Scanning without device manufacturer's approval of MRI safety

What is it?

Sometimes the assessment of device safety is not straightforward and so further investigation is required. Some examples include:

- You cannot meet the conditions specified by the manufacturer of a MR Conditional device
- The device manufacturer labels the device as MR Unsafe
- The device manufacturer does not provide clear or perhaps any MR safety advice
- You cannot get information about the device manufacturer

Why is it important?

There is always a degree of risk associated with any clinical procedure. There may be situations where the clinical need for the MRI scan outweighs the risks associated with not having reassurance from the device manufacturer that it is safe to scan a patient with the implanted device, and it is in the patient's best interest that the MRI scan is performed.

Are we allowed to do it?

Section 4.11.4 in the MHRA guidelines highlights if the benefit to the patient outweighs the potential risk of the procedure, then scanning can be undertaken provided the following are documented and available before the scan:

- A risk assessment
- Identification and implementation of appropriate precautions to minimise the risk
- Provision of procedures to ensure that a suitable clinician is available and in the department at the time of the scan
- Procedures for post scan evaluation of the patient

Do we have to do this?

The MHRA highlights that **units should not feel pressured into adopting this procedure** if they do not feel confident in the skills and experience available to them, and it may be appropriate to refer particular patients to another MR facility with more experience. One of the challenges for the MR community is to increase the level of awareness and understanding about MRI safety issues so more sites feel able to take on this process in an appropriate way, which should translate into fewer delays and cancellations for patients where the clinical need for the MRI outweighs the risks.

What are ways of understanding and mitigating the risk?

Importantly, some of the stated conditions for MR Conditional devices describe the limits to which the device has been tested, not thresholds above which they are unsafe. The device manufacturer cannot condone going beyond their stated limit, but this does not necessarily mean it is unsafe to do so. It can be useful to discuss with the device manufacturer. Once they understand that you are looking at going down an "off-label" process and taking on responsibility, they can be very helpful in providing advice to help understand the risks involved. Reviewing the scientific literature can also help to understand the risk presented by specific categories of medical devices (for example - some cardiac devices). Also it may be appropriate to have generic policies for lower-risk categories of implant (e.g.: cardiac stents) that mitigate gaps in manufacturer-provided information. Speak to your MR Safety Expert for advice.

Further Reading

Risk Assessment form for Implants (one of the generic MRI risk assessments provided by the BIR)
https://www.bir.org.uk/media/291846/ra_12._implants.pdf

MHRA 2016: Safety Guidelines for Magnetic Resonance Equipment in Clinical Use. https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use

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