NICE advice

# microINR for anticoagulation therapy

Medtech innovation briefing
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This advice should be read in conjunction with HTG353.

## Summary

- The **technology** described in this briefing is the microINR. It is used for measuring international normalised ratio (INR) levels for people having anticoagulation therapy.
- The **innovative aspects** are that the device offers portable self-monitoring for coagulation with reduced blood sample needs and increased connectivity capabilities.
- The intended **place in therapy** would be as an alternative to hospital-based testing and alongside alternative point-of-care tests in people who need INR monitoring.
- NICE's HealthTech guidance on atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers looks at using other INR monitoring devices for anticoagulation therapy.
- The **main points from the evidence** summarised in this briefing are from 5 observational comparative studies including a total of 906 adults across primary and

secondary care settings. They show that microINR can be as effective as laboratory-based and alternative point-of-care meters in INR monitoring.

- **Key uncertainties** around the evidence are that 1 study did not meet the accuracy criteria and 1 study did not meet the imprecision criteria. No studies were done in the UK.
- The **cost** of microINR meters range from £299 to £470 per unit (excluding VAT) and microINR chips (disposable test strips) cost between £2.76 and £2.99 per strip; variations seen reflect different distributors. Standard care is alternative point-of-care tests which range from £299 to £590 (excluding VAT) with comparable consumable costs of £2.71 to £3.10 (excluding VAT) per test strip.

# The technology

The microINR system (iLine Microsystems) is a hand-held point-of-care coagulometer. It is designed to measure international normalised ratio (INR) to show the clotting tendency of blood for people having oral anticoagulation therapy with vitamin K antagonist drugs.

The system includes a meter, microINR chips (disposable test strips), case, charger and plug adaptor. There are currently 2 meters available; the microINR meter and the microINR Link meter. The microINR chips can be used for both systems. The only difference is in their connectivity. The microINR Link offers the advantage of communicating through wireless Bluetooth technology to a software or smartphone application for data management. The disposable microINR chip is inserted into the meter and a finger prick sample of blood is applied to the chip. The chip dispenses a small amount of recombinant tissue factor reagent. As blood moves through the chip's capillary channels, it clots, and the blood flow slows. The INR is then determined by algorithms and an integrated machine vision system. The system is designed and approved for use by healthcare professionals as well as for self-monitoring by the user or carer.

## Innovations

The microINR claims to offer a faster and more portable solution to monitoring and managing coagulation than laboratory-based INR measurements. Alternative point-of-care coagulometers are available, but the microINR reports to be able to analyse INR from smaller samples of blood (minimum of 3 microlitres) than comparator devices (minimum of 8 microlitres). Also, microINR has Bluetooth capability. The device also offers automatic

and individual calibration of each test to potentially minimise any risk of human error in testing.

# Current care pathway

There are several conditions that may need treating with anticoagulation therapy, including atrial fibrillation and heart valve disease (congenital or acquired heart valve conditions), as well as those with venous thromboembolism.

Alternatives to standard anticoagulation therapy include non-vitamin K direct oral anticoagulants (apixaban, rivaroxaban, dabigatran etexilate), which have the benefit of not needing regular INR monitoring. However, this may be unsuitable for some people, such as those with mechanical heart valves, certain people with renal or liver dysfunction and may need consideration of other concurrent drugs that cannot be taken with non-vitamin K antagonist oral anticoagulants.

Those individuals who need vitamin K oral anticoagulants (warfarin) must have their INR measured regularly. Warfarin, especially if taken incorrectly, can cause severe bleeding (haemorrhages), therefore it is necessary to monitor blood coagulability. The frequency of monitoring may vary between daily and once every 12 weeks, depending on the stability of the INR.

In some cases, this monitoring is recommended to take place with venous plasma samples using the laboratory-based method. This includes conditions that can affect the activity of vitamin K antagonist oral anticoagulants such as primary and secondary antiphospholipid syndrome, high heparin concentrations and haematocrit out of the 25% to 55% range.

For those people with stable INR values within a standard range, their INR testing can take place by either laboratory-based plasma testing or using point-of-care test devices.

The following publications have been identified as relevant to this care pathway:

- NICE's key therapeutic topic on anticoagulants, including direct-acting oral anticoagulants (DOACs)
- NICE's quality standard on atrial fibrillation
- NICE's guideline on atrial fibrillation: management (this is currently being reviewed,

see the guideline in development)

- NICE's HealthTech guidance on atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system)
- NICE's specialty guide on the management of anticoagulant services during the coronavirus pandemic
- British Committee for Standards in Haematology guideline on patient self-testing and self-management of oral anticoagulation with vitamin K antagonists
- NICE's guideline on venous thromboembolic diseases: diagnosis, management and thrombophilia testing.

# Population, setting and intended user

The microINR system is suitable for individuals that need INR monitoring for their vitamin K anticoagulation therapy. Anticoagulation therapy services can be delivered in several different ways and 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, or by the individual with self-testing or self-management (collectively described as self-monitoring). Both primary and secondary settings may use either point-of-care tests or laboratory analysers in a central hospital laboratory shared provision setting. This variation means that anticoagulation monitoring may be delivered by a range of healthcare professionals including nurses, pharmacists, general practitioners, and individual users and or carers.

# Costs

## Technology costs

- The microINR and microINR Link meters cost between £299 and £470 (excluding VAT), varying across distributors. It has an expected lifespan of 5 years.
- Additional consumable costs include:
  - microINR chips (disposable test strips) cost between £2.76 and £2.99 per strip, varying across distributors. One strip is needed per test and they can be

purchased in boxes of 25 for £60.41 (excluding VAT).

- iLine EasyControl kit is for quality control purposes of the device, for use by health professionals only. This costs £69.94 (excluding VAT) and includes 5 × 2 ml bottles of control plasma, 5 bottles of calcium solution and 5 pasteur pipettes.

### Costs of standard care

Alternative point-of-care coagulometer devices cost between £299 and £590 (excluding VAT). Additional consumable costs include test strips ranging from £2.71 to £3.10 (excluding VAT) per strip. Monitoring control reagents for quality control purposes vary in their volume and costs. One comparator example was £24.20 (excluding VAT) for 4 bottles of 1.5 ml control solution, 4 pipettes and 1 code chip.

The cost effectiveness of comparator point-of-care tests compared with standard care were presented on page 101 of the NICE 2014 costing statement on the clinical and cost effectiveness of point-of-care tests. This stated the annual cost of self-monitoring with a point-of-care test to be £229.90 based on 35 tests per year and reduced to £127.81 per year if used in a self-management capacity. Because the costs of treating adverse events are considerably higher than those of self-monitoring, it was reported that avoiding a small number of high-cost adverse events has the potential to make the initial investment cost saving.

## Resource consequences

The company states that the technology is currently used in 2 NHS trusts. The NICE 2014 costing statement reviewing this type of device estimated 450,000 people may be eligible for self-monitoring. Although an initial investment in the purchase cost over standard care is needed, evidence in similar devices suggests that this results in improved adherence to management, improved health outcomes and minimised costly hospital interventions to treat adverse incidents. There is the additional benefit of the reduction in face-to-face appointments for monitoring therefore releasing primary and secondary care resources for reallocation.

Training provided by the company to healthcare professionals is included in the cost of the device. Individuals who go on to self-test or self-manage at home will need training and ongoing support with relevant healthcare professionals which will have resource consequences. Further training materials such as videos and easy guides are provided by

the company. Users with cognitive, visual, or physical impairments may need a care partner to be co-trained to assist. The company report that the device is designed to be easy to use and any learning curve for a new user (professional or lay) would be brief.

# Regulatory information

The microINR and microINR Link are both individually CE-marked in vitro diagnostic (IVD) medical devices for professional use (general IVD device) and for self-testing.

# Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination, and fostering good relations between people with particular protected characteristics and others.

Older people, people from south Asian groups and people who are male are all disproportionately affected by heart disease. Age, race and sex are all protected characteristics under the Equality Act 2010.

Access to the device may be of particular benefit to groups having long-term vitamin K antagonist therapy, such as adults in work or education, adults with disabilities or older people, who may find travel to clinics for international normalised ratio (INR) testing difficult or demanding. Users must be physically and cognitively able to self-test accurately.

# Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology.

Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

# Published evidence

There are 5 studies summarised in this briefing, including a total of 906 individuals, selected as the most relevant and best quality evidence relating to the technology. There are several further studies reported in conference abstracts in Italy which cover similar evidence and are not included here. All studies discussed were observational and prospective. All studies refer to the microINR meter, without 'link' capability.

The clinical evidence and its strengths and limitations are summarised in the overall assessment of the evidence.

# Overall assessment of the evidence

The evidence of the technology is of moderate methodological quality. All studies had comparators. Three used multi-site recruitment and 4 showed good size populations. No studies were done in the UK. Only 1 study reported on user friendliness of the device. Four studies were done by healthcare professionals, 1 study assessed self-management. The studies show some discrepancy in the accuracy and imprecision of the microINR meter in 2 studies. Larger studies with direct comparisons to point-of-care tests, showing self-testing and with representation of patient experience with long-term outcomes, would be beneficial.

## Refaai et al. (2020)

### Study size, design and location

Prospective study of 313 adults (including 68 controls), across 3 medical sites in the USA (Michigan, California, New York).

### Intervention and comparators

microINR point-of-care system, ACL laboratory analyser and CoaguChek XS point-of-care system.

### Key outcomes

The microINR results show adequate imprecision and accuracy to both ACL analyser and

CoaguChek XS. Agreement for the combined international normalised ratio (INR) ranges was 96% against ACL (for the combined INR ranges of less than 2.0, 2.0 to 4.5, and at least 4.5 within the limits of ±0.4, ±20% and ±25%, respectively) and more than 96% against the CoaguChek XS for the same ranges. The microINR system's imprecision (repeatability) showed coefficient of variation of 5.03% for INR less than 2.0 and 4.68% for the therapeutic INR range 2.0 to 3.5.

### Strengths and limitations

This study was the first multi-site study with this version of device and supports the adequate imprecision and accuracy for use in warfarin monitoring. The study was funded by the company (iLine Microsystems).

## Joubert et al. (2018)

### Study size, design and location

Observational prospective study of 210 consecutive adult patients attending the International Normalised Ratio (INR) clinic in Bloemfontein, South Africa.

### Intervention and comparator

microINR and Sysmex CS2100i analyser.

### Key outcomes

Comparison of microINR values to venous laboratory values measured on the Sysmex CS2100i analyser showed high levels of dosage concordance (93.8%) and expanded clinical agreement (95.7%) were found. Assessment of precision showed no significant differences between instruments and test chips (variation in sample means, F=0.07, p=0.9299 and F=0.22, p=0.8067 respectively). In a total of 390 tests, 11 (2.8%) instrument or test chip errors were seen, and 26 (6.7%) operator or patient errors were seen. No test failures were recorded.

### Strengths and limitations

This study supports the accuracy and precision of microINR for use by healthcare

professionals in monitoring warfarin. The study limitations highlighted the low number of instruments and test chip lots used to evaluate test chip variability, the low number of patients in a supratherapeutic range as well as the low number of patients with possible interfering factors. This study was funded by the company's scientific group.

## Larsen et al. (2017)

### Study size, design and location

Prospective study across 1 outpatient clinic and 2 primary healthcare centres in Norway (n=186).

### Intervention and comparator

microINR (point-of-care) and the STA-R Evolution (laboratory).

### Key outcomes

microINR imprecision, as measured against laboratory tests, was 6% in the outpatient clinic and 6.3% in the primary healthcare centres, which did not meet the quality goal needed for imprecision (less than or equal to 5.0%) defined by Scandinavian evaluation of laboratory equipment for primary healthcare (SKUP).

microINR accuracy fulfilled the SKUP quality goal in both outpatient clinic and primary healthcare centres. User friendliness of the operating manual was rated as intermediate, operation facilities were rated as unsatisfactory and time factors satisfactory.

### Strengths and limitations

No conflicts of interest declared.

## van den Besselaar et al. (2015)

### Study size, design and location

Prospective study with 60 patients in the Netherlands.

### Intervention and comparators

microINR, the ProTime InRhythm system, the CoaguChek XS system and the InRatio2 system compared with international standard for thromboplastin rTF/09.

### Key outcomes

INR differences were significantly different for all point-of-care systems compared with international standards, except for the CoaguChek XS. The microINR showed a bias of -10.9% and -16.2% (for INR values less than 2.5 and at least 2.5, respectively). The imprecision coefficient of variation in venous blood was 5.0% for the microINR and considered acceptable.

### Strengths and limitations

The number of capillary blood determinations were done with samples from a single individual which is a limitation of the study and may explain the different coefficient of variation values between capillary and venous blood. iLine Microsystems highlighted to the author that the calibration parameters of the microINR test chips had been amended for the Dutch market before the study, so this did not reflect the parameters on the chips in the market and therefore the data results may misrepresent the publicly available device. This study was funded by Roche Diagnostics, a manufacturer of a competitor device (the CoaguChek).

## Food and Drug Administration Home Use Approval study 2020

### Study size, design and location

Prospective non-randomised multicentre user study of 117 individuals across 4 sites.

### Intervention and comparators

The microINR meter compared with individual self-user, healthcare professional as well as laboratory-based INR analysis.

### Key outcomes

Usability of the device was assessed by individuals at a mean score of 4.69 (where 1 is

least favourable and 5 favourable usability). The accuracy of the measurements were assessed against both healthcare professional measurements and the reference laboratory method. Results obtained indicate that the microINR system patient self-testers are able to get results as accurate as those obtained by healthcare professionals using the microINR system.

### Strengths and limitations

This data set is available as part of the Food and Drug Administration decision and therefore limited detail is available. It is the first study showing the device use for self-management by users. The study is expected to be published in full.

## Sustainability

The company submitted no sustainability claims.

## Recent and ongoing studies

No ongoing or in-development trials were identified.

# Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 experts were familiar with the type of technology, but none had used this device before.

## Level of innovation

All 3 experts agreed that the use of point-of-care tests is established practice and this device offers a minor variation on current point-of-care tests available. Two experts highlighted the variation is a minor improvement in offering Bluetooth and wireless connectivity as well as smaller blood volume needs.

# Potential patient impact

All 3 experts highlighted the patient impacts are the same as those from any point-of-care tests in supporting patients in self-monitoring in their own home, not having to attend appointments and having more control over their life. One expert highlighted that the specific innovation of smaller blood samples may make collection and results more reliable. Two experts discussed those on warfarin to benefit from this technology and 1 expert highlighted that those who are needle phobic or have poor venous access may particularly benefit.

# Potential system impact

All experts felt it would contribute similarly to current point-of-care tests that are available. One expert highlighted the known benefits for those using point-of-care tests improving the time in therapeutic range than when managed with traditional international normalised ratio (INR) testing. One expert raised that the addition of this device in the market may encourage other hospital-based warfarin clinics to move to this less-invasive approach. This is potentially relevant because another expert highlighted that standard care is disparate across NHS organisations with some adopting point-of-care tests more readily than others.

All experts raised the cost increase of replacing secondary care laboratory-based testing. However, 1 expert highlighted the benefit of increasing the number of people seen and maximising clinic time by using a point-of-care test, removing the delay waiting for laboratory test results. Two experts felt the stated price points appeared to be comparable cost implications in the primary care setting with alternative point-of-care tests.

Introduction of this device was not reported to need any facility changes, but 2 experts discussed the resource implications in training healthcare professionals. One expert highlighted the variation in training time needed for individual users to be competent. Two experts discussed the resource need for ongoing support and calibration checks once this type of technology is adopted.

# General comments

Two experts reported that the number of people this device would be suitable for is reducing because of the introduction of direct oral anticoagulants which do not need INR

monitoring. Experts suggested that warfarin monitoring using point-of-care tests would be suitable for between 5% and 10% of people having anticoagulation.

One expert raised the issue that individuals can purchase the devices directly, which can cause difficulties if the healthcare professionals are not consulted and are unfamiliar with the device. One user of a competitor point-of-care test reports to have used this satisfactorily, however raised the disadvantage that having had no competitor in the market has potentially limited competition-driven pricing. This expert highlighted that often patients buy their devices themselves, so cost stops many from using the device.

One expert highlighted the limited evidence for patients with antiphospholipid antibodies using point-of-care tests. Further research to show reliable responses for these people would be useful. One expert called upon trials comparing this device with alternative point-of-care tests as well as 2 or 3 national laboratory-based analysers to confirm compliance based upon local verification.

# Patient organisation comments

Key benefits for patients identified by patient organisations included the practical impact on people in reducing time needed visiting clinics, minimised trauma using capillary testing and the speed and accuracy of results to inform their individual management. Two organisations also highlighted the known benefits of self-management in empowering people to take responsibility for their health. This can improve adherence to medicine regimes, offer an increased likelihood of staying within the therapeutic range, improve quality of life and better manage the condition to reduce the risk of atrial fibrillation-related stroke.

Patient organisations noted that those who could particularly benefit from the technology were those who needed frequent monitoring as well as those who have difficulty attending clinics, either because of reliance on family or hospital transport to travel or because of educational or work commitments. Also, 1 organisation suggested a benefit to those who are needle phobic and are attending for venous samples. Another organisation highlighted care home residents (being at particular risk of bleeding and clotting) would benefit from the timely and less-invasive capillary testing using point-of-care machines.

All 3 organisations highlighted that individuals considered for self-testing would need to be physically and cognitively capable of performing and following instructions for the procedure and action of the test independently, or a family member or carer trained to

assist with testing regime.

Two organisations highlighted that because guidance now recommends that where appropriate direct oral anticoagulants should be offered (rather than warfarin), this may result in less people needing regular monitoring and be a potential obstacle in the adoption of the device. Two organisations highlighted that despite guidance supporting the use of point-of-care international normalised ratio (INR) monitors and the broader goal across the NHS to encourage self-management, provision of self-monitoring options continues to be varied, based on local clinical commissioning group decision making. One organisation stated that devices are often being self-funded by users, making affordability an important barrier alongside support for training, calibration and access to test strips affecting implementation. One organisation highlighted the challenge of only 1 device currently being supported in guidance and the importance of increasing availability and choice of devices to maximise reach to this population.

# Expert commentators

The following clinicians contributed to this briefing:

- Ms Sue Rhodes, venous thromboembolism clinical nurse specialist and joint anticoagulant lead, Great Western Hospital, Swindon. Did not declare any interests.
- Dr Matthew Fay, GP principal, The Willows Medical Practice. Honorary clinical lecturer, Warwick Medical School trustee. Trustee of Thrombosis UK and Atrial Fibrillation Association. Did not declare any interests.
- Mr Peter Baker, clinical scientist, Oxford University Hospitals NHS Foundation Trust. Did not declare any interests.

Representatives from the following patient organisations contributed to this briefing:

- Atrial Fibrillation Association
- Thrombosis UK
- Anticoagulation UK

# Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

# Update information

**Minor updates since publication**

**December 2025:** Links have been updated throughout to NICE's HealthTech guidance 353, which replaces NICE's diagnostics guidance on atrial fibrillation and heart valve disease.

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