Unintended overexposure of a patient during palliative radiotherapy treatment at the Edinburgh Cancer Centre, in December 2017

Covering note

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It is notable that this report follows closely on a report published by the Scottish Ministers in 2016 on an 'Unintended overexposure of a patient during palliative radiotherapy treatment at the Edinburgh Cancer Centre' (http://www.gov.scot/Publications/2016/07/8854/1) in September 2015.

It should be stressed, however, that the nature of the errors considered here and in this earlier report was quite different.

The particular circumstances of the September 2015 incident were that the treatment was appropriately prescribed by the practitioner in accordance with the applicable Edinburgh Cancer Centre (ECC) treatment protocol, but errors were made in the subsequent process of calculating how the prescribed treatment was to be delivered. The result was that the treatment was delivered to the correct target volume but at twice the intended dose of radiation.

In the incident considered in this report, the error again occurred at the stage of treatment planning, but in this instance in defining the target volume. The result was that the dose of radiation delivered to the patient was correct but was delivered to the wrong target volume.

The finding of this report is, therefore, that the most likely cause of this incident was an error by an individual in the process of defining the target area, rather than any identifiable planning miscalculation or error of clinical judgement.

In no sense, therefore, should the close occurrence of these two incidents be construed as suggesting a systemic weakness in treatment planning at the ECC.

However, it is apparent from this investigation that staffing and workload pressures were a contributory factor in this incident, and such pressures are not confined to the ECC. This highlights again the need for effective workload management to ensure that staff performance is not unduly compromised by predictable instances of excessive demand.

Many thousands of life-saving radiotherapy treatments are successfully prescribed, planned and delivered at the ECC and at the other radiotherapy centres in Scotland every year. The occasional appearance of reports such as this should therefore be regarded as reassuring evidence of the transparency of the provisions that are in place to identify, investigate, and address any concerns arising from these very occasional incidents.

Dr Arthur M Johnston
Warranted Inspector appointed by the Scottish Ministers

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Report of an investigation by the Inspector appointed by The Scottish Ministers for The Ionising Radiation (Medical Exposures) Regulations 2017

Executive Summary

Summary of the incident.

A CT scan carried out on 28th November 2017 for a patient with a history of metastatic breast cancer and related left vocal cord palsy, showed an increase in size of the largest left hilar lymph node when compared with previous scans. The patient was therefore referred to the relevant Edinburgh Cancer Centre (ECC) oncology clinic.

At the oncology clinic, the patient was seen by Clinical Oncologist B, who completed a standard ECC informed consent pro-forma for treatment of the 'Mediastinum'. The aim of this treatment was 'To shrink the hilar mass', thought to be causing the left vocal cord palsy by affecting the left recurrent laryngeal nerve.

Between 27th December 2017 and 4th January 2018 the patient was given a palliative radiotherapy treatment at the ECC. The prescribed radiation dose, method of delivery, and fractionation were as expected for treatment of this condition.

Following completion of this treatment, a CT scan in March of 2018 showed, unexpectedly, that the target tumour had actually increased in volume. A second clinical oncologist, Clinical Oncologist A, therefore arranged for reassessment of the patient's imaging and treatment planning.

The outcome of this reassessment was the discovery that as part of treatment planning for this patient, Clinical Oncologist B had defined a treatment field that did not (as per the completed informed consent pro-forma) encompass the 'hilar mass' and therefore had no possibility of achieving the hilar mass shrinkage referred to therein.

While no definite conclusions can be made, the most likely scenario appears to be that Clinical Oncologist B made an initial treatment field placement as a square that covered an area of the mediastinum that included the hilar mass, but then, on observing on the computer screen another area of possible concern immediately outside the lower right corner of this area, sought to extend this square to include this area. However, in attempting

to do so, it appears that Clinical Oncologist B shifted rather than extended this treatment field to a different part of mediastinum that no longer covered the original intended hilar mass target.

The patient was fully informed of the error and underwent subsequent radiotherapy to the area originally intended.

The ECC has reported that there have been no adverse clinical outcomes associated with this error and that none are expected to occur.

The conclusion of this investigation is that Clinical Oncologist B was appropriately entitled to carry out all of the functions undertaken (as referrer, practitioner and operator), and in no sense did Clinical Oncologist B fail to comply with the duty-holder responsibilities specified in the IR(ME) Regulations. Neither was there clear evidence of an error in clinical judgement, in that Clinical Oncologist B believed 'at the time' that the presentation on the CT scan justified an extension of the mediastinal field to the lower right. It appears, therefore, that the error was one of treatment field placement, whereby Clinical Oncologist B inadvertently shifted rather than extended the treatment field on the computer screen.

Contributory factors

This incident occurred on the last working day (Friday) before the Christmas Bank Holiday when Clinical Oncologist B was the only member of the relevant team on site. The usual compliment for the team Monday to Thursday is between three and five clinical oncologists, but normally only two on a Friday.

At interview, Clinical Oncologist B accepted that lone working on that particular day when subject to abnormal pressure for urgent treatment ahead of the impending hiatus in treatment over the Christmas break had probably contributed to difficulties in focussing on the various tasks in hand.

These staffing issues are considered further in the main body of the report.

The investigation also considered compliance with the duties of the employer under the IR(ME) Regulations. In this regard there is evidence of a failure by the employer to keep proper training records and to maintain employer's written procedures to an appropriate standard. However, there is no evidence to suggest that these shortcomings contributed in any way to the error in field placement.

The employer has recognized the need to address these issues.

Recommendations for further action

A number of actions have been recommended in the ECC's internal report on this incident (Section 6 of this report) and senior management within the ECC have confirmed that these have been or are being properly addressed.

Further recommendations arising from this investigation and relating to improvements in recording of staff training prior to entitlement, quality control of employer's written procedures and protocols, and to improvements in working practices are also included in this report.

Conclusions

The main conclusions of this report are:

- The error was made by Clinical Oncologist B in the process of defining the radiotherapy treatment field.
- Clinical Oncologist B was adequately trained, deemed competent and appropriately entitled by the employer for this function.
- The patient has been properly apprised of the nature and circumstances of the error and has been given appropriate aftercare.
- The ECC has reported that there have been no unusual adverse clinical outcomes associated with this error and that none are expected to occur.
- Deficiencies have been identified in this report in recording of training and in document quality control by the employer. However, these did not contribute to this incident.
- The occurrence of this incident during an ad-hoc planning clinic on the last working day before the Christmas when Clinical Oncologist B was working alone leads to the general conclusion that staffing pressures were a contributory factor in the occurrence of this incident.
- No evidence has emerged to indicate a need for enforcement action under the IR(ME) Regulations.

Unintended overexposure of a patient during palliative radiotherapy treatment at the Edinburgh Cancer Centre, in December 2017

1. The subject of this investigation.

Between 27 December 2017 and 4 January 2018 a patient undergoing a course of radiotherapy at the Edinburgh Cancer Centre (ECC) in Scotland received a dose of ionising radiation much greater than that intended. Since the incident resulted from a procedural error, rather than from equipment failure, it has been reported and investigated under the provisions of the extant *Statutory Instrument 2000 No. 1059, The Ionising Radiation (Medical Exposures) Regulations 2000* (as amended) [1] (referred to in this report as the IR(ME) Regulations).

The regulator for the IR(ME) Regulations (the 'appropriate authority') in Scotland is the Scottish Ministers.

2. The format and scope of the investigation and report.

This report records the findings of an incident investigation carried out by Dr Arthur Johnston, as the Inspector warranted by the Scottish Ministers, in accordance with the provisions of the IR(ME) Regulations, for the functions described in Sections 19, 20 and 21 of the Health and Safety at Work Act 1974. The investigation was supported by Ms Úna Findlay of Public Health England, who provided independent expert advice throughout.

The scope of the investigation and of this report extends beyond consideration of compliance with the statutory provisions of the IR(ME) Regulations to more detailed assessment of the circumstances that caused this incident and of the measures that should be enacted to minimize the potential for adverse incidents at the ECC and at other radiotherapy centres in Scotland and elsewhere.

Information obtained by the Inspector during the course of this investigation is subject to restrictions on disclosure, particularly those pertaining to Section 28(7) of the Health and Safety at Work Act 1974. Reporting of any information that might be regarded as personal data is further restricted under the provisions of the Data Protection Act of 2018. To address the issues arising from this legislation, the relevant consents were sought from those who provided information and from those for whom it was intended that personal data be included

in this report. These have included representatives of the ECC's senior management and clinical staff, including the person referred to as 'Clinical Oncologist B' in this report. Consent to disclosure of information under the Health and Safety at Work Act was obtained from all of those asked.

With particular regard to the provisions of the Data Protection Act 2018, the content of this report has been anonymized to the degree considered necessary by the Inspector to accommodate the consents received from ECC staff. In seeking these consents, staff were advised of the need for job titles to be used in this report to identify individual responsibilities. The particular titles used are, 'Radiographer', and 'Clinical Oncologist'. In addition, to avoid gender identification, the pronouns '*his*', '*he*' and '*him*' and '*himself*' are used throughout and are italicised accordingly.

Regarding the possibility of legal action arising from this incident, the regulatory powers of the Inspector appointed by the enforcing authority (the Scottish Ministers) extend to issuing of Improvement Notices and Prohibitions Notices under the provisions of Sections 21 and 22 of the Health and Safety at Work Act 1974. Any consideration of additional legal proceedings in Scotland is a matter for the Crown Office and Procurator Fiscal Service and is not within the scope of this report.

3. Incident reporting by the ECC

This incident occurred in December 2017, prior to implementation of the new IR(ME) Regulations on the 6th February 2018, but was first reported after that date.

The reporting requirements therefore arise from Regulation 4(5) of the IR(ME) Regulations 2000, which required that: '*Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while undergoing a medical exposure was, otherwise than as a result of a malfunction or defect in equipment, exposed to ionising radiation to an extent much greater than intended, he shall make an immediate preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt that no such overexposure has occurred, he shall forthwith notify the appropriate authority and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received*.'

The incident investigation and reporting provision arise from the new IR(ME) Regulations 2017, which include a new provision (Regulation 9) that '*The relevant enforcing authority*

must put in place mechanisms enabling the timely dissemination of information, relevant to radiation protection in respect of medical exposures, regarding lessons learned from significant events'.

With regard to this new provision, this is considered to have been a 'significant event', and this report addresses the resulting duties of the relevant enforcing authority (the Scottish Ministers).

The treatment error was first identified by the ECC on 7th March 2018. The first, notification to the 'appropriate authority' was an e-mail from the ECC to the Warranted Inspector dated 14th March 2018, indicating that an error had been identified and was under investigation. This was followed by an e-mail, from the ECC's Associate Medical Director of Cancer Services dated 12th April 2018, to which was attached a report of the internal incident investigation dated 11th April 2018,

In all senses, it is the view of the inspector that notification was both timely and comprehensive and fully in accordance with the requirements of Regulation 8 of new IR(ME) Regulations 2017 'Employer's duties: accidental or unintended exposure'.

4. The nature of the error

4.1 The treatment received

Radiotherapy treatments are normally considered in two categories, 'radical treatment' where the aim is to achieve a cure, and 'palliative treatment' is where the aim is to improve the quality of life of patients by reduction in the size of the cancer or to relieve pain or other associated symptoms. This incident relates to a palliative treatment, one further feature of which is that whereas radical treatments involve individual outlining of a target (with the addition of small margins to allow for known planning and delivery conditions) the margins of the targeted treatment area for palliative treatment normally are bigger and less precisely delineated.

In August of 2017 a patient with breast cancer and with a 3-month history of hoarseness was referred by a General Practitioner to the Ear, Nose and Throat Department of NHS Lothian's University Hospitals Division. Examination showed left vocal cord palsy.

Since August of 2015, the patient was known to have had a metastatic left anterior hilar lymph node tumour invading the mediastinum (the central area between the lungs), and in August of 2017 a repeat CT scan showed that the size of this tumour remained unchanged.

The patient was then referred to the ECC and had a repeat CT scan on 28th November 2017 which showed an increase in the size of the tumour. The Clinical Oncologist who reviewed this scan (Clinical Oncologist A) therefore arranged for the patient to attend the relevant ECC oncology clinic on Monday 18th December 2018. The intent was that a suitable course of palliative radiotherapy aimed at reducing the left anterior hilar lymph node tumour should be considered.

At the oncology clinic, the patient was seen by Clinical Oncologist B. This was the first time that Clinical Oncologist B had met the patient.

The outcome of this consultation was that Clinical Oncologist B completed a standard ECC informed consent pro-forma for treatment of the 'Mediastinum' with the intent 'To shrink the hilar mass', which the patient then signed. The mediastinum was to be treated with the aim of alleviating the vocal cord palsy by targeting the enlarged hilar lymph node thought to be affecting the left recurrent laryngeal nerve.

Clinical Oncologist B then completed the standard ECC Radiotherapy Booking Form as the 'Referrer' and signed the justification section of the form as the 'Practitioner'. The 'Treatment Site' was completed on the form as 'Mediastinum', with no further elaboration of the particular area of the mediastinum on which the treatment should be focussed.

On the same day (Monday 18th December 2018) Clinical Oncologist B submitted a request for an 'ad-hoc'* treatment planning session and this was arranged for the morning of Friday 22 December 2018. (The term 'ad-hoc' is used by the ECC to refer to treatment planning sessions that are not part of the site specific scheduled weekly planning sessions.)

With regard to the IR(ME) Regulations, in addition to acting as 'referrer and 'practitioner' for the pre-treatment and treatment exposures, in carrying out the practical aspect of field placement, Clinical Oncologist B was also acting as an 'operator'.

The treatment prescribed by Clinical Oncologist B was a total dose of 20Gray (Gy) of X-ray radiation to be delivered to the mediastinum in 5 fractions, each of 4Gy.

The prescribed radiation dose, method of delivery, and fractionation were as expected for treatment of this condition, and in accordance with the relevant ECC Employer's Written Protocol for 'Clinical management guidelines for lung cancer'.

The patient commenced radiotherapy on 27 December 2017 and completed 5 fractions of radiotherapy on 4 January 2018.

On 4 January 2018, the patient complained of retrosternal pain radiating to the back and was seen by another clinical oncologist (Clinical Oncologist C). The diagnosis was radiation-related pain flare, and analgesia was advised.

On 21 January 2018, the patient was seen by the ENT Consultant who documented that the voice was much improved.

On 5 February 2018, the patient was reviewed by Clinical Oncologist A, who documented voice improvement and some mediastinal discomfort which had been present for approximately one week following completion of radiotherapy. The patient had no other new symptoms. A repeat CT scan was requested.

On 5 March 2018, the patient attended the follow-up clinic and was told by Clinical Oncologist A that the CT scan showed that the metastatic tumour in the left anterior hilar lymph lobe had increased in volume when compared with the scan conducted prior to the radiotherapy treatment. No other new sites of disease were identified. Since the result from this CT scan was unexpected following radiotherapy, Clinical Oncologist A arranged for the patient's imaging to be reviewed and for reassessment of the radiotherapy planning scan.

On 6 and 7 March 2018, Clinical Oncologist A together with another clinical oncologist from the relevant ECC Team (Clinical Oncologist D) reviewed the radiology and radiotherapy fields and found that the tumour in the left anterior hilar lymph lobe had not been covered by the radiotherapy. Therefore, the treatment given had no possibility of achieving the hilar mass shrinkage referred to in the completed consent pro-forma.

This report considers compliance with IR(ME) Regulations, the circumstances of these errors, and the measures necessary to minimize the risk of recurrence at the ECC and elsewhere.

4.2 Treatment Planning

Radiotherapy is a stepwise process that starts with clear identification of the size, shape, and position of the tumour (or other region of tissue) to be treated, followed by planning of how best to direct the radiation at the treatment site while avoiding damage to healthy

surrounding tissue. The resulting plan is then used to direct the treatment machine (the 'Linear Accelerator' or 'Linac') in delivering the prescribed radiation dose.

In the Friday 22nd December 2017 planning session the radiographers positioned the patient on a CT scanner and scanned the relevant part of the patient as described on the treatment prescription form. The images from this CT scan were displayed on a computer screen in the control area, whereon Clinical Oncologist B used the applicable software to define the borders or extent of the area for treatment.

This process is known as 'field placement' undertaken using virtual simulation software.

At the ECC, this information is then transferred to a system of lasers in the CT scanning room which identify the centre of the area for treatment on the skin of the patient. This point is then marked with a small tattoo. When the patient later attends for radiotherapy treatment, this tattoo defines the centre of the area or field that will be irradiated during treatment.

The treatment field defined by Clinical Oncologist B was a square measuring 10 by 10 cm.

When questioned as to why this field appears shifted to the lower right of the mediastinum (the initial concern having been for the left anterior hilar lymph node tumour) Clinical Oncologist B stated that at the time of viewing the planning CT images an area of concern to the lower right (possibly a further metastatic tumour) had also been noted. *He* therefore considered it clinically appropriate to place the treatment field so as to include this newly identified area.

Beyond this, Clinical Oncologist B, who confirmed awareness at the time of the need to cover the left anterior hilar lymph nodes, was unable to clarify further how the resulting field placement failed to do so. However, Clinical Oncologist B has since agreed that the most likely scenario was that in seeking to expand an initial field, which had been placed centrally on the mediastinum, by extending it to the lower right, this field was unintentionally shifted (rather than extended) by Clinical Oncologist B during the planning process and the error remained unnoticed by Clinical Oncologist B.

5. Investigation of the causes of the error

Investigation of the error has focussed on any failures by the employer or by Clinical Oncologist B with regard to the duties of the employer under the IR(ME) Regulations and on any other circumstances that might have been contributory factors.

5.1 Duties of the employer

The duties of the employer under the IR(ME) Regulations 2000 which were in place at the time of the incident and which are pertinent to this investigation include:

1. Ensuring that appropriate written procedures and protocols are in place and are kept up to date, (Regulation 4 (1), (2), (3)).

2. Ensuring that all duty holders are properly trained and entitled to undertake their assigned duties, and keeping relevant training records for inspection as required, (Regulation 11).

With regard to the first of these, the ECC documents of particular relevance to this treatment are:

EP2\ECC\1043 'Simple palliative radiotherapy for metastases to locations other than bone, skin, brain or chest'

and

EP2\ECC\1070 'Clinical management guidelines for lung cancer',

Examination of both of these documents found them to be in date and available at the time of the incident, and the content to be appropriate.

With regard to the second of these requirements; training and entitlement of duty holders, document EP2ECC\002 'Induction of staff and training and training records of entitled Practitioner and Operators' was also provided. The version provided was out of date (next review 21/9/17), but, as noted below, was covered by a 'concession'. It did not include details of the familiarization programme for incoming staff, nor of how this should be recorded.

In this regard it was confirmed by the ECC that Clinical Oncologist B underwent a six week induction/familiarization process on joining the ECC. However, no formal record of successful completion of this process was available in support of subsequent operator entitlement. (A similar report published by the Scottish Ministers on a previous ECC incident (Johnston A M 2016) recommended that 'where possible, there should be a clear linkage between each of the authorized competences and the training required prior to entitlement.')

During this investigation a general review of ECC documentation was undertaken to assess compliance with the ECC's documented approach to document quality control, as required by the IR(ME) Regulations. A copy of the index of current ECC documents was provided to the inspector at a meeting at the ECC on 9th May 2018. Of these, 6 of the 9 documents (all

of those that should have been reviewed in 2017) that relate to IR(ME) Regulation compliance were found to be out of date and designated as ‘concession’.

In this regard, the term ‘concession’ means permission to use a procedure that does not conform to specified requirements within specified limits. In this case the concession related to the timeliness of document review which was extended. The concession is generally limited for a period of time, and in this case the concession was granted pending finalization of the new IR(ME) Regulations (in February of 2017).

While there is merit in the decision to await implementation of the new IRME Regulations before reviewing some of the ECCs Employer’s Written Procedures, it is also the case that it should have been known that any new requirements were highly unlikely to affect the content of some of these documents. Taken together with the concerns raised by ECC staff about staffing pressures, and the fact that these ‘concessions’ were still in place at the end of July 2018, it might reasonably be concluded that these pressures, together with the absence of the formal document quality control software available in other areas of NHS Lothian, were a contributory factor in postponing the required reviews of these documents.

However, in no sense was this considered to have been a contributory factor in this particular incident.

In summary, the current ECC provisions for recording of training prior to entitlement of duty holders were found to be deficient, and there is evidence for concern about for quality control of Employer’s Written Procedures and Protocols.

5.2 Responsibilities of the duty holder

The legal responsibilities of referrers, practitioners, and operators under the IR(ME) Regulations 2000 (as amended in 2006) which were in place at the time of the incident which are pertinent to this investigation included:

1. The practitioner and the operator must comply with the employer’s procedures, (Regulation 5(1)).
2. The practitioner is responsible for the justification of an exposure, (Regulation 5(2)).
3. The operator is responsible for each practical aspect which the operator carries out, (Regulation 5(4)).

4. The practitioner and the operator must cooperate, regarding practical aspects, with other specialists and staff involved in an exposure, as appropriate, (Regulation 5(6)).

With regard to item 3, field placement is an operator responsibility and in this case was the responsibility of Clinical Oncologist B. While an error was clearly made in carrying out this 'practical aspect' of the exposure, there is no indication that this was done carelessly or negligently or in any way that could be construed as the operator having failed to comply with the employer's procedures.

Further to this, evidence was provided that Clinical Oncologist B was adequately trained and appropriately entitled to 'justify, prescribe and define the target volume' for 'Palliative nodes'.

In no sense, therefore, was Clinical Oncologist B (or any other individual duty holder) found to have failed to comply with these requirements.

5.3 Other relevant factors

5.3.1 Staffing

The relevant ECC team for this form of treatment comprises five Clinical Oncologists. Of these the usual compliment for Monday to Thursday is between three and five, but normally only two on a Friday. The relevant team does not have routine site specific planning sessions on Fridays.

This incident occurred on the last working day (Friday) before the Christmas Bank Holiday when Clinical Oncologist B was the only member of the relevant team on site.

With regard to these provisions generally and to this Friday in particular, at interview, Clinical Oncologist B identified the following concerns:

- Clinical Oncologist B is often the only appropriately trained clinical oncologist from the relevant team in the department on a Friday. This was the case on the day that the patient attended (22 December 2017 – i.e. the Friday before the Christmas break) when Clinical Oncologist B was very busy and as such did not have the time to process *his* thoughts about the planning for this case.

- They often feel isolated within the team as there is no one available to ask for advice or reassurance on those occasions when it might be required. This is due to the pattern of work of clinical oncologists within the team which includes part time working

and off site work for the outreach service. This has resulted in some communication difficulties, e.g. mostly email rather than phone or face to face communication.

In response to these concerns, the ECC has indicated that on those occasions where there is only one Consultant Clinical Oncologist from a particular team on site at the ECC, if there is another Consultant Clinical Oncologist from the same team involved in off-site work for the outreach service, they can be contacted by phone for advice, support or reassurance. If this is not available and advice is still required, for non-urgent cases the Clinical Oncologist can discuss the case at a subsequent team meeting or peer review meeting, and for urgent cases which require immediate treatment decision because of clinical urgency, such as spinal cord compression, an on-call Clinical Oncologist is available 24/7 to provide telephone advice, support and reassurance, or to attend the ECC site. All ECC Consultant Clinical Oncologists have been reminded of these provisions.

- Clinical Oncologist B felt somewhat unsupported in certain aspects of *his* IR(ME) Regulations entitlement for *his* expanded role, in that these did not appear to have been reviewed or updated and feedback on an appropriate action plan and progression had been scant.

In addition to these concerns Clinical Oncologist B also expressed concerns about lack of continuity of care within the relevant oncology clinic at the time of the event which resulted in clinical oncologists looking after patients who were not previously known to them (as in this case) and planning for their radiotherapy for metastatic disease.

When questioned further about particular staffing pressures on the day of the incident, Clinical Oncologist B accepted that lone working on a day (the last working day before the Christmas break) when 'loose ends' were being addressed and, in the case of this patient, the abnormal pressure for urgent treatment that arose because of the impending hiatus in treatment over the Christmas break, had probably contributed to difficulties in focussing on the various tasks in hand.

5.3.2 'Ad-hoc' versus regular treatment planning sessions

A further contributory factor cited by Clinical Oncologist B was that planning for this patient was carried out during an 'ad-hoc' rather than a 'regular;' planning clinic. When questioned further on this concern, the following points were noted:

- The need for ad-hoc clinics for the planning of urgent cases is an essential aspect of the work of the ECC.
- The term ‘ad-hoc’ simply means that these single planning sessions occur at a different time from the regular planning clinics wherein more appointments for similar site specific treatments are planned together. In all other senses, prior booking, available time etc., the sessions are the same.
- The principal concerns for these ad-hoc clinics that were cited by Clinical Oncologist B and acknowledged by ECC senior staff are that these sessions are more subject to distraction and interruption, and that regular sessions allow for greater ‘focus of mind’. However, the view of the ECC remains that whereas there is an increased possibility of error, the risk is not unacceptable in relation to necessity of this aspect of the service.

5.3.3 Conclusions regarding contributory factors

In considering the various concerns cited above, there seems little doubt that the occurrence of this incident during an ad-hoc planning clinic on the last working day before the Christmas when Clinical Oncologist B was working alone (in this case due to sickness absence of a second colleague) was not coincidental. Indeed, it has been acknowledged by the ECC that non-uniformity of staffing provision is an issue that needs to be addressed.

The general conclusion must therefore be that staffing pressures were a contributory factor in the occurrence of this incident.

6. Recommendations arising from the ECC internal investigation, and resulting actions

The recommendations included in the ECC internal report were that:

1. The patient is kept informed throughout the process and is supported. The consultation should include an apology.

2. The relevant oncology team will operate in a culture of openness with both patient and staff involved in this incident with maintenance of dignified confidentiality.

3. The Department continues with regular peer reviews of radical plans and should consider a regular retrospective audit of volumes for palliative treatment.

4. The clinical oncologist involved is supported to mitigate adverse effects of the incident, physical and psychological, both actual and potential.

5. The Directorate should review the palliative work flow and ensure adequate clinical oncologist staffing in the relevant team to minimise unduly busy clinical and planning sessions.

6. The Directorate should consider a named clinical oncologist review of patients for continuity of care by the relevant team.

7. The Directorate should recommend a departmental consideration for more descriptive information on the proposed treatment fields on the radiotherapy booking form, so that if a clinical oncologist finds themselves in a position of planning radiotherapy in a patient they do not know, they have clearer instruction from the referring colleague.

8. The relevant team should also consider regular team building exercises and seek support and help from the Directorate to achieve this.

9. Clinical Oncologist B's IR(ME)R entitlement for more complex plans should be reviewed with an agreed timeline and action plan.

The ECC has advised that as of 31st July 2018, actions arising from Recommendations 1 to 7 had been completed, with the exception of the 'retrospective audit of volumes for palliative treatment' (in Recommendation 3) which is scheduled for completion in November of 2018. Action arising from Recommendations 8 is described as 'ongoing', and action arising from Recommendation 9 is scheduled for completion on 31st December 2018.

With particular regard to Recommendation 5, the ECC has highlighted the difficulties of workforce planning for consultant oncologists in the face of 'severe external constraints', including the need to operate efficiently and flexibly 'at near 100% capacity'.

Actions taken by ECC management in response to these difficulties include detailed management review of individual job plans to ensure, for example, that leave is planned sufficiently in advance to ensure that adequate cover is available,

Having, in accordance with Recommendation 5, reviewed 'the work flow and adequate consultant staffing', the ECC has concluded that with regard to their principal aim of 'the safe and effective provision of patient centred care', 'NHS Lothian Cancer Services provides a

safe and efficient clinical service through the continuing pressures of increasing demands and services at full capacity'.

7. Summary of principal findings

The principal findings arising from investigation of this incident are summarized in the following paragraphs.

A patient with a history of metastatic breast cancer, and left vocal cord palsy, thought to be associated with the patient's cancer diagnosis was referred by the Ear, Nose and Throat Department of NHS Lothian's University Hospitals Division to the ECC.

At the ECC oncology clinic, Clinical Oncologist B completed a standard ECC informed consent pro-forma for a suitable course of palliative radiotherapy of the 'Mediastinum' with the intent 'To shrink the hilar mass', and made arrangements for an 'ad-hoc'* treatment planning session.

The prescribed radiation dose, method of delivery, and fractionation were as expected for treatment of this condition, and in accordance with the relevant ECC Employer's Written Protocol for 'Clinical management guidelines for lung cancer'.

In this case, however, Clinical Oncologist B, defined a treatment field that did not (as per the completed informed consent pro-forma) encompass the 'hilar mass' and therefore had no possibility of achieving the hilar mass shrinkage referred to therein.

Palliative treatment was planned accordingly and was delivered between 27 December 2017 and 4 January 2018.

While no definite conclusions can be made, the most likely scenario appears to be that Clinical Oncologist B made an initial field placement as a 10cm x 10cm square that covered an area centred on the mediastinum and included the hilar mass, but then, on observing on the screen another area of possible concern immediately outside the lower right corner of this area, sought to extend this field to include this area. However, in attempting to do so, it appears that instead of extending this initial radiotherapy treatment field, Clinical Oncologist B shifted this treatment field to a different part of mediastinum that no longer covered the original intended hilar mass target

The patient was fully informed of the error and underwent subsequent radiotherapy to the area originally intended.

The magnitude of this overexposure is such that there was a significant possibility of harm to the patient. However, the ECC has reported that there have been no unusual adverse clinical outcomes associated with this error and that none are expected to occur.

Clinical Oncologist B was properly entitled to carry out all of the functions undertaken (as referrer, practitioner and operator), and in no sense did Clinical Oncologist B fail to comply with the duty-holder responsibilities specified in the IR(ME) Regulations. Neither was there clear evidence of an error in clinical judgement, in that Clinical Oncologist B believed 'at the time' that the presentation on the CT scan justified an extension of the mediastinal field to the lower right. The error appears therefore to be one of process in inadvertently shifting rather than extending the field.

The investigation also considered compliance with the duties of the employer under the IR(ME) Regulations. In this regard there is evidence of a failure by the employer to keep appropriately detailed training records and concern about the resources being deployed to maintain employer's written procedures and protocols to an appropriate standard. However, there is no evidence to suggest that these shortcomings contributed in any way to the error in field placement.

No evidence has therefore emerged to indicate need for enforcement action under the IR(ME) Regulations.

8. Conclusions and recommendations.

8.1 The causes of the error

The findings of this investigation lead to a conclusion that staffing pressures contributed to this error.

In particular sickness absence of a colleague meant that Clinical Oncologist B was the only team member available on a particularly busy Friday, this being the last day before the Christmas break, when there was pressure to 'tie up loose ends'.

However, it is apparent also that inconsistences in the levels of staffing for clinical oncologists (in this case lack of staff on Fridays) and the functioning of the specialist teams are problematical throughout the year.

The ECC has acknowledged these difficulties, but has advised that a staffing review has been completed and the staffing levels are considered by the ECC to be ‘adequate’.

While this might indeed by the case, it is clear that problems remain, as identified in Section 5.3.1 of this report.

With regard to the duties of the employer under the IR(ME) Regulations, this investigation has concluded that the lack of appropriate documentation of training prior to entitlement of Clinical Oncologist B as an operator within the ECC constitutes a failure on the employer to comply with the relevant provision of the IR(ME) Regulations for training and entitlement of duty holders.

Concerns about the maintenance of Employer’s Written Procedures and Protocols, have also been identified.

Neither of these concerns with regard to the duties of the employer is considered to have been a contributory factor in this error.

8.2 Recommendations for further action by the ECC

In addition to the actions recommended in the ECC internal report (Section 6 of this report) the following corrective actions are recommended:

Documentation relating to training of staff prior to entitlement should be reviewed with a view to ensuring that the training required prior to entitlement for each particular competence is clearly documented and that there is clear definition of how such successful completion of such training must be recorded (preferably by completion of an authorised pro-forma).

Pro-forma training plans should include details of the training that must be completed, and should include provision for identification of the person undergoing the training, the person confirming satisfactory completion of that element of the training, and the date on which this is done.

An inclusive review of the working practices of all ECC clinical oncology teams should be undertaken with the aims of identifying and addressing weekly inconsistences in staff provision and any other deficiencies in palliative radiotherapy working practices and processes that might contribute to errors.

The current ‘team based’ approach to patient care should be reviewed with due consideration of replacement of this approach with an ‘individual named clinical oncologist’ approach (whereby patient care is assigned to an individual member of each team rather than to the team as a whole).

Current provisions for document control should be re-examined in the light of those provisions that are in place in other areas of Lothian NHS Board.

9 Acknowledgements

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10 References

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