UK Health Security Agency

Significant accidental or unintended exposures

IR(ME)R notifications to Healthcare Inspectorate Wales
April 2024 to March 2025

ANONYMISED REPORT

Contents

Executive summary

Every day, tens of thousands of patients undergo planned exposures to radiation as part of their medical care. Inevitably, in a small number of cases things can go wrong. It is imperative these events are monitored and learning shared to help mitigate their frequency and magnitude.

As part of its programme for assessing compliance with the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R), Healthcare Inspectorate Wales requested that the Medical Exposures Group within the UK Health Security Agency (UKHSA) undertake a review of IR(ME)R significant accidental or unintended exposures notifications submitted to them. This report considers closed notifications and covers the period between 1 April 2024 and 31 March 2025.

In total 119 notifications were subject to analysis for this period involving 203 patients across the modalities of diagnostic and interventional radiology, nuclear medicine, and radiotherapy. This represents an increase of 85% from the previous reporting period (2023/24), where 110 patient notifications were received. It should be emphasised that those reporting higher numbers of notifications represent providers with mature reporting cultures and should be encouraged to continue reporting. On occasions a single notification for an event involving several individuals is submitted, which explains the disparity in number between affected patients and notifications. Throughout the report each affected individual will be considered and referenced as a single patient notification.

Diagnostic and interventional radiology made up the largest proportion of the patient notifications with 132 in total (65%). This is likely due to the greater volume of diagnostic examinations performed compared to radiotherapy and nuclear medicine exposures. There were 45 radiotherapy patient notifications received representing 22% of the total, and 26 patient notifications in nuclear medicine, 13% of the total.

During the review period, the number of patient notifications varied by employer, with numbers ranging across 12 employers from 1 to 49. It should be noted when reviewing notification numbers that they have not been normalised for activity levels or technique complexity.

Accidental exposures accounted for 15% (n = 31) of the patient notifications received. Accidental exposures occur when an individual receives an exposure in error, when no exposure of any kind was intended.

Unintended exposures made up 66% (n = 134) of notifications. Unintended exposures occur when an individual is referred for radiation exposure, but the exposure delivered was significantly different to what was intended.

Additionally, voluntary notifications contributed 19% (n = 38) of the notifications received. Voluntary notifications include incidents that may have not met the criteria or reporting threshold but are shared for learning so that similar events in the future might be mitigated.

The report does not include an assessment of the clinical outcome for the patient, or the efficacy of actions put in place following any individual incident.

Five recommendations for providers have been included within this report.

Background

The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) provide a legislative safety framework to protect patients against hazards associated with ionising radiation. In the event when there is a significant accidental or unintended exposure to ionising radiation, the IR(ME)R employer must investigate the incident and notify the Healthcare Inspectorate Wales (HIW) under Regulation 8(4).

HIW is the independent regulator of healthcare and the inspectorate for NHS services in Wales. Our role is to check that healthcare is safe, effective, and meets the needs of people and communities. HIW encourages continuous improvement in the quality of services carrying out medical and non-medical exposures involving ionising radiation using medical radiological equipment, through a planned programme of inspections and reviews.

As part of its programme for assessing compliance with IR(ME)R, HIW requested that the Medical Exposures Group (MEG) within the UKHSA undertake a review of submitted IR(ME)R significant accidental or unintended exposures notifications where the incident occurred between 1 April 2024 and 31 March 2025. The scope of this review is to identify themes and consider learning opportunities from shared notifications. It does not include an assessment of the clinical outcome for the patient, or the efficacy of actions put in place following any individual incident.

Under IR(ME)R Regulation 9, HIW is required to put in place mechanisms to disseminate relevant information regarding significant events. To support this requirement, HIW may decide to publish key learning points from this report. This provides IR(ME)R employers and staff within Wales the opportunity to learn from the experience of others and implement effective corrective and preventative measures proactively. In turn, this may minimise the probability of similar events happening and thereby improve patient safety. HIW may also use this report to inform inspection themes and the overall inspection programme.

Detailed criteria are available to guide IR(ME)R employers on when to make a notification to HIW. This was last updated 21st August 2024 (Version 4). Prior to this date the notification criteria was covered by Version 3 of the guidance, which came into effect on 19 April 2023. Version 3 criteria were therefore effective from 1st April 2024 to 20th August 2024, approximately a third of the reporting period. The notification codes, categories and criteria that were in use during this reporting period are included in Appendix 1.

The amendments to Version 4 (August 2024) of the reporting criteria included:

- Revised information on clinically significant accidental or unintended exposures (CSAUE)
- Amended notification criteria for interventional radiology and cardiology
- Amended notification criteria relating to radiotherapy imaging exposures

Of the patient notifications included in this analysis, 62 occurred before 21st August 2024. The appropriate SAUE guidance was applied to the analysis, dependent on the incident date.

Accidental or unintended exposures (AUE) are defined in guidance as follows:
Accidental exposure: an individual has received an exposure in error when no exposure of any kind was intended.
Unintended exposure: although the exposure of an individual was intended, the exposure they received was significantly greater or different to what was intended. For example, in the dose received, there may have been an error in either the modality or technique carried out, anatomy, radiopharmaceutical, timing of exposure or equipment malfunction. These can happen for many reasons including procedural, systematic, human error or equipment malfunction.
In addition, duplicate referrals that lead to repeat imaging are considered unintended exposures if occurring in the same episode and same condition.

AUE may be classified as significant or clinically significant.
SAUE: Significant accidental or unintended exposures (SAUE) include those that are significantly greater than intended or significantly lower than intended for radiotherapeutic exposures.
CSAUE: The concept of clinically significant accidental or unintended exposures (CSAUE) was introduced with IR(ME)R in 2017. Criteria to define clinically significant accidental or unintended exposures for diagnostic and therapeutic exposures were published for the clinical setting in June 2020.

Of note, the IR(ME) (Amendment) Regulations came in to effect on the 1st of October 2024 within Great Britain. The amendments provide an updated definition for accidental exposure consistent with SAUE Guidance, and require the employer to establish a system for taking appropriate action following analysis of actual or potential accidental or unintended exposure events.

Methodology

HIW shared relevant, anonymised notification data securely with MEG. The information included in each notification varied across the dataset. Most notifications included some, or all, of the following information:

- HIW notification of accidental or unintended exposure forms
- primary investigation reports
- Medical Physics Expert (MPE) dose assessment
- other supporting evidence

Key questions were generated by MEG to inform the analysis of the data. All data sources were reviewed by MEG and, where relevant information was available, entered in a Microsoft Excel® incident tracking spreadsheet to enable frequency trend analysis. A list of the fields used to analyse the data is included in Appendix 2.

All analysis was carried out per individual patient notification, rather than grouping incidents involving multiple individuals together.

Analysis

IR(ME)R patient notifications by modality

In total there were 119 notifications submitted for analysis. This included 19 notifications where multiple patients were included (n = 103). Therefore, notifications involving 203 patients were reported to HIW under the SAUE notification criteria between 1 April 2024 and 31 March 2025 and included within the analysis. A breakdown of the 203 patient notifications from 2024-25 is shown in Figure 1.

Diagnostic and interventional radiology contributed the largest proportion of patient notifications with 132 in total (65%). This is likely to be due to the greater volume of diagnostic examinations performed compared to nuclear medicine and radiotherapy exposures. Radiotherapy patient notifications received accounted for 45 patients representing 22% of the total notifications. There were 26 patient notifications in nuclear medicine, representing 13% of the total notifications.

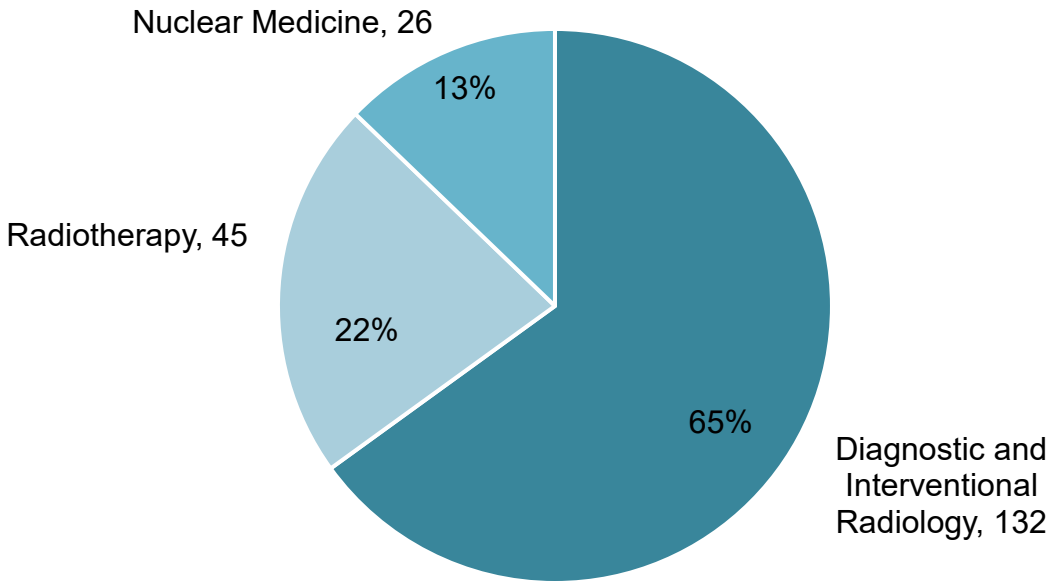

Figure 1. Number and percentage of individual patient notifications per modality (n = 203)

Table 1 shows a comparison with the previous year's analysis (April 2023 - March 2024). There has been a 40% increase in the number of notifications submitted (n = 85), and an 85% increase in the numbers of patients affected (n = 110). In addition, the proportion of diagnostic and interventional radiology patient notifications contributing to the total has reduced from 73% (n = 80), whilst the proportion of radiotherapy notifications has increased from 15% (n = 17) in 2023-2024. The proportion of nuclear medicine notifications has remained broadly consistent (12% 2023-2024, 13% 2024-2025).

Reporting year	Number of notifications	Number of patients affected			
		Diagnostic and interventional radiology	Nuclear medicine	Radiotherapy	Total
2023 – 2024	85	80	13	17	110
2024 – 2025	119	132	26	45	203

Table 1: Number of notifications received by HIW, and numbers of patients affected between 1 April 2023 to 31 March 2025, by modality

IR(ME)R patient notifications per employer

Notifications of IR(ME)R incidents were received by HIW from 12 employers crossing all relevant sectors during the specified period. Figure 2 shows the breakdown of patient notifications per IR(ME)R employer.

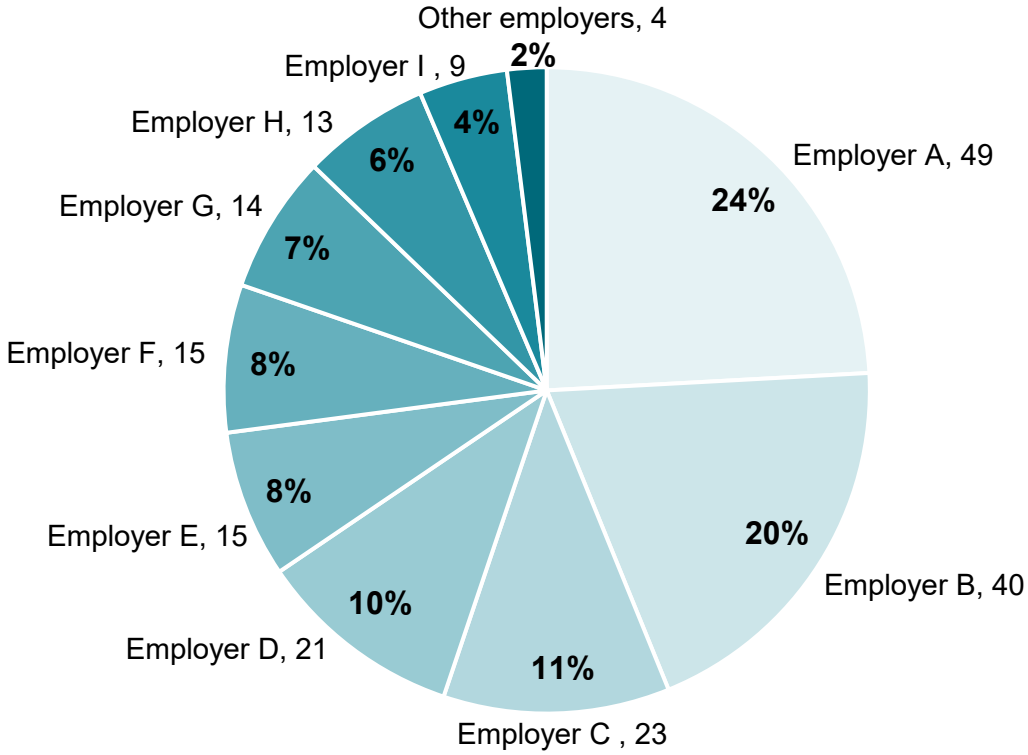

Figure 2. Number and percentage of patient notifications by employer (n = 203)

It should be noted the number of notifications per employer is not normalised by activity, patient attendances and type, or number of exposures undertaken at site.

IR(ME)R patient notifications per employer by sub-modality

The sub modalities included in notifications are:

- Diagnostic and Interventional Radiology: General X-ray, Computed Tomography (CT), dental, fluoroscopy, interventional radiology, cardiology, dual energy X-ray absorptiometry (DXA) and mammography
- Radiotherapy (RT): imaging for planning, verification imaging and treatment exposures
- Nuclear Medicine (NM): Positron Emission Tomography / Computed Tomography (PET/CT), Single-Photon Emission Computed Tomography (SPECT), Single-Photon Emission Computed Tomography / Computed Tomography (SPECT/CT), NM planar and NM non-imaging

Diagnostic and interventional radiology

Figure 3 describes the number of patient notifications per employer by sub-modality for diagnostic and interventional radiology submitted in 2024-2025.

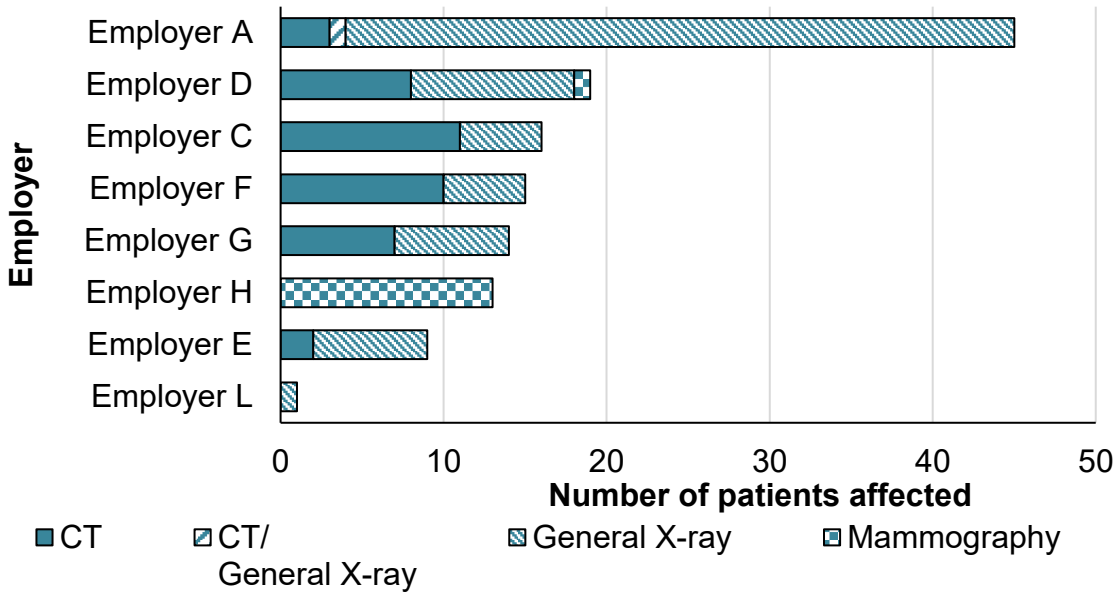

Figure 3. Diagnostic and interventional radiology patient notifications per employer by sub-modality (n = 132)

The largest proportion of patient notifications submitted involved general X-ray (n = 76, 37%), this is an increase in volume and proportion from 2023-2024 (n = 32, 29%). These were spread across all Health Boards and included a notification with 34 patients undergoing

X-ray procedures where the incorrect detector was selected at the time of exposure. Further details are included in the case study below. Another example was where a single patient received an accidental X-ray and CT examination.

Patient notifications involving CT totalled 41 (20%), a reduction in proportion from 2023-2024 (27%, n = 30). Examples include duplicate referrals and referrals made using incorrect demographic information.

There were 14 (7%) mammography patient notifications submitted, a reduction in proportion from the previous year (13%). A notification including 11 patients concerned equipment malfunction. Two related to patients who failed to disclose to operators that they remained under the care of hospitals where they had previously received treatment, therefore should not have attended for mammograms.

Case study – Incorrect detector selection

Scenario: During routine analysis of rejected images performed in an X-ray examination room, a number of blank exposures were identified. On further investigation, the blank exposures occurred due to incorrect detector selection at the time of exposure.

Investigation: Analysis of rejected images for all X-ray examinations rooms at the site was performed, which identified a number of blank exposures due to incorrect detector selection. The audit was expanded across the health board, which identified a small number of additional exposures due to incorrect detector at another site within the health board.

The incidents occurred as a result of exposures being performed with the incorrect detector selected for the examination. This resulted in blank exposures, which required the exposure to be repeated with the correct detector selected.

On further investigation, it was observed that the wireless detector was involved in each of the incidents. The system incorrectly recognises the wireless detector as an available detector option when it is being charged. When docked detectors are selected for use, the system can identify if the X-ray tube is not centred on the detector and alert the operator. This helps the operator identify if the incorrect detector has been selected. However, when the wireless detector is selected as the detector for exposure, the system cannot recognise if the X-ray tube is appropriately centred over this detector.

During pre-exposure checks, the operator selects the appropriate protocol and detector. If the operator changes the protocol, the system reverts the detector selection. Where the incidents occurred, the system reverted to the wireless detector option (as it was charging and displayed as available), which was the inappropriate detector for the exposure. The operator did not notice this, as they had selected the appropriate detector before changing the protocol.

Corrective actions included:

- Following engagement with the manufacturer, an additional step on the system was introduced, prior to performing the exposure where the operator must confirm the detector selection.
- Additional equipment training for operators around detector selection
- Equipment training records were reviewed and updated to reflect this key component of the training and competency required for this piece of equipment
- Shared learning disseminated via an incident alert, reminding staff to perform the pause and check process prior to the exposure.

Nuclear Medicine

Figure 4 describes the number of patient notifications per employer by sub-modality for nuclear medicine submitted in 2024-2025.

Of 9 PET/CT reports, equipment malfunction caused 5, whilst in 3 reports, a standard scan protocol was used instead of the required extended protocol to cover relevant anatomy. These reports were submitted under the multiple SAUE category. HIW were informed of a single cardiac nuclear medicine SPECT notification comprising of 7 patients where processed computer image data was lost.

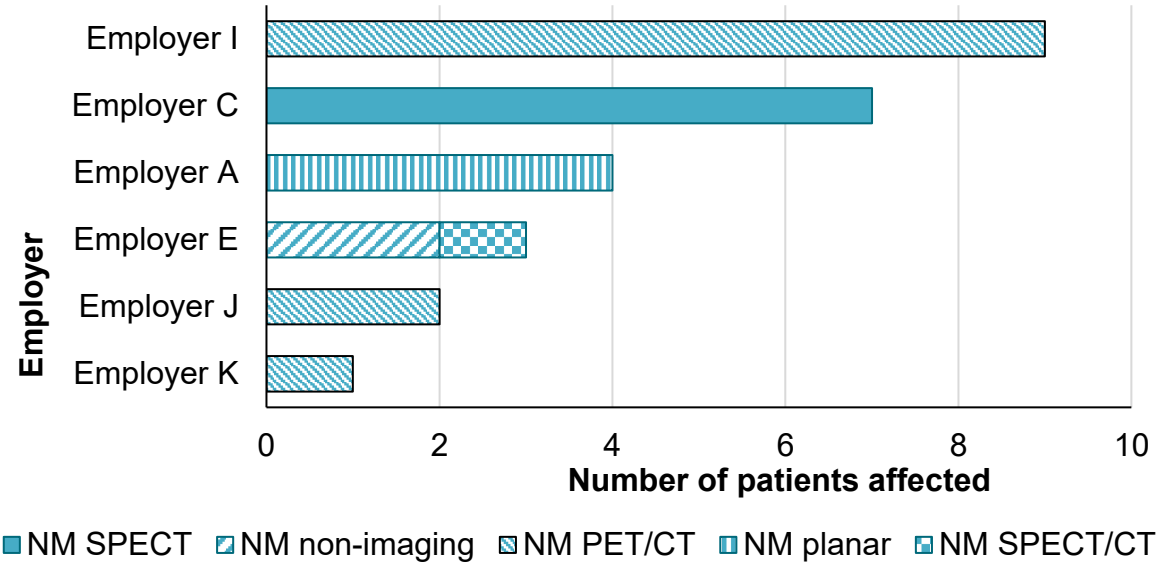

Figure 4. Nuclear Medicine patient notifications per employer by sub-modality (n = 26)

Employer E submitted 2 patient notifications where radiopharmaceuticals were administered for sentinel node imaging and probe-led biopsy (NM non-imaging), but the surgical procedure was cancelled. A further notification involved a duplicate referral for bone SPECT/CT scan. One provider submitted 2 notifications, the first based on a patient receiving a repeat PET/CT scan due to a duplicate referral, the second where extravasation led to acquisition of images of insufficient diagnostic quality, therefore requiring a repeat

PET/CT scan. Of other nuclear medicine notifications, one was submitted over a concern whether the correct patient had received the correct scan or not. After further investigation it was confirmed that all clinicians were satisfied the correct patient had the correct scan at the correct time. Finally, Employer A submitted a single report involving 4 patients undergoing imaging where the incorrect calibration factor was used to measure the activity of radiopharmaceutical vials which were subsequently administered, resulting in an overexposure to the patients, this notification is the focus of the case study below.

Case study: Incorrect calibration factor used

Scenario: Prior to dispensing and patient administration, radiopharmaceutical vials for multiple (four) patients were measured using an incorrect calibration factor. This resulted in the overexposure of four patients.

Investigation: The investigation concluded that the calibrator factor used was not changed from the quality assurance testing of the calibrator. The procedure to return the calibrator factor to the original setting after performing the quality assurance test was not followed. Furthermore, operators performing the radiopharmaceutical vial measurements did not identify that an incorrect calibration factor was selected.

Corrective actions included:

- Procedure and dispensing sheet amended to include requirement of check of calibration factor prior to measurement and dispensing.
- Nuclear medicine staff made aware of updates.

Radiotherapy

Figure 5 describes the number of patient notifications per employer by sub-modality for radiotherapy submitted in 2024-2025.

There were 33 patient notifications submitted from all three Welsh radiotherapy providers involving radiotherapy verification imaging. Employer B submitted 30 patient notifications, 26 of which were due to equipment malfunction. Employer E submitted 2 patient image verification notifications. One report related to equipment malfunction. The other was due to inaccurate imaging data preparation. Finally, Employer D submitted a single notification due to inaccurate imaging data preparation.

Two notifications were submitted relating to CT planning scans that needed to be repeated twice. One event was attributed to the patient experiencing difficulties achieving the necessary breath hold for planning purposes, the second event involved issues with insufficient scan length and reference tattoo position.

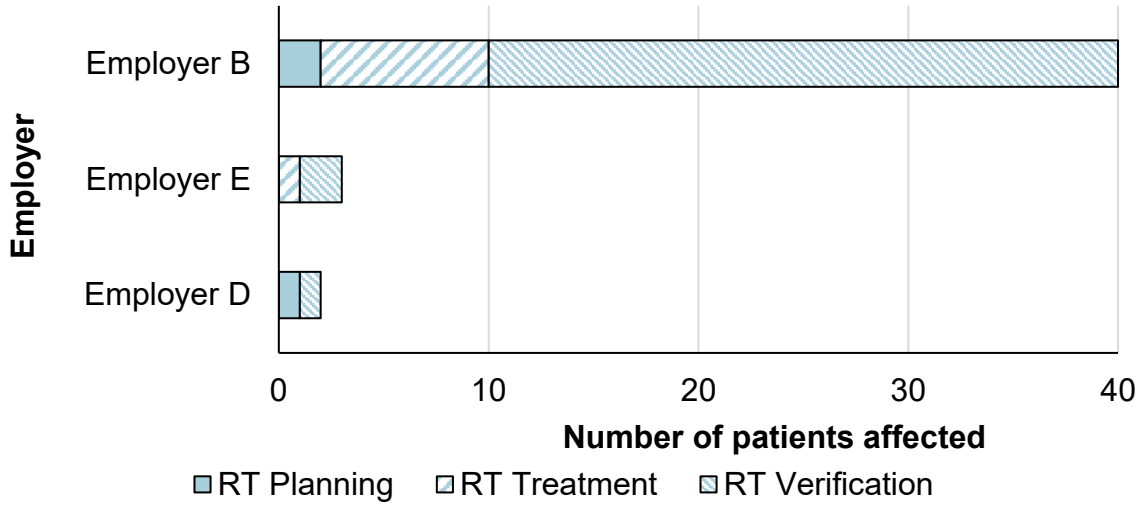

Figure 5. Radiotherapy patient notifications per employer by sub-modality (n = 45)

The remaining 10 notifications affected patients' radiotherapy treatment delivery. Employer B submitted 8 treatment patient notifications. A radiotherapy patient support system was found to have the potential to infringe upon posterior treatment fields, thereby reducing the dose to patients. An audit investigating historical treatment over of period of years identified 6 patients where an underdose had occurred. This event is described in more detail in the case study on page 20. The two further treatment notifications from this employer related to; an occasion where a partial geographic miss occurred, and another when a patient received once daily treatment rather than the intended twice daily treatment. The latter was a clinically significant notification. The notification was received from Employer E where part of a patient's treatment was delivered at an incorrect gantry angle. Finally, Employer D submitted a notification where the incorrect area had been treated. This notification was considered clinically significant.

For all modalities combined, 22% (n = 45) of all notifications referenced equipment failure or design as a contributory factor to the event. The majority of these were from radiotherapy notifications.

IR(ME)R patient notifications per hospital site

Figure 6 shows a breakdown of the number of patient notifications at hospital and clinic sites where notifications were made. Reports were submitted from 21 hospitals, an increase from 17 in the previous year's analysis, as well as several other clinical facilities.

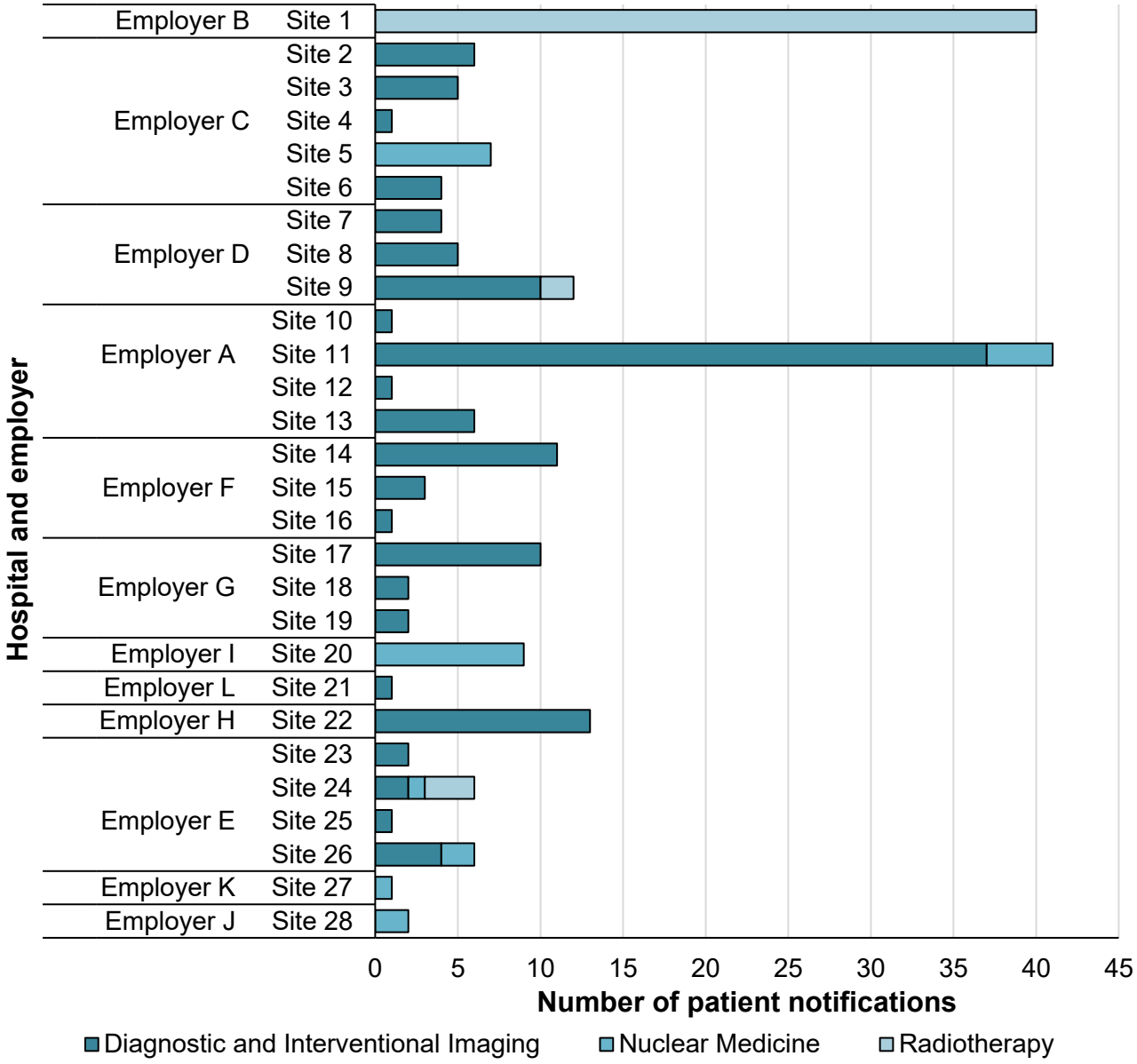

Figure 6. number of patient notifications per site and employer by modality (n = 203)

Nature of patient notification

Notification reports were analysed to group themes relating to the nature of the incident. Where available, SAUE codes supplied were reviewed with the incident reports. MEG applied the SAUE coding criteria to those notifications based on the information shared by HIW where the coding was missing. Figure 7 shows the SAUE code applied to the patient notifications for 2024-2025.

There were 31 (15%) accidental exposures (shown as SAUE code 1 in Figure 7). Accidental exposures occur when an individual receives an exposure in error, when no exposure of any

kind was intended. Examples of these types of errors include referrals for patients who were never intended to undergo exposures, and failure to follow patient identification procedures.

Unintended exposures made up 66% (n =134) of the patient notifications received. Unintended exposures occur when an individual is referred for radiation exposure, but the exposure delivered was significantly different to what was intended. Examples of these types of notifications include radiotherapy treatment verification imaging events, whereby the number of imaging exposures undertaken may be greater than that intended.

Several notifications (n = 34, 17%) were classed as accidental by the reporting provider, however during UKHSA analysis were re-categorised as voluntary for consistency across the dataset. The majority of these re-categorised notifications were where patients received unnecessary repeat exposures due to duplicate referrals or timing errors. Whilst all these cases were considered notifiable by the provider, none of them met the criteria for accidental or unintended exposure notification under SAUE. Therefore all 34 were reclassified within the analysis as voluntary. There were a further 4 notifications highlighted as voluntary and were shared for learning so that incidents might be mitigated in the future. Therefore, it is encouraging to see employers voluntarily report notifications which did not reach the SAUE notification criteria. This demonstrates a positive reporting culture within these organisations.

Six clinically significant accidental or unintended exposures (CSAUE) notifications were submitted by providers. This is an increase from a single CSAUE the previous year. Further information on these events is found in the discussion section.

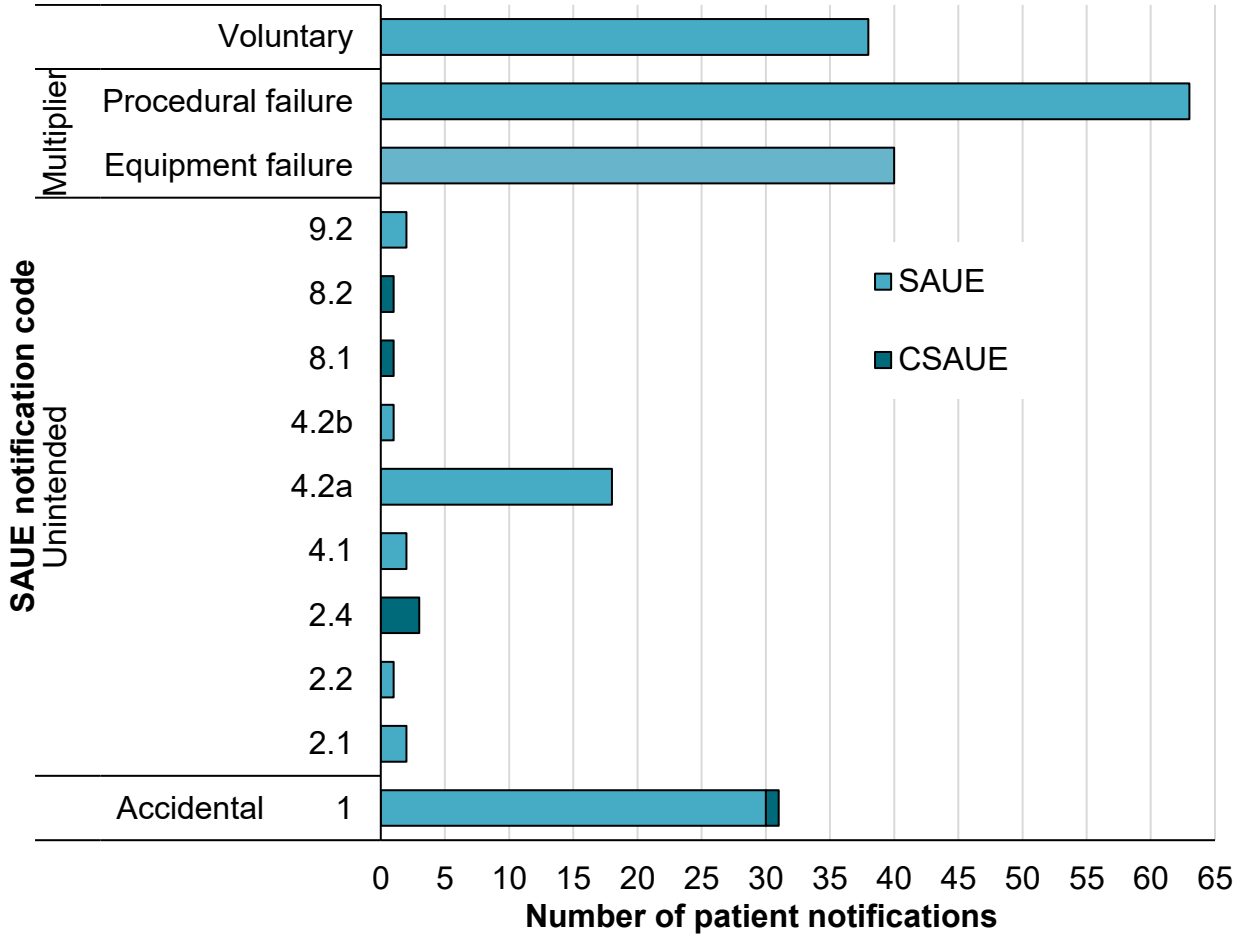

Figure 7. SAUE code of patient notifications by theme (n = 203)

Notifications affecting multiple individuals

Examples of notifications that affected multiple individuals include one where 34 patients underwent X-ray procedures, and the incorrect detector was selected at the time of exposure. Although each incident on their own did not constitute a significant unintended exposure, the criteria based on any theme affecting multiple patients was met. A second involved six patients whose radiotherapy treatment was partially obstructed by a radiopaque part of the treatment couch. A case study detailing the incident, corresponding investigation and corrective actions that followed are detailed below.

Case study – Attenuation of treatment beams by radiotherapy couch support structure

Scenario: In September 2024 a providers Head of Radiotherapy Physics received an alert from another Head of Physics via a group email to advise that, with a sufficiently large longitudinal couch extension, the patient couch support structure can obstruct the X-ray treatment beam on a specific manufacturer's linear accelerators. Being solid metal, this couch support structure would have a dosimetric impact (geometric underdose) if the treatment field were to pass through it during delivery of a patient's treatment.

Investigation: An investigation for patients currently undergoing treatment was performed immediately and concluded none were affected. A departmental review was launched to investigate whether, and to what extent, any previous patients treated at the centre may have had their treatment affected.

The review identified six cases. Although the degree of underdose was minor and not considered sufficient to trigger the requirement for SAUE notification on an individual basis, the numerous patients involved has triggered a SAUE notification requirement under the 'M' complimentary notification code. A MHRA Yellow Card report was compiled and submitted.

Corrective actions included:

- Radiographers were immediately notified of the issue and informed that they should contact physics for any patients with extended couch long positions
- Systematic review of QMS documents and appropriate updates applied
- Investigate treatment control settings to hard-limit couch longitudinal position
- Risk assessment undertaken for ongoing use of the affected equipment
- The learning and actions from the incident were shared locally and nationally

Notification risk data

Out of 203 patient notifications, data on total effective dose was included in 146 reports (72%), a reduction compared to reporting in 2023-2024 (83%). Twenty-two reports (11%) did not include effective dose (mSv), but provided an assessment of other dose parameters, for example mGy, cGycm^2 or DLP. Thirty-five of the patient notification shared for review (17%) did not provide complete total delivered dose data.

Notifications with an estimate of the total effective dose were reviewed, expressed in millisieverts (mSv). Figure 8 shows a dose histogram from the relevant 147 patient notifications. The total effective dose (planned and unplanned exposures) ranged from 0.00012 mSv to 70mSv with an average of 5.3 mSv. The median dose received was 0.95mSv and mode of 15.8mSv.

There were 73 patient notifications with estimates of effective dose which resulted in a total dose of less than 1mSv.

The maximum dose delivered (70mSv) resulted the equivalent to 17 years of background radiation. This incident was considered a CSAUE and occurred when the patient attended for a CT Virtual Colonoscopy scan and the rectal catheter was inserted incorrectly, which required the patient to be reimaged. The procedure was completed as intended on the second occasion.

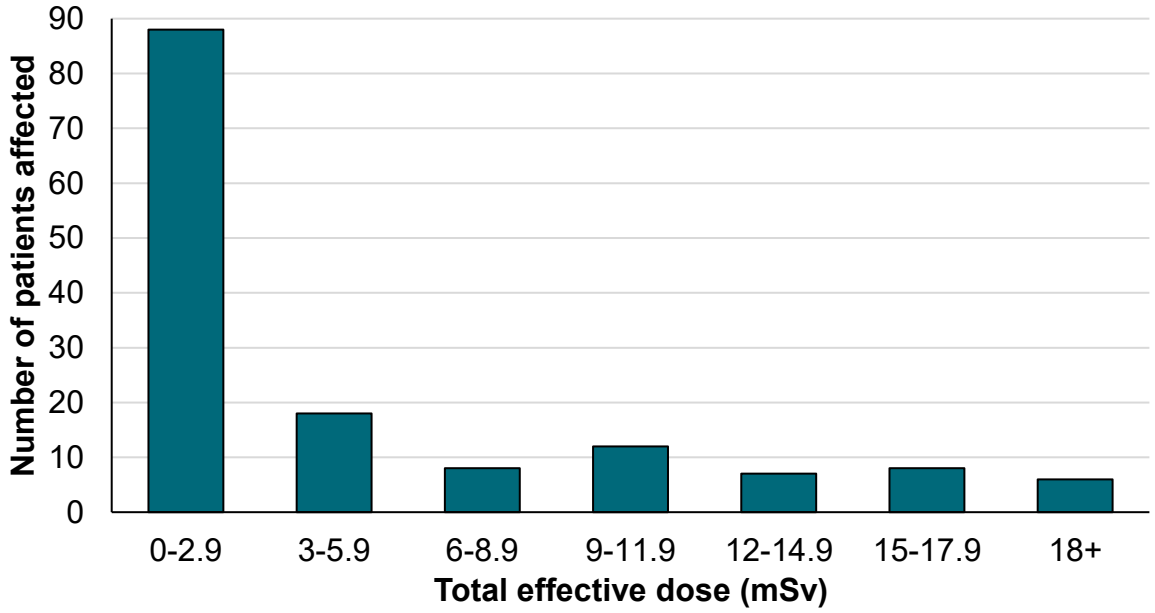

Figure 8. Histogram of total effective dose delivered (mSv) (n = 147)

Demographics

The age range of the patient cohort was from one to 95 years old with an average age of 64 years old. The median reported age was 67 years. The ages of 46 patients were not described in notifications. The age distribution of the affected patients is summarised below in Figure 9.

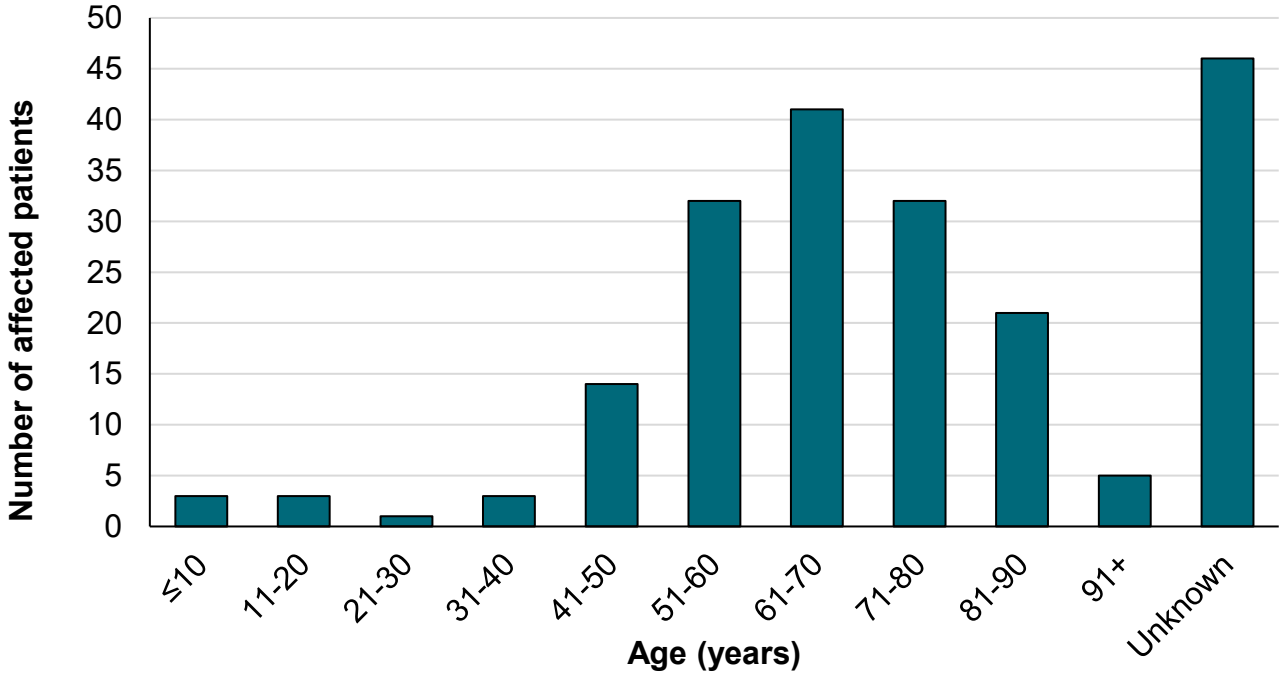

Figure 9. Age histogram of affected patients (n = 203)

Who was informed of the incident

There is a requirement under IR(ME)R to inform the referrer, practitioner, and the patient (or their representative) of CSAUE and the outcome of the investigation of the event. Whilst six CSAUE notifications were submitted during this reporting period, providers may inform the relevant duty holders and individuals concerned of significant accidental or unintended exposures as a matter of good practice.

Table 3 highlights the number of times the referrer, practitioner, individual or representative were informed of events.

Informing others	Informed	Not informed	Not known
Referrer	72	7	124
Practitioner	68	6	129
Individual/representative	150	35	18

Table 3. Referrer, practitioner, individual or representative informed

Of note, the referrer was stated as being informed in 72 patient notifications (36%), and the practitioner in 68 patient notifications (34%). There was insufficient detail in the reports submitted to determine if the referrer and practitioner were informed for 124 (61%) and 129 (64%) patients respectively. The patient or their representatives were informed on 150 occasions (74%). There may be some cases where the referrer, practitioner and individual or their representative were informed of the incident following notification to HIW, but this was not reflected in the data shared for analysis.

Application of national event taxonomies

When reporting clinical events (incidents and near misses), applying a comprehensive event coding taxonomy offers the benefit of providing a standardised approach to event reporting and analysis. This can elicit improved understanding of event causes by facilitating effective trend analysis, thereby identifying vulnerable areas within clinical pathways and salient contributing factors. The notifications received by HIW with the associated taxonomy coding, were either from the National coding taxonomy for incident learning in clinical imaging, MRI and nuclear medicine, or the National radiotherapy patient safety event taxonomy.

On occasions where taxonomy coding was incomplete or absent, relevant coding was considered by UKHSA staff using the supporting text supplied by the local provider. Whilst providers are encouraged to provide fully coded taxonomy when submitting notifications, for

the purposes of this report the primary pathway subcode and contributory factor code results are presented. Whilst the national coding taxonomies for diagnostic and interventional radiology and nuclear medicine, and radiotherapy have different pathway codes, the contributory factor taxonomy is shared.

Diagnostic and interventional radiology

Figure 10 shows the most frequently reported pathway subcodes for the diagnostic and interventional imaging modalities. The most frequent was ‘equipment set-up and protocol selection’ at 31% (n = 40/129), this includes 34 patients from a single X-ray notification.

The second most common process subcode was ‘insufficient or inaccurate demographic information or duplicate referral’ which comprised 29% (n = 37/129), with a broadly equable split between CT and general X-ray, plus a single mammography notification. Most mammography notifications originated from ‘equipment malfunction’ (n = 11/14).

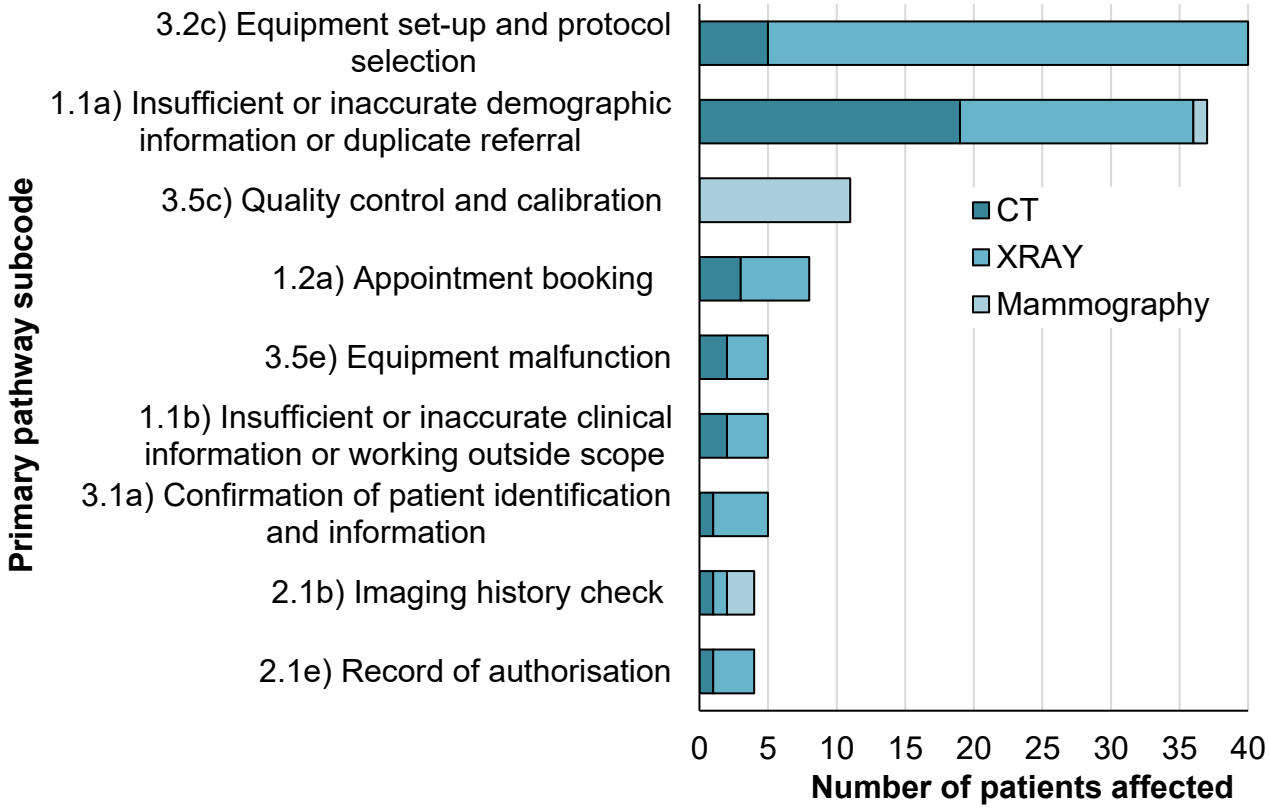

Figure 10. Most frequent primary pathway subcode for diagnostic and interventional imaging events (n = 119/129)

There is often a complex chain of events and influences that lead to an event occurring. The benefit of applying the contributory factor taxonomy is to identify system failures or conditions that precipitated the event. If the contributory factors are addressed, overall system safety can be improved. Multiple contributory factors can be, and often should be, assigned to a single event. In the case of diagnostic and interventional radiology, 107 contributory factors were assigned to 98 notifications, either by providers or by UKHSA staff

based on information provided in supporting text, leaving 34 reports without contributory factor coding. Therefore, the highlighted analysis does not represent the full diagnostic imaging dataset. Figure 11 shows the most frequently identified contributory factors for diagnostic and interventional radiology. The most attributed contributory factor was 'failure to follow procedures, protocols or guidelines' (n =61, 57%).

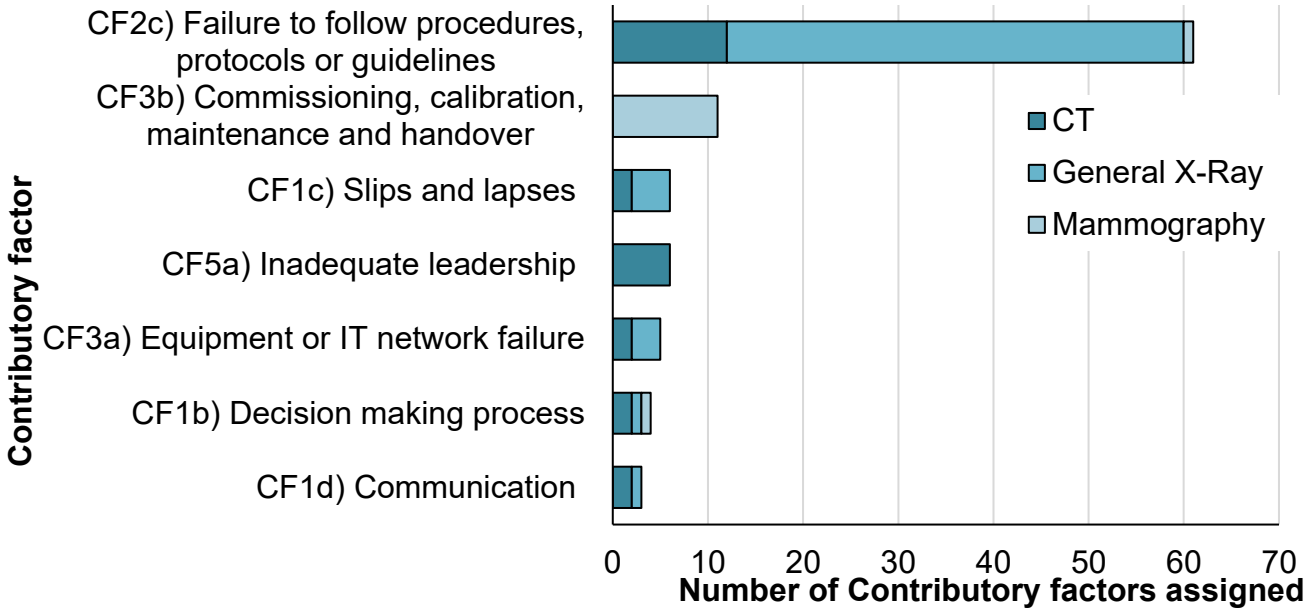

Figure 11. Most frequent contributory factors for diagnostic and interventional imaging events (n = 96/107)

Nuclear Medicine

Figure 12 highlights the assigned pathway codes for nuclear medicine notifications. 'Equipment malfunction' and 'pharmaceutical (preparation)' were the most cited, with 8 (32%) and 4 (16%) respectively.

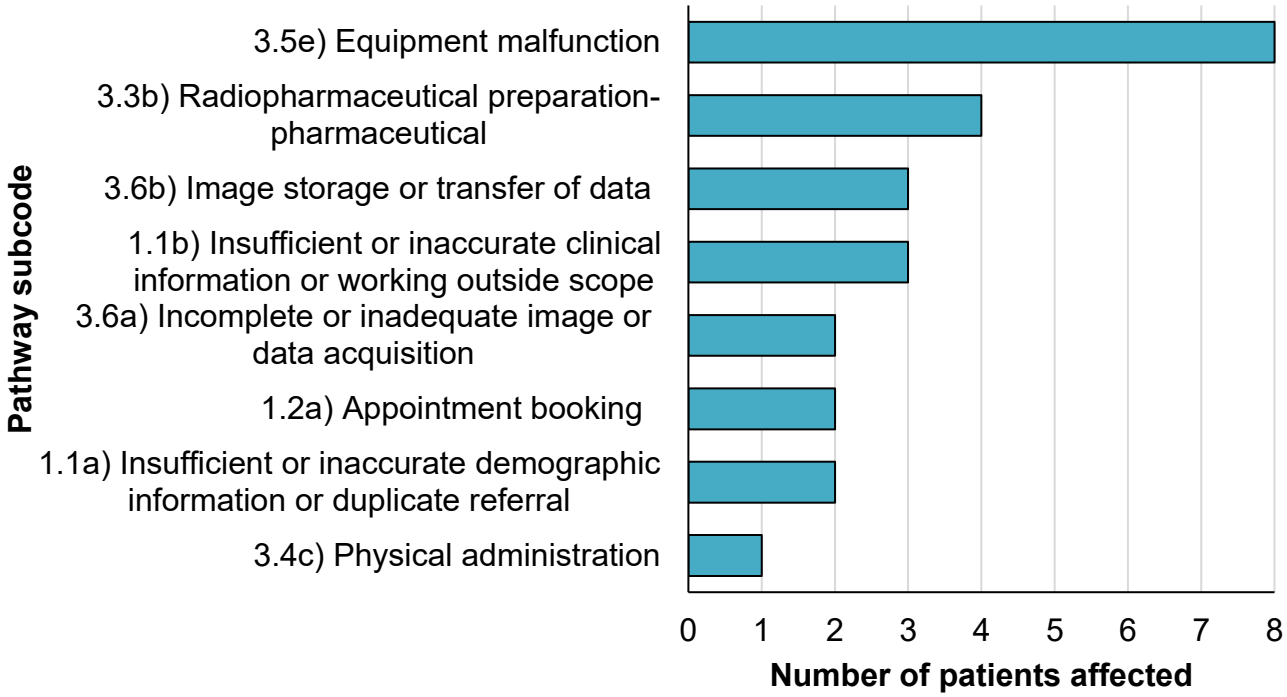

Figure 12. Primary pathway subcode for nuclear medicine events (n = 25)

Figure 13 shows the contributory factors associated with nuclear medicine reports. 'Equipment or IT network failure' was the most cited contributory factor (n = 6, 40%).

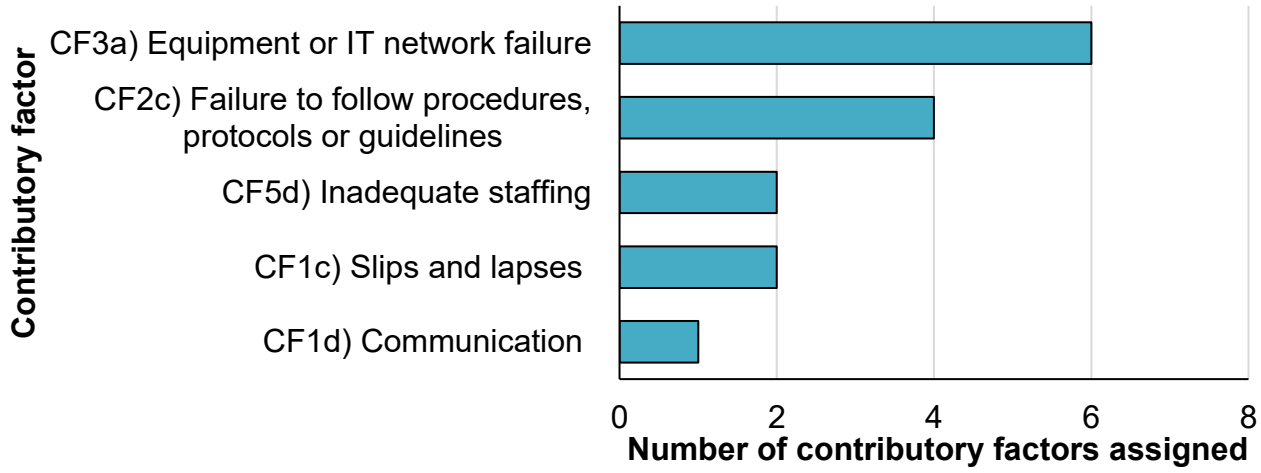

Figure 13. Contributory factors for nuclear medicine events (n = 15)

Radiotherapy

The primary process subcodes for radiotherapy are presented in figure 14. 'On-set imaging: production process' was most frequently reported with 62% (n = 28/45).

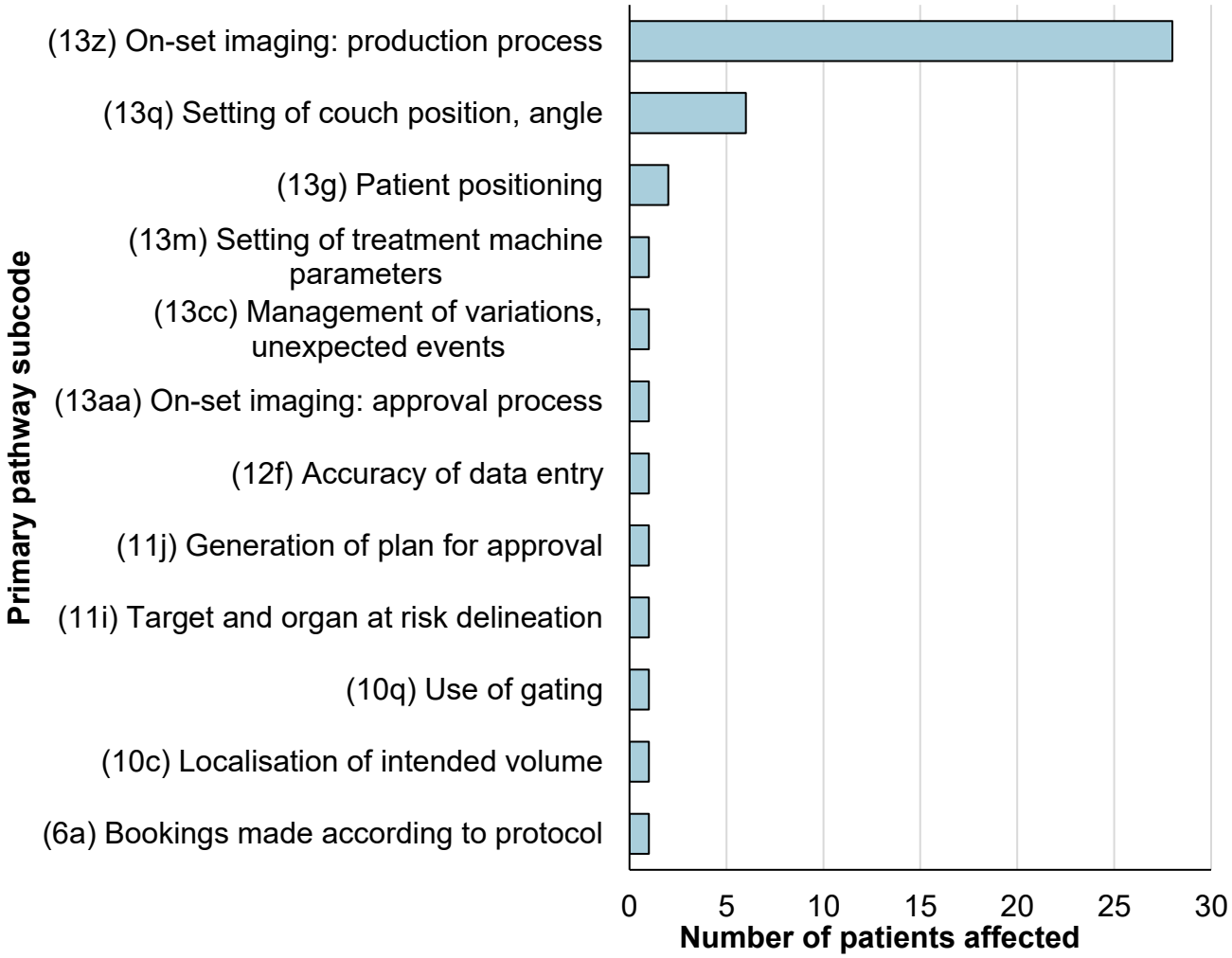

Figure 14. Primary pathway subcode for radiotherapy events (n = 45)

Figure 15 demonstrates the most often cited contributory factor for radiotherapy events was ‘equipment and IT network failure’ with 60% of the share (n = 27). ‘Device or product design was the second most frequently cited with 18% (n = 8).

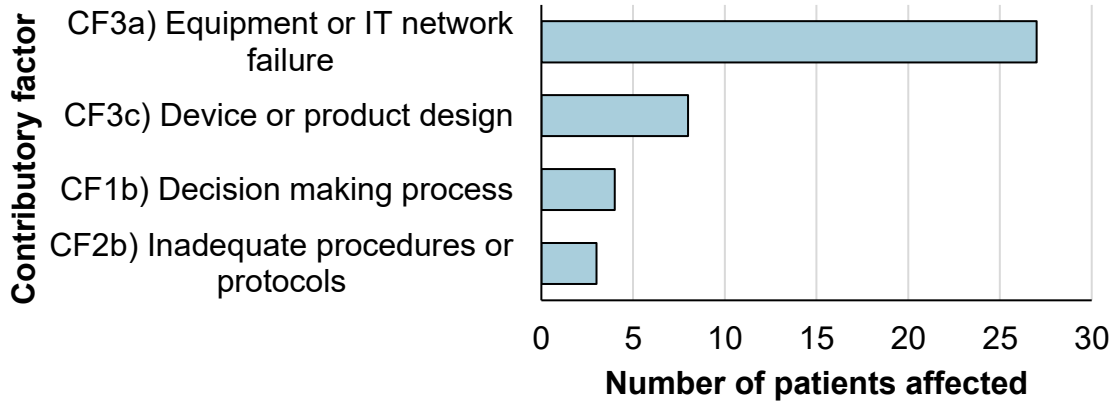

Figure 15. Assigned contributory factors for radiotherapy events (n = 42/45)

For all three modalities combined, 22% (n = 45) of all notifications referenced either equipment failure or equipment design as a contributory factor to the event. The majority of these were from radiotherapy notifications.

Discussion

As part of HIW's proactive IR(ME)R inspection programme, it is clear that there are employers with an excellent incident reporting culture, generating learning from analysis of incidents and near misses in order to improve patient safety. However, inevitably there are variations in notification levels across providers.

It should be noted the number of notifications from providers within this report are not normalised by activity or number of exposures undertaken at each site. Population numbers and demographics (for example, rural or city, age, depravation, healthy life expectancy), geographical area covered, and number of hospitals should also be considered when comparing the number of notifications to HIW by each employer.

Further confounders include differences in service provision. Nuclear medicine and radiotherapy are only provided at certain sites, and this should also be appraised when reviewing the variation in levels of notifications.

The population numbers served by Local Health Boards range from approximately 692,000 to 134,000. One NHS Trust is the South and Mid Wales specialist tertiary oncology centre and therefore serves a population of approximately 1.7 million delivering specialist cancer services such as radiotherapy.

From the data analysis, there is clearly an increasing trend of providers reporting greater volumes of SAUE events to the HIW. This can be interpreted as evidence of maturing safety cultures within providers where staff feel safe to raise, and therefore are increasingly willing to report, safety concerns. Nevertheless, these reports are composed of the highest severity of events and careful analysis and transparent dissemination of learning is required to understand salient contributory factors and provide opportunities for improvement.
All Health boards submitted diagnostic and interventional radiology imaging notifications this year, including one who had submitted none the previous year.

In terms of nuclear medicine, the same number of employers submitted reports.
Unlike last year, all three radiotherapy centres in Wales submitted notifications. However, there appears to be notable variation in the numbers submitted by these centres, with Employer B demonstrating a particularly strong reporting culture.

Notification information

In terms of consistency, all incident notifications assessed within this report were submitted to HIW using the recognised IR(ME)R notification form. However, the inclusion of supporting information, including MPE delivered dose assessments, was not consistent. The variable level of information provided can lead to relevant details being omitted from some

notifications such as dose delivered, or dose intended and SAUE criteria, as well as relevant learning and mitigations.

IR(ME)R requires the involvement of an MPE for radiation incident analysis (Regulation 14(3)(f)). An MPE dose assessment is key in providing an indicator of risk and potential degree of harm to the individual, whether it is a SAUE and notifiable to the regulator. Of the patient notifications shared for review 170 included a MPE dose assessment (84%). Whilst this could be a separate report it was more commonly included within the incident investigation report or IR(ME)R notification. Most complete dose assessments included estimates of equivalent dose in mSv (n = 147). Of the remaining 56 notifications, 23 contained dose information using alternative dose indicators such as Gray (Gy), dose length product (DLP) and dose-area product (DAP). There were 8 reports where duplicate scans had taken place, however the complete dose information, including previous scan dose data, was not provided.

This left 25 patients where a dose assessment was missing from the shared documentation. A notification featuring 34 patients supplied a dose report but only for 31 of the patients, dose assessment for the remaining 3 were missing. An incident report of a notification involving eleven patients referred to an appendix for imaging dose assessment that was not included in shared data. One report failed to ascribe a unit of measure. One notification of 6 patients stated the MPE had been contacted to carry out a dose assessment but was not included within shared data. A further notification concerning 3 patients advised the dose assessment would follow in a detailed report as one of the patients had not been rescanned. Finally, a further notification advised that dose information would follow, in order not to delay the notification. HIW may wish to emphasise that employers should include estimates of the doses involved when investigation reports are submitted, and no later than 12 weeks after the incident was discovered. HIW might also consider that the provision of dose assessment reports prior to closing an event should be a mandatory provider requirement.

Several notifications were classed as accidental by the reporting provider, however during UKHSA analysis these were deemed to meet the definition of an unintended exposure. UKHSA consider duplicate referrals that lead to repeat imaging as unintended exposures if occurring in the same episode and same condition.

National taxonomy

Whilst the National patient safety radiotherapy event taxonomy is well established, national taxonomies for the coding and classification of Clinical Imaging, MRI and Nuclear Medicine patient safety events have only been recently introduced. Welsh diagnostic and interventional radiology imaging and nuclear medicine providers are already adopting the use of this taxonomy. These codes should be applied to notifications to aid analysis, and for submission via the Once for Wales Concerns Management System to the UKHSA as part of the UK wide incident learning system for diagnostic imaging, MRI and nuclear medicine.

Radiotherapy providers in Wales contribute radiotherapy event data voluntarily via the Once for Wales Concerns Management System to the UKHSA as part of the UK wide event learning system for radiotherapy. Welsh radiotherapy providers demonstrate good adherence in coding local reports using national patient safety radiotherapy event taxonomy. A series of reports summarising trends in radiotherapy errors are available for the UK.

Diagnostic and interventional radiology

Analysis using the taxonomy codes provided within notifications, and through UKHSA assessment of event descriptions, raised several associated themes; notifications raised due to erroneous referrals, the failure to check for previous imaging and insufficient identification checks being carried out. Providers may wish to consider encouragement of better practice for these tasks and procedures.

The most common pathway points where generation of SAUE events occurred in diagnostic and interventional radiology imaging are ‘equipment set-up and protocol selection’ and ‘sufficient or inaccurate demographic information or duplicate referral’. ‘Equipment set-up and protocol selection’ was predominantly cited in general X-ray events. These included a single report that involved 34 patients where operators selected an incorrect detector at the time of exposure. Whilst examples of event detection through comprehensive audit is welcomed, effectiveness of subsequent actions taken to mitigate likelihood of events recurring must be monitored to ensure that the desired outcomes have been achieved, for example, through further audit.

Pathway subcode ‘insufficient or inaccurate demographic information or duplicate referral’ was the second most frequently cited with 37 patient notifications. This pathway code included similar numbers of CT and general X- ray patients, and one mammography exposure.

There were eight patient notifications with contributory factors from the ‘teamwork, management and organisation’ group, assigned, suggesting evidence of a systems thinking approach to investigation.

Nuclear Medicine

The most frequent pathway code cited was ‘equipment malfunction’ with ‘image storage or transfer of data’ another common code. These notifications caused by a single equipment or file transfer fault affected multiple patients. The individual additional exposure received by patients did not meet the SAUE threshold, but they were reported to HIW under the multiple complementary code.

Radiotherapy

Most radiotherapy notifications were associated with pathway subcode ‘on-set imaging: production process’ (62%, n = 28/45) and 93% of these notifications were associated with contributory factor code ‘equipment or IT network failure’ (n 26/28). This reflects the UK

picture where RTE associated with equipment or IT network failure continue to be a persistent and growing trend. Providers may wish to consider flagging these types of notifications in parallel to the MHRA.

Clinically significant accidental or unintended exposures (CSAUE)

In this reporting period there were six CSAUE notifications, an increase on the previous year's single CSAUE. Definitions for the criteria for CSAUE events are established by the professional bodies for both diagnostic and therapeutic exposures. Two diagnostic and interventional radiology imaging CSAUE were reported. The first related to a repeat of a CT colonography (CTC) procedure. The primary stochastic threshold for a diagnostic imaging dose reportable as a CSAUE, as defined by professional body guidance, is an excess lifetime risk of developing cancer of over 1 in 1,000. In this case the risk was calculated as 1 in 560. The second patient received two CT scans when duplicate referral forms were submitted. The lifetime risk of developing cancer was not stated but the event was deemed to qualify as a CSAUE.

Although nuclear medicine patient notifications were fewer in number to diagnostic and interventional radiology imaging and radiotherapy, two notifications were classed by providers as CSAUE. The first concerned a patient who received a repeat PET/CT scan unnecessarily. The dose assessment confirmed an increased lifetime risk of developing cancer of over 1 in 1,000. The second patient received a duplicate bone scan. The additional dose (3.85mSv) was approximately equivalent to 1.7 years of natural background radiation and a 1 in 17,000 increase in lifetime risk of fatal cancer. Whilst this does not meet the stochastic criteria (an excess lifetime risk of developing cancer of over 1 in 1,000) there may have been other factors not included within the report that led to this notification being defined as a CSAUE.

A CSAUE in radiotherapy is defined to be one that has had, or is expected to have, a measurable effect on the patient's tumour control, normal tissue toxicity or quality of life. The first of the two CSAUE radiotherapy events arose when a patient was treated for part of their radiotherapy course once daily when the treatment was requested and prescribed as a twice daily schedule. The second radiotherapy CSAUE patient received a course treatment to an incorrect area. Whilst the patient was able to have subsequent treatment to the correct area the event was considered to meet the criteria for a CSAUE.

Timing of notification

SAUE notification guidance states that the initial investigation report must be submitted to HIW within 2 weeks of identifying the incident. A total of 68 (34%) initial reports were submitted within 2 weeks of the incident date. The average time to notification was 58 days.

Care needs to be taken when making comparisons based on lag time between incident date and report date. There are occasions where the date an incident is detected will be much later than the incident date. This can be due to a variety of reasons. Events, often involving multiple patients discovered during retrospective audits following an incident investigation will be, by their nature, less contemporaneous. However, they are indicative of a robust incident investigation approach taken by some IR(ME)R employers.

Likewise, there are occasions where historical events are discovered during subsequent follow up. Finally, there are occasions where delays in reporting an event to HIW occurred due to oversights within the patient safety/governance team. In those circumstances providers are encouraged to review their reporting processes.

Effectiveness of actions and learning from notifications

Providers must be committed to learning from events that arise. Every reportable event provides an opportunity for providers to evaluate their service and look for areas of improvement. To maximise potential learning from each event, providers must ensure that event learning systems are robust and accessible, encourage safety reporting, and ensure that appropriate responses are seen to be actioned. Providers must be prepared to interrogate the many diverse, interacting components of their healthcare system and consider system level improvements. There was considerable variation in the recommendations that were made to mitigate the possibility of further events. The most common actions recommended to guard against repeats were:

- staff reminders of responsibilities within employer's procedures and under IR(ME)R
- opportunities for staff to reflect on their role in an event
- raising awareness and sharing learning with relevant staff groups via team meeting, emails, posters etc.

Such people-focused corrective measures can be less effective if used in isolation. For example, providers should seek to understand the reasons where a gap exists between what a protocol or procedure lays out and how staff operate in practice. Reminders of responsibility, including reissues of memos, and staff reflection are invariably insufficient measures in these circumstances.

Incident investigations should include a system level review involving key stakeholders to identify appropriate corrective actions. Consideration should be given to actions linked to system improvements such as review and refinement of processes, improvement of infrastructure and operational environments, and automation of manual processes. Simplifying processes, including the removal of redundant or duplicate tasks, and adding in

additional safety measures can also support reducing incidents. The most effective preventative strategies to mitigate incidents are linked to addressing all contributory factors of an incident. Examples of systems improvements included:

- providing appropriate working environments, including quieter areas and necessary IT infrastructure, to reduce distractions and facilitate safe practice
- review of staffing levels to ensure appropriate and safe staffing levels are provided
- review of IT infrastructure to ensure sufficient equipment is available for use when performing specific tasks
- providing enhanced support for staff including adequate mentorship, manageable workloads, and growth opportunities to improve recruitment and retention.

These systems processes are more difficult to adopt and implement. It is recommended that providers take a methodical, blended approach, assigning corrective / preventative actions to named individuals and providing a summary of actions, study of risk for mitigating actions, and monitoring and evidencing their successful completion. Auditing the effect of measures put in place following an incident helps ascertain if applied actions are, indeed, effective in leading to improvements in patient safety.

HIW shared the report on IR(ME)R notifications to Healthcare Inspectorate Wales (April 2023 to March 2024) with Health boards to disseminate learning and mitigate these types of events. Health boards responses to the report are shared in Appendix 3. This shows that a number of providers are already moving towards a system-based response to SAUE.

Conclusion

This is the second analysis carried out by the UKHSA on behalf of HIW for significant accidental or unintended exposure notifications to ionising radiation submitted under IR(ME)R Regulation 8(4). Assessment of data has shown that notifications have arisen mainly in the hospital setting, with one notification from a GP surgery. All modalities; diagnostic and interventional radiology, nuclear medicine, and radiotherapy, were included. The number of notifications submitted increased in all modalities since 2023 - 2024.

The notification data in this report is not normalised by activity or complexity of work at different sites. From the data analysis, however, it is evident there are variations in the levels and quality of notifications between providers. It was reassuring that, unlike last year, all Health Boards submitted notifications.

It is encouraging to see many voluntarily reported notifications, which do not reach the SAUE notification criteria. This demonstrates a positive reporting culture within these organisations. Six CSAUE were reported during the period assessed, an increase on the previous year. Incident investigations should include a system level review to identify appropriate corrective actions. The most effective preventative strategies to mitigate incidents are linked to the contributory factors of the incident. From the data analysis, further improvements could be made to identify more effective strategies.

Within this analysis, it was not possible to determine how often providers audited the efficacy of actions put in place following any individual incident and identify whether any had any measurable impact. HIW may consider this as an inspection theme in the future. Notifications provide intelligence that can be used to inform proactive IR(ME)R inspection programmes. It is encouraging to see employers with a positive reporting culture, and this is not taken as a sign that patient care or safety is compromised, more that there is a willingness to share learning from patient safety events. Employers whose notification frequency is limited might benefit from a proactive inspection to ensure they have a full understanding of notification requirements as part of Regulation 8(4) and to understand whether there are underlying challenges or barriers to reporting.

Recommendations for employers

Based on the findings of this report employers may wish to consider the following:

1. Employers should ensure current criteria for SAUE notifications are understood by staff locally. This is especially relevant where unintended exposures are being incorrectly coded as accidental exposures.

2. Employers should ensure that notifications are submitted to HIW within 2 weeks of the incident date where possible.
3. Employers should ensure all relevant information is included in the notification and investigation report including dose assessments and corrective measures adopted.
4. Employers should continue to ensure that investigations include a system review and identify corrective actions which target all contributory factors.
5. Employers should use the themes and learning identified across notifications to inform local practice.

Appendix 1

SAUE notification codes, categories and criteria

Version 3 - Reporting period 1 April 2024 to 20 August 2024

Accidental exposure

Notification code	Exposure category	Criteria for notification
1 (England only)	All modalities including therapy	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child) *In England, Wales and Northern Ireland, a child is someone who has not yet reached their 18th birthday. In Scotland, this is someone who has not yet reached their 16th birthday.*
1 (Northern Ireland, Scotland & Wales)	All modalities including therapy	All, regardless of dose

These notification criteria apply to the total exposure from the incident, including any intended component plus over-exposure and/or necessary repeat exposures. Where a multiplication factor is specified, this is defined as **the total dose from the incident divided by the intended dose**.

Where the exposure is not easily estimated in mSv or the dose unit is not specified, you may apply an alternative recognised unit and specify this in the notification.

Unintended exposure

All modalities including nuclear medicine and radiotherapy imaging

Notification code	Exposure category	Criteria for notification
2.1	Intended dose less than 0.3mSv	3mSv or above (adult) 1mSv or above (child)
2.2	Intended dose between 0.3mSv and 2.5mSv	10 or more times than intended
2.3	Intended dose between 2.5mSv and 10mSv	25mSv or above

2.4	Intended dose more than 10mSv	2.5 or more times than intended.
3	Interventional/cardiology	Where there has been a procedural failure resulting in observable deterministic effects. Procedures that do not have a procedural error but result in unintended or unpredicted observable deterministic effects.
4.1	Radiotherapy planning scans	If a planning scan needs to be repeated twice to obtain an appropriate dataset (3 scans in total, including the intended scan).
4.2a	Radiotherapy treatment verification images	Set-up error leads to 3 or more imaging exposures in a single fraction (including the intended image, 3 images in total). *This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).*
4.2b	Radiotherapy treatment verification images	When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **protocol failure**. *This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).*
4.2c	Radiotherapy treatment verification images	When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **thematic hardware or software failure**. *This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).*
5	Foetal All modalities	Where there is an unintended foetal exposure **AND** the resultant foetal dose is **10mGy** or more.

6	Breast feeding infant Nuclear medicine only	Where there has been a failure in procedure **AND** the resultant infant effective dose is 1 mSv or more.
7	Incorrect radiopharmaceutical	Any administration of the incorrect radiopharmaceutical to a patient, regardless of dose.

Radiotherapy delivered dose (including brachytherapy)

Notification code	Exposure category	Criteria for notification
8.1	Therapy over-exposure	Delivered dose to the planned treatment volume or organs at risk is 1.1 or more times (whole course) or 1.2 or more times (any fraction) the intended dose.
8.2	Therapy under-exposure	Delivered dose to the planned treatment volume is 0.9 or less times the intended dose (whole course). *This excludes where the under-exposure to the target volume is a result of a geographical miss, which is reportable under either 8.1 or 8.2.*

Radiotherapy geographical miss (including brachytherapy)

Notification code	Exposure category	Criteria for notification
9.1	Total	All total geographical misses, even for a single fraction or significant part thereof.
9.2	Partial	Where the miss exceeds 2.5 times the locally defined error margin AND the guideline dose factors (codes 8.1 and 8.2) for the planning target volume or organs at risk are exceeded. *A surrogate for the locally defined error margin might be a displacement of 2.5 times the local imaging action level for specific anatomical site and treatment intent.*

Nuclear medicine therapy

Notification code	Exposure category	Criteria for notification
10.1	Selective internal radiation therapy	Delivered activity is outside +/- 20% of the prescribed activity.
10.2	All other nuclear medicine therapies	Delivered activity is outside +/- 10% of the prescribed activity.

Complementary notification codes

For these codes, you need to add the relevant suffix code 1 to 9. For example:

- M1 (accidental exposure of more than one individual within the same incident or theme)
- M2.1 (unintended exposure of more than one individual within the same incident or theme)

Notification code	Exposure category	Criteria for notification
M	More than one individual exposed within the same incident or theme. (plus relevant suffix code 1 to 9)	All cases regardless of dose.

Notification code	Exposure category
E	Equipment fault exposure (plus relevant suffix code 1 to 9)
V	Voluntary notification (plus relevant suffix code 1 to 9)
C	Clinically significant event (plus relevant suffix code 1 to 9)

Version 4 - Reporting period 21 August 2024 to 31 March 2025

Notification code	Exposure category	Criteria for notification [a], [b]
Accidental exposure		
1 (England only)	All modalities including therapy	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child) [c]
1 (Northern Ireland, Scotland & Wales)	All modalities including therapy	All, regardless of dose
Unintended exposure		
All modalities including nuclear medicine and radiotherapy pre-treatment imaging		
2.1	Intended dose less than 0.3mSv	3mSv or above (adult) 1mSv or above (child)
2.2	Intended dose between 0.3mSv and 2.5mSv	10 or more times than intended
2.3	Intended dose between 2.5mSv and 10mSv	25mSv or above
2.4	Intended dose more than 10mSv	2.5 or more times than intended
3	Interventional/cardiology	Where there has been **NO** procedural failure **AND** either: the dose is 10 or more times the Local Diagnostic Reference Level **OR** there are observable deterministic effects excluding transient erythema
4.1	Radiotherapy pre-treatment planning scans	If CT planning scan needs to be repeated twice to obtain an appropriate data set (3 scans in total, including the intended scan)
4.2	Radiotherapy treatment verification images	Set-up error leads to 3 or more imaging exposures in a single fraction (including the intended image, i.e. 3 images in total) **OR** when the number of additional imaging exposures is 20% greater than intended over the course of treatment or than was described in the protocol [d]

5	Foetal All modalities	Where there has been a failure in the procedure for making pregnancy enquiries **AND** the resultant foetal dose is 1mGy or more
6	Breast feeding infant Nuclear medicine only	Where there has been a failure in procedure **AND** the resultant infant effective dose is 1 mSv or more
	Radiotherapy delivered dose (including brachytherapy)	
7.1	Therapy over-exposure	Delivered dose to the planned treatment volume and/or organs at risk is 1.1 or more times (whole course) or 1.2 or more times (any fraction) the intended dose
7.2	Therapy under-exposure	Delivered dose to the planned treatment volume is 0.9 or less times the intended dose (whole course) [(e)]
	Radiotherapy geographical miss (including brachytherapy)	
8.1	Total	All total geographical misses, even for a single fraction or significant part thereof
8.2	Partial	Where the miss exceeds 2.5 times the locally defined error margin [(f)] **AND** the guideline dose factors above (as 7.1 & 7.2) for the PTV or OAR are exceeded
	Nuclear medicine therapy	
9.1	Selective Internal Radiation Therapy	Delivered activity is outside +/- 20% of the prescribed activity.
9.2	All other nuclear medicine therapies	Delivered activity is outside +/- 10% of the prescribed activity.

Complementary notification codes		
M	More than one individual exposed within the same incident/theme. (plus suffix with relevant 1 to 9 code)	All cases regardless of dose
E	Equipment fault exposure (suffix as above)	
V	Voluntary notification (suffix as above)	
C	Clinically significant event (suffix as above)	

Notes to the table

(a) Criteria apply to the total exposure from the incident, including any intended component plus over-exposure and/or necessary repeat exposures. Where a multiplication factor is specified this is defined as **the total dose from the incident divided by the intended dose**.

(b) This column of the table defines the various notification criteria. Where the exposure is not easily estimated in mSv or the dose unit specified, an alternative recognised unit may be applied and specified in the notification.

(c) In England, Wales and Northern Ireland, a child is someone who has not yet reached their 18th birthday. In Scotland, this is someone who has not yet reached their 16th birthday.

(d) Excluding where there has been no breakdown in protocol and repeat verification imaging has facilitated correction of a 'setup' error so preventing a geographical miss in treatment.

(e) Excluding where the under-exposure to the target volume is a result of a geographical miss, which is reportable under 8.1 or 8.2.

(f) A surrogate for the locally defined error margin might be a displacement of 2.5 times the local imaging action level for specific anatomical site and treatment intent.

Appendix 2

List of fields used to analyse data

The data input spreadsheet contained the following fields:

- incident reference number
- date of incident
- notification date
- health board, trust, or independent employer
- hospital site
- type of exposure (diagnosis or treatment, health screening)
- modality (diagnostic and interventional radiology imaging, nuclear medicine or radiotherapy)
- sub-modality
    - diagnostic imaging general X-ray
    - diagnostic imaging CT
    - diagnostic imaging dental
    - diagnostic imaging DXA
    - diagnostic imaging fluoroscopy/interventional
    - diagnostic imaging mammography
    - nuclear medicine PET/CT
    - nuclear medicine SPECT
    - nuclear medicine SPECT/CT
    - nuclear medicine planar
    - nuclear medicine non-imaging
    - radiotherapy planning imaging
    - radiotherapy treatment
    - radiotherapy verification imaging
- number of individuals affected
- reported age and gender of the individual(s) affected
- reported as clinically significant
- referrer informed
- practitioner informed
- individual or representative informed
- intended dose
- total dose delivered (planned and unplanned)
- actions preventing reoccurrence
- reported SAUE code
- National patient safety radiotherapy event taxonomy and National coding taxonomy for incident learning in clinical imaging, MRI and nuclear medicine

Appendix 3

Learning from the 2023/24 HIW report

On 16 June 2025, HIW published an analysis of SAUE reports received in the period between 1 April 2023 and 31 March 2024. This report made eight recommendations, four for HIW and four for employers. IR(ME)R employers were requested to review the report and tell HIW how they have, or are, addressing the recommendations in the report. Comprehensive responses were received from 12 IR(ME)R employers and general themes from the replies are listed below:

Recommendation 1: Employers should continue to develop their local reporting and learning culture and encourage openness, voluntary reporting and routine analysis and learning from these events.

Employers noted enhanced reporting culture which was evidenced through an increase in the number of reports submitted to HIW. Investigation documents are standardised to ensure structured investigations and improve compliance. Employers are implementing national incident coding taxonomies in radiotherapy and clinical imaging to support thematic analysis and proactively identify training needs. Regular governance meetings are held to review incidents and share learning locally and at national forums. Safety memos, newsletters, and dashboards are used to share lessons learned. Ongoing education sessions have been undertaken by different staff groups including incident investigators.

Recommendation 2: Employers should ensure current criteria for SAUE notifications are readily available and understood by staff locally.

Employers noted that SAUE criteria are embedded in departmental IR(ME)R documents and Employer's Procedures which are accessible via intranet, SharePoint, QMS platforms, and printed copies in departments. To support staff understanding, regular training is provided to cover SAUE, targeted IR(ME)R sessions and case-based learning.

Recommendation 3: Employers should ensure that local reporting systems are accessible, efficient and where notifications are required to be submitted to HIW, that this is done in a timely fashion.

Employers within the NHS use Datix Cymru as the primary platform for reporting SAUE or other radiation incidents, and this is accessible by all staff. Staff receive training on Datix use during induction and regular updates. Employer's Procedures include reporting timescales, flowcharts, action logs, and other resources to provide step-by-step guidance for incident management. Improvements have been made in communication and reporting pathways to ensure timely reporting, for example, initial notifications can be sent to HIW by service managers without Executive Board engagement to avoid delays. More detailed reports are then sent by senior executives to maintain employer accountability. Governance

arrangements are in place to ensure oversight, monitor incident investigations, corrective actions and to review reporting times and trends.

Recommendation 4: Employers should ensure that corrective actions implemented after incidents or near misses are effective. These should target contributory factors and include a system review. Corrective actions should be audited to monitor their effectiveness in mitigating against incidents and addressing improvements in patient safety.

Employers have established structured review and monitoring to embed lessons learned into routine practice. The effectiveness of changes is reviewed at set time points post implementation with results reported to governance forums. Datix is used to monitor corrective actions with clear ownership, timeframes and outcome measures.

Some employers make use of reflective statements as part of their local investigations, as noted earlier in this discussion, people-focused corrective measures can be less effective if used in isolation.

Some employers design corrective actions to address underlying contributory factors which are more likely to result in effective preventative strategies.

About the UK Health Security Agency

UK Health Security Agency (UKHSA) prevents, prepares for and responds to infectious diseases, and environmental hazards, to keep all our communities safe, save lives and protect livelihoods. We provide scientific and operational leadership, working with local, national and international partners to protect the public's health and build the nation's health security capability.

UKHSA is an executive agency, sponsored by the Department of Health and Social Care.

© Crown copyright 2026
Version 1.0

Prepared by: Medical Exposures Group, UK Health Security Agency
For queries relating to this document, please contact: MedicalExposures@ukhsa.gov.uk

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence v3.0. To view this licence, visit OGL. Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

Corporate member of Plain English Campaign
Committed to clearer communication
339

UKHSA supports the Sustainable Development Goals