

Ionising Radiation (Medical Exposure) Regulations Inspection Report (Announced)

Radiotherapy Department, Velindre
Cancer Centre, Velindre University
NHS Trust

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

Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

Our values

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

- Independent - we are impartial, deciding what work we do and where we do it
- Objective - we are reasoned, fair and evidence driven
- Decisive - we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive - we value and encourage equality and diversity through our work
- Proportionate - we are agile and we carry out our work where it matters most

Our goal

To be a trusted voice which influences and drives improvement in healthcare

Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.



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1. What we did

Full details on how we conduct Ionising Radiation (Medical Exposure) Regulations inspections can be found on our [website](#).

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of the Radiotherapy Department at Velindre Cancer Centre, Velindre University NHS Trust on 10 and 11 May 2023. During our inspection we looked at how the department complied with the Regulations and met the Health and Care Quality Standards.

Our team for the inspection comprised of two HIW Senior Healthcare Inspectors, a HIW Healthcare Inspector and a Specialist Radiation Protection Scientist from the Medical Exposures Group (MEG) of the UK Health Security Agency (UKHSA), who acted in an advisory capacity. The inspection was led by a HIW Senior Healthcare Inspector.

Before the inspection we invited patients or their carers to complete a questionnaire to tell us about their experience of using the service. We also invited staff to complete a questionnaire to tell us their views on working for the service. A total of 42 questionnaires were completed by patients or their carers and 94 were completed by staff. Feedback and some of the comments we received appear throughout the report.

Where present, quotes in this publication may have been translated from their original language.

Note the inspection findings relate to the point in time that the inspection was undertaken.

This (full) report is designed for the setting, and describes all findings relating to the provision of high quality, safe and reliable care that is centred on individual patients.

A summary version of the report, which is designed for members of the public can be found on our [website](#).

2. Summary of inspection

Quality of Patient Experience

Overall summary:

Patients provided positive feedback about their experiences of attending the Radiotherapy Department at the hospital. They also told us they had been involved as much as they had wanted to be in decisions about their treatment.

We found staff were courteous to patients and they made efforts to protect patients' privacy and dignity. We also found care and treatment were provided to patients in a way that protected and promoted their rights.

Information available within the department was generally available in English only. However, the Trust had a website where patients with access could find information in both Welsh and English.

This is what we recommend the service can improve

- The Trust is required to provide HIW with details of the action taken to review the area used for Brachytherapy to determine whether further environmental changes can be made to help promote patients' dignity and privacy.

This is what the service did well:

- Patients provided very positive feedback and comments about the service they had received
- We found all staff interacted with patients in a polite and courteous manner
- Generally, the environment and furnishings in the department were well maintained, providing a pleasant environment for patients.

Delivery of Safe and Effective Care

Overall summary:

We found very good compliance with The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017.

We also found suitable arrangements were in place to provide safe and effective care to patients.

This is what we recommend the service can improve:

- The employer is required to provide HIW with details of the action taken to better reflect the referral guidelines for the range of exposures performed at the department in the joint protocols, taking into account relevant guidance
- The employer is required to provide HIW with details of the action taken to better reflect the governance arrangements for research trials in the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R 2017 in Radiotherapy document
- The employer is required to provide HIW with details of the action taken to show the rationale where a decision is made to delay annual equipment checks.

This is what the service did well:

- The documents provided to HIW as part of the inspection showed a good understanding of the IR(ME)R requirements
- Very good arrangements were described and demonstrated in relation to the management of accidental and unintended medical exposures
- Very good arrangements were described for the optimisation of Computerised Tomography (CT) and Cone Beam Computerised Tomography (CBCT)
- We saw patient choice was promoted around the use of masks and other personal protective equipment (PPE) in relation to COVID-19.

Quality of Management and Leadership

Overall summary:

The Chief Executive of the NHS Trust was the designated employer under IR(ME)R and clear lines of reporting and accountability were described and demonstrated. Interim arrangements were in place for two key management positions.

Staff provided mixed feedback about working for the organisation.

We saw training records in relation to IR(ME)R were complete and comprehensive. However, documentation we reviewed showed that not all the Clinical Oncologists had confirmed they had read the employer's written procedures.

Suitable arrangements were in place for patients and their carers to provide feedback about their experiences. However, feedback from patients showed they did not always know how to make a complaint.

This is what we recommend the service can improve:

- The Trust is required to provide HIW with details of the action taken to address the less favourable staff comments described in this report
- The Trust is required to provide HIW with details of the action taken to recruit to the Clinical Lead, Professional Lead, Radiotherapy Services Manager and Deputy positions
- The employer is required to provide HIW with details of the action taken to show Clinical Oncologists have read the employer's written procedures
- The Trust is required to provide HIW with details of the action taken to improve staff awareness of the system for seeking patient feedback
- The Trust is required to provide HIW with details of the action taken to improve the amount of information displayed or available, so patients know how to make a complaint and are aware of other organisations they may contact for help and advice.

This is what the service did well:

- The management team demonstrated a commitment to learn from HIW's inspection findings and make improvements where needed
- The staff team was committed to providing a good service and were patient focussed
- There was good staff compliance with mandatory training and training records in relation to IR(ME)R were complete and comprehensive.

Details of the concerns for patient's safety and the immediate improvements and remedial action required are provided in [Appendix B](#).

3. What we found

Quality of Patient Experience

Patient Feedback

Responses received through HIW questionnaires were positive across all areas considered, with all respondents (42/42) rating the service as ‘very good’ or ‘good’.

Patient comments included the following:

“Staff are welcoming, cheerful and reassuring. Staff are patient and kind. The setting is pleasant and user-friendly.”

“First rate care and support in every aspect. A credit to the NHS.”

“All staff (including the ladies on reception) foster an atmosphere in which patients (often new to treatment or distressed because of their situation) are put at ease and reassured. This encourages patients to speak to each other, offer encouraging advice etc.

Every act of patience or kindness has a beneficial effect somewhere along the line. Commendable.”

We asked what could be done to improve the service. Comments included the following:

“Where the treatment takes place is very dull not painted nicely like the corridors or toilets etc. The radiotherapy rooms are very yellow and run down in colour which makes the experience a little dull at times.”

“...THE GOWNS. These are ridiculously ill fitting. I have been resigned to wearing a vest top, which is indeed far easier. The majority of them are far too small.”

“It would be useful to understand in more detail how the treatment works, more detail about side effects and post treatment care. The telephone review process is ok but would have preferred a face-to-face meeting. Delays to treatment are not really explained and this affects pre-treatment preparation.”

Person Centred

Health Promotion

We saw a variety of leaflets were displayed in the main waiting rooms for patients and their carers. These provided written information about the different types of cancer and cancer treatments. They also provided information on the support available.

Information for patients and their carers, including what to expect when they attended the Radiotherapy Department, was also available on the Trust's website. The website also included links to the websites and contact details of other organisations who produce their own information leaflets and who can provide help and support for persons affected by cancer.

Dignified and Respectful Care

During our inspection, we found staff were courteous to patients and they made efforts to protect patients' privacy and dignity.

Sub waiting areas were located near the treatment rooms, which provided a greater level of privacy away from the main waiting room. Individual changing rooms were available, providing privacy when patients were required to change out of their clothes for their treatment. We also saw doors to rooms where treatment was performed were closed when being used.

Generally, the environment helped promote patient privacy and dignity. However, the area used for Brachytherapy presented significant challenges for staff in this regard. Staff used privacy screens and were mindful when scheduling appointments to help mitigate these.

The Trust is required to provide HIW with details of the action taken to review the area used for Brachytherapy to determine whether further environmental changes can be made to help promote patients' dignity and privacy.

All respondents who completed a HIW patient questionnaire (42/42) told us staff had treated them with dignity and respect. In addition, the majority of respondents who answered the question (39/41) felt measures had been taken to protect their privacy and dignity. The majority of respondents (38/42) also told us they were able to speak to staff without being overheard by other patients.

The majority of staff who answered the question in the HIW questionnaire (82/93) told us patients' privacy and dignity are maintained in the department

We saw there was no designated waiting area in use for children visiting the department. We were told children were not often treated at the department. However, when children did receive treatment, we were told arrangements would be made to use a designated treatment room, and there was a paediatric team available to offer appropriate support and play therapy.

Individualised Care

The majority of respondents (39/42) who answered a HIW patient questionnaire told us they had been given information on how to care for themselves following their treatment. All respondents who answered the question (41/41) also told us they had been given written information on who to contact for advice about any after effects following their treatment.

The majority of respondents who completed a HIW patient questionnaire (41/42) told us they had been involved as much as they had wanted to be in decisions about their treatment.

The majority of staff who answered the question in the HIW questionnaire (91/93) told us patients are involved in decisions about their care. The majority of staff who completed a questionnaire (74/94) told us they were satisfied with the quality of care and support they give to patients. However, the remainder (20/94) disagreed with this.

All respondents who completed a HIW patient questionnaire (42/42) told us staff had explained what they were doing, had listened to them and answered their questions.

Timely

Timely Care

Staff told us when unexpected delays were experienced these would be communicated to patients on the day of their appointments. We were told patients would be informed verbally by reception staff. We also saw a large screen monitor in the waiting area was used to inform patients of any delays.

The majority of respondents who completed a HIW patient questionnaire (41/42) told us they thought the wait between referral and their appointment was reasonable. In addition, the majority of respondents (39/42) also told us when at the department, they were told how long they would likely have to wait to be seen.

Staff described suitable arrangements to provide emergency on-call radiotherapy treatments during weekends and public holidays.

Equitable

Communication and Language

We saw bilingual signage, in both Welsh and English, displayed within the department. There were also symbols displayed to inform patients they may converse with staff in Welsh and we also saw some staff wearing lanyards to show patients they were Welsh speakers.

Information for patients was available on the Trust's website in both Welsh and English. However, written patient information leaflets available in the department were, generally, available in English only. This meant some patients may not have been able to access this information in their preferred language.

The Trust is required to provide HIW with details of the action taken to make patient information leaflets in the department available in Welsh and other languages taking into consideration the needs of the patient population.

Posters were displayed advising patients who are or might be pregnant to inform staff prior to them receiving their treatment. This information was provided in multiple languages.

Staff we spoke to told us they could access a translation service, if required, to assist communication with patients whose first language is not English.

All respondents who completed a HIW patient questionnaire told us their preferred language is English.

The majority of staff who completed the question in the HIW questionnaire told us they were not a Welsh speaker (29/86). Under half of the staff who told us they did speak Welsh (3/7) told us they wore a badge or lanyard to show patients they could speak Welsh. Responses in the HIW questionnaire showed patients were not always asked to state their preferred language, with most telling us patients were either asked sometimes (4/7) or not asked (2/7). This meant patients may not have always been able to speak to staff in their preferred language.

The Trust is required to provide HIW with details of the action taken to encourage those staff who are Welsh speaking to wear a suitable badge or lanyard to show patients they are happy to converse in Welsh and the action taken to consistently ask patients to confirm their preferred language.

Rights and Equality

We found care and treatment at the department was provided in a way that protected and promoted patients' rights.

We were told Equality, Diversity and Human Rights training formed part of the Trust's mandatory staff training programme. Data provided to HIW showed good staff compliance with such training.

The majority of respondents who completed the question (34/41) in the HIW patient questionnaire told us they felt they could access the right healthcare at the right time. The remaining respondents either told us they could not (6/41) or preferred not to say (1/41).

All respondents who completed a questionnaire (42/42) told us they had not faced discrimination when accessing the radiotherapy service.

The majority of staff who answered the questions in the questionnaire told us the workplace was supportive of equality and diversity (77/85), that staff have fair and equal access to workplace opportunities (69/84) and had not faced discrimination at work (78/83). However, there were staff who disagreed with these or preferred not to say.

Delivery of Safe and Effective Care

Compliance with The Ionising Radiation (Medical Exposure) Regulations 2017

Employer's Duties: Establishment of General Procedures, Protocols and Quality Assurance Programmes

Procedures and Protocols

The employer had established written procedures and protocols as required under IR(ME)R 2017. These demonstrated a clear understanding of IR(ME)R.

We recommended consideration be given to the rationalisation of the written procedures and systems used to manage documentation to avoid unnecessary duplication across the documents and to streamline the suite of documents used within the department.

Suitable arrangements were described for the quality assurance of written procedures and protocols used in the department. These arrangements included a process for developing and reviewing written documents, an agreed frequency for review and a system for communicating changes to relevant staff. The employer had suitable written procedures in this regard.

The sample of written procedures and protocols we reviewed demonstrated the above arrangements, and their status was clear. However, we identified two Trust wide documents had passed their review dates. We highlighted this to senior staff, who agreed to check whether these were still needed given the other written procedures in place. This was dealt with before the end of the inspection.

Referral Guidelines

The employer had established referral guidelines and suitable arrangements were described for making these available to individuals entitled as referrers.

However, we felt the range of exposures performed at the department could be better reflected in the joint clinical protocols. We recommended these documents be revised and consideration be given to the guidance set out in the Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy, Guidance from the Radiotherapy Board¹.

¹ <https://www.rcr.ac.uk/sites/default/files/guidance-on-irmer-implications-for-clinical-practice-in-radiotherapy.pdf>

The employer is required to provide HIW with details of the action taken to better reflect the referral guidelines for the range of exposures performed at the department in the joint protocols, taking into account relevant guidance.

We also recommended reference could be made to the referral guidelines being included in the joint clinical protocols under the section 'Referral' in the overarching document, specific to radiotherapy, describing how the department implements the requirements under IR(ME)R 2017².

Diagnostic Reference Levels

Diagnostic reference levels are not a requirement of radiotherapeutic exposures.

Medical Research

We were told the department participated in research involving medical exposures. The arrangements for this were set out in an overarching document.

The completed self-assessment form described suitable governance arrangements for research trials, the process for managing for research exposures and the measures in place to ensure adherence to dose constraints. However, we felt these could be better reflected in the overarching document.

We recommended the document be revised and consideration be given to the guidance set out in the 'Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy, Guidance from the Radiotherapy Board'.

The employer is required to provide HIW with details of the action taken better reflect the governance arrangements for research trials in the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 in Radiotherapy document.

The employer may also wish to develop specific written employer's procedures in this regard to supplement the overarching document.

Entitlement

There was a suitable employer's written procedure to identify individuals entitled to act as referrer, practitioner, or operator within a specified scope of practice. This clearly described the task of entitlement was delegated to the Medical Director who in turn delegated authority to departmental managers or service leads.

² Velindre NHS Trust - Ionising Radiation (Medical Exposure) Regulations (IR(ME)R 2017 in Radiotherapy

Entitlement was also referenced within the overarching document, specific to radiotherapy.

The entitlement of Clinical Oncologists was well described in the self-assessment form and evidenced at site during inspection. However, we felt this practice could be better reflected in the local employer's procedures.

The employer is required to provide HIW with details of the action taken to better reflect the entitlement of Clinical Oncologists in the local employer's written procedures.

We saw entitlement was recorded on a matrix document. This clearly set out each individual's entitlement.

Patient Identification

There was a suitable employer's written procedure in place to correctly identify the individual to be exposed to ionising radiation.

The employer's written procedure clearly addressed those situations where more than one operator was involved in the exposure and where the individual may not be able to identify themselves fully.

We reviewed the referral and treatment documentation for two patients. These had evidence of staff completing the identity check in accordance with the employer's procedure.

Staff we spoke with had a clear understanding of the patient identification procedure.

We identified there was also a Trust wide patient identification policy (Green 68), which had passed its review date. We highlighted this to senior staff, who agreed to check whether this policy was still needed given the other written procedure was in place. This was dealt with before the end of the inspection.

Individuals of Childbearing Potential (Pregnancy Enquiries)

There was a suitable employer's written procedure in place for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding.

Language used within the written procedure considered the diversity of the gender spectrum in the population. In addition, the written procedure included reference

to the Inclusive pregnancy status guidelines for ionising radiation: Diagnostic and therapeutic exposures³.

The employer's written procedure clearly addressed the situation where the individual may not be able to respond to the pregnancy enquiry.

The sample of referral and treatment documentation we reviewed evidenced operators had made enquiries regarding the pregnancy status of individuals in accordance with the employer's written procedure.

Staff we spoke to were able to describe the action they would take to make pregnancy enquires of individuals. This was consistent with the employer's written procedure.

Benefits and Risks

Suitable arrangements were described for providing patients with adequate information on the benefits of having the exposure and the risks associated with the radiation dose. We were told this information was provided to patients during discussions as part of the consent to treatment process.

Written information leaflets were also provided to patients to help support these discussions and a copy of the written consent form was also available for patients.

All respondents who completed a HIW patient questionnaire (42/42) told us they had been given enough information to understand the risks and benefits of their treatment.

Clinical Evaluation

There were suitable employer's written procedures for the evaluation of each exposure performed at the radiotherapy planning, verification, and treatment stages of the patient's care pathway.

We identified there was a Trust wide policy for providing a clinical evaluation of a medical exposure (Green 48), which had passed its review date. We highlighted this to senior staff, who agreed to check whether this policy was still needed given the other written procedures were in place. This was dealt with before the end of the inspection.

³ https://www.sor.org/getmedia/1d256f96-40cb-4eeb-b120-90fe27daf7e9/Inclusive-Pregnancy-Status-Guidelines-for-Ionising-Radiation_LLv2

Non-medical Imaging Exposures

The employer's written procedures clearly stated non-medical imaging exposures were not performed at the department.

Employer's Duties - Clinical Audit

We were told there was a department within Velindre Cancer Centre specialising in clinical audit.

We were provided with examples of clinical audits that had been carried out and we saw a multidisciplinary approach had been used. We identified this as noteworthy practice. A programme for clinical audit was in place.

When asked how the outcomes of the clinical audit have influenced or changed practice, we were provided with a positive example in relation to stereotactic ablative body radiotherapy (SABR) treatment for oligometastatic prostate.

Employer's Duties - Accidental or Unintended exposures

There was a suitable employer's written procedure in place for the reporting, recording, investigating and the analysis of significant accidental or unintended exposures involving radiation. This clearly described individuals' roles and responsibilities and the thresholds for when such incidents were required to be reported. The arrangements for informing the referrer, practitioner and the patient were also well described in the written procedure.

We identified noteworthy practice in relation to the management of accidental and unintended exposures. This extended to the study of risk of accidental or unintended exposures.

The majority of staff who answered the questions in the HIW questionnaire told us their organisation encourages them to report errors, near misses and incidents (86/87), treats staff who are involved in incidents fairly (68/85), takes action to ensure they do not happen again (76/87) and gives feedback to staff about changes made in response to incidents (73/87).

Duties of Practitioner, Operator and Referrer

Staff we spoke with demonstrated a good understanding of their duty holder roles and responsibilities under IR(ME)R 2017. However, documentation we reviewed showed that not all the Clinical Oncologists had confirmed they had read the employer's written procedures. This meant we could not be fully assured this group of staff were aware of the correct employer's written procedures they needed to follow.

The employer is required to provide HIW with details of the action taken to show Clinical Oncologists have read the employer's written procedures relevant to their roles.

The employer had suitable written procedures in place for managing referrals to the department. Senior staff also described a suitable process for making referrals to the department. Suitable processes were also described for prioritising and cancelling referrals.

We saw an electronic referral system was in place and this included mandatory fields for completion, which ensured referral documentation was complete before being received by the department.

We reviewed the referral records for two patients and saw these had been completed fully and in accordance with the established referral guidelines. Senior staff described suitable arrangements for conducting IR(ME)R audits and shared three examples demonstrating the audit process.

Justification of Individual Exposures

Suitable arrangements were described for the justification and authorisation of each exposure performed at the radiotherapy planning and re-planning, verification, and treatment stages of the patient's care pathway. There was also a suitable employer's written procedure and protocols in place in relation to justification.

The sample of referral documentation we reviewed had evidence of the exposure having been justified by the practitioner, demonstrated by them signing the form.

Optimisation

A suitable employer's written procedure and protocols were in place in relation to the optimisation of exposures performed for treatment planning, positional verification for radiotherapy treatment and monitoring purposes. These included optimising exposures to children, exposures involving high doses, and to individuals in whom pregnancy cannot be excluded.

We identified noteworthy practice in relation the optimisation of exposures from CT and CBCT scans. The department had applied national dose reference levels to their CT scanning protocols and had developed local dose reference levels for commonly used CBCT scanning protocols.

Suitable arrangements were described to involve a Medical Physics Expert (MPE) in the optimisation of exposures.

Paediatrics

Suitable arrangements were described for the treatment of paediatric patients. We were told specific written protocols were in place for the treatment of children. We were told treatment plans would be discussed with the Clinical Oncologist at the treatment planning stage.

Carers or Comforters

The local rules included a statement to reflect carers or comforters are not allowed to remain with patients during any medical exposures. This should be included in the employer's procedures.

The employer is required to provide HIW with details of the action taken to revise the employer's written procedures to show carers or comforters are not allowed to remain with patients during any medical exposure.

Expert Advice

We confirmed the employer had appointed and entitled MPEs to provide advice on radiation protection matters and compliance with IR(ME)R. Each MPE had a clearly defined scope of practice.

Senior staff described and demonstrated suitable arrangements for the MPEs to be involved in, and provide advice on, medical exposures performed at the department.

Equipment: General Duties of the Employer

The employer had a quality assurance programme in respect of the equipment used in the department. We saw quality assurance procedures included the treatment planning and the operation management systems. We identified this as noteworthy practice.

We reviewed the quality assurance schedule for the equipment, and we saw this was generally up to date. However, we saw the annual checks for two pieces of equipment had not been recorded on the electronic record system. Staff confirmed these checks had been completed but the system had not been updated. In addition, the record did not show the rationale for the decision made to safely delay checks to ensure continuity of the radiotherapy service.

The employer is required to provide HIW with details of the action taken to update the electronic system in a timely manner when equipment checks have been completed and to show the rationale where a decision is made to delay annual equipment checks.

We confirmed the employer had suitable arrangements in place to improve inadequate or defective equipment. This involved processes for identifying,

reporting and escalating equipment faults to senior staff and taking corrective action, including removing equipment from service.

A suitable process was described for the assessment of patient dose following each exposure performed at the radiotherapy planning, verification, and treatment stages of the patient's care pathway.

An up-to-date equipment inventory was available, and this contained the information required under IR(ME)R 2017.

Safe

Risk Management

Generally, the environment appeared well maintained and in a good state of repair. However, we saw some areas of the floor in corridors was visibly damaged or worn. This may present a trip hazard.

The Trust is required to provide HIW with details of the action taken to repair or replace areas of the floor which are visibly worn and presenting a hazard.

We did not identify any other obvious hazards to the health and safety of staff working in the department or to patients and other individuals visiting the department.

Most staff who answered the question in the HIW questionnaire (64/93) told us they were content with the efforts made by their organisation to keep them and patients safe.

The department was signposted from the main entrance of the hospital, and we found the signs generally easy to follow. A second designated entrance to the department was also signposted. The department was located on the ground floor making it accessible to patients using both the hospital's main entrance and the department's entrance.

The majority of respondents who completed a questionnaire (39/42) told us they were able to find the department easily. However, some (3/42) told us they were not able to find it easily.

We saw waiting areas were of a suitable size, and sufficient seating was provided for the numbers of patients attending the department. We also saw chairs of various heights, some with armrests, were available. We identified this as noteworthy practice as it meant these may provide a higher level of comfort to patients and also

make it easier for patients with mobility impairments to sit down and get up from a seated position more easily.

We saw signage clearly displayed to alert patients and visitors not to enter controlled areas when radiotherapy treatment was being given.

Infection Prevention and Control (IPC) and Decontamination

All areas of the department we saw were visibly clean and tidy and the equipment we saw was also clean.

Suitable handwashing and drying facilities were available and hand sanitising stations were located throughout the department. Personal protective equipment (PPE) was readily available for staff to use.

At the time of our inspection, we were told general precautions, previously in place to reduce the spread of COVID-19, were no longer mandatory and had been removed. However, we were told face masks were available to both staff and patients who wished to continue wearing them according to their needs and preference. We saw these were readily available, together with hand sanitiser, at the main entrance of the department. We were also told that staff would still be required to take precautions to reduce the spread of COVID-19 and other infections when treating patients with suspected infections or patients susceptible to infections.

The majority of respondents who completed a HIW patient questionnaire (35/42) told us they felt infection prevention and control measures, such as staff wearing masks and staff washing hands, were being followed. The remaining respondents told us either measures were sometimes/partially being followed (6/42) or they were not being followed (1/42). Similar responses were received regarding the cleanliness of the department. The majority of respondents (35/42) felt the department was very clean, with the remainder feeling the department was fairly clean (6/42) or not very clean (1/32).

The majority of staff who completed the questions in the HIW questionnaire told us their organisation implements and effective infection control policy (81/86), there is an effective cleaning schedule in place (73/87), appropriate PPE is supplied and used (85/86) and the environment allows for effective infection control (76/87).

We were told Infection Prevention and Control training formed part of the Trust's mandatory staff training programme. Data provided to HIW showed very good staff compliance with this training.

Safeguarding of Children and Safeguarding Adults

Staff we spoke to were aware of the Trust's safeguarding policies and procedures and where to access these. Staff were also able to describe the actions they would take should they have a safeguarding concern.

We were told Safeguarding training formed part of the Trust's mandatory staff training programme. Data provided to HIW showed good staff compliance with this training.

The majority of staff who answered the questions in the HIW questionnaire (81/87) told us they would know how to report a concern about unsafe practice and would feel secure in doing so (66/87). However, responses were more mixed when asked whether they felt confident the organisation would address the concerns, with just under half (40/87) telling us they were and the remainder either telling us they were not (27/87) or they didn't know (20/87).

The Trust is required to provide HIW with details of the action taken to assure staff that when they report concerns about unsafe practice, the organisation will address these.

Effective

Record Keeping

The sample of referral and treatment records we reviewed had a clear layout and had been completed in full.

The records showed evidence of the employer's written procedures being followed by staff, such as those in relation to patient identification checks and confirmation of pregnancy status.

Efficient

Efficient

Senior staff described patient care pathways were kept under continuous review as part of the service improvement and efficiency process.

We were also told work was ongoing to refine the number of planning and treatment vendor systems in use, so as to improve the consistency of approach and efficiency of the service.

At the time of our inspection, work was progressing with a new radiotherapy department as part of the development of cancer services in South East Wales. We were told this provided an opportunity to improve efficiency in delivering the

radiotherapy service. Some staff we spoke with also told us how they had been involved in the planning and decision making for the new department.

Quality of Management and Leadership

Staff Feedback

Responses received through HIW questionnaires were mixed. While over half the staff would recommend their organisation as a place to work, few staff felt there were sufficient staff for them to do their job properly.

The Trust is required to provide HIW with details of the action taken to address the less favourable staff comments described in this report.

Staff comments included the following:

“We do manage well as a team regardless of the time pressures, workload and staff shortages. But each week the stress of work is increasing due to the number of patients, reduced staff and not enough scanners.”

“At this point in time staff morale is at an all time low, and many staff are reaching the point of burnout. Staff are under incredible stress, pressure and worry as there are huge capacity issues in conjunction with staffing issues. Staff do not feel supported at this time and are being worked to breaking point in order to meet patient demands. Staff are on a regular basis working overtime to treat patients due to delays throughout the day, causing increased tiredness and stress for staff. This is also having huge impacts on staffs' work/life balance...”

“Staff really care about the service they provide for patients and always try to go above and beyond - this is evidenced in the feedback patients give us verbally about their treatment and care.”

“I think leadership/management for our med phys department is very strong. Managers are approachable, easy to communicate with and are fair in decisions they make. I enjoy working here and feel like I'm supported well to do my job. That being said, I do think our department is over-worked and I think this increases staff stress and could cause risks/delays to patient treatment...”

“Staff are made to feel unappreciated. Whenever change is required e.g. extending working days due to capacity, it is suggested staff are involved but ultimately never listened too - management make decisions without caring and there is no empathy or thought to the effect it has on staff...”

“It often feels that the organisation's primary focus is reaching targets and numbers of patients without considering the impact on patient care as pushing capacity is resulting in poor patient experience due to long waiting times and machine breakdowns.”

Leadership

Governance and Leadership

The Chief Executive of the NHS Trust was the designated employer under IR(ME)R. They had overall responsibility for ensuring the regulations are complied with. Where appropriate the employer had delegated tasks to other professionals working in the Trust to implement IR(ME)R.

Senior staff submitted details of the organisational structure. Clear lines of reporting and responsibilities under IR(ME)R were described and demonstrated.

The self-assessment form completed by the department ahead of the inspection was submitted within the agreed timescale and was comprehensive. All staff engaged fully with the inspection process and managers demonstrated a commitment to acting on HIW's inspection findings, making improvements where needed.

The organisational structure included a Clinical Lead and a Professional Lead, however, we were told these positions were vacant at the time of our inspection. In addition, interim arrangements were in place for the Radiotherapy Services Manager and their Deputy.

The Trust is required to provide HIW with details of the action taken to recruit to Clinical Lead, Professional Lead, Radiotherapy Services Manager and Deputy positions.

Senior staff described the arrangements in place to monitor the quality and safety of services provided in the department and to provide assurance to the Trust as part of the governance and monitoring arrangements.

Over half of the staff who answered the question in the HIW questionnaire (55/93) told us they would recommend their organisation as a good place to work. The remainder of staff told us they would not. Most staff who answered the question (57/93) told us their organisation was supportive, with the remainder (36/93) disagreeing with this.

Responses were mixed regarding the organisation supporting staff to identify and solve problems, with around half of staff who answered the question (47/93) agreeing with this and the remainder disagreeing. Most staff (59/92) who answered the question told us they did not agree their organisation takes swift action to improve with few staff (33/92) agreeing.

The majority of staff who answered the question in the HIW questionnaire (74/93) told us the care of patients is their organisation's top priority, with the remainder disagreeing (19/93) with this.

When asked about their immediate manager, most staff who answered the question in the HIW questionnaire (61/89) told us their immediate manager could be counted upon to help them with a difficult task in work, with the remainder disagreeing with this. Over half who answered the question (53/89) told us their manager gave them clear feedback about their work. However, the remainder disagreed. Less than half who answered the question (43/89) told us their manager asks for their opinion before making decisions that affect their work, with the remainder (46/89) disagreeing.

When asked about senior managers, over half the staff who answered the question (49/89) felt they were visible. Most staff (63/88) also told us senior managers were committed to patient care. However, few staff (33/88) felt communication between senior management and staff was effective.

Workforce

Skilled and Enabled Workforce

A range of staff worked in or on behalf of the department and included Clinical Oncologists, Clinical Oncology Registrars, Consultant/Advanced Practice Radiographers, Radiographers, MPEs, Clinical Scientists, Dosimetrists and Clinical Technical Officers. The department also provided clinical placements for Radiotherapy and Radiotherapy Physics students.

It was evident the staff team was committed to providing a good service and were patient focussed.

Senior staff reported there were some long term vacancies at the time of the inspection in relation to Radiotherapy and Physics staff, which would need to be recruited to meet recommendations made by relevant professional bodies.

Most staff who answered the question in the HIW questionnaire told us there were not enough staff for them to do their job properly (61/93), with just over half feeling they were able to meet the conflicting demands on their time at work (49/94). While most staff who answered the question in the HIW questionnaire told us their job was not detrimental to their health (56/88), there were some who disagreed (32/88). Similar responses were received regarding being able to achieve a good work life balance and the organisation taking positive action on staff health and wellbeing. The majority of staff were aware of the Occupational Health support available to them (66/88).

Most staff who answered the questions in the HIW questionnaire told us they had adequate materials, supplies and equipment to do their job (62/94) and they were able to access ICT systems they needed (68/93).

We reviewed the training records in relation to IR(ME)R for three staff. These demonstrated staff had completed suitable training relevant to their duty holder roles as practitioner and operator, and relevant to their specific area of practice. The records showed clear evidence of assessing competence, evidence of entitlement and their scope of practice. We also found there was a suitable system to identify when reviews had taken place to take account of an individual's change in scope of practice or before they used new equipment.

We saw a new approach was used for recording MPE training in relation to Brachytherapy. These clearly set out individuals' scope of practice, and consideration should be given to using this approach for other teams.

We also reviewed data showing staff compliance with the Trust's mandatory training programme. Staff were expected to complete training on a range of topics relevant to their role. The data showed a good level of staff compliance with mandatory training.

The majority of staff who completed a HIW questionnaire told us they felt they had appropriate training to perform their role (74/94). The remainder either answered with 'partially' (18/94) or told us they had not had appropriate training (2/94). When asked what other training they would find useful, staff comments included:

"My role specific training has been excellent and equips me appropriately. However, I would like some more quality improvement, project planning and leadership training to allow me to progress further."

"Future training in IRMER forms for role."

"Local training around managing machine delays/patient comfort available."

"Updated imaging problem solving training, training towards service improvement to ensure best quality treatment and techniques for patients."

Other comments also included:

"The new IT changes (DHCR and all tasks within that) would have benefited from better training - we've had to have additional training after their introduction. We also now have Raystation - I have had no training on that at all."

“It would be useful to have time offset to undertake training. However, due to staff shortages and huge capacity issues it is currently impossible to be released to undertake any training, CPD or keeping up to date with mandatory training requirements.”

“More time for training as a team would be helpful.”

The data provided to us also showed the majority of staff had received an appraisal of their work within the last 12 months. The majority of staff who completed a HIW questionnaire (82/94) also told us they had an appraisal of their work.

Culture

People Engagement, Feedback and Learning

We saw posters with a QR code prominently displayed in the department. These allowed patients with suitable mobile devices, such as mobile phones with cameras, to provide feedback or make a complaint. We also saw an electronic tablet was available in the main waiting area for patients to use to provide feedback. There was no information displayed on other organisations patients can contact for help and advice on making a complaint. However, we were told this was available on request.

When asked whether they would know how to complain, 50% of respondents who completed a questionnaire (21/42) told us they would and 50% told us they would not.

The Trust is required to provide HIW with details of the action taken to improve the amount of information displayed or available, so patients know how to make a complaint and are aware of other organisations they may contact for help and advice.

A ‘You Said, We Did’ notice board was in the main waiting area. While the intention is for this board to show patients and visitors the feedback received and the action taken by the department in response, we felt information in this regard was limited.

The Trust is required to provide HIW with details of each action taken to improve the information available on how the department has acted on patient feedback received.

When asked whether patient experience feedback is collected within the department, most staff who answered this question in the HIW questionnaire (68/92) told us it was. The remainder either told us it was not (2/92) or they did not

know (22/92). **The Trust is required to provide HIW with details of the action taken to improve staff awareness of the system for seeking patient feedback.**

When asked whether they receive regular updates on patient feedback, most staff who answered the question told us they did (59/92).

Senior staff were aware of the Duty of Candour and described changes had been made to incident reporting forms to reflect the Duty requirements. We were told engagement sessions for staff had been delivered and training had recently been introduced. We were also told resources for staff were available on the Trust's intranet.

Generally, staff we spoke to were aware of the Duty of Candour and confirmed they had received information on its implementation.

The majority of staff who answered the questions in the HIW questionnaire told us they understood the Duty of Candour (77/81), they understood their role in meeting the associated standards (73/79) and their organisation encouraged them to raise concerns and share this with the patient (72/81). The remainder disagreed.

4. Next steps

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.

The improvement plans should:

- Clearly state how the findings identified will be addressed
- 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
- Ensure required evidence against stated actions is provided to HIW within three months of the inspection.

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.

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 plan

Service: Radiotherapy Department, Velindre Cancer Centre

Date of inspection: 10 and 11 May 2023

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.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
No immediate improvement plan required.				

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

Service: Radiotherapy Department, Velindre Cancer Centre

Date of inspection: 10 and 11 May 2023

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
The Trust is required to provide HIW with details of the action taken to review the area used for Brachytherapy to determine whether further environmental changes can be made to help promote patients' dignity and privacy.	Standard - Person Centred	Environmental review already completed and determined Swipe access door controls required	Infrastructure and Design Manager	31 st October 2023
		Door replacements being installed within 4-6 weeks.	Infrastructure and Design Manager	31 st October 2023
		Access control permissions to be developed into a Standard Operating Procedure (SOP).	Infrastructure and Design Manager	31 st October 2023
		Communication of revised access control permission to staff in Velindre Cancer Centre.	Infrastructure and Design Manager	31 st October 2023

<p>The Trust is required to provide HIW with details of the action taken to make patient information leaflets in the department available in Welsh and other languages taking into consideration the needs of the patient population.</p>	<p>Standard - Equitable</p>	<p>Trust Radiotherapy Team are working with Wales Cancer Network (WCN) and the other Wales Radiotherapy centres to review current patient information leaflets in use with the view to reduce duplication, have consistency and to ensure availability in English, Welsh and other core languages aligned to the needs of the patient population.</p> <p>Gap analysis of information leaflets currently in use and available is underway.</p>	<p>Radiotherapy Service Manager</p>	<p>Meeting arranged for September 2023 with Wales Cancer Network to review patient population requirements.</p> <p>31st January 2024 revised information to be available in language requirements identified</p>
<p>The Trust is required to provide HIW with details of the action taken to:</p> <ul style="list-style-type: none"> encourage those staff who are Welsh speaking to wear a suitable badge or lanyard to show patients they are happy to converse in Welsh 	<p>Standard - Equitable</p>	<p>Lanyards are not permitted within clinical areas due to infection risks.</p> <p>Corporate communications to release periodic update reminders to all staff to wear laith gwaith badge if Welsh Speaking and able to converse in Welsh or Welsh learner badge if learning to speak Welsh.</p>	<p>Welsh Language Officer / Corporate Communication team</p>	<p>Initial Communications 31st July 2023</p>

<ul style="list-style-type: none"> to consistently ask patients to confirm their preferred language. 		Uniforms with embroidered laith gwaith logo to be sourced and provided to all Welsh speaking staff.	Radiotherapy Services Manager	31 st January 2024
		Baseline audit to be undertaken to assess current level of information gained on language preference, and detailed actions to target specific aspect of patient pathway to follow. Implement changes based on the audit findings and follow with a review to ensure patients are asked to confirm their preferred language.	Deputy Radiotherapy Service Manager Radiotherapy Oncology Lead	31 st January 2024
		Investigate most appropriate information system location to indicate preferred language.	Deputy Radiotherapy Service Manager Lead Radiotherapy Clinical Oncologist Deputy Head of Radiotherapy Physics	30 th August 2023

<p>The employer is required to provide HIW with details of the action taken to better reflect the referral guidelines for the range of exposures performed at the department in the joint protocols, taking into account relevant guidance.</p>	<p>IR(ME)R - Regulation 6 (5)(a)</p>	<p>Update all joint Clinical protocols and update format more in keeping with template included in Ionising radiation Medical Exposure) Regulations: Implications for clinical practice in radiotherapy. Guidance from the radiotherapy board.</p> <p>Starting with Joint breast protocol in preparation for treatment on Halcyon then each document to be updated at annual review.</p> <p>Each joint Clinical protocols will be updated on rolling monthly update and complete within one year.</p>	<p>Radiotherapy Clinical Governance Manager</p> <p>Deputy Head of Radiotherapy Physics</p>	<p>1st document to be ready for January 2024 document issue</p> <p>All Joint protocols expected will be updated by 31st July 2024</p>
<p>The employer is required to provide HIW with details of the action taken better reflect the governance arrangements for research trials in the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R 2017 in Radiotherapy document.</p>	<p>IR(ME)R - Regulation 11 (1)(d)</p>	<p>Update IR(ME)R in RT document to include governance arrangements for research trials.</p>	<p>Radiotherapy Clinical Governance Manager</p>	<p>30th November 2023</p>

The employer is required to provide HIW with details of the action taken to better reflect the entitlement of Clinical Oncologists in the local employer's written procedures.	IR(ME)R Regulation 6 (1) (a) and Schedule 2 (1)(b)	Update IR(ME)R in RT document to include the entitlement of Clinical Oncologists in the local employer's written procedures.	Radiotherapy Clinical Governance Manager	30 th November 2023
The employer is required to provide HIW with details of the action taken to show Clinical Oncologists have read the employer's written procedures relevant to their roles.	IR(ME)R - Regulation 6 (2)	SOP to be developed to define process for monitoring, follow up and escalation of any non-compliance with the SOP.	Clinical Director / Clinical Oncologist Lead for Radiotherapy	31 st October 2023
		IRMER training to be moved to ESR to provide a more reliable and robust method of monitoring compliance.	Clinical Director / Clinical Oncologist Lead for Radiotherapy	31 st October 2023
The employer is required to provide HIW with details of the action taken to revise the employer's written procedures to show carers or comforters are not allowed to remain with patients during any medical exposure.	IR(ME)R - Regulation 6 (1)(a) Schedule 2 (1)(n)	Update IR(ME)R in RT document by adding a statement to show carers or comforters are not allowed to remain with patients during any medical exposure.	Radiotherapy Clinical Governance Manager	30 th November 2023
The employer is required to provide HIW with details of the		A simplified process is to be established to ensure engineering equipment tasks are	Deputy Head of Radiotherapy Physics	31 st October 2023

action taken to update the electronic system in a timely manner when equipment checks have been completed and to show the rationale where a decision is made to delay annual equipment checks.	IR(ME)R - Regulation 15 (3)	logged within the electronic system in a timely manner. This will include the addition of a simple check box.		
		The machine QA procedure is to be updated to include the process to be followed when a decision is made to rearrange scheduled preventative maintenance and QC. If a decision is made to reschedule a service or Quality Control (QC) review, then the rearranged (QC) or service, will be scheduled for a date as soon as reasonably practicable. This will trigger a concession raised in the Q-Pulse Quality Management System containing the justification for the postponement.	Deputy Head of Radiotherapy Physics	31 st October 2023
The Trust is required to provide HIW with details of the action taken to repair or replace areas of the floor which are visibly worn and presenting a hazard.	Standard - Safe	Estates to review all flooring for any hazards and make safe.	Estates Manager	30 th August 2023

The Trust is required to provide HIW with details of the action taken to assure staff that when they report concerns about unsafe practice, the organisation will address these.	Standard - Safe	Set up a reactive focus group to discuss and address staff concerns when they arise. Safety concerns outside of our control will be escalated and timely responses back to staff.	Radiotherapy Services Manager Clinical Director Head of Radiotherapy Physics	30 th August 2023
		Psychological safety and safe reporting to be included on agendas for all staff meetings.	Radiotherapy Services Manager Clinical Director Head of Radiotherapy Physics	30 th August 2023
		Trust Safe Care Collaborative leadership priority identified as enhancing psychological safety across the Trust. An element of this is to engender a positive reporting culture.	Executive Team	Long term culture change programme commenced in April 2023
The Trust is required to provide HIW with details of the action taken to address the less favourable staff comments described in this report.	Standard - Workforce	All disciplines to review all staff comments on report, consider the different views and identify any associated follow up if not addressed elsewhere in existing work plans.	Radiotherapy Services Manager	30 th August 23

		Set up an MDT group consisting of representation of all three disciplines to address comments, amend processes and discuss feedback to staff. Produce an action plan for immediate commencement of delivery reflecting differences for different staff groups.	Clinical Director Head of Radiotherapy Physics Radiotherapy Services Manager	30 th September 2023
		Address specific actions within own department as appropriate.	Clinical Director Head of Radiotherapy Physics Radiotherapy Services Manager	All outcomes from actions to complete 31st December 23
The Trust is required to provide HIW with details of the action taken to recruit to Clinical Lead, Professional Lead, Radiotherapy Services Manager and Deputy positions.	Standard - Leadership	RSM and DRSM posts undergoing job evaluation for JDs and active recruitment. Finalise the new approach to clinical leadership to update current approach and finalise the approach to ensuring robust professional leadership roles are sufficient and aligned appropriately.	Head of Radiation Service Director of Cancer Service	30 th August 2023 30 th October 2023

The Trust is required to provide HIW with details of the action taken to improve the amount of information displayed or available, so patients know how to make a complaint and are aware of other organisations they may contact for help and advice.	Standard - Culture	Work ongoing with Velindre Quality and Safety Team to improve CIVICA access. Discussions ongoing regarding increasing the size/access of the touch screen terminal in RT reception. Potential second screen in pre-treatment area to promote feedback opportunity.	Radiotherapy Services Manager	30 th October 2023
		Develop and issue updated patient leaflet regarding sharing thoughts, opinions, and concerns.	Deputy Radiotherapy Service Manager	1 st August 2023
		Make leaflet available in all RT pathway patient contact points.	Radiotherapy Clinical Governance Manager	1 st August 2023
		Trust wide how to raise a concern poster to be developed and provided to each department.	Head of Quality & Safety	31 st August 2023
		Review opportunity for poster display across the service for Trust wide how to raise a concern poster and other	Radiotherapy Clinical Governance Manager	30 th August 2023.

		appropriate organisations, particularly Llais.		
The Trust is required to provide HIW with details of the action taken to improve the information available on how the department has acted on patient feedback received.	Standard - Culture	<p>We have reviewed the ‘you said, we did’ notice areas.</p> <p>We will be enlarging the area and developing large display boards and reviewing publications in a range of languages following the assessment of population language distribution.</p>	Radiotherapy Services Manager	30 th September 2023
The Trust is required to provide HIW with details of the action taken to improve staff awareness of the system for seeking patient feedback.	Standard - Culture	Radiotherapy Clinical Governance Manager to work with Information and Support Radiographer and the radiotherapy department Patient support group, to improve staff awareness of the system. This will be shared with staff through targeted information sharing sessions, covering why it is so important and how we collect patient feedback, and how we respond to it.	Radiotherapy Clinical Governance Manager	1 st December 2023

		Issue updated patient leaflet regarding sharing thoughts, opinions, and concerns and share with staff via Radiotherapy weekly update how to access and share this information with patients.	Radiotherapy Clinical Governance Manager	1 st August 2023
		Patient feedback to be discussed at each radiotherapy staff meeting, and shared through departmental meetings and SST leads.	Radiotherapy Service Manager Deputy Radiotherapy Service Manager Clinical Director	30th October 2023

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): Nicola Williams

Job role: Executive Director of Nursing, AHP's & Medical Scientists

Date: 14/07/23