MR safety week 2021

MR Unlabelled: a new MR safety term for the realities of clinical MRI

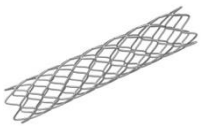
There are 3 established MR safety terms, **MR Safe**, **MR Conditional** or **MR Unsafe**. Historically, people were told to consider anything that was not labelled for MR safety as **MR Unsafe**. Under its current definition (="unacceptable risk") this means unlabelled items should not be brought into the MR Environment. While this is a safe approach, in practice it can be overly conservative in some cases, resulting in patients being denied MRI scans where the needs of the MRI strongly outweigh the relatively low MR safety risks.

The MHRA guidelines for MRI safety had a small update at the start of 2021 which introduced the term **MR Unlabelled**, defined as:

MR UNLABELLED – an item without an MR SAFE, MR CONDITIONAL or MR UNSAFE label.

Importantly, the definition of **MR Unlabelled** makes no suggestion about the risks or the acceptability of bringing such an item into the MR Environment. Consequently, a local assessment of the risks and a decision on how to proceed based on the risks and likely benefits is required, a common practice throughout medicine.

The risk associated with bringing some **MR Unlabelled** items into the MR Environment is clearly very low or zero



The risk associated with bringing many **MR Unlabelled** items into the MR Environment may not be immediately clear and may lie somewhere on a range between the two extremes.

The risk associated with bringing some **MR Unlabelled** items into the MR Environment is clearly very high

low — **Risk** — high

Who is responsible for the local risk-benefit decision may depend on the circumstances. Two examples include the following.

- The local organisation, where the risk-benefit decision is made and documented as part of a local procedure. This may be appropriate for **MR Unlabelled** items that are considered locally to be "low-risk", e.g. tattoos, orthopaedic implants, heart valves.
- An individual consultant radiologist (or consultant cardiologist for a cardiology led MR service) following a risk assessment with involvement from the MR Responsible Person, MR Safety Expert and the referrer. This may be appropriate for "higher-risk" scenarios, such as **MR Unlabelled** cardiac devices. For several years the MHRA guidelines have offered advice on this process (section 4.11.4 in the MHRA guidelines for MRI safety).

MR Unlabelled versus "off-label"
In the context of medical devices, "off-label" describes any use of the device that is not intended by the manufacturer. "off-label" use is well-established, but in this case the local organisation takes on additional responsibilities. "off-label" is regulatory-speak. **MR Unlabelled** is MR safety-speak, and simply describes the absence of any of the 3 recognised MR safety labels. Bringing an **MR Unlabelled** item into the MR Environment may or may not be "off-label" use depending on the instructions for use.

MR Unlabelled versus "non-MR Conditional"
The phrase "non-MR Conditional" is sometimes used in publications to describe stuff (particularly cardiac devices) that are either **MR Unlabelled** or **MR Conditional** but with unmet MR conditions. However, it is not a term that is formally defined in any international standard, and some people find it confusing, e.g. MR Safe and MR Unsafe items are not MR Conditional. MR Unlabelled is simple and clear. Does it have an MR safety label? No? Then, it is unlabelled.

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