Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

DRIVING IMPROVEMENT THROUGH INDEPENDENT AND OBJECTIVE REVIEW

HIW activities and enforcement under the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)

Annual Report 2015 - 2016

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Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To provide the public with independent and objective assurance of the quality, safety and effectiveness of healthcare services, making recommendations to healthcare organisations to promote improvements.

Our values

- **Patient-centred: we place patients, service users and public experience at the heart of what we do**
- **Openness and honesty: in the way we report and in all our dealings with stakeholders**
- **Collaboration: building effective partnerships internally and externally**
- **Professionalism: maintaining high standards of delivery and constantly seeking to improve**
- **Proportionality: ensuring efficiency, effectiveness and proportionality in our approach.**

Our outcomes

Through our work we aim to:

Provide assurance:	**Provide independent assurance on the quality, safety, and effectiveness of healthcare by reporting openly and clearly on our inspections and investigations.**
Promote improvement:	**Encourage and support improvements in care through reporting and sharing good practice and areas where action is required.**
Strengthen the voice of patients:	**Place patient experience at the heart of our inspection and investigation processes.**
Influence policy and standards:	**Use our experience of service delivery to influence policy, standards and practice.**

1. Foreword

This is HIW's second annual report on its activity regarding the Ionising Radiation (Medical Exposure) Regulations.

The purpose of this report is to summarise our findings from our inspections of radiology departments during 2015-16 and to highlight the areas for improvement we have identified across services.

While HIW is responsible for monitoring compliance against the Ionising Radiation (Medical Exposure) Regulations, healthcare organisations, health boards and duty holders have legal obligations to ensure their compliance and that patients receive safe and effective care.

We hope that healthcare organisations and health boards working in this area will carefully consider the contents of this report and our overarching recommendations and use this to make improvements to their services.

2. Executive summary

Healthcare Inspectorate Wales (HIW) is responsible for monitoring compliance against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (and its subsequent amendments 2006 and 2011). The regulations are intended to protect patients from the hazards associated with ionising radiation. We achieve this through a programme of inspection of organisations that use ionising radiation. We also review incidents notified to us involving exposures 'much greater than intended'[1].

What follows is a summary of the key issues identified from our activity during 2015-16.

IR(ME)R compliance inspections

During 2015-16, HIW undertook a total of four IR(ME)R compliance inspections. Three of these inspections were conducted in diagnostic imaging departments within independent hospitals at Nuffield Health: Cardiff Bay Hospital and The Vale Hospital and Spire Healthcare: Spire Cardiff Hospital. One inspection was conducted in the radiotherapy department at Velindre Cancer Centre, Velindre NHS Trust, Cardiff.

We identified the following key themes from our four IR(ME)R compliance inspections.

This is what departments did well:

- Overall, we found safe and effective practice across the departments
- It was clear that staff are committed to providing a high standard of service
- Patients were positive about their experiences of the services and were particularly positive about staff
- All departments had an audit programme in place and evidence of a variety of audit activity being completed to assess their practice and procedures, as a way of improving the quality and the outcome of patient care
- We found there was positive work regarding the development of local diagnostic reference levels[2], good practice initiatives such as 'pause and check'[3] and sharing learning from near miss incidents.

This is where departments should make improvements:

- Written procedures and protocols needed to be updated to ensure they accurately reflect the requirements of IR(ME)R and detail what actually happens in practice, so that this is clear for staff to follow
- Staff needed to be provided with clear procedures about the use of diagnostic reference levels and what to do if these are consistently exceeded.

[1] Where incidents occur in which a person, whilst undergoing a medical exposure, has been exposed to ionising radiation much greater than intended, this should be investigated by the health care organisation and reported to HIW.

[2] Diagnostic Reference Levels (DRLs) are dose levels for typical examinations on standard sized adults or children for broadly defined types of equipment. They are used as a guide to help promote improvements in radiation protection practice.

[3] The 'pause and check' initiative encourages staff to check three forms of patient identification and clinical details/past imaging history with the patient prior to exposure, in an effort to reduce the risk of errors.

- Entitlement procedures were often not sufficiently detailed and needed to clearly explain what actually happens to entitle each duty holder[4] to carry out their functions.
- Varying degrees of improvement were needed across the departments to ensure referral criteria[5] are in place and made available to all referrers, including any external referrers.
- Further information was needed within procedures for areas which the regulations have defined should be given special attention, including checking pregnancy status and exposures of children.

Following our inspections, we received completed improvement plans from each organisation which provided HIW with sufficient assurance that the findings from the inspections had been addressed or that there was evidence to demonstrate that progress was being made. We use the findings from our inspections, together with the organisation's improvement plan, as part of our risk based approach to inspection and escalation.

IR(ME)R follow-up inspection

HIW conducted one follow-up inspection at Royal Glamorgan Hospital Radiology Department within Cwm Taf University Health Board, due to the concerns identified during HIW's last inspection in 2014. As a result of this follow-up inspection, we were able to conclude that the health board had taken appropriate actions to address the areas for improvement identified during our previous inspection and we were able to see evidence of the progress being made.

IR(ME)R and dentists

During 2015-16, HIW conducted 133 inspections of general dental practices. As part of these inspections we considered how practices met the requirements under IR(ME)R, Ionising Radiation Regulations (IRR) 1999 and any other relevant professional standards and guidance. In many practices, we found there were suitable arrangements in place to protect patients from ionising radiation and for the safe use of dental radiographic (x-ray) equipment. However, we also identified several practices which did not fully comply with their obligations under IR(ME)R and IRR and we issued 16 immediate assurance letters in this regard[6]. Particular issues identified included:

- Insufficient training records to demonstrate that staff had completed training in ionising radiation
- Failure to meet the requirements of IR(ME)R regarding procedures and/or practice around justification and clinical evaluation of x-rays and a lack of audit activity.

[4] Duty holders are individuals or groups defined under the IR(ME)R regulations. Further information in this respect is provided on pages 7-8.

[5] Referral criteria helps guide healthcare professionals, who are referring patients for any type of exposure/imaging, to determine the most appropriate investigation(s) or interventional procedure for a given problem. It should include an indication of the expected dose of radiation attributable to each procedure.

[6] Further information was needed within procedures for areas which the regulations have defined should be given special attention, including checking pregnancy status and exposures of children.

Notifications of exposures ‘much greater than intended’

During 2015-16, we received a total of 45 notifications. Of these, two occurred in radiotherapy with the remainder occurring in diagnostic imaging services. HIW evaluated each of the 45 notifications to consider the severity of the incident and assessed whether the organisation had taken the appropriate actions to prevent similar occurrences in future and ensure patients were appropriately safeguarded.

We found there were common causes that emerged from these notifications, which have been detailed within the body of this report in Section 3.2.

3. What we did

HIW is responsible for monitoring compliance against IR(ME)R 2000 (and its subsequent amendments 2006 and 2011). We achieve this by:

- Delivering a programme of assessment and inspection of clinical departments that use ionising radiation
- Reviewing incidents notified to HIW involving 'exposures much greater than intended'
- Delivering a programme of general dental practice inspections within which we consider how each practice meets the requirements set out in IR(ME)R, IRR and any other relevant professional standards and guidance.

The current regulations place responsibilities on practitioners, operators, those who refer patients for medical exposure and the employers of these three groups. The employer is required under the regulations to create a framework for the safe, efficient and effective delivery of ionising radiation by the provision of procedures and protocols. A breach of the regulations can result in the issue of prohibition, improvement notices or criminal proceedings.

For the purpose of this report, we refer to the responsibilities of groups/persons defined under IR(ME)R, known as duty holders. IR(ME)R duty holders include the following:

- **Employer:** Any natural or legal person who, in the course of a trade, business or other undertaking, carries out, or engages others to carry out, medical exposures at a given radiological installation
- **Referrer:** A registered health care professional who is entitled in accordance with employer's procedures to refer individuals for medical exposure to a practitioner
- **Practitioner:** A registered health care professional who is entitled in accordance with employer's procedures to take responsibility for an individual medical exposure
- **Operator:** Any person who is entitled by the employer, to carry out practical aspects of medical exposures. An operator does not have to be a registered healthcare professional, but is required to be adequately trained for their scope of practice.

The regulations are designed to ensure that:

- Patients are protected from unintended, excessive or incorrect exposure to medical radiation and that, in each case, the risk from exposure is assessed against the clinical benefit (justification)
- Patients receive no more exposure than necessary to achieve the desired benefit within the limits of current technology (optimisation)
- Practitioners and operators do not undertake any medical exposure without being adequately trained. Employers ensure adequate training is provided and records of this training are maintained.

IR(ME)R compliance inspections

During 2015-16, HIW undertook a programme of IR(ME)R compliance inspections of the following radiology departments:

Radiotherapy within the NHS:

- Velindre Cancer Centre, Cardiff.

Diagnostic imaging within independent hospitals:

- Nuffield Health: Cardiff Bay Hospital
- Nuffield Health: The Vale Hospital
- Spire Healthcare: Spire Cardiff Hospital.

We selected the organisations to be inspected as part of HIW's annual announced IR(ME)R inspection programme based on intelligence gathered by HIW's wider work programme, incidents reported to us and how often the organisation had been inspected in the past.

IR(ME)R inspection format

Each inspection was announced and the organisation was notified in writing (generally six weeks in advance) and a self-assessment form was issued, which the organisation was required to complete and return to HIW prior to the inspection. This information allowed the inspection team to plan the approach to the visit and prioritise the key areas to focus on.

The inspections were conducted by a small team which included an inspection manager from HIW, who was supported by a Senior Clinical Officer from Public Health England (PHE)[7], acting in an advisory capacity.

We published our findings within our inspection reports under four themes:

- Quality of the patient experience
- Compliance with IR(ME)R
- Management and leadership
- Delivery of a safe and effective service.

During the inspections, we reviewed documentation and information from a number of sources including:

- Information held by HIW
- Interviews with staff (where appropriate) and senior management
- Conversations with patients and relatives (where appropriate)
- Examination of a sample of patient records

[7] Given the specialist nature of this area of work, HIW works with the Medical Exposures Group of Public Health England. PHE provides HIW with support on matters relating to radiation protection and radiological practice in the context of IR(ME)R. There is a service level agreement between HIW and PHE which sets out the terms of this working relationship.

- Examination of policies and procedures
- Examination of treatment rooms and the environment
- HIW patient questionnaires.

At the end of each inspection we provided an overview of our main findings to representatives of the service to ensure that they receive appropriate feedback.

Inspections capture a snapshot on the day of the inspection of the extent to which services are meeting essential safety and quality standards and regulations.

Where inspections point to wider issues about the quality and safety of services provided, HIW takes note of this and other intelligence when considering its future inspection programme. We also share any wider concerns we have with other relevant stakeholders who have a role in the quality and safety of services provided by healthcare organisations, including, for example, the Welsh Government, Community Health Councils and the Welsh Audit Office.

IR(ME)R follow-up inspection

HIW also undertook a follow up inspection in diagnostic imagining within the NHS at the following department:

- Royal Glamorgan Hospital, Cwm Taf University Health Board.

The purpose of the announced follow-up inspection at Royal Glamorgan was for HIW to seek further assurance about the progress made by Cwm Taf University Health Board to address the areas for improvement identified during our inspection of the radiology departments at the Royal Glamorgan and Prince Charles Hospitals that took place in November 2014[8].

IR(ME)R and dentists

On 1 September 2014, HIW began a three year programme of inspections of all general dental practices in Wales. During 2015-16, HIW conducted 133 dental practice inspections.

HIW inspections of general dental practices seek to establish how well practices meet the Health and Care Standards 2015, and where private dentistry is provided, the provisions of the Private Dentistry (Wales) Regulations 2008 and the Private Dentistry (Wales) (Amendment) Regulations 2011.

During these inspections, we also considered how practices meet the requirements under IR(ME)R, IRR and any other relevant professional standards and guidance. In relation to the IR(ME)R, we considered the measures in place for the protection of patients.

Each inspection was announced and was conducted by a team which included an inspection manager from HIW and an external reviewer who is an experienced dentist.

[8] The inspection report of Royal Glamorgan and Prince Charles Hospital that took place in November 2014 can be found here on HIW's website.

Notifications of exposures 'much greater than intended'

HIW reviewed the notifications it received from healthcare organisations where incidents occurred in which a person, whilst undergoing a medical exposure, had been exposed to ionising radiation much greater than intended.

During 2015-16, HIW received 45 notifications of exposure much greater than intended. HIW evaluated each of these notifications to consider the severity of the incident and assessed whether the healthcare organisation had taken the appropriate actions to prevent similar occurrences in future and ensure patients were appropriately safeguarded. Where further information was required, HIW requested this from the organisations to further inform our assessment.

We issued acknowledgement letters to healthcare organisations within five working days of receiving a notification, with the requirement for the organisation to provide HIW with a completed investigation report and supporting information within 12 weeks of discovering the incident.

We considered the investigation reports from healthcare organisations to these incidents to ensure that the action taken was appropriate to mitigate the likelihood of a similar incident occurring in the future. Patient safety was a key consideration in each case we reviewed. In particular, we considered the risk to the patient(s) directly involved in the incident and whether there were wider implications that might have the potential to impact on others. In some cases we wrote to the healthcare organisation with follow-up queries or recommendations.

Incidents were closed when HIW was content with the information provided and the action taken by the healthcare organisation.

4. What we found

4.1. IR(ME)R inspections

Quality of the patient experience

On the whole, we found that patients were very satisfied with their experiences whilst visiting the radiology services we inspected.

We issued questionnaires to individuals as part of our inspections in order to gather the views of patients and their families about the service they received. A total of 55 questionnaires were completed across the departments.

The majority of patients gave positive feedback about their experiences of the services. Patients told us that the information they had received about their treatments was good and arranging an appointment was straight forward. The majority of patients provided positive feedback that the departments were generally clean and tidy. Feedback was particularly positive about staff with comments including:

"Staff are very friendly and helpful."

"Pleasant and efficient."

"Wonderful! All staff are welcoming, reassuring and extremely patient…."

A small number of patients mentioned difficulties with the scheduling of appointments and information regarding appointments at Spire Hospital. The majority of patients at Velindre Cancer Centre said they had a good experience, but a number of patients said they had experienced delays of between 20 to 45 minutes and some had difficulties with parking. Two patients also raised issues regarding infection control, including the separation of clean and dirty linen. We made recommendations for the Trust to address these areas.

Delivery of safe and effective care

Overall, we observed safe and effective practice across the departments we inspected. It was also clear that staff are committed to providing a high standard of service and that patient safety was a priority for the departments. While we identified areas for improvement regarding IR(ME)R compliance across each of the departments, we were satisfied that were no patient safety issues.

From the inspections undertaken in 2015-16, we found that there were key themes that arose regarding compliance with IR(ME)R which we have detailed below.

The only location where we identified breaches of the requirements under IR(ME)R was at Velindre Cancer Centre. Two breaches of regulation were identified during this inspection regarding a lack of an equipment inventory and the need to have referral criteria with associated dose estimates in place. This was discussed at the time of inspection and we received assurance following the inspection that this had been addressed as a matter of urgency.

In general, we found that all departments were doing the following well:

- **Patient identification:** All departments had suitable patient identification procedures in place to help ensure that the correct patient received the exposure, but we recommended that areas of good practice such as the use of the 'pause and check' initiative should be included within documentation
- **Expert advice:** All departments had the involvement of and access to a medical physics expert who was available for advice in the event of an unintended or accidental exposure
- **Incident notifications:** Generally, departments had sufficient procedures in place regarding the notification of incidents to the appropriate authorities.

We identified the following key themes and areas for improvement during our inspections:

Procedures and protocols

The regulations require the employer to have written procedures and protocols in place.

Across the departments, we found that a review of the contents of procedures was needed to ensure they accurately reflected the requirements of IR(ME)R and contained sufficient detail about what actually happens in practice, so that this is clear for staff to follow. We made recommendations regarding the storage and presentation of documentation in some departments, in order to avoid confusion for staff about the correct guidance to follow.

Diagnostic Reference Levels

The regulations require the employer to establish diagnostic reference levels (DRLs) for radio diagnostic examinations stating that these are not expected to be exceeded for standard procedures for an average size patient when good and normal practice regarding diagnostic and technical performance is applied.

Across the three independent hospital diagnostic imaging departments, we found that procedures for the use of DRLs needed to be reviewed to include information to guide staff about their use. We found that DRLs were not displayed and information was not readily available for staff about what to do if DRLs are consistently exceeded.

We found that the three departments had conducted positive work in establishing local DRLs. However, we found that for some examinations more than one set of DRLs were in place (both national and local DRLs). This means that staff could be confused about which DRLs to use.

Entitlement

The regulations require that duty holders must be entitled, in accordance with the employer's procedures for the tasks they undertake. They must also be adequately trained and the employer must keep up to date records of this training.

Overall, we found that entitlement procedures were not sufficiently detailed and needed to clearly explain what actually happens to entitle each duty holder to carry out their functions. This also needed to include references to their scope of practice and the training records which are required to support this. We recommended all departments to make improvements in this area.

Referral criteria

IR(ME)R states that the employer shall establish recommendations concerning referral criteria for medical exposures, including radiation doses, and shall ensure that these are available to the referrer.

We found that referral criteria needed improvement across all departments, but to varying degrees. At Velindre Cancer Centre, while decisions to refer each patient for radiotherapy were discussed at multi-disciplinary meetings, no written referral criteria were in place, as required by the regulations. This was disappointing to find, especially as this was highlighted as an area for improvement during HIW's last inspection of the department.

While Nuffield Health and Spire Hospitals had written referral criteria in place, this needed to be reviewed and updated. At Nuffield Health Hospitals there were no formal mechanisms in place to inform referrers (who were external to the organisation) about the referral criteria in use or to remind them of their responsibilities as described in the employer's procedures. At Spire Hospital, we found updates were needed to improve the accuracy of the referral criteria and that dental imaging criteria needed to be made available to referrers.

Special attention areas

IR(ME)R states that written procedures for medical exposures should include procedures for making enquiries of females of child bearing age to establish whether the individual is or maybe pregnant. IR(ME)R also states that the practitioner and operator shall pay special attention to the optimisation of medical exposures of children.

We found staff were clear about how they should check the pregnancy status of females of child bearing age before undertaking exposures. However, procedures needed to be updated to include all information about checking pregnancy status, including how pregnancy testing happens and reference to any support needed for language barriers.

As good practice, we advised departments to include reference to how to access the child protection procedure should a minor provide a positive response to the pregnancy question.

Across the departments, relatively few paediatric examinations were undertaken. However, we recommended departments detail the special attention needed to optimising exposures of children within their procedures.

Quality of management and leadership

Across the departments we found that there was effective management and leadership in place and staff were committed to providing a high standard of service. All staff recognised and accepted the work that needed to be undertaken in order to meet all the requirements of IR(ME)R.

HIW's inspections were well received by management and staff who engaged positively in the process. We were also pleased to see that staff at Velindre Cancer Centre had chosen to engage with other colleagues from radiotherapy departments across Wales and had invited them to attend the inspection in order to share learning.

Although we observed safe practice at Velindre Cancer Centre saw evidence of learning from incidents and near misses, such as newsletters and audit activity, it was disappointing to find regulatory breaches, some of which were identified during HIW's previous inspection of the department. Due to this, the Trust was required to take appropriate action to address these historic matters in addition to the improvements identified during the 2015 inspection. HIW received assurance from the Trust that this would be addressed.

Policies and procedures

Staff across the departments told us they were clear about their roles and responsibilities under IR(ME)R. However, at two departments, we found what was described by staff was not always reflected in the policies and procedures which could potentially cause confusion. We reinforced the importance of simplifying and clarifying documentation across all departments to ensure that what happens in practice is clearly described for staff to follow.

Training

The regulations require that all practitioners and operators are adequately trained for the tasks undertaken and the employer keeps up to date records of this training. We found that the majority of training records and documented induction training were in place for staff working in the independent departments. However, we found that equipment training records for radiologists were not in place. We discussed this with the teams at the time of inspection and highlighted the importance of putting these in place. Whilst there were a number of different systems for recording training at Velindre Cancer Centre, which would benefit from a consistent approach, the system used for radiographers was comprehensive, clear and consistent with all IR(ME)R requirements.

Clinical audit

We found that all departments had suitable clinical audit programmes in place and we saw evidence of a variety of audit activity being completed, including audits of image quality, clinical evaluation, dose and referral audits. Effective clinical helps improve the quality and the outcome of patient care.

Inspection outcome

Following our four compliance inspections, each organisation was required to complete an improvement plan detailing the actions they are taking to address the findings from the inspection. Each improvement plan was evaluated to determine whether or not any further action by HIW was necessary. Overall, the completed improvement plans provided HIW with sufficient assurance that the findings had been addressed or there was evidence to demonstrate that progress is being made.

As a result of the follow-up inspection we conducted at Royal Glamorgan Hospital radiology department[9] in October 2015, we were able to conclude that the health board had taken appropriate actions to address the areas for improvement identified during our previous inspection and saw evidence that significant progress been made. Specifically, we found the health board were addressing the concerns relating to:

[9] The follow-up inspection report for Royal Glamorgan Hospital radiology department in October 2015 can be found here on HIW's website.

- Diagnostic reference levels and the need for local levels to be established
- Improvements needed to policies and procedures including the radiation safety policy and employers procedures to ensure these were reviewed, kept up-to-date and that staff are made aware of any changes
- The development of appropriate training records for all staff.

4.2 IR(ME)R and dentists

Of the 133 dental practices we inspected in 2015-16, many practices had suitable arrangements in place to protect patients from ionising radiation and for the safe use of dental radiographic (x-ray) equipment. However, not all practices were adhering to the requirements of IR(ME)R and we issued 16 immediate assurance letters in this regard. HIW issues immediate assurance letters when it has immediate concerns that need to be addressed within specified timescales.

Examples of issues we found include the following.

Training

We found that training records/certificates confirming that dental team members involved in radiographs were not always available for inspection. All staff who are involved in radiographs must have regular training in Ionising Radiation to ensure compliance with IR(ME)R 2000. The General Dental Council recommends this training takes place every five years.

Justification and clinical evaluation of exposures

In our review of the patient records, we found that over a quarter of practices did not satisfy the IR(ME)R requirements regarding procedures and/or practice around justification[10] and clinical evaluation (what the images show) of x-rays. The recording of clinical findings from the x-ray examinations were also missing in a number of cases.

Audit

In addition to the above, we found that a number of practices did not record the necessary information needed for audit activity, such as the grading of x-ray images to assess image quality. Therefore, in approximately a quarter of practices we inspected, quality assurance audits were not being performed in accordance with IR(ME)R and IRR. Audit activity helps assess practice and procedures, as a way of improving the quality and the outcome of patient care.

[10] Justification is the process of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose. Before any patient is exposed to ionising radiation justification must be completed.

Ionising Radiation Regulations 1999

Whilst not covered under IR(ME)R, HIW also inspects dentists for IRR compliance and we found the following issues with the arrangements for radiation protection under IRR at a number of practices:

- Incomplete or missing radiation protection file. This information is required to demonstrate the safe use of radiographic equipment used at the practice
- Insufficient servicing and maintenance documentation to demonstrate that x-ray equipment has been checked and is safe for use
- Insufficient evidence that all practices had notified the Health and Safety Executive (HSE) of the radiographic equipment being used on the premises
- No checks conducted of the chemicals used to process x-ray images, to help ensure images are clear and of good quality.

In Section 5, we have included our plans to develop our work in relation to IR(ME)R and dentistry.

4.3 Notifications of exposures much greater than intended

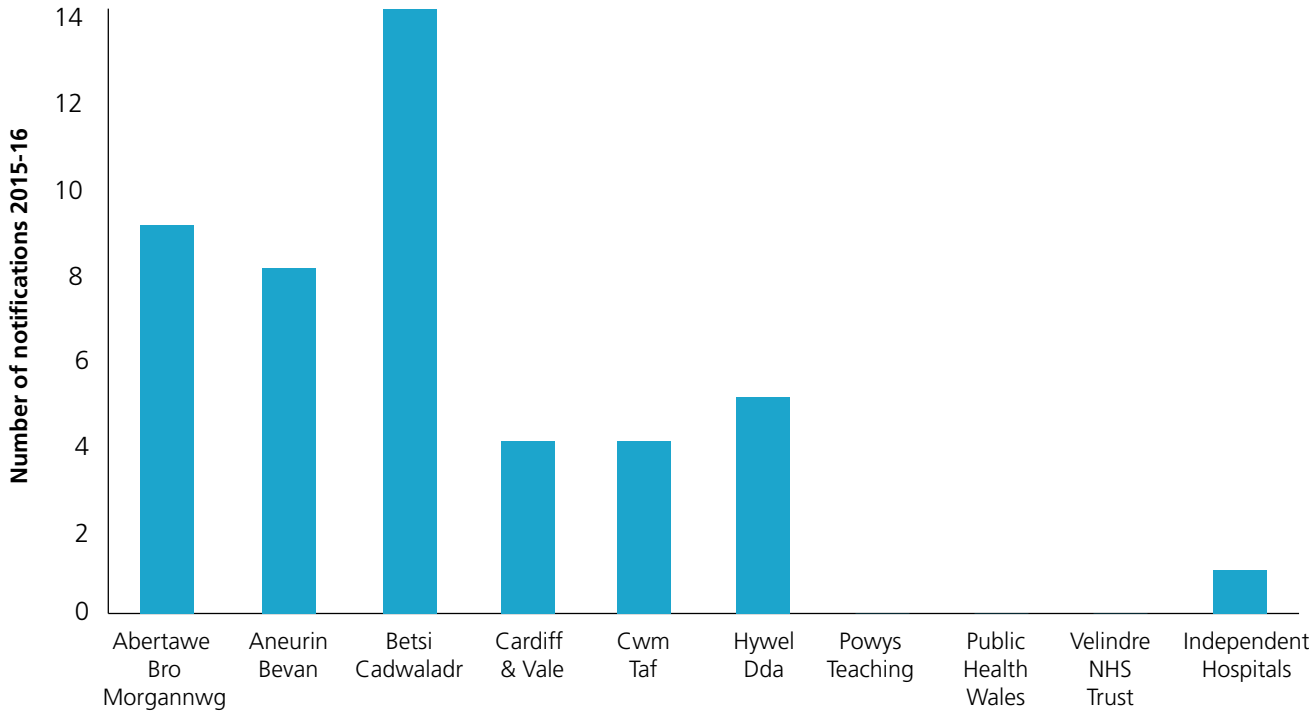
During 2015-16, HIW received 45 notifications of exposure much greater than intended.

The following table shows the annual number of notifications received by HIW between 2011 to 2016, as part of our IR(ME)R enforcement responsibilities in Wales.

	Year notifications received				
Number of notifications	2011-12	2012-13	2013-14	2014-15	2015-16
	26	32	47	46	45

We attribute the steady increase of notifications since 2012 to changes in the Department of Health's guidance on what constitutes a notification of exposure much greater than intended, which requires providers to disclose repeat 'high dose' exposures, including Computed Tomography (CT).

We have continued to find variation in the number of notifications received from healthcare organisations and health boards across Wales. The following chart illustrates the number of notifications received by each organisation during 2015-16.



Of concern is that some organisations continue to report far fewer notifications than others. While the higher numbers of notifications from particular organisations may be due to an open and positive reporting culture, rather than indicative of failures in procedures or safety issues, it is uncertain whether the lower number of notifications received from other organisations provides an accurate picture of all reportable incidents. Currently, there is no agreed threshold either nationally or in Wales for what constitutes an exposure of 'much greater than intended'. As a result, each healthcare organisation and health board reference multiple sources of guidance which may lead to different interpretations and variations in what constitutes an exposure of 'much greater than intended'. This may contribute to variations in the numbers of notifications received by HIW across Wales.

It has been disappointing to find that despite the legal requirement for reporting incidents of exposures 'much greater than intended', a significant proportion of investigation reports, required from healthcare organisations following incidents, were not submitted to HIW in a timely way. HIW will be reviewing the notification process and writing to healthcare organisations regarding this later this year.

Type of notifications

Of the 45 notifications received, two occurred in radiotherapy and the remainder occurred in diagnostic imaging services. It was notable that there were no notifications in nuclear medicine received during 2015-16. We found that there were common themes that emerged from the notifications we received in 2015-16 which are summarised below.

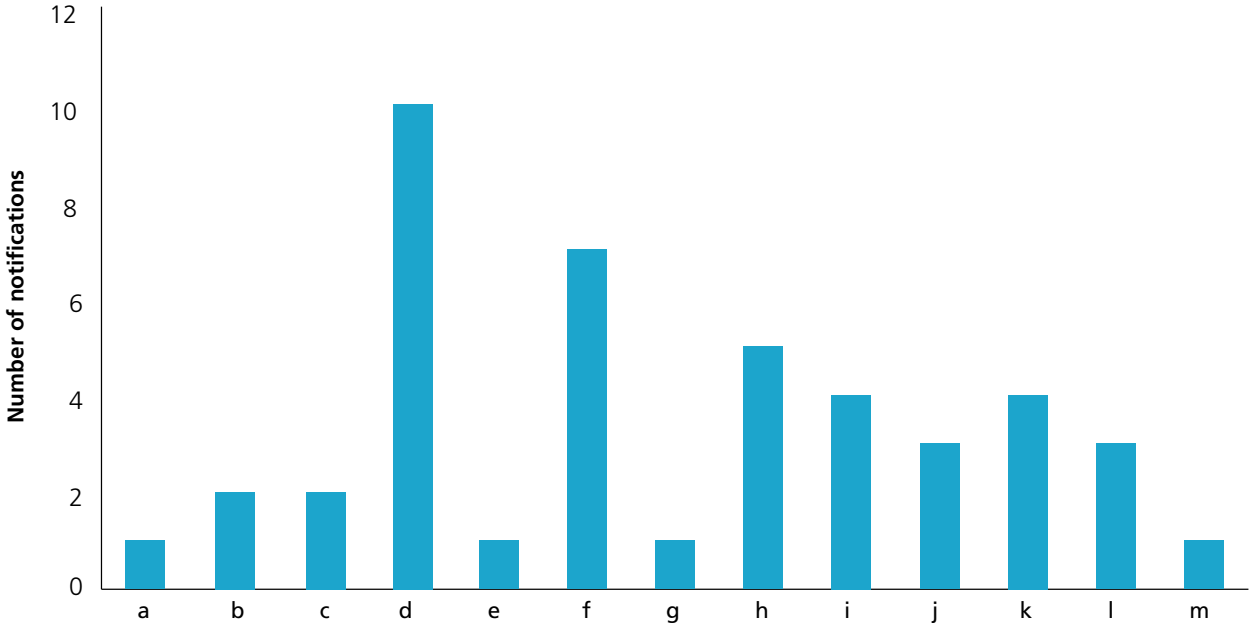
Radiotherapy notifications

We received two notifications from radiotherapy departments in 2015-16, the same as received in 2014-15. Due to the small number of notifications received in this area, it is not possible to identify common themes. However, we have briefly described the nature of these incidents below and we have detailed our overall conclusions regarding the actions needed by organisations to prevent future incidents occurring in Section 6.

The first incident occurred due to a positioning error, which meant that an area of the patient's tissue received a dose higher than intended for the whole treatment. The second error occurred when staff experienced difficulties with the machine during a patient's scan, which meant that the scan was repeated and the patient received a dose higher than expected. At the time of writing, HIW is awaiting an investigation report from the health board with further details regarding this second incident.

Diagnostic imaging notifications

Of the 43 notifications received from diagnostic imaging departments, 60% occurred due to operator errors and 37% occurred due to referrer errors. The following figure illustrates the distribution of notifications under these common causes. Descriptions and examples of these causes are detailed further below.



Types of Notifications

a - Referrer error - wrong anatomy
b - Referrer error - wrong modality
c - Referrer error - no check back
d - Referrer error - wrong addressograph label
e - Referrer error - other
f - Operator error - wrong anatomy/laterality
g - Operator error - wrong exposure set
h - Operator error - failur to ID patient
i - Operator error - no check of previous imaging
j - Operator error - image archive / labelling
k - Operator error - modality selection
l - Operator error - other
m - Other (volunteered notification)

Operator error

Operator errors often occur due to failure to accurately read the patient's referral form, carry out sufficient patient identification checks or check the patient's imaging history to see if they have already received the procedure. This may mean the wrong patient receives the examination, the incorrect part of the patient's body is examined (e.g. right arm and not left arm) or the patient unnecessarily receives another examination.

A porter collected a patient from the A&E department and took them to the radiology department for a CT scan of the head. The radiographer checked the patient against the details on the form and the CT scan was performed. On return to A&E it was discovered that the wrong patient had been sent to radiology. The details on the request form did not match the patient scanned. Therefore, the patient had an unintended dose of radiation.

Referrer error

The wrong patient or referrer errors notified to HIW were predominantly due to the wrong addressograph label[11] being applied on the patient's referral form, leading to the incorrect patient receiving the examination. The implementation of the 'pause and check' approach should assist in reducing this type of error.

Example - referrer error

An incorrect addressograph label was attached to a request form, resulting in the patient having a chest and abdomen x-ray which was not needed. Therefore, the patient had an unintended dose of radiation.

[11] Addressograph label - this is a sticker/label that can be placed on a referral/ request form that shows a patients details for example, name, date of birth and hospital number.

5. Conclusions

Across the radiology and radiotherapy departments we inspected during 2015-16, we found staff were generally clear about their roles and responsibilities under IR(ME)R. However, this was not always the case for staff at the general dental practices we inspected and some dental professionals were unclear about the requirements of the IR(ME)R. In Section 5, we have included our plans to develop our work in relation to IR(ME)R and dentistry.

We have continued to find significant variation in the number of notifications, submitted by healthcare organisations across Wales, for incidents of exposures 'much greater than intended'. We believe this variation indicates a need for a consistent approach to incident notifications across Wales, including agreed criteria for what constitutes an exposure 'much greater than intended' and increased awareness of the requirement to report such incidents.

From the inspections we undertook during 2015-16, we saw examples of good practice which had been introduced to learn from incidents and near misses, such as newsletters, sharing via departmental staff meetings and audit activity. It was also positive to find that departments we inspected had implemented good practice initiatives, such as the 'pause and check' initiative, which encourages staff to check clinical details with the patient in an effort to reduce the risk of errors.

In order to adequately safeguard patients from unintended or accidental exposures, sharing learning from incidents and near misses is fundamentally important. Learning should be shared with all staff working within the area and not just those involved in the incident. As part of an incident investigation, measures should be put in place to prevent similar incidents happening in the future. This may be addressed through ensuring:

- Incidents are audited in order to identify any recurrent issues and learning is used to inform practice
- Near misses are reported, as these may prevent actual incidents from happening
- The employer's procedures are reviewed and kept up-to-date
- Policies and procedures are accurate, sufficiently detailed and reflect what actually happens in practice so they are clear for staff to follow
- Any training needs identified during incident investigations are promptly addressed.

6. What next

Our plans for next year include a number of new developments aimed at improving the way HIW delivers its responsibilities in this area.

In 2015-16, HIW attended an IR(ME)R workshop organised by the office of the Welsh Government Chief Scientific Officer. The key themes of this event included learning from inspections and learning from notifications. Contributors to the event included the Chief Scientific Officer, HIW and Public Health England, with attendees invited from all health boards in Wales. This was an important event as it provided attendees with the opportunity to share their experiences/learning from recent inspections and discuss the incident reporting process. Following on from this, HIW will be establishing a reference group to obtain the views of a range of stakeholders who would challenge and support the development of our work and activities regarding IR(ME)R. The role of the group will be to advise HIW on its activity for IR(ME)R in Wales, including inspection methodology, to ensure that the inspections are credible and fit for purpose. The first reference group meeting is planned for early 2017.

With input from this stakeholder reference group, HIW will be undertaking a review of the processes for reporting notifications of exposures 'much greater than intended'. This will include the process for submitting notifications, review of the timescales for healthcare organisations to provide investigation reports following incidents and consideration regarding the criteria for what constitutes an exposure 'much greater than intended'. HIW will be contacting healthcare organisations and health boards across Wales in regards to this.

HIW has a well established dental stakeholder reference group, which has played an important and significant role in the development of our work in this area. We will be further consulting with this reference group given our findings with regard to IR(ME)R in dentistry in Wales. These discussions will focus on the guidance and training for dental professionals, with a view to ensuring that they are sufficiently aware of their duty to comply with IR(ME)R.

HIW has recently met with the Health and Safety Executive and we are currently exploring how we can best share information and the common interests we have together in this area.

With help from the Medical Exposures Group of Public Health England, HIW will be updating its IR(ME)R inspection and self-assessment tools. As committed to in its operational plan for 2014-15, HIW has taken action to help build in-house expertise to lead and support its IR(ME)R activity. We have worked closely with the Medical Exposures Group of Public Health England, who has developed a training programme which has been delivered to HIW staff in April 2016.

HIW's operational plan for 2016-17[12] sets out its commitment with regard to IR(ME)R. The plan includes undertaking IR(ME)R inspections in nuclear medicine, radiotherapy, and diagnostic and interventional imaging facilities.

[12] HIW's operational plan for 2016-17 can be accessed here on HIW's website.

Appendix A

Recommentions

As a result of the findings from our general practice inspections in 2015-16, we have included the following overarching recommendations for practices and health boards to consider as part of service delivery in the table below.

Recommendations	Regulation / Standard
IR(ME)R compliance	
Written procedures and protocols should accurately reflect the requirements of IR(ME)R and detail what actually happens in practice, so that this is clear for staff to follow.	Regulation 4 & Schedule 1
Staff should be provided with clear procedures about the use of diagnostic reference levels and what to do if these are consistently exceeded.	Regulation 4 & Schedule 1
Entitlement procedures should be sufficiently detailed and clearly explain what actually happens to entitle each duty holder to carry out their functions.	Regulation 4 & Schedule 1
Organisations should ensure referral criteria are in place and made available to all referrers, including any external referrers.	Regulation 4 & Schedule 1
Organisations should ensure that procedures are sufficiently detailed for areas which the regulations have defined should be given special attention, including checking pregnancy status and exposures of children.	Regulation 4 & Schedule 1
All practitioners and operators must be adequately trained for the tasks undertaken and up-to-date records of this training must be maintained.	Regulation 4(4), 11 & Schedule 2

Recommendations	Regulation / Standard
IR(ME)R and dentists	
Practices and employers must ensure that staff have completed sufficient training in ionising radiation.	Regulation 4(4), 11 & Schedule 2
The requirements of IR(ME)R regarding justification and clinical evaluation of x-rays must be met and clearly recorded.	Regulation 6 & 7
There must be robust quality assurance and audit programmes in place in relation to IR(ME)R.	Regulation 4 & 8