



INR Self-Testing

A. SUMMARY

INR home testing devices are available to patients. They are often reimbursable by insurance carriers. Warfarin management through patient self-testing at home is at least as effective and safe as INR testing through a physician's office or a warfarin clinic, if patients are well selected. The well-done large THINRS trial published in 2010 clearly showed this, and a 2011 systematic review of the medical literature confirmed that [references 1,2].

B. WARFARIN AND THE INR

If you are on warfarin (Coumadin[®], Jantoven[®]), you regularly need a blood test called *prothrombin time, protime or PT*, with the result of the test called *INR* - International Normalized Ratio. Because too high an INR puts an individual at risk for bleeding and too low an INR at risk for clotting, monitoring of the INR is essential. There are four different ways to get your INR tested and warfarin adjusted:

- 1. Traditional way:** In the physician's office or anticoagulation clinic, blood is drawn from a vein stick and then sent to a laboratory. It takes some time to get the INR value back: 1-2 hours at the fastest, 1-2 days if the blood sample needs to be sent to a laboratory. You will need to be called at home once the result is back and your new warfarin dose needs to be discussed. This is a somewhat cumbersome, time-consuming way for warfarin management.
- 2. Physician office point-of-care testing:** In your physician's office a small drop of blood from a finger stick can be transferred onto a small, so called "point of care instrument" (POC device). The INR result is available within minutes, while you are still in your physician's office. You can, therefore, immediately be informed of the result and your further warfarin dosing discussed with you. These POC instruments make warfarin management easier and lead to improved, faster and more efficient communication with patients.
- 3. INR self-testing:** You can use these same "point of care" instruments at home or when traveling to check your INR. You can then inform your physician, anticoagulation clinic pharmacist or nurse, or the IDTF (independent diagnostic testing facility; further discussion below) of the result (by phone or through the Internet) and get instructions on further dosing of your warfarin. This is referred to as "Patient self-testing" (PST).



- 4. INR self-management:** Patients who use the “point of care” instruments themselves can not only check their own INR, but can also be taught to adjust their own warfarin dosing. While this type of anticoagulant management has gained acceptance in the medical community in some European countries, it has, at this point, not been promoted by the health care systems in the U.S. or Canada.

C. REASONS TO DO INR SELF-TESTING

High quality anticoagulation therapy can certainly be delivered through physicians’ offices and anticoagulation clinics. For many patients these are good, effective, safe and convenient set-ups. For many people, INR self-testing is also a good and attractive option. There are some advantages of INR self-testing over routine office-based care [ref 1-4].

- Patient self-testing can improve patient’s quality of life and give you more freedom, particularly, if you (a) have difficulty getting time off from work, (b) have to rely on a caregiver for transportation, (c) have a long drive to your physician’s office or lab, or (d) travel frequently.
- It may give you peace of mind eliminating the worry of where your INR is between routine physician office visits. Your INR can be easily checked when instructed by your physician in common situations such as: starting a new medication, discontinuing a medication, becoming sick, or changing your diet. If you have a history of fluctuating (unstable) INRs and need to have frequent INR checks, it is easier to test more frequently if you have your own instrument at home;
- It allows you to travel with your own INR device, eliminating the need to search for a lab and potential language barriers;
- It may empower you by having you actively involved in your medical care;
- It may lead to less bleeding complications, as it allows you to test your INR weekly. Studies have shown that weekly INR testing can improve the time in the desired INR range (= target range) compared to monthly testing. Weekly testing is typically not practical when a patient has to go to a physician’s office or a warfarin clinic for monitoring.
- If it is difficult to get a venous sample from you from an i.v. stick and your physician’s office does not have a “point of care” instrument, the self-testing from a finger stick may be a good solution for you.
- Whether INR self-testing is less or more expensive for you than having your INR checked through a physician’s office depends on your insurance coverage and copay-situation.



D. WHO IS SUITABLE FOR INR SELF-TESTING?

Self-testing may be suitable for you if

- you have shown good compliance with previous anticoagulation management;
- you have the manual and visual dexterity to perform testing or have a committed support person to assist you with testing;
- the clinic or physician’s office following you has a policy that approves patient use of the instrument;
- you and your health care provider agree upon a method of communication regarding the INR results that you will obtain, either by phone or email.

If you are motivated, receive appropriate training, and remain adherent to your physician’s orders, self monitoring may be safe and effective for you.

E. WHAT INR HOME MONITORING INSTRUMENTS ARE ON THE MARKET?

Three instruments are being marketed in North America (table 1). Any one of them is a good option for patient self-testing.



INRatio2®

CoaguChek®XS

ProTime®

Table 1: FDA Approved INR Home Monitoring Instruments

Name of Instrument	Company	Website	Phone number
CoaguChek®XS	Roche	www.coaguChek.com	800-852-8766
INRatio2®	Alere	www.alereinratio.com	800-504-4394
ProTime®	ITC	www.protimesystem.com	800-631-5945



The instruments are small and light, weighing only between 5.3 and 28.8 ounces (150 to 815 grams). For INR testing, only a small amount of blood needs to be applied to a test strip (for INRatio[®], CoaguChek[®] XS) or a cuvette (for ProTime[®]), i.e. one small to large blood drop (between 10 and 27 microliters). Prices for the machines are roughly between \$ 1,500 and 2,500, and prices for one test strip or cuvette, i.e. for one INR test, \$ 7.00 – 18.00. For this reason –patients rely on Medicare or private insurance to cover the costs of self-testing.

When trying to make a decision which of these instruments to purchase, you may want to consider:

- your physician's or anticoagulation clinic personnel's recommendation, based on their experience and knowledge of the instruments;
- other patients' experience and satisfaction with (a) their home monitoring device, and (b) the educational and support services provided to them by the manufacturer and/or distributor called an independent diagnostic testing facilities (IDTF).
- support and education services provided by the company making the instrument or (IDTF);
- amount of blood needed for the test strip or cuvette (10 microliters for CoaguChek[®] XS; 15 microliters for INRatio2[®]; 27 microliters for ProTime[®]);
- ease of testing, INRatio2 does not require time to warm the test strips, the others do;
- ease of operation of the instrument;
- If you take the instrument on travels, size and weight of the instrument may matter to you (CoaguChek[®] XS, 4.5 ounces; INRatio2[®] 9.3 ounces; ProTime[®] 28 ounces).

F. DO INR HOME MONITORING INSTRUMENTS GIVE RELIABLE INRs?

- Yes. INR values obtained with finger stick home monitoring devices are typically very well reproducible and correlate well with INR determinations obtained from blood sticks from a vein and tested in a laboratory [ref 5,6].
- However, above INRs of 4.0, discrepancies to INR values obtained with other test methods may exist. This is a general limitation of the INR and not unique to the home monitors. It is not clear which of such discrepant values is more reliable and accurate: the INR determined in the laboratory or the POC instrument INR.
- INRs from POC instruments are unreliable in about 1/3rd of patients with the clotting disorder called antiphospholipid antibody syndrome (APLA syndrome) who are on warfarin [ref 7]. In these patients, the POC devices give INR readings that are too high, or the instruments report error messages. This is the case with any of the 3 instruments on the market. If you have APLA syndrome, your INRs should be checked from blood drawn from a vein and tested in a laboratory. That value can then be compared to the INR obtained with a POC instrument from a finger stick.



Only if both values correlate well may it be acceptable for you to use the POC machine for self-testing.

G. DO INSURANCE COMPANIES PAY FOR THEM?

- Medicare pays for patient self-testing if you have the following medical conditions [ref 8,9]: atrial fibrillation, mechanical heart valve(s), venous thromboembolism (blood clots in veins; DVT and PE). You must be on warfarin for 90 days or more and have undergone face-to-face training. You must demonstrate continued proper use of your device and test up to but not to exceed weekly testing unless medical conditions warrant.
- Patients with Medicare as their primary insurance and a secondary or supplemental insurance typically have no out of pocket costs at all for patient self-testing (including their monitor and testing supplies).
- Medicaid coverage of INR self-testing varies. Check with your state's Medicaid office for coverage details.
- Private insurance often follow Medicare's coverage policy and therefore; most private insurance reimburse for patient self-testing. One of the benefits of using an IDTF includes these companies will submit your prescription for self-testing and contact you your coverage status based on your insurance plan design.

H. HOW DO I GET AN INSTRUMENT?

If you are interested in having one of these home monitoring devices you should discuss this with your anticoagulation provider. Your physician needs to be supportive because he/she

- will need to write a special, self-testing specific prescription for it,
- will need to be available for the on-going oral warfarin dose adjustments if this is needed,
- is medically responsible for your anticoagulation management.

Once a prescription has been written you can contact one of the companies that help you obtain an instrument (table 2). These independent diagnostic testing facilities specialize in:

- checking with the insurance companies for reimbursement and or copays,
- communicating with you during the submission process,
- providing you with the instrument and testing materials,
- arranging for face-to-face training on how to use it,
- support for any questions or if problems with the testing device arise or retraining
- offering software and methods to help track your INR results and communicate the results to your health care provider.



Table 2: Companies that Assist Patients in Getting an INR Home Monitoring Instrument

Name of company	Supports which instruments?	Website	Phone number
<i>In the U.S.</i>			
Advanced Cardio Services	CoaguChek®	www.AdvancedCardioServices.com	866-416-8989
Alere	INRatio® Protime® CoaguChek®	www.alereinratio.com www.ptinr.com www.ptinr.com	800-504-4394
Raytel	INRatio® Protime®	www.inrselftest.com	800-295-3530
Roche	CoaguChek	www.coagucheck.com	800-779-7616
<i>In Canada</i>			
ManthaMed Inc	INRatio®	www.manthamed.com	905-814-1040
Sorin	ProTime®	www.sorin.com	800-387-4563 (Western Canada) 800-268-6552 (Eastern Canada)
Roche	CoaguChek®	www.coagucheck.com	450-680-4367

I. WHAT GUIDELINES FROM MEDICAL SOCIETIES EXIST?

The widely respected ACCP (American College of Chest Physician) guidelines from 2012 state: “For patients treated with vitamin K antagonists (i.e. warfarin) who are motivated and can demonstrate competency in self-management strategies, including the self-testing equipment, we suggest patient self-management rather than usual outpatient INR monitoring” [ref 10].

J. PATIENT INFORMATION RESOURCES

- www.clotconnect.org
- www.ismaap.org
- The websites of the companies involved with INR self testing (table 2)

K. REFERENCES

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ABBREVIATIONS

- CMS – Centers for Medicare and Medicaid Services
- IDTF – independent diagnostic testing facility
- INR – International Normalized Ratio
- i.v. – intravenous
- POC device – point of care device
- PST – patient self-testing

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