Ionising Radiation (Medical Exposure) Regulations 2017

Findings from CQC's IR(ME)R inspection programme of specialist paediatric radiology services

July 2019

The Care Quality Commission

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- We use our legal powers to take action where we identify poor care.
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- Excellence – being a high performing organisation.
- Caring – treating everyone with dignity and respect.
- Integrity – doing the right thing.
- Teamwork – learning from each other to be the best we can.

Published July 2019

Contents

Background

The Ionising Radiation (Medical Exposure) Regulations 2017, known as IR(ME)R, provide a regulatory framework to protect people from the risk of harm from exposure to ionising radiation as part of their medical diagnosis or treatment.[1]

As an enforcement authority, the Care Quality Commission (CQC) carries out inspections to test the compliance of IR(ME)R employers against their regulatory duties. These inspections are either part of a proactive inspection programme or in response to concerns or notifications received that we judge to be high-risk. In this report we summarise the findings from our proactive IR(ME)R inspection programme of specialist paediatric radiology services in NHS children's hospitals.

Regulation 9 of IR(ME)R requires the enforcement authority to publish information about lessons learned from significant events to raise awareness and share learning. CQC does not currently publish individual reports following IR(ME)R inspections, but through this report, we share the key findings from this latest inspection programme.

Although the programme was dedicated to specialist paediatric trusts, many of the findings are relevant to other non-specialist services in other types of provider.

Medical exposures of children

Children* are more radiosensitive to ionising radiation than the population as a whole as they are more vulnerable than adults to developing certain types of cancer. The longer lifespan of children also provides more opportunity for long-term effects to emerge.[2] The exact lifetime cancer risk for people exposed to ionising radiation as children remains uncertain, but estimates suggest a factor of two to three times higher than that for a population exposed at all ages.[3] Because of this increased risk, IR(ME)R requires providers to pay particular attention to medical exposures of children (Regulation 12(8)(a)).

The use of ionising radiation is fundamental to patient care in diagnosing and treating a range of conditions. In 2017/18, 42.7 million diagnostic imaging examinations were carried out on NHS patients in England, of which 29.7 million used ionising radiation.** Over the last five years, the use of diagnostic imaging has grown by 12.5%; although the number of plain film X-rays carried out has only increased by 4.9%, more complex types of examinations, which use higher doses of radiation, have seen a larger increase, with CT scans increasing by over 36% in this period.[4]

NHS England carries out the monthly Diagnostic Imaging Dataset collection, which covers diagnostic imaging tests on NHS patients in England. The most recent annual publication of activity presents data by age categories, which showed around 6.4% of examinations were carried out on children under 15 years old.[5]

* In this report, we use the legal definition of a child as a person under the age of 18 as set out in the Children Act 1989, Children Act 2004 and Care Standards Act 2000. NHS England's Diagnostic Imaging Dataset collects data on children aged 0 to 14 years.

** Examinations including plain film X-rays, CT, fluoroscopy, nuclear medicine, PET-CT and SPECT.

Figure 1: NHS imaging activity in England carried out on children under 15 years of age by modality, 2017/18

Modality	Age 0-14	Total (all ages)	% of total
Plain film X-ray	2,001,165	22,908,795	8.7%
Computed tomography (CT)	55,850	5,146,475	1.1%
Fluoroscopy	55,195	1,025,330	5.4%
Nuclear medicine	17,365	417,460	4.2%
PET/SPECT	1,015	194,285	0.5%
Ultrasound	438,490	9,507,560	4.6%
Magnetic resonance imaging (MRI)	149,140	3,464,010	4.3%
Total	2,720,215	42,701,460	6.4%

Source: Diagnostic Imaging Dataset 2017-18 Data, NHS England

Notifications of errors

CQC's IR(ME)R team receives and investigates notifications of errors. From April 2015 to March 2018, the majority of notifications were of exposures 'much greater than intended' under the previous regulations (IR(ME)R 2000). During this period, errors involving children made up around 7% of the total received (Figure 2). This broadly aligns with the activity seen in the Diagnostic Imaging Dataset.

Figure 2: Number of notifications submitted to CQC involving children under 18, April 2015 to March 2018

Financial year	0-17	Total (all ages)	% of total
2015/16	81	1,269	6.4%
2016/17	70	1,258	5.6%
2017/18	93	969	9.6%
Total	244	3,496	7.0%

Source: CQC notification data

In 2017/18, the total number of notifications received was different, compared with the previous two years because of a change in guidance on what constituted a notification. In February 2018, with the release of IR(ME)R 2017, there was a further change in definition to 'significant accidental or unintended exposures'. For more information about this change in guidance, please see our IR(ME)R annual report[6], and the online guidance on notifications.

Our inspection programme

Between April 2017 and March 2019, we inspected 12 NHS providers of specialist paediatric radiology services across England that had not been separately inspected under IR(ME)R in the previous 12 months. Three were stand-alone children's hospital trusts and the remainder were either hospitals within a trust or specialist centres.

Inspections focused on paediatric radiology services, but also included the wider services for adults where we either had trust-wide concerns, or children's and adult services were not distinct. We carried out three inspections under IR(ME)R 2000, and the remaining trusts were inspected after the implementation of IR(ME)R 2017.

In the majority of cases, inspections consisted of one day on site. We reviewed and discussed policies, procedures and protocols related to IR(ME)R in the first part of the day, then visited the clinical departments where we observed practice and talked to the staff carrying out examinations.

Key findings

We identified a number of themes through this programme and this report provides recommendations where appropriate, to help all providers to improve their practice.

IR(ME)R employer's procedures

A common theme was the lack of up-to-date or incomplete procedures, which are required under schedule 2 of IR(ME)R. We carried out five inspections after IR(ME)R 2017 was implemented and found that the employer's procedures had not been reviewed to reflect the new requirements. We issued three Improvement Notices in relation to documentation and governance processes under Regulation 6(1)(a), 6(1)(b), 6(2) and/or 6(5)(b). There is more information on the specific breaches in our enforcement registry.[7]

In these cases, although the breaches were similar, we followed our enforcement policy[8] and reviewed each case on its own merit as different factors affected our decision making, such as the level of risk management and length of time between the formal sign-off and implementation of the requirements.

During the early stages after IR(ME)R 2017 was implemented, we recognised there was a lack of guidance, specifically around some of the new requirements under IR(ME)R, for example communication with patients about the benefits and risks from an examination. It became apparent that the trusts believed that they did not have to review and develop these procedures until the new guidance was published. Although we allowed a period of grace while the new regulations were being implemented, after six months, we found some were still not reviewing these new requirements and had no plans to address them.

Another theme that we found related to the actual content of the employer's procedures. During several inspections we found that practice did not always follow its related procedure. We attributed this to a number of factors:

- Staff were not always aware of the content of the procedures and therefore did not always follow them. Although we saw records that staff had read procedures, we were not assured that they followed them as they did not familiarise themselves with the content often enough.
- Procedures did not always align with clinical practice or provide sufficient detail on processes. Some procedures were not written by the clinical staff that they were intended for. This meant that they did not always match with an established practice. Some procedures did not provide enough detail to follow in areas that were not standard practice. For example, identifying patients who needed translation services or who were unconscious.
- Poor document control. A number of employers had multiple versions of some procedures, some of which included conflicting information. This meant that staff were not always using the most up to date versions, for example staff referred to an old paper copy of a procedure but a more up-to-date version was available on the intranet.

Recommendation for providers

Reviewing and developing procedures should be undertaken as a multidisciplinary team. This should include staff who regularly carry out the tasks, as well as using professional guidance or evidence-based practice where appropriate.

Example of good practice

When developing and implementing procedures, audit is a useful way to review their effectiveness.

In response to our inspection, one trust developed a 'procedure verses practice' audit, where clinical staff were each given a procedure to review and then required to audit compliance with it, to ensure they were aligned. These audits helped to identify and understand where there was non-compliance with procedures, and allowed employers to implement measures to improve compliance, either by educating staff, or further developing procedures.

Pregnancy enquiries

Schedule 2(c) of IR(ME)R requires providers to establish a procedure for making enquiries of individuals of childbearing potential to establish whether they are or may be pregnant or breastfeeding.

All the hospitals we inspected in this programme had a procedure in place, but the quality and type of procedural steps varied. We also commonly found that staff were often unaware of the correct procedure to follow. The content of the procedures themselves varied between different employers. For example, some procedures required staff to follow well-established professional guidance for low-dose radiological procedures and others just questioned the individual about whether they

thought they might be pregnant or not, irrespective of the date of their last menstrual cycle. All trusts we inspected took into account the need to have more extensive checks in place for higher dose procedures.

We also observed variation in the use of pregnancy tests, especially for high-dose procedures. Some trusts indicated that they did not rely on using pregnancy tests for patients potentially in the early stages of pregnancy, whereas others used them for any patient who was unsure of their pregnancy status.

We saw some procedures that did not have clear lines of responsibility to waive the need to make pregnancy checks when urgent clinical circumstances presented. Some procedures established that it was the role of the referrer or practitioner to determine this. Procedures in one trust stated that the decision sat with the operator as the duty holder. But when questioned, radiographer staff we spoke to indicated that this was not the case and they would always take such cases to a practitioner (such as a senior radiographer or radiologist).

We were also not always assured that staff were recording a clear audit trail when they made a pregnancy enquiry. This included scanning signed documentation into radiology information systems or relying on tick boxes with no supporting evidence. This was sometimes because procedures did not clearly define what was required.

Most staff understood local safeguarding arrangements for children if pregnancy enquiries indicated the possibility of pregnancy, particularly if the patient was under 13 years old.

Recommendations for providers

Reviewing and developing procedures should be undertaken as a multidisciplinary team, involving paediatric radiologists, radiographers, paediatric hospital consultants and the provider's obstetrics services.

Procedures should make clear who is responsible for making pregnancy enquiries and who is responsible for determining the circumstances when exposures can go ahead without making enquiries about potential or actual pregnancies. They should also clearly state how to record evidence of making pregnancy enquiries.

Locally derived flow charts act as a clear visual resource to help staff decide what steps to take in determining whether to expose a person of childbearing age. These should be readily available for staff in the clinical area for ease of reference.

Example of good practice

At one trust, we found a well-designed and evidence-based procedure. Following a multidisciplinary review, which also included evidence from teachers of sex-education from local schools, the trust provided clear and age-appropriate pre-examination information for children and their parents or carers. This literature aimed to prepare them for questions that would be asked once in the X-ray room.

Entitlement

Schedule 2(b) of IR(ME)R requires providers to establish a procedure to identify individuals as duty holders who are entitled to act as referrer, practitioner or operator within a specified scope of practice. We observed considerable variation in entitlement of duty holders during this inspection programme and a lack of adequate understanding of the justification and authorisation of exposures.

In some trusts, referrers were trained in the procedures and process for requesting examinations and were entitled to carry out this task, including training on IR(ME)R; whereas some trusts did not consider this to be necessary. Under IR(ME)R, referrers do not require specific training but, where we found evidence of robust training, we found fewer errors, for example with non-medical referrers, or systems training during induction for junior doctors.

There was variation in the entitlement of radiographers as practitioners. Some trusts had entitled Band 5 radiographers who had recently qualified to be practitioners for plain film imaging. Although this is entirely possible within the scope of IR(ME)R, employers could not routinely demonstrate associated training or training records. We believed these trusts were working on the understanding that justification of requests for plain film imaging was solely included within undergraduate training. However, our inspections found that most radiographers were authorising under guidelines and not acting as the practitioner, particularly for paediatric exposures.

In all trusts, a range of professional groups acted as operators, and we found some entitlements had been well-documented, with training records available to support their scope of practice. Although the employer has the right to determine who should be entitled to do a task (with the required training records), it is important to ensure that decisions are appropriate. For example, local procedures in a number of trusts had entitled students to act as operators. Regulation 17(3) states that students do not need to be entitled as part of practical training when they are supervised by an entitled operator.

Recommendations for providers

Radiographers are registered healthcare professionals and can therefore work in the capacity as IR(ME)R practitioners. However, they must be trained and correctly entitled to do so and be able to demonstrate training records to the enforcement authority. Where relevant, providers need to ensure that staff acting as IR(ME)R practitioners have adequate training to improve their understanding of the justification and authorisation process, and to clarify whether they are acting as a practitioner themselves or as an operator authorising against guidelines issued by a practitioner.

Equipment training records

IR(ME)R requires providers to keep an up-to-date record of all relevant training undertaken by all practitioners and operators that they engage, and to have this available (Regulation 17(4)). During our paediatric inspection programme, we found detailed training records for radiographers at almost all trusts visited. These were often supported by an overarching matrix, which described how radiographers had been assessed to be competent to operate each piece of equipment. We also saw that departments had processes to ensure that agency radiographers had been assessed to operate imaging equipment to entitle them to work unsupervised.

However, the same was not true for other staff groups operating imaging equipment for example, radiologists (using interventional radiology equipment), cardiologists (using cardiology equipment) and surgeons using a mini C-arm in theatre. We found equipment training records for these medical staff groups in only a small number of trusts, and some of those were not detailed.

As well as equipment training records, we saw other training records relating to clinical practice, for example related to the complexity of CT scans. One trust had a three-stage approach where radiographers were signed off for each level when they had completed the associated training. This included, Level 1 - CT brain and standard CT chest abdomen and pelvis (i.e. examinations that an on-call radiographer would perform routinely out of hours), Level 2 - slightly more complex examinations such as CT angiograms, and Level 3 - cardiac or colon examinations.

Recommendations for providers

Providers must ensure that they can demonstrate that **all** employed IR(ME)R practitioners and operators have been adequately trained and deemed competent to carry out the tasks they have been entitled to perform. These training records should include those requirements set out in schedule 3.

This is particularly important for staff working outside the conventional radiology department, such as in operating theatres, where staff must understand the requirements to keep these records, with clear responsibilities for who will retain them.

Referral guidelines

Regulation 6(5)(a) requires providers to establish referral guidelines (including radiation doses) for medical exposures and to make them available to the referrer. Our paediatric inspection programme showed a range of compliance with this regulation.

Some trusts had purchased referral guidelines, while others created their own ‘in-house’ version, which they had made available to all referrers. However, some trusts only made their referral guidelines available to internal referrers and had not considered external referrers such as GPs.

A small number of trusts had no referral guidelines. This was because they could no longer access a newer digital version of referral guidelines proposed by the Royal College of Radiologists following an update, as their product licence was no longer valid, and they had not developed their own.

Recommendations for providers

Although IR(ME)R does not specify the format of referral guidelines or which ones to use, providers must ensure that the guidelines they adopt reflect the range of examinations carried out. This should include all imaging modalities, including cardiology and interventional imaging if performed.

Providers must make guidelines available to all referrers who use their services and it is important to ensure that referrers are aware of them. This can either be through induction processes or regular communications with referrers.

A set of iRefer paediatric referral guidelines is available as a free download from The Royal College of Radiologists.

Diagnostic reference levels

Regulation 6(5)(c) requires providers to regularly review diagnostic reference levels (DRLs) and make them available to operators.

We found most trusts had adopted DRLs, with the majority adopting national or European levels for paediatric examinations. However, a small number had set local DRLs across a range of examinations following a local patient dose survey. Some centres had not set any paediatric DRLs and were unable to demonstrate 'special attention' in optimising exposures to children as required by Regulation 12(8).

The majority of trusts had adopted an age-based system, comprising locally-derived DRLs based on ages, with some using a weight-based approach. We are aware that the national DRL working party is carrying out work to provide advice on this in 2019, with an aim to develop more weight-based DRLs where possible.

Most trusts based their DRLs on a dose review, which was itself based on radiology information system (RIS) data. We saw this was commonly carried out annually or every three years by auditing a selection of protocols, reviewing doses and establishing or amending local DRLs. However, some were not able to meet this review frequency.

A small number of trusts had access to a dose management system. They provided local DRLs based on a dose assessment of large numbers of patients who had undergone that examination. Some trusts told us about the difficulties in setting local DRLs because of the low frequency of some examinations for paediatric patients. In these cases, there was not enough data to establish a DRL for each examination, based on a specific patient age or weight. This may be unique to paediatric examinations where, even in specialist children's hospitals, radiological activity is much lower compared with adult examinations carried out in a general setting.

We felt the concept of DRLs was not particularly well-understood by radiographers who we spoke with. Although we often saw DRLs displayed, radiographers were not always able to explain how they were used in practice. Most organisations used a local dose audit to determine when doses were consistently exceeding DRLs as required by Regulation 6(7) and at one trust we saw a flow diagram that clearly stated what actions were required of radiographers between dose audits if they suspected that DRLs were being consistently exceeded.

Recommendations for providers

Medical physics experts should be involved in carrying out patient dose surveys, using established guidance from the Institute of Physics and Engineering in Medicine or Public Health England, where appropriate. Providers should consider factors such as frequency of examinations, reliability of data, optimisation requirements, and access to age/weight data when determining the most appropriate approach.

Where there is insufficient data available, providers can consider adopting national or European DRLs, alternatively it may be possible to discuss with other centres that use similar techniques.

Engaging radiographers in the process gives them a better understanding of what DRLs are used for. This will also assist in optimisation. It may be possible to have short lunchtime lectures to improve understanding, which may also help in continuous professional development of radiographers as required under Regulation 6(3)(b).

Quality assurance of equipment

We inspected nine trusts following the transfer of equipment responsibilities to IR(ME)R in February 2018.

Compliance with equipment quality assurance (QA) requirements was varied. We took enforcement action (under Regulation 15(1)(a)(i) and/or 15(3)(b)) at three trusts following failures in maintaining a QA programme of equipment and failures to perform testing at regular intervals. These Improvement Notices were not specific to paediatric equipment and covered a range of equipment types. Most of these failures related to the more frequent type of testing, but one service was also not regularly performing more in-depth annual tests.

We found a pattern of non-compliance with these regulations, particularly for equipment outside of the radiology department, such as image intensifiers in theatre, particularly mini C-arms. In many cases, there was insufficient understanding of responsibilities or the regulatory requirements outside of radiology.

Medical physics experts set the frequency and carried out most of the high-level testing, with reference to criteria defined in IPEM report 88. The regular local tests were generally carried out by radiographers who built this activity into their schedule rather than a ‘specialist’ QA radiographer. Most trusts used a spreadsheet to monitor

local quality assurance, but a number of trusts were developing programmes or using free online packages to track results.

The equipment handover form developed by AXREM (Association of X-ray Equipment Manufacturers) was frequently used to determine whether medical physics or radiographers required additional QA tests before equipment was used clinically.

Recommendations for providers

Providers must ensure that the responsibilities for equipment QA testing are made clear. This should include clarity on who should carry out the testing, how often they should do it and how records should be kept.

This is particularly important for equipment outside of radiology, where QA testing should be subject to management oversight to ensure that it is carried out and that action is taken where appropriate. This can be carried out by a member of staff with a special interest in this activity, but we recommend that routine equipment QA testing activities are subject to annual review by medical physics experts, who will often have a good understanding of standards for acceptable performance and actions required.

Sharing good practice

During the inspection programme we discussed the opportunities to share areas of good practice and help develop a good culture of radiation protection between departments. Many departments felt there was little opportunity to do this. Although medical physics experts share information regularly, this was not the case among other staff groups. Many of the clinical forums available did not have a specific focus on radiation protection, and of those that did, they did not appear to cover radiation protection frameworks in detail.

Recommendations for providers

Where possible, providers should share areas of good practice to allow wider learning and support between organisations, particularly around governance frameworks. This could be within special interest groups or through online forums.

Next inspection programme

We intend to continue proactive inspection programmes to assess the compliance of IR(ME)R in a range of areas. We will focus separately on nuclear medicine, radiotherapy and diagnostic radiology and will establish a full planned inspection programme across all three modalities. The aim is to adopt a risk-based approach in line with CQC's approach to inspections and to continue to publish our findings.

References

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CQC-444-072019