THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY
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BELFAST CITY HOSPITAL
RADIOTHERAPY DEPARTMENT

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PALLIATIVE PATHWAY REVIEW

14 DECEMBER 2016

1.0 General Information

Name of Establishment:	Northern Ireland Cancer Centre Belfast City Hospital
Address:	Lisburn Road Belfast BT9 7AB
Department Inspected:	Radiotherapy
Telephone Number:	028 9032 9241
Name of Employer:	Dr Michael McBride
Hospital Director/Co-Director:	Gillian Traub
Registered Manager	Joanne McCarthy
Radiation Protection Supervisor:	Dr Roy Mooney
Medical Physics Expert/Radiation Protection Advisor:	Professor Alan Hounsell
Date and Time of Inspection:	14 December 2016 09:30 – 16:30
Name of Inspector:	Hall Graham
Name of PHE Advisor:	Una Findlay

2.0 Introduction

The Regulation and Quality Improvement Authority (RQIA) is the independent health and social care regulatory body for Northern Ireland. RQIA encourages continuous improvement in the quality of services, through a planned programme of inspections and reviews.

In 2005, RQIA was established as a non departmental public body (NDPB) under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003. The vision of RQIA is to be a driving force for positive change in health and social care in Northern Ireland through four core activities:

- Improving Care: we encourage and promote improvements in the safety and quality of services through the regulation and review of health and social care.
- Informing the Population: we publicly report on the safety, quality and availability of health and social care.
- Safeguarding Rights: we act to protect the rights of all people using health and social care services.
- Influencing Policy: we influence policy and standards in health and social care.

The responsibility for assessing compliance with and enforcing The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 known as IR(ME)R transferred from the DHSSPS to the Regulation and Quality Improvement Authority (RQIA) on 15 March 2010 under The Ionising Radiation (Medical Exposure)(Amendment) Regulations (Northern Ireland) 2010.

The regulations are intended to:

- Protect patients from unintended, excessive or incorrect exposure to ionising radiation and ensure that, in each case, the risk from exposure is assessed against the clinical benefit.
- To ensure that patients receive no more exposure than is necessary to achieve the desired benefit within the limits of current technology.
- To protect volunteers in medical or biomedical, diagnostic or therapeutic research programmes and those undergoing medico-legal exposures.

The Belfast City Hospital Radiotherapy Department was inspected for compliance against IR(ME)R in May 2015 and the findings were shared in a report with the centre. No key areas of concern were identified.

However, following the publication, in July 2016 of a Scottish Government[1] report of an investigation following an incident relating to an exposure much greater than intended in a Scottish Radiotherapy department, RQIA wished to seek assurance that the potential for a similar incident to occur in Northern Ireland had been sufficiently mitigated.

[1] http://www.gov.scot/Publications/2016/07/8854

3.0 Methodology

On 14 December 2016, a warranted IR(ME)R inspector from RQIA, with advice being provided by Public Health England (PHE) staff, visited the Radiotherapy Department of the Belfast City Hospital, as part of RQIA's IR(ME)R inspection programme.

Prior to the visit, the hospital was requested to provide RQIA with its palliative clinical protocol, patient referral form and procedures for calculation and checking of palliative plans. This information was shared with PHE prior to the review visit and was used to direct discussions with key members of staff working within the radiotherapy department, and provide guidance for the review process.

The review team met with representatives of the senior team, to take them through the process and also to ensure that there was clarity as to the purpose of the visit.

Training records and staff entitlement were also examined with regard to the palliative aspects of the service and time was spent in the clinical department, following the patient and associated data pathway. The review team met with a range of staff to ensure they fully understood how the palliative pathway and associated processes fitted together at an operation level and to review evidence of the application of protocols and procedures locally.

Belfast City Hospital staff in attendance for the senior management opening meeting included:

- Professor Alan Hounsell - Head Of Radiotherapy Physics
- Joanne McCarthy - Radiology Services Manager
- Dr Roy Mooney - RPS
- Debbie Wightman - Services Manager Oncology and Haematology
- Gillian Traub - Co-Director Cancer and Specialist Medicine
- Fionnuala Houghton - Clinical Lead for Radiotherapy
- Jean Smith - Section Manager
- Cathy Millar - Clinical Co-Ordinator
- Stacy Heatherington - Clinical Co-Ordinator
- Shirley Gray - Section Manager
- Dr Denise Irvine - Radiotherapy Physics Service
- Beth Young - Radiographer
- Barry O'Hara - Information Support Radiographer

Staff involved in the review were found to be open and willing to engage in the process. Their engagement was greatly appreciated in facilitating the visit.

The purpose of this report is to provide a summary of the findings made during the review.

4.0 Focus of Review

Between 14th September 2015 and 18th September 2015, a palliative patient received a dose of ionising radiation much greater than that intended while undergoing a course of radiotherapy in Scotland. The Inspector warranted by Scottish Ministers for IR(ME)R, subsequently published a report recording the findings of the incident investigation. It identified the errors that caused this overexposure and included consideration of the deficiencies that contributed to the errors and where responsibility for these deficiencies lay. It also made recommendations intended to minimise the possibility of recurrence of similar errors and to enhance patient safety in radiotherapy in general.

In terms of learning from these types of events, the focus of this review was to ascertain whether every effort had been made to mitigate the risk of a similar event occurring in the radiotherapy department at Belfast City Hospital.

The review comprised of meetings with key stakeholders and observation of clinical areas where radiotherapy treatments were planned or delivered. This was supplemented with informal discussions with staff members during the time spent observing current processes.

A review of a sample of relevant documents was also undertaken prior to attendance at the Radiotherapy Department; these are listed below and have been referenced for the purposes of this report.

- Palliative Radiotherapy Clinical Protocol
- Procedure for Patients Referral and Booking for Radiotherapy
- Procedure for Checking and Treatment Delivery (External Beam)
- RadCalc (Work Instruction)
- Chart / Aria Checks for External Beam photon Treatment (Work Instruction)
- Chart Check Form Manual Calculations by Radiographers / TP Non-Optimised Plans

It was advised that the primary output for the visit should be an action plan based on the recommendations made, generated by the key stakeholders with an agreed timeline for implementation.

5.0 Profile of Service

The Belfast City Hospital Radiotherapy Department treats cancer patients from all over Northern Ireland. The Cancer Centre is located on the Belfast City Hospital site, adjacent to the main hospital building, and is managed by Belfast Trust. The Radiotherapy Department is located on the ground floor of the Centre. Each year, approximately 4000 new patients are treated with radiotherapy in Northern Ireland.

The Cancer Centre has a comprehensive Radiotherapy Department, with external beam and brachytherapy treatments planned and delivered on site. Computed Tomography (CT), PET/CT and MR scanning are available as part of the radiotherapy treatment planning process. On treatment imaging is available as 2D planar and conebeam CT (CBCT) imaging.

The radiotherapy team in the Cancer Centre includes clinical oncologists (doctors who are trained in radiotherapy and chemotherapy), specialist radiographers, nursing staff and administrative staff.

6.0 Findings

6.1 Departmental

6.1.1 During the opening meeting, several areas of good practice were shared which should be encouraged and continued. These are outlined below (6.1.2 to 6.1.6).

6.1.2 Of note, minutes of an extraordinary meeting of the senior management team of the radiotherapy department held on the 2nd August 2016 to discuss the Scottish Government report were shared during the visit. The minutes included actions identified in response to the report which had been allocated to clearly identified staff members, with appropriate timelines associated with them. The actions focused on a review of update training on calculations to be reflected in training records and audited.

6.1.3 The clinical protocol for palliative radiotherapy was written to a high standard, comprehensive and up to date. It included an outline of IR(ME)R responsibilities, summary of doses prescribed, treatment rationale, referral criteria, information for patients, consent and specific considerations for bone pain, spinal cord compression, brain metastases and clinical trials.

6.1.4 It was reported that the vast majority of palliative patients were discussed in a site specific multi-disciplinary (MDT) meeting prior to treatment. It was understood that only emergency patients were discussed in the MDT meeting post treatment, when waiting for the next MDT meeting would delay their treatment.

6.1.5 The Radiotherapy Department is actively engaged in reporting and learning from all radiotherapy error and near miss events both locally and at a UK level. Learning is used to inform practice and examples were shared during the review. This is in line with best practice.

6.1.6 The department has specific competencies in place for the planning and treatment of patients as part of out of hours (on-call) working arrangements.

6.1.7 Comprehensive and complete training records were seen for a number of staff from each of the professional groups working in the Radiotherapy Department. Competencies associated with the planning and treatment of palliative patients provided the focus for the review. Consideration should be given to developing a single approach to the format of training records for all professional groups.

6.1.8 One area identified by the radiotherapy department as requiring improvement is the documentation of the patient record in radiotherapy. It was reviewed during the visit and found to be particularly paper heavy. A review of current documentation to identify areas of duplication of data or redundant data collection should be completed, as the department moves towards being more paper light.

6.2 Referral

6.2.1 Palliative patients were seen to follow the same referral route as radical patients. A list of site specific referral criteria was seen to be included in the palliative clinical protocol.

6.2.2 Estimates of the doses associated with the radiotherapy planning CT scan were not seen during the visit. The review team was assured that these would shortly be made available as required under IR(ME)R.

6.2.3 Those members of staff engaged with during the review process could clearly articulate their responsibilities under IR(ME)R and could demonstrate where this was evidenced. These discussions related in particular to referral.

6.3 CT Scanner / Simulator

6.3.1 The department is currently operating a CT scanner and simulator to support the localisation of target volumes for palliative treatments. There is a plan in place to decommission the simulator in 2018. Currently, on-call patients are being planned on the simulator. It was reported that the localisation methodology was similar for palliative and radical patients during core hours and that a plan was in place to move on-call patients onto the same pathway, once on-call staff training was complete on CT and virtual simulation procedures.

6.3.2 Those members of staff engaged with during the review process could clearly articulate their responsibilities under IR(ME)R and could demonstrate where this was evidenced. These discussions related in particular to authorisation and justification of planning exposures, patient identification procedure, pregnancy status checking, recording of factors associated with the pre-treatment exposures.

6.4 Calculation

6.4.1 In line with national recommendations[2] it was positive to note that there was a fully independent calculation check of monitor units in place.

6.4.2 Individual roles and responsibilities were clearly defined in terms of completion and checking of manual calculations. There was a clear procedure in place to follow, in the eventuality there was any incongruence between the primary calculation and secondary check on the calculation.

6.4.3 The calculation methodologies and training packages derived for palliative work have all been approved by the local medical physics expert.

[2] https://www.rcr.ac.uk/system/files/publication/field_publication_files/Towards_saferRT_final.pdf recommendation 11

6.4.4 It was reported the department was currently planning and calculating palliative patients using parallel fields which were either fixed at 100cm fixed distance from the patient or isocentre in nature. There was a plan in place to move all patients over to isocentric calculations, thus further streamlining the planning and calculation requirements for this patient group.

6.5 Treatment

6.5.1 Those members of staff engaged with during the review process could clearly articulate their responsibilities under IR(ME)R and could demonstrate where this was evidenced. These discussions related in particular to authorisation and justification of treatment exposures, patient identification procedure, pregnancy status checking, recording of factors associated with the treatment and on-treatment imaging exposures and the clinical evaluation of on-treatment exposures.

6.5.2 Estimates of the doses associated with on-treatment imaging were not seen during the visit. The review team was assured that these would shortly be made available as required under IR(ME)R.

6.6 Patient review

6.6.1 A schedule for review of palliative patients was clearly set-out in the Palliative Radiotherapy Clinical Protocol. This was reflected in discussions with staff during the review.

6.6.2 Those members of staff engaged with during the review process could clearly articulate their responsibilities under IR(ME)R and could demonstrate where this was evidenced. These discussions related in particular to the clinical evaluation of treatment exposures.

7.0 Recommendations

7.1 A review of current documentation to identify areas of duplication of data or redundant data collection should be completed as the department moves towards being more paper light.

7.2 Estimates of the doses associated with radiotherapy planning CT scans and concomitant imaging should be made available as required under IR(ME)R.

7.3 All patients requiring standard parallel opposed treatments should be moved from 100cm FSD over to isocentric set-ups to further streamline the planning, calculation and treatment requirements for this patient group, reducing the potential risk of error. .

8.0 Provider Compliance Improvement Plan

High level findings from the visit were fed back to the senior management team on the day of the visit. The senior management team is asked to consider this report and respond to the recommendations made in section 7 of this report with 3 months of receipt.

Requirements are based on The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 and The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010.

Recommendations are based on other published standards which promote current good practice and should be considered by the management of the Radiotherapy Department, Belfast City Hospital, to improve the quality of service experienced by patients.

The employer is required to record comments on the quality improvement plan.

Enquiries relating to this report should be addressed to:

Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
BELFAST
BT1 3BT

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Hall Graham **Date**
Inspector/Quality Reviewer

Provider Compliance Improvement Plan

A provider compliance improvement plan should be completed detailing the actions taken and planned to achieve the recommended actions outlined below. This improvement plan should be returned to Hall.Graham@rqia.org.uk for assessment. The Employer should note that failure to comply with the findings of this inspection may lead to escalation action. The Employer should ensure that all recommended actions are taken within the specified timescales.

Radiotherapy Department Belfast City Hospital

Reference number	Recommended Actions	Responsible Person	Action/ Required	Date for completion/ timescale
7.1	A review of current documentation to identify areas of duplication of data or redundant data collection should be completed as the department moves towards being more paper light.	FH/JMcC/AH	To streamline the patient record a working group will be set up; this working group will have representatives from each stage of the patient pathway who can systematically review the documentation e.g. pre-treatment, treatment planning and treatment. This group will analyse the patient record to see where there is duplication of data or where redundant data is being collected. Once the review has been completed then the working party can begin to streamline the patient record. Removing documentation will mean that some processes will have to change and	3 months July 2017

Reference number	Recommended Actions	Responsible Person	Action/ Required	Date for completion/ timescale
			changes will have to be reflected in the respective Quality Management Systems and communicated to staff. The changes made as a result of the review of documentation will then be risk assessed to ensure that streamlining the patient record does not remove existing safety barriers.	
7.2	Estimates of the doses associated with radiotherapy planning CT scans and concomitant imaging should be made available as required under IR(ME)R.	AH	Pre-treatment Imaging: Working with the Diagnostic Imaging Medical Physics Experts from the Regional Medical Physics Service dose estimates for standard scan protocols will be determined. Scan protocol information has been shared with Diagnostic Physics group who are in the process of calculating the doses. These values will be made available as required. Verification Imaging: Standard dose values for CBCT, kV and MV imaging protocols have been determined and are available as required in the Departmental Imaging Protocols.	3 months July 2017

Reference number	Recommended Actions	Responsible Person	Action/ Required	Date for completion/ timescale
7.3	All patients requiring standard parallel opposed treatments should be moved from 100cm FSD over to isocentric set-ups to further streamline the planning, calculation and treatment requirements for this patient group, reducing the potential risk of error.	JMcC/AH/FH	Parallel opposed Isocentric set-ups are already an established technique for some patients so some of the processes are already in place. Working group to be set-up with representatives from pre-treatment, treatment planning and treatment to address outstanding issues to allow this technique to be used routinely for all parallel opposed treatments. Issues to be addressed: Review of set-up tolerances and action levels Review of palliative imaging protocols Staff training: Previous training for radiographers regarding the calculation process including use of RadCalc software needs reviewed. Training programme implanted. Staff Training: Clinicians advised on any changes regarding prescribing and virtual simulation software	6 months Oct 2017

Reference number	Recommended Actions	Responsible Person	Action/ Required	Date for completion/ timescale
			Calculation process / data availability for 15MV plans. Programme for radiographer calculation competence to be implemented e.g. annual competence. Identification of circumstances not suitable for isocentric techniques e.g. sitting up patients. Review of Work instructions / procedures within the Quality Management System and process to be risk assessed.	