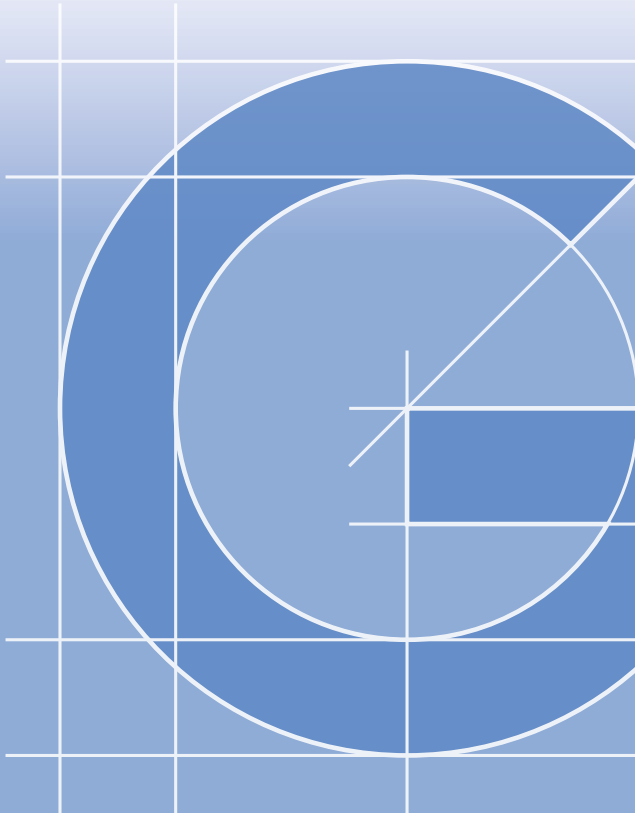
mgp

Guidelines

– summarising clinical guidelines for primary care

SUPPLEMENT



Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor)

• National Institute for Health and Care Excellence •

This Diagnostic Guidance supplement is funded by Roche Diagnostics. See inside back cover for full disclaimer.

Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor)

Guidelines

CoaguChek XS system: NICE DG14

Guidance[1]

1.1 The CoaguChek XS system is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if:

- the person prefers this form of testing **and**
- the person or their carer is both physically and cognitively able to self-monitor effectively.

1.2 The InRatio2 PT/INR monitor is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if:

- the person prefers this form of testing **and**
- the person or their carer is both physically and cognitively able to self-monitor effectively.

Although there is greater uncertainty of clinical benefit for the InRatio2 PT/INR monitor than for the CoaguChek XS system, the evidence indicates that the precision and accuracy of both monitors are comparable to laboratory-based INR testing.

1.3 Patients and carers should be trained in the effective use of the CoaguChek XS system or the INRatio2 PT/INR monitor and clinicians involved in their care should regularly review their ability to self-monitor.

1.4 Equipment for self-monitoring should be regularly checked using reliable quality control procedures, and by testing patients' equipment against a healthcare professional's coagulometer which is checked in line with an external quality assurance scheme. Ensure accurate patient records are kept and shared appropriately.

1.5 For people who may have difficulty with or who are unable to self-monitor, such as children or people with disabilities, their carers should be considered to help with self-monitoring.

Clinical need and practice

- The point-of-care coagulometers are designed to monitor the clotting tendency of blood in people on long-term vitamin K antagonist therapy, such as those with atrial fibrillation or artificial heart valves who are at risk of thrombosis.

- The tests allow monitoring by 2 different methods of care: self-testing and self-managing. Both methods are based on the international normalised ratio (INR), which is a standardised unit for measuring the time it takes for blood to clot.

- Self-testing refers to the user doing the INR test themselves and then contacting their healthcare professional with the reading for advice on any change to the dosage of the anticoagulant that may be needed. Self-managing refers to the user doing the INR test themselves and then self-adjusting the dosage of their anticoagulant medication by following an agreed care protocol. Together, these methods of care are referred to as self-monitoring.

- The use of these coagulometers may reduce the frequency of visits to hospital or clinics for patients and enable them to be monitored more regularly. This may improve health outcomes by enabling the dose of therapy to be adjusted more accurately, thereby avoiding adverse events that can result from an over- or under-dose of long-term vitamin K antagonist therapy, such as stroke and major haemorrhage.

The diagnostic and care pathways

- Guidelines on oral anticoagulation with warfarin, published by the British Committee for Standards

CoaguChek XS system: NICE DG14

in Haematology,[2] outline the process for INR monitoring for those receiving warfarin. The NICE clinical knowledge summary for oral anticoagulation[3] states that INR can be most accurately measured in venous blood samples, but that capillary blood samples are also used because they are more convenient. People being tested should receive a written copy of their INR result including any necessary dose adjustments and a date for the next check.

- The summary states that the INR should be measured:
  - daily, or on alternate days, until it is within the therapeutic range (usually between 2.0 and 3.0, ideally 2.5) on 2 consecutive occasions
  - then twice weekly for 1–2 weeks, followed by weekly measurements until the INR is stable within the therapeutic range
  - thereafter, depending on the stability of the INR, at longer intervals (for example, up to every 12 weeks, if agreed locally)

- More frequent monitoring of the INR is recommended for patients at risk of overcoagulation or bleeding, or those having problems adhering to treatment. Intravenous drug users, and people with hepatitis B, hepatitis C, or HIV, may be referred to a specialist clinic according to local arrangements.

- INR monitoring can be managed by local anticoagulant clinics in primary care, but sometimes clinics are based in secondary care, involving travel to hospital. The NICE anticoagulation commissioning guide (2013)[4] states that anticoagulation therapy services can be delivered in a number of different ways, and that mixed models of provision may be needed across a local health region. This could include full service provision in secondary or primary care, shared provision, domiciliary provision and self-management. Services may be managed by a range of healthcare professionals including nurses, pharmacists and general practitioners.

Implementation tool

NICE has developed the following tool to help organisations put this guidance into practice. The tool is now available to download from the NICE website: **guidance.nice.org.uk/DG14**

Costing statement explaining the resource impact of this guidance

References

1. NICE. *Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor).* NICE Diagnostic Guidance 14. NICE, September 2014. **guidance.nice.org.uk/DG14**
2. Keeling D, Baglin T, Tait C et al. Guidelines on oral anticoagulation with warfarin—fourth edition. *Br J Haematol* 2011; **154** (3): 311–324. **www.bcshguidelines.com/documents/warfarin_4th_ed.pdf**
3. NICE Clinical Knowledge Summaries. *Anticoagulation—oral.* **cks.nice.org.uk/anticoagulation-oral** (accessed August 2014)
4. NICE. *Support for commissioning: anticoagulation therapy.* NICE Commissioning guides. NICE, May 2013. **www.nice.org.uk/guidance/cmg49**

The production and printing of this Diagnostic Guidance supplement has been funded by Roche Diagnostics.
Roche Diagnostics has reviewed this supplement for technical accuracy and regulatory compliance.

This supplement only displays the concise recommendations; readers are strongly advised to refer to the full diagnostic guidance at guidance.nice.org.uk/DG14

Date of preparation: September 2014

NICE recommended

Roche

It takes Liz an afternoon's unpaid leave, 2 buses and 84 steps each month to find out she's still in her INR range

INR self-monitoring with CoaguChek® takes seconds, not hours. Recommended by NICE for patients on long-term vitamin K antagonist therapy who prefer self-monitoring,[1] this simple device can help reduce the risk of thromboembolic events and mortality while easing pressure on NHS resources.[2–4]

For more information, please visit **www.coaguchek.co.uk**

CoaguChek®
Because it's my life

References: 1. NICE guidelines on CoaguChek, 2014. **2.** Heneghan C *et al. Lancet* 2012; 379(9813): 322–334. **3.** Garcia-Alamino JM *et al. Cochrane Database of Syst Rev* 2010; 4: CD003839. **4.** NHS Patient Experience Framework. Available at: www.institute.nhs.uk/patient_experience/guide/the_policy_framework.html. Last accessed 01.09.14.