



Inappropriate anticoagulation of patients with a mechanical heart valve

Date of issue:

14 July 2021

Reference no:

NatPSA/2021/006/NHSPS

This alert is for action by: general practices, NHS-funded services providing anticoagulation review services (eg in community pharmacy, general practices and hospitals), and mental health and learning disability trusts providing general practice care (eg within forensic services).

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in anticoagulation services and cardiology.

Explanation of identified safety issue:

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. Thrombosis of a prosthetic valve is potentially life-threatening as it can result in haemodynamically severe stenosis or regurgitation and acute heart failure. The risk depends on the type of valve, its position, and other factors.¹

Early in the Covid-19 pandemic, published guidance² supported clinical teams to review patients treated with a VKA and, where appropriate, change their medication to an alternative anticoagulant (eg a low molecular weight heparin (LMWH) or a direct oral anticoagulant (DOAC)). This was partly to reduce the frequency of clinic attendance for monitoring, and thus reduce the risk to patients. The guidance listed exceptions where specific patients **should not** be switched from a VKA, including patients with a mechanical heart valve.

Since 1 March 2020, 14 incidents have been reported of patients with a mechanical heart valve being switched to a LMWH or a DOAC; two patients were hospitalised due to valve thrombosis and/or required emergency surgery and one was admitted due to severe anaemia. The reports included cases where patients' anticoagulation was switched from warfarin in primary and in secondary care.

Working with colleagues in NHS England and NHS Improvement, the OpenSAFELY team at The DataLab, and using the EMIS and TPP software systems, we identified around 750 patients who have a code for a mechanical heart valve and are being prescribed a DOAC.³ On 6 July and 8 July respectively TPP and EMIS contacted practices with identified patients, asking them to urgently review these specific patients.

Actions required



Actions to be completed as soon as possible and no later than 28 July 2021

1. General practices:

- Practices using EMIS:** If you have received a 'task' from EMIS identifying specific patients who have a record of a mechanical heart valve and are receiving a DOAC, and you have not already actioned this request, urgently review these patients to ensure they are on the most appropriate anticoagulation therapy and monitoring.¹
- Practices using TPP:** If you have received a 'task' from TPP identifying specific patients who have a record of a mechanical heart valve and are receiving a DOAC, and you have not already actioned this request, urgently review these patients to ensure they are on the most appropriate anticoagulation therapy and monitoring.¹ (see NOTE A)
- Practices using other GP system software:** If your practice does not use EMIS or TPP software, urgently review all patients with a mechanical heart valve to ensure they are on the appropriate anticoagulant therapy and monitoring.¹

2. Providers of anticoagulation services:

- Urgently check patient records from January 2020 to identify any patient with a mechanical heart valve who has been switched from a VKA to an alternative anticoagulant.
- For identified patients you should either:
 - Urgently review these patients if still under the care of the service to ensure they are on the appropriate anticoagulant therapy and monitoring¹ or
 - Work with the patient's GP to ensure the patient receives an urgent review.

For further detail, resources and supporting materials see: <https://www.england.nhs.uk/2021/07/inappropriate-anticoagulation-of-patients-with-a-mechanical-heart-valve>

For any enquiries about this alert contact: patientsafety.enquiries@nhs.net

Additional information:

Notes

A. Practices using TPP software will have been previously contacted in relation to this topic (17 May 2021 and 4 June 2021) when a wider list of codes relating to valve replacement was used.

Patient safety incident data

The NRLS was searched for incidents reported to have occurred on or after 1 March 2020 and uploaded to the NRLS by 1 May 2021 containing reference to a mechanical heart valve and treatment with a DOAC or a LMWH (reference PSI011.2021). All incidents were reviewed; in fourteen incidents anticoagulation for patients with a mechanical heart valve had been switched from treatment with warfarin to treatment with either a LMWH (one patient) or a DOAC (thirteen patients). The reports included cases where patients' anticoagulation was switched in primary care (4 cases) and in secondary care (10 cases).

Of these 14 reports:

- Two reports suggested that the rationale for changing from treatment with warfarin may have been to reduce the frequency of attendance at the anticoagulant clinic during the COVID pandemic, and thus reduce risk to patients from clinic attendance.
- Seven reports did not include an explicit rationale for the change in anticoagulant, but the date of the switch coincides with the review of anticoagulant services undertaken early in the Covid-19 pandemic.
- Five reports were unclear or described other reasons.

References

1. Keeling D, Baglin T, Tait C et al. British Committee for Standards in Haematology. Guidelines on oral anticoagulation with warfarin (4th edition). British Journal of Haematology 2011; 154(3): 311-324 <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2141.2011.08753.x>
2. NICE Clinical guide for the management of anticoagulant services during the coronavirus pandemic. Updated February 2021. <https://www.nice.org.uk/Media/Default/About/COVID-19/Specialty-guides/specialty-guide-anticoagulant-services-and-coronavirus.pdf>
3. OpenSAFELY code list: <https://www.opencodelists.org/codelist/opensafely/mechanical-or-artificial-valves/72fdabd8/>

Stakeholder engagement

- OpenSAFELY team at The DataLab
- EMIS
- TPP
- National Patient Safety Response Advisory Panel (for a list of members and organisations represented on the panel see <https://www.england.nhs.uk/patient-safety/patient-safety-alerts/>)

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to [CHT/2019/001](#) your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.