


Methodology Article

MRI safety management in patients with cardiac implantable electronic devices: Utilizing failure mode and effects analysis for risk optimization

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Abstract

Introduction: Cardiac implantable electronic devices (CIEDs) are increasing in prevalence. Exposing patients with CIEDs to magnetic resonance imaging (MRI) can lead to adverse outcomes. This has led certain radiology departments to not accept MRI referrals related to patients with CIEDs. Patients with MR-conditional CIEDs can be safely scanned under specific conditions. Our institution has accepted such referrals since 2014. The aim of this study was to systematically identify and reduce risk in our CIED-MRI protocol using failure mode and effects analysis (FMEA).

Methods: A multidisciplinary FMEA team was assembled and included senior stakeholders from the CIED-MRI protocol. A process map was constructed followed by risk analysis and scoring. Targeted interventions were formulated and implemented; high-risk failure modes were prioritized. A new process map and protocol were drafted and repeat risk analysis was performed. Monitoring and re-evaluation of the CIED-MRI pathway were instigated at departmental quality assurance (QA) meetings.

Results: Interventions included direct CIED characterization using wireless technology pre-MRI, CIED programming and reprogramming in the MRI suite before and immediately after MRI reducing device downtime and continuous patient monitoring during MRI by a cardiac physiologist. The cumulative risk priority number (RPN) decreased from 1190 pre-FMEA to 492 post-FMEA.

Discussion: Despite the risk of exposing CIEDs to the MR environment, patients with MR-conditional CIEDs can be safely scanned with an appropriate multidisciplinary support. We found FMEA an indispensable tool in identifying and minimizing risk with no adverse events recorded since FMEA recommendations were implemented.

Key words: FMEA-failure modes and effects analysis, healthcare quality improvement, patient safety, process mapping, risk management

Introduction

Cardiac implantable electronic devices (CIEDs) is a term that refers to pacemakers, implantable loop recorders and implantable defibrillators. The increasing prevalence of CIEDs has been documented in the literature [1–5] and noted at our institution which has seen rising

numbers of magnetic resonance imaging (MRI) referrals for patients with CIEDs. It is estimated that patients with CIEDs have a 75% chance of requiring an MRI in their lifetime [5]. There are numerous potential complications when exposing CIEDs to MRI including device failure, induction of ventricular fibrillation and heating of the

adjacent soft tissue [6, 7]. Patients may also have hardware from previous devices that is therapeutically inactive but can pose a risk if exposed to MRI [6]. As a result, the presence of a CIED had until recently been considered a contraindication to MRI [8, 9].

The term MR-conditional CIED refers to a device 'that has been shown to pose no known hazards in a specified MR environment with specific conditions of use' [10]. The 2017 Heart Rhythm Society guidelines made a class I (strong) recommendation that MR-conditional CIED patients should only undergo MRI in institutions with a standardized workflow model [9]. It is thus essential that such institutions develop, implement and intermittently improve standardized CIED-MRI protocols to minimize risk.

Scanning of MR-nonconditional CIEDs is not currently supported by device manufacturers [11–14]. There is a reluctance to perform MRI in such patients [15, 16]. Recent large-scale, prospective studies have suggested that MR-nonconditional CIEDs can also safely undergo MRI using a standardized, protocol-driven approach [8, 17].

At our institution, we have processed over 600 CIED-MRI referrals since 2014 using a defined protocol and multidisciplinary support; 350/600 patients went on to MRI. In order to minimize the inherent risk of MRI in CIED patients, a failure mode and effects analysis (FMEA) was undertaken. An FMEA is a systematic methodology that allows for proactive identification and reduction of risk in complex clinical processes [18–20]. A recent review article described FMEA in the medical setting as an 'efficient method' in reducing risk and 'improving service quality' [21]; others have noted the benefits of FMEA in complex radiology care pathways [18].

Aims

We aimed to identify and reduce risk in our CIED-MRI protocol using FMEA and to share our findings.

Methods

Our private institution operates in an inner-city, tertiary referral environment. All our CIED-MRI patients are scanned in a 1.5-T magnet. We have onsite support from cardiology, cardiac physiology, medical physics and experienced radiographers and radiologists and access to 24-hour critical care facilities. We perform MRI on patients with MR-conditional CIEDs on an inpatient and outpatient basis.

FMEAs are composed of six sequential steps [18]. First, a topic was defined. We chose to critically appraise our local CIED-MRI protocol. Second, a committed team was assembled which included 10 individuals who were clinical contributors to the protocol. The team was made up of two members from the medical physics department, the chief cardiac physiologist and the MRI clinical specialist radiographer, three representatives from the quality department and three physicians including a radiology consultant, a radiology resident and an intern. Next, a process map of the current CIED-MRI protocol was constructed (Fig. 1) which allowed the team to gain a holistic understanding of the referral pathway.

Fourth, a risk analysis was performed where each step on the process map was discussed and critically analysed by the FMEA team. Potential failure modes were identified; a failure mode is defined as anything that can go wrong during the completion of a step in a process [22]. An example of a failure mode would be the referring physician forgetting to mention that the patient has a CIED. 'Likelihood of occurrence', 'likelihood of detection' and 'severity of impact' scores were assigned to each failure mode and

multiplied to yield a risk priority number (RPN) (see Table 1). RPNs provide a numeric assessment of risk for each failure mode; higher RPNs denote an increased risk. Team consensus was required when assigning RPNs.

Fifth, an action plan was developed and implemented with targeted interventions aimed at addressing the highest-risk areas. A new process map was constructed including all interventions (Fig. 2). Finally, a repeat risk analysis was performed by the team post-intervention. Several methods were used to try and standardize RPN designation and limit subjectivity where possible. For example, the FMEA team utilized data from a recent departmental review of 125 CIED-MRIs when assigning 'likelihood of occurrence' scores [23], personal experience of team members was taken into account when assigning 'likelihood of detection scores', and the same team members were used for both risk analyses. Individual and cumulative RPNs were calculated to compare clinical risk in the new protocol to the original protocol. Continuous monitoring and re-evaluation of the CIED-MRI pathway was instigated at departmental quality assurance (QA) meetings.

Ethical considerations

This quality improvement project was deemed exempt from ethics review by the local institutional ethics committee.

Format

The reporting of this quality improvement project follows the proposed Standards for Quality Improvement Reporting Excellence guidelines [24].

Results

Main interventions and evolution of protocol

80% of the CIED-MRI referrals received at our institution were from external sources. The heterogeneity of information and quality in these referrals underlines the importance of having a standardized process for vetting and safety assessment. Incorrect CIED information in the referral was identified as a potential failure mode. As a result, pre-MRI CIED interrogation by a cardiac physiologist with wireless equipment was introduced to fully characterize the CIED components. In addition, a mandatory review of the patient's CIED insertion note was implemented. This meant that staff were no longer solely reliant on the Heart Rhythm Ireland (HRI) website and chest X-ray for device characterization.

It was also noted that some referrers may not realize the risks of exposing CIEDs to MRI. To combat this, educational material has been shared locally with referrers and nationally with the Health Products Regulatory Authority (HPRA). These interventions were associated with a reduction in RPN for this failure mode from 180 pre-FMEA to 30 post-FMEA.

In some cases, CIED boxes or leads can be changed. As a result, a patient may have an MR-conditional box with an MR-nonconditional lead or vice versa. Failure to identify such cases has potential adverse consequences. The introduction of direct device interrogation and CIED insertion note review as described above was associated with an RPN reduction from 120 pre-FMEA to 60 post-FMEA for this failure mode.

The HRI website stores CIED make and model information and is a useful resource for patient-specific device characterization. However, this information is manually entered into the website and

Pre-FMEA CIED-MRI Referral Process Map

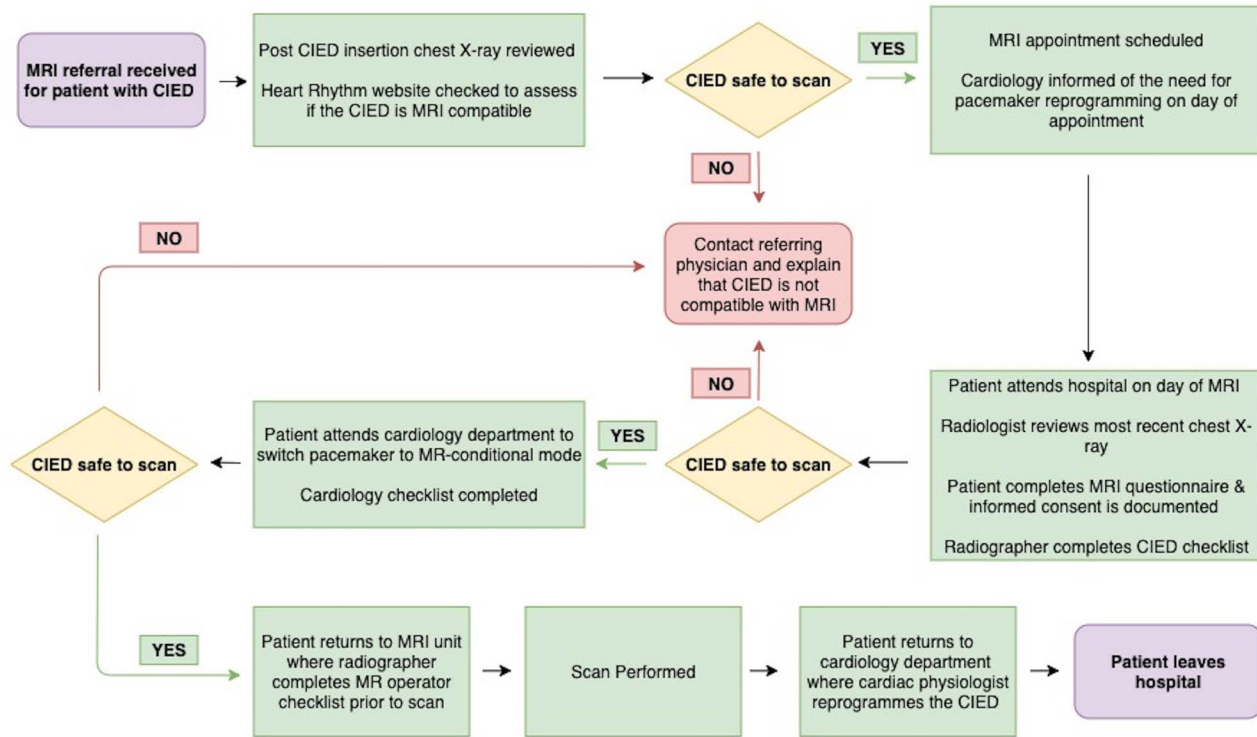


Figure 1 Pre-FMEA process map.

Table 1 CIED-MRI process map FMEA: risk analysis measures and interventions

Step in the Process	Failure Mode	Failure Causes	Failure Effect(s)	Likelihood of Occurrence (1-10)	Likelihood of Detection (1-10)	Severity (1-10)	Pre FMEA RPN	Post FMEA RPN	Protocol Risk Reduction Changes
MRI referral received	CIED not mentioned	Poor referrer knowledge	CIED scanned leading to device malfunction	2 2	4 2	10 10	80	40	Education sessions for referrers locally & nationally Pre-MRI questionnaire for all patients to screen for CIED
MRI referral received	Incorrect CIED information received	Random referrer error. Lack of knowledge of the significance of accurate information in this context	Device incorrectly characterised	3 3	6 1	10 10	180	30	Cardiac physiologist interrogates device & leads prior to scanning with wireless equipment to characterise CIED components Obtain patient's CIED implant notes for comparison Referrer education
MRI referral received	Radiographer not aware of procedures around scanning CIEDs	Poor Radiographer Education	Protocol not followed leading to adverse outcome	3 2	1 1	10 10	30	20	Local staff education and training Competence-based initial training for radiographers with sign off by a supervisor
MRI referral received	The referring doctor overrides safety concerns	The pressure to facilitate throughput	Protocol not followed leading to adverse outcome	3 2	1 1	10 10	30	20	Enforcement of local MRI and hospital policy Referrer education

Continued

Table 1 Continued

Step in the Process	Failure Mode	Failure Causes	Failure Effect(s)	Likelihood of Occurrence (1-10)	Likelihood of Detection (1-10)	Severity (1-10)	Pre FMEA RPN	Post FMEA RPN	Actions to Reduce Occurrence of Failure
MRI referral received	Radiologist overrides safety concerns	The pressure to facilitate throughput	Protocol not followed leading to adverse outcome	2 1	1 1	10 10	20	10	Enforcement of local MRI and hospital policy Staff education
HRI website checked to characterise CIED	Inaccurate information on HRI website	Human error during data entry	Incorrect characterisation of CIED	2 2	6 1	10 10	120	20	CIED component interrogation by cardiac physiologist prior to MRI Correlation with patient's CIED implant notes
HRI website checked to characterise CIED	Failure to identify a device with MR-conditional and MR-nonconditional components	CIED component alteration post insertion	Incorrect characterisation of CIED	4 3	3 2	10 10	120	60	CIED component interrogation by cardiac physiologist prior to MRI Correlation with patient's CIED implant notes to confirm the lead type
HRI website checked to identify CIED components	Incorrect CIED model selected by the user during the search	Human error	Incorrect characterisation of CIED	2 2	3 2	10 10	60	40	Screen-shot of search printed so that CIED model can be compared to insertion note and device interrogation results
Safe MRI sequence planned	MRI gradient and radiofrequency parameters incorrectly selected	Human error	CIED malfunction	3 2	2 2	8 8	48	32	Senior radiographer consults vendors and manufacturers online regarding appropriate sequences for CIED
Radiologist reviews chest X-ray to assess CIED components	No X-ray available for review	The patient had imaging in another hospital or has not had a prior X-ray	Patient scanned with MR-nonconditional components	1 1	2 1	10 10	20	10	Chest X-ray is acquired and reviewed on the day of MRI
The Ppntt attends cardiology to switch CIED to MR-conditional mode	The cardiac physiologist fails to switch CIED to MR-conditional mode	Human Error Inexperience	Device malfunction	5 3	1 1	10 10	50	30	Competence-based initial training with sign off from supervisor CIED programming sign off by senior cardiac physiologist
Patient attends MRI	The patient does not inform radiographer that they have a CIED	The patient does not understand the dangers of CIEDs in MRI Patient forgets about CIED	Device malfunction	2 2	2 1	10 10	40	20	Pre-MRI questionnaire for all patients to screen for the presence of CIED
Patient attends MRI	Incorrect patient scanned	Error in patient identification	Device malfunction	2 1	1 1	10 10	20	10	Include mandatory triple identification pre-MRI checklist

Continued

Table 1 Continued

Step in the Process	Failure Mode	Failure Causes	Failure Effect(s)	Likelihood of Occurrence (1-10)	Likelihood of Detection (1-10)	Severity (1-10)	Pre FMEA RPN	Post FMEA RPN	Actions to Reduce Occurrence of Failure
MRI Performed	Patient unaware of risks associated with CIEDs in the MRI environment	Inadequate information provided to patient pre-MRI	Medicolegal consent issues	2 1	3 2	4 4	24	8	Include risk information in the pre-scan questionnaire to ensure the patient is informed
MRI Performed	CIED complication occurs despite adequate controls	Inherent risk with CIEDs and MRI	Device malfunction	2 2	2 1	10 10	40	20	Patient monitored throughout scan by a senior cardiac physiologist
MRI Performed	Radiographer selects incorrect scanning sequence	Human error Inexperience	Device malfunction	3 2	2 2	8 8	48	32	MRI qualified senior radiographer selects scanning sequence
CIED deemed not safe to scan	The patient is unable to have a management altering scan	Restrictive selection criteria	Delayed diagnosis	3 2	2 2	8 8	48	32	The radiologist should suggest an alternative diagnostic modality and inform the patient's referrer
The patient returns to cardiology department for CIED reprogramming	The patient fails to return to cardiology	The patient forgets or does not realise the importance resetting CIED	Cardiac event occurs during CIED downtime	2 1	6 1	10 10	120	10	Cardiac physiologist resets CIED in MRI suite immediately following MRI scan
The patient returns to cardiology department for CIED reprogramming	Device incorrectly reset	Human error Inexperience	Cardiac event	1 1	6 4	10 10	60	40	CIED reprogramming sign-off by a senior cardiac physiologist Competence-based initial training with sign off from supervisor
The patient returns to cardiology department for CIED reprogramming	Cardiac event occurs during CIED downtime in an isolated area	Patient uses bathroom	Morbidity or mortality	2 1	2 1	8 8	32	8	Cardiac physiologist resets CIED in MRI suite immediately following MRI scan reducing CIED downtime
						SUM of All RPNs	1190	492	

Failure mode: What could go wrong?
 Failure causes: Why would failure happen?
 Failure effects: What would be the consequences of failure?
 Likelihood of occurrence: 1–10, 10 = very likely to occur
 Likelihood of detection: 1–10, 10 = very unlikely to detect
 Severity: 1–10, 10 = most severe effect
 RPN: likelihood of occurrence x likelihood of detection x severity

is thus open to human error. Instigation of device interrogation and CIED insertion note review decreased the RPN of this failure mode from 120 to 60. HRI is now informed of any errors or discrepancies noted on their website so that they can be corrected. In addition, we have contacted HRI and recommended the introduction of barcode scanning technology to replace manual data entry on the website.

In our pre-FMEA protocol, the patients attended the cardiology department on the day of their MRI where their CIED was set to MR-conditional mode by a cardiac physiologist. The patient was then sent to MRI. Once the MRI was complete, the patient returned to the cardiology department so that full CIED functionality could be restored before leaving the hospital. Whilst switching to MR-conditional mode CIEDs are not fully functional, this is a particularly

Post-FMEA CIED-MRI Referral Process Map (*changes in bold italics*)

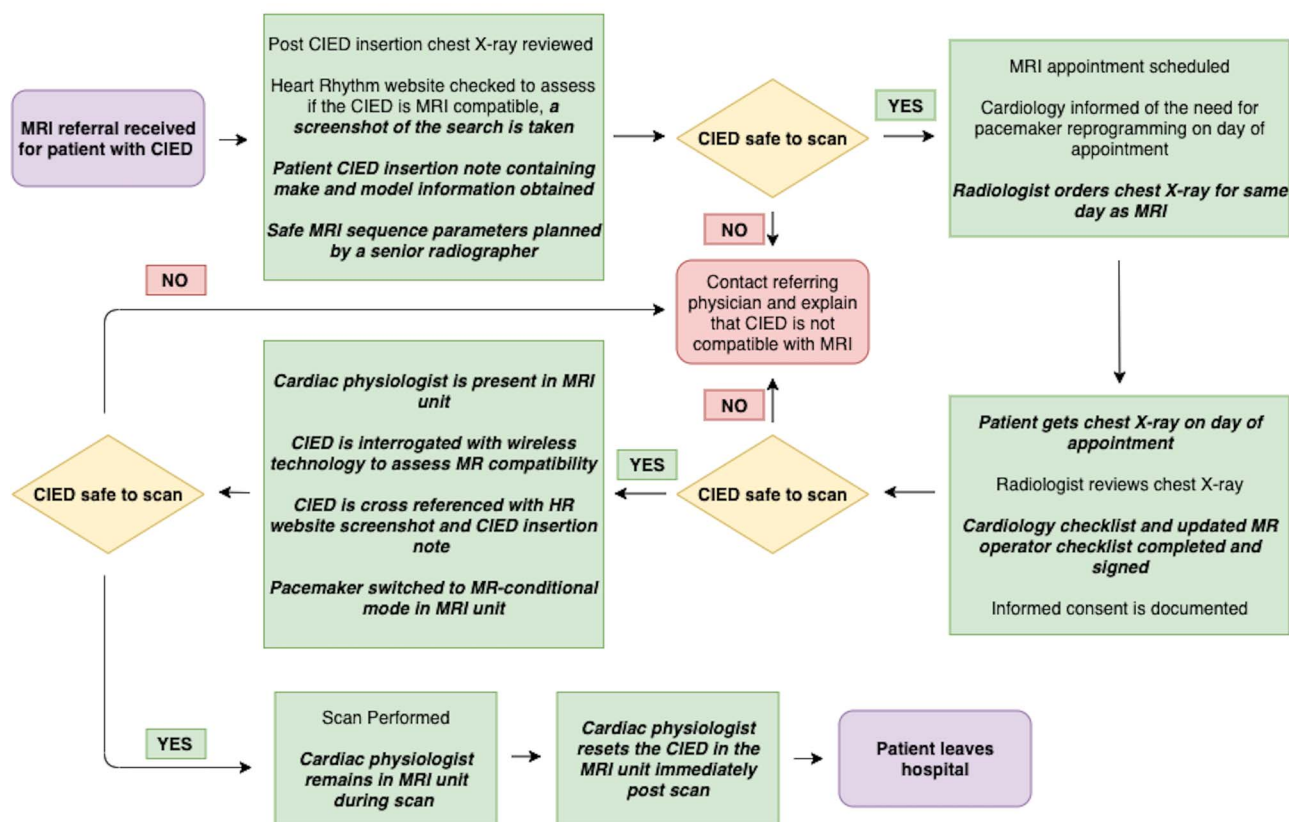


Figure 2 Post-FMEA process map.

vulnerable time for patients. The FMEA team noted that the patient may not return to the cardiology department post-MRI or could potentially have a cardiac event in an isolated area during CIED downtime, e.g. in the bathroom. To prevent such occurrences and minimize CIED downtime, the cardiac physiologist now attends the MRI suite for the duration of the patient visit, programming the CIED to MR-conditional mode, monitoring the patient continuously during the scan and reprogramming the CIED immediately post-MRI. This intervention reduced the RPN from 120 to 10 for this failure mode.

Secondary interventions

The HRI website is consulted for all CIED patient referrals to obtain make and model information. This search requires the user to select options from drop-down menus, a process that is prone to human error. The FMEA team noted this and introduced a policy whereby all HRI searches are compared to the CIED insertion note and to the findings from device interrogation on the day of the MRI, thus reducing the risk of incorrect device characterization. This new policy also facilitates the identification of errors on the HRI website. Competence-based training and CIED checklist sign-off for cardiac physiologists have been introduced to improve staff knowledge and accountability. Revision of the MR-operator checklist to include additional patient risk information has helped to ensure that patients are adequately informed pre-MRI. MRI parameter selection responsibilities have been designated to senior MR radiographers, thus decreasing the risk of inappropriate sequence selection.

Please refer to Table 1 for a step-by-step account of the risk analysis and interventions. The highest impact interventions are highlighted in grey on Table 1.

Discussion

We utilized the methodical approach afforded by FMEA to systematically identify risk within our CIED-MRI pathway, formulate interventions and develop a new protocol with an improved safety profile. The diverse nature of our team facilitated the identification of failure modes and interventions. Senior FMEA team members from radiology, medical physics, radiography, cardiology and the quality department helped ensure that interventions were implemented and adhered to locally. This project has given rise to a departmental mentality of iterative process improvement, facilitated by monthly QA meetings.

The cumulative RPN for our CIED-MRI protocol decreased from 1190 pre-FMEA to 492 post-FMEA indicating a decreased risk. To our knowledge, the benefits of FMEA in CIED-MRI protocols have not been documented in the literature. We believe that FMEA provides a defined path to risk reduction in the clinical setting and is generalizable to other MRI units and complex clinical processes outside of radiology as evidenced by prior studies [25–28].

Our MRI unit has accepted MR-conditional CIED referrals since 2014. An institutional review of 125 CIED patients who underwent MRI revealed temporary complications in three patients including

diaphragmatic stimulation, transient dizziness and difficulty reprogramming the CIED post-MRI [23]. We have not experienced any long-term patient morbidity or mortality.

FMEA also allowed for the identification of several ancillary areas for improvement in the MRI suite including regular interval cardiac arrest simulation and the introduction of MRI suite safety signs to increase visitor awareness of the risks associated with MRI. Performing the FMEA in a multidisciplinary fashion led to stronger collegial links between various departments and specialities involved.

On a background of increasing demand, many hospitals still do not accept referrals from CIED patients despite evidence that such scans can be safely performed using standardized processes. Surveys performed in the UK and Ireland in 2017 and 2018, respectively, revealed that <50% of MRI units accepted referrals for patients with CIEDs [23, 29]. FMEA may provide a framework for MRI units that did not previously accept CIED-MRI referrals to plan and implement risk optimized protocols.

Limitations

There is an unavoidable element of subjectivity associated with failure mode RPN designation. The utilization of identical methodology and the same FMEA team members in both risk analyses provided consistency of interpretation and yielded pre- and post-intervention risk score that was directly comparable.

Staff members were afforded dedicated project time to participate in the FMEA, which was carried out in a cost-neutral fashion. Not all institutions may be able to provide staff with dedicated project time.

To date, we have not scanned MR-nonconditional CIEDs at our institution. However, there is evolving evidence to support this as a safe practice [8, 17].

Conclusion

We believe that lessons learnt from our FMEA study are widely applicable to other institutions given the multidisciplinary complex processes involved.

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References

1. Uslan DZ, Tleyjeh IM, Baddour LM *et al.* Temporal trends in permanent pacemaker implantation: a population-based study. *Am Heart J* 2008;155:896–903.
2. Bradshaw PJ, Stobie P, Knuiman MW *et al.* Trends in the incidence and prevalence of cardiac pacemaker insertions in an ageing population. *Open Hear* 2014;1:e000177.
3. Greenspon AJ, Patel JD, Lau E *et al.* Trends in permanent pacemaker implantation in the United States from 1993 to 2009. *J Am Coll Cardiol* 2012;60:1540–5.
4. Celentano E, Caccavo V, Santamaria M *et al.* Access to magnetic resonance imaging of patients with magnetic resonance-conditional pacemaker and implantable cardioverter-defibrillator systems: results from the really ProMRI study. *Europace* 2018;20:1001–9.
5. Nazarian S, Roguin A, Zviman MM *et al.* Clinical utility and safety of a protocol for noncardiac and cardiac magnetic resonance imaging of patients with permanent pacemakers and implantable-Cardioverter defibrillators at 1.5 tesla. *Circulation* 2006;114:1277–84.

6. Expert Panel on MR Safety E, Kanal E, Barkovich AJ *et al.* ACR guidance document on MR safe practices: 2013. *J Magn Reson Imaging* 2013;37:501–30.
7. Delfino JG, Krainak DM, Flesher SA *et al.* MRI-related FDA adverse event reports: a 10-year review. *Med Phys* 2019;46:5562–71
8. Russo RJ, Costa HS, Silva PD *et al.* Assessing the risks associated with MRI in patients with a pacemaker or defibrillator. *N Engl J Med* 2017;376:755–64.
9. Muthalaly RG, Nerlekar N, Ge Y *et al.* MRI in patients with cardiac implantable electronic devices. *Radiology* 2018;289:281–92.
10. Colletti PM, Shinbane JS, Shellock FG. “MR-conditional”; pacemakers: the radiologist’s role in multidisciplinary management. *AJR Am J Roentgenol* 2011;197:W457–9.
11. Faris OP, Shein M. Food and Drug Administration perspective. *Circulation* 2006;114:1232–3.
12. Smith JM. Industry viewpoint: Guidant: pacemakers, ICDs, and MRI. *Pacing Clin Electrophysiol* 2005;28:264.
13. Stanton MS. Industry viewpoint: Medtronic: pacemakers, ICDs, and MRI. *Pacing Clin Electrophysiol* 2005;28:265.
14. Levine PA. Industry viewpoint: St. Jude Medical: pacemakers, ICDs and MRI. *Pacing Clin Electrophysiol* 2005;28:266–7.
15. Nordbeck P, Ertl G, Ritter O. Magnetic resonance imaging safety in pacemaker and implantable cardioverter defibrillator patients: how far have we come? *Eur Heart J* 2015;36:1505–11.
16. IRNICH W, IRNICH B, BARTSCH C *et al.* Do we need pacemakers resistant to magnetic resonance imaging? *Europace* 2005;7:353–65.
17. Nazarian S, Hansford R, Rahsepar AA *et al.* Safety of magnetic resonance imaging in patients with cardiac devices. *N Engl J Med* 2017;377:2555–64.
18. Thornton E, Brook OR, Mendiratta-Lala M *et al.* Application of failure mode and effect analysis in a radiology department. *Radiographics* 2011;31:281–93.
19. Abujudeh HH, Kaewlai R. Radiology failure mode and effect analysis: what is it? *Radiology* 2009;252:544–50.
20. McGrath K, Casserly M, O’Mara F *et al.* Zap it track it: the application of lean six sigma methods to improve the screening systems of low-grade mucinous neoplasms of the appendix in an acute hospital setting. *International J Qual Health Care* 2019;31:35–44.
21. Asgari Dastjerdi H, Khorasani E, Yarmohammadian MH *et al.* Evaluating the application of failure mode and effects analysis technique in hospital wards: a systematic review. *J Inj Violence Res* 2017;9:51–60.
22. Chiozza ML, Ponzetti C. FMEA: a model for reducing medical errors. *Clin Chim Acta* 2009;404:75–8.
23. Murray AS, Gilligan PJ, Bisset JM *et al.* Provision of MR imaging for patients with cardiac implantable electronic devices (CIEDs): a single-center experience and national survey. *Ir J Med Sci* 2019;188:999–1004. doi: 10.1007/s11845-018-1922-y.
24. Ogrinc G, Davies L, Goodman D *et al.* SQUIRE 2.0 (standards for QQuality improvement reporting excellence): revised publication guidelines from a detailed consensus process. *BMJ Qual Saf* 2016;25:986–92.
25. Frewen H, Brown E, Jenkins M *et al.* Failure mode and effects analysis in a paperless radiotherapy department. *J Med Imaging Radiat Oncol* 2018;62:707–15.
26. Justinvil GN, Leidholdt EM, Balter S *et al.* Preventing harm from fluoroscopically guided interventional procedures with a risk-based analysis approach. *J Am Coll Radiol* 2019;16:1144–52.
27. Shen J, Wang X, Deng D *et al.* Evaluation and improvement the safety of total marrow irradiation with helical tomotherapy using repeat failure mode and effects analysis. *Radiat Oncol* 2019;14:238.
28. Su FCF, Huang YHJ, Rassiah P *et al.* FMEA-guided transition from microSelectron to Flexitron for HDR brachytherapy. *Brachytherapy* Published Online First: 15 February 2020.
29. Bhuvana AN, Feuchter P, Hawkins A *et al.* MRI for patients with cardiac implantable electronic devices: simplifying complexity with a one-stop service model. *BMJ Qual Saf* 2019;28:853–8.