



# Self-testing – everyone benefits

The case for providing state support in Ireland  
to encourage **self-testing** for patients  
with heart disease and other blood clotting disorders  
who are on anticoagulation therapy such as warfarin.

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## EXECUTIVE SUMMARY

This report demonstrates the benefit for both patients and the health service in providing state support to encourage self-testing for patients with heart disease and other blood clotting disorders who are on anticoagulation therapy such as warfarin.

Clearly if patients can self-test the pressure and costs on hospital facilities are reduced. A cost benefit analysis is provided here to demonstrate the actual and potential cost savings. The figures show that self-testing is less costly than a conventional test in a hospital laboratory by €66,000 per 1,000 patients.

The benefit to patients is equally dramatic in terms of empowerment and quality of life. The process is much more convenient for patients. It can be done in their own time. There is no need to take time from work, or from school in the case of children. Self-testing provides many patients with the freedom to take a holiday or travel. For many patients on anticoagulation therapy it is impossible to be away from their home for any length of time because their lives are conditioned by hospital timetables.

Self-testing is carried out in partnership and with the agreement of healthcare professionals. This report recommends procedures for identifying people suitable for self-testing and provides an example of the protocol which should be agreed between patient and doctor.

This report also highlights the portability, efficacy and quality assurance of the equipment required for self-testing. It explains the verification process, which the equipment currently available has undergone.

Details of how self-testing is encouraged in other countries such as the UK and Germany are also provided.

Finally a detailed proposal for including OAT strips on the GMS and for supporting health boards in the supply of the CoaguChek S monitor is provided. Such support will not only prove cost-effective for the national health service but it will be an invaluable support for thousands of Irish people whose lives are of necessity dictated by the routine of regular hospital visits.

## PATIENT SELF-TESTING

Patient self-testing is not a new concept and has been established in diabetes for many years. Patient self-testing in anticoagulation therapy is also well established in other European countries. In Germany there are over 70,000 patients who self-test and have done so for over ten years, indeed, many are now self managing their own anticoagulation therapy. The reagent testing strips for the CoaguChek S have been available on prescription in England and Wales since May 2002, in Northern Ireland since July 2002 and in Scotland since December 2002. It is now supported in Germany, the Netherlands, Denmark, England, Wales, Scotland and Northern Ireland. Trials have also begun in Italy and Spain.

There have been several trials that have shown benefits from self-testing compared to conventional management. The importance of good quality anticoagulation control cannot be over emphasised, as it has been shown that poor control, with a high percentage of INR's outside the therapeutic range is a major independent risk factor for reduced long-term survival, particularly after valve replacement. <sup>(1)</sup>

## BENEFITS FOR PATIENTS

There are numerous benefits for patients which we have outlined below:

1. Patient self-testing considerably improves the patient's quality of life. Allowing them to take a part in their own health care and work with the doctors to ensure that they remain within their therapeutic range. Patients who self-test also want more information about how to help themselves to live a healthy lifestyle. This can also have benefits for those with co-morbidities.
2. It allows the patient to be independent. Not to have to spend so much time at the doctors or the hospital. Not to have to take regular time off work or school in order to attend clinic. For patients in outlying or rural areas it also reduces the amount of time spent travelling to and from clinics and the cost of transportation. Patients have the freedom to travel as part of their employment or on holidays, without having to research the availability of clinics in other countries.
3. Patient self-testing provides the possibility of more frequent checks and adjustment to dosage if necessary, thus improving the amount of time spent with the patient's therapeutic range. <sup>(2)</sup>

### **Below are some examples of what patients have said about being able to self-test... in their own words**

*"A common impression is that most people taking anticoagulation therapy are elderly and retired and have time on their hands. I am twenty-seven, work and lead an active life. I cannot do this if I have to travel to the doctor's surgery, which takes several hours on each occasion. I would like to educate those in charge of the health budget in Ireland about the better health and the freedom that self-testing gives to someone like myself." (Galway)*

*"I have a six month old baby on warfarin. Being able to use the self-testing equipment at home saves me a 70-mile round trip every week and makes my baby's life happier by not having needles stuck in her arm." (Cork)*

*"Self-testing has made such a difference to my life. I no longer have to travel miles and also the small bleeds that I suffered from have stopped as I am able to better control my INR range." (Kildare)*

*"Before self-testing I felt as though I was spending all my time at hospital. Now the whole process takes as long as it does to make a cup of tea, it has given me a new lease of life." (Scotland)*

*"I found the management of my INR levels the most difficult, restrictive and potentially alarming aspect of my post operative life. I was therefore delighted to learn about patient self-testing." (Wales)*

*"Self-testing has given me my life back. I now feel that I am controlling my warfarin rather than it controlling me." (England)*

## COST BENEFITS TO THE HEALTH SYSTEM

Irish hospitals are under pressure on many fronts. Anticoagulation clinics within hospitals are as crowded daily as A&E departments. Tallaght Hospital has recently had to move its anticoagulation clinic to another part of the hospital to facilitate the increased number of patients using it. St James's Hospital currently has approximately 1,500 patients registered to its anticoagulation department.

The numbers on anticoagulation therapy internationally are growing at a rate 10% - 20% per annum. Some hospitals in the United Kingdom however, have seen an annual increase of 48%. This has been largely due to the numbers of patients with atrial fibrillation now being treated with anticoagulation therapy.

Self-testing has been found to cut indirect costs by 60%.<sup>(3)</sup> On the basis of known thromboembolic and haemorrhagic complication rates and treatment of complications, and taking into account the cost of the coagulation monitoring device, in clinical practice there is an annual saving of approximately €350 per patient with PST.

## COST REDUCTION IN OAT COMPLICATIONS ASSOCIATED WITH PST

### Assumptions

- Based on a Cohort of 1,000 patients

#### *Usual Care Patient*

- Tested 12 times a year at €4.75 per test – €177
- Usual care complication rate is 6.31%

#### *PST Patient*

- Uses 48 test strips per year €158.35
- PST complication rate is 3.38%

- 3% of total complications are fatal at a cost of €29 each
- 13% of total complications are major (Stroke) at a cost of €3,859 each, plus a rehabilitation cost of €4,842
- 84% of total complications are minor at a cost of €527 each

**Savings: €66,000 per 1,000 patients**

## NUMBERS INVOLVED

Based on the UK population numbers where there are 750,000 people on anticoagulation therapy. We estimate approximately 45,000 Irish people are on similar therapy.

## SUITABLE PATIENTS AND PROTOCOLS

Self-testing is not suitable for every patient and ideally the suitability or otherwise should be agreed between the patient and his/her healthcare professional. Carers and members of the family may be involved.

It is also essential that a clear protocol is drawn up which determines a range of issues regarding the testing period, range and tolerance, methodology, reporting procedures and action.

Appendix 11 shows a sample protocol for patient self-testing.

## COAGUCHEK S VERIFICATION

The most widely used device for self-testing is the CoaguChek S which has been evaluated by the Medicines and Healthcare Regulatory Agency in the UK. This device is hand-held, easy to use and accurate. It measures INR within two minutes.

A recent study at the University of London Hospital has found that there is strong evidence for the validity of home testing. Professor S. Machin, Professor of Haematology at the hospital said, "We have shown that the accuracy of the device is equal to that of the gold standard hospital testing."<sup>(4)</sup>

## TESTING & QUALITY ASSURANCE PROCEDURES

Self-testing is a remarkably simple procedure. Patients place a reagent testing strip into the device and then place a drop of blood onto the strip. Within two minutes the INR result is displayed on the screen. The CoaguChek S device has a memory for storing past results for comparison.

The CoaguChek S system has a number of in-built features that ensure the results are reliable:

- 1) Each batch of strips is compared to a reference material to standardise results and minimise the variability between batches
- 2) Whenever the meter is switched on, it carries out a series of self-checks to make sure it is working properly
- 3) The machine stops working if insufficient blood is applied to the test strip

Patients can test the unit by applying a liquid control solution to a test strip in the same way that they would apply a blood sample. If the system is working correctly the meter will give an INR value within the accepted range for that quality control batch.

Quality control tests should be done:

- When first setting up the device
- When starting a new box of strips
- If the INR result is over 5.0 or under 1.5
- If the test strip have been stored incorrectly
- If the machine has been dropped
- Every three months
- Patients may also need to perform a quality control test at times specified in the protocols agreed between them and their health care professional.

## ACCESS TO EQUIPMENT IN REPUBLIC OF IRELAND

CoaguChek S has been systematically reducing in price as more and more patients begin to self-test. Currently it costs approximately €500. Ideally it should be available on the GMS but as the numbers currently self-testing are relatively small at present, various methods of supply are being studied. We understand that some Health Boards are investigating the opportunities for supplying devices free-of-charge to patients. The Heart Children Ireland has donated 10 CoaguChek S to Our Lady's Hospital in Crumlin for use in the hospital. While this experiment does not constitute self-testing it does reduce the need for using laboratory services. This obviates the need for a child to be brought to the hospital simply for test results and has a significant cost saving for the hospital.

## ACCESS TO OAT STRIPS IN REPUBLIC OF IRELAND

OAT strips cost in the region of €3.75 at present. To help promote the concept of self-testing which empowers patients we would urge the Department of Health and Children to make the OAT strips available on the GMS.

## CONCLUSION

The benefits of self-testing for both the patient and the health service are clear. The medical profession in many countries are now encouraging self-testing for suitable patients. Dr. Martin Daly, Vice-Chairman of the IMO GP Committee has said that it is a good idea. He has said that he had no problem with self-testing as it would allow for more frequent testing and would lead to better anticoagulation control. It has been shown in other areas, such as diabetes, where patients had taken responsibility for monitoring that better control was achieved.

*(Irish Medical Times 9/06/03)*

## References

- 1) *Self managed anticoagulation: Results from a two year prospective randomised trial with heart valve patients.* Pushpinder Sidhu FRCSI and Hugh O'Kane FRCS *Annals of Thoracic Surgery* vol. 2 No. 5 Nov 2001.
- 2) *A Bernado: Optimising long-term anticoagulation by patient self management and management by specialist anticoagulation clinic. A randomised cross over comparison.* *Lancet* 2000;356:97-102.
- 3) *Anticoagulant monitoring service delivery. A comparison of hospital and community clinics.* A Davies, MJ Buxton, DLH Patterson, J Webster-King. *Clinical and Laboratory Haematology* Feb 2000.
- 4) *Preliminary data from the MDA study of the CoaguChek S in a patients self-testing environment.* K Williams, C Gardiner, I J Mackie, S J Machin, H Cohen, Dept of Haematology, UCLH.

## **APPENDIX I**

### **AntiCoagulation Europe (ACE)**

AntiCoagulation Europe (ACE) is a patient group that was established in response to the growing number of people on oral anticoagulation therapy (OAT). ACE specialises in providing information and support specifically to this group of patients.

- ACE provides patients, their carers and clinicians with information and support on OAT and its effects.
- OAT is prescribed for patients who have conditions that put them at high risk of developing blood clots. For example, it is required for people with a mechanical heart valve, or who suffer from atrial fibrillation, thrombophilia, deep vein thrombosis, stroke and other clotting disorders.
- ACE works with other organisations to broaden understanding of the specific issues facing patients receiving the treatment.
- It also plans to contribute to the development and implementation of UK Government policies such as the Expert Patient Programme and other European Government initiatives to encourage patients to take an active role in their own care.

## APPENDIX II

### Phase I Training Programme – Patient Protocol Patient Self-testing using the CoaguChek S system

#### What is involved in the self-testing trial period?

Once your training has been undertaken you will be required to perform weekly capillary blood tests for INR and quality controls for the first 4 tests. You will then be requested to attend the clinic.

After this period the frequency of testing will be performed according to the stability of your INR.

You should report any concerns you have during the home trial to the trainer as promptly as possible.

#### How often should a capillary whole blood sample be taken for an INR test?

The minimum period for capillary whole blood testing using the CoaguChek S system should be daily and the maximum interval should not exceed 10 weeks.

The re-test period should be reduced in the case of new medication being commenced or before/after any medical or surgical procedures (including dental treatment). Contact the Anticoagulation Team for advice.

If you experience any excessive bruising or bleeding you should contact the Anticoagulation Team (please refer to the leaflet “Anticoagulants” for further information).

#### When should a Quality Control (QC) be undertaken?

During the self-testing trial period you will be required to carry out a quality control test with the first 4 tests. After this period we would advise that a quality control test is undertaken with every 10th INR blood test and/or with every new batch of test strips.

Quality control test results should be recorded in the quality control section of your self-testing record. If the quality control is within range, capillary whole blood testing may be performed. If the quality control is out of range you should contact the Anticoagulation Team urgently for advice. The unit **must** not be used for further capillary whole blood testing until advice has been obtained from the Anticoagulation Team.

An additional quality control should be performed if the INR result obtained is less than 1.5 or greater than 5.0. If the quality control is out of range you should contact the Anticoagulation Team urgently for advice. The unit **must** not be used for further capillary whole blood testing until advice has been obtained from the Anticoagulation Team.

### **What action should be taken if the INR result is outside my therapeutic range?**

You should record all INR and quality control results in your self-testing record. If the INR is outside your therapeutic range you should contact the Anticoagulation Team for your new anticoagulant dose instructions. We will require that you have details of your INR and quality control results to hand.

If the INR result is less than 1.5 or greater than 5.0 the INR test should be repeated. A quality control test should also be performed.

### **What action should be taken if the INR results is greater than 8.0?**

If the INR result is greater than 8.0 you **must** contact the Anticoagulation Team immediately. You will be required to attend the hospital or your local general practice for a venous blood test.

If the INR result is confirmed as greater than 8.0 you will be required to have a dose of vitamin K. This medication is used to reverse the effect of the oral anticoagulant. It will help to lower your INR.

The supply and delivery of this medication will be undertaken by the Anticoagulation Team (nurse or doctor).

The Vitamin K medication should be taken (as directed) the same day and the dose of oral anticoagulant omitted. A repeat venous blood test should be taken at the hospital or your local general practice the following day.

### **What action should be taken if I experience any bruising or bleeding?**

All incidents of excessive bruising or blood loss **must** be reported to your general practice or the Anticoagulation Team. We would advise that you carry out a capillary whole blood INR test and have this information to hand when you call.

Any excessive bruising or bleeding events should be recorded in your self-testing record.

### **How do I report problems with the CoaguChek S unit?**

Faults should be reported to the Roche help line and the Anticoagulation Team. If the problem cannot be resolved over the telephone a replacement unit will be delivered to you and the faulty unit collected.

### **How often do I need to be reviewed by the Anticoagulation Team?**

You will be required to attend the anticoagulant clinic once every 6 months in order for us to take a comparative venous blood sample and check your meter.

## Patient / Trainer Agreement

I have read and understand the self-testing protocol outlined above and agree to abide by the terms outlined above. I understand that if I do not adhere to these terms the Anticoagulation Service may be required to withdraw their self-testing support.

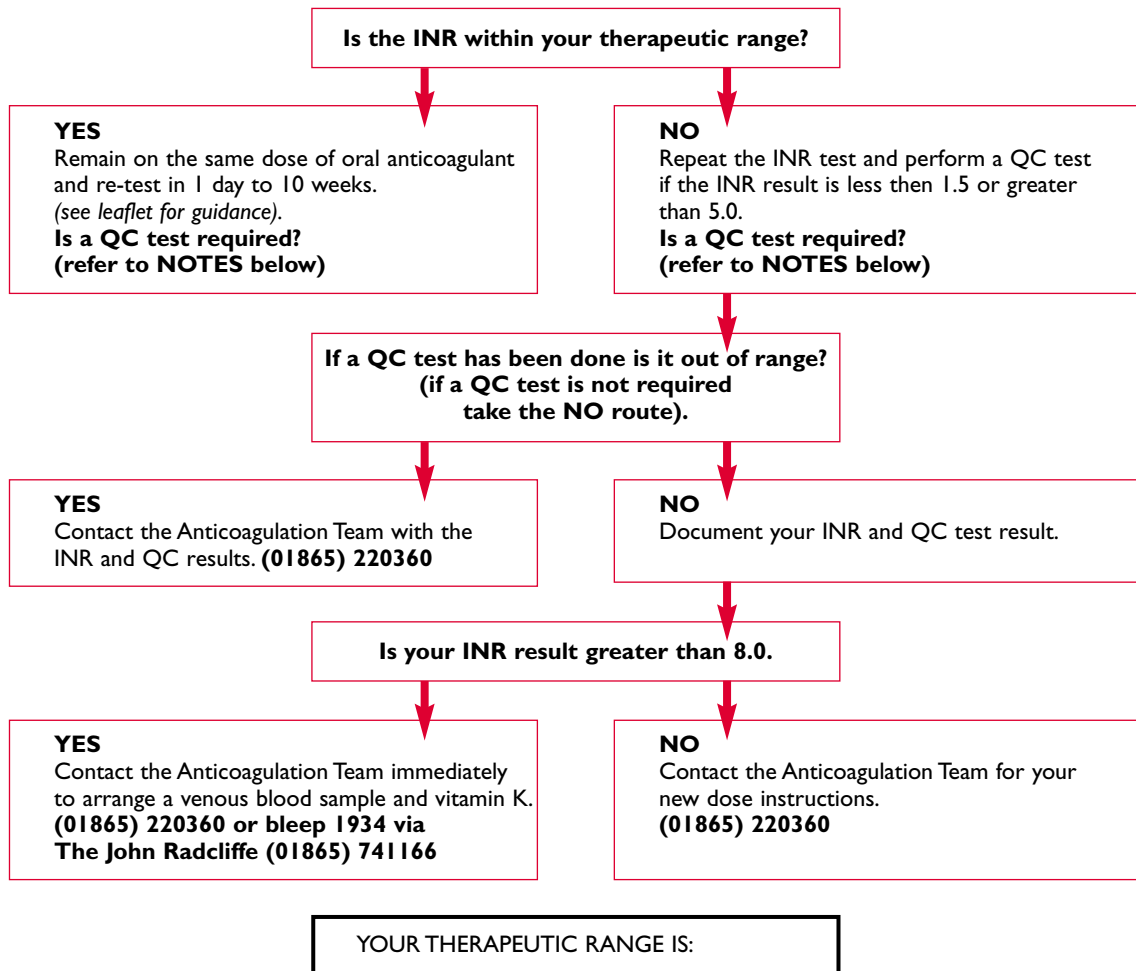
Name of self-tester (patient) \_\_\_\_\_

Signed (patient) \_\_\_\_\_

Signed (trainer) \_\_\_\_\_

Date \_\_\_\_\_

**Training Centre - Oxford Radcliffe Hospitals NHS Trust**  
**John Radcliffe Hospital (01865) 220360, The Horton Hospital (01295) 229224**



**NOTES:** A quality control (QC) test should be performed with every INR test during the patient self-testing home trial. After this period a QC test should be performed with every 10th INR test and with every new batch of test strips.

## APPENDIX III

### Training Programme Guide Phase I – CoaguChek S Home Testing

#### Session I

- Suitability screening
- Outline training programme
- Demonstration of monitor
- Perform INR test (trainer)
- Obtain venous sample (1st of 3)
- Theory

#### Suitability Screening

Is the patient's eyesight sufficient to enable them to self-test (+ or - visual aids)?	YES	NO
Is the patient sufficiently dextrous to self-test?	YES	NO
Is the patient on long-term oral anticoagulant treatment?	YES	NO
If NO, is the patient planning to use a loan meter?	YES	NO
Has the patient discussed their interest in self-testing with their GP?	YES	NO
If YES, is the GP willing to prescribe the meter test strips & lancets?	YES	NO
Is the patient currently dosed by the Oxfordshire Anticoagulation Service?	YES	NO
If NO, is the GP willing to provide dosing instructions?	YES	NO
Is the patient prepared to sign the Patient/Trainer Agreement?	YES	NO

#### Outline Training Programme

3 sessions / Self-test period / Feedback session

#### Demonstration of Monitor

PERFORM INR TEST using CoaguChek S (trainer)

#### Theory

Provide 'Anticoagulant' patient information leaflet / other leaflets as applicable.

Develop an understanding of the need for anticoagulation and the importance of good INR control.

- What is an anticoagulant?
- What are the side effects?
- What action should be taken if side effects occur?
- What is the duration of your treatment with oral anticoagulation?
- When should the anticoagulant be taken?
- What action should be taken if a dose of oral anticoagulation is missed or an extra dose taken?
- What dose of anticoagulation should you be taking?
- What potential effect does other medication have on the INR?
- What potential effect does the diet have on the INR?
- What potential effect does alcohol have on the INR?
- What action should be taken in the event of an injury?
- What action should be taken if dental treatment, surgery or medical interventions are required?
- What action should be taken in the event of illness (including hospitalisation), vomiting or diarrhoea?
- If relevant, what action should be taken in the event of becoming pregnant while taking oral anticoagulation?

## Session 2

- Appointment one week after patient has received meter and watched training video
- Theory feedback
- Perform INR test (patient)
- Perform quality control test
- Obtain venous sample (2nd of 3)

## Theory Feedback

Multiple choice questions

Review and discussion of any queries

## Perform INR test using CoaguChek S (patient)

### Perform quality control test (patient)

Develop knowledge and practical experience in the use of the CoaguChek S system.

- o) What preparation should be undertaken prior to using the CoaguChek S system?
- p) How do I switch on the CoaguChek S system?
- q) How do I check the "code chip" against the test strip?
- r) How do I perform an International Normalised Ratio (INR) test?
- s) What action should be taken if the INR result is out of range?
- t) How do I obtain a good capillary sample of blood?
- u) How and why do I perform a quality control (QC) test?
- v) What action should be taken if the quality control is out of range?
- w) How do I store the test strips and control preparations?
- x) How do I clean and maintain the CoaguChek S system?
- y) How do I recognise a problem with the CoaguChek S system and what action should be taken?
- z) Where do I record the results of the INR tests and quality controls?

## Session 3

- Perform INR test (patient assessed)
- Perform quality control test (patient assessed)
- Obtain venous sample (3rd of 3)
- Discuss self-test procedure

## Perform INR test using CoaguChek S (patient assessed)

### Perform quality control test (patient assessed)

Using 'CoaguChek S – Practical Assessment' form

## Discuss self-test procedure

Self-testing trial period paperwork and go through flow chart

## Feedback Session

- Review of self-testing trial period
- Air flight letter
- ID Card
- Set date for 6 monthly review





