Inappropriate anticoagulation of patients with a mechanical heart valve

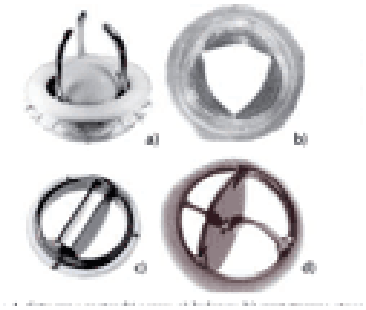
A National Patient Safety Alert – July 2021

Introduction
You may be aware of the recent Patient Safety Alert relating to patients with a mechanical heart valve being inappropriately switched from warfarin to a LMWH or a DOAC (e.g. apixaban).

All patients with prosthetic mechanical heart valves require life-long oral anticoagulation with a vitamin K antagonist (VKA), usually warfarin, as these valves predispose the patient to systemic embolism.

Since 1 March 2020, 14 incidents have been reported of patients with a mechanical heart valve being switched to a LMWH or a DOAC in NHS England. As a result the Patient Safety Alert was issued in England, and was subsequently adopted by Health Improvement Scotland, and implemented in the Scottish Boards. Searches of GP practice systems identified a cohort of patients. This cohort required review as a result of the challenge in searching practice systems, due to variation in coding and also considering the specialist nature of the alert.

The purpose of this communication therefore is to clarify exactly which patients should be included in the safety alert.



An artificial heart valve prosthesis is categorised as either **'mechanical'** or **'tissue'** (bioprosthesis), and this specifically refers to the nature of **what the mobile leaflets are made from,** that is the flapping component of the valve which repetitively open and shut during the heart beating cycle.

What is a prosthetic *mechanical* heart valve?
Prosthetic heart valves have been implanted by cardiac surgeons, most commonly to replace the mitral and aortic valves, since the first valve replacement operation was performed in 1960. *Mechanical* heart valves are made entirely of prosthetic materials including metal alloys, plastics, pyrolytic carbon, ceramics and a dacron sewing ring.

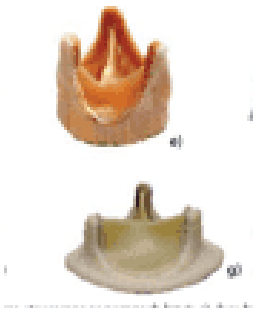
Examples Include: **(these are the valves covered by the alert)**

- St Jude Medical (SJM) Bileaflet: **Masters** and **Regent** models
- Carbomedics
- Medtronic Hall
- Bjork Shilley
- ATS

- On-X
- Sorin Bicarbon
- Starr Edwards

What is *not* a prosthetic *mechanical* heart valve? – <u>Bioprosthetic valves</u>
An issue with the search term used in Lothian is that not all prosthetic valves are mechanical, in fact the majority of surgically implanted heart valves are not mechanical and therefore NOT covered by the alert. *Bioprosthetic* or tissue heart valves are made from porcine valve or bovine pericardial tissue.

In practice, most tissue heart valves that are implanted into patients, come suspended in a rigid supporting frame, which can be made from metal alloy or plastic, and these are known as the *'stented'* tissue valves. Tissue or bioprosthetic heart valves can also come without a rigid stent support, and these are called *'stentless'* tissue valves



The following are all examples of tissue or bioprosthetic valves and these patients may be treated appropriately with a DOAC for standard indications

- Edwards pericardial series: **Perimount, Magna Ease, Inspiris-Resilia,** and **Intuity**
- Medtonic: **Mosaic**, **Hancock II** and the stentless **Freestyle** models
- Liva-Nova **Perceval-S**
- Sorin **Mitroflow**
- St Jude **Epic** and **Trifecta** models
- Vascutek **BioValsalva** Composite Aortic Root Graft (with **Elan** valve)

What is *not* a prosthetic *mechanical* heart valve? – <u>Other Valve Implants</u>
The GP practice search function has identified some other patients who do **not** have a mechanical heart valve and may be treated appropriately with a DOAC for standard indications. Transcatheter aortic valve implantation (**TAVI**) valves are all biological valves, **not** mechanical. Patients who have had a valve repair, usually for mitral or tricuspid valve dysfunction, sometimes called a *plastic* repair do **not** have a mechanical heart valve and may be treated appropriately with a DOAC for standard indications. Finally an aortic homograft is also a type of bioprosthetic valve replacement

Dr David Northridge
Consultant Cardiologist
Royal Infirmary of Edinburgh
August 2021