The Regulation and Quality Improvement Authority

Inspection Report

8 February 2023

Royal Victoria Hospital, Cardiac Cath Labs

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Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/ and The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 known as IR(ME)R

1.0 Service information

Organisation/Registered Provider: Belfast Health and Social Care Trust (BHSCT)	**Department Inspected:** Royal Victoria Hospital (RVH) Cardiac Cath Labs
Name of Employer: Dr Cathy Jack, Chief Executive Officer (CEO) BHSCT	**Superintendent Radiographer Cardiac Cath Labs:** Mr Gerard McCrickard
Clinical Director of Cardiology : Dr Conor McCann	**Medical Physics Expert:** Mr Adam Workman

Brief description of how the service operates:

The RVH Cardiac Cath Labs provides a regional adult interventional cardiology service Monday to Friday 8.30am to 4.30pm with designated 'Hot' labs for emergencies during the day and includes an emergency percutaneous coronary intervention (PCI) service 24/7. The out of hours service is provided by an on call cardiology team comprising of two staff nurses, a radiographer, a cardiac physiologist, a consultant cardiologist and an anaesthetist (if required).

Before the inspection Mr Gerard McCrickard, Superintendent Radiographer Cardiac Cath Labs and his team were asked to complete a self-assessment form (SAF). The submitted SAF confirmed that each year, the cardiac cath labs provided approximately 5871 cardiology procedures. The department consists of six cardiac cath labs, five of which can be operational at any one time and one is spare to facilitate servicing.

The department is staffed by 24 consultant cardiologists (also covering cardiology services in Belfast City Hospital (BCH) and Mater Hospital), 12 specialist registrars, 13 radiographers (who rotate between the BCH and the RVH cath labs); and the team is supported by a Medical Physics Experts (MPE) contracted from Regional Medical Physics Service (RMPS) based in the Belfast Health and Social Care Trust (BHSCT).

2.0 Inspection summary

On 8 February 2023, warranted IR(ME)R inspectors from the Regulation and Quality Improvement Authority (RQIA), with advice being provided by the United Kingdom Health Security Agency (UKHSA) staff carried out an IR(ME)R inspection of RVH Cardiac Cath Lab, as part of RQIA's IR(ME)R inspection programme. Remote IR(ME)R inspections had been conducted for inspection years 2020/21 and 2021/22 in line with COVID -19 restrictions. A decision has been taken to resume site based IR(ME)R inspections for the 2022/23 IR(ME)R inspection programme.

For the 2022/23 inspection year the inspections will focus on four key themes:

- Incident management with a focus on audit/action plans and shared learning
- Optimisation including establishing local Diagnostic Reference Levels (DRLs)
- Entitlement of staff to include training and competency with a focus on those duty holders outside of the radiology department
- Equipment quality assurance (QA) programmes
- Any other areas identified through the review of the submitted self-assessment form and supporting documentation

The purpose of our focus was to minimise risk to service users and staff, whilst being assured that ionising radiation services were being provided in keeping with Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.

Previous areas for improvement (if applicable) will also be reviewed.

The service was notified of the inspection date and time; and requested to complete and submit a self -assessment form (SAF) and include supporting documentation to be reviewed in advance of the inspection. The site inspection process included:

- Discussion with management and staff
- Examination of relevant radiology documentation
- Review of the department and facilities
- Review of patient records to ensure compliance with IR(ME)R
- Discussion with patients/representatives (where appropriate)

IR(ME)R is intended to protect individuals undergoing exposure to ionising radiation as follows:

- Patients as part of their own medical diagnosis or treatment
- Individuals as part of health screening programmes
- Patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes
- To carers and comforters
- To asymptomatic individuals

3.0 How we inspect

RQIA is responsible for monitoring, inspecting and enforcement of IR(ME)R. The inspection process includes the gathering and review of information we hold about the service, examination of a variety of relevant written procedures, protocols and records, and discussion with relevant staff. RQIA inspection reports reflect on how a service was performing at the time of inspection, highlighting both good practice and any areas for improvement.

The information obtained is then considered before a decision is made on whether the service is operating in accordance with the relevant legislation and professional standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the relevant staff in charge and detailed in the Quality Improvement Plan (QIP).

As already stated, prior to the inspection, the service was requested to complete a SAF and provide RQIA with all relevant supporting information including written policies and procedures. This information was shared with UKHSA prior to the inspection and was used to direct

discussions with key members of staff working within the radiology department and provide guidance for the inspection process.

It is the responsibility of the Employer to ensure compliance with legislation, standards and best practice, and to address any deficits identified during our inspections.

4.0 What people told us about the service

As this was a day procedure cardiology service and patients were awaiting or immediately recovering from cardiac procedures, it was deemed inappropriate to seek to speak to these patients on the day of the inspection.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since the last inspection?

A previous inspection had not been undertaken of the RVH cardiac cath labs under the current IR(ME)R legislation.

5.2 Inspection findings

5.2.1 Does the service manage ionising radiation incidents in accordance with the legislation, professional standards and guidance?

Management and clinical staff described the internal process for reporting accidental or unintended exposures and how notifiable incidents are reported to the appropriate enforcing authority.

We were informed that there had been no reported radiology incidents or near misses in the cardiac cath labs.

The culture of incident reporting across notifiable, non-notifiable incidents and near misses was fully discussed with management and staff who demonstrated an understanding of the importance of robust reporting. A clear reporting pathway was outlined which ensured senior radiology management would be informed of radiology incidents occurring within the cardiac cath labs. The investigation of incidents by the Trust and the identification of learning outcomes and the implementation of safety barriers, as well as providing support for those duty holders involved in the incident, was confirmed.

It was confirmed that the local manager/modality lead would ensure the radiation incident is added to the Radiation Incident Log on Teams. The Radiation Incident Governance Group (RIGG) meets weekly and the superintendent radiographer for cardiac cath labs attends.

As part of the agenda, all new radiation incidents which occurred in the seven days prior are reviewed, as well as review of ongoing incidents. The minutes from RIGG are shared at the weekly divisional governance huddle, which is chaired by the Co-Director and Chair of Division.

If the cause of the incident is due to an equipment defect or failure, the Northern Ireland Adverse Incident Centre (NIAIC) may also be informed.

The clinical decision as to when an incident should be classified as a clinically significant accidental and unintended exposures (CSAUE) was discussed. It was confirmed that there was a process for establishing and dealing with a CSAUE. Review of Employers Procedures (EPs) relating to managing incidents noted that EP K(ii), radiation incident investigation and reporting and EP L, clinically significant accidental and unintended exposures (CSAUE), largely reflected the management of radiation incidents and the decision making process in relation to a CSAUE outlining clear roles and responsibilities within this process. However it was suggested to include a link to the significant accidental and unintended exposures (SAUE) guidance August 2020 in EP K(ii) for completeness.

Staff confirmed that feedback to cardiology staff for all incidents is through daily meetings, team meetings, a fortnightly newsletter and learning summary reports via email.

Radiation incidents are reviewed as part of the radiology governance structures including at the six monthly Diagnostic Radiology and Nuclear Medicine (DRNM) committee and any wider organisational learning or remedial actions identified. Learning from incidents may be shared regionally where there is appropriate learning to be disseminated. Image optimisation teams (IOTs) have been established and part of the terms of reference of the IOTs is the review of incidents and near misses and the dissemination of learning from incidents. Staff demonstrated a good understanding of the action to take in the event of an incident occurring.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection, evidenced that the RVH cardiac cath labs have arrangements with respect to the management of ionising radiation incidents and are enthusiastic to ensure these arrangements are regularly reviewed and if necessary improvements are made. The inspection team acknowledge the commitment of staff in this regard.

5.2.2 Does the service have appropriate arrangements in relation to optimisation including establishing local Diagnostic Reference Levels (DRLs)?

Optimisation is a key principle of the radiation protection framework within IR(ME)R. The optimisation process is the joint responsibility of the practitioner, operator and MPE. The aim of optimisation is to achieve the image quality required to answer the clinical question using the lowest dose possible.

Staff and management outlined a range of measures in place to ensure that medical exposures are kept as low as reasonably practicable (ALARP). EP K(i) reflected the arrangements in place, these include:

- Applications training
- Modality specific training
- Radiographic protocols

- Standard operating protocols for cardiology
- Employer's procedures
- IR(ME)R documents are subject to review and amendment
- Routine equipment maintenance
- Equipment quality assurance
- Use of national and establishment of local DRLs (LDRLs) which are displayed in the cardiac cath labs
- Appropriate exposure charts
- Incident management arrangements
- Management of near misses
- Dose audits
- IOTs
- Posters for operators such as pause and check and supplementary information checks
- Advice and support available to staff from senior members of staff

The MPE involvement in the service was discussed, whilst being found to be largely in accordance to legislation it was confirmed that the MPE had not been fully involved in the procurement of radiology equipment for the cardiology cath labs. An area of improvement has been identified to ensure the MPE is involved in the procurement of radiology equipment.

It was good to note that LDRLs had been established for cardiology examinations for adult patients which as stated are displayed in the cardiac cath labs. The staff confirmed that operators pay attention to the LDRLs and report to the radiation protection supervisor or superintendent radiographer if they appear to be consistently exceeded for standard sized patients. LDRLs for cardiology examinations were noted to be lower than the national DRLs. It was good to note that plans are in place to develop LDRLs for additional cardiology examinations.

It was confirmed that members of the cardiac cath labs team including a consultant cardiologist and superintendent radiographer are part of the interventional imaging IOT. The IOT is involved in the collection of data for a range of examinations including cardiology which is used to establish and review LDRLs. Dose audit data has been collated for cardiology and it was confirmed it would be reviewed by the MPE to decide if new LDRLs are required. LDRLs are assessed and approved by the DRNM committee. Final approval is by the Radiation Safety Committee.

As required under IR(ME)R written protocols for the cath labs have been devised and these were dated November and December 2022. The written protocols included sufficient detail that will support the operator in setting up and carrying procedures such as patient positioning; protocol selection; frame rates; magnification and collimation and the levels of contrast required.

It was good to note a 'protocol for monitoring and recording significantly high skin dose cases within interventional cardiology BHSCT' had been devised. It outlined set levels for actions required at each dose level, a three to six week follow up for the patient with skin burns and patients being referred to the tissue viability team if necessary. It was confirmed that high doses would only happen when unexpected complications in the procedure occurred which led to prolonged exposure to X-rays. However, it was confirmed that alert levels on the equipment had been established for cardiology procedures.

These alert the operator and practitioner (green light becomes red) during the examination where doses to patients start to become significant and give the opportunity to consider the

risks and benefits and justify the continuing use of radiation. They also provide a mechanism to indicate where the dose to the patient's skin may approach levels where it may exceed the threshold for the induction of deterministic radiation effects.

The staff informed the inspection team that the alert national algorithm has changed and the procedure may be broken into more than one visit to avoid high doses.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the cardiac cath labs have arrangements with respect to optimisation of medical exposures and are enthusiastic to ensure these arrangements are regularly reviewed and if necessary improvements are made. The inspection team acknowledge the commitment of staff in this regard.

5.2.3 Does the service adhere to legislation in relation to the entitlement of duty holders including assessing training and competency ?

Entitlement is the term used to describe the process of endorsement by an appropriate and specified individual within an organisation. They must have the knowledge and experience to authorise on behalf of the Employer, that a duty holder or group of duty holders have been adequately trained and deemed competent in their specific IR(ME)R duty holder roles.

The entitlement arrangements within the cardiac cath labs were reviewed. Management and staff informed the inspection team that consultant cardiologists are entitled as a referrer; practitioner and operator. Several samples of consultant cardiologist entitlement forms including training and competency assessments were provided. Overall they provided a basic framework for entitlement. From valuable discussions with consultant cardiologists it was clear that each consultant cardiologist has a specific scope of practice. However this was not reflected in the entitlement records. An area of improvement has been identified to ensure that entitlement for consultant cardiologists fully reflects their individual scope of practice.

The entitlement records and training and competence records for radiographers working in the cardiac cath labs were reviewed. The training and competency records were found to be well completed. The entitlement records were in place and had evidence of regular review, including a return to work review following a period of absence. It was noted that radiographers are entitled as non-medical referrers (NMRs) for chest X-rays and this was underpinned by training and competence. The Trust NMRs database included these cardiac radiographers.

The role of carers and comforters (C&C) was discussed and staff confirmed that it would not be appropriate for carers and comforters to be involved in the delivery of the cardiac cath labs procedures. However the entitlement forms for radiographers outlined that they had been entitled as operators to authorise exposures to C&C using guidance. There was no written authorisation guidance relating to C&Cs and radiographers do not carry out this operator function. An area of improvement was made to ensure the entitlement records for radiographers are reflective of their scope of practice in relation to C&C.

The role of the specialist registrars for cardiology was discussed and it was confirmed that they are not entitled as duty holders and act under the supervision a consultant cardiologist. However the consultant cardiologists described the rigorous ongoing assessment of competency of the specialist registrars, as part of attaining registration to the General Medical Council (GMC) specialist registrar as a cardiologist. Through discussion it was agreed

specialist registrars should be included in the entitlement process and an area of improvement has been identified on the matter.

As part of discussion in relation to the justification and authorisation, the process for medical exposures undertaken in the cardiac cath labs was examined. Management and staff including two consultant cardiologists clearly outlined the process of justification as undertaken by the consultant cardiologists acting as practitioners.

The referral process was discussed and a range of referral information was described including the whiteboard, a care pathway and consent form, as being used to justify the cardiac procedure. A robust process was described including holding a multi disciplinary team meeting to discuss a more complex referral. It was confirmed that the referrer was always a consultant cardiologist. It was less clear what referral criteria is used for cardiac cath labs procedures and the referral process as described was not outlined clearly in the EP A(i). An area of improvement has been identified to establish referral criteria and further develop EP A(i) to include the referral process for the cardiac cath lab.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that whilst radiology and cardiology staff demonstrated a sound understanding of their duty holder roles, the formal entitlement arrangements requires to be further developed. Management and staff were receptive to the areas for improvement identified to strengthen the arrangements for entitlement. The inspection team acknowledge the commitment of staff in this regard.

5.2.4 Does the service adhere to legislation with regard to equipment quality assurance (QA)?

An inventory of radiological equipment was supplied which contained all of the information as specified within the legislation. This list of equipment will be kept under constant review and will be updated when there is a change.

The inspection team sought to ensure that all QA equipment tests are undertaken and to schedule, that the results of the tests are recorded and interpreted in a suitable manner and that any actions necessary as a result of the tests are followed through appropriately. In addition that the Trust staff liaise with external providers of QA and advise on performance and optimisation. e.g. Regional Medical Physics Service (RMPS).

The equipment QA programme should specify two levels of testing, Level A which is carried out internally by the radiology staff and Level B testing which is carried out by an external provider, RMPS.

The RMPS programme for external QA is undertaken using recommended QC test methods and at a frequency advised by The Institute of Physics and Engineering in Medicine (IPEM). The IPEM set the ‘Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems’ in their IPEM Report 91.

It was confirmed that Level B testing in accordance with IPEM Report 91 for the radiology equipment in the cardiac cath labs had been carried out for six of the eight cath labs across the RVH and BCH sites. However there was no oversight of this programme by the management of the cardiac cath labs department and a report had not been received of the findings. It was

confirmed that the RVH cardiac cath labs had not been subject to an internal audit by the RMPS which examines the equipment QA programme carried out including Level A testing.

It was good to note staff involved in performing QA testing had evidence of training and a competency assessment to undertake this role and had been entitled to do so. Written 'Fluoroscopy and Fluorography Tests' work instructions for each cath lab was in place dated 16 January 2023.

A review of completed Level A two monthly testing schedule from December 2021 to January 2023 confirmed it had not been carried out in line with the frequency set out in the QA procedures. There had been significant gaps, with only one cath lab having two monthly QC checks carried out and a number of cath labs had no QC checks for four to six months. The QA radiographer had carried out a compliance audit in January 2023 and had noted the findings outlining the reasons for the non-compliance as staff pressure and labs being unavailable. The QA radiographer outlined the action taken on the matter which included requesting staff to come in early or stay late to carry out QC checks, streamlined the procedure to make the testing quicker and requested admin to look at scheduling of labs to book in QC testing. These actions have been implemented since January 2023. Radiographers in the cath labs confirmed the recent changes had led to some improvement in the QC testing programme.

It was confirmed that the findings had not been escalated through the governance structures and there was no evidence of oversight of the equipment QA programme by senior management as outlined in EP D(ii).

The equipment QA programme for the cath labs requires to be strengthen and the following areas of improvement have been identified:

- Establish a robust equipment QA programme and ensure it is fully implemented
- Establish robust clear governance arrangements for oversight of the equipment QA programme and ensure individuals within the governance structures are fully aware of their roles and responsibilities as outlined in EP D(ii)
- Ensure the MPE internal audit of the equipment QA programme for the cath labs is carried out as a priority

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the arrangements for the internal and external equipment QA programme require to be strengthened. The management and staff were responsive to matters raised and have already implemented some changes to the equipment QA programme. The inspection team acknowledge the commitment of management and staff in this regard.

5.2.5 Additional areas reviewed - other areas identified through the review of the submitted self-assessment form and supporting documentation

Employer's Procedure(EPs)

EPs for all areas which use diagnostic and interventional x-rays were in place and had been updated in September 2022. On review and through discussion with staff and management it was noted that a number of the EPs did not accurately reflect practice within the cardiac cath labs and lacked sufficient detail. An area of improvement was identified to review the following EPs to accurately reflect practice within the cardiac cath labs:

- EP A(ii)– patient identification include how this check is carried out and recorded in the cath labs
- EP E – pregnancy enquiries information in flow chart needs to be added to text involvement of MPE in cases where a patient is pregnant

It was noted that there was inconsistency between the care pathway documentation for cardiac cath labs procedures and the EP E in relation to the 10 day rule/28 day rule and checking the age range. An area of improvement has been made on this matter.

Research

It was noted that the cardiac cath labs are involved in a number of research studies. The consultant cardiologist who oversees these research studies provided detailed information on the research. It was advised to consider including in the research protocols details of the role of radiology staff in the research studies.

6.0 Conclusion

There were ten areas of improvement identified as a result of this inspection. These are fully outlined in the appended quality improvement plan (QIP).

The management team and staff are to be commended for their ongoing commitment and enthusiasm to ensuring that the cardiac cath labs are striving to operate within the legislative framework and maintaining optimal standards of practice for patients.

The inspection team would like to extend their gratitude to the management team and staff for their contribution to the inspection process.

7.0 Quality Improvement Plan/Areas for Improvement

Areas for improvement have been identified where action is required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 known as IR(ME)R and other published standards which promote current best practice to improve the quality of service experienced by patients.

Total number of areas for improvement	10

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with senior management as part of the inspection process. The timescales commence from the date of inspection.

It is the responsibility of the Employer to ensure that all areas for improvement identified within the QIP are addressed within the specified timescales.

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The employer should confirm that these actions have been completed and return the completed QIP via BSU.Admin@rqia.org.uk for assessment by the inspector.

Quality Improvement Plan	
Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018	
Area for improvement 1 **Ref:** Regulation 14 (3) (g) **Stated:** First time **To be completed by:** 8 February 2023	The Employer should ensure that the Medical Physics Expert (MPE) is involved in the procurement of radiology equipment. Ref 5.2.2
	Response by Employer detailing the actions taken:
Area for improvement 2 **Ref:** Regulation 6 (2) Schedule 2 (b) **Stated:** First time **To be completed by:** 8 May 2023	The Employer must ensure that the entitlement for consultant cardiologists fully reflects their individual scope of practice. Ref 5.2.3
	Response by Employer detailing the actions taken:
Area for improvement 3 **Ref:** Regulation 6 (1) Schedule 2 (b) **Stated:** First time **To be completed by:** 8 May 2023	The Employer must ensure the entitlement records for radiographers are reflective of their scope of practice in relation to carers and comforters. Ref 5.2.3
	Response by Employer detailing the actions taken:
Area for improvement 4 **Ref:** Regulation 6 (2) Schedule 2 (b)	The Employer must ensure specialist registrars for cardiology are entitled as operators in line with their scope of practice. Ref 5.2.3

Stated: First time **To be completed by:** 8 May 2023	**Response by Employer detailing the actions taken**:
Area for improvement 5 **Ref:** Regulation 6 (5) (a) **Stated:** First time	The Employer must establish referral criteria for cardiology and further develop EP A (i) to include the referral process for the cardiac cath lab. Ref 5.2.3
To be completed by: 8 May 2023	**Response by Employer detailing the actions taken**:
Area for improvement 6 **Ref:** Regulation 15 (1) (a) Schedule 2 (d) **Stated:** First time **To be completed by:** 8 April 2023	The Employer must establish a robust equipment QA programme for the cath labs and ensure it is fully implemented. Ref 5.2.4
	Response by Employer detailing the actions taken:
Area for improvement 7 **Ref:** Regulation 15(3) Schedule 2 (d) **Stated:** First time **To be completed by:** 8 April 2023	The Employer must establish robust governance arrangements for oversight of the equipment QA programme and ensure individuals within the governance structures are fully aware of their roles and responsibilities as outlined in EP D(ii). Ref 5.2.4
	Response by Employer detailing the actions taken:
Area for improvement 8 **Ref:** Regulation 14 (3) **Stated:** First time **To be completed by:** 8 May 2023	The Employer must ensure the MPE internal audit of the equipment QA programme for the cath labs is carried out as a priority. Ref 5.2.4
	Response by Employer detailing the actions taken:
Area for improvement 9 **Ref:** Regulation 6 (1) Schedule 2 **Stated:** First time	The Employer must review the following Employer Procedures (EPs) to include practice within the cardiac cath lab: • EP A (ii)– patient identification, include how this check is carried out and recorded in the cath labs • EP E – pregnancy enquiries, information in flow chart needs to be added to text in relation to involvement of MPE in cases where the patient is pregnant.

To be completed by: 8 May 2023	Ref 5.2.5
	Response by Employer detailing the actions taken:
Area for improvement 10 **Ref:** Regulation 6(2) Schedule 2(c) **Stated:** First time **To be completed by:** 8 May 2023	The Employer must ensure that the care pathway documentation for cath lab procedures and the EP E in relation to the 10 day rule/28 day rule and checking the age range are consistent with each other. Ref 5.2.5
	Response by Employer detailing the actions taken:

Please ensure this document is completed in full and returned via the Web Portal

The Regulation and Quality Improvement Authority

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