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## PRACTICE AND POLICY

# Developing patient-centred MRI safety culture: a quality improvement report

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**Objective:** Despite having a detailed MRI-safety questionnaire check at the point of referral, we have encountered a significant number of near-misses with patients being identified with MRI-Unsafe devices at the time of appointments, making this an important safety hazard.

**Methods and materials:** A two-part survey was performed to assess referrer compliance of asking MRI-questionnaires. 120 outpatients across 3 MRI sites were interviewed at the time of appointment to confirm whether their referrers completed the MRI questionnaires with them at the time of referral.

Location:

Department of Radiology, Ninewells Hospital, Perth Royal Infirmary and Stracathro Hospital in Scotland.

**Results:** Only 50–55 % of patients confirmed that they were asked about presence of a pacemaker at the point of referral. Less than 50 % of patients reported being asked about other potential hazards.

Suggested strategies for change: (1) Risk Alert—Sent to all MRI referrers in the organization. (2) Changes to MRI Safety Questionnaire. (3) Feedback mechanism to referrers—NHS trust website publications on number

of recorded near-misses and wasted appointments due to MRI-safety issues. (4) Compulsory education/training of future referrers (junior doctors/allied health professionals). (5) Education of patients/public on MRI safety—Displaying patient information leaflets/posters in waiting areas of the hospital.

Key measures for improvement: (1) Reduction in number of recorded near-misses. (2) System improvements, referrer and patient education, reduction of wasted MRI appointments and improvement of waiting-times for MRI appointments

**Effects of survey and conclusions:** The survey highlights the possibility of inadequate referrer attention, and poor patient communication about MRI safety questionnaire with regards to potential hazards of MRI examination in presence of undeclared implants. It initiated several interventions resulting in improved patient safety, with no events in next 12 months, whilst promoting public and referrer's understanding of potential MRI safety issues. Such actions are recommended for all NHS centres across UK since there are significant similarities in functioning across UK.

Conducting comprehensive screening prior to MRI examinations is essential to maintaining a safely run MRI unit.<sup>1,2</sup> Identifying the presence of metallic implants, devices or foreign bodies is key to avoiding adverse interactions with the main magnetic field, radio frequency-field or switching gradient fields while the patient is in the MR Environment and during imaging.<sup>2,3</sup>

There are two tiers of patient safety checks; the first occurs at the point of referral and the second takes place immediately prior to the MRI examination and is undertaken by radiographic staff.

Most radiology departments within NHS trusts in United Kingdom accept MRI referrals from a variety of sources that include hospital doctors, general practitioners and non-medical referrers. MHRA guidelines<sup>1</sup> and local NHS rules require referrers to provide accurate information about the patient and the presence of any implants or other devices at the time of referral, in order that suitability for an MRI scan can be determined. Routine practise should involve referrers asking the patient (or a close relative) the MRI safety check questions in person. This can be supplemented with information or relevant history from the patient's records.

It is assumed that referrers understand that some implants are either MRI Unsafe or MR Conditional (*i.e.* safe to scan only under certain conditions) and can result in injury if not declared. The MRI questionnaire is designed to identify all potential implants and/or foreign bodies that the patient has. These are then assessed to decide whether there is a risk involved in scanning the patient. In cases where implants are common or well-known, radiographers will decide whether imaging can proceed. Unusual implants, devices or situations are referred to an MR Safety Expert for advice.

## BACKGROUND

MRI is a widely performed diagnostic test worldwide and in the UK. It is estimated that, UK-wide, there are about 350 MRI sites with about 500 MRI scanners, although numbers may be more due to unspecified number of mobile units.<sup>4</sup> Patients are subjected to strong magnetic fields that at 1.5 T, can be up to 30,000 times Earth's magnetic field. Clinical MRI is generally considered safe, a significant contributor to safety being appropriate patient selection. A significant proportion of patients have implants, devices or foreign bodies. An ever increasing diversity are being developed and implanted to manage a variety of medical conditions. ; Some are metallic devices which may be MRI Unsafe or MR Conditional.

MRI Unsafe implants can be detrimental in several ways: they may move as a result of attraction or alignment with the main magnetic field, heat up as a result of radio frequency deposition or malfunction. Scanning MR Unsafe implants may result in significant morbidity or even death.

MR Conditional devices can safely be scanned only under appropriate conditions. Restrictions can apply, *e.g.* to the field strength, gradient field strength, specific absorption rate or area of the body scanned.

It is therefore of utmost importance that all implants are identified and assessed.

Most NHS hospitals in the UK (including ourselves) accept MRI referrals from a variety of sources. These include hospital doctors (hospital consultants and registrars), general practitioners [and non-medical referrers (these can include nursing practitioners, physiotherapists etc)]. Whilst no published data are available, most NHS trusts have protocols for MRI safety training and educational activities before new referrers are allowed to make MRI requests. We are not currently aware of any compulsory training for MRI referrers required to make safe referrals.

## SETTING

We are an 1100 bedded NHS organization in Scotland, with MRI facilities across three sites, comprising four 1.5 T NHS scanners. In our institution (NHS Tayside), we have an MRI safety protocol as per MHRA guidelines<sup>1</sup> which includes having an MRI Responsible Person, MRI Safety Experts, MRI physicists and MRI radiographers in charge of all aspects of MRI safety. We implement a robust induction teaching programme for new doctors and non-medical referrers, before they are allowed to

make any MRI requests. As most centres, we follow a 2-Tier approach to MRI safety.

Tier 1 involves the referrer identify potential MR safety issues at the time of making a request. This is achieved by carefully answering all MRI safety questions on our electronic (ICE) referral system. The information required includes presence of cardiac pacemakers, artificial valves, other implants, nerve stimulators, dentures etc. while other issues such as pregnancy and claustrophobia are also declared.

All implants are carefully recorded on the request form, to enable the radiology departments to assess if they are MRI Safe, Conditional or Unsafe. As per MHRA guidelines,<sup>1</sup> it is the responsibility of the referrers for providing accurate information at the time of request.

Tier 2 comprises of further assessment of patient's suitability in terms of MRI safety, led by the radiology department. A radiographic assistant goes over the MRI safety questionnaire again with the patient in order to seek further clarification from patients with declared implants. Safety checks are carried out initially by MRI radiographers and if necessary, by MRI Safety Experts and MRI physicists, in collaboration with radiologists, to determine if these patients can and should undergo an MRI examination. Tier two therefore acts as a fail safe, should Tier 1 fail, however, late discovery of implants often results in unnecessary delays or the cancellation of scans while further information is sought and assessments made and is considered a "near-miss."

In addition, where a patient receives an appointment by mail, a Patient Information Letter regarding MR Safety included.

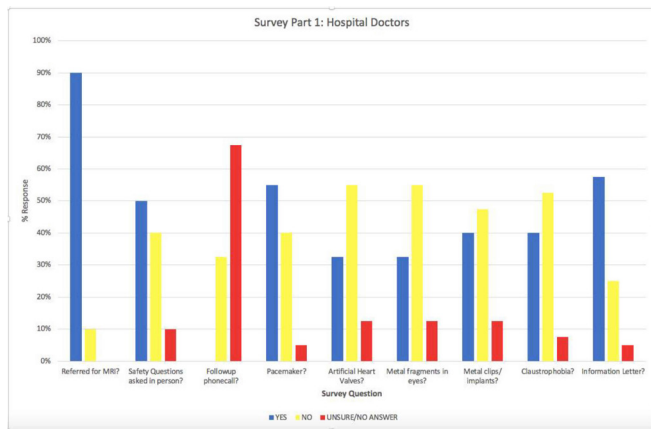
The importance of accurate information being provided at the time of completing the MRI referral/request form must be highlighted. It is paramount that both tiers of safety work effectively, as failure of Tier 1 check puts the entire onus of MRI safety upon Tier 2, and a further failure could result in potentially catastrophic outcomes, with the very least of concerns causing delayed appointments and difficulty in meeting patients' expectations.

## BREACH OF MRI SAFETY AND NEED FOR ACTION

Breaches of MR Safety protocol are addressed robustly. Referrers who fail to provide vital patient information are sent a warning letter by an MRI Safety Expert, on behalf of the MRI Safety Committee, informing them of the breach and reminding them of their responsibilities. A record is made in our incident reporting software (DATIX) to ensure that it is properly recorded and acted upon.

All breaches are discussed during monthly MRI Quality and Improvement and Bi-annual MRI Safety Committee meetings. Action is taken as and when necessary, taking the form of: sending periodic group reminder emails to all referrers, writing to individual referrers and highlighting issues in our local training and induction programmes for new referrers.

Figure 1. Survey Part 1. Distribution of answers from patients referred by hospital doctors. Please refer to Supplementary Material 1 for detailed questions.

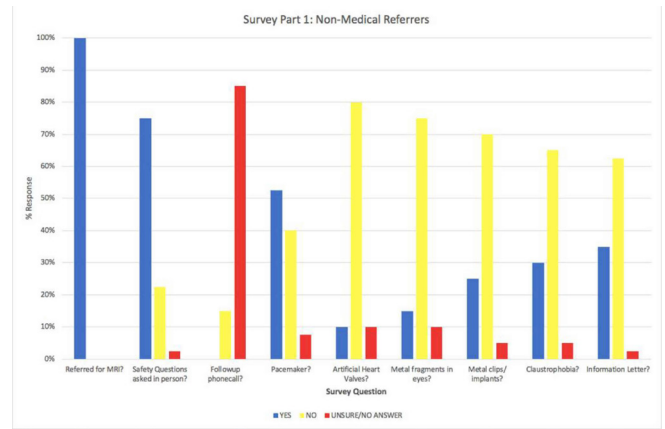


Despite constant efforts, there have been recurrent incidences of safety breaches with patients attending MRI department with implants, including pacemakers when none have been declared.

### MRI PATIENT SURVEY (PART 1)

In order to develop a deeper understanding of the problem, we performed a survey of patients to identify the consistency of use of MRI safety questionnaire by referrers at the time of referral. A set of nine questions were framed (Supplementary Material 1). Outpatients were canvassed from three groups: those referred by hospital doctors, general practitioners and non-medical referrers. Patients completed the survey questionnaire sheet

Figure 3. Survey Part 1. Distribution of answers from patients referred by non-medical referrers. Please refer to Supplementary Material 1 for detailed questions.



(Supplementary Material 1) at the time of attendance at the radiology department. The survey was conducted over a period of 10 weeks (April–June 2017) at all three MRI sites. 120 outpatients were included (40 in each group).

### RESULTS OF SURVEY (PART 1) (FIGURES 1-3)

The results suggested that all three groups of referrers were failing to ask patients important safety information before making an electronic referral. All groups achieved between 50 and 55% score for asking the patient if they had a pacemaker fitted, but other questions relating to the presence of heart valves, clips in

Figure 2. Survey Part 1. Distribution of answers from patients referred by General Practitioners. Please refer to Supplementary Material 1 for detailed questions.

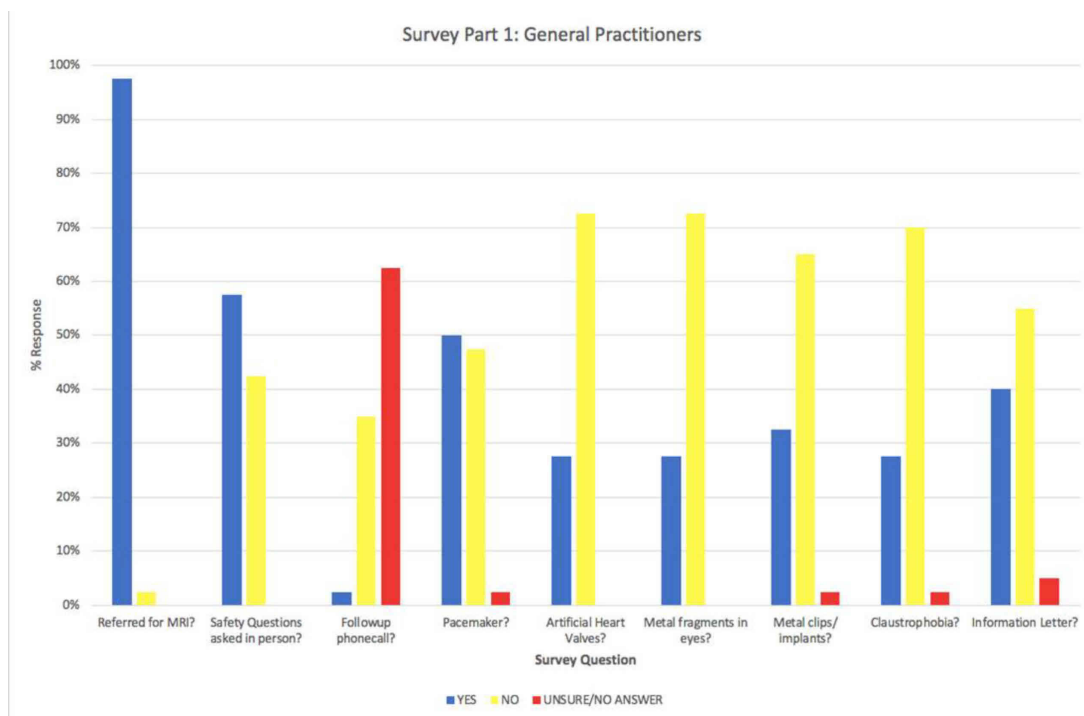
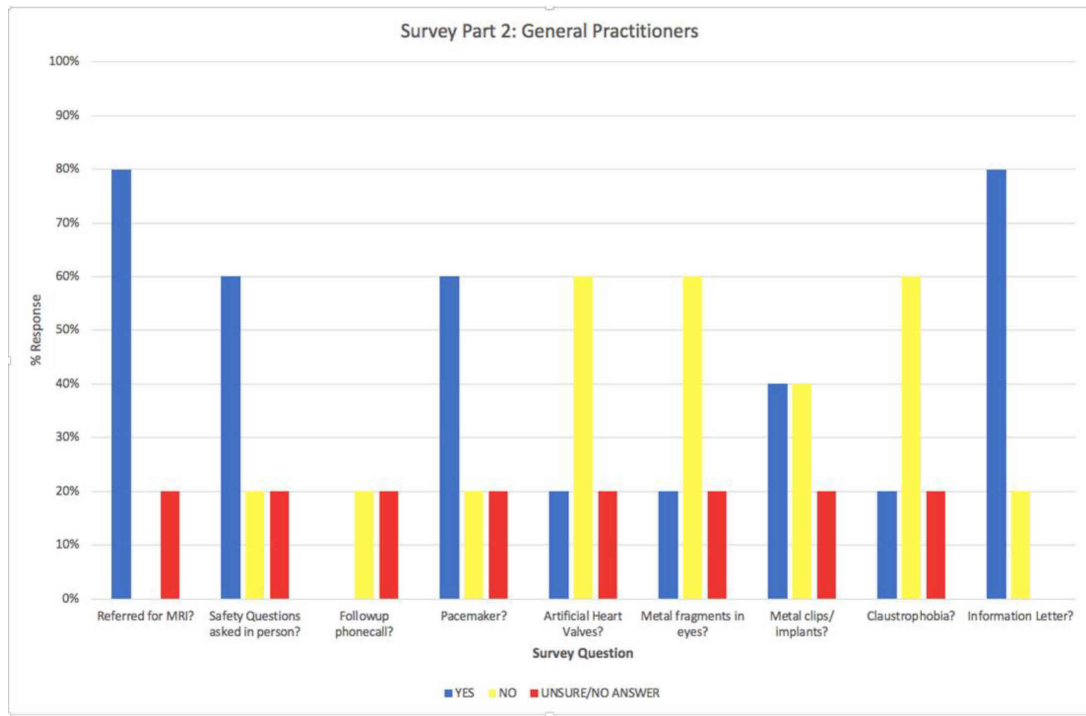


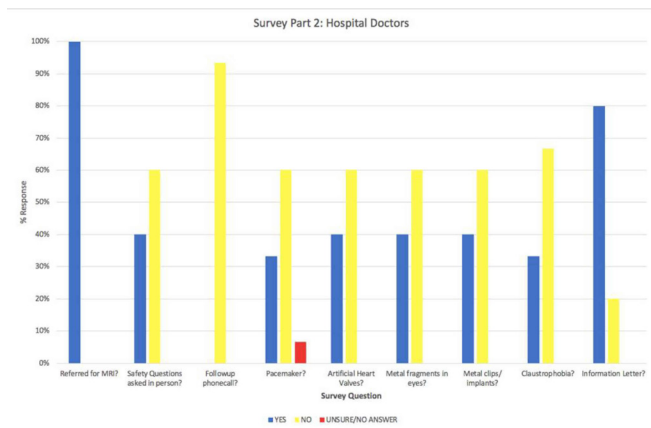
Figure 4. Survey Part 2. Distribution by percentage of answers from patients referred by GP referrers. Please refer to Supplementary Material 1 for detailed questions. GP, general practitioner.



the body, metal in the eyes and claustrophobia were less than 50% for all groups.

What was even more unexpected was that 25% of patients denied having received a Patient Information Letter with their appointment letter. The pattern of responses from patients referred by the three referral groups was broadly similar. There were concerns that patients had perhaps not clearly understood the questions on the safety forms at point of referral. On this basis, a decision was made to perform a second "mini survey."

Figure 5. Survey Part 2. Distribution by percentage of answers from patients referred by Hospital Doctors. Please refer to Supplementary Material 1 for detailed questions.



**MRI PATIENT SURVEY (PART 2)**

The second survey was performed with 20 outpatients at our largest MRI site with two scanners. The patients were asked the same survey questions directly by one of our Radiographic Assistants who were able to clarify any safety questions from patients and recorded responses. There were no referrals made by non-medical referrers for this survey; only GP and hospital doctor referrals were included, particularly as their results were fairly similar on first survey.

**RESULTS OF SURVEY (PART 2) (FIGURES 4 AND 5)**

The results for all questions were similar to the first survey apart from the Patient Information Letter question. Most patients (80%) confirmed receipt of a Patient Information Letter. The other 20% of patients stated that they had been contacted via telephone for their appointments and had therefore not received any letter.

**DISCUSSION**

Awareness of MRI safety has improved over time, assisted by continuing induction and educational programmes for new referrers. It is therefore reasonable to assume that trained clinicians and other referrers understand the significance of MRI safety and purpose of the MRI safety questionnaire. There is substantial literature available addressing the issue of MRI safety which includes the practice of using a safety questionnaire.<sup>2,5,6</sup>

As such, it is expected standard practice that the referrers ask the patients or their attendants MRI safety questions directly

and refer to medical records wherever necessary. Declaration of implants and wherever possible, details of their make and model should also be made available.

On certain occasions, direct questioning of patients at point of referral may not be possible. In this case, it would be anticipated that the patient would be asked safety questions prior to leaving the clinic or asked over the phone to complete the safety questionnaire.

## INTERPRETATION

The results of the surveys indicate that a significant number of patients were not aware of being asked MRI safety questions either in the clinic or over the phone. To reduce any inconsistencies of the survey, for some patients who may have forgotten if they had been directly asked on MRI safety questions, a separate column was kept for any "unsure" responses. We have considered the possibility that some patients genuinely didn't remember being asked these questions. However, given that these are not one or two questions but a series of questions and considering the referrer should ideally have emphasized the reason for asking these questions, it is unlikely that such patients would constitute a significant proportion. Even for those who may have genuinely forgotten being asked, it may highlight the lack of emphasis on MRI safety on part of referrer.

One potential cause for the poor survey results may stem from the possibility that hospital doctors are completing MRI safety forms based entirely on patients' records rather than through direct patient questioning, potentially due to time constraints. This is not an ideal situation, since not all the records are necessarily in electronic form and the information required may not be easily accessible or even available. It is expected that the hospital doctors or the GP/non-medical referrer contact patient directly, before making a request.

Another possibility is that the process of filling an MRI request is being delegated to junior staff who may not necessarily understand the importance of MRI safety.

Furthermore, in cases where a patient has had a previous MRI, he/she and/or the referrer may be falsely reassured that they are automatically safe to have a new MRI scan. This is not the case if the patient had received an implant in the interim. It is also important to emphasize that previous successful MRI examination with a known implant is no guarantee that subsequent scans will also be safe<sup>5,6</sup> due to differences in field strength, imaging sequences, scanner design and/or patient positioning.

Until recently, all pacemakers were considered MRI Unsafe. However, with the introduction of newer "MRI Conditional pacemakers," some referrers may feel that these are completely safe and that there is no need to declare their presence. However, they are safe only under carefully specified conditions and are normally scanned under strict supervision, requiring significant additional support from MRI physicists and cardiac physiologists. It is crucial to stress that all components of a pacemaker, including the leads must be MRI Conditional, and the entire

combination should also be identified as MRI Conditional, before undertaking a scan in strictly controlled conditions.<sup>5</sup> This has to be carefully documented before MRI suitability can be assessed. More recently following recent studies,<sup>7</sup> the British Cardiovascular Society and the BIR published an open statement<sup>8</sup> encouraging access to MRI for patients with both MR Conditional pacemakers and ICDs (implantable cardioverter defibrillators) and those that are non-MRI Conditional, provided pre-defined protocols are followed. The Institute of Physics and Engineering in Medicine expanded on the requirements for those protocols<sup>9</sup> by saying "The scanning of both MR Conditional and non-MR Conditional cardiac devices requires specialist on-site knowledge and staffing resource, including radiographers, radiologists/MRI cardiologists and appropriately trained cardiac physiologists working with the MRSE and the MR Responsible Person. Additionally, such activities need to be supported by appropriate equipment, in particular MR Conditional monitoring equipment."

These changes of practice will require further education of referrers to emphasize that pacemakers and ICDs are not automatically safe, but need to be identified so that appropriate precautions can be undertaken to allow suitable scanning where possible.

Having considered the influencing factors, we conclude that in a significant number of referrals, the referrer did not ask the patient the MR safety questions. This has implications for the integrity of our MR safety management and therefore required further action:

## STRATEGY FOR CHANGE

1. A "Risk Alert" document was created ([Supplementary Material 2](#)) and forwarded by our Clinical Governance and Risk Management Department to all referrers (both primary and secondary care) within the organization to remind them of their responsibility towards MRI safety.
2. An additional question has been included on the electronic request form, asking the referrer to confirm that all MRI safety questions were completed based on an in-person discussion with the patient or his/her carer/guardian/attendant, checking with patient records if necessary.
3. Our question regarding pacemakers and ICDs has been rephrased to highlight the need to identify all such devices, whether they are MRI Conditional or not, so that appropriate imaging conditions can be achieved.
4. Courses on MRI safety exist and we are aware that online training courses on MRI safety are underdevelopment. Ideally, completion of a course endorsed by the relevant professional bodies will become compulsory for all referrers. This requires further national development and acceptance before becoming widespread practice, but is a worthwhile goal in the view of these authors.

## SHORT TERM OUTCOMES

Subsequent to the issuance of the "Risk Alert," in the following 12 months, there was no incident of any undeclared implant, across our organization at Tier 1 level. This was in sharp contrast to the

continuous stream of significant events earlier that had prompted our intervention in the first instance. We consider this very significant and although we believe that issuance of “Red Alert” document has made a significant contribution, it is likely that it is a combined outcome of all actions undertaken. We intend to continue to monitor adverse safety events as part of clinical governance. We anticipate to take further actions whenever they become necessary, including repeating this type of survey.

### KEY MESSAGES AND NEXT STEPS

- We believe that our survey results are reflective of practices across UK, since most of NHS Trusts have similar referral patterns. We have not encountered any similar survey being performed elsewhere.
- The results of this survey highlight the need to shift our focus to training and education of MRI referrers in MRI safety as a complement to our existing feedback mechanism to referrers notifying them of near-misses.
- Raising patient awareness of the potential hazards of an MRI with an undeclared implant or foreign object should be considered in order to highlight the importance of giving a full and accurate history at the time of referral.

- Reminders of good MRI referral safety practice coupled with information on the number of MRI safety related near misses each month and the resultant number of wasted appointments will be disseminated via the local Trust’s intranet.

### CONCLUSION

The results of our survey indicate that patients are not consistently being asked MRI safety questions by the referrers, prompting the described strategy for change. After implementation there was a period of 12 months where there were no MR Safety near misses suggesting a highly successful outcome in the short term, We are aware that the pathways for MR referral and acceptance are broadly similar throughout the UK. We believe therefore that this survey could be usefully applied to provide further insight to other NHS centres on MRI safety issues. It is expected that the results may prompt them to take further action locally, contributing to improvement of quality of MRI referrals, patient suitability for MRI and overall enhancement of MRI safety across the UK.

### ACKNOWLEDGMENT

All radiologists, radiographers, MRI physicists, Radiographic assistants in NHS Tayside.

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