Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Diagnostic Imaging Department, Wrexham Maelor Hospital, Betsi Cadwaladr University Health Board

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

Our purpose

To check that people in Wales receive good quality healthcare

Our values

We place patients at the heart of what we do. We are:

- Independent
- Objective
- Caring
- Collaborative
- Authoritative

Our priorities

Through our work we aim to:

Provide assurance:	Provide an independent view on the quality of care
Promote improvement:	Encourage improvement through reporting and sharing of good practice
Influence policy and standards:	Use what we find to influence policy, standards and practice

1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) inspection of the Diagnostic Imaging Department of Wrexham Maelor Hospital within Betsi Cadwaladr University Health Board on 19th and 20th October 2021.

Our team, for the inspection comprised of two HIW Inspectors and a Senior Clinical Diagnostic Officer from the Medical Exposures Group, United Kingdom Health Security Agency, who acted in an advisory capacity.

HIW explored how the service:

- Complied with the Ionising Radiation (Medical Exposure) Regulations 2017
- Met the Health and Care Standards (2015).

Further details about how we conduct Ionising Radiation (Medical Exposure) Regulations inspections can be found in Section 5 and on our website.

2. Summary of our inspection

Overall, from the evidence we examined, we found that compliance with IR(ME)R 2017 was good. Discussions with staff demonstrated that awareness of responsibilities in line with IR(ME)R was also generally good.

Policies and written procedures required under IR(ME)R 2017 were available and up to date. These helped the department to comply with the requirements of the regulations as they apply to radiology.

Both patients and staff who completed the survey were positive about their experiences whilst in the department.

Discussions with managers and department staff throughout our inspection provided assurance that arrangements were in place to ensure examinations were being undertaken safely.

Some areas for improvement were identified.

This is what we found the service did well:

- Staff treated patients with dignity, respect and kindness
- Feedback from patients indicated that they were highly satisfied with the service provided
- Overall, we found good compliance with the Ionising Radiation (Medical Exposure) Regulations 2017
- The training process for non-medical referrers
- Good working links between Medical Physics Experts (MPEs)[1] and staff working within the department

[1] An MPE is a person having knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure in diagnostic radiology, nuclear medicine

- Information provided indicated that appropriate arrangements had been implemented to allow for effective infection prevention and control
- Senior staff were receptive to our inspection and demonstrated a willingness to make improvements as a result
- Mandatory training and IR(ME)R training compliance was good.

This is what we recommend the service could improve:

- Ensure staff consistently check on a patients' pregnancy status prior to exposure to ionising radiation and document the check
- Implementing arrangements to routinely collate patient feedback on the services provided within the department
- Ensure staff appraisals are being carried out, to allow for training and development needs to be identified and monitored
- Eliminate any potential areas of discrimination.

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and radiotherapy, whose competence in this respect is recognised by a competent authority. All employers who carry out medical exposures are required in IR(ME)R to appoint a suitable medical physics expert.

3. What we found

Background of the service

Betsi Cadwaladr University Health Board was established on 1 October 2009 and provides primary, community, mental health and acute hospital services for a population of around 690,000 people, across the six counties of North Wales (Anglesey, Gwynedd, Conwy, Denbighshire, Flintshire, and Wrexham).

The health board has three main hospitals (Ysbyty Gwynedd in Bangor, Ysbyty Glan Clwyd in Bodelwyddan and Wrexham Maelor Hospital), along with a network of community hospitals, health centres, clinics and mental health units.

The department equipment included diagnostic general radiography, mobile X-ray equipment including mobile C-arm[2], general fluoroscopy[3] equipment, dedicated interventional equipment, computed tomography (CT)[4] scanners and dental equipment.

The department employs a number of staff including advanced practice reporting radiographers, radiographers, consultant radiologists, radiology department assistants as well as domestic, administrative and clerical staff. There were also 21 rotational student radiographers in the department who worked under the direct supervision of the radiographers.

The department provided an out-of-hours service staffed by radiographers and was also supported by a third-party provider providing justification and clinical evaluation of out of hours CT scans. There was also back up cover from the health board radiologists, when required.

The department also had advice and support provided by Medical Physics Experts (MPE) employed by the health board.

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[2] A C-arm is an imaging scanner intensifier. The name derives from the C-shaped arm used to connect the X-ray source and X-ray detector to one another. C-arms have radiographic capabilities, they are used primarily for fluoroscopic intraoperative imaging during surgical, orthopedic and emergency care procedures.

[3] Fluoroscopy is a type of medical imaging that shows a continuous X-ray image on a monitor,

[4] A CT scanner is a large, donut-shaped machine with a tunnel in the middle where the scanning takes place. A person lies on a flat table that slides in and out of the tunnel.

Quality of patient experience

We spoke with patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective was at the centre of our approach to inspection.

Feedback from patients indicated that they were highly satisfied with the service provided by staff within the radiology department.

We saw that arrangements were in place to promote the privacy and dignity of patients and found that staff treated patients in a kind and respectful manner.

Information provided indicated that overall there were adequate arrangements in place to meet the communication needs of patients attending the department.

The service needs to implement a process to routinely collate patient experience feedback and ensure that subsequent findings and actions are shared with patients and staff.

HIW issued both online and paper surveys to obtain patient views on the Diagnostic Imaging Department at the hospital. In total, we received 28 responses, all online. Not all respondents answered all of the questions. Patients made a number of positive comments about the service, but elected not to have their comments published.

Patients were asked in the questionnaire to rate their overall experience of the service. Over 96 percent of the patients who answered the question rated the service as 'very good' or 'good'.

We also issued an online survey to obtain staff views on the diagnostic imaging department at the hospital. In total, we received 62 responses from staff at the hospital. Again, not all respondents answered all of the questions.

Staying healthy

Senior managers that we spoke with confirmed that all leaflets had been removed and destroyed as a result of COVID-19. We saw one leaflet in the department main waiting area which related to cancer support. However, we did notice a smoking cessation poster displayed next to the main reception desk.

We also saw a number of posters displayed throughout the department advising patients to notify staff if they were, or there was a chance that they could be pregnant. Posters were also displayed throughout the department relating to benefits and risks associated with the radiation dose from the exposure. Additionally, we noted other information on posters, including advice for patients on receiving the results following their procedure.

Dignified care

Patients were greeted by reception staff and the radiographer would collect them from the waiting area, when ready. During our time in the department we observed staff speaking to patients in a polite, sensitive and professional manner. We did not overhear any sensitive conversations taking place within the department during our visit. Almost all of the patients who answered the question said they were able to speak to staff about their examination or procedure without being overheard by other people. Similarly, almost all of the patients said they were listened to by staff during their appointment.

The department's main waiting area had been reorganised to allow for social distancing between waiting patients. The number of seats available within the department appeared appropriate for the number of patients attending, during our visit. The secondary waiting room immediately outside the examination rooms also had chairs arranged to ensure social distancing.

There were changing cubicles available adjacent to treatment areas throughout the department. Each cubicle had a curtain which could be closed to allow patients to change clothing in private, when required. Within the cubicles there was a mirror and posters about the relevant procedure, as well as pregnancy posters. The curtains on each cubicle seen, had a no entry sign stating 'do not disturb' which was visible when the curtains were closed. Almost all of the patients who completed the survey said that they had been treated with dignity and respect by staff. Almost all staff who completed the questionnaire said that patients' privacy and dignity was 'always' or 'usually' maintained.

Patient information

As described above, we saw posters throughout the department, including the main reception, sub-waiting areas and within changing cubicles, making information available to patients about their examination. Bilingual signage and information was seen throughout the department. The vast majority of patients (96 percent) said that:

- They felt involved as much as they wanted to be in any decisions made about their treatment

- They had received clear information to understand the benefits and risks of their examination
- They had been given information on how to care for themselves following their procedure or treatment.

There was an employer's procedure in place that described how the benefits and risks of an exposure to ionising radiation should be communicated to patients. This procedure set out the information that should be given to the patient in a consistent format. Staff told us that information on the benefits and risks of the exposure would be sent out to patients in advance of their examination, in addition to posters being displayed in the department.

However, it could not be confirmed if theatre patients received benefit and risk information prior to the exposure. Evidence of the check must be added to the consent form to allow for compliance with this regulatory requirement.

Improvement needed

The employer must ensure that there is a documented process for informing patients of the benefits and risks of the radiation exposure when undergoing all radiological examination including during theatre procedures. This must include who will deliver the information and how this is recorded.

Communicating effectively

We were informed by staff that there was a hearing loop installed within the main reception area, to assist patients wearing hearing aids, when communicating with staff. Reception staff confirmed that it was turned on as and when required to help patients with hearing impairments, and for those who wear a hearing aid. There was a bilingual sign displayed on the main reception desk advising patients to notify reception staff if they would like to use the hearing loop. Signage throughout the department was bilingual. All the posters displayed relating to pregnancy enquiries, radiology procedures and feedback mechanisms were also bilingual.

Staff informed us that access was available to telephone translation services, should a patient attend the unit who was unable to communicate in English. We were also informed that there were Welsh speaking staff available in the

department, should a patient prefer to communicate in Welsh. However, there was no sign displayed with regards to the 'Active Offer'[5].

Improvement needed

The health board is required to ensure that action is taken to promote the availability of Welsh speaking staff or support within the department to help deliver the 'Active Offer'.

Timely care

We spent some time in the main reception observing the patients and the area. Whilst we did not hear patients being told of waiting times by reception staff on arrival to the department, we did not observe any patients waiting excessively long periods for their examination. Only four percent of patients, who responded to the question on the questionnaire, said they had to wait over 30 minutes. 70 percent of patients said they were not told on arrival how long they would likely to wait before having their examination. However, staff we spoke with said that if there were any delays they would inform the main reception desk. Staff also said that, typically they would not tell patients about normal waiting times but they would communicate any excessive waiting times. We also noted that there were sub-waiting areas for each speciality.

We asked patients in the survey various questions relating to timely care and 93 percent said it was 'very easy' or 'fairly easy' to find their way to the department. Additionally, 89 percent told us it was 'very easy' or 'fairly easy' to get an appointment for their procedure or treatment.

Staff responses to the survey were also positive in this area with 95 percent, who expressed an opinion, saying they were at least 'usually' satisfied with the quality of care they gave to patients. Similarly, 97 percent said patients were 'always' or 'usually' involved in decisions about their care. Additionally, 85 percent of staff said senior managers were committed to patient care.

[5] An 'Active Offer' simply means providing a service in Welsh without someone having to ask for it. The Welsh language should be as visible as the English language.

Individual Care

Peoples Rights

The department was located off the main corridor of the hospital. There were also corridors linking the department to the accident and emergency unit, to allow easy access to patients, when required. There was level access throughout the department to enable individuals with mobility issues to attend the department. 90 percent of patients said they felt they could access the right healthcare at the right time regardless of any protected characteristics[6]. Two patients said they had faced discrimination when accessing or using this health service. This area is referenced further, later in this report.

All the patients said their preferred language was English, that they were able to communicate with staff in their preferred language and that healthcare information was available in their preferred language.

Listening and learning from feedback

Staff told us that on the occasions where verbal concerns were raised by patients, attempts were made, where possible, to speak with the patient immediately, to try to resolve any issues or concerns quickly and efficiently. We were told that there was a complaints process that should be followed. Where it was not possible to deal with a complaint at a departmental level, we were told that patients were signposted to the health board's patient advisory service, who managed these concerns. There were also posters displayed within the department on the all Wales NHS complaints procedure, known as Putting Things Right (PTR)[7].

[6] Protected characteristics are specific aspects of a person's identity defined by the Equality Act 2010, age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation). The 'protection' relates to protection from discrimination.

[7] 'Putting Things Right' (PTR), is the integrated process for the raising, investigation of and learning from concerns. Concerns are issues identified from patient safety incidents, complaints and, in respect of Welsh NHS bodies, claims about services provided by a Responsible body in Wales.

There were posters displayed throughout the department advertising the 'Gwrando / Listen' health board feedback system. A quick response[8] (QR) code was displayed on the poster for patients to access the online feedback form. However, when the inspection team tried to access the form, it stated that the survey was closed. Adjacent to the department reception desk there were paper 'Gwrando / Listen' feedback forms and a box for individuals to put their completed forms.

Staff we spoke with confirmed that previously the service had a method for allowing patients to provide their feedback on a specific question. Tokens were provided to them and the individual had to put their token into the box linked to their answer. Questions previously included, was a staff member bare below the elbow, were patients happy with their appointment and was the department clean and tidy. Information was displayed on the wall along the main entrance corridor to the department relating to previous feedback received from patients. Staff confirmed that this was done on a monthly basis for a period during 2017/18. The most recent information displayed was from 2018. All the results of the questions were generally positive.

Staff responses in the questionnaire relating to the patient and service user experience within their department were:

- 81 percent said feedback was collected
- 62 percent said they received regular updates on the feedback
- 45 percent said that feedback was used to make informed decisions, although 47 percent answered to say they did not know.

The health board must consider having a standardised approach to collating patient feedback for the department. Findings, analysis and any subsequent action should be fed back to patients and department staff.

[8] QR Code is a two-dimensional version of the barcode, typically made up of black and white pixel patterns.

Improvement needed

The health board must ensure that:

- There is a system in place to ensure feedback is requested from patients, and staff, on a regular basis
- Results of the feedback are made know to patients and staff
- Staff understand how patient feedback is used to make improvements.

Delivery of safe and effective care

We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.

Overall, we found that compliance with IR(ME)R 2017 was good from the evidence available and discussions undertaken with staff.

Staff awareness of their IR(ME)R 2017 roles and responsibilities was also good. We found arrangements were in place to provide patients visiting the department with safe and effective care.

Information provided indicated that appropriate arrangements had been implemented by the service to allow for effective infection prevention and control within the department.

Policies and written employer's procedures required under IR(ME)R were available. These helped the department to comply with the requirements of the regulations as they applied to radiology.

We identified some areas for improvement including the need to ensure pregnancy checks were carried out appropriately and that these checks were documented.

Compliance with Ionising Radiation (Medical Exposure) Regulations

Prior to our inspection, HIW required senior staff within the department to complete and submit a self-assessment form (SAF). This was to provide HIW with detailed information about the department and the employer's key policies and procedures in respect of IR(ME)R 2017. This document was used to inform the inspection approach.

The SAF was returned to HIW within the agreed timescale and was comprehensive. Where we required additional information or clarification in respect of the responses within the self-assessment, senior staff provided this promptly.

Duties of employer

Patient identification

The employer had an up to date employer's procedure for staff to follow to correctly identify patients prior to their exposure. This aimed to ensure that the correct patient had the correct exposure in accordance with the requirements of the procedure. The procedure set out that staff were expected to confirm the patient's full name, home address and date of birth. This approach was in keeping with current UK guidance[9]. The procedure also described alternative approaches that staff must use, should patients be unable to verbally confirm their identity themselves.

Staff we spoke with were able to describe the correct procedure to identify patients. Also, all patients who completed our questionnaire told us that they were asked to confirm their personal details by staff before starting their examination.

Individuals of childbearing potential (pregnancy enquiries)

During the inspection we found evidence that the pregnancy enquiry was not being carried out in all relevant cases. We checked online records and there were clear gaps in the recording of pregnancy status. For the pregnancy enquiry a yes or no answer was required. If the operator obtained additional information, this would be written on the form but there was not a specific place for this information. However, we did note two instances where the pregnancy check had not been recorded on the relevant paperwork.

Also, the internal IR(ME)R audit highlighted this issue and there was little evidence to show this had being acted upon as the numbers are getting worse since the last audit.

There was an employer's procedure in place in relation to the process for carrying out pregnancy enquiries for individuals of childbearing potential, prior to any exposures. This procedure aimed to ensure that such enquiries were made in a standard and consistent manner. The procedure identified the staff responsible for making the relevant enquiries and set out the process to follow, depending on the individual's response. Whilst the procedure included the age range of patients

[9] Department of Health and Social Care (2018); Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017.

who should be asked about pregnancy, in accordance with UK guidance, the flow chart included as an appendix did not include the age range.

We also noted that posters were displayed within the department advising individuals to speak with staff if they either pregnant or thought they may be pregnant. This was important to minimise potential harm to an unborn child from the exposure to ionising radiation.

Staff we spoke with were able to describe their responsibilities in regard to the pregnancy enquiries, which were in line with the written employer's procedure described above. We were also informed that pregnancy status would be verbally checked with carers and comforters prior to any exposure. A record of the carers or comforters that were present with the patients during exposures was kept locally in a book. The use of this book should be further extended to include that pregnancy checks were completed on the carer or comforter. Staff we spoke with were able to describe the process used when carers or comforters accompanied a patient receiving treatment. This was in accordance with the employer's procedure for carers and comforters.

Non-medical imaging exposures

The employer had a written procedure in place which set out the criteria for carrying out non-medical imaging exposures[10]. Referrals for non-medical imaging examinations would only be accepted from registered healthcare professionals.

The list of current non-medical imaging performed included suspected inflicted injury (also termed non medical imaging or suspected physical abuse). This is not generally classified as a non-medical imaging under IR(ME)R as there will be a direct health benefit to the individual being exposed. Additionally, included in the list of non-medical imaging were sports performance and physical development. As these are not currently included in the list of non-medical imaging within section 4 table 1 of the employer's procedure, consideration should be given to updating this list to reflect current examination being provided.

[10] Non-medical imaging exposures include those for health assessment for employment purposes, immigration purposes and insurance purposes. These may also be performed to identify concealed objects within the body.

Referral guidelines

The referral guidelines used by the employer were the Royal College of Radiologist (RCR) iRefer[11] publication, which set out the referral criteria and also provide an indication of the radiation dose. Information provided indicated that referrals are accepted from entitled referrers, who have been registered on the system on condition that it is in accordance with the set guidance for referral.

The information required included the relevant patient details, the referrer identity and signature, the examination required and sufficient medical data to allow the practitioner to justify the exposure.

The SAF also described how diagnostic imaging and interventional radiology referrals were made to this department. Referrals were made using a standard paper template which is sent to the department either with the patient, in the post, or the referrer may bring the request directly to the department. Some primary care practices send the paper form scanned via e-mail to a standard address box.

Referral forms in theatres were completed by the operating surgeon. The radiographer is responsible for justifying referrals in theatres.

A project had just been commenced to introduce electronic requesting into the department.

Incomplete request forms are returned to the referrer with a proforma identifying the reason for the return. A radiation physics audit report identified issues with the process of incomplete referrals and how patients could miss out on an appointment, when forms were returned to the referrer. Management representatives we spoke with during the inspection were confident that the current process in place, would ensure that this would not occur.

The SAF stated that non-medically qualified referrers had to complete a training programme and formally request entitlement. This is reviewed via a radiology panel who provide formal entitlement, if the application was accepted. The non-medical referrer would then be added to the non-medical referrer register. In view

[11] iRefer is widely accepted as a major tool to promote evidence-based imaging. iRefer evaluates clinical evidence from diverse sources and uses a network of clinical experts to validate information. It reflects current best practice.

of this evidence of good practice, the health board should consider extending this training to medical referrers where areas of non-compliance are identified.

Improvement needed

The employer must ensure that the:

- Pregnancy checks are carried out for every individual of childbearing potential where relevant and the record of this check is documented
- Age range of patients who should be asked about pregnancy is included in the flowchart as described in the relevant employer's procedure
- Non-medical imaging employer's procedure is update to in line with current examinations being provided
- Record of pregnancy checks carried out on carers and comforters is recorded in the relevant book in the examination rooms.

Duties of practitioner, operator and referrer

The employer had a system in place to identify the different roles and responsibilities of the professionals involved in referring and performing radiology examinations. The employer's procedure on how IR(ME)R 2017 was implemented within the department identified, by staff group, who were entitled to be referrers[12], practitioners[13] and operators[14] (known as duty holders).

Staff we spoke with had a clear understanding of their relevant duty holder roles and scope of entitlement under IR(ME)R. Staff confirmed that they were able to

[12] Under IR(ME)R a referrer is a registered healthcare professional who is entitled, in accordance with the employer's procedures, to refer individuals for medical exposures.

[13] Under IR(ME)R a practitioner is registered healthcare professional who is entitled, in accordance with the employer's procedures, to take responsibility for an individual medical exposure. The primary role of the practitioner is to justify medical exposures.

[14] Under IR(ME)R an operator is any person who is entitled, in accordance with the employer's procedures, to carry out the practical aspects of a medical exposure.

access up to date electronic versions of policies and procedures via the health board online shared drive.

Training records were provided for a range of staff grades and groups. The evidence provided of the training matrix that held records for entitlement and scope of practice was seen and no issues were noted. The equipment training for radiologists consisted of refresher training dated September 2021. The induction and training records checked did not have all the relevant columns completed including trainer initials. Additionally, not all training records included signatures and dates to show that the competency had been completed.

Improvement needed

The employer must ensure that all induction and training records are completed in full, with signatures and dates to show the training has been completed.

Justification of Individual Medical Exposures

Staff we spoke with had a clear understanding of the justification process. Justification of individual medical exposures was recorded on the radiology referral forms, with the date and signature of the practitioner.

Out of hours provision was supplied by Everlight Radiology and we were satisfied the process was compliant.

The process for authorisation was described in the SAF. The practitioner has delegated the task of authorisation to the IR(ME)R operator, through the use of authorisation guidelines. The guidelines detailed the authorisation criteria for each examination listed. However, it was not clear from the authorisation guidelines provided, who the named practitioner was. Additionally, for the trauma CT authorisation guidelines it was not clear who the practitioner was that took responsibility for referrals authorised under these guidelines. We were told that the clinical director would be the practitioner. This needs to be added to the authorisation guidelines to ensure the operators authorising to them know who the individual practitioner is, that they are working under.

We were provided with results of an IR(ME)R audit, on a retrospective review of referral forms for justification of examinations dated March 2021. This was one of the five rolling audits to ensure compliance with IR(ME)R. The sample was individually checked to see if the justification box had been signed by the radiographer or radiologists. If it was found to be missing from the referral form RadIS2 was also checked. The audit results showed almost 100 percent compliance. We checked a sample of referrals and noted that the relevant clinical information was seen to justify the referral. There was also evidence of

authorisation, from an appropriately entitled practitioner, confirming the justification process had taken place.

Improvement needed

The employer must ensure that the authorisation guidelines have an identifiable practitioner named.

Optimisation

Optimisation is the process of keeping exposures as low as reasonably practicable (ALARP) while achieving the best image quality to answer the clinical question. The employer had arrangements in place for the optimisation of exposures. The SAF stated that practitioners and operators ensured doses were ALARP[15] via a number of factors. Staff we spoke with were able to describe the process that they used to ensure the doses were optimised.

Diagnostic reference levels (DRLs)[16]

There was an employer's procedure in place for determining, implementing and reviewing diagnostic reference levels (DRLs). We were told this was under revision at the time of the inspection. During our tour of the department, we noted that local and national DRLs were clearly displayed in each area visited. The local DRLs were all equal to, or less than, the national DRLs. The department should consider setting local DRLs for paediatrics, when there is sufficient data available.

The SAF showed that the task of DRL review was included in the terms of reference for the relevant Radiology Image Optimisation Team (RIOT). It was described that a review of DRLs would take place annually at the first quarter RIOT meeting. This check would include a review of the preceding years' median doses, including how this data was trending. Additionally, we were told that as

[15] ALARP ("as low as reasonably practicable), is a principle in the regulation and management of safety-critical and safety-involved systems. The principle is that the residual risk shall be reduced as far as reasonably practicable.

[16] DRLs are a level used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the amount of radiopharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure.

part of the computed tomography (CT) RIOT, the research radiographer looked at doses across the three main sites in the health board. It was stated that this achieved a significant dose reduction in some CT examinations. This showed evidence of collaborative working across the health board assisted by RIOTs, and providing an area of facilitating shared learning. It was also positive to note that there was an intention for a RIOT in the future for interventional radiology.

Paediatrics

The SAF provided stated that staff would deploy a variety of techniques to prevent movement of children during X-ray examinations to reduce the need for repeat exposures. These included feed and wrap[17] and various distraction techniques. The SAF further referred to the CT scanner having specific programmes for imaging children that optimised the dose. In addition, for general X-ray and fluoroscopy, the equipment had anatomical programme setting optimised for the imaging of children based on age ranges.

We were also told that a post for a paediatric lead radiographer has been introduced in the general X-ray department to support the imaging of paediatrics, to ensure exposures were optimised. Additionally, a research radiographer had completed and published research on the optimisation of neonatal incubator X-ray imaging. This work was being used to standardise techniques and protocols. It had also been used to support the purchase of incubators that facilitated dose optimisation.

Clinical evaluation

There was a procedure in place which described the process regarding clinical evaluation. The purpose of this procedure was to ensure that each medical exposure was clinically evaluated and that evaluation was documented. It further stated that the evaluation of the outcome of a medical exposure was communicated to the referrer or other relevant staff, in a timely manner. This was to facilitate appropriate clinical management of the patient.

The SAF stated that radiology provided a formal report in RadIS2 for examinations performed by the service. Regular checks were made to ensure all

[17] 'Feed and wrap' is a technique used with young babies instead of sedation or general anaesthesia. Generally babies tend to fall asleep after a feed, babies are then scanned while asleep.

examinations had a report. Performance monitoring took place to measure the report turnaround times in accordance with the guidance from the medical imaging sub-committee (MISC). A monthly check was also carried out to monitor the backlog against the MISC guidance. This monitoring was reported to the radiology senior team and the secondary care clinical effectiveness group.

We spoke with senior managers about how the employer satisfied themselves that all operators making clinical evaluation were entitled, competent and trained to do so. We were told that training and competency were checked prior to the entitlement to clinically evaluate the exposure. A letter would be issued to each operator to show this entitlement and scope of practice.

Equipment: general duties of the employer

The employer had an up-to-date inventory (list) of the equipment used within the radiology department. The inventory contained the information required under (IR(ME)2017.

Safe care

Almost all the staff who expressed an opinion, said their organisation had the right information to monitor the quality of care across all clinical interventions and took swift action when there were shortcomings, at least on some occasions. The vast majority of staff said that they were content with the efforts of their organisation to keep them and patients safe, again at least ‘sometimes’. From the staff who expressed an opinion, the survey also showed that:

- 90 percent agreed that care of patients and service users was the organisation's top priority
- 96 percent agreed that the organisation acted on concerns raised by patients and service users
- 82 percent agreed they would recommend their organisation as a place to work
- 81 percent agreed they would be happy with the standard of care provided by their organisation for them or for their friends or family.

Managing risk and promoting health and safety

There was signage throughout the department, on the floor and the walls, to direct patients from the main waiting area to the separate sub waiting areas for the relevant examinations. Whilst there were some trolleys and wheelchairs lined up in the corridors, there was still sufficient space in these areas. We saw patients and beds being transported past these areas without any issues.

Arrangements were in place to promote the safety of staff, patients and visitors. For example, appropriate signage and restricted access arrangements were in place to deter and prevent unauthorised persons entering areas where radiology equipment was being used.

The majority of staff who completed the questionnaire said that if they were concerned about unsafe clinical practice, they would know how to report it. The majority also said they would feel secure raising concerns about unsafe clinical practice. Whilst only 51 percent felt confident their organisation would address their concerns once reported, 33 percent answered that they did not know.

Infection prevention and control

The department appeared clean and in a good state of repair. There were hand washing facilities noted in the patient toilets and staff areas within the department. Additionally, hand sanitiser gel was available throughout the department. Face masks and hand sanitising gel were available at the reception desk. 96 percent of patients who answered the questionnaire said that the setting was 'very clean' or 'fairly clean'.

The stock of personal protective equipment (PPE) was observed in staff areas adjacent to examination rooms. Staff we spoke with, also confirmed that should further PPE be required it could be accessed within the department. Staff stated that they were confident and competent at using PPE and there was sufficient supplies of this equipment. Staff had also been fit tested to use the FFP3[18] mask.

There were signs displayed at the entrance to the department stating that patients only were permitted beyond that point, to keep to the left within the department and to report to reception and to sanitise their hands. Signage was displayed within the department to remind individuals to keep left and to ensure social distancing.

We observed patients arriving with relatives or partners, but only the patients were allowed to go from the reception to the sub-waiting areas and treatment rooms. Staff confirmed that only in certain circumstances were patients allowed to be accompanied, for example children with a parent or carers of patients.

[18] FFP3 masks provide the highest level of respiratory protection that a disposable mask can offer. A well-fitting FFP3 mask can protect users against fine toxic particulates including asbestos, bacteria, viruses and radioactive particles.

Information provided by staff indicated that there were arrangements in place for effective infection prevention and decontamination within the department. We were informed that these arrangements had been strengthened as a result of COVID-19.

We asked patients a question about COVID-19 compliant procedures being evident during patient visits. 93 percent said these were 'very evident' during their time at the setting. We also asked staff a series of questions about COVID-19 compliance. All staff agreed their organisation had implemented the necessary environmental changes and all agreed their organisation had implemented the necessary practice changes. 92 percent said that there had been a sufficient supply of PPE and 93 percent of staff said that infection prevention and control procedures were 'always' or 'usually' followed. However, all staff agreed there were decontamination arrangements for equipment and relevant areas. Staff comments included:

> *"PPE was an issue initially"*
>
> *"Short on certain PPE and masks meaning some staff were unable to work in certain areas. They were very slow to address this"*
>
> *"There have been shortages nationally and we were short of PPE then, but since I have not noticed a shortage."*

Staff we spoke with were able to described the cleaning methods used after all patients, whether COVID-19 was suspected or not. We were told that there had been various videos available to staff in relation to donning and doffing[19] PPE, as well as fit testing for the FFP3 mask. We were also told that staff had received training in the use of a portacount[20] mask as well as being trained on the masks used in the intensive therapy unit (ITU).

Safeguarding children and adults at risk

Discussions with staff within the department demonstrated that there was an awareness of current safeguarding procedures in place. We were also informed

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[19] Donning – putting on personal protective equipment (PPE); Doffing – taking off personal protective equipment (PPE)

[20] The Portacount is an ambient particle counting device which is used to conduct fit testing by providing a quantitative assessment of faceseal leakage.

that staff had completed online training to help them keep up to date with relevant safeguarding issues. We were informed that safeguarding guidance and support was also available on the health board intranet page.There was over 88 percent staff compliance, based on information supplied, with this mandatory training.

Effective care

Quality improvement, research and innovation

Clinical audit

We were provided with a copy of the clinical audits for the year. The SAF stated that each quarter a joint audit meeting was held sharing information across the whole service. These meetings were recorded so that staff unable to attend, could view the meeting notes at another time. The local radiology quality, safety and patient experience groups were informed of the results and as appropriate the results were reported to the senior team meeting.

We were told of the joint clinical audit with involvement from the clinical team, radiographers and MPEs looking at the imaging of facial bones referrals from the emergency department. The audit findings resulted in a change in practice for mid face imaging.

The department performed annual audits on IR(ME)R compliance in areas including pregnancy status checks, recording doses, patient identification, and justification of exposure. The results of the annual audits were presented to staff on site and also highlighted in staff huddles to provide learning points.

Expert advice

The SAF completed showed that the MPEs and Radiation Protection Advisors[21] played a full role in the department. They were involved in high dose interventional and high dose CT services. Also, they were members of a number of committees and groups that were part of the governance of the department. These included membership of the health board area Radiation Protection

[21] RPA are competent to advise employers on the safe and compliant use of Ionising Radiations. The post is a legally recognised position and is a requirement of IR(ME)R 2017.

Committee (RPC)[22] and the health board overarching RPC. They were also core-standing members and actively involved in the various RIOTs. In addition, they contributed on an all Wales basis as members of the All Wales Quality Forum[23] and the All Wales Radiation Protection Specialist Standing Group (RPSSAG)[24].

We were told that the MPEs and quality assurance (QA) radiographers were in the process of drafting a health board policy for QA, which they hoped would become an all Wales policy. The quality assurance programme was established for each piece of equipment, developed with advice from the manufacturer and the MPE. The QA programme specified the frequency and method of testing as well as the remedial and suspension levels for tests performed by radiographers. They also acted on professional guidance and advised on the implications for regulation compliance across the health board, both locally to departments and via the RPC. The links between the MPEs and the department were described by staff as excellent.

We were also provided with the radiation protection audit report for CT for the health board (including Wrexham Maelor). We were told that where areas had been highlighted for improvement or training needed in certain groups, the department had taken the opportunity to look at these areas and provided additional training.

Medical research

The SAF provided showed that there was an employer's procedure in place with regard to research involving ionising and non-ionising radiation. There was also a policy in place relating to research involving ionising and non-ionising radiation. Additionally, the department employed research radiographers and a QA radiographer.

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[22] The RPC has members from Radiology, Radiotherapy, RPA/MPE and other radiation users. These members provide advice and guidance to the employer in relation to any guidance that has been issued from regulators or professional bodies. It is chaired by the Executive Director of Therapies and Health Science who holds the delegated responsibility for the regulations

[23] A sub-committee of the National Imaging Programme Board that works to set standards across the whole of Wales. During

[24] The Radiation Protection Specialist Standing Advisory Group (RPSSAG) is working with other Welsh Scientific Advisory Committee groups to develop 'once for Wales' guidance related to 'carers and comforters' and 'risk benefits information for patients'

The SAF indicated that the research radiographer received all requests for research trials. Referrals are reviewed, and for nuclear medicine all licencing requirements are checked, prior to approval being given. These checks would be done in accordance with the procedure and included discussions with the practitioners and MPEs.

Once a trial is agreed, the research radiographer created a set of documentation for that particular trial that included the imaging protocol, dose constraints and number of expected patients to be recruited. The research nurse informs the research radiographer when patients were recruited and the patient's RadIS2 record would be amended to reflect the trial they were on. For trials where the radiology department held the principal investigator role, the research radiographers would recruit to the trial.

Information governance and communications technology

Information management systems within the department were described and demonstrated by staff. The systems in place allowed for relevant patient details and information about diagnostic and interventional procedures performed, to be recorded and easily accessed by staff.

Record keeping

We reviewed a sample of patient referral records. The majority of records reviewed had been completed with appropriate details by those staff involved in the exposure. The forms were clear and completed to a good standard with relevant clinical information seen to justify the referral. All forms had three points of identification[25] and the referral had been signed and the name of the signer was clear in all cases. The dose was recorded along with the initials of the operator and practitioner and the practitioner in CT also wrote the specific protocol to be used.

We also noted that there was a regular annual audit on the Last Menstrual Period (LMP)[26]. The audit was conducted to ensure that all radiographers were correctly checking the pregnancy status of all patients of child bearing age (12-55). The

[25] Name, date of birth and address

[26] LMP refers to the first day of your last menstrual period. Health care providers measure pregnancies in weeks starting from the first day of the LMP.

audit in 2021 showed that 32 percent of patients selected in the sample had not been correctly identified or documented.

Quality of management and leadership

We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also considered how the service review and monitor their own performance against the Health and Care Standards

We found there was a robust management structure with clear lines of reporting in place. There were effective governance arrangements in place to support ongoing regulatory compliance.

Staff demonstrated they had the correct knowledge and skills to undertake their respective roles within the department.

Senior staff confirmed that there were staffing issues. However this was being actively managed by the health board to minimise the impact on the delivery of services.

Some issues were identified that needed to be addressed by the employer.

Over the course of our inspection, senior management staff made themselves available and facilitated the inspection process. They were receptive to our feedback and demonstrated a willingness to make improvements as a result of the issues highlighted.

As previously detailed, as part of our inspection a staff survey was made available to provide all staff working within the department with the opportunity to provide their views. Additionally, discussions were held with senior managers of the service, as well as a selection of staff working within the department. The three members of the department staff we spoke with, spoke clearly and well.

Governance, leadership and accountability

We spoke with three members of staff and three senior managers about items relating to health and care standards.

Senior management we spoke with stated that the department was a pilot site for Wales in the Quality Standards in Imaging[27]. The department was working towards accreditation, there were four tiers to complete before the site could apply for accreditation. The department were currently at tier three and they hoped to be fully accredited within the next 18-24 months.

We were told that the radiology services manager met the heads of service every week. There were regular modality lead meetings held with each area to provide updates on status and challenges. Each site lead had their own arrangements for sharing information within each site. A COVID-19 meeting was held every fortnight for the heads of modalities to share the latest guidance and to make staff aware of the issues.

At the department there were heads of department meetings once a week which included the principle leads from each area. These meetings allowed staff to provide feedback to the head of the department as well as providing updates. Senior management confirmed that radiology briefings were circulated to all staff via emails at least once a week, but usually around two or three times a week. Face to face meetings had not restarted due to COVID-19 and the department were relying on sending out messages by email.

The management structure in place, had clear lines of reporting, which was described by senior staff and demonstrated through an organisational chart. We found that governance arrangements were in place to support the effective operation of the department.

We asked some questions relating to senior managers as part of the staff questionnaire. The vast majority of staff who responded said they knew who senior managers were and said that communication between senior management and staff was at least ‘sometimes’ effective. The majority of staff said senior managers at least ‘sometimes’ tried to involve staff in important decisions.

[27] The quality standard for imaging (QSI) has been developed by The Royal College of Radiologists and the College of Radiographers to set out the criteria that defines a quality imaging service. UKAS accreditation of imaging services is a patient-focused assessment that is designed to give stakeholders, service users, patients and their carers, confidence in their diagnosis and all aspects of their care. The QSI provides a framework for the NHS and private sector to provide consistently high quality services delivered by competent staff working in safe environments.

Duties of the employer

Entitlement

The process for the entitlement of duty holders for medical exposures was evidenced in the employer's procedure and in an appendix to the Ionising Radiations Safety Policy. This described how staff were entitled to be referrers, practitioners or operators (including MPEs).

The SAF provided stated the process by which each operator or group of operators were made aware of their entitlement and scope of practice. Radiology operators had a signed letter of entitlement that was issued at the start of employment and then reissued if there were any amendments to their scope of practice for entitlement or regulatory changes. Entitlement was also confirmed annually via the appraisal process.

Practitioners are identified through inclusion on the IR(ME)R entitlement matrix and we saw evidence of this. The SAF stated that practitioners have a session on IR(ME)R compliance on their induction programme. Practitioners receive a letter of entitlement for their scope of practice.

We were told that each non-medical referrer is written to, annually, to confirm their competency. The radiology service issue an annual letter of entitlement to GP practices and all consultants (for sharing with their team) which includes a reminder of good referral practice. As part of recruitment processes all new staff will have their registration and qualifications checked. Radiology would perform a check every 2 years of the GMC professional registers, to ensure medical referrers are still registered. When non-medical referrers make a referral outside their scope of practice, it is turned down by the radiographer and their line manager is informed. Additionally, the SAF went on to state that annually or when there are changes to the regulations, the department would write to secondary care consultants and all primary care practices to remind them of their entitlement to refer and of the referral guidelines available.

Staff we spoke with were aware of their duties and scope of entitlement under IR(ME)R. Entitlement was linked to successful completion of the relevant training and competency checks for specific equipment and examinations. These entitlements were recorded on a training matrix in the department. Overall, the staff entitlement records we saw as part of our inspection were complete and up to date.

Written procedures and protocols

The Chief Executive of the health board was designated as the IR(ME)R employer. This arrangement was detailed within the Ionising Radiation Protection Policy. The Chief Executive could delegate tasks, but not responsibility, for

ionising radiation safety appropriately through the organisational arrangements in order to effectively manage and control the risks from ionising radiation. The Chief Executive appointed the Executive Director of Therapies and Health Science to be responsible for the co-ordination of radiation-related health board activities.

Staff we spoke with, as part of our inspection, confirmed that they had access to current versions of the policies and procedures in place. Also, senior staff confirmed that changes would be communicated to staff in a number of ways depending on the change. These included emails, during daily huddles, at radiology site briefings, the radiology monthly newsletter and the procedure would be updated on the radiology SharePoint site. Staff we spoke with confirmed this process of communication of information.

We saw that written procedures and protocols had been developed and implemented in accordance with IR(ME)R 2017. There was also an employer's procedure on the quality assurance of IR(ME)R written procedures, protocols and equipment. The purpose of this procedure was to ensure that all procedures and protocols related to IR(ME)R were subject to a quality assurance programme. Similarly, that all equipment covered by IR(ME)R was subject to a quality assurance programme.

Staff we spoke with, as part of our inspection, confirmed that they had access to current versions of the policies and procedures in place. Also, senior staff confirmed that when any changes to documents occur, notifications were circulated to department staff, who were subsequently asked to confirm that they had read and understood the relevant changes. This was also confirmed as part of the performance appraisal and development review (PADR).

We were told that there was a peer review system for reporting radiographers. The percentage accuracy was reported to the radiology quality, safety and effectiveness group. All non-medical referrers were required to perform audits, which radiology would request from time to time for assurance purposes. This was not reviewed during the inspection.

The department were working towards a peer review system for radiologist and Everlight. Senior staff said that Everlight had an internal process of five percent peer review. They were not peer reviewed by the health board currently, due to availability of staff.

The employer had a set of employer's procedures for radiology that were required under Schedule 2 of IR(ME)R 2017. In addition, there were protocols documented for diagnostic examinations such as a general X-ray technique protocol and the CT technique protocols. However, it was not clear who had signed the protocols, whilst there was a signature there was not a printed name

to easily identify the signature. The employer needs to ensure that the protocols have a name printed on them.

Significant accidental or unintended exposures

A third of staff said they had seen patient safety errors, near misses, or incidents in the last month. The majority of respondents agreed the last time they saw an error, near miss or incident, it was reported.

All respondents agreed staff who are involved in the investigation and reporting of an error, near miss or incident were treated fairly and that the organisation encouraged them to report errors, near misses or incidents. Almost all agreed their organisation treated reports of errors, near misses or incidents confidentially and that their organisation did not blame or punish people who were involved in these. Again, almost all respondents agreed that, when errors, near misses or incidents were reported, their organisation took action to ensure that they do not happen again. One member of staff commented:

> *"A DATIX was completed in relation to the incident, plus my immediate manager and relevant colleagues were notified. Following the incident, the relevant department supplies regular information in order to help avoid future errors."*

Almost all staff who expressed an opinion agreed they were informed and given feedback about changes made in response to errors, near misses and incidents that happen in the organisation. Although, only 60 percent said there were 'usually' enough staff working in the department to do their job properly, the remaining 40 percent said they 'sometimes' were.

The procedure for reporting and investigating accidental or unintended exposures and other incidents was described by staff we spoke with. This included the member of staff reporting the incident on Datix, the incident reporting tool used by the department and the process of investigation by a senior member of staff.

The employer had a written employer's procedure for reporting and investigating accidental or unintended exposures within the department. The employer's procedure set out the process staff should follow if they suspected that a significant accidental or unintended exposure (SAUE) had occurred. The procedure guided staff of the process to follow and subsequently resulting in HIW being informed of such incidents in a timely manner, where necessary. However, it was not clear from the employer's procedure who would establish when an incident was deemed clinically significant.

Staff interviewed were aware of the procedure for reporting accidental or unintended exposures. Senior management stated that the procedure for

reporting and investigating would also involve a dose and risk estimation provided by the MPE for the report. Staff stated that they would be made aware of the lessons learned to avoid a repetition of any event.

Improvement needed

The employer must ensure that:

- The employer's procedure relating to dealing with accidental or unintended exposures gives clear guidance on who would establish when an incident is deemed clinically significant
- The protocols have the authors name printed on them, in addition to a signature.

Staff and resources

Workforce

We were concerned to find that six members of staff, who completed our survey, answered the question that they had faced discrimination at work within the last 12 months. The health board must ensure that processes are in place to allow any member of staff to report any issues of concern internally, as well as to ensure that any concerns raised are appropriately investigated and responded to.

92 percent of staff agreed with the comment that staff had fair and equal access to workplace opportunities regardless of the protected characteristics[28], the remaining eight percent answered 'prefer not to say'. Similarly, 90 percent agreed their workplace was supportive of equality and diversity, the remainder answered 'prefer not to say'. Staff we spoke with said there was equal access to workplace opportunities for all staff and that they would go to their line manager to report discrimination.

Senior staff we spoke with said that the interview process for any vacancies was open and transparent. Additionally, any requests for study leave were discussed at a weekly meeting to ensure fairness across all sites in the health board. They

[28] Regardless of Age, Disability, Gender reassignment, Marriage and civil partnership, Pregnancy and maternity, Race, Religion or belief, Sex and Sexual orientation

also said there was an anonymous health board reporting system that could be used to report any discrimination noted.

Wellbeing

We asked a series of questions relating to staff wellbeing. Their responses are given below:

- 88 percent agreed their job was not detrimental to their health
- 93 percent agreed their immediate manager takes a positive interest in their health and well-being
- 86 percent said their organisation takes positive action on health and well-being
- 88 percent agreed their current working pattern and off duty allows for a good work life balance.

Members of staff comments included the following:

> *"…they have been very flexible with hours to suit my family life"*

> *"Feel as though I work a lot, and a lot out of hours, so not necessarily nailing the work life balance. Although I haven't talked to management about this, so not their fault"*

Staff we spoke with, were aware of how to access occupational health and wellbeing at the health board. Senior staff described the wellbeing initiatives that were available to support staff due to COVID-19. These included drop in counselling sessions, cycling to work and measures if struggling with masks, as well as signposting staff to wellbeing and occupational health. Whilst 89 percent of staff agreed they were aware of the Occupational Health support available we received two negative comments in the staff survey, these were:

> *"Occupational health department is very poor and takes weeks to speak to staff or access an appointment"*

> *"Occupational health in this trust is not fit for purpose. Approximately 4 days to respond to needlestick injuries"*

However, 95 percent of staff agreed that they are offered full support in the event of challenging situations.

Improvement needed

The health board must ensure that processes are in place:

- To allow any member of staff to report any issues of concern internally, as well as to ensure that any concerns raised are appropriately investigated and responded to
- To ensure that staff are treated fairly and equally and that any instances of discrimination will not be tolerated and appropriate action taken

The health board must ensure that arrangements are put in place to reduce the perceived issues with occupational health.

Staffing

Senior staff that we spoke with said that staffing levels were not appropriate and that the radiologist numbers were the lowest in Europe. They said that they had received some investment this year and were now working on a sustainable plan. Additionally, the department were about to advertise for 23 more radiology staff across the health board. There were a number of vacancies in ultrasound, we were told that there were not available applicants to fill these vacancies. The department were also advertising for 3 consultant posts. Due to the number of vacancies in the department, the SAF stated that there were a number of radiographers who take part in advanced practice or extended roles. They were required to follow a formal training programme agreed by the radiology service. Where there was a recognised post-graduate training programme the member of staff would be required to complete this training.

Where there was no identified formal qualification, the radiology service would develop a bespoke training package which would include, theory and practical elements and cover all governance aspects.

All staff completing advanced or extended practice were required to complete training and demonstrate competence. This was in line with the governance documentation for the practice before being formally entitled in writing and adding to the entitlement matrix. This also gave staff additional training and opportunities to advance within the department.

We were told that there would be an increase in students in the department in the coming year. The department were speaking to the university on a plan to manage and mentor the students in practice. This was to ensure there would be a workable spread of students to allow staff to support them on top of their own roles. In addition they would be making much more use of our community sites to help with student placements. For example there was a student based at Mold

Community Hospital. The university has now also implemented virtual reality training for students.

Staff we spoke with said that they felt that the number and skill mix of staff in the department was sometimes understaffed and that they believed that the department was struggling with staffing levels. They also commented on the challenge of completing their own workload and supervising the students in the department.

The responses were also similar in the staff surveys with 60 percent who expressed an opinion said there 'always' or 'usually' enough staff working in the department to do their job properly. The remaining 40 percent said there were 'sometimes' enough staff working in the department.

The majority of staff said they were at least 'usually' able to meet all the conflicting demands on their time at work and had adequate materials, supplies and equipment to do their work. Almost all staff were at least 'sometimes' able to make suggestions to improve the work of their team / department and were involved in deciding on changes introduced that affected their work or area. Similar numbers of staff also said that their organisation at least 'sometimes' encouraged teamwork and were supportive.

Staff comments included:

> *"Too much pressure on frontline staff who are working with patients and short staffed. Made to feel like whinging and not enough time to sort things out. When requiring support no management are around to talk to the patients."*

> *"I have been employed by BCUHB since November 2019 and have found it a welcoming and friendly place to work. The Mammography, and wider Radiology, staff are always there for guidance and support. From my limited experience working here, my impression is that the Radiology department are caring, hard-working health professionals."*

> *"I have needed support and advice a lot from my managers over the past year and they have been extremely supportive and helpful. Experience of other hospitals and health boards has shown me that in Betsi and in Radiology specifically the support here is extremely important to me and very much appreciated."*

> *"Managers have been very helpful especially over the past year or so where I have needed support much more than usual."*

72 percent, said front-line professionals who dealt directly with patients, were ‘always’ or ‘usually’ sufficiently empowered to speak up and take action if they identified issues in line with the requirements of their own professional conduct and competence. 23 percent said they ‘sometimes’ were empowered

63 percent of staff who expressed an opinion said there was ‘always’ or ‘usually’ a culture of openness and learning within the organisation that supported staff to identify and solve problems, 32 percent said there ‘sometimes’ was. One member of staff commented:

> *“The department where I work does not encourage staff to voice concerns about the management of the department. Staff are disciplined for speaking up, therefore creating a culture of ‘just put up with it’… Morale is very low. No encouragement from management when staff are doing a good job, only criticism when things go wrong”*

We also asked a series of questions about the immediate and senior manager of staff, of those who expressed an opinion relating to their immediate manager we noted the following:

- 86 percent said their immediate manager encouraged those who work for them to work as a team
- 76 percent said their immediate manager could be counted on to help with a difficult task at work
- Whilst 64 percent said their immediate manager gave clear feedback on their work, 23 percent also said they ‘sometimes’ did. They also said that 42 percent of senior managers acted on staff feedback and 42 percent said they ‘sometimes’ did
- Again whilst 67 percent said their immediate manager asked for their opinion before making decisions that affect work and 20 percent said they ‘sometimes’ did
- 84 percent said their immediate manager was supportive in a personal crisis.

Training

A review of the mandatory training records for staff showed there was clear evidence that the majority of staff had completed the relevant training. The percentage completion was in between 83 percent for manual handling and 98 percent for violence and aggression training.

Almost all staff who expressed an opinion, said they had completed their mandatory training. Additionally, we asked staff about the training they had received in relation to IR(ME)R. Approximately 90 percent said they had received training in IR(ME)R relevant to their functions as practitioner or operator. A similar percentage also said they had up to date training in accordance with IR(ME)R relevant to their specific area of practice and other training relevant to their area of work. We received comments on training staff would find useful, some of which are shown below:

> *"The mandatory training is of course essential but I would like more training relevant to my job such as image interpretation, improving techniques, training to help with supervising students"*
>
> *"Suspected Inflicted Injury (SII) E-learning"*
>
> *"Leadership/Management"*
>
> *"Disability/Carer awareness"*

In response to a series of questions relating to training, the percentages of staff who expressed the opinion of 'always' or 'usually' included:

- 87 percent said training helped them do their job more effectively
- 91 percent said training helped them stay up-to-date with professional requirements
- 81 percent said training helped them deliver a better patient experience.

Appraisals

The information supplied showed that 66 percent of the PADRs were up to date. This figure was similar to the 69 percent of staff who expressed an opinion, in the questionnaire, that they had an annual review or appraisal within the last 12 months.

Senior staff told us that this is one of the weekly agenda items on the heads of department meetings. Staff had been encouraged to ensure that their appraisal were carried out with their supervisors and all outstanding appraisals had now been booked in management diaries. Whilst the appraisals should include identifying training, learning and development needs, only 55 percent said that these were covered in these meetings. Additionally, 73 percent of staff said their manager supported them to receive training and development.

Improvement needed

The health board must ensure that:

- Processes are put in place to ensure that appraisals are completed annually
- The appraisals are completed in full, including identifying training, learning and development.

4. What next?

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any immediate concerns regarding patient safety where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking
- Appendix C: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Where we identify any serious regulatory breaches and concerns about the safety and wellbeing of patients using the service, the registered provider of the service will be notified via a non-compliance notice. The issuing of a non-compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings.

The improvement plans should:

- Clearly state when and how the findings identified will be addressed, including timescales
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

5. How we inspect services that use ionising radiation

HIW are responsible for monitoring compliance against the Ionising Radiation (Medical Exposure) Regulations 2017 and its subsequent amendment (2018).

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
- Patients receive no more exposure than necessary to achieve the desired benefit within the limits of current technology
- Volunteers in medical research programmes are protected

We look at how services:

- Comply with the Ionising Radiation (Medical Exposure) Regulations
- Meet the Health and Care Standards 2015
- Meet any other relevant professional standards and guidance where applicable

Our inspections of healthcare services using ionising radiation are usually announced. Services receive up to twelve weeks notice of an inspection.

The inspections are conducted by at least one HIW inspector and are supported by a Senior Clinical Officer from Public Health England (PHE), acting in an advisory capacity.

Feedback is made available to service representatives at the end of the inspection, in a way which supports learning, development and improvement at both operational and strategic levels.

These inspections capture a snapshot of the standards of care relating to ionising radiation.

Further detail about how HIW inspects the NHS can be found on our website.

Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
No immediate concerns were identified on this inspection.			

Appendix B – Immediate improvement p

Hospital: Wrexham Maelor Hospital

Ward/department: Diagnostic Imaging Department

Date of inspection: 19 and 20 October 2020

The table below includes any immediate concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

Immediate improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
No immediate assurance issues				

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative:

Name (print):

Job role:

Date:

Appendix C – Improvement plan

Hospital: Wrexham Maelor Hospital

Ward/department: Diagnostic Imaging Department

Date of inspection: 19 and 20 October 2020

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
Quality of the patient experience				
The employer must ensure that there is a documented process for informing patients of the benefits and risks of the radiation exposure when undergoing all radiological examination including during theatre procedures. This must include who will deliver the information and how this is recorded.	IR(ME)R 2017 Schedule 2 1(i)	RAD 072 Communicating of the benefits and risks of ionising radiation prior to an examination as required by IR(ME)R to be updated to make it explicit in relation to patients undergoing theatre procedures that this needs to be included in the consent process. The annual notification of entitlement to medical referrers will include a section on risk benefit discussions and information on dose and it's risk	Head of Quality and Governance Radiology Professional Services Manager Radiography	5th February 2022 31st January 2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		Remind clinical staff when they are consenting for a procedure that uses X-ray guidance that this should be included in the consent discussion this will be done as part of the radiology annual notification and compliance monitored via BCU audit of consent processes	Medical director or Director of Therapies & Healthcare Sciences	Continuous
The health board is required to ensure that action is taken to promote the availability of Welsh speaking staff or support within the department to help deliver the 'Active Offer'.	3.2 Communicating effectively	All staff reminded of the availability of language line particularly for out of hours when none welsh speaking staff are on duty Welsh Language posters displayed in the department for patients to be informed that they can ask for a welsh speaker	Head of Quality & Governance	Completed November 21 31st January 2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The health board must ensure that: • There is a system in place to ensure feedback is requested from patients, and staff, on a regular basis • Results of the feedback are made know to patients and staff • Staff understand how patient feedback is used to make improvements.	6.3 Listening and Learning from feedback	CIVICA (Patient experience platform) has been rolled out across the health board. The posters for the QR codes will be in place across the radiology departments from January 2022. Feedback from this system will be received on a regular basis and shared via quality meetings Staff can feedback via a number of routes either directly with in radiology or via the confidential health board systems Feedback to staff is via the department briefing and the Newsletter, audit days and Quality and experience meetings. Improvements made will be fed back to patients via posters in the departments and via reports to the Patient & Carer experience committee)	Head of Quality & Governance	31st January 2022 Continuous Continuous
Delivery of safe and effective care				

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer must ensure that the: • Pregnancy checks are carried out for every individual of childbearing potential where relevant and the record of this check is documented • Age range of patients who should be asked about pregnancy is included in the flowchart as described in the relevant employer's procedure • Non-medical imaging employer's procedure is update to in line with current examinations being provided • Record of pregnancy checks carried out on carers and comforters is recorded in the relevant book in the examination rooms.	IR(ME)R 2017 Regulation 6 (8) Schedule 2 1(c) IR(ME)R 2017 Schedule 2 1(m) IR(ME)R 2017 Regulation 12 (5) Schedule 2 1(c) (n)	Radiology improvement notice circulated immediately following the inspection and staff reminded via briefings and huddles. Monthly snap shot assurance audits introduced Flowchart amended to include age range Procedure up dated to reflect current guidance Holding document amended to include a column on pregnancy check being carried out for comforters and carers.	Head of Quality & Governance Radiology Head of Quality & Governance Radiology Head of Quality & Governance Radiology MPE/Professional Service Manager Radiography Head of Quality & Governance	Completed 4th Nov 2021 Continuous Completed Dec 2021 5th Feb 2022 5th Feb 2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer must ensure that all induction and training records are completed in full, with signatures and dates to show the training has been completed.	IR(ME)R 2017 Regulation 6 (3) (b) Regulation 17 Schedule 3 1	Radiology Service Managers and Clinical leads reminded of the need to ensure that all induction and training records are signed off and dated once completed prior to entitlements being issued. Assurance of compliance will be done as part of the IR(ME)R annual audit process	Professional Service Manger Radiography	Continuous
The employer must ensure that the authorisation guidelines have an identifiable practitioner named.	IR(ME)R 2017 Regulation 6(1) Regulation 11 (1) (c) Regulation 11(5)	Delegated authorisation procedures updated to clearly indicate who the IR(ME)R practitioner is	Professional Service Manager Radiography	Completed November 2021
Quality of management and leadership				
The employer must ensure that: • The employer's procedure relating to dealing with accidental or unintended exposures gives clear guidance on who would establish when an incident is deemed clinically significant	Governance, Leadership and Accountability IR(ME)R 2017 Regulation 8 (1) Schedule 2 (1) (l)	Procedure to be updated to indicate who will establish when an incident is deemed clinically significant.	Head of Quality & Governance Radiology	5th February 2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
• The protocols have the authors name printed on them, in addition to a signature.	IR(ME)R 2017 Regulation 6(4)	Protocol document amended to include date	Radiology Service Manager East	Completed 6th Jan 2022
The health board must ensure that processes are in place: • To allow any member of staff to report any issues of concern internally, as well as to ensure that any concerns raised are appropriately investigated and responded to • To ensure that staff are treated fairly and equally and that any instances of discrimination will not be tolerated and appropriate action taken	7.1 Workforce	All radiology staff complete Equality training as part of mandatory training compliance BCU have the following policies in place to ensure staff are treated fairly and any discrimination is not tolerated: • WP6 (Code of Conduct) • WP8 (Equality and Human Rights Policy) • WP42 (Dealing with Hate incidents Policy) BCU has rolled out the Speak out Safely programme. Promote and raise awareness of the above policies and Speak out Safely portal to radiology staff via:	Professional Service Manager Radiography/Head of Quality & Governance Radiology	February 2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The health board must ensure that arrangements are put in place to reduce the perceived issues with occupational health.		Posters Awareness sessions Section in the radiology newsletter There is an advice line available for needle stick injuries 5 days per week with a 45 minute KPI for providing advice. Out of hours the Emergency Department. Occupational health are recruiting additional staff to support service delivery. There is an advisory service available for staff to self-refer 5 days a week.	Head of Occupational Health	April 2022
The health board must ensure that: • Processes are put in place to ensure that appraisals are completed annually	7.1 Workforce	Radiology Quality & Safety group monitor compliance with appraisals (PADR) on a monthly basis All appraisers to ensure a date is in the diary for the next appraisal (PADR)	Professional Service Manger Radiography	30th March 2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
• The appraisals are completed in full, including identifying training, learning and development.		Training plans are required as part of the appraisal (PADR) process. All Appraisers reminded of the need to ensure training, learning and development needs are identified		

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative

Name (print): Helen Hughes

Job role: Professional Service Manager Radiography

Date: 6th January 2022