Public Health England

Protecting and improving the nation's health

Learning from the past 10 years of the Radiotherapy Clinical Site Visit

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

Prepared by: Medical Exposures Group
For queries relating to this document, please contact: radiotherapy@phe.gov.uk

Published October 2018
PHE publications
gateway number: 2018540

PHE supports the UN
Sustainable Development Goals

Contents

Executive summary

In 2006, the then Chief Medical Officer for England, Sir Liam Donaldson launched a range of initiatives relating to patient safety in radiotherapy[1]. One of these initiatives involved the Health Protection Agency (HPA, now Public Health England) recruiting clinically trained staff to establish a dedicated and impartial resource to support the radiotherapy (RT) community, with the knowledge and skills to work in partnership with healthcare professionals within the clinical setting.

The Medical Exposures Group (MEG) within Public Health England (PHE) was tasked with delivering this work. MEG is made up of a small team of healthcare professionals who provide independent advice on RT medical exposures across the UK. This involves the analysis of RT error (RTE) and near miss events and promulgation of learning across the community; the provision of independent on-site support to individual departments; work with professional bodies to provide guidance on good practice; the provision of support to inspectorates, Department of Health and Social Care, and liaison with UK professional bodies and international organisations. The provision of advice to a clinical department is wide ranging. It may be simply a response to a telephone enquiry from a healthcare professional or may involve a clinical site visit (CSV) where members of MEG will attend a clinical RT department. Interactions with clinical departments depend on the nature of the request for advice and the needs of the individual department. The CSV provides a vehicle to deliver key safety messages to all those involved in the delivery of radiotherapy. In the delivery of this service MEG have conducted 113 visits and produced 44 written reports and found variation in service profile and delivery across RT providers with many common themes highlighted within written reports of CSVs. This review of the past ten years of the CSV service is intended to share learning to all radiotherapy professionals. This document will allow RT professionals to review the key themes and link to their own procedures.

The most common high level theme in the findings from these visits was related to departmental issues (43 out of the 44 written reports) as described in section 4.1.1. These highlighted central efficiency issues that impacted across the department which could be grouped into a need to further streamline the pathway, reduction in a replication of effort through running paper and electronic systems, optimisation of the quality management system and redundant checking processes. During visits there was a sense that personnel were responding to the workload and ensuring maintenance of service delivery. This left little opportunity for effective teams to step back and review their overall approach to service delivery resulting in service evolution as opposed to service planning. Frequently service users could identify these inefficiencies but simply had not had the resource to pull these together into a report with an action plan.

The second most common high level theme in the findings were issues related to the implementation of Radiation (Medical Exposure) Regulations (IR(ME)R)[2] (41 reports) as presented in section 4.1.2. It should be noted that IR(ME)R 2000 and the associated amendments are referenced within this document. These regulations were updated on the 6th February 2018[3]. However much of the learning is still very pertinent in light of these new regulations. The most commonly reported theme was related to correct patient identification (21 reports). This was followed closely by training and entitlement of staff and confirmation of pregnancy status (20 reports). Each of the themes did not highlight breaches in IR(ME)R but the requirement to strengthen documentation, practice and adhere to national guidance[6,7]. Most frequently it was seen that clinical practice exceeded the practice described in the supporting documentation and it was a simple matter of updating the IR(ME)R procedures to reflect practice. Due to a variance in workflow in individual departments the area reviewed the least was virtual simulation which was included in 16 reports (see table 1).

Recommendations of the Francis report[15] into failings at the Mid-Staffordshire NHS Foundation Trust included a requirement for openness, transparency and candour throughout the NHS to support a culture of protecting patients and removing poor practice. Participation in external peer review visits such as the Clinical Site Visit in part addresses this recommendation, by encouraging departments to be open and transparent about their practice.

The common themes highlighted within this document show that streamlining of working processes are ongoing within RT departments. Recommendations within the reports emphasised a need to adhere to national guidance, which is imperative when implementing new technologies. Although this document highlights common themes where improvements could be made, the CSV also gives the opportunity to share good practice across departments.

1. Introduction

In 2006, the then Chief Medical Officer for England, Sir Liam Donaldson launched a range of initiatives relating to patient safety in radiotherapy[1]. One of these initiatives involved the Health Protection Agency (HPA, now Public Health England) recruiting clinically trained staff to establish a dedicated and impartial resource to support the radiotherapy (RT) community, with the knowledge and skills to work in partnership with healthcare professionals within the clinical setting.

The Medical Exposures Group (MEG) within PHE was tasked with delivering this work. MEG is made up of a small team of healthcare professionals who provide independent advice on RT medical exposures across the UK. This involves the analysis of RT error (RTE) and near miss events and promulgation of learning across the community; the provision of independent on-site support to individual departments; work with professional bodies to provide guidance on good practice; the provision of support to inspectorates, Department of Health and Social Care, and liaison with UK professional bodies and international organisations. The provision of advice to a clinical department is wide ranging. It may be simply a response to a telephone enquiry from a healthcare professional or may involve a clinical site visit (CSV) where members of MEG will attend a clinical RT department. Interactions with clinical departments depend on the nature of the request for advice and the needs of the individual department.

The assurance of patient safety combined with optimal service efficiency, whilst maintaining compliance with legislation are the cornerstones of everyday clinical practice. The ongoing demands facing healthcare professionals providing quality services in an efficient and timely manner are well known. MEG aims to support clinical departments, particularly as they adopt new technologies into existing care pathways and practices. The CSV provides a vehicle to deliver key safety messages to all those involved in the delivery of RT to patients. This face to face interaction with clinical departments allows MEG to positively influence local safety cultures and help clinical departments understand the safety implications of their own processes.

This document aims to share key learning from CSVs conducted by PHE between December 2007 and November 2016.

2. Background to clinical site visits

The CSVs were initiated at the RT department's invitation and with the primary objective of providing independent on-site support and reassurance on issues related to patient safety and process efficiency within the context of the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)[2]. These regulations were updated on the 6th February 2018[3]. However much of the learning is still very pertinent in light of these new regulations.

PHE offered a tailored service, with visits lasting between one and three days depending on the needs of the individual department. The site visit usually began with a meeting with the Heads of Service for the department to ensure that there is participation from all involved professional groups. The patient pathway provided the focus for the visit with time spent in key areas within the clinical department, talking to individual members of staff and reviewing a sample of department procedures. At the end of the visit, feedback of findings and agreement of an action plan was achieved in consultation with key stakeholders from the clinical department. Responsibility for developing and implementing the action plan remained with the clinical department. However, PHE agreed to undertake a follow up visit to review progress on the implementation of the action plan where invited to do so. Ongoing support was offered throughout the process.

The CSV was planned in advance with key stakeholders (usually the Heads of Service) from the department via email contact or telephone and the remit for the visit and work programme agreed. An example of a two day programme can be seen in Appendix A. PHE also reviewed sample clinical protocols and IR(ME)R procedures relevant to the intended purpose of the visit where requested to do so.

The visit usually consisted of a review of the patient and associated data pathways. The focus for the visit was tailored depending on the needs of the individual department. This frequently included a key theme for review during the visit. Examples of themes included paper-light working or checking processes. However, depending on the requirements of the clinical department the review did not always encompass the entire patient pathway.

Visits consisted of a series of observations of key areas within the clinical department, informal discussion with individual members of staff and a review of departmental processes. As PHE also undertake analysis of national RT error and near miss data, opportunities were taken to share learning from these events where appropriate to reduce the potential for these events[4].

The CSVs were developed in partnership with the clinical community and informed through working with service users and non-users. Feedback on the visits from key stakeholders reported that clinical sites valued and benefited from an independent review of all aspects of the pathway without the pressure of inspection. It was reported the CSV often identifies redundant processes so resources could be refocused into areas of potential improvement. During the visit, examples of good practice were shared between departments. Practical advice on the implementation of guidance documents was also given.

3. Methodology

Between the first CSV conducted in December 2007 and November 2016 PHE staff conducted 113 visits over 227 days to 54 departments across 50 healthcare providers. Feedback for these visits included verbal feedback at the time of the visit, email and telephone correspondence and formal written reports.

Upon request, PHE have shared 44 reports directly with individual departments, this document aims to explore the overall learning gained from these reports. Analysis was carried out across the 44 reports to extract common themes. This involved reading through the reports, reviewing where and how patterns within these reports occurred, searching for themes and reviewing these themes. This thematic analysis approach allowed a method for identifying and analysing patterns across the reports[5].

Common themes, including the identification of where improvements could be made and examples of good practice, have been extracted from the reports. National guidance documents published by professional bodies have been referenced within the reports. These include 'Towards Safer Radiotherapy'[6] which sets out recommendations to improve patient safety in RT and 'A guide to understanding the implications of the Ionising Radiation (Medical Exposure) Regulations in Radiotherapy'[7], which aims to help professionals involved in delivering RT to understand and implement IR(ME)R. It is noted across UK RT departments that there is variation in available and commissioned hardware and software, skill mix, professional roles and responsibilities, but the simple patient pathway normally follows from referral to follow up as shown in figure 1. The CSVs usually follow this pathway.

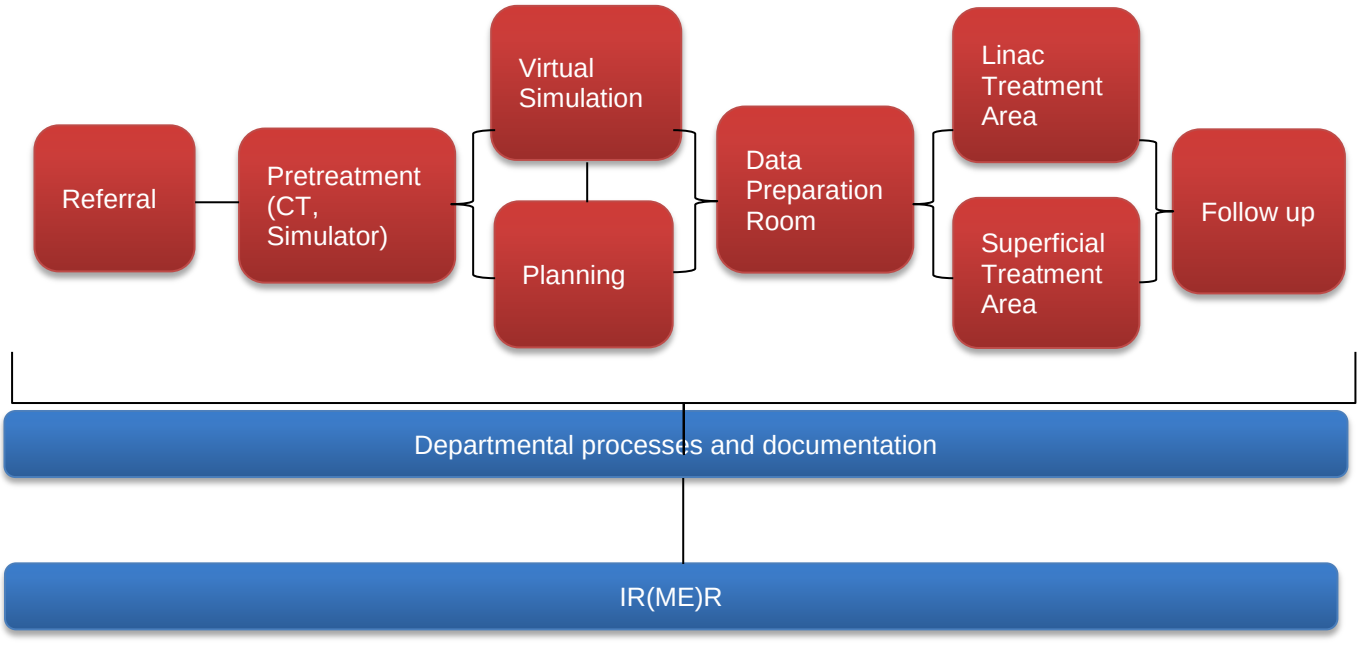


Figure 1: Simple patient pathway

4. Findings

The reasons for a clinical department to initiate a CSV were wide-ranging but included:

- independent review of established working practices
- support whilst implementing new technique/s
- relocating to a new building
- setting up a satellite department
- opening of a brand new clinical department
- a repeat visit focusing on a key area identified in the initial visit
- response to an error or a series of near misses

PHE does not have an inspectorate function and any PHE visit following an incident does not replace the requirement to report exposures much greater than intended, as defined by IR(ME)R, to the relevant inspectorate.

The premise for most CSVs required a review of the entire patient pathway. However, in some cases a more focused review was asked for, so in these cases only part of the pathway was reviewed.

The most common themes in the 44 reports were departmental issues affecting the entire pathway (43), the implementation of IR(ME)R (41), pretreatment (40) and the linac treatment area (40). Table 1 shows the number of reports associated with each section of the pathway.

Table 1: High-level themes identified within each report

Work area	Number of reports
Departmental	43
IR(ME)R	41
Pretreatment	40
Linac treatment area	40
Planning	36
Data preparation room	29
Documentation review	28
Superficial treatment area	25
Virtual simulation	16

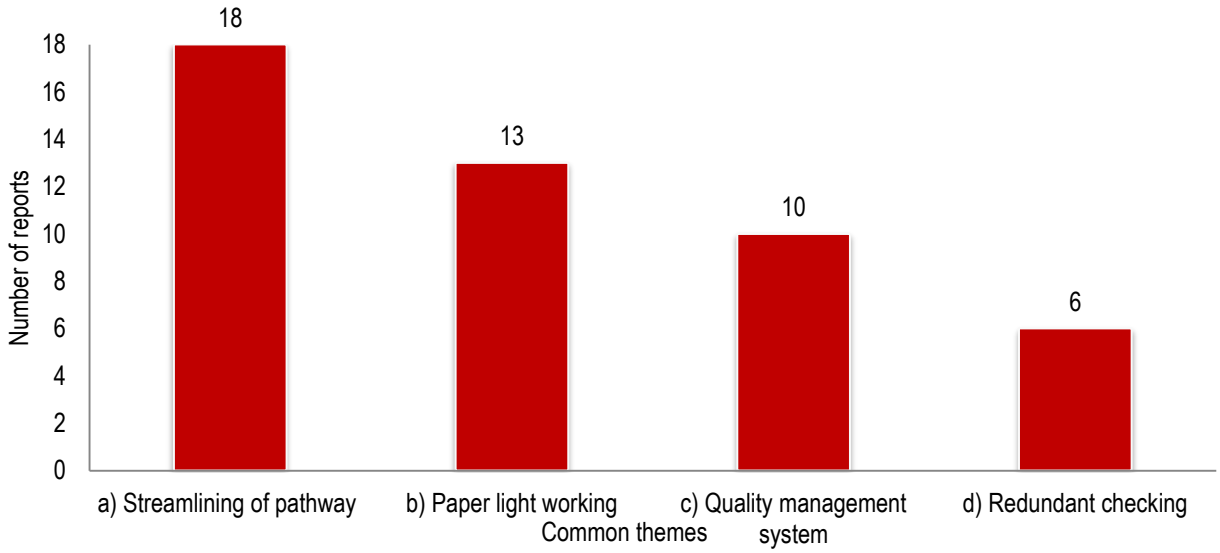
4.1 Common themes

Each report section has been reviewed and common themes are shared below. Areas of good practice and areas where improvements could be made are highlighted. National guidance and recommendations can be associated with the majority of the following common themes; these and associated guidance are presented in Appendix B.

4.1.1 Departmental

From the 44 reports written, 43 contained sections specifically relevant to the overall organisation of the department. The common themes in this section can be seen in figure 2.

Figure 2: Most common themes found related to departmental issues



The most common themes found in this section are summarised as follows:

Streamlining of pathway
A combination of scheduling methods and work planning were frequently seen within individual departments. Maintenance and updating of multiple systems can be resource heavy especially where efforts are duplicated across systems. Where a single system was not centrally available, operators reported delays in seeking information related to planning and treatment and a need to disturb others so they could access the required data. Duplication of tasks was indicated across 18 reports. This included using the oncology management system (OMS) to schedule appointments, which were then transcribed at different points across the department onto white boards; papers based systems, electronic systems and excel spread sheets to manage tasks. Although centres had capabilities to schedule tasks at the appointment booking phase a number of sites scheduled tasks at each handover stage.

Good practice has been seen at sites which used centrally available software to map and streamline the patient pathway, reduce untimely interruptions and allow the workload to be managed more effectively. Reports containing this type of theme have reduced in recent years, with only 3 reported after 2013; this could be due to an uptake in electronic, paper-light systems.

Paper-light working

Departments frequently reported plans to move to paper-light working, through optimisation of the OMS and links to the treatment planning system. Discussions across 13 reports included the necessity to have a secure IT infrastructure in place and appropriate licensing. Both of these elements have been outlined as key requirements for paper-light working[8].

Good practice has been seen in departments where appropriate contingency planning and business continuity arrangements are in place for possible IT failures.

Quality management system

All documentation related to RT treatment planning and delivery should be included within the quality management system (QMS)[6]. A review of the QMS and its utilisation was indicated as required across 10 reports. This included not having department wide access to the QMS and not having all documents within the QMS. Furthermore a number of departments described utilising dual QMS within the department where version control was not identical across systems and documentation replicated.

Good practice was seen when departments incorporated all documents into the QMS and appropriate training on the use of the QMS was part of all new start induction packages. Only 2 reports contained themes relating to a review of the QMS after 2013. It is expected that this reflects how well external peer review of QMS is established within clinical departments and the adoption of electronic systems to manage this aspect of departmental documentation.

Redundant checking

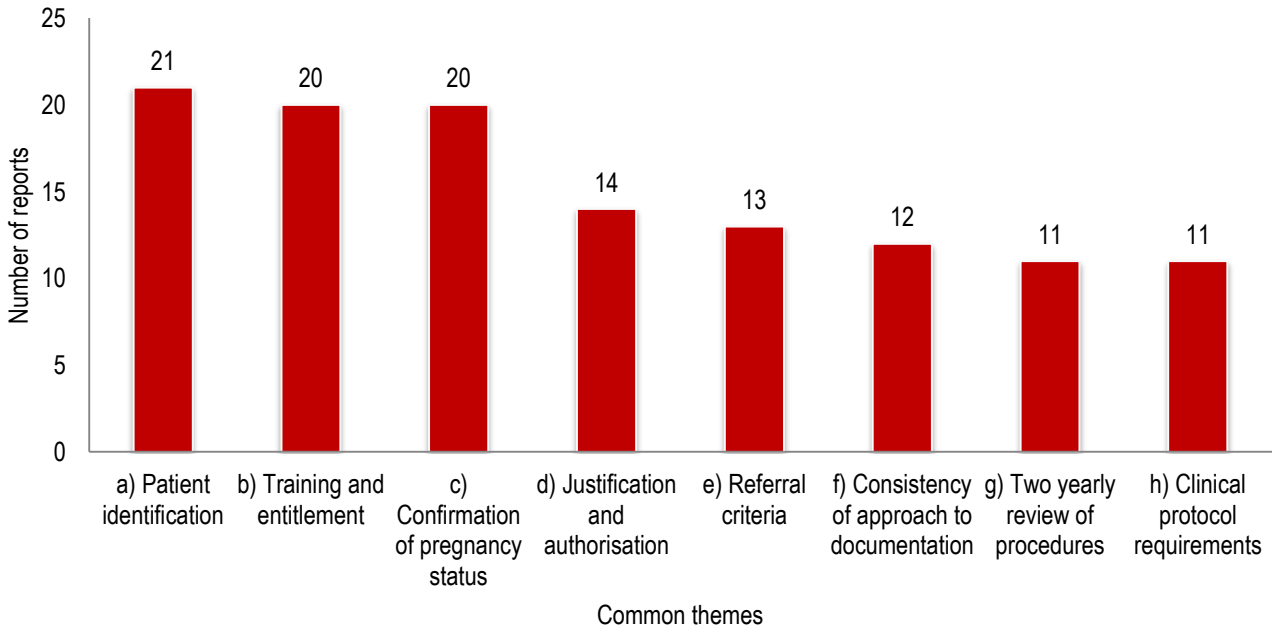
A review of checking processes was described across 6 reports; these reports included the need to review all checklists at time of data hand-offs across the pathway to identify replication. Minimum criteria for checking should be in place at each stage of the process which includes safety critical elements of the pathway. These should be reflected in the supporting documentation[7].

Good practice was seen when a regular review of checking processes formed part of the departmental audit program and led to a change in practice. A range of pause and check posters have been developed as national reminders as an addition to checking processes to prevent errors[9].

4.1.2 IR(ME)R and documentation review

From the 44 reports, 41 contained sections specifically relevant to IR(ME)R and 28 specific to documentation review. When reviewing the text within these sections similar themes were seen, therefore these have been amalgamated within the findings. The common themes in this section can be seen in figure 3. At the time of the CSVs IR(ME)R 2000[2] and amendments were in force. The following text is based on this legislation. Since the 6th February 2018[3] new legislation has come into place and is not referred to within this document, however much of the content is similar so the text remains pertinent to clinical practice.

Figure 3: Most common themes found related to IR(ME)R and documentation review of the reports



The most common themes found in these sections are summarised as follows:

Patient identification
Robust patient identification is required at all points along the patient pathway; this is to ensure the correct individual is exposed to radiation (IR(ME)R Employers Procedure Schedule 1a)[2]. From the 41 reports, 21 included the need to strengthen the patient identification processes. This included only using a single unique identifier or not utilising original source data to identify patients.

Positive examples of patient identification processes included the utilisation of three unique identifiers[6] and ensuring robust identification processes were in place for datasets[7]. Some sites have also included additional photographic identification into their processes.

Training and entitlement

Across 20 reports it was not clear if complete training and entitlement records were in place. This ranged from the need to clarify who held training and entitlement records to individuals being entitled as practitioners but not entitled as operators for the practical aspects of their work. Examples included individuals entitled as a practitioner to justify and authorise treatment prescriptions, but not appropriately entitled as an operator for the purposes of volume delineation in the treatment planning system. IR(ME)R requires the employer to take steps to ensure that every practitioner or operator is adequately trained (Regulation 11(1)[2], undertakes continuing education and training (Regulation 4 (4)b), and keeps and has available for inspection an up-to-date record of training (Regulation 11(4)[2]. Training records should reflect this continuous development and local department-specific training, as well as that achieved through additional external qualifications and courses[7].

Sites where comprehensive up-to-date training records were viewed included description of the training, trainer and assessor sign off, a date when refresher training was due, and records were clearly linked to competency and entitlement.

Confirmation of pregnancy status

An employer's procedure is required under IR(ME)R Schedule Employers Procedures 1(d) 2 to establish whether an individual is or may be pregnant. Departments usually ascertain and document pregnancy status, where appropriate, in writing at referral; this is then confirmed at pretreatment and on the first day of treatment.

Good practice was seen in the displaying of patient posters explaining the need to inform staff if patients thought they could be pregnant. The need to improve the pregnancy status checks was highlighted in 20 reports; this ranged from the absence of clear documentation to demonstrate pregnancy status had been checked, to staff not being fully aware of the departmental age range for confirmation of pregnancy status. It is usual for clinical departments to adopt an age range which reflects their Trust policy and local circumstance. The age range of 12 to 55 years referenced by ARSAC[10] is commonly adopted for this purpose.

Justification and authorisation

Across 14 reports, there were discussions with staff which noted that there was some confusion about the understanding of justification and authorisation in relation to IR(ME)R. Within RT practice this is a practitioner function, unless an operator is authorising under guidelines[7]. Further confusion was reported in 4 reports in relation to the justification and authorisation of concomitant images; further national guidance is available[7].

A good example of a justification and authorisation process for concomitant imaging was seen when these exposures were considered as part of the treatment protocol and prescription process. The concomitant images were included in the treatment protocol which included a maximum number of exposures. If required further concomitant images were then justified

and authorised by an appropriately entitled practitioner. This approach was clearly documented in the underpinning documentation.

Referral criteria
The employer has a responsibility for putting referral criteria in place and ensuring these are available to referrers (Regulation 4((3)a)[2]. In 13 reports this was not clearly evidenced in the documentation reviewed at the time of the visit. It was recommended that diagnostic, histological and clinical findings were included as 'sufficient clinical data' for referral[7]. This approach was sometimes seen to be documented within clinical protocols. Of note, all of these 13 reports were produced during or before 2012.

Consistency of approach to documentation
Within 12 reports the inconsistent use of terminology and approach to documentation was highlighted, this included protocols, procedures and work instructions. The key points for discussion in this area were the need for consistency of nomenclature across documentation including units, terminology and contents[6]. Only 2 reports contained themes relating to a review of the consistency of approach to documentation after 2013; this may be due to the continual uptake of electronic document control which offers more efficient logging of required document changes between reviews.

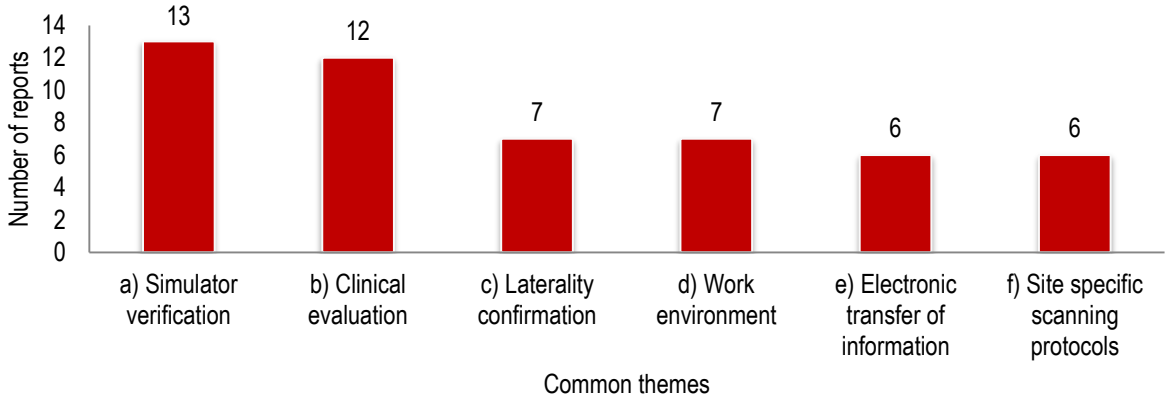
Two yearly reviews of procedures
There is a national recommendation to review all IR(ME)R procedures every two years or whenever there is significant change[6]. A total of 11 reports highlighted that this was not always the local practice. Good practice was seen when clinical departments conducted external audits on their quality management system (QMS), which included their IR(ME)R procedures, and had a robust system in place for document management with MDT input.

Clinical protocol requirements – IR(M)ER requires written protocols for every type of standard radiological practice for each piece of equipment (Regulation 4(2). A protocol has been defined as 'guidance on the detail of a treatment process based on consensus of opinion'[7]. Clinical protocols should be clear about specific responsibilities and include version control and an evidence base for practice[7]. There were 11 reports which included discussions about potential improvements to existing clinical protocols in terms of inclusions. These ranged from the opportunity to improve the evidence base and the omission of key fields, including clinical investigations required prior to decision to treat, immobilisation requirements and follow up requirements[11].

4.1.3 Pretreatment, including CT, simulator and virtual simulation

From the 44 reports written, 40 contained sections specifically relevant to CT and simulator and 16 specific to virtual simulation. When reviewing the text within these sections similar themes were seen, therefore the two sections have been amalgamated within this document. The common themes in this section can be seen in figure 4.

Figure 4: Most common themes related to pretreatment



The most common themes found in these sections are summarised as follows:

Simulator verification

Across 13 reports the verification of some radically planned techniques was shown to be undertaken at a separate patient appointment on the simulator. It was recommended to consider the justification of the extra dose during verification imaging and the potential to introduce errors due to added processes in the pathway. Although this is shown as the most common theme within this section its prevalence has reduced in recent years with only 3 reports after 2013. This reduction may be due to the uptake of on treatment verification imaging and the decreased usage of simulators.

Clinical evaluation

Regulation 7(8) and Schedule 1(j) of IR(ME)R[2] requires that all exposures are clinically evaluated; the evaluation of planning exposures can be demonstrated by their use[7]. The benefit of documenting the number of CT slices and confirming on import was highlighted in 12 reports.

Good practice was seen where the documentation of CT slices was confirmed at import, facilitating a quick QA on the export/import of CT slices between software packages and providing assurance that all slices were used during planning as part of the process of clinical evaluation and optimisation.

Laterality confirmation

The need to strengthen laterality checks was indicated across 7 reports: primarily the need to confirm laterality with the referral form against original source data and the patient before exposure. Laterality verification is the confirmation that data recorded is consistent with primary source data[6] such as histology/pathology data and diagnostic imaging.

Good practice was seen when the laterality from a referral form was confirmed independently against diagnostic images and histology/pathology reports before the planning exposure and during planning processes.

Work environment
It was identified in 7 reports that the virtual simulation work environment could be improved. Examples of a good virtual simulation practice were seen at sites where there was a quiet work environment with the removal of interruptions including telephone queries[6].

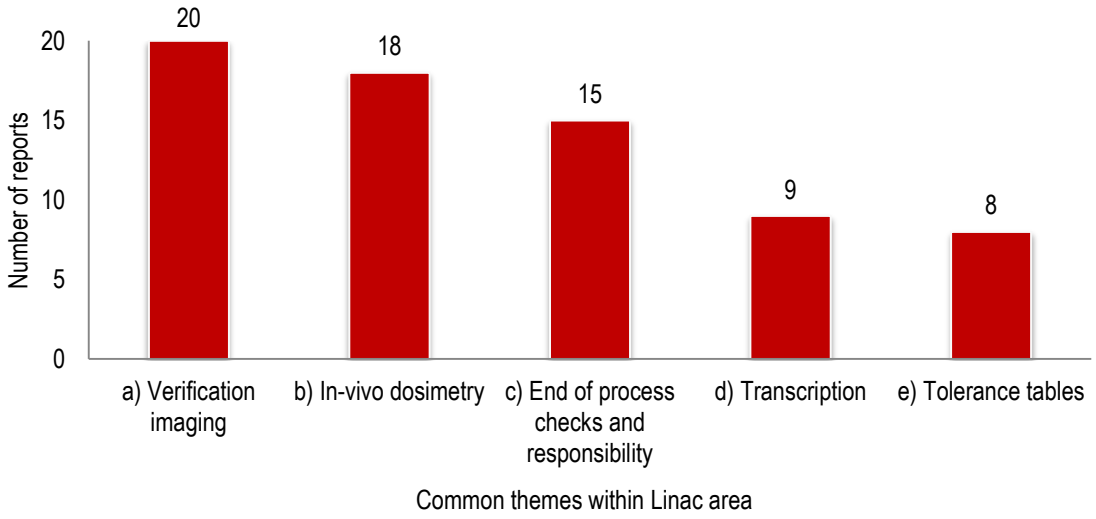
Electronic transfer of information
The transfer of information electronically was discussed across 6 reports. This included the transfer of patient data from the hospital system to the CT scanner and the transcription of set up information in line with national guidance. Good practice was seen at sites where manual and multiple transcriptions were minimised[6].

Site-specific scanning protocols
It was unclear during visits if site-specific scanning protocols were documented and if the estimated dose was available across 6 reports. National guidance recommends a review of these documents every two years or whenever there is significant change[6]. Reflective of themes found in the documentation review, site-specific scanning protocols were not always reviewed every two years.

4.1.4 Linac treatment area

From the 44 reports written, 40 contained sections specifically relevant to the Linac treatment area. The common themes in this section can be seen in figure 5.

Figure 5: Most common themes related to the Linac treatment area



The most common themes found in this section are summarised as follows:

Verification imaging
Across 20 reports imaging protocols were discussed. This included poor quality imaging and staff being unsure of local imaging tolerances. Further national guidance is available[12,13].

Good practice was seen when staff had access to departmental flow charts outlining imaging protocols. The requirement to improve imaging protocols was highlighted in only 5 of the 20 reports after the publication of the image guided radiotherapy clinical support programme in England in 2013[14].

In-vivo dosimetry
National guidance recommends the use of in-vivo dosimetry for most patients[6]. A total of 18 reports stated routine in-vivo dosimetry was not utilised. It was recommended that risk-based position statements regarding the use of in-vivo dosimetry within the departments were established.

Good practice was seen with the use of in-vivo dosimetry on the first treatment of all patients, this was documented within the departmental protocol which also included appropriate tolerances.

End of process checks and responsibilities
The responsibility associated with checks and the replication of checks was highlighted within 15 reports. These reports included senior team members completing all weekly chart checks, verbal verification of all treatment parameters every day and the need to ensure source data was utilised for checking.

Good practice was seen at sites where a review was undertaken across checking processes to assess their need and or value. Tasks were competency based as opposed to grade based. A range of pause and check posters have been developed as national reminders as an addition to checking processes to prevent errors[9].

Transcription
Treatment sheets were reviewed and areas of replication and transcription identified across 9 reports. These reports contained recommendations to assess the use of current paperwork to minimise the need for transcription, duplication of tasks and to ensure identified primary source data was used at all times.

Good examples were seen where transcription of data across paper and electronic systems was minimal. Reports containing recommendations for areas of replication and transcription have reduced in the past few years, with only 2 reported since 2013. As departments become paper-light the use of treatment sheets and transcription of data will continue to decrease.

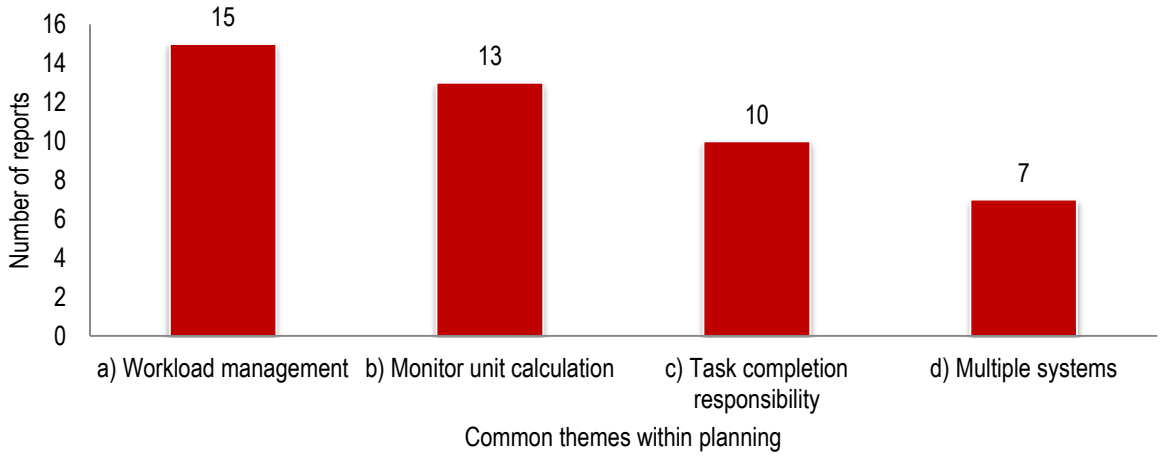
Tolerance tables
Across 8 reports treatment couch tolerances were discussed. This included departments not having site-specific tolerances or these tolerances not being appropriate.

Good practice was seen at sites where couch tolerances were site-specific and appropriate to minimise the risk of geographical errors.

4.1.5 Planning

From the 44 reports written, 36 contained sections specifically relevant to pretreatment planning. The common themes in this section can be seen in figure 6.

Figure 6: Most common themes related to the planning area



The most common themes found in this section are summarised as follows:

Workload management
Across 15 reports the workload in the planning area was shown to be managed using a combination of a paper tray system, and transposing work from the OMS to spreadsheets, paper lists, bespoke electronic systems or white boards, resulting in duplication of effort.

Good practice was seen at sites where the planning tasks were included into the OMS, allowing the workload to be monitored remotely thus reducing interruptions and also allowing prospective management of the workload.

Monitor unit calculation
The monitor unit calculation methodology was highlighted across 13 reports. This included the need to model the couch top and ancillary equipment within the planning system, which eliminates the need for manual manipulation of calculated monitor units for planned treatments.

Good practice was seen at sites where the monitor unit calculation did not require manual transcription or manipulation. Reports including recommendations for improving monitor unit calculations have reduced and only 3 reports have contained this theme since 2013.

Task completion responsibility
Responsibility for completion of tasks was not clear within the planning area across 10 reports. This included responsibilities for outlining and checking of plans, furthermore a number of reports indicated that the significance of signatures was not clear.

Good practice was seen when staff responsibilities for each task and the checking of these tasks was clear, and supported within documentation[6] and training packages.

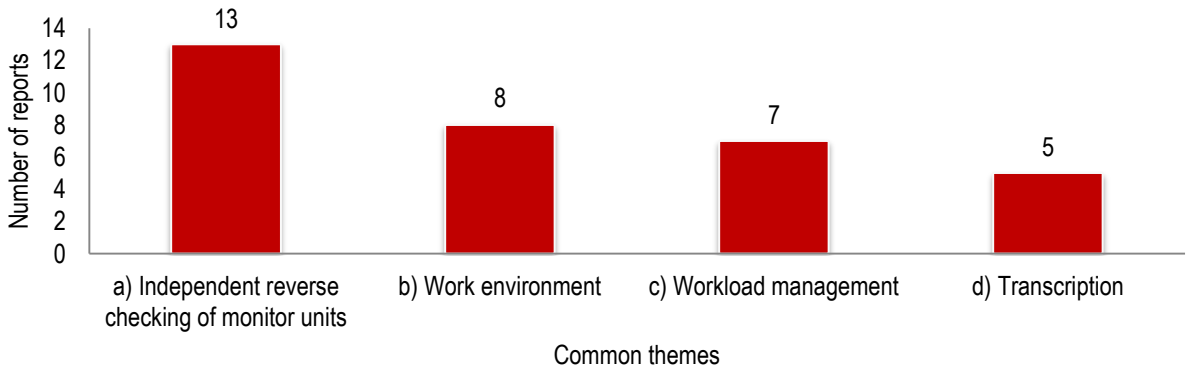
Multiple systems
Multiple software packages within planning were reported across 7 reports. Whilst it is recognised that aspects of each system present benefits to the planning process; a review of all systems full functionality and the associated risks surrounding the use of multiple systems was recommended in these instances to ascertain if all systems were indeed required.

Good practice was seen with the use of a single system which achieved all the planning and virtual simulation requirements for that department.

4.1.6 Data preparation room

From the 44 reports written, 29 contained sections specifically relevant to the data preparation room or calculation room. The common themes in this section can be seen in figure 7.

Figure 7: Most common themes related to the data preparation room



The most common themes found in this section are summarised as follows:

Independent reverse checking of monitor units
There were 13 reports highlighting that different methods were not utilised when checking calculations in the data preparation room.

Good practice was seen when national guidance recommendations were followed and calculations were checked by a different entitled operator using a different method and a separate data set[6].

Work environment
The work environment and staff rotation was described across 8 reports. These included inappropriate work environments where multiple interruptions occurred. It was recommended that a quiet work environment was required for this considerative work[6]. National guidance recommends alternating repetitive tasks with other more diverse activities[6], however across the 8 reports it was highlighted that this was not put into practice.

Good practice was seen when there was allocated quiet space for this type of work to be completed by individuals, who were on a rota to complete considerative work and more diverse activities.

Workload management
Across 7 reports the workload in the data preparation room was shown to be managed using a combination of methodologies: paper tray system and transposing work from the OMS to spreadsheets, paper lists or white boards, resulting in duplication of work. This is similar to a theme highlighted within the planning area.

Good practice was seen with the inclusion of data preparation into the OMS, allowing the workload to be monitored remotely thus reducing interruptions and also allowing prospective management of the workload.

Transcription
The transcription of data within this area was highlighted across 5 reports; this included transcription of set up information, immobilisation and digital moves. Good practice was seen at sites where data was transferred electronically and manual manipulation of data was minimised. This has reduced in recent years, with only 1 report containing this theme since 2013.

4.1.7 Superficial treatment area

From the 44 reports written, 25 contained sections specifically relevant to a superficial unit. The common themes in this section can be seen in figure 8.

Figure 8: Most common themes found within the superficial treatment area

The most common themes found in this section are summarised as follows:

Independent reverse checking of monitor units
Similar to themes found in the data preparation room, 15 reports highlighted independent methods were not utilised when checking calculations for superficial treatments. National guidance recommends that 'calculations should be checked by a different entitled operator, preferably using a different method and a separate data set'[6].

An example of good practice was seen when the departmental protocols utilised robust independent calculation checking, replicating work carried out elsewhere within the department.

Staff allocation
Consideration of staffing levels was indicated across 5 reports. The need to have a group of individuals with up to date competencies to maintain the service was addressed. Also, it was observed in one department that a single operator delivered superficial treatments. Concerns around the potential for error were raised and a recommendation given that two adequately trained, competent and entitled operators should always be directly involved in the exposure.

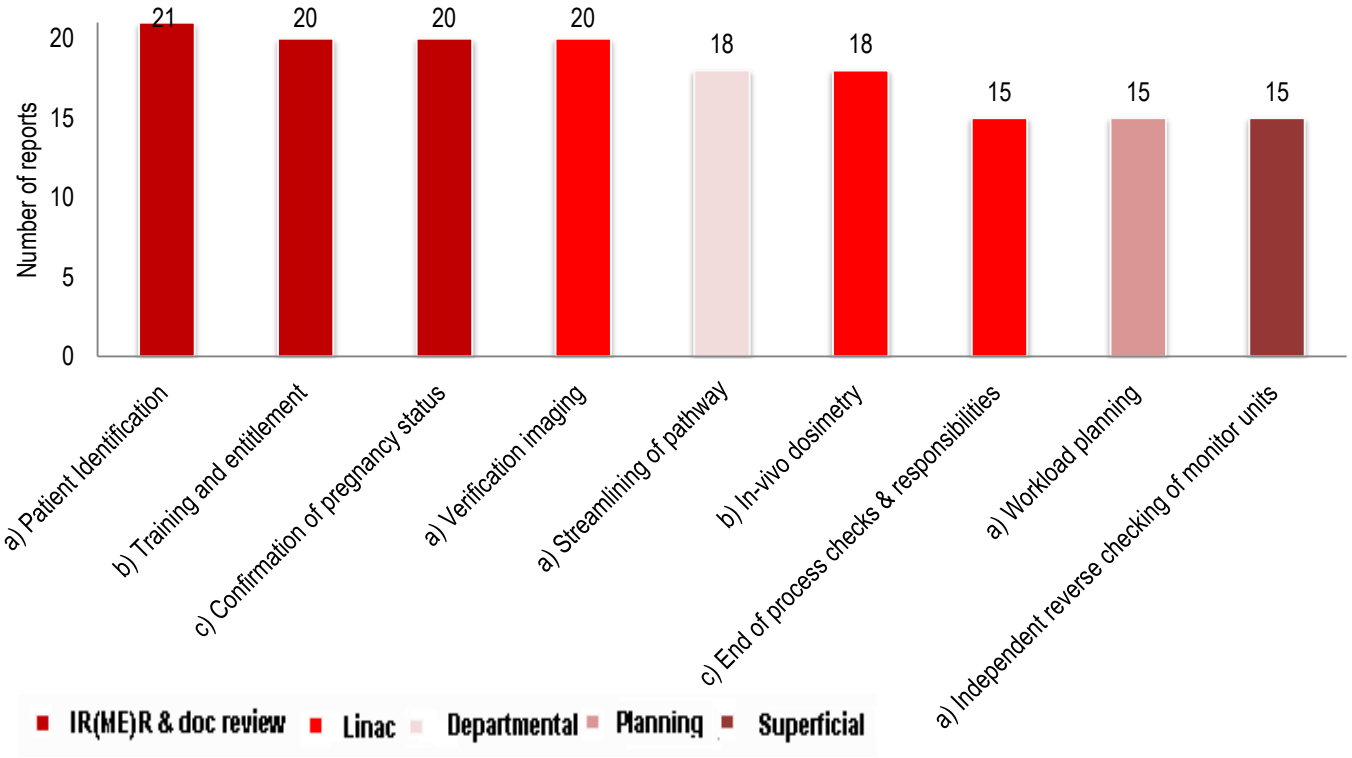
Reduction of paperwork
The reduction of paperwork in this area was discussed within 4 reports. This included the adoption of the OMS for bookings.

Good practice was seen when the workflow in this area mirrored linac work flows including utilising the OMS for bookings, recording patient treatments and streamlining of the pathway.

4.1.8 Most common themes

The most common themes across the 44 reports are represented in Figure 9. This indicates that patient identification is the most common theme across the pathway (21 reports). Training and entitlement, confirmation of pregnancy and verification imaging were each highlighted within 20 reports.

Figure 9: Most common themes across the entire pathway (161/ 390 subset of data)



5. Discussion

Recommendations of the Francis report[15] into failings at the Mid-Staffordshire NHS Foundation Trust included a requirement for openness, transparency and candour throughout the NHS to support a culture of protecting patients and removing poor practice. Participation in external peer review visits such as the Clinical Site Visit in part addresses this recommendation by encouraging departments to be open and transparent about their practice.

In the delivery of this service over the past 10 years MEG have conducted 113 visits and produced 44 written reports, and found variation in service profile and delivery across RT providers with many common themes highlighted within written reports of CSVs.

The most common high level theme in the findings from these visits was related to departmental issues (43 out of the 44 written reports) as described in section 4.1.1. These highlighted central efficiency issues that impacted across the department which could be grouped into a need to further streamline the pathway, reduction in a replication of effort through running paper and electronic systems, optimisation of the quality management system and redundant checking processes. During visits there was a sense that personnel were responding to the workload and ensuring maintenance of service delivery. This left little opportunity for effective teams to step back and review their overall approach to service delivery, resulting in service evolution as opposed to service planning. Frequently service users could identify these inefficiencies but simply had not had the resource to pull these together into a report with an action plan.

The second most common high level theme in the findings was issues related to the implementation of IR(ME)R (41 reports) as presented in section 4.1.2. The most commonly reported theme was related to correct patient identification (21 reports). This was followed closely by training and entitlement of staff, and confirmation of pregnancy status (20 reports). Each of the themes did not highlight breaches in IR(ME)R but the requirement to strengthen documentation, practice and adhere to national guidance[6,7]. Most frequently it was seen that actual practice exceeded the described practice in the supporting documentation and it was a simple matter of updating the IR(ME)R procedures to reflect actual practice. Due to a variance in workflow in individual departments, the area reviewed the least was virtual simulation which was included in 16 reports (see table 1).

During the review of the 44 reports, 34 themes were identified across the entire patient pathway and are presented within this document in section 4.1. Patient identification was the most common theme across the pathway (21 reports). Training and entitlement, confirmation of pregnancy and verification imaging were each highlighted within 20 reports as shown in section 4.1.8. All but one of these common themes was highlighted within the IR(ME)R review section of the reports. Other common themes contained within 18 reports were streamlining of

the pathway across the department and the use of in-vivo dosimetry within the Linac treatment area. Again, these common themes highlighted when guidance was not followed. National guidance and recommendations can be associated with the majority of the common themes indicated across the reports analysed; this is displayed in Appendix B.

There were a number of common themes repeated across the high level themes of the report. This included the need to review the work environment in the pretreatment (section 4.1.3(d) and data preparation area (section 4.1.6(b). The need to improve workload planning was highlighted in both the planning (section 4.1.5(a) and data preparation (section 4.1.6(c) areas. The independent checking of monitor unit calculations was highlighted as an area requiring improvement in the data preparation (section 4.1.6 (a) and superficial (section 4.1.7 (a) sections of the reports, the use of an independent reverse calculation is a known safety barrier in preventing errors[5].

A number of common themes have reduced over the years including streamlining of the pathway across the department (section 4.1.1(a), transcription issues within the Linac area (section 4.1.4(a) and workload planning within planning (section 4.1.5(a). This may be due to the uptake in the use of electronic systems and removal of unnecessary paperwork in paper-light systems. Furthermore the uptake in the use of electronic systems can be seen with the reduction in the transcription of data within the data preparation area (section 4.1.6(d), with only 1 report containing this theme since 2013; this is reflected in the reduction in RT errors associated with accuracy of data entry[16].

Further tools available to enhance patient safety in RT include the Towards Safer Radiotherapy Self- assessment[17] and the checklist for pro-active inspections found in the understanding the implications of IR(ME)R guidance document[7].

The CSV offers the opportunity for an independent review of all aspects of the patient pathway without the potential pressures associated with inspections. Service users reported the CSV identifies redundant processes so resources can be refocused into areas of potential improvement. During the visits, examples of good practice were shared between departments and learning from RT error analysis shared to change practice. Practical advice on the implementation of guidance documents was also given.

MEG's interaction with clinical departments depends on the type and needs of individual departments. By working in partnership, real improvements can be made and any advice given is done in consultation with local sites and with local practice in mind. MEG are in the unique position of being able to provide an independent overview of a clinical department's practices without any preconceived ideas and draw on good practice from elsewhere, as well as their own experiences. Flexibility of approach when undertaking a site visit is a key factor in tailoring advice as each site or situation can be unique. By giving individuals the confidence to challenge their existing practices and identify redundant work processes, more efficient ones can be implemented.

6. Conclusion

The common themes highlighted within this document show that streamlining of working processes is ongoing within RT departments. Recommendations within the reports emphasised a need to adhere to national guidance, which is imperative when implementing new technologies. Although this document highlights common themes where improvements could be made, the CSV also gives the opportunity to share good practice across departments. The CSV provides a vehicle to deliver key safety messages to all those involved in the delivery of RT to patients.

By working in partnership, real improvements can be made and any advice given is done in consultation with local sites and with local practice in mind. MEG staff provide an independent overview of a clinical department's practices without preconceived ideas and is able to draw on good practice from elsewhere, as well as their own experiences. Each site or situation is unique therefore flexibility of approach when undertaking a site visit is a key factor in tailoring advice. By giving individuals the confidence to challenge their existing practices and identify redundant work processes, more efficient ones can be implemented, but always within the appropriate legal framework and within the context of an enhanced safety culture.

7. References

1. Chief Medical Officer's Annual Report 2006 Radiotherapy: hidden dangers. Chapter 5. (2007). Available at http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH_076817
2. The Ionising Radiation (Medical Exposure) Regulations (2000). The Stationery Office, London. SI 2000/1059. Available at www.opsi.gov.uk/si/si2000/20001059.htm. The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) (2000) The Stationery Office, London NISR 2000/194. Available at www.legislation.gov.uk/nisr/2000/194/contents/made The Ionising Radiation (Medical Exposure) (Amendment) Regulations (2006). The Stationery Office, London. SI 2006/2523. Available at www.opsi.gov.uk/si/si2006/20062523.htm The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010. The Stationery office, London NISR 2010/29. Available at www.legislation.gov.uk/nisr/2010/29/contents/made and the Ionising Radiation (Medical Exposure) (Amendment) Regulations (2011). The Stationery Office, London. SI 2011/1567. Available at www.legislation.gov.uk/uksi/2011/1567/introduction/made
3. The Ionising Radiation (Medical Exposure) Regulations (2017). The Stationery Office, London. SI 2017/1322. Available at www.legislation.gov.uk/uksi/2017/1322/contents/made. The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) (2018) The Stationery office, London NISR 2018/17. Available at www.legislation.gov.uk/nisr/2018/17/contents/made. The Ionising Radiation (Medical Exposure) (Amendment) Regulations (2018) The Stationery Office, London. SI 2018/121 www.legislation.gov.uk/uksi/2018/121/contents/made
4. PHE: Safer radiotherapy: radiotherapy newsletter of PHE and supplementary data analysis. Nos 1to26. Available at www.gov.uk/government/publications/safer-radiotherapy-error-data-analysis-report
5. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006; 3, 2, 77-101.
6. RCR, SCoR, IPEM, NPSA, BIR. Towards safer radiotherapy. London, (2008). Available at www.rcr.ac.uk/publication/towards-safer-radiotherapy
7. RCR, SCoR, IPEM. A guide to understanding the implications of the ionising radiation (medical exposure) regulations in radiotherapy. London. (2008). Available at www.rcr.ac.uk/publication/guide-understanding-implications-ionising-radiation-medical-exposure-regulations-0
8. IPEM, IPEM 93 – guidance for commissioning and quality assurance of a networked radiotherapy department (2006). Available at www.ipem.ac.uk/Publications/GuidanceforCommissioningandQAofaNetworkedR.aspx
9. Pause and check, SCoR Available at www.sor.org/ezines/toptalk/issue-153/radiotherapy-pause-and-check-posters-published

10. ARSAC, notes for guidance: good clinical practice in nuclear medicine (2017). Available at www.gov.uk/government/publications/arsac-notes-for-guidance
11. CQC, Compliance with IR(ME)R in radiotherapy departments across England: A summary of our programme of inspections during 2007 to 2009, (2011). Available at www.cqc.org.uk/sites/default/files/documents/cqc_findings_from_rt_inspections.pdf
12. RCR, SCoR, IPEM. On-target: Ensuring geometric accuracy in radiotherapy. London (2008) available at www.rcr.ac.uk/publication/target-ensuring-geometric-accuracy-radiotherapy
13. National Radiotherapy Implementation Group. Image Guided Radiotherapy. Guidance for implementation and use. National Cancer Action Team (2012). Available at www.sor.org/sites/default/files/document-versions/National%20Radiotherapy%20Implementation%20Group%20Report%20IGRT%20Final.pdf
14. SCoR, IGRT clinical support programme 2012-13 (2013). Available at www.sor.org/learning/document-library/image-guided-radiotherapy-igrt-clinical-support-programme-england-2012-2013
15. Francis R. Report of the Mid Staffordshire NHS Foundation Trust public enquiry. HMSO, London (2013). Available at www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry
16. PHE: Radiotherapy errors and near misses: biennial report: report 4, December 2013 to November 2015. Available at www.gov.uk/government/publications/radiotherapy-errors-and-near-misses-data-report
17. NPSA, Towards safer radiotherapy: self-assessment tool (2009). Available at www.nrls.nhs.uk/resources/type/toolkits/?entryid45=74225

Appendix A

An example of a draft programme for a site visit:

Sample programme for clinical site visit		
	Day 1	Day 2
09:30-10:00	Opening meeting	Treatment unit 1
10:00-10:30	Tour of the Dept	
10.30-11.00	CT/simulator	Treatment unit 2
11.00-11.30		
11.30-12.00	Virtual sim	Feedback clinical protocol & procedure, IR(ME)R procedures, review RTE reporting & analysis as required
12.00-12.30		
12.30-13.00	Superficial unit	
13:00-13.30		Feedback preparation
13:30-14.00		
14.00-14.30	Treatment planning	
14:30:15:00		Feedback session
15:00-15.30		
15:30-16.00	Calc & prep area	
16:00-16.30		

Appendix B

Most common themes found across the patient pathway, with associated national guidance and recommendations.

Common themes	Associated towards safer radiotherapy[6] recommendation or page	Associated a guide to understanding the implications of IR(ME)R[7] page	Other guidance
Most common themes found across 4.1.1 the overall department			
a) Streamlining of pathway	Page 32		
b) Paper-light working			IPEM report 93[8]
c) Quality management system	Page 5		
d) Redundant checking		Page 18/28	
Most common themes found across 4.1.2 IR(ME)R and documentation review			
a) Patient identification	Recommendation 8	Page 29	
b) Training and entitlement	Recommendation 3	Page 12	
c) Confirmation of pregnancy status		Page 25	
d) Justification and authorisation		Page 16/18/25	
e) Referral criteria		Page 15	
f) Consistency of approach to documentation	Recommendation 10	Page 33	
g) Two yearly review of procedures	Recommendation 30		
h) Clinical protocol requirements		Page 33	
Most common themes found within 4.1.3 pretreatment			
a) Simulator verification		Page 26/27	
b) Clinical evaluation		Page 28	
c) Laterality confirmation	Page 35		
d) Work environment	Page 5		
e) Electronic transfer of information	Recommendation 13		
f) Site-specific scanning protocols	Recommendation 30		
Most common themes found within 4.1.4 the linac treatment area			

a) Verification imaging	Recommendation 16 & page 45	On-Target[12]
b) In-vivo dosimetry	Recommendation 17	
c) End of process checks and responsibility	Recommendation 7 & page 24	
d) Transcription	Recommendation 13	
e) Tolerance tables	Recommendation 9	
Most common themes found within 4.1.5 planning		
a) Workload management	-	
b) Monitor unit calculation	Recommendation 12	
c) Task completion responsibility	Recommendation 5 & 7	
d) Multiple systems	Recommendation 27 & page 48	
Most common themes found within 4.1.6 data preparation room		
a) Independent reverse checking of monitor units	Recommendation 11	
b) Work environment	Page 5 & 9	
c) Workload management	-	
d) Transcription	Recommendation 13	
Most common themes found within 4.1.7 the superficial treatment area		
a) Independent reverse checking of monitor units	Recommendation 11	
b) Staff allocation	Recommendation 2	
c) Reduction of paperwork	Recommendation 30	