MRI Generic Implant Safety Policy (GISP): Detailed review

Title: Review of Cardiac closure and occlusion devices to treat congenital heart defects such as Patent Ductus Arteriosus (PDA), Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD) and Patent Foramen Ovale (PFO)

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 misidentify 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 cardiac closure or occlusion devices

This review considers a range of cardiac closure or occlusion devices. We have adopted the same categorisation as detailed on Dr Shellock's MRIsafety.com for these devices. While some of the abnormalities in the heart are typically spotted prior to birth or soon after birth, some of the conditions can persist into adulthood unnoticed. Congenital heart disease more generally has a prevalence of around 8 births in every 1000 and as such are a fairly frequent occurrence in healthcare. (Dolk et al)

All of these conditions can be closed by either surgical techniques or transcatheter techniques. There are a number of clinical factors which dictate the choice of intervention. Services have evolved over the years as device technologies have changed, but both approaches appear still to be in use. Farooqi et al, 2019.

Surgical techniques can enable closure by ligation, by clip or by suture.

The terms used will be briefly explained such as to provide context of the device and the underlying pathology the closure device or occluder is designed to repair.

This section references:

There are many types on congenital defect, some of the most common are: atrial septal defect (ASD) and a **patent foramen ovale** (PFO). Although both are holes in the wall of tissue (septum) between the left and right upper chambers of the heart (atria), their causes are quite different. An ASD is a failure of the septal tissue to form between the atria, and as such it is considered a congenital heart defect, something that you are born with. Generally an ASD hole is larger than that of a PFO. The larger the hole, the more likely there are to be symptoms.

PFOs, on the other hand, can only occur after birth when the foramen ovale fails to close. The foramen ovale is a hole in the wall between the left and right atria of every human fetus. This hole allows blood to bypass the fetal lungs, which cannot work until they are exposed to air. When a newborn enters the world and takes its first breath, the foramen ovale closes, and within a few months it has sealed completely in about 75 percent of us. When it remains open, it is called a patent foramen ovale, patent meaning open. For the vast majority of the millions of people with a PFO, it is not a problem, even though blood is leaking from the right atrium to the left. Problems can arise when that blood contains a blood clot

Patent Ductus Arteriosus (PDA),

Information below was sourced from the Great Ormond Street Hospital Website (https://www.gosh.nhs.uk/)

The ductus arteriosus is a blood vessel that connects the pulmonary artery (main vessel supplying the blood to the lungs) to the aorta (main vessel supplying the blood to the body). This connection is present in all babies in the womb, but should close shortly after birth. In some babies, especially in those born prematurely, this vessel may remain open. This is called a patent or persistent ductus arteriosus.

Atrial Septal Defect (ASD),

Information below was sourced from the NHS website (https://www.nhs.uk/conditions/congenital-heart-disease/types/)

An atrial septal defect (ASD) is where there's a hole between the two collecting chambers of the heart (the left and right atria). When there's an ASD, extra blood flows through the defect into the right side of the heart, causing it to stretch and enlarge.

Ventricular Septal Defect (VSD)

Information below was sourced from the NHS website (https://www.nhs.uk/conditions/congenital-heart-disease/types/)

A ventricular septal defect (VSD) is a common form of congenital heart disease. It occurs when there's a hole between the 2 pumping chambers of the heart (the left and right ventricles).

This means that extra blood flows through the hole from the left to the right ventricle, due to the pressure difference between them. The extra blood goes to the lungs, causing high pressure in the lungs and a stretch on the left- sided pumping chamber.

Small holes often eventually close by themselves, but larger holes need to be closed using surgery.

Patent Foramen Ovale (PFO)

Information below was sourced from the Great Ormond Street Hospital Website. (https://www.gosh.nhs.uk/conditions-and-treatments/conditions-we-treat/patent-ductus-arteriosus-pda)

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

Patients with closure and occlusion devices are frequently referred for MRI. While the quality of and systems used for surgical recording is improving, these are not perfect and circumstances can occur whereby MRI units are unable to determine the details of the occluder or closure device. A further issue can be that of devices that were implanted a long time ago and the patient's note have subsequently been destroyed. Thus MRI units are faced with the decision as to whether to proceed with the MRI scan in the absence of implant specific information.

Hypothesis

Based on the authors experience of having reviewed many closure and occlusion devices for MRI safety over a period of 15 years, my strong impression is that all such devices are MR Safe or MR Conditional where the MRI conditions would typically be satisfied on both 1.5T and 3T clinical systems. This hypothesis will be revisited following this detailed review.

Aim

To determine a clear and simple generic implant safety policy for cardiac occlusion and closure devices such as to inform subsequent risk assessments and policy statement that can be deployed safely in routine clinical practice.

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

MRIsafety.com

PDA's

4 PDA devices with the following names and MRI status

Nit-Occlud PDA-R Occluder

PFM s.r.l.

https://www.pfmmedical.co.uk/products-category/cardio-vascular-technologies/

Status on MRIsafety.com: 3T, conditional 6

Notes: A company called PF medical also have a device called: Nit-Occuld ASD

Occlutech PDA Occluder

Occlutech, www.occlutech.com

https://www.occlutech.com/ (international i.e. non US site)

Status on MRIsafety.com: 3T, conditional 8

Rashkind PDA Occlusion Implant

12 mm, occluder (304V SS)

C.R. Bard, Inc.

Billerica, MA

Status on MRIsafety.com: 1.5T, conditional 5

Rashkind PDA Occlusion Implant

17 mm, occluder (304 V SS)

C.R. Bard, Inc.

Billerica, MA

Status on MRIsafety.com: 1.5T, conditional 5

Notes: Company 'CR BARD' became simply 'BARD'. C. R. Bard, Inc., now branded simply as Bard, headquartered in Murray Hill, New Jersey, USA, is a multinational developer, manufacturer, and marketer of medical technologies in the fields of vascular, urology, oncology, and surgical specialties. In April 2017, the company has announced that it will be acquired by Becton Dickinson.

The author's impression of Rashkind product is that it is no longer available and was an early device developed in this area. Thus, we are not likely to get more information from commercial websites on this product, however the peer reviewed literature might contain some information.

Summary: All PDA devices on Dr Shellock's site (as of Jan 2020) are MR conditional, though information for Rashkind device is limited to 1.5T

ASD's

3 ASD devices with the following names and MRI status

Figulla Flex II ASD Occluder

All Sizes

Occlutech GmbH, www.occlutech.com

Status on MRIsafety.com: 1.5T, 3T, conditional 8

HELEX

ASD closure device

occluder

size 15 mm

nitinol

W. L. Gore and Associates, Inc.

Flagstaff, AZ

Status on MRIsafety.com: 1.5T, MR Safe (though this is unusual as usually Dr Shellock states all devices containing metal are (as a minimum), MR conditional.

HELEX

ASD closure device

occluder

size 35 mm

nitinol

W. L. Gore and Associates, Inc.

Flagstaff, AZ

Status on MRIsafety.com: 1.5T, MR Safe (though this is unusual as usually Dr Shellock states all devices containing metal are (as a minimum), MR conditional.

Note: WL Gore and associates became Gore Medical

https://www.goremedical.com/

https://www.goremedical.com/products

https://www.goremedical.com/products/helex

There are now many products on Gore's website now. The HELEX being only one such product. It is noted that the HELEX product is discontinued (noted at Jan 2020 but likely to have been discontinued earlier). No IFU for Helex product was readily available.

Note: The Nit-Occuld ASD-R device is not noted on Dr Shellock's website.

Summary: All ASD devices on Dr Shellock's site (as of Jan 2020) are MR Safe or MR Conditional, though information for the Helex device is limited to 1.5T.

VSD's

6 ASD devices with the following names and MRI status

AMPLATZER Muscular VSD Occluder

AGA Medical Corporation

Plymouth, M

Status on MRIsafety.com: 3T, conditional 6

AMPLATZER Muscular VSD Occluder

St. Jude Medical, www.sjm.com

Status on MRIsafety.com: 1.5T,3T conditional 8

AMPLATZER Muscular VSD PI Occluder

AGA Medical Corporation

http://international.amplatzer.com

Status on MRIsafety.com: 3T, conditional 6

Occlutech Muscular VSD (mVSD) Occluder

Occlutech Ltd., www.occlutech.com

Status on MRIsafety.com: 1.5T, 3T conditional 5

Perimembranous Ventricular Septal Defect (PmVSD) Occluder

Occlutech, www.occlutech.com

Status on MRIsafety.com: 1.5T, 3T conditional 8

Post Myocardial Infarction Ventricular Septal Defect (PIVSD) Occluder

Occlutech, www.occlutech.com

Status on MRIsafety.com: 1.5T, 3T conditional 8

Notes: The Amplatzer device is now an SJM product.

Summary: All VSD devices on Dr Shellock's site (as of Jan 2020) are listed as MR conditional.

PFO's

5 PFO devices with the following names and MRI status

PFO's from Shellock's website

AMPLATZER PFO Occluder

Nitinol, SS, Platinum/iridium, Polyester

AGA Medical Corporation

Plymouth, M

Status on MRIsafety.com: 3T conditional 6

BioTREK

PFO closure device

NMT Medical,

Boston, MA

Status on MRIsafety.com: 3T conditional 6

Intrasept

patent foramen ovale (PFO) closure device

Nitinol, Titanium

Cardia Inc.

Burnsville, M

Status on MRIsafety.com: 3T conditional 6

Premere PFO Closure System

Patent foramen ovale (PFO) closure device

St. Jude Medical

www.sjmprofessional.com

Status on MRIsafety.com: 3T conditional 6

Note: An IFU or other *corporate information on this product could not be sourced. It could not be found on the SJM website. The company was emailed but no response was forthcoming.*

Ultrasept PFO Occluder

Cardia, Inc., www.cardiainc.com

Status on MRIsafety.com: 3T conditional 6

Note: *Emailed Cardia http://www.cardia.com/index.html for IFU for Intrasept and Ultrasept products and any other products. Note the FAQ site on Cardia states that MRI is ok for the Ultrasept device http://www.cardia.com/faq.html.*

Note: The Amplatzer PFO falls under several companies: AGA, SJM, Abbott. Some historical IFU's were obtained.

https://www.cardiovascular.abbott/us/en/hcp/resources/mri-ready-resources/structural-heart-mri-safety.html

Summary: All PFO devices on Dr Shellock's site (as of Jan 2020) are listed as MR conditional.

Review of manufacturer implant information

It is notable that there has been an evolution of devices. This can be seen on the Occultech website that here are now further ranges of 'derivative' devices https://www.occlutech.com See 'UNI', 'PLD', mVSD, PmVSD, and AFR. There is the potential for confusion between the acronym for the device and the acronym for the underlying pathology. However, it is expected that any derivative device, would not be 'worse' in terms of MR safety properties than its parent device

PDA's are sold by Occultech and Pfmmedical.

ASD

In addition to the devices list on Dr Shellock's website there is a further ASD device marketed by pfmmedical called Nit-Occult ASD (mirroring their PDA product).

PFO

NMT: also make CardioFlex and StarSeal, septal repair devices?

Ceraflex (see Abdelgani)

Review of the peer reviewed literature

n/a

Review of the SMRT MR Technologist mail base

The SMRT technologist google groups was searched for articles of relevance to this topic. This archive goes back to 2015. The following search terms were used: PFO, PDA, ASD, VSD, UNI, PLD, mVSD, pmVSD and Occluder.

For the most part these searches returned blank responses with the exception of 'PDA' which had a couple of responses.

One discussed the Rashkind device and stated it was MR Conditional (conditional 5 in Dr Shellock's terms). On another message thread discussing a PDA clip, Dr Shellock highlights that '…not all PDA implants have been tested'.

Overall, there is no suggestion of any occlusion device that has been tested is MRI unsafe though there is an acknowledgement that not all of these devices may have been tested. No specific examples of devices that have not been tested were noted.

Review of the UK MRI mail base

The MRIPhysics mailbase which dates back to June 2012 was searched using the same terms used above to search the SMRT google group.

There were very few questions raised about these devices. One query that did appear related to the Amplatzer device and satisfying maximum spatial gradient considerations. The two responses suggested to consider a risk/benefit approach.

Internet Search

No further internet search was conducted.

Facebook: MRI Safety group

Facebook review: MR safety of devices to correct PDA, PFO, VSD, ASD

ASD

A post from April 2019, regard an ASD repair done in 2004. Among a number of replies it was noted that Dr Shellock highlighted that at that time (of the Facebook post) there are no ASD on his website listed as MR unsafe.

VSD

From a post in Sept 2019 in regard to MR safety of PFO devices. Among a number of replies Dr Shellock noted that 'to the best of his knowledge, there are no MR unsafe PFO, VSD or ASD implants' and that 'All conditional PFO implants can be scanned immediately'. Other replies back up this statement indicating devices were either scanned safely or suggesting check make/model to determine the device MR safety status. That is, there was nothing to contradict Dr Shellock's view.

PFO

From a post in Sept 2019 in regard to MR safety of PFO devices. Among a number of replies Dr Shellock noted that 'to the best of his knowledge, there are no MR unsafe PFO, VSD or ASD implants' and that 'All conditional PFO implants can be scanned immediately'. Other replies back up this statement indicating devices were either scanned safely or suggesting check make/model to determine the device MR safety status. That is, there was nothing to contradict Dr Shellock's view.

PDA

It is notable that there are also coil devices as well as closure or occlusion devices that can be used to correct PDA.

Occluder

Summary from Facebook posts

From the Facebook posts reviewed there is no reliable information to suggest that any of the closure or occlusion device used for these assorted cardiac conditions are MR Unsafe.

Summary of locally implanted devices *'Optional section'*

Given the breadth of GGC and the lack of clear and detailed historical records it was determined that a local review would not be of benefit. That is, a review of the broader context of these devices is simpler to conduct and more generally applicable.

Empirical evidence

Regarding the surgical methods for closure by ligation by clip or by suture. To the best of my knowledge, no such surgical intervention has ever led to a case where a patient has subsequently been injured as a result of an MRI scan. Though Dr Shellock has noted that not all clips have been tested and that therefore some might be MR Unsafe, clips are typically non-ferrous or weekly ferrous. Clips are also likely to be too small to be a concern in regard to heating in the MRI. Moreover, clips will typically become fibrosed, providing a degree of support.

It is the experience of the author that no device of this nature has been reported as leading to patient harm as a result of an MRI scan. Patients with these devices have been scanned in MRI, since the inception of MRI and no adverse event has been noted.

Anecdotal data

No anecdotal data in regard to these devices.

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

It is still relatively early days in regard to imaging patient populations with implants in 7T. Circumstances at 7T can also be more involved due to the use of local transmit/receive coils. Therefore at this stage, no general statement about these devices at 7T is being made.

Consideration of risks, specific to this implant category

It is not anticipated that these devices will be confused other implants.

Discussion

All the evidence that was found indicate cardiac occlusion devices are either MR Safe or MR conditional. There are few queries regarding these devices in the community. The inference of this being, that patients with these devices will typically be getting their MRI scan without any concern. Where queries have arisen. These typically reflect circumstances where MR conditions may have been exceeded, where a risk – benefit approach is advised.

There are no reported cases in the peer review literature highlighting injuries to patient that were a result of MRI scans being performed. Worldwide, it is expected that many patients have these devices and many will of these patients will have had MRI. It is therefore highly unlikely any such device poses a high risk of injury.

As these devices have evolved, the designs and material have become increasingly more subtle and specific. These 'derivative' devices typically have a lineage of device technology and therefore it is also highly unlikely any such derivative device would be designed that was MRI Unsafe.

Even in the event that such a device was developed that was MR Unsafe, the device would need to go through clinical trials and regulatory approval (e.g FDA or CE) before being released to the market. Therefore, it is highly unlikely any such device would catch the MRI community unaware i.e. if a new device was found to be an issue for MRI, this is likely to spread through the MRI safety community very rapidly.

This policy does not cover that of vascular closure devices i.e. occlusion or closure devices outside of the heart.

Conclusion

Based on the evidence above, it seems reasonable to state that the risk to patients with clips, occlusion and closure devices to treat a range of cardiac conditions coming to harm as a result of an MRI scan is very low.

Appendix

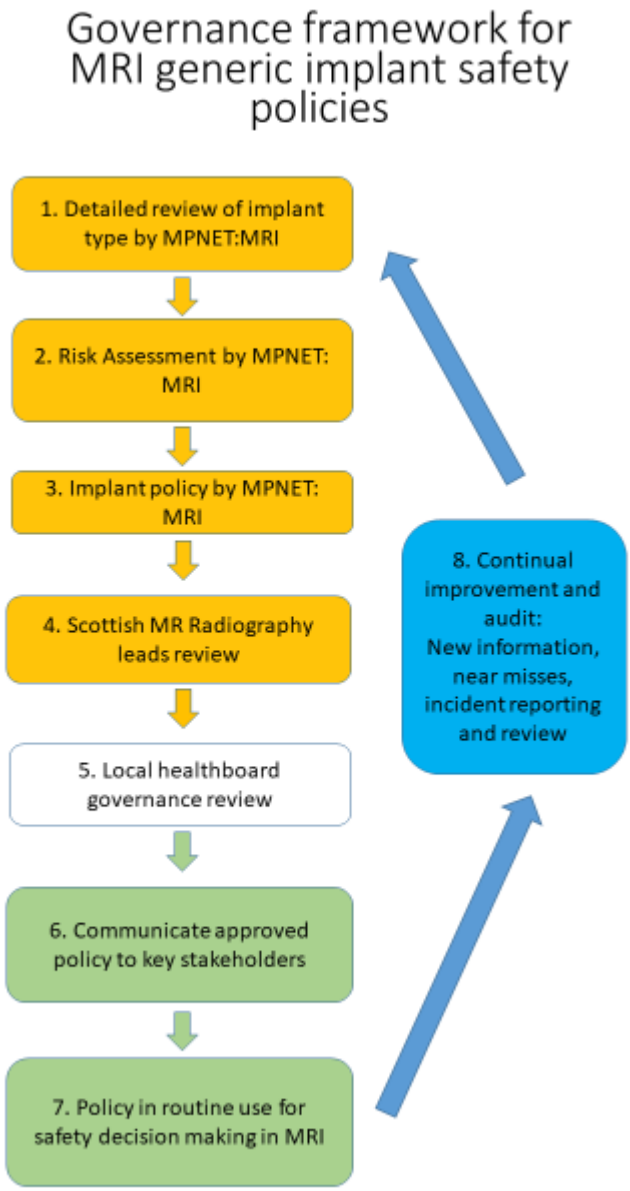
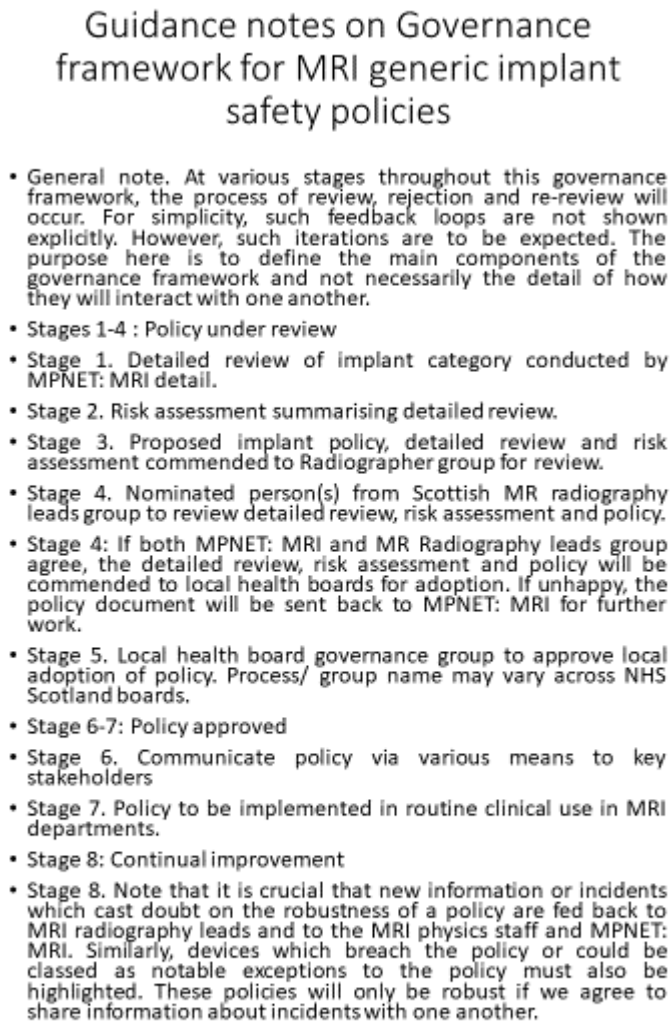


Figure AX: Governance Framework for Generic Implant Safety Policies, creation to deployment



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

References

'Include any relevant references used throughout this detailed review here'

MRIsafety.com Information

http://mrisafety.com/SafetyInformation_view.php?nobtn=1&editid1=191

PDA

https://www.gosh.nhs.uk/conditions-and-treatments/conditions-we-treat/patent-ductus-arteriosus-pda

ASD

https://www.nhs.uk/conditions/congenital-heart-disease/types/

VSD

https://www.nhs.uk/conditions/congenital-heart-disease/types/

PFO

https://www.gosh.nhs.uk/conditions-and-treatments/conditions-we-treat/patent-ductus-arteriosus-pda

Incidence rates from link and ref below.

https://bjcardio.co.uk/2018/06/congenital-heart-disease-an-ageing-problem/

Dolk H, Loane M, Garne E. Congenital heart defects in Europe: prevalence and perinatal mortality, 2000 to 2005. *Circulation* 2011;**123**:841–9. https://doi.org/10.1161/CIRCULATIONAHA.110.958405

Abdelgani et al, Historical developments of atrial septal defect closure devices: what we learn from the past, EXPERT REVIEW OF MEDICAL DEVICES, 2016; VOL. 13, NO. 6, 555–568; http://dx.doi.org/10.1080/17434440.2016.1182860

Farooqi et al, Trends in surgical and catheter interventions for isolated congenital shunt lesions in the UK and Ireland. Heart 2019;0:1–6. doi:10.1136/heartjnl-2018-314428.