Neurointerventional imaging

In 2019, we published our guidance on the criteria for significant accidental and unintended exposures (SAUE). This introduced a category for notifying non-transient deterministic effects (also called tissue effects), regardless of whether they involved any errors. This is the effect of radiation on health, where the severity varies with the dose administered.

We first reported back on findings in our annual report for 2019/20, where we reported 10 notifications of skin injuries – all from neurointerventional procedures. Based on this, we initiated a programme of inspections to look at these specialist services as part of our graded approach. In England, there are 24 specialist centres in the NHS, and a further centre provided by an independent provider that opened in 2022.

We contacted 11 NHS trusts whose diagnostic imaging services we had previously inspected within the previous 7 years. Although these employers were not a priority for the inspection programme, we asked for some basic information that allowed us to support our findings and consider where we target future resources.

Notifications

We received 9 notifications of hair loss following these procedures in 2021/22. All 9 notifications came from 3 centres that carry out the most complex procedures under the specialty. When we reviewed them, we found all procedures were fully justified and their side effects were known, with patients giving consent where appropriate. However, learning was identified for all cases, including a raised awareness of the effects of the procedures.

Inspections

We developed an inspection programme, which started in 2019, specifically for the neurointerventional services of the 24 specialist NHS centres. We had inspected many trusts within the previous 7 years under other programmes, such as the paediatric programme from 2017 to 2019, so this neurointerventional programme prioritised the other centres. The programme involved 10 inspections between 2018 and 2022.

As a result of these inspections, we took enforcement action at 3 locations for breaches of Regulations 6, 8 and 17 and issued Improvement Notices relating to:

- poor quality training records
- poor quality assurance of documentation and failure to complete statutory notifications following recommendations from the medical physics expert.

None of these Notices linked directly to the neurointerventional departments themselves, but to general governance issues within radiology departments. See our enforcement register for more information on these notices.

What we found

There were some common themes from this inspection programme, although many may also be relevant to other cardiology or radiology interventional services.

Documentation

We regularly found that the employer's procedures were not representative of the practice carried out in the department. This was usually because they were more general in nature and intended to cover several services within a trust. For example:

- There was no reference to the WHO checklists in the patient identification procedure.

- The procedures to check for pregnancy did not take into account the tests carried out pre-operatively by admission nurses.
- The consent process for informing patients of the benefits and risks was not included in the relevant employer's procedure.

To address this, some employers had adopted local procedures covering the specific services in detail. These were sometimes developed alongside LOCSSIPs (local safety standards for invasive procedures).

Actions for employers

- Review your employer's procedures to make sure that they cover the range of services you provide.
- Make sure your employer's procedures are useful to staff.
- Consider adapting specific procedures or separate them from the high-level overall trust procedures.

Referral guidelines

Most neurointerventional services visited had not implemented referral guidelines. We have also seen this in cardiology inspections. The most common route for referrals was between specialist consultants or neuroradiologists occasionally acted in all 3 duty holder roles. Under IR(ME)R, referral guidelines, which include radiation doses, must still be made available to referrers.

Equipment

Ageing equipment was identified as a risk in 3 inspections, with some between 15 to 19 years old – well past its recommended life cycle. From the data requests to trusts, we identified a further two employers that also had ageing equipment.

Although equipment replacement is not a direct requirement of IR(ME)R, it is important for employers to ensure equipment is replaced and updated as part of a planned programme. Ageing equipment does not have the latest new software and dose saving technologies, which offer significantly lower doses and enable exposures to be optimised effectively. There is also a potential risk, as seen during one inspection, from repeated equipment failures either causing procedures to be cancelled or patients to be moved to other labs.

The European Society of Radiology (ESR) recognised the clinical importance of planning for timely equipment replacement in its 2014 position paper on renewal:

- equipment up to 5 years old reflects the current state of technology and offers opportunities for economically reasonable upgrade measures
- equipment between 6 and 10 years old is still fit for use if properly maintained, but already needs replacement strategies
- equipment older than 10 years is no longer state-of-the art and replacement is essential.

Actions for employers

- Make sure you have a proactive replacement programme that includes interventional equipment. Consider using a risk register to manage the risk for ageing equipment.
- To ensure the system is safe for its intended purpose, use professional guidance and manufacturers' recommendations to clearly define the criteria to consider when deciding to decommission equipment.
- Also consider quality assurance, and whether a more frequent testing schedule would be appropriate.

Patient doses

The 2021 report from the Committee on Medical Aspects of Radiation in the Environment (COMARE), Radiation doses in interventional radiology: issues for patients and staff within the UK, identified that the lack of data about patient doses has delayed establishing national diagnostic reference levels (DRLs) for interventional radiology procedures. Because of the small numbers of procedures, which sometimes varied significantly between patients, it is difficult to develop local diagnostic reference levels. Nevertheless, all services we visited had adopted levels for a range of examinations. From the data requests, all but 4 employers have set local diagnostic reference levels. One had not because the equipment had only recently been installed and the employer was waiting to carry out a dose survey.

From our discussions during the inspections, we found only limited sharing or benchmarking of some of this data with other specialist services within the network But of those that did share data, this was relatively comparable.

As well as carrying out standard dose audits, we saw examples of physicians leading more stringent audits including looking at reasons behind data outliers and comparing doses from different embolic materials.

Some services did not have skin dose policies. At the time of our inspection or data request, 6 employers had no formal policies covering neurointerventional services, or had only just introduced them.

Policies varied significantly in quality and used different levels to trigger certain follow-ups.

Formal action levels for observations during procedure, such as the ones recommended in the COMARE report, were not commonplace. However, there was exceptional dose awareness – both during and after procedures – from all members of the multidisciplinary team.

The International Atomic Energy Agency is launching an international study of patient doses and tissue reactions from fluoroscopy guided interventional procedures in 2022, to improve the amount of information relating to tissue reactions.

Actions for employers

- Make sure you're familiar with the COMARE report when carrying out any complex interventional imaging. Sharing information will enable benchmarking of protocols, data and optimisation to improve patient doses.;
- Introduce or review skin dose policies to ensure they reflect up-to-date guidance and consider introducing action levels during a procedure as stated in table 7.3 of COMARE report.
- Consider participating in the International study of patient doses and tissue reactions from fluoroscopy guided interventional procedures and using the IAEA's SAFRAD system to increase the amount of international intelligence.