MRI Generic Implant Safety Policy (GISP): Detailed review

Title: *MRI safety of heart valves and annuloplasty rings, including their use in combination with stenting systems (i.e. for TAVI, TAVR and PAVR procedures)*

Executive summary:

This review covered the MRI safety of heart valves and annuloplasty rings, including their use in combination with stenting systems (i.e. for TAVI, TAVR and PAVR procedures). There is no evidence to suggest any of these devices or combination of these devices area MR Unsafe and that would lead to patient injury at clinical field strengths of 1.5T and 3T. This detailed review will form the basis of a risk assessment which will lead to a concise policy statement that will be deployed into clinical use.

Date detailed review completed: *2/6/2021*
Date of next review: *2/6/2023*

Introduction

Generic benefits of generic implant safety policies for MRI

Ensuring the safety of patients undergoing MRI is of paramount importance. An appreciable portion of the population has medical implants or devices and in many cases an individual patient may have multiple implants. Identifying every patient implant can be difficult for a number of reasons and the purpose of the GISP's is to review specific categories of implants such that general statements of safety can be made. Key benefits of GISP's are as follows:

- Facilitates scanning when implant information is not readily available.
- Speeds up scanning when implant information takes some time to obtain.
- Avoids unnecessary cancellations.
- Reduces resources required to obtain and evaluate specific implant information

Generic risks of generic implant safety policies for MRI

It should be noted that generic implant safety policies and their use are not without risk. Some of the risks involved are listed below

- Newly developed unsafe implant
- Previously unrecognised unsafe implant
- Failing to identify a specific patient implant has the potential to mis-identify an implant due to some misunderstanding

- Updated safety information that adversely changes the safety status of an implant might take some time to filter through to the GISP

Clinical context of the 'insert implant / device category'

Heart valve replacement is a procedure to replace leaking, narrowed or infected valves. Damaged or faulty heart valves can affect how efficiently the heart pumps blood around the body. The opening and closing mechanism of the valve leaflets enables the healthy valve to

regulate the flow of blood into or out of the heart. Failure of this mechanism (e.g. through calcification) can result in poor circulatory efficiency alongside other more complicated pathologies such as 'reverse flow'. If a damaged heart valve cannot be repaired then it can be replaced with a prosthetic heart valve.

There are two main types of prosthetic heart valve: mechanical valves and bioprosthetic valves.

Mechanical valves are made from materials such as titanium and carbon. They typically consist of two or three leaflets and a metal ring surrounded by a ring of knitted fabric which is sewn into the heart in place of the original valve. The main advantage of a mechanical heart valve is the durability with a lifespan of 20-30 years, making them favourable for younger patients (1). However, these valves provide a surface for blood clots to form meaning the patient has to be on blood thinning medication, such as warfarin. For this reason, mechanical valves are not used in women of child-bearing age as warfarin is not used in pregnancy due to the higher risk of bleeding.

Bioprosthetic heart valves are made from human or animal (bovine (cow), equine (horse) or porcine (pig)) tissue treated with a preserving solution that is mounted on to a flexible frame to assist in deployment during surgery. Bioprosthetic valves do not require the patient to be on blood-thinning medication. However, bioprosthetic valves are less durable than mechanical valves and require replacement every 10-15 years (1).

The procedure for replacing heart valves is usually performed by open heart surgery. This involves an incision into the chest to access the heart. The heart is stopped and a heart-lung machine is used to maintain cardiac function during the operation. The damaged or faulty valve is removed and replaced with the new prosthetic one. The heart is then restarted and the opening in the chest is closed. Alternative procedures are available if open heart surgery is deemed too risky, such as a transcatheter aortic valve implementation (TAVI) where the replacement valve is guided into place through the blood vessels, rather than through a large incision in the chest.

An annuloplasty is a procedure to tighten or reinforce the ring around a valve in the heart. The ring around a valve can widen and change from its normal shape which may occur if the heart is enlarged. Widening of the ring can cause the valve leaflets to not close properly which can cause blood to leak backwards through the valve. To perform an annuloplasty doctors sew a ring to the existing ring around the valve which may be rigid or flexible.

<u>Outline the challenge / issue from a MRI unit context in dealing with the 'implant / device category'</u>

(1) In the presence of the static magnetic field ferromagnetic materials will experience a force that may cause a device to be moved, rotated, dislodged or accelerated towards the magnet.
(2) Currents within electrically conductive devices may be induced by time-varying magnetic fields which may impact device function.
(3) Device heating may occur through the absorption of RF energy if the device is metallic.

Heart valves are not constructed from ferromagnetic materials and are therefore not a projectile risk. The force exerted on the valve from an MRI is reported to be less than either (i) the force experienced through gravity or (ii) the beating heart and resultant pulsatile flow (2).

A number of studies have considered the Lenz effect on heart valve prosthesis in the presence of the B0 field. Edwards et al. considered the Lenz Effect on heart valves at 1.5T. They assessed the Lenz forces on 9 heart valve prostheses and assessed the risk of impedance of valve function. Irregularities were observed on the pressure profiles of 4 prostheses providing

evidence that the Lenz effect due to exposure to the MR B0 field causes functional valve impedance. While this study hints at a possible mechanism for an interaction between the MRI and heart valves, this hasn't been replicated. Furthermore, empirically there have been no reported issues as a result of the lenz effects in patients with heart valves at 1.5 and 3T.
Robertson et al. evaluated the Lenz effect on mathematical models of two common forms of single-leaflet valves and the magnitude of the torque which opposes the motion of the valve leaflet. They reported that at 1.5T the magnetic effect is ≤ 1 % of the pressure effect for both mitral and aortic valves based on the differences between normal and delayed opening times of the valve in a given magnetic field. However, the authors calculated that these magnetic effects increase to nearly 10 % for native mitral (9.95%) and aortic (9.91%) valves at field strengths between 3T and 4.7T, suggesting there is a significant increase in the risk of valve impedence with increasing field strength (4).

The Lenz effect is discussed in the safety article "Heart Valves and Annuloplasty Rings" on Frank Shellocks website (www.mrisafety.com). It is discussed that there is a theoretical change of forces being stimulated in a heart valve prostheses that have metallic disks or leaflets with the potential to inhibit both the opening and closing aspects of the valve. Edwards et al. conducted an in vitro study on the occurrence of Lenz-related forces on various heart valve prostheses at 1.5T and assessed the risk of the impedance of valve function. Their findings provided further evidence of the Lenz effect on certain cardiac valve prosthesis exposed to the static magnetic field (3).

Whilst there is a body of evidence that the Lenz forces do act upon heart valve prosthesis, at 1.5T there have been no known incidents relating to patient's being scanned with prosthetic heart valves. At this field strength the forces exerted on the prosthesis due to the Lenz effect are minimal compared to the forces exerted onto the prosthesis from the beating heart. It has been mentioned in all papers analysed that the Lenz forces are proportional to the magnetic field strength and that at higher field strengths (≥ 3T) the risk of valve impedence due to the Lenz force may become significant. Effects at higher field strengths have been considered theoretically with mathematical models, however no studies have been found testing at higher fields.
Due to the lack of evidence at higher field strengths of the impact of Lenz forces on heart valve prostheses advice in this policy should only apply to 1.5 and 3T field strengths where it is known the forces acting on the valve are minimal compared to the forces from the beating heart.
Testing has shown the temperature changes due to RF pulses in these implants to be minimal (2). From Frank Shellock's website the temperature changes were recorded for a selection of devices. In non-clinical testing, these devices produced the following temperature rises during MRI performed for 15 minutes (i.e. per pulse sequence) in 1.5 and 3 Tesla MRI systems, using an MRI system reported whole-body-averaged SAR of 2 W/kg or less were ≤ 6 ◦C at 1.5T/64MHz and ≤ 6◦C at 3T/128MHz.

Hypothesis

The working hypothesis for this MR safety review is to propose that heart valves and annuloplasty rings are considered 'MR conditional' at 1.5 and 3T, provided that scanning is performed within the normal mode of operation.

Aim

MRI Generic Implant Safety Policy (GISP): Detailed review v10

The aim is to provide a detailed review from all available sources in regard to the MRI safety status of heart valves and annuloplasty rings. This is with a view to creating the basis to inform subsequent risk assessments on this topic. This will in-turn be used as the basis for guidance and safety policies to be used by Radiology staff to inform decisions on performing MRI scans on patients with these implants or devices.

Methods

A range of MRI safety resources will be reviewed with the aim of gathering as much information as possible in regard to the MRI safety status of the implant category under investigation. As far as possible, detail should be included on search terms used and time periods reviewed such as to allow provenance of the information to be established and if necessary, replicated or audited at a later date.

Results

Review of MRI implant safety databases

A full review was taken of heart valve safety information on www.mrisafety.com (5). The author has performed a comprehensive literature review on guidelines for the management of patients with heart valve prostheses and annuloplasty rings referred for MRI procedures.
The review covered heart valve prostheses, including transcatheter aortic valve replacements (TAVR), transcatheter aortic valve implantation (TAVI) devices, percutaneous aortic valve replacement (PAVR) implants, transcatheter heart valves (THV), as well as other similar valve implants used in association with minimally invasive procedures and annuloplasty rings.
The review concluded that the following guidelines apply to using MRI in all patients with heart valve prostheses and annuloplasty rings:

(1) Patients with all commercially available heart valve prostheses and annuloplasty rings can be scanned at 1.5 Tesla/64 MHz or 3 Tesla/129 MHz, regardless of the value of the spatial gradient magnetic field.
(2) Patients with all commercially available heart valve prostheses and annuloplasty rings can undergo MRI immediately after placement of these implants.
(3) The MRI examination must be performed using the following parameters:

- 1.5 Tesla or 3 Tesla only.
- Whole body average specific absorption rate (SAR) of 2 W/kg, operating in the normal operating mode for the MR system.
- Maximum imaging time, 15 minutes per pulse sequence (multiple sequences per patient are allowed).

Any deviation from the above MRI conditions requires approval by a radiologist.

Review of manufacturer implant information

A comprehensive search of all the manufacturers listed on www.mrisafety.com was performed covering 231 heart valves and annuloplasty rings. The number of heart valves or annuloplasty rings are summarised in Table 1 along with their MRI safety status defined on www.mrisafety.com and the magnetic field strength the safety status applies to (5). The definition of each safety status is outlined below.

Manufacturer	MRI Safety Status							
	Safe		Conditional 5		Conditional 6		Conditional 8	
	Field Strength (Tesla)	Number of implants	Field Strength (Tesla)	Number of implants	Field Strength (Tesla)	Number of implants	Field Strength (Tesla)	Number of implants

AorTech	-	-	1.5	2	-	-	-	-
Arbor Surgical Technologies, Inc	-	-	3	1	-	-	-	-
ATS Medical	-	-	1.5	2	3	10	-	-
Autogenics	1.5	2	-	-	-	-	-	-
Axion Medical Ltd.	1.5	2	-	-	-	-	-	-
Caratomic Inc.	-	-	1.5	2	-	-	-	
Corlife	1.5, 3	2	-	-	-	-	-	-
Cutter Laboratories	-	-	1.5	1	-	-	-	-
Durafic	1.5	2	1.5	2	-	-	-	-
Edwards Lifesciences	1.5	16	1.5	16	3	2	1.5, 3	4
	3	1	3	5	-	-	-	-
	1.5, 3	1	-	-	-	-	-	-
Heart leaflet Technologies Inc.	-	-	-	-	3	1	-	-
JenvaValve Technology	-	-	1.5, 3	3	-	-	-	-
Johnson & Johnson	1.5	1	1.5	2	-	-	-	-
Labcor Laboratorios Ltda.	1.5, 3	3	3	1	-	-	-	-
LivaNova (Includes Sorin and Carbomedics)	1.5	25	1.5	4	3	9	1.5, 3	1
	3	6	-	-	-	-	-	-
	1.5, 3	1	-	-	-	-	-	-
Medical Inc. Inver Grove Heights	-	-	1.5	4	-	-	-	-
Medtronic	1.5	13	1.5	5	3	2	-	-
	3	35	3	4	-	-	-	-
	1.5, 3	1	-	-	-	-	-	-
Neovasc	-	-	1.5, 3	1	1.5, 3	1	-	-

On-X Life Technologies Inc.	-	-	-	-	3	3	-	-
Percutaneous Valve Technologies, Ltd.	3	1	-	-	-	-	-	-
Pfizer Inc.	1.5	4	1.5	6	-	-	-	-
St Jude	-	-	1.5	1	-	-	1.5, 3	1
	-	-	3	13	-	-	-	-
Sulzer-Medica and Mitroflow International	1.5	2	-	-	-	-	-	-
TRI Technologies	1.5	1	-	-	-	-	-	-
TTK Healthcare Limited.	-	-	-	-	3	1	-	-
Vascular Innovations Co. Lid.	-	-	-	-	-	-	1.5, 3	1
Xenofic	1.5	1	-	-	-	-	-	-

Safety Status Definitions as defined on www.mrisafety.com:

Safe

The object has undergone testing to demonstrate that it is safe or it is made from material(s) considered to be safe with regard to the MR environment (e.g. plastic, silicone, glass etc.) or an MR procedure.

Conditional 5

The object is acceptable for a patient undergoing an MR procedure or an individual in the MR environment only if specific guidelines or recommendations are followed provided by the manufacturer or mrisafety.com.

Conditional 6

Non-clinical testing demonstrated that the implant/device is MR conditional. A patient with this implant/device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field 3T or less.
- Maximum spatial gradient magnetic field of 720 Gauss/cm (a higher value for the spatial gradient magnetic field may apply if properly calculated).
- Specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (per pulse sequence).

MRI image quality may be compromised if implant is in the scanning field of view.

Conditional 8

Non-clinical testing demonstrated that the implant/device is MR conditional. A patient with that implant/device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 1.5T and 3T.
- Maximum spatial gradient magnetic field of 720 Gauss/cm (a higher value for the spatial gradient magnetic field may apply if properly calculated).
- Maximum MR system reported whole-body-averaged SAR of 2 W/kg for 15 minutes of scanning (per pulse sequence) MRI related heating.

In non-clinical testing, the implant/device produced the following temperature rises during MRI performed for 15 minutes (i.e. per pulse sequence) in 1.5 and 3 Tesla MRI systems, using an MRI system reported whole-body-averaged SAR of 2 W/kg or less were ≤ 6 ◦C at 1.5T/64MHz and ≤ 6◦C at 3T/128MHz.

Review of the peer reviewed literature

Theodoros D. Karamitsos et al. performed an MRI literature review of heart valves and annuloplasty rings. They concluded there is no evidence to date of why a patient with one of these devices should be excluded from MRI, including imaging of the heart itself. Although not a direct safety concern, the image quality may be affected if the implant is in the scanning field of view; however this depends on the type of device and they state that the images may remain diagnostic in most centres with relevant experience (2). The authors also confirmed that the Pre-6000 Starr-Edwards caged-ball prosthesis (available from 1960 to 1964) is MRI safe at 1.5T, including when imaging the heart itself.

The heart valve and annuloplasty ring safety information article on Frank Shellock's website performed testing on many of these devices up unit 4.7 T and states that an MR procedure is not considered hazardous for a patient that has any heart valve prosthesis or annuloplasty ring (6). This recommendation includes the Starr-Edwards model Pre-6000 heart valve prostheses previously suggested to be a potential risk for a patient undergoing an MR examination.

Frank Shellock et al. considered imaging patients where the labelling information of the manufacturer and model of heart valves or annuloplasty rings are unknown (7). After considering peer-reviewed literature and other related documents he suggested conservative guidelines for scanning of these patients:

- Patients with all commercially available heart valve prostheses and annuloplasty rings can be scanned at 1.5T/64MHz or 3T/128MHz, regardless of the value of the spatial gradient magnetic field.
- Patients with all commercially available heart valve prostheses and annuloplasty rings can undergo MRI immediately after placement of these implants.
- The MRI examination must be performed using the following parameters:
    - 1.5-Tesla or 3-Tesla only.
    - Whole body averaged specific absorption rate (SAR) of 2-W/kg, operating in the Normal Operating Mode for the MR system.
    - Maximum imaging time, 15 minutes per pulse sequence (multiple sequences per patient are allowed).

Any deviation from the above MRI conditions requires prior approval by a radiologist or supervising physician.

Review of the SMRT MR Technologist mail base

Emails from the MRTechnologist list (From Sept 2006))

Kerry Cannan: We scan heart valves all the time. The pressure of the heart beating exerts more force than the potential attraction of the magnet. Since you are scanning a knee, you are not irradiating the valve with RF therefore thermal heating is of no concern. (Even if it was, the flowing blood is a great coolant). If you need proof for your Radiologist, direct him/her to Dr. Shellock's site www.MRIsafety.com which provides info and lists the Starr

Edwards valves as conditional 1. We don't even bat an eye at a heart valve here. Scan away. J

Shellock: If it's been in place since 1985, it's not going anywhere due to magnetic field interactions and heating will not be an issue
Question (30/7/2015): Patient with a Star Edwards aortic valve placed in 1985. Not on list, Hospital records unable to locate, not much on the net.
Other than it is Titanium. Patient states there are no numbers on his card. (Will investigate this further). Thought I would d reach out to the list to see if anyone of you have come across this in the past?
Study ordered is a Knee, will use a T/R coil on a 1.5 GE
Seeking any additional information before giving to Radiologist.

Courtney Solen: Keep in mind, this is a hospital where I work and I have a lot of latitude because of my situation and position. My facility has a policy for this that goes something like this and in this order: get information from patient, history and chart, family or significant
other, films, risk verse benefit decision made by ordering physician and consulting Radiologist, alternate tests. While having a policy is good and covers most situations just fine, there are times when the policy just doesn't meet every situation and only results in unnecessary delays or no scans when there could have been one. I am referring to these exceptions, but stress we have to as technologists be open to making these exceptions and using reasonable decisions to guide us, not only in emergent situations, but with ALL patients we scan.
To directly answer your question the answer depends on the situation (of course!), because my facility does not do anything with my patients, I do, I operate under this philosophy and should not be interpreted to work for you. To focus on your specific question, I believe that this applies to other scenarios as well; what do I do for patients who are new to the system, with no prior imaging or history on the patient, time is of the essence. (Truth be told, my approach is not much different for any patient, I just take more time with those that can be dealt with that way). I talk directly to the ordering physician and get as much information about the patient I can. I physically go and examine the patient myself (scars, etc.), and gather all the information I can from whoever might be there with the patient, and then if not satisfied I order films head, chest, abdomen. My relationship with my doctors is such that I pretty much have a standing order to get these. I, of course, get everyone's blessing for these in essence, but I get the ball rolling and do not sit around for someone including doctors, nurses or patients to fill out forms or debate about safety. I will make decisions, that frankly I know a lot of techs are not comfortable with, but they should be. I take a form to fill
out myself to document my decisions and the rationale for them, sometimes after the fact. I do not waste time getting everyone's signatures and getting everyone in conference together, as this is often fruitless and devolves into pissing matches.
Frankly, I am not too worried about most implants beyond knowing about their presence. Call this flippant or cavalier if you like, but honestly there are few things I feel like I really need to worry about, that go beyond common sense, I get films to learn about what might be present and build my confidence that this person is safe to go in my scanner. Most films

only tell presence and not specifics about an implant. Any facility hiding behind films, as a lawsuit deterrent in their policy is plainly (no pun intended) misguided. An any tech who believes this will prevent lawsuits is naive. Almost all our procedures when scanning are the

same regardless of what implant is present. This is where I think an understanding of physics and our craft is helpful. Most implants are fixed, sewn, or not magnetic enough to cause injury from movement or torque. My SARs limits are the same, most implants require the kind of scanning I will not be doing to cause burns, and even if they would how would you know, as we often do not have enough information to make these calls, getting an accurate weight is more important sometimes. Where there is something present that I cannot feel safe I will urge a different exam, otherwise I will scan it. What are the things that do concern me? BB's (these have real potential to migrate, these will remain round in the human body, shrapnel and lead flatten when they hit the body so no worries there); pacemakers and bone and neurostimulators, random wires of considerable length, electronics, and aneurysm clips. I can care less if they have a heart valve or a stent, random shrapnel or metal, shunts, orthopedic implants, surgeries, clips, or just about anything else you name. I feel confident with this because I read the Safety "Bible" every year, keep up with devices, not just by name, but what they look like, how they are used, what they are made of, and what devices come through my hospital old and new. I call manufacturers every year and get a list of everything new they are making, learn how they are made and what they are made of. This is actually easier than it might sound, as most deices are made by only a hand full of manufacturers.
Now my two cents and this is what I tell the techs I train:
I have confidence from doing my homework and have earned the confidence from my doctors, nurses, and administrators because of how I handle my patients. I am not just some button pushing, alogrythm tech, but am treated as someone they can rely on and an integral part of a team. They seek my input and listen to me, I believe because of how I deal with screening. I am not a hurdle to leap over or a road block. You'll help yourself and the profession. Not only that you'll find real protection, because you'll be doing the right thing. You must know things and have the confidence in what you know. So many device salespeople are inadequately trained and training in our field so woefully incorrect or inadequate you cannot rely on what you are being told or even reading sometimes. I cannot tell you how many times salespeople tell me something is MRI safe, when it isn't even close. So much of the device labeling and information is incomplete (hello, please just tell me what a device is made of this will save so much time), misleading (conditional, yeah how is it conditional and under what circumstances? Really that seen in heart valve and coronary stent is conditional, really?), rendering screening a painful experience for the uninitiated or meaningless in any real risk verse benefit analysis. You have to judge a lot of this against what you know about physics and against your experience and other training; take it all in total and evaluate it. You cannot rely on doctors, nurses, and manufacturers, labeling, or even policies. If you rely on these people as a line of defense you are putting yourself at risk. Minimize it by educating yourself and constantly questioning.

As technologists we have to get comfortable with making these kinds of decisions, sometimes taking risks, and making allowances for our patients to not fit a norm, and the only way to do this is to get familiar with our craft. Surprisingly most technologist do not realize they operate in these grey areas all the time (but they have become the standard of care and therefore are acceptable) An example: we gad almost everyone off label and not according to the documentation, for those who have not read it, check it out. Gad is only approved for a couple of kinds of exams, and technically used off label. Anyone who has used language interpretation should understand this too. I cannot tell you how many times I have had interpreters get things wrong: dialect, words or concepts that do not translate. My patient's families are often no better than asking strangers, but you would not know that if you followed the policies so many have. Sometimes I cannot tell if my patient is lying,

misinformed, or plain out of their mind and really are in no position to be filling out a form, much less be giving me their medical history in any way that I can believe it. That is why I have to look at my patient, learn all their history that is reasonable, and make a decision that I feel is best form the best assessment I can get, that some would call a risk.
We should not be surprised that we scan people all the time not in accordance to all the coil, implant, and scanner manufacturers guidelines. Ever read the safety manuals for your contrast, scanner, coils, and implants? Are you placing your coils in with proper padding, proper distance from patient, under the proper conditions as outlined by the manufacturer? Are they medicated and monitored? You are not putting any foreign material or device in the scanner right? Sure you aren't. Can you guarantee the SAR limit based on the limited information we have? Can you guarantee no migration with the limited information you have? How about that risk verse benefit, do you really know what the risk is? I guarantee that to follow some of these safety guidelines precisely would render scanning impossible, infeasible, or ridiculous. How many stents are overlapped, their location, how much SAR are you producing with this sequence verse this sequence, where does this implant line up on a non-existent gradient map, was this device defect in it's manufacture, was it tested properly, the amount of things we could worry about to cause us doubt are routinely accepted by techs all the time and also turned away when they should not be. I do not want to paint a picture that nothing can be trusted, some manufacturers label is better than others, and there is a standard of care we can follow, so we can have confidence. If anything, though I have learned, it is that we must be adaptable: Zenith stents and Boston Scientific intestinal clips anyone? I am not going to turn away a patient, delay anyone's care, or even flinch so I can fill out my screening form. Are you going to turn away a patient from 600 to 1500 miles who has no information on their recent stent, heart valve, or shunt? (Some of my patient come from Alaska.) Really? Why? How about my patient from across the street that has no information on that stent put in a couple of months ago? Really? Why? People should not fear MRI, but understand it; I do not want to be the source of fear.
Most accidents I have witnessed or heard about have come from external issues being introduced in the environment, people in a hurry, improper medication and patient monitoring, improper use of equipment and coils, rather than implants, not that these cannot be a problem, but they are usually the least of my worries. No amount of screening and paper forms will cure these issues, only good training and exercise of that training. Minimize your risk by being educated, making rational decisions routinely, making these good practice, keeping up with the standards of care, and working with your doctors and nurses so they are your allies not your adversaries. My goal is get everyone who needs a scan and not get hung up on paperwork or ridiculous adherence to rules and policies that may not apply.

I hate that policies even have to have clauses for alternate tests in them and questions of necessity as part of the policy for screening. In a perfect situation the ordering physician will have already contacted the Radiologist about the situation, so no time is wasted on the question is this really necessary and two competent physicians have discussed this and the possibility of alternate tests and risk verse benefit. It would be best if I could assume that every order that comes my way is necessary and for the benefit of the patient. Unfortunately my experience tells me that I cannot assume this, so I have to go to my Radiologist, who more often than not, knows nothing more than I do about the patient, so I better be armed with a firm grasp of what I can do, the limits of my test and equipment, have all the information I can, and be prepared to offer advice and advocate for my patients. Sometimes I have scanned patients that have doctors that say they cannot be scanned, because they are misinformed.

Sorry if this seems like a rant, but I want smart policies and room to practice what makes sense; not blind allegiance to stupid policies that only delay and hinder care, create barriers and harm patients; not to mention make my training and expertise irrelevant. I want smart policies that leave room for every patient's situation to be considered and not come down on caregivers as a penal action for those rare exceptions. If, no form, no scan is your policy, and you follow that, I guess that is fine; I wouldn't hire you or refer patients, friends, or family
to you, most certainly wouldn't be my first pick, if I had a choice. We are techs not robots.
Question (14/11/14): I have a question in regards to screening sheets. Are there any facilities that waive the screening process if a patient cannot fill out the form, and then scanned on a 1.5T ? My department does NOT do this, but a conversation had taken place that there ARE facilities that do this to expedite a study. Very curious as to the groups input on this subject. Thank you.

Shellock: In place 4 years, highly unlikely significant mag field interactions and risk of heating is very low
Your Radiologist should decide based on risk vs benefit

Question (30/6/2014): Looking for information on a heart valve. It was placed in 2010 and the report refers to it as a 23 or #23 Pericardial Heart Valve. No sticker, no manufacturer info was sent with report. Any help would be appreciated

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Greg Brown: The Bjork Shiley ABP series is a single disc valve from the "conical Spherical
Series". They are known to be prone to strut fractures and failures.
They were used from 1979 manufactured finally by Pfizer. Pfizer bought Shiley in 1979, pre internet. Like you can't find a reference on Dr Shellock's site which generally means there was no testing reported on the device.
The document I found describes them as a metal cage with Derlin or carbon leaflet.
I think your Radiologist has to make a reasoned decision on the basis of materials.
Can send you the document direct if you prefer. It's a Cedars Sinai handbook on cardiac valves design and history.
Shellock: How long in place? Very old valve Have your Radiologist assess risk: benefit for the pt.

Question (6/6/2012): Does anyone have MR safety info for a Bjork-Shiley aortic valve, no model number on the wallet card, serial number 23ABP33249. I cannot seem to identify the valve from the serial number, and I don't think the manufacturer exists anymore.

Shellock: St Jude Medical makes many types of heart valves, listed with info on www.MRIsafety.com. No wait time is necessary for any of them.
Posh: The forces placed on the valve by the beating heart are far greater than anything the MRI can do so waiting time is not relevant as long as you are not exceeding the other conditions as specified on the card.
Question (4/6/12): Is there any wait on St Jude heart valve when scanning on 1.5 T Toshiba, C-spine? He has a card with conditions, but no mention of wait time.

Shellock: Yes...if that is your approach to screening, then the Radiologist must sign off on such a strategy.
What if a heart valve or stent is developed that is unsafe in the near future and you have this

screening procedure in place? How would you know that the pt. presented with the unsafe valve or stent?
Greg Brown: I think the answer depends on if you personally want to scan under expressed safe conditions (no harm, warranted by the manufacturer), or if your Radiologist will support and sign off on a position that is justifiably unlikely to be unsafe. Subtle but important distinction. You still need to be aware of the specific device and get information to base the latter decision on.
Question (22/8/11): In the past we have scanned patients with heart valves and stents any time after 8 weeks implantation. With current conditional labeling specific to max spatial gradient fields, are you checking every heart valve and stent regardless of how long it has been in place. I do not want to compromise safety but want to make sure not over reacting. Any information or sharing of policy regarding this will be appreciated.

Greg Brown: Side note
The EMITRON factory was "illegally privatized" in 1996.
http://www.themoscowtimes.com/news/article/a-brief-look-at-the-stories-making-headlines-in-the-russian-language-press/274963.html

The initial single leaflet valves made at EMITRON were also reported to be called EMIX. Same name, different spelling.
http://www.htex.ru/en/analytics/view/?id=82
Greg Brown: Russian heart Valves

LIKS valves use a carbon leaflet with a titanium body.
http://archive.pepublishing.com/content/x381627j4624h111/fulltext.pdf?page=1

EMIKS valves are Russian copies of US valves, significantly made of "superior Russian materials" in a military factory called EMITRON
http://www.roscardioinvest.ru/eng/news.php?n_id=15

It appears to me that the EMIKS became the MIKS valve, after the EMITRON factory was destroyed.
You could try to check the specifications cites at Roscardioinvest
http://www.roscardioinvest.ru/eng/index.php?id_subpart=10

MIKS is titanium and carbon single leaflet valve, similar to the HALL valve, also made of pyrolytic carbon and titanium (http://www.ncbi.nlm.nih.gov/pubmed/8843515)

So in principle, it is MR conditional The Radiologist will have to be satisfied of the construction and make a local reasoned decision.
There will be no FDA type testing.
The valves are not listed on mrisafety.com (understandably)
Question (12/4/2011): I have recently received a request to scan a patient with 2 Russian made heart valves in place. They are a EMIKS-21 and EMIKS-27 implanted in 1996. As best I can gather these were made by a "factory" called Emitron which apparently was
"destroyed". In its place is a company called Roscardioinvest which appears to have
developed their own version of the valves. As you could probably guess I'm not having a lot of luck working out MRI safety of these. Does anyone have any experience with these

valves and their safety in MRI, especially at 3T?

(Note from Jonathan: I have also seen a comment which states that the St Jude Heart Valve – perhaps not this particular one – only had a deflection angle of 10 degrees when it also had a low spatial gradient limit)
Shellock: nothing will be stuck partially open for those valves I tested many of them
Gilk: Is the spatial gradient limitation for the St. Jude valves based on deflection concerns or is it a functional concern that there's a potential that the valve could be partially / fully stuck in one position for the duration of exposure? Do we have information from the manufacturer regarding the nature of this limitation?

Question (21/4/2010): I have a patient with two St. Jude valves (25mj-501 and 21afhj-505). Both are conditional 5 for MR safety.
St. Jude fax states STATIC MAGNETIC FIELD OF 3 TESLA OR LESS but then the SPATIAL GRADIENT OF 535 GAUSS/CM OR LESS is disappointing.
Our 1.5T is 577 gauss/cm and our other scanner is a GE 3T (most likely
Around 720 but I won't put it in writing).

Shellock: For such a valve, it is highly unlikely that no MRI is allowed, as I am sure you are aware.

Question (20/5/2010): I have a patient soon to attend for a MRI lumbar spine on a 1.5T Siemens Avanto. The patient has informed us that she has a Sorin Monostrut mitral heart prosthesis inserted in 1994. The patient also stated that she had been informed that "she could never have an MRI scan", but apparently now she wants one!
I have obtained the patient's operation notes, but the letter I have makes no mention of serial numbers etc, stating only that "Sorin monostrut mitral prosthesis was inserted".
I have tried everything to find out whether this prosthesis is safe to scan, with no luck.
I have trawled the internet and can find references to SORIN monostrut, but none relevant to MRI. The SORIN website makes no mention of a monostrut mitral valve prosthesis.
mrisafety.com mentions either a monostrut valve OR a valve manufactured by sorin, but not a sorin monostrut valve!

Manny: Frank and I seem to be in complete agreement on this one as well. However, I absolutely do understand what you are asking and trying to say: namely, that TODAY, if someone comes in with a heart valve of unknown type implanted 10 years ago, how should we respond? At our institution we try to identify the implant, but failing that we inform the patient that we are not aware of any FDA approved clinically utilized heart valve that has been demonstrated to be problematic on presently asymptomatic patients (i.e., no sign of heat valve loosening) at up to 3 Tesla - and if there is a good clinical indication for the scan we do accept them for study.
Shellock I do (and thanks for the provocative statement).
(1) Under what MRI conditions? 8 and 9.4-Tesla also?
(2) Not all heart valves have been tested.
(3) New ones are developed on an on-going basis
(4) At least one prototype valve incorporates tiny magnets
(5) General statements should not be made for any class of implants

Question (2/5/2007) **NOTE: ALL CARDIAC VALVES ARE SAFE**

Does anyone else have a problem with the above statement?

We are putting together a cardiac requisition which includes MRI screening questions to be filled out by the referring MD. The Radiologist wants to put a blanket statement on there regarding cardiac valves because she gets so many calls about them, citing the MRIsafety.com website as reference.

This, of course, would not be the final line of defense. When the patient arrives in the department, they will be asked to fill out our regular MRI screening form. I understand that the majority of them are compatible but I'm having a hard time with that statement and didn't know if it was just me…

Review of the UK MRI mail base

An archive search for 'heart valves', 'valves', 'cardiac' and 'annuloplasty ring' was performed for the MRI Physics mailbase which returned no results.

Internet Search

A more general internet search was not conducted in this case as it was felt that the evidence covered elsewhere was adequate.

Summary of locally implanted devices *'Optional section'*

An MRI safety review for NHS Tayside (NHST) has been performed twice (in 2016 and 2018) for scanning heart valves and annuloplasty rings. Information was sourced from previous safety investigations within NHST, local discussions, manufacturer guidelines, relevant literature and Frank Shellock's website. Table 2 summarises the results from these audits. The MRI Conditional devices were scanned at 1.5 T in normal mode.

2016 Review		**Total: 136**
Manufacturer	**Number of Products Reviewed**	**Safety Status**
AorTech	2	MR Conditional
ATS Medical	11	MR Conditional
Pfizer Inc.	8	MR Safe
Edwards Lifesciences	21	MR Safe
	29	MR Conditional
Johnson & Johnson	1	MR Safe
	3	MR Conditional
Medtronic	18	MR Safe
	2	MR Conditional
LivaNova (Includes Sorin and Carbomedics)	2	MR Safe
	16	MR Conditional
St Jude	23	MR Conditional
2018 Review		**Total: 53**
Edwards Lifesciences	1	MR Safe
	15	MR Conditional
St Jude	9	MR Conditional
Medtronik	8	MR Conditional

LivaNova (Includes Sorin and Carbomedics)	6	MR Conditional
Unrecorded	2	MR Safe
	12	MR Conditional

The result of both MR safety audits supports the literature that all devices are safe to scan within the conditions stated in the section 'Review of MRI implant safety Databases'. Something to note from the 2018 audit is that 14 of the safety requests did not reference the device manufacturer. However, they were still recommended as safe to scan provided the above guidelines were adhered to.

Additionally, NHST does not perform implantation of prosthetic heart valves or annuloplasty rings. These patients usually come from other centres in Scotland and so the manufacturers represented in the NHST audit results should provide a good overview of typical implants used in Scotland.

Empirical evidence

At the Institute for Neurosciences in NHS Greater Glasgow and Clyde they have been scanning patients with heart valves at 3T for more than 15 years without any incidents.

Anecdotal data

A search for Heart Valves and Annuloplasty Rings safety queries was performed on the Facebook Groups UK MRI Safety Group and MRI World and returned no results.

MRI Safety Facebook Group results for Heart Valves and Annuloplasty Rings safety queries

22nd February 2018:
"I have a question regarding heart valve replacements and the Bjork Shiley aortic valve with serial #21ABC17311 that was implanted in a patient in 1983. The Shiley company recalled these valves shortly after my patient had this implanted but her doctors chose to leave the valve in place. The patient was part of a class action law suit because of the recall. To date the patient has not had any problems with this valve. She has never had an MRI scan. The Shiley company then sold their company to Pfizer at some point in time. I contacted Pfizer and they faxed me a blank statement which stated that there has not been any MRI safety testing on this particular valve. They stated that the valve is made of Hayne Alloy #25. Our patient is scheduled for an out-patient MRI brain and orbits with diagnosis of chronic visual disturbance and headache. Our MRMD is hesitant to do the MRI scan and will probably recommend a CT in this case. Any suggestion/recommendations would be greatly appreciated."

Frank Shellock MRI:

MRI Generic Implant Safety Policy (GISP): Detailed review v10

Follow these guidelines, because the information applies to that particular valve, no problem, Lisa Anne:

Guidelines for the Management of Patients with Heart Valve Prostheses and Annuloplasty Rings Referred for MRI Procedures

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www.MRIsafety.com

In the clinical magnetic resonance imaging (MRI) setting, it is often necessary to manage patients with heart valve prostheses [including transcatheter aortic valve replacements (TAVR), transcatheter aortic valve implantation (TAVI) devices, percutaneous aortic valve replacement (PAVR) implants, transcatheter heart valves (THV), as well as other similar valve implants used in association with minimally invasive procedures] and annuloplasty rings (1-20).

MRI labeling information exists for many heart valve prostheses and annuloplasty rings. By following the pertinent MRI labeling information (i.e., presented in the Instructions for Use, Patient Identification Card, etc.), patients with heart valve prostheses and annuloplasty rings have safely undergone MRI examinations, including those performed at 1.5- and 3-Tesla (15, 20, 22). Notably, there has never been an adverse event reported in association with performing MRI in patients with these particular implants.

Unfortunately, the standard policy that MRI labeling information is required before allowing the use of MRI in a patients with heart valve prostheses and annuloplasty rings limits access to this important diagnostic imaging modality for those patients for which labeling information is unavailable. However, in consideration of the relevant peer-reviewed literature and other related documents (1-22), it is acceptable and safe to perform MRI examinations in all patients with heart valve prostheses and annuloplasty rings by following specific guidelines developed by taking into consideration possible safety concerns (i.e., magnetic field interactions and MRI-related heating) for these implants.

Notably, by adhering to these admittedly conservative MRI conditions, all patients with heart valves and annuloplasty rings can benefit from the diagnostic imaging information provided by one of the most important noninvasive imaging modalities.

Guidelines. The following guidelines apply to using MRI in all patients with heart valve prostheses and annuloplasty rings:

(1) Patients with all commercially available heart valve prostheses and annuloplasty rings can be scanned at 1.5-Tesla/64-MHz or 3-T/128-MHz, regardless of the value of the spatial gradient magnetic field.

(2) Patients with all commercially available heart valve prostheses and annuloplasty rings can undergo MRI immediately after placement of these implants.

(3) The MRI examination must be performed using the following parameters:

1.5-Tesla or 3-Tesla, only
Whole body averaged specific absorption rate (SAR) of 2-W/kg, operating in the Normal Operating Mode for the MR system
Maximum imaging time, 15 minutes per pulse sequence (multiple sequences per patient are allowed)

Important Note: Any deviation from the above MRI conditions requires prior approval by a radiologist or supervising physician.

Important Note: These guidelines must be reviewed on an annual basis to confirm that no new heart valve prosthesis or annuloplasty ring has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe.

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[*The "Guidelines for the Management of Patients with Heart Valve Prostheses and Annuloplasty Rings Referred for MRI Procedures" should only be implemented for use after the careful review by the supervising radiologist or physician responsible for the MRI facility and adoption as a written policy.]

12th August 2016:

"We have a pt without an identification card for her mitral valve. We have her CT and chest X-ray that doesn't show apparent metallic device in the heart. She does have some wires on her sternum and some surgical staples. Scan or No Scan? BTW, We are awaiting word from the radiologist but we're curious what the MRI safety community has to say. We are to scan a hip on a 1.5 t magnet. I would probably use the body coil and and maybe a flex array coil."

Response: "I don't profess to be able to read films accurately, so I'll take it on faith that all that is seen in these films are staples (which I see) and a sternal wire (which I also see).

If that's the case... that there is nothing radio-opaque where the mitral valve replacement is (supposed to be), then that would indicate to me that there is nothing metallic or significantly electrically conductive. Nonmetallic means that it can't be magnetic (except for rare magnetic ceramics, which aren't - to my knowledge - used in cardiac implants, andwould also show up radio-opaque). Nonmetallic also means that it's not likely to have appreciably better electrical conductivity than the patient's own tissues.

If the sternal wires and staples are cleared (and these are pretty standard), I see nothing that offers a direct safety contraindication to an MR study..."

Frank Shellock: "FYI, the guidelines for managing patients with heart valves prostheses and annuloplasty rings are posted in the Safety Info section of my website, they'll be in the next edition of my Reference Manual for Magnetic Resonance Safety, Implants, and Devices (2017 Edition), and are now posted on the ISMRM/SMRT MRI Safety Page, here:

http://www.ismrm.org/mr-safety-links/

It is my understanding that many in the MRI community have now embraced these guidelines and have incorporated them as part of their policies/procedures."

16th June 2016

"I have a question. Pt has edwards sapien 3 heart valve. Conditional 8 with max sar of 2w/kg for body. We would be scanning his head which is max 3.2/kg on our scanner in normal mode, for head. This is the first time I have run into this. He had a prior lumbar at another facility yhat has same magnet. But for that scan was 2w/kg in normal mode. Bottom line is this safe to scan since we are scanning head and it is higher sar."

Frank Shellock: "No problem for that SAR level related to the head. Proceed with MRI."

8th November 2017

"When looking at Dr Frank Shellock Mri guidelines for heart valves .... wondering if that includes all (even older ones).... has there ever been a heart valve that is considered unsafe?"

Frank Shellock: "The guidelines apply to ALL heart valve prostheses, as stated"

19th April 2017:

"Is a St. Jude Heart valve from 1988 MRI safe. No documentation as of yet, still waiting. I am of the understanding that all St. Jude Heart valves are conditional/safe, but not how sure how far it goes back."

Frank Shellock:
"Read this please, Kellie Knight No need to delay the MRI exam for your patient. By the way, our group started testing heart valves back in 1986 and continue to test many types, even now. To date, there is no MR Unsafe heart valve.''

8th September 2018:

"Anyone familiar with Medtronic CG Future Annuloplasty ring? Guidelines say max whole body sar 1.1 w/kg. Im scanning lumbar on 1.5T...may be more difficult to achieve and need to change protocol yes? Does anyone mind sharing which scans they run for their protocol?"

Frank Shellock:
''The testing and resulting labeling represents outdated techniques and requirements for MRI that are excessively restrictive for a patient with and annuloplasty ring. Follow the guidelines below:

Guidelines for the Management of Patients with Heart Valve Prostheses and Annuloplasty Rings Referred for MRI Procedures"

Summary of risks from implant associated with static field, RF and imaging gradients

An internet search for imaging heart valves and annuloplasty rings at 7T was conducted which returned no results. There was no discussion on the facebook groups or the mailbase regarding 7T imaging. Therefore, more work to be done to determine safety status of heart valves and annuloplasty rings at 7T.

Consideration of risks, specific to this implant category

Conclusion

This document has considered the MRI safety status of heart valve prosthesis and annuloplasty rings. A review of the manufacturers on www.mrisafety.com which considered 27 manufacturers and 231 implants demonstrated there are no devices that are considered MRI unsafe. Of the implants considered all were MRI conditional at 1.5T. Only certain devices were MRI conditional at 3T, upon closer investigation these devices are likely to be bioprosthetic valves, which contain less metal than mechanical valves. Therefore, advice applicable to all valves should be applied at 1.5T field strength.
Some valves are implanted through open chest surgery. These patients will have additional sternal wires from this surgery. Extra care for these patients should be taken to ensure there is

no direct contact with the scanner and that there are no current loops. Scanning should be performed in normal mode to minimise power deposition.
The artefacts generated by these devices are proportional to the amount of metal present. This will be higher for mechanical valves than bioprosthetic valves. Although this is not a direct safety issue it may be of interest to healthcare workers.
The Lenz effect has been considered at 1.5T and deemed insignificant compared to the forces of the beating heart at this field strength or less. There is opportunity to evaluate at higher field strengths to confirm whether the Lenz forces become a safety concern.
In summary the evidence collected in this document confirms that patients with heart valves or annuloplasty rings can safely be scanned provided the following conditions are adhered to:

- Field strength of 1.5 or 3 Tesla.
- Whole body averaged specific absorption rate (SAR) of 2-W/kg, operating in the Normal Operating Mode for the MR system.
- Maximum imaging time, 15 minutes per pulse sequence (multiple sequences per patient are allowed).

Appendix

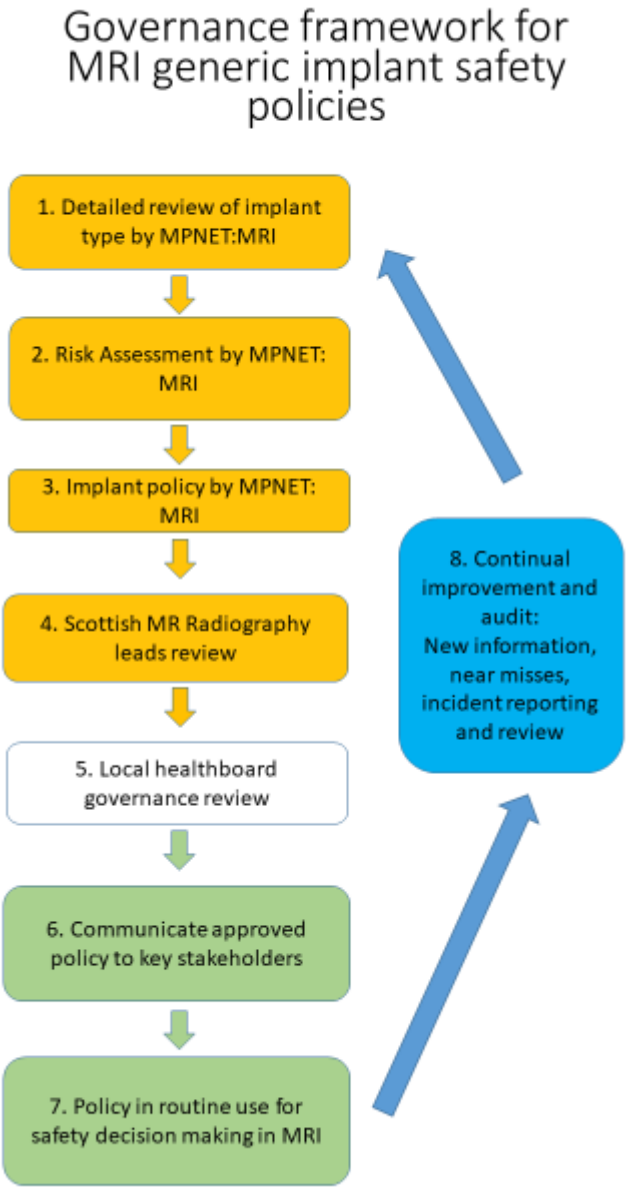
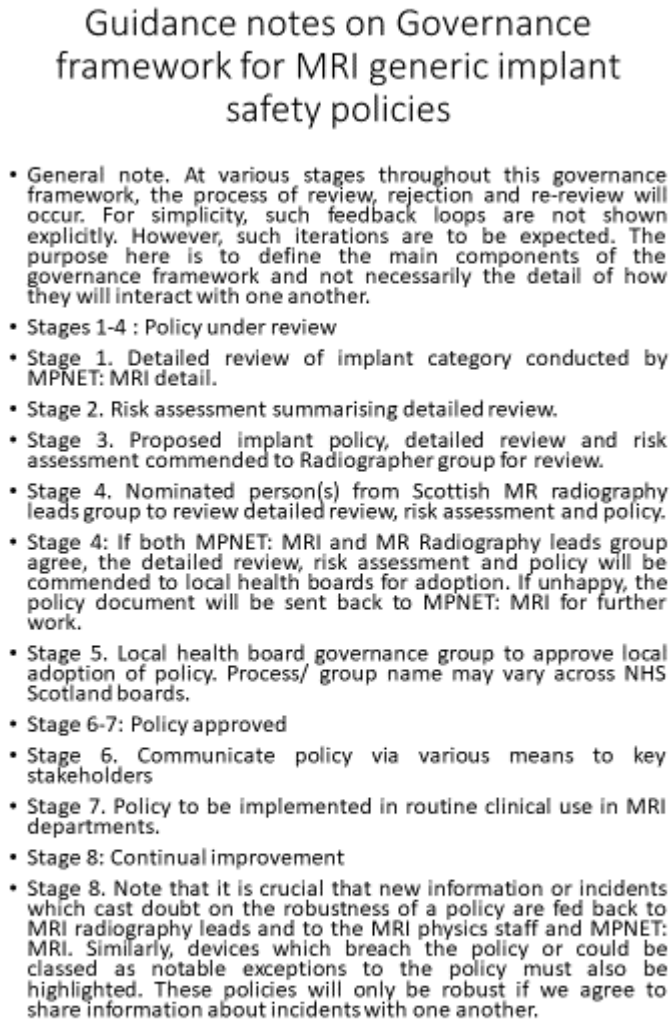


Figure AX: Governance Framework for Generic Implant Safety Policies, creation to deployment



Guidance notes on Governance framework for MRI generic implant safety policies

- General note. At various stages throughout this governance framework, the process of review, rejection and re-review will occur. For simplicity, such feedback loops are not shown explicitly. However, such iterations are to be expected. The purpose here is to define the main components of the governance framework and not necessarily the detail of how they will interact with one another.
- Stages 1-4 : Policy under review
- Stage 1. Detailed review of implant category conducted by MPNET: MRI detail.
- Stage 2. Risk assessment summarising detailed review.
- Stage 3. Proposed implant policy, detailed review and risk assessment commended to Radiographer group for review.
- Stage 4. Nominated person(s) from Scottish MR radiography leads group to review detailed review, risk assessment and policy.
- Stage 4: If both MPNET: MRI and MR Radiography leads group agree, the detailed review, risk assessment and policy will be commended to local health boards for adoption. If unhappy, the policy document will be sent back to MPNET: MRI for further work.
- Stage 5. Local health board governance group to approve local adoption of policy. Process/ group name may vary across NHS Scotland boards.
- Stage 6-7: Policy approved
- Stage 6. Communicate policy via various means to key stakeholders
- Stage 7. Policy to be implemented in routine clinical use in MRI departments.
- Stage 8: Continual improvement
- Stage 8. Note that it is crucial that new information or incidents which cast doubt on the robustness of a policy are fed back to MRI radiography leads and to the MRI physics staff and MPNET: MRI. Similarly, devices which breach the policy or could be classed as notable exceptions to the policy must also be highlighted. These policies will only be robust if we agree to share information about incidents with one another.

Figure AY: Notes on Governance Framework for Generic Implant Safety Policies
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'Include any relevant references used throughout this detailed review here'

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