

Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Cardiac Department / Morriston
Hospital / Abertawe Bro
Morgannwg 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 are receiving good care.

Our values

- **Patient-centred:** we place patients, service users and public experience at the heart of what we do
- **Integrity:** we are open and honest in the way we operate
- **Independent:** we act and make objective judgements based on what we see
- **Collaborative:** we build effective partnerships internally and externally
- **Professional:** we act efficiently, effectively and proportionately in our approach.

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 inspection of the Cardiac Department at Morriston Hospital within Abertawe Bro Morgannwg University Health Board on the 12 and 13 September 2017. The following areas were visited during this inspection:

- Cardiac Catheter Laboratories (A, B and C)
- Pacing Room
- Cardiac Short Stay Unit

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

HIW explored how the service:

- Complied with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (and its subsequent amendments 2006 and 2011)
- 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

We found that the Cardiac Department delivered safe and effective care in accordance with the Ionising Radiation (Medical Exposure) Regulations and the Health and Care Standards.

This is what we found the service did well:

- patients told us they were happy with the care they had received
- procedures required under IR(ME)R were up to date, clear and concise
- staff had a good awareness of the risks associated with ionising radiation and their responsibilities in this regard
- staff were committed to providing safe care to patients
- senior staff provided effective management and leadership
- an innovative training programme had been implemented which aimed to promote patient safety.

This is what we recommend the service could improve:

- address the environmental issues within the Cardiac Short Stay Unit to promote patients' dignity.

3. What we found

Background of the service

Abertawe Bro Morgannwg University Health Board was formed on 1st October 2009 as a result of a reorganisation within the NHS in Wales and consists of the former Local Health Boards (LHBs) for Swansea, Neath Port Talbot and Bridgend and also the Abertawe Bro Morgannwg University NHS Trust. The Health Board covers a population of approximately 500,000 people.

The Health Board has four acute hospitals providing a range of services; these are Singleton and Morriston Hospitals in Swansea, Neath Port Talbot Hospital in Port Talbot and the Princess of Wales Hospital in Bridgend. There are a number of smaller community hospitals and primary care resource centres providing clinical services outside of the four main acute hospital settings.

The Cardiac Department at Morriston Hospital performs a range of procedures for adults using specialist X-ray equipment. These include cardiac angiograms¹, cardiac angioplasties², trans catheter aortic valve insertion³, electrophysiology⁴, ablations⁵ and pacing⁶ procedures.

¹ A cardiac angiogram is an examination using ionising radiation (X-rays) to show the patency of cardiac vessels.

² A cardiac angioplasty is a non surgical procedure using ionising radiation (X-rays) to treat narrowing of the vessels of the heart.

³ A trans catheter aortic valve insertion involves the insertion of a new artificial heart valve by use of a catheter and X-ray guidance and so avoiding open heart surgery.

⁴ Electrophysiology is a test which looks at the heart's electrical activity.

⁵ Ablation is a procedure used to destroy small amounts of abnormal heart tissue responsible for heart rhythm problems.

⁶ Pacing refers to the insertion of a pacing wire and pacemaker to treat abnormal heart rhythms

At the time of our inspection 17 consultant cardiologists, nine specialist registrars, six radiographers and three medical physics experts supported the Cardiac Department. No substantive long term vacancies were reported.

Quality of patient experience

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

We saw staff treating patients with dignity, respect, compassion and kindness.

Patients told us they were happy with the care they had received. They also told us that they felt they had been given enough information about their care.

Whilst staff promoted patients' privacy and dignity as far as possible, environmental issues provided some challenges in this regard.

Prior to the inspection, we asked senior staff to distribute HIW questionnaires to patients to obtain their views on the services provided. A total of 20 were completed and returned. We also spoke to a number of patients during the inspection. Patients who completed questionnaires and those we spoke to, had either previously attended, or were attending, the Cardiac Short Stay Unit (CSSU) attached to the cardiac catheter laboratories.

Patient comments included the following:

"This is the second time I have been... and both occasions have been as pleasant as they could make things."

"Very happy with the care I have received."

"Staff are a credit."

"I just think that staffing levels could be increased because when it gets busy, you can see that there is not enough staff..."

Staying healthy

There were a range of patient information leaflets available to patients and their families within the CSSU. These provided information about procedures carried out within the cardiac catheter laboratories and advice on discharge. This

meant that patients had information on how to care for themselves following their procedures and who to contact for further advice.

The employer had a written procedure for the management and follow up of patients who have received a (managed) high dose of radiation. This set out the verbal and written information that needed to be provided to patients before and after the procedure together with the arrangements to inform their GP. This meant that if the patient experienced any after effects following the procedure (usually skin reddening) they would have written information on who to contact for advice. The patient's GP was also kept informed and is therefore able to advise the patient appropriately should he/she present to their surgery. In addition the procedure set out when the patient would need to be followed up by staff in the Cardiac Department for any further investigation and treatment.

Dignified care

We saw staff treating patients with respect dignity, respect, compassion and kindness.

Arrangements were in place to promote patients' privacy and dignity within the cardiac catheter laboratories. Patients were wearing dignity gowns and were not overly exposed during procedures. Screens could be used within the cardiac catheter laboratories to create a private area for patients and their families at particularly sensitive times.

We were told that the CSSU had been intended to provide an environment for patients to remain for relatively short periods of time both before and after their procedures (on a booked admission basis). However, it was evident that the service provided by the Cardiac Department had since developed and expanded to meet the needs of the local and wider population. At the time of our inspection some patients, for example, those transferred from other hospitals now needed to remain on the CSSU for longer. The unit was made up of one mixed gender area with individual trolleys or beds separated by dignity curtains. There was one mixed gender toilet with a hand washing basin and no other washing facilities. This current arrangement provided particular challenges for the staff team to promote patients' privacy and dignity. Senior staff were aware of the challenges this posed and recognised that improvements were needed. Arrangements should be made to improve the environment to promote patients' dignity.

Patient information

As described above, we saw that information leaflets were available to patients and their families. Patients who returned a completed questionnaire and those we spoke to felt they had been given sufficient information about their care.

Timely care

When asked whether they had experienced any delay in having their procedure, comments from patients were mixed. Most patients indicated they had not experienced any delay, whilst some described delays with having their procedure performed. We were unable to establish whether this was due to clinical reasons or service pressures.

Listening and learning from feedback

Within the CSSU we saw information was displayed for patients and their families on how they could provide feedback. Feedback could be provided by completing cards and returning them via a post box on the unit or on line via the health board's website.

We found that a designated team within the health board captured this feedback and provided staff with the results regularly.

Delivery of safe and effective care

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

We found compliance with the Ionising Radiation (Medical Exposure) Regulations.

There were up to date written procedures for medical exposures as required by the regulations and with the aim of delivering safe and effective care to patients.

Staff were clearly committed to providing safe care and had a good awareness of the risks associated with ionising radiation and their responsibilities in this regard.

Compliance with Ionising Radiation (Medical Exposure) Regulations

Duties of employer

Patient identification

The employer had a written procedure to correctly identify the patient to be exposed to ionising radiation. This set out that operators⁷ were responsible for ensuring the correct identification of patients undergoing medical exposures.

The procedure required operators to conduct a three point identification check (to confirm the individual's name, date of birth and address). It also described the alternative procedure operators must follow should patients be unable to confirm their identity verbally or in writing (for example, unconscious patients).

⁷ 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.

Staff we spoke to were aware of the procedure to follow. It was evident that staff placed a strong emphasis on correctly identifying patients to promote patient safety and wellbeing.

Females of child bearing age

The employer had a written procedure for making enquires with regard to pregnancy. This aimed to ensure that enquires were made in an appropriate and consistent manner.

The procedure required operators to make relevant enquires and set out the actions they must follow depending on the individual's responses. The written procedure applied to all women of childbearing age (12 - 55 years) which is in accordance with UK guidance⁸.

Medico-legal exposures

The employer's procedures clearly indicated that medico-legal exposures were not performed within the Cardiac Department.

Medical research

Senior staff confirmed that the Cardiac Department participated in research involving medical exposures. The employer had a written procedure with the aim of promoting patient safety and well being. It set out the arrangements for ensuring research programmes are approved by an ethics committee, the provision of relevant information to patients and restricting any dose of ionising radiation to the minimum required.

The employer's procedure referred to the 'services manager' maintaining a register of approved research studies. Senior staff were receptive to our comments around the need to clearly define which individual to whom this title referred.

⁸ British Institute of Radiology, Society and College of Radiographers and the Royal College of Radiologists. 'A guide to understanding the implications of the Ionising Radiation (Medical Exposure) Regulations in diagnostic and interventional radiology'. London: The Royal College of Radiologists, 2015. https://www.rcr.ac.uk/sites/default/files/bfcr152_irmer.pdf

Referral criteria

The employer's overarching policy on the implementation of IR(ME)R clearly set out the employer provided referral criteria. Information provided by senior staff ahead of our inspection gave a clear explanation of the referral criteria used (based on recognised national and international guidelines) for procedures performed in the cardiac catheter laboratories.

Diagnostic reference levels

The employer had a written procedure for the use of diagnostic reference levels⁹ (DRLs). This set out the arrangements to establish DRLs for procedures performed in the Cardiac Department together with the action to be taken should DRLs be exceeded.

We saw national and local DRLs were available to staff working in the laboratories in accordance with the above procedure. Staff were aware of the procedure to follow for checking and recording the doses delivered.

Assessment of patient dose

The employer had a written procedure setting out the arrangements for recording and monitoring doses (of ionising radiation) delivered to patients

Duties of practitioner, operator and referrer

The employer had written procedures for the entitlement and identification of practitioners¹⁰, operators¹¹ and referrers¹² (known as duty holders). These

⁹ The objective of diagnostic reference levels is to help avoid excessive radiation doses to patients. DRLs are used as a guide to help promote improvements in radiation protection practice.

¹⁰ 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.

¹¹ 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.

clearly described the arrangements for entitlement and identified duty holders by staff group. The procedures set out the expected level of training for each entitled staff group together with their scope of practice.

Justification of Individual Medical Exposures

The employer had a written procedure for the justification¹³ and authorisation of medical exposures. This stated that consultant cardiologists and locum consultant cardiologists were entitled to justify medical exposures. We saw examples of patients' records that demonstrated authorisation (i.e. evidence of justification) of medical exposures.

Optimisation

The employer had arrangements in place concerning the optimisation¹⁴ of medical exposures. These arrangements aimed to ensure that doses delivered to patients as a result of medical exposures are kept as low as reasonably practicable (also referred to as ALARP).

Whilst arrangements were in place and senior staff could clearly explain the work being undertaken by the medical physics experts¹⁵ (MPEs), the radiographers and cardiologists, the employer did not have a specific written procedure in this regard. The employer should set out these arrangements within a written procedure. These could be included within the existing employer's procedure 'EP11 - Reducing the probability and magnitude of accidental or unintended doses to the patient so far as is reasonably practicable.'

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 Justification refers to the intellectual process of weighing up the potential benefit of a medical exposure against the detriment for that individual from the ionising radiation risk.

¹⁴ Optimisation refers to the process by which individual doses are kept as low as reasonably practicable.

¹⁵ A medical physics expert is a person who holds a science degree or its equivalent and who is experienced in the application of physics to diagnostic and therapeutic uses of ionising radiation.

We saw a clear example, supported by clinical audit activity that demonstrated opportunities had been taken to optimise exposures.

Paediatrics

Senior staff confirmed that the Cardiac Department did not perform diagnostic or treatment procedures for children.

Clinical evaluation

The employer had written procedures concerning the clinical evaluation of all medical exposures. These clearly stated that consultant cardiologists were responsible for recording their clinical evaluation and radiographers were responsible for recording an indication of the dose to patients (for each medical exposure).

We saw examples of patients' records confirming the above procedures were being followed by staff.

Clinical audit

The employer had a written procedure concerning clinical audit activity. Senior staff described the process for audit and confirmed that a multidisciplinary approach was used.

Examples of audit activity were provided together with how this had influenced practice.

Expert advice

Senior staff confirmed that medical physics experts (MPEs) and radiation protection advisers (RPAs) were involved as appropriate in medical exposures. The responsibilities of MPEs and RPAs were also described in the employer's overarching policy on the implementation of IR(ME)R.

Equipment

The employer provided an up to date inventory of radiological equipment used within the Cardiac Department. This contained all the information required under IR(ME)R.

Safe care

Managing risk and promoting health and safety

Arrangements were in place to promote the safety and wellbeing of staff and patients.

We saw that personal protective equipment (PPE) was available and being worn by staff to protect them from exposure to ionising radiation during procedures. We also saw that active dose monitoring was being used in the two newer laboratories. This alerted staff so that they could take appropriate and immediate action to reduce their level of exposure to ionising radiation. In addition we saw that floors had been marked to identify those areas where staff could potentially be exposed to higher levels of ionising radiation, again so they could take action as appropriate.

Staff we spoke to demonstrated a good awareness of ionising radiation risks and their responsibilities in this regard.

Within the cardiac catheter laboratories staff had implemented the use of a 'Time Out' board. This recorded relevant details about the patient and the procedure with the aim of promoting patient safety and is in keeping with the World Health Organisation (WHO) Surgical Safety Checklist¹⁶ initiative. Senior staff also described an innovative training programme which aimed to promote the safety of staff and patients in the event of a (patient) emergency (see section - Quality of management and leadership).

Infection prevention and control

Arrangements were in place to protect patients and staff from preventable healthcare associated infections.

We saw that the CSSU, cardiac catheter laboratories and pacing room were clean and designed to promote effective cleaning. In addition to the PPE to protect staff from ionising radiation, suitable PPE was also available to protect

¹⁶ The World Health Organisation Safety Checklist is intended to be used within theatre environments to promote patient safety and reduce avoidable complications. http://www.who.int/patientsafety/safesurgery/ss_checklist/en/

staff and patients from infection. Staff we spoke to were aware of their responsibilities in relation to infection control procedures.

Patients who provided comments praised the cleanliness of the CSSU.

Effective care

Information governance and communications technology

Comprehensive information management systems were described and demonstrated. This allowed for relevant patient details and information about diagnostic and interventional procedures performed in the Cardiac Department to be recorded and easily accessed by staff.

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 effective leadership being provided by senior staff. Clear lines of reporting and accountability were described and demonstrated.

Arrangements were in place for the entitlement of duty holders and we saw evidence that staff had received training required under IR(ME)R.

Governance, leadership and accountability

Duties of the employer

Entitlement

The employer had a written procedure for the entitlement of practitioners, operators and referrers (known as duty holders). This clearly described the arrangements for entitlement¹⁷ and set out the expected level of training for each entitled staff group together with their scope of practice.

Whilst reference was made to medical physics experts being entitled as operators in the Radiology Department, the employer's procedure should be amended to explicitly reflect that MPEs also carry out operator functions within the Cardiac Department.

¹⁷ Entitlement refers to the process of defining the duty holder roles and tasks that individuals are allowed to undertake

Procedures and protocols

The chief executive of the health board was designated as the employer. This is in keeping with the national guidance¹⁸ on implementing IR(ME)R as they apply to the Cardiac Department (i.e. diagnostic and interventional radiology).

We saw that written procedures and protocols had been developed and implemented in accordance with IR(ME)R. We saw that these were up to date and review dates were clearly stated. Whilst issue or approval dates were stated on the procedures and the overarching policy, the employer may wish to use the same format for consistency.

Senior staff were receptive to our comments about some of the wording within the employer's overarching policy and procedures. This was around clearly reflecting that the employer could delegate but not discharge responsibilities under IR(ME)R, identifying the designation of staff having responsibility for actions within the employer's procedure 'EP 8 - Patients receiving substantial radiation dose levels in cardiology' and defining the 'service manager' referred to in the employer's procedure 'EP 9 - Exposures of individuals participating in medical research studies'.

Incident notifications

The employer had a written procedure for recording, reporting and investigating incidents resulting in individuals being exposed to ionising radiation to an extent 'much greater than intended'. This correctly set out that such incidents must be notified to Healthcare Inspectorate Wales or The Health and Safety Executive as appropriate. Senior staff confirmed that there had been no reportable (medical exposure) incidents within the Cardiac Department.

¹⁸ British Institute of Radiology, Society and College of Radiographers and the Royal College of Radiologists. 'A guide to understanding the implications of the Ionising Radiation (Medical Exposure) Regulations in diagnostic and interventional radiology'. London: The Royal College of Radiologists, 2015. https://www.rcr.ac.uk/sites/default/files/bfcr152_imer.pdf

Staff and resources

Workforce

Training

As described earlier in this report, the employer had written procedures for the identification and entitlement of practitioners, operators and referrers. These set out the expected level of training for each entitled staff group. In addition the employer also had a written procedure for training operators on the use of new X-ray equipment.

Senior staff described a comprehensive induction process for new staff and provided evidence of this process. Training records were available for all staff groups and these were available for inspection. We looked at a sample of local training records and saw that these were complete. These clearly demonstrated that trainees had been provided with training by an appropriate person. However, the training record template did not require trainees to sign it to demonstrate that they had understood the training provided. The employer may wish to consider reviewing the local training records so that they demonstrate trainees have understood the training given to them.

Senior staff described an innovative training programme (cardiac laboratory emergency medical simulation) that had been implemented in the cardiac catheter laboratories. This involved simulating real (patient) emergency situations that could occur in the laboratories and aimed to reinforce team members' understanding of their roles and responsibilities in an emergency. We identified this as noteworthy practice in promoting both staff and patient safety in the event of a (patient) emergency.

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, measureable, 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 \(IR\(ME\)R\) 2000](#) (and its subsequent amendments [2006](#) and [2011](#)).

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 at this inspection.			

Appendix B – Immediate improvement plan

Hospital: Morriston Hospital
Ward/department: Cardiac Department
Date of inspection: 12 - 13 September 2017

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	Service action	Responsible officer	Timescale
No immediate improvement plan was 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

Hospital: Morriston Hospital
Ward/department: Cardiac Department
Date of inspection: 12 - 13 September 2017

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	Service action	Responsible officer	Timescale
Quality of the patient experience				
The health board was not required to complete an improvement plan				
Delivery of safe and effective care				
The health board was not required to complete an improvement plan				
Quality of management and leadership				
The health board was not required to complete				

Improvement needed	Standard	Service action	Responsible officer	Timescale
an improvement plan				

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: