in five notifications, there was a substantial time lag between the event date and when it was discovered, although, once identified, these incidents were subsequently notified to HIQA.

In line with the regulations, all incidents notified to HIQA were investigated by the undertaking and the results of these investigations were mostly provided to HIQA within the prescribed 120 days. However, a small number (n=6) were not submitted within the prescribed timelines and required follow up by HIQA.

2.6 Methods used to submit notifications to HIQA

Of the 76 notifications received, just over half (57%) were submitted using HIQA's online Provider Portal system, while the remaining 33 notifications were submitted via email.

The Provider Portal system offers a more streamlined, secure and easy to use method to submit notifications. It also provides undertakings with an accessible record of the notification history, which allows undertakings to recognise trending in notifications submitted to HIQA. HIQA is currently progressing a new information technology system which will facilitate the use of the portal as the only system for sharing information, both to and from undertakings and HIQA.

2.7 Summary

What was good?

- Despite extraordinary challenges posed by the COVID-19 pandemic, most undertakings met their regulatory requirements in notifying HIQA of significant events in a timely way.
- Notifications received increased by 11%.
- Notifications were received for the first time from the modalities of mammography, interventional cardiology and fluoroscopy.
- In general, investigation reports detailing their associated corrective actions were submitted within the 120 day timeline.

What can improve?

- Incident reporting from undertakings should reflect activity levels within their service. All undertakings should have mechanisms in place to identify and report significant events.
- Undertakings should utilise the HIQA portal system to submit all notifications.
- HIQA is progressing the development of a new information technology system to help support undertakings to share information more efficiently with HIQA.

3. What HIQA found from notifications submitted in 2020

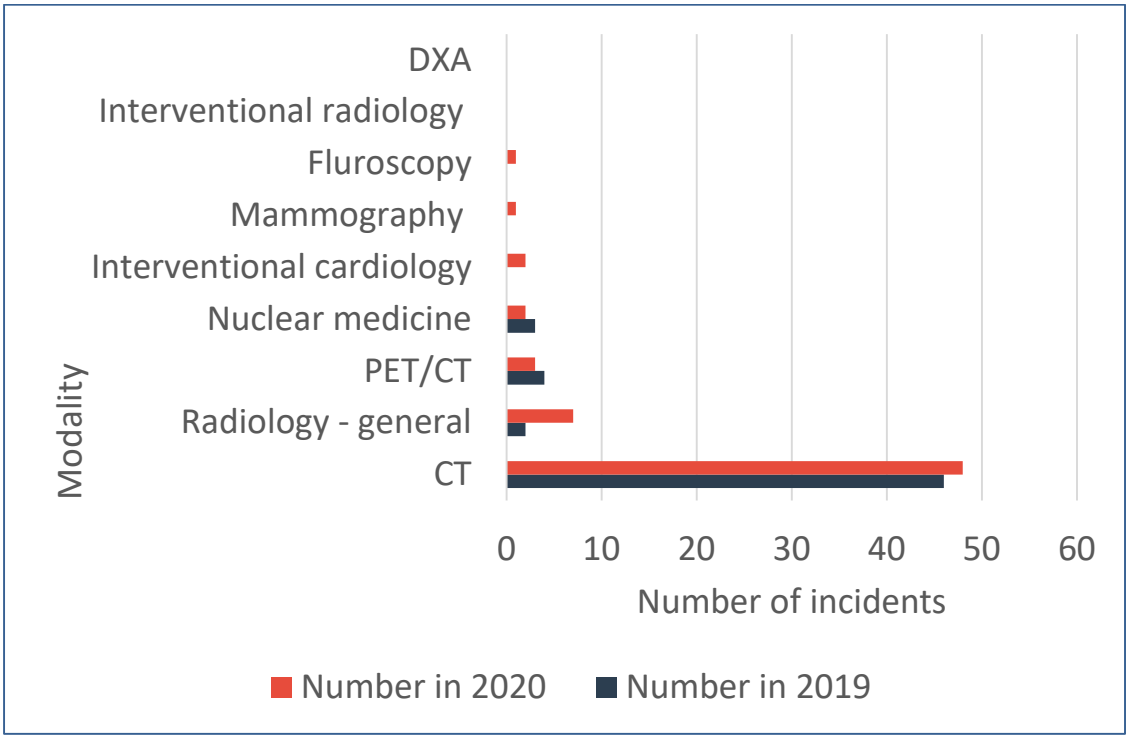
This section takes a closer look at what HIQA found following the review of the incident notifications received in 2020 and the associated investigation reports. Findings from these notifications were compared with the notifications received in 2019. Recurring themes seen in notifications, common corrective measures implemented and the assessment of trending by undertakings through their own monitoring systems are also included. In addition, HIQA's inspection findings of compliance against Regulation 17, which governs the management of accidental and unintended exposures, is also discussed. Lessons learned from this review are also included in this section.

3.1 Comparison of significant events reported in 2019 and 2020

There was a slight increase in the number of notifications received in 2020 when compared with those received in 2019. This represented an increase of 11%. However, the data shows that overall reporting levels remain relatively low when considered in the context of the numbers of medical exposures conducted annually across all radiological settings in Ireland.

In diagnostic imaging, similar to 2019 and shown in Figure 3, the majority of notifications received were from CT services, which is likely given the activity levels within the service and also their potential to meet reporting thresholds should an incident occur. This trend is also consistent with international reports.[6,7]

Figure 3: Incidents in diagnostic imaging modalities - 2019 and 2020



Specific to radiotherapy, although an increase was seen in the number of overall incidents reported to HIQA in 2020, the number of incidents dropped from 13 in 2019 to 11 in 2020. Considering the number of radiotherapy treatment sessions delivered each year across the 13 facilities providing radiotherapy services, this number is relatively low. However, given the potential for very serious implications in radiotherapy, extensive systems are typically in place to prevent or reduce errors and near misses. Thus, radiotherapy is recognised as one of the safest areas of medicine.[8] Similar to 2019, the majority of incidents were reported to have occurred during the treatment delivery stage, rather than at the planning or pre-treatment review stage, and the majority of incidents involved patients receiving a course of radical rather than palliative treatment.

HIQA identified scope to improve reporting across all sectors in 2020. For example, notifications were only received from 20% of all medical facilities registered with HIQA. Furthermore, reporting from large medical facilities such as hospitals was low considering the high levels of medical exposure routinely conducted in these services. This could mean that there are very effective processes in place to prevent accidental or unintended exposures. Alternatively, there is a potential that not all radiation safety incidents that had occurred are identified. For services to be assured that patients are adequately protected from the potential harm caused by radiation incidents, undertakings

must first have effective systems and processes in place to ensure actual accidental and unintended exposures or near misses are readily identified, and appropriately reported and managed. These systems should actively promote a positive patient safety culture where reporting is encouraged and should enable analysis, tracking and trending of radiation incidents.

3.2 Additional radiation dose received by service users

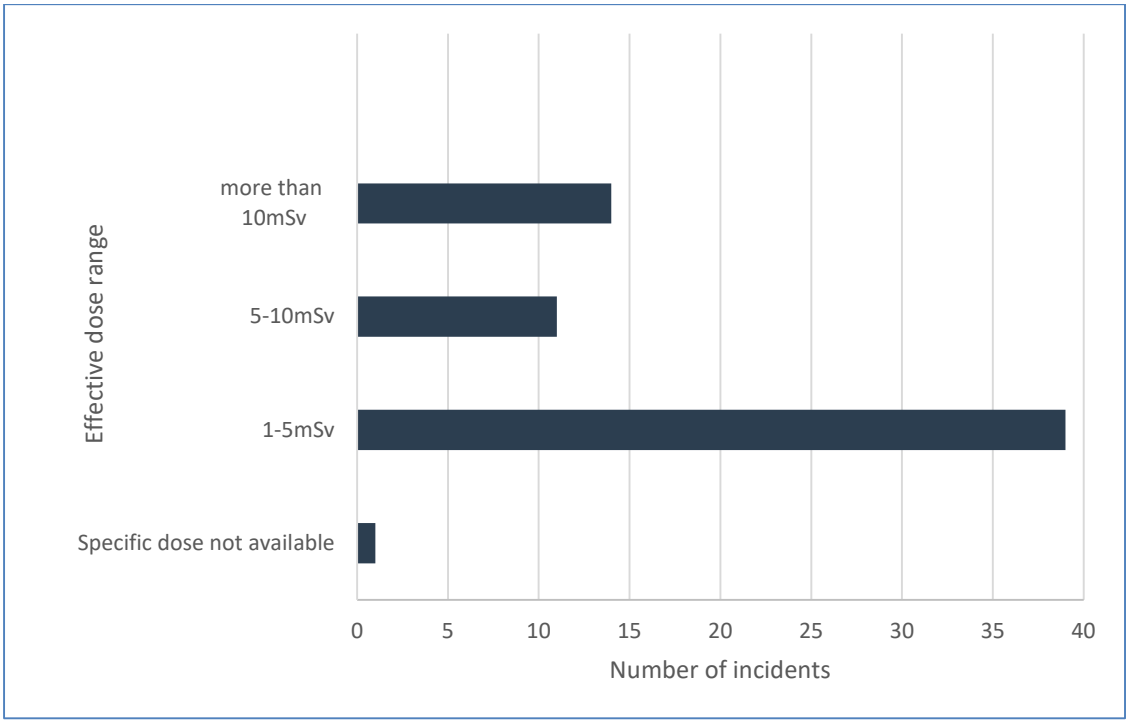
Ionising radiation has the potential to cause harmful effects which can manifest in tissue reactions (deterministic effects) such as skin injury or may take longer to appear and can potentially induce cancer (stochastic effects). Therefore, optimisation of patient dose is essential to keep doses as low as possible and ensure good radiation safety practice. Higher radiation doses are generally associated with modalities such as radiotherapy, interventional radiology[‡‡] and interventional cardiology.

From notifications submitted in 2020, it was noted that radiation incidents in diagnostic imaging resulted in relatively low radiation doses with limited risk to service users. As shown in Figure 4, the majority of incidents resulted in an additional dose delivered to service users in the range of 1-5mSv. This is comparable to the typical dose that each person receives annually from background radiation in Ireland which is approximately 4mSv a year.[9] However, one incident in diagnostic imaging (CT) resulted in a dose in the range of 31-36mSv, which is equivalent to approximately eight-to-nine years of background radiation dose in Ireland.

Of the incidents reported in 2020 from radiotherapy services, more than half resulted in a 20% or greater variation in the dose given or the volume treated for one of the radiotherapy sessions (treatment fraction). These variations were generally managed and corrected throughout the remainder of the treatment course.

[‡‡] Interventional radiology is a broad term which refers to the use of ionising radiation to enable minimally invasive, image-guided procedures and interventions to help treat disease.

Figure 4: Effective dose ranges in notifications received from diagnostic imaging services



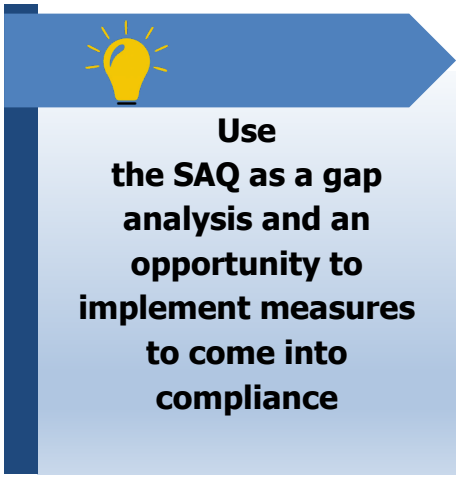
Similar to 2019, incident notifications were not received from interventional radiology services. Skin or tissue damage may not manifest at the time of the procedure and is therefore often not detected.[10] This highlights the importance of routine patient dose assessment and follow up to monitor potential skin or tissue damage after high modality procedures, such as those seen in interventional radiology. The practice of using dose thresholds to trigger follow up of service users was identified during an inspection in an undertaking where a quality improvement initiative was implemented. This was part of routine clinical care to assess potential tissue reactions after interventional cardiology procedures and is an example of good practice.[11] Undertakings providing interventional services should review systems and processes to ensure that patients are appropriately monitored for potential skin or tissue damage following high dose procedures.

Due to the potential for high doses associated with interventional procedures, interventional services are a specific focus for HIQA in 2021 with a plan to establish national DRLs for common interventional procedures, using information gathered as part of a survey request.

3.3 Incident tracking and trending

The value of undertakings tracking, trending and analysing all accidental and unintended exposures was identified in some notifications received in 2020. For example, a small number of incidents reported to HIQA involved a number of service users and were related to medical radiological equipment. While radiation doses to the individual service user may have been below the threshold for reporting, collectively they were reported. This shows that tracking and trending of radiation safety incidents was carried out in these services as part of continuous monitoring and identified specific concerns which were subsequently addressed. However, inspections to date have indicated that tracking and trending of incidents is an area for improvement and an ongoing focus of inspections.

During inspections carried out between September 2019 and the end of 2020, inspectors assessed compliance with the management of accidental and unintended exposures and significant events in 29 services. Findings indicate that there is scope to improve compliance levels in this area. For example, of the 29 facilities, seven facilities who had self-assessed their service as compliant with this regulation were found to be substantially compliant at the time of inspection. Areas identified for improvement related to enhancing the reporting culture and ensuring that processes were in place to enable trending and analysis of all radiation safety incidents and near misses. In addition, two undertakings who had self-assessed their service as compliant with respect to this regulation were found not to be compliant at the time of inspection.



In contrast, HIQA found instances where some undertakings who self-assessed their service as not compliant were found to be compliant at the time of inspection. These facilities had proactively used the self-assessment questionnaire (SAQ) as a gap analysis and had implemented measures in order to come into compliance, which was seen as an example of good practice.

Another finding on inspection related to uncertainty about reporting to HIQA. For example, two radiation safety incidents which occurred within the same service were identified through internal tracking and trending, but were not reported to HIQA. However, these incidents were noted during an inspection

and subsequently notified to HIQA. In situations where uncertainty may arise as to whether an identified incident is reportable, it is advised to liaise with HIQA to seek clarification.

3.4 How quickly undertakings identified significant events and notified HIQA

Early recognition and follow up of significant events enables the early assessment of the consequences for the person or persons affected by the unintended or accidental exposures. It also facilitates the identification of what happened, what went wrong and the measures required to prevent recurrence.

As part of the information submitted on notifications of accidental and unintended medical exposures to ionising radiation, undertakings submit the date of occurrence of the incident and the date of discovery. Statutory notifications of this type are required to be submitted to HIQA within three working days from discovery. On review of the 76 notifications submitted, HIQA found that most incidents were identified promptly, with two identified and reported on the same day. However, as previously mentioned, some incidents (23%) took longer to identify, with a small percentage discovered several months following occurrence. These events occurred in the higher dose procedures such as interventional services, radiotherapy and CT. Generally, these were discovered through look-back, clinical audit and HIQA inspection. This highlights the importance of having the appropriate mechanisms in place to track, trend, analyse and review notifications. Information gathered from analysis and trending of significant events enables the sharing of learning and ultimately improves patient safety.

3.5 Investigation methodologies and corrective actions used by undertakings

Various methods for reviewing radiation incidents were employed by undertakings, for example, root cause analysis and systems analysis. In the majority of investigation reports submitted, HIQA was satisfied that the investigation conducted was proportionate with the level of risk identified. However, further information was requested by HIQA relating to investigation reports for 23 notifications. A small number of these related to investigation reports not submitted within the prescribed 120 days. The most common information required to provide further assurance to HIQA related to the types of corrective actions and recommendations that were implemented following the investigation of the significant event.

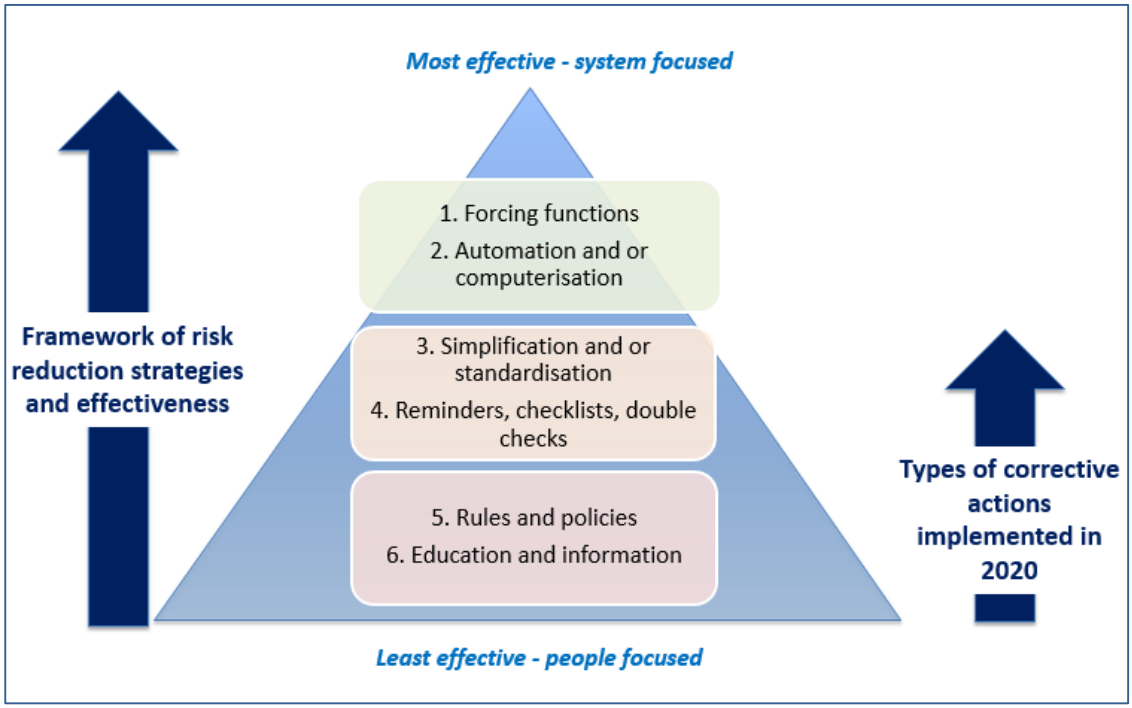
A review of the types of corrective actions implemented by facilities found that low to medium level strategies were implemented in 86% (65 of 76) of all notifications received in 2020 (outlined in Table 3). Undertakings also implemented multiple measures for 18 incidents which combined a mixture of low to medium level strategies. These included education and information, reminders, checklists, double checks and updating of rules and policies. These measures were, in general, people focused but were proportionate with the identified risk associated with the notifications. Higher impact strategies such as simplification and standardisation of processes, and automation and computerisation were employed for nine notifications. No corrective actions or measures were taken for two incidents which undertakings identified as isolated low risk errors unlikely to reoccur. In these scenarios, the importance of tracking and trending is valuable in identifying the likelihood of recurrence and therefore the level of corrective measures required.

Table 3: Evaluation of corrective measures implemented

Corrective measures implemented	Number of undertakings taking this measure following a significant event
Education and information	26
Multiple measures implemented	18
Reminders, checklists, double checks	17
Simplification and or standardisation	6
Rules and policies	4
Automation and or computerisation	3
Forcing functions	0

Figure 5 illustrates the effectiveness of the corrective measures taken in 2020 within the hierarchy of the least to the most effective measures.[12] Types and levels of corrective actions implemented to address both reportable and non-reportable incidents, errors and near misses in a service remains a focus for future HIQA inspections.

Figure 5: Corrective actions taken in 2020 in terms of effectiveness[12]



Although low to medium level measures can be appropriate for some individual reportable notifications, undertakings should strive to identify trends across all incidents occurring in the facility as these may require higher level actions focused on system changes, rather than solely focusing on the human element. Services that examine what happened rather than focusing on who caused the error demonstrate a commitment to ensuring a just culture[§§] in which people working in the service are supported and encouraged to report errors or incidents and patient safety issues that may lead to an error.[13,14] Investigation reports showed that human error was the main cause of 58% (44 of 76) of the notifications submitted. However, human error was not the sole cause, with contributory factors also identified in 87% of these incidents. This demonstrates that undertakings were looking beyond the human factor when determining causation which is a positive finding.

[§§] A just culture is the reverse of a blame society where it is accepted that mistakes are generally a product of faulty organisational cultures and systems, rather than brought about by the person or persons directly involved. Accountability is therefore balanced between the organisation responsible for ensuring work place systems are in place to support safe practices and the individuals who work there.

In addition to examining the cause of incidents, in order to reduce the likelihood of incidents occurring, undertakings should strive to identify potential weaknesses which can led to a significant event or error occurring along the medical exposure pathway. The Swiss cheese model[***] is one such method which was used by some undertakings to identify weaknesses. HIQA's review of the notifications received in 2020 highlighted specific weaknesses in communication, and identified the points at which the intervention of a healthcare professional or staff member, as gatekeeper, could have prevented an incident from happening. The justification processes[†††] also played a role at different points along the pathway which lead to errors occurring.

3.6 Recurring themes in received notifications

In addition to the undertakings' responsibility to examine trends in the incidents which occur at facility level, HIQA also examined the incidents and subsequent investigation reports in order to identify recurring themes or trends. The themes of communication, and to a lesser degree, justification were identified from this review.

3.6.1 Communication

Communication is recognised as an important element in promoting a patient safety culture and was found to be a recurring issue highlighted in incidents reported in 2020.[15,16,17] Misinformation, failure to communicate and weaknesses in internal processes were identified in reports as having led to human error. Examples of incidents submitted included the wrong person undergoing imaging or treatment, or a person receiving imaging or treatment to the wrong body area. Examples from notifications where communication was an issue are discussed further in this section and in the case studies presented.

Correct patient identification is a critical element of patient safety. Patient identification errors were the most commonly reported significant events in diagnostic imaging in 2020. The majority of these errors occurred in the CT sector (n=18), the remaining errors were reported from PET CT (n=2), mammography (n=1) and interventional cardiology (n=1) services. In many of the reported significant events, undertakings identified that internal procedures

[***] James Reason's Swiss cheese model of accident causation is a model used in risk analysis and risk management. It compares human systems to multiple Swiss cheese slices with the slices acting as walls or barriers and the holes represent gaps or breaches. When these holes align errors or incidents can occur.
[†††] The process of justification in ionising radiation means that consideration must be given to ensure that the benefits of the procedure are greater than the risk of the procedure in each individual situation.

for identifying the correct service user were not followed. An essential element of correct identification is communication with the service user referred for imaging. The following case study highlights communication issues that led to a significant event which was reported to HIQA.

Case study (1) – How a lack of communication between undertakings sharing responsibility for a medical exposure can contribute to a significant event occurring

Scenario

- To help reduce waiting lists in an acute medical facility, the undertaking (undertaking A) outsourced some of its imaging service to another undertaking (undertaking B).
- Justification for imaging remained the responsibility of undertaking A.
- This particular referral was expedited due to increased urgency and the scan was performed by undertaking A.
- Undertaking B was informed that the scan had taken place, however this information was not communicated to radiology staff.

Consequence

The service user underwent an unnecessary second scan

Contributing factors identified and corrective actions taken: Simplification and standardisation of processes

The process for referring medical exposures to another undertaking was reviewed and streamlined.
Resources were allocated to specifically manage outsourced referrals.

Other issues identified

There was uncertainty as to who was responsible for notifying this significant event to the regulator. In this scenario, although the referral originated in one facility, it was the responsibility of undertaking B to ensure appropriate mechanisms are in place for the safe conduct of medical exposures.

Learning

Increased work pressure, resourcing issues or changes to work practices as reported in this case can lead to errors occurring. In addition, ineffective communication contributed to the occurrence of this significant event. Effective communication is even more important when the medical exposure pathway is shared across two radiological facilities or between two undertakings. Better communication with the patient may also have helped to prevent this incident occurring.

3.6.2 Justification

The second theme noted by HIQA's evaluation of notifications was justification. Of the 76 notifications received, inappropriate or incorrect justification was identified in two notification event circumstances. However, a review of the investigation reports found that the process of justification was a potential underlying contributory factor in 37% of the notifications submitted.

HIQA found the following issues relating to the justification process:

- clinical details on the referral did not match the requested scans
- previous imaging was not reviewed before imaging
- repeat imaging was not conducted within the requested timeframes
- poorly informed decision to treat
- difficulty reading the referral details
- internal justification policy was not adhered to.

The findings relating to justification show there is potential to improve adherence to the process of justifying medical exposures, particularly in relation to reviewing previous imaging before conducting a medical exposure.

Case study (2) – How a lack of communication led to radiotherapy that was not justified

Scenario

- A patient was referred for radiotherapy.
- The condition of the patient deteriorated between the planning phase and treatment phase.
- The patient was admitted to hospital and attended for the treatment phase as an inpatient.
- Before proceeding with the treatment, the plan for radiotherapy was not reviewed in consideration of the change in the patient's condition.

Consequence

The patient received a number of radiotherapy sessions before the need for treatment was reviewed. Further treatment was stopped following consultation with the patient and the medical teams involved in this case.

Contributing factors identified and corrective actions taken: Standardisation of processes

There was an absence of protocols, policy or procedure to require staff to check with medical team on the reason for admission to hospital and whether this admission or patient's conditions would impact on the decision to proceed with the planned treatment. Protocols were subsequently updated as one of the corrective actions taken.

Learning

The radiotherapy patient pathway involves many steps between the initial consultation, referral and treatment delivery. A patient's condition may change significantly between each of the steps along the way. It is very important to ensure that the information which informs the decision to deliver treatment is based on the most up-to-date information available. Effective communication with relevant medical, oncology and radiotherapy teams is critical to avoid similar incidents.

3.7 Summary

What was good?

- Reporting increased despite the challenges faced during the pandemic.
- First notifications received from modalities such as mammography, fluoroscopy and interventional services.

What can improve?

- Early identification of significant events.
- Mechanisms to ensure reporting of significant events in high dose modalities such as interventional radiology and cardiology.
- Trending and analysis to inform corrective measures and identify what needs to be reported to HIQA.
- Include all necessary information in investigation reports.
- Emphasis on improving communication and justification pathways in undertakings, and between undertakings where appropriate.

4. What this report means for the patient

Learning from notifications submitted to HIQA in 2020 is shared through this report to prevent further incidents and increase patient safety. This section considers the notifications received by HIQA from the perspective of the person who is using these services. It provides a summary of our findings, and suggests ways that the service user can actively participate in helping to prevent or reduce radiation safety incidents and improve their safety when undergoing medical exposures.

4.1 What findings in this report should the patient know about?

- Accidental and unintended exposures involving medical ionising radiation are reported to HIQA.
- Once identified, incidents are appropriately managed by undertakings in the majority of cases.
- The majority of accidental and unintended exposures result in relatively low effective doses delivered with negligible risk to the service user.
- The service user was informed in all cases where incidents were deemed clinically significant as required by the regulations.
- Even when incidents were not deemed to be clinically significant, the service user was informed in the majority of cases. However, more work can always be done by undertakings in ensuring open disclosure always occurs when harm or suspected harm occurs.

4.2 Empowering and engaging patients regarding radiation safety

Engaging patients and families is a key action area in building safe healthcare both nationally[18] and internationally.[19] The regulations require that persons undergoing a medical procedure should be adequately informed of the benefits and risks associated with the radiation dose from the medical exposure. Therefore, active involvement of service users in their own care has the potential to improve the safety of the care provided and should be encouraged and promoted within each radiological facility.

4.2.1 Informing patients about the procedure

A third of the notifications received in 2020 related to service user identification errors, which occurred at varying points along the medical exposure pathway. These errors resulted in a wrong person receiving an exposure to radiation, or a service user having the wrong body area examined. For many of these incidents, the findings of the investigation reports indicated that, although undertakings had established identification policies and

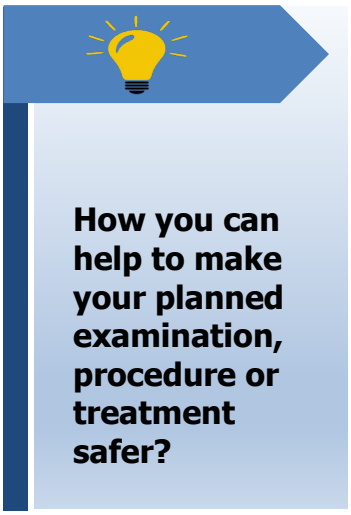
procedures, these were not always adhered to by the staff involved. Therefore, corrective measures following these incidents were often focused on education and information of staff. Other examples of corrective measures implemented to reduce the risk of identification errors included introducing and monitoring a comprehensive system of identification such as a triple identification process which verifies name, date of birth and address of the service user. However, given the proportion of identification errors reported in 2020, it is clear that more needs to be done when informing service users about the procedure if identification errors are to be prevented. For example, on review of investigation reports received in 2020, HIQA identified the potential for undertakings to consider higher level strategies to strengthen undertakings' engagement with service users. Measures to actively promote the involvement of service users at various points along the medical exposure pathway should be considered. In addition, service users can play a role in making medical exposures safer by following guidance outlined at the end of this section.

4.2.2 Being informed about the risks related to medical exposure

To ensure patient safety, all medical exposures must be justified before proceeding. This means that before an examination, procedure or treatment involving radiation takes place, the benefits should first be assessed against the risks of having the exposure. In most cases, the benefits far outweigh the risks, but all relevant factors must be taken into account when making this assessment.

For example, radiation exposure to the pelvic region, or from higher foetal dose procedures[‡‡‡] should be conducted with added assessment. Such exposures can potentially lead to a higher risk of childhood cancers above the rate of natural childhood cancer risk. HIQA received two notifications in 2020 where a foetus was inadvertently exposed to a radiation dose greater than 1 milligray (mGy). In both of these incidents, the investigations found that local policy and procedures were followed and both procedures were justified based on clinical data and presenting symptoms. Women of child-bearing years can play an important role in helping to prevent accidental foetal exposure. Where there is any degree of uncertainty relating to pregnancy status, this should be communicated by the service user to the referrer and person conducting the medical exposure so a complete assessment can be conducted and a decision taken as to whether the exposure is justified.

[‡‡‡] High foetal procedures with a foetal dose range of between 10 to 50 mGy may be seen in some modalities such as CT, PET/CT, Nuclear Medicine.



How you can help to make your planned examination, procedure or treatment safer?

- know **what** examination or procedure you are referred for
- know **why** you are undergoing this examination or procedure
- know what **risks** are associated with your examination or procedure
- **ask** your referring doctor or the person carrying out the procedure, if you are unsure
- ask for **information leaflets** for your planned procedure
- **tell** the healthcare professional if you have had a recent X-ray or scan.

4.3 Summary

What was good?

- Medical exposures to ionising radiation are generally safe.
- When errors occur, in the majority of cases, you will be informed if you are accidentally or unintentionally exposed to ionising radiation from a medical exposure.

What can improve?

- Your participation in medical exposures is important as this may help to prevent an accidental or unintended exposure to ionising radiation.
- Be informed of the procedure or treatment you are referred for and be aware of the associated risks.

5. Conclusion

This report presents many positive findings and generally demonstrates the commitment of undertakings to promote radiation safety for persons undergoing medical exposures across numerous sectors. In 2020, HIQA received notifications of 76 significant events demonstrating a modest increase of 11% when compared with numbers for 2019. Similar to 2019, the most common error reported to HIQA involved medical exposures to the wrong service user which accounted for 34% of all notifications reported. In addition, notifications from the modalities of interventional cardiology, mammography, and fluoroscopy were received for the first time. This increase, although marginal, and the expansion of reporting from a broader range of modalities are to be welcomed, particularly when considered within the context of extraordinary challenges faced by undertakings in 2020 due to the COVID-19 pandemic. Undertakings should continue their efforts to improve the level of reporting to HIQA. This can be achieved by promoting an organisational culture that empowers, encourages and supports staff to report and communicate issues of concern relating to radiation safety.

Human error was identified as the main cause in 58% of notifications received, however it was found that undertakings looked beyond the human factor and determined that other factors contributed to these errors in the vast majority of incidents. Higher level corrective strategies applied to individual reportable incidents may prove more successful in preventing incidents from reoccurring, for example, the recurring incidents seen in service user identification errors.

Since 2019, inspections conducted by HIQA in relation to medical exposures found that while compliance with respect to Regulation 17 relating to the management of accidental and unintended exposures was generally good, there was scope to improve local incident management systems. Improvements in the local incident tracking and trending for all radiation safety incidents, errors and near misses was identified during inspections as an area requiring improvement along with the corrective actions reported following investigations. Additionally, there was evidence in a small number of cases of an overestimation of compliance when completing the HIQA self-assessment questionnaire (SAQ). However, some undertakings used the SAQ as a gap analysis and had implemented changes to be compliant by the time of inspection.

The medical exposure pathway involves many steps which require the input from several healthcare professionals and the service user. Weaknesses in communication and justification processes were identified as recurring

contributory causes in notifications received in 2020. Some of the issues identified relating to miscommunication or ineffective communication were demonstrated in the case studies included in this report. HIQA found that some improvement is also required with respect to the justification process which contributed to more than a third of the significant events received in 2020. Verification of the service users' personal details, clinical history and previous imaging is key to ensuring a medical exposure is justified in advance of the exposure. Therefore, undertakings should evaluate compliance with, and the effectiveness of, the policies and procedures in place and the corrective measures taken to reduce the recurrence of these incidents.

A review of radiation doses experienced by service users as a result of the reported incidents indicated that doses were relatively low when compared with annual background radiation experienced by individuals living in Ireland. These findings emphasise that in general, medical exposures in the Irish setting may be considered safe for the service user. In addition, service users involved in these events were informed in the majority of cases and were always informed when the incident was deemed to be clinically significant.

Overall, the key messages in this report should be used by undertakings to improve the radiation protection for all. Undertakings, service users and HIQA as the regulator are all stakeholders, each one with an active role to play in enhancing the radiation protection of persons undergoing medical exposures in Ireland. In 2021 and beyond, the programme of monitoring and inspecting services will continue in order to ensure that radiation protection practices for service users in public and private radiological facilities in Ireland are compliant with the regulations. HIQA will continue to build upon its programme to date to promote patient safety in relation to radiation protection and to improve the quality and safety of services for all.

Appendix A - Significant events of accidental or unintended exposures that are notifiable to HIQA

Category Number	Category details
1	Administration of a Reference Point Air Kerma (Ka,r) of 15 Gray (Gy) or greater as a result of a single interventional radiological procedure (including interventional cardiology) or a cumulative Ka,r dose of 15 Gy arising from a series of interventional radiological procedures carried out over a six month period
2	Tissue reactions (deterministic effects) as a result of interventional radiology/cardiology
3	Diagnostic overexposure of an adult of more than twice the exposure intended that leads to a dose that is greater than 10 millisievert (mSv) or 20 times the dose intended
4	Diagnostic overexposure of a child of more than twice the exposure intended that leads to a dose that is greater than 3 millisievert (mSv) or 15 times the dose intended
5	Dose given to comforters and carers greater than 3 millisievert (mSv) for adults under 60 years of age and 15 millisievert (mSv) for those over 60 years of age
6	Dose to a breastfed child greater than 1 millisievert (mSv)
7	Inadvertent dose to a foetus greater than 1 milligray (mGy)
8	Incorrect anatomy greater than 1 millisievert (mSv)
9	Incorrect procedure greater than 1 millisievert (mSv)
10	Incorrect radiopharmaceutical
11	Therapeutic dose given instead of diagnostic dose, for example, in the use of radioiodine
12	Administered activity variation of 20% from intended dose during use of therapeutic nuclear medicine

13	No dose intended/incorrect service user exposed to greater than 1 millisievert (mSv)
14	Radiotherapy dose or volume variation of 10% or greater from the total prescribed
15	Radiotherapy dose or volume variation of 20% or greater from the fraction prescribed
16	Unexpected tissue reactions (deterministic effects) as a result of radiotherapy treatment
17	Any other radiation exposure incident considered to have serious service user safety implications, for example, multiple non-notifiable incidents of a similar nature

Glossary of terms

Accidental exposure: an exposure of individuals, other than emergency worker, as a result of an accident.

Comforters and carers: persons who care for service users who are undergoing a diagnostic or therapeutic medical exposure and may be exposed to ionising radiation in this capacity.

Computed tomography (CT): a technique for imaging the body in sections or slices using specialised computers and imaging equipment. An alternative name for CT is computer-aided tomography or CAT scan.

Diagnostic imaging: medical exposures to ionising radiation undertaken to identify a disease or injury.

Dual-energy X-ray absorptiometry (DXA or DEXA): is a type of medical exposure used to assess bone density in service users where low bone density.

Effective dose: Effective dose is an indicator of dose received from an exposure to ionising radiation. This is calculated considering the absorbed dose and the potential effect the exposure is likely to have on the tissues and organs in the body. Effective dose of typical diagnostic examinations are usually recorded in millisieverts (mSv).

External beam radiotherapy: is a treatment that uses high-energy beams to destroy cancer cells. The beams are given using equipment similar to a large X-ray machine called a linear accelerator.

Fluoroscopy: a type of medical exposure that uses a continuous beam of ionising radiation to create an image on a monitor. During a fluoroscopy procedure, the image that is transmitted to the monitor displays the movement of a body part, instrument or contrast agent through the body in real-time.

Fractions: the smaller doses that a series of treatment sessions are divided into to make up a full radiotherapy course. This allows healthy cells to recover between treatments.

Gray (Gy): a unit of measurement for absorbed dose. It is equivalent to one joule of energy absorbed per kilogram of material.

Individuals participating in research: any persons who participate in medical or biomedical research involving a medical exposure of ionising radiation.

Interventional cardiology: procedures that use fluoroscopy equipment to obtain real-time imaging to help introduce and guide devices and equipment used for diagnostic or treatment purposes in cardiology.

Ionising radiation: radiation with enough energy so that during an interaction with an atom, it can remove tightly bound electrons from the orbit of an atom, causing the atom to become charged or ionised. It has a higher energy than light and therefore can pass through the body. Ionising radiation is not without risks, as the body can absorb some of the energy. However, ionising radiation is a valuable medical tool for the diagnosis and treatment of diseases and injuries. Types of ionising radiation commonly used in medical exposures are alpha, beta, gamma radiation and X-rays.

Justification: is one of the core principles of radiation protection and means that for each individual exposure the benefits of the exposure should be considered to outweigh the risk associated with the exposure. This means that a justified procedure should do more good than harm.

Mammography: the specialised area of radiology involved in the imaging of breast tissue.

Medical exposure (ionising radiation): an exposure of ionising radiation delivered to service users or asymptomatic individuals as part of their own medical or dental diagnosis or treatment. Medical exposures are intended to benefit an individual's own health. Additionally, comforters or carers and volunteers in medical or biomedical research can receive medical exposures.

Medical ionising radiation incident: accidental, unintended or other incidents occurring or potentially occurring within an undertaking which could impact on the safety and welfare of service users, comforters and carers or research volunteers.

Medical physics expert (MPE): an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure and whose competence is recognised by the Minister for Health.

Near miss: a potential incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for

believing could have resulted in unintended or unanticipated injury or harm to a service user during the provision of a health service.

Non-notifiable incident: an event relating to medical exposures to ionising radiation which is managed at a local level and does not need to be reported to HIQA as a significant event.

Notifiable incident: a significant event relating to medical exposures to ionising radiation which is reportable to HIQA. A list of reportable incidents is included in this document.

Nuclear medicine: a type of medical exposure where a radiopharmaceutical or radioactive dye is used which is designed to go to a target organ. It is administered to a service user by injection, inhalation or ingestion. Areas of disease and injury can then be diagnosed by imaging the service user under a detector called a gamma camera.

Palliative radiotherapy: is radiotherapy that is delivered to shrink tumors and relieve patients' pain or other symptoms. It is intended to help make patients comfortable and improve their quality of life.

Positron emission tomography (PET): a specialist, functional type of nuclear medicine which uses a radiopharmaceutical to assess the metabolic processes within the body. PET scanners are often combined with CT scanners which allow highly detailed images to be obtained. This procedure is often referred to as PET/CT imaging.

Practitioner: a person who is entitled to take clinical responsibility for a medical exposure under the regulations.

Radical radiotherapy: is radiotherapy that is intended to destroy cancer cells and give long term benefits.

Radiation dose variation: is the difference in delivered dose of radiation from that which was intended or planned to be delivered.

Radiopharmaceutical: pharmaceuticals (drugs) that are labelled (attached) with a radioactive tracer designed to go to a target organ such as the thyroid or bones. Radiopharmaceuticals can have diagnostic or therapeutic uses.

Reference point air kerma (Ka, r): a quantity of radiation dose used to estimate the peak skin dose (the highest dose to a single area of the skin) for interventional radiological and cardiology procedures.

Referrer: a person who is entitled to refer individuals for medical radiological procedures to a practitioner in line with the regulations.

Service user: a person or persons who attends an undertaking for the purpose of undergoing a medical exposure. This includes a patient, comforters and carers and volunteers participating in research.

Sievert (Sv): the measurement unit of both equivalent and effective dose to a service user. Equivalent and effective dose consider the absorbed dose and the effect this is likely to have on the tissues and organs in the body. Effective dose of typical diagnostic examinations are usually recorded in millisieverts (mSv).

Significant event: an event which should be notified to HIQA (and other competent authorities, if required) according to legislation.

Stochastic effect: the random or probable occurrence of a hereditary change or the possibility of an induced cancer due to a medical exposure to ionising radiation.

Therapeutic medical exposures: medical exposures to ionising radiation that are used to treat a disease.

Tissue reaction: (previously known as deterministic effects) a harmful tissue reaction due to tissue death or malfunction following a medical exposure to ionising radiation which delivers a dose above a specific threshold level. Examples of tissue reactions include skin reddening or hair loss.

Undertaking: a person or body who has a legal responsibility for carrying out, or engaging others to carry out, a medical radiological procedure, or the practical aspects of a medical radiological procedure, as defined by the regulations. For the purpose of this guidance, this means the person or body legally responsible for medical exposures of ionising radiation. Please refer to the Undertaking information handbook for more information.

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