


PATIENT CAMPAIGN PACK



**CAMPAIGNING FOR NHS
FUNDING OF TEST STRIPS
FOR YOUR ANTICOAGULATION
MONITOR**

PATIENT CAMPAIGN PACK

ORAL ANTICOAGULATION TESTING STRIPS: REIMBURSEMENT RESOURCE PACK

AntiCoagulation Europe has received numerous reports from patients who are unable to get the reagent testing strips needed for oral anticoagulation testing available on prescription. Despite the Department of Health's commitment to funding these test strips and the fact that anticoagulation self-testing/ self-management is very much in line with the government's strategies of patient choice and patient self-care, some Primary Care Trusts (PCTs) are not currently funding the strips. The result is that the cost falls to patients, many of whom can ill afford to pay for them and should not have to.

AntiCoagulation Europe has therefore developed the 'Reimbursement Resource Pack' to help patients to campaign in their local area. This pack contains:

- A **template letter from ACE to be sent to relevant parties (e.g. your GP, MP, PCT, Public Health Director and/ or local Pharmacy Group)** calling for a revision of the current policy and requesting that test strips be made available on prescription
- An **example cover letter**, to help you in writing a letter to accompany the letter from ACE
- A **guide to identifying your MP, PCT stakeholders and other relevant parties**
- A **guide to working with local media** and additional background information on anticoagulation that can be used to help the media understand the therapy area
- A **summary of documents outlining government policy on self-care, patient choice and the Expert Patient**
- A **summary of clinical papers** which provide evidence that patient self-testing/self-management is a safe and effective model of care
- A **first hand patient account** to help demonstrate what can be achieved by campaigning for your cause and some **top tips from patients** who have already achieved success with their campaign.

We hope these materials will help you in your campaign and result in you and others in your area receiving test strips on prescription. Downloadable copies of these documents are available on our website www.anticoagulationeurope.org

If you require any further information please email anticoagulation@ntlworld.com

Yours sincerely



**Eve Knight, Executive Director,
AntiCoagulation Europe**

HOW TO USE THIS PACK

This pack is designed to help you to campaign for National Health Service (NHS) funding of test strips for your anticoagulation monitor. Whether this is simply by writing to your General Practitioner (GP) or Primary Care Trust (PCT) or whether you also want to involve your local Member of Parliament (MP) and/or the local media is up to you, and will depend on your individual circumstances, the amount of time you are willing to invest, and the results you achieve from your initial campaigning activities.

Campaigning doesn't need to take a lot of time – it can be as simple as sending a letter and can achieve great results. Of course, there is no guarantee that you will achieve funding for your strips straight away. However, don't underestimate the impact you can have in raising awareness of this issue and bringing about change in the longer term.

Whilst AntiCoagulation Europe (ACE) are pleased to support you wherever we can, as an individual campaigner you do not represent ACE formally, and therefore we ask you describe yourself as a person on warfarin.

DEVELOPING CAMPAIGN LETTERS

You will find enclosed a **template letter from ACE which you can send to your GP/PCT/Public Health Director/ local pharmacy group and/ or local politician**. Here, all you need to do is insert the date. Please see page 2 for how to identify the appropriate local contacts.

You will need to write a **cover letter** to be sent alongside the letter from ACE to make the correspondence personal and more meaningful to those who will receive it. Refer to page 4 for an **example letter to provide you with an idea for the sort of cover letter you might write**. You will need to **adapt this letter to reflect your experiences and to include your name and the names, job titles and addresses of the appropriate GP/PCT/Public Health Director/Pharmacy contact and/ or local politician**. The example letter enclosed is written from the perspective of a patient who is keen to start self-testing but is worried about the costs of test strips. The content should be adapted to reflect your personal experiences. The letter should include:

- **Why you self-test or why you would like to**
- **The difference self-testing has made/is likely to make on your life**
- **Examples to illustrate this e.g. you are able to work full time without having to take time off to go to hospital/ you are able to go abroad on holiday etc.**
- **What you want to happen as a result of your letter**

Some example paragraphs are provided below to help you:

If you would like to self-test but have been prevented from doing so due to the cost of strips:

I feel the regular time off work I have to take to attend these appointments is affecting my job and have recently spoken with my GP to discuss the option of self-testing so I can check my own INR levels at home. I am keen to get started as soon as possible as I feel self-testing would make a real difference to my life, not only in making my work easier to manage but also in giving me more time to spend with my family. However, the cost of buying test strips for a point of care monitor is not something I can afford in the long-term.

Or

Having spoken to ACE and to my GP I think self-testing my INR at home would make a big difference to my life as it is not easy for me to make regular trips to the anticoagulation clinic. However, I am not currently working and cannot afford to pay for the test strips myself.

If you used to receive strips on prescription but have had them withdrawn:

I have grown accustomed to self-testing and the freedom it gives me. The prospect of reverting to regular clinic appointments is shattering. To have this lifeline thrown to me only to have it withdrawn is so disappointing – knowing that this will spell the end of being able to organise my testing around my life rather than the other way around.

If you have been self-testing and paying for the strips but are finding the cost too expensive long-term:

I have been self-testing for several months now and I cannot put into words the difference it has made to my life. My GP says I am doing really well and I've spent more time within my target therapeutic range than when I was monitored at the hospital clinic. However, having to buy test strips is becoming too expensive for me and I have been seriously evaluating whether I can continue to self-test on this basis.

LETTER WRITING TIPS

- Your cover letter should not be too long – certainly no more than 1-2 sides of A4
- Be polite and clear in what you are trying to get across
- Be careful not to criticise individuals – you are campaigning for change within the PCT and their decision not to fund strips- this decision is unlikely to have been made by one individual
- Don't be afraid to use examples specific to your own experience but avoid generalising and keep the needs of other warfarin patients in mind, for example, you may live a long way from the anticoagulation clinic but others may live close by but want to self-test at home for other reasons
- You may want to write a more general letter and invite other patients in your area to co-sign the letter rather than all writing individually
- We suggest you keep a copy of the letter for your own files, in case you need to refer back to it

PATIENT CAMPAIGN PACK

IDENTIFYING YOUR LOCAL PCT REPRESENTATIVE

For simplicity throughout this document we have referred to Primary Care Trusts (PCTs) as the organisation responsible for funding healthcare products and services. However, as the structure of the NHS varies from country to country within the UK, the organisation responsible for commissioning will vary. The organisations you need to contact are as follows:

- **England** - Primary Care Trusts (PCT)
- **Wales** - Local Health Boards (LHB)
- **Scotland** - Area Health Boards (AHB)
- **Northern Ireland** - Health and Social Services (HSS) Boards

The best way to identify the appropriate contact is to **ask your GP or surgery administrative staff**. They should be able to inform you of the specific Lead contact for anticoagulation. If you are not able to identify the **Anticoagulation Lead**, we suggest addressing your correspondence to the **Chief Executive** or **Public Health Director**.

A directory of PCTs, including the name of the Chief Executive, is available on the internet at:
<http://www.networks.nhs.uk/189.php>

For Welsh patients:

A directory of Local Health Boards, can be found at:
<http://www.wales.nhs.uk/catorgs.cfm#5>

For Scottish patients:

A directory of Area Health Boards can be found at:
<http://www.show.scot.nhs.uk/organisations/orgindex.htm>

For Northern Irish patients:

A directory of Health and Social Services Boards can be found at:
<http://www.healthandcareni.co.uk/index.php?link=boards#>

IDENTIFYING OTHER RELEVANT HEALTHCARE PROFESSIONALS

We would recommend sending a copy of the letters to your GP and/or consultant so they are informed of the action you are taking. You may like to discuss your campaign with them before sending the letter.

Consider sending a copy of the letter to your local pharmacy group. Again you should be able to find the contact details on the internet or through your anticoagulation clinic.

IDENTIFYING YOUR LOCAL POLITICIAN

You can find out who your local MP is by asking in your local **public reference library** or your local **town hall**. You can also telephone the **House of Commons Information Service on 0207 2194272**. If you have access to the internet and know your full post-code you can find out who your local MP is via the **Constituency Locata service** at: <http://www.locata.co.uk/commons/>

The best way of contacting your MP is to **write to him/her at the House of Commons, London SW1A 0AA**. All MPs have Westminster offices and will make arrangements for their mail to be redirected when they are away from London. For this reason it is best to write to them there rather than their constituency or home address.

You can telephone your MP by calling 0207 2193000 and asking for your MP's office. However, we strongly recommend writing first so your MP has all the details and a record of your correspondence.

Some MPs can be contacted by email. You can contact the House of Commons Information Service to find out if your MP has an email address or you can check the list of MPs on the internet at the Parliamentary website: <http://www.parliament.uk/directories/hciolists/alms.cfm>

Most MPs will have times when they are available at different places within their constituency for constituents to meet with them. These sessions are often called surgeries and details are usually advertised in the local public library or in local papers. Your MP's secretary or local party office will also be able to advise you on the timings and location of these surgeries.

WORKING WITH LOCAL MEDIA

Consider whether you feel it is necessary to involve the local media. Local publicity for your campaign may generate further pressure if you don't achieve a satisfactory response from your PCT or MP. However, we would recommend giving your MP/ PCT time to respond in the first instance.

If you do decide to involve the media you will need to be prepared to talk to journalists on the phone. Depending on the interest you receive, you may be invited to be quoted in the press, to speak on the radio, and perhaps be photographed/ filmed.

Identifying local media

You will need to develop a list of the local media you wish to target. This may include just print media (i.e. newspapers) or also broadcast (i.e. radio and television), depending on whether you feel comfortable and confident with giving radio interviews/ appearing on television.

You will probably be aware of the main newspapers and radio stations in your area. To find details for the editor, visit their websites or look at the listing inside the newspapers themselves. Copies of local newspapers are usually available in public libraries.

What next?

You can approach the media in a number of ways:

- Consider writing a letter to the editor – this is probably the easiest way to get your opinion noticed. Ensure you keep the letter succinct and to the point, focussing on the key points you want to get across.
- Alternatively, you might like to contact the news editor by phone – highlighting your campaign. Before you call, think carefully about why the editor would be interested in your story. Why is your campaign relevant to their readers?

Please find enclosed **background information on oral anticoagulation** that can be posted/ emailed to the journalist to help them to understand the area. Electronic copies of these materials can be found at www.anticoagulationeurope.org

We would recommend you follow up with your media contacts by phone. Ask for the contact by name. Journalists are likely to be very busy, therefore you will need to keep to the point and make sure you communicate the key messages you are trying to get across. An example of what you might say is as follows:

“My name is X. I am following up on the letter I sent you about my test strips for anticoagulation monitoring not being available on the NHS in our area, even though they are funded in other PCTs across the UK. There are many patients on warfarin in our area, several of whom would like to self-test but the costs of having to pay for test strips is preventing this. I have been on warfarin for x years myself and self-testing would save me about x hours travelling to the hospital/GP clinic. Self-testing at home would mean I can xxxxxxxxxx (e.g. work full-time, travel abroad, spend more time with my family etc.). Would you be interested in covering my story?”

Remember that there is no guarantee that your story will be printed and it will have to compete with everything else that arrives at the editorial offices that day, week or month. It may be that only a few lines of what you said are printed – therefore it is important you keep focussed on the key message you are trying to communicate and don't get sidetracked into talking about something else.

We hope you find the pack useful. Good luck with your campaign!

If you would like further information or support please email anticoagulation@ntlworld.com

TIPS FOR INTERVIEWS

Apply these simple rules when the telephone rings:

- Find out who the journalist is and what angle they are taking with their story – call back if you need to prepare. Find out their name, publication and deadline and promise to call back at a specific time (and make sure you do!)
- Sound confident
- However friendly the journalist may seem – remember there is no such thing as ‘off the record’
- Do as much preparation as you can in advance of an interview. If you don't think you can put across your story in the right light, don't do it!
- Don't do an interview in a hurry –ask for more time if necessary
- You have something important to say, try to sound animated and make it interesting. Ask yourself “*Why would they be interested in what I am saying?*”

Try and make your story easy to relate to in terms of how it is affecting your life – think of it as telling your story to a family friend or relative

- Make it easy to understand – the journalist is unlikely to be familiar with technical terms such as INR or self-testing
- Think of key phrases that will help reinforce your message – short, punchy sayings that people will remember – these are called ‘sound bites’ e.g. ‘*Self-testing has given me my life back*’ or “*It seems unfair that whether strips are on prescription depends on where you live*”
- Don't make anything up or say anything you're not sure about
- Don't be tempted or pressurised to comment on matters about which you haven't gathered your thoughts or done the research, simply say “*I will find out the answer for you and get back to you*” or “*I'm not sure about that I'm afraid*”

PATIENT CAMPAIGN PACK

EXAMPLE COVER LETTER

THIS LETTER IS AN EXAMPLE ONLY AND IS NOT DESIGNED TO BE DISTRIBUTED
The names in this letter are not those of actual individuals but are for illustration purposes only.

15 Woodlands Place
Lane End
High Wycombe
Bucks
HP14 XXX

14th April 2007

Dear Mr Smith

RE: AVAILABILITY OF ORAL ANTICOAGULATION TESTING STRIPS

I am writing to ask you to reconsider your current policy on the funding of the test strips for anticoagulation monitoring. I am writing as part of a campaign supported by the charity AntiCoagulation Europe (ACE) – please find a letter from ACE attached, providing more detail.

Two years ago, I started to experience palpitations and shortness of breath and was diagnosed with atrial fibrillation by my GP. I was referred to a consultant, who prescribed warfarin and explained that I would need to be regularly checked to ensure my blood was kept at the right thickness. As you can imagine, the idea of having to spend the rest of my life going in and out of hospital was devastating.

I go to hospital every four weeks to have my INR levels monitored. It is a 45 minute drive to my local hospital and there are considerable parking charges. It is not uncommon to wait up to an hour for my blood test results and I rarely see the consultant. Inevitably this has an enormous impact on both my work and social life due to the time spent at these appointments.

I feel the regular time off work I have to take to attend these appointments is affecting my job and have recently spoken with my GP to discuss the option of self-testing so I can check my own INR levels at home. I am keen to get started as soon as possible as I feel self-testing would make a real difference to my life, not only in making my work easier to manage but also in giving me more time to spend with my family. However, the cost of buying test strips for a point of care monitor is not something I can afford in the long-term.

Friends who I have met through ACE tell me their strips are funded by the NHS and it seems unfair that I would have to pay for mine just because of where I live. I urge you to reconsider the reimbursement of anticoagulation test strips in this area as it would have a huge impact on my life and the lives of many other people in a similar situation.

I look forward to your reply.

Yours sincerely,

Mark Brown

cc: **Dr Nick Harris, General Practitioner, The Surgery, High Wycombe**
Mr John Smith, Wycombe Primary Care Trust
Mr Paul Goodman, Wycombe MP, Houses of Parliament

RE: AVAILABILITY OF ORAL ANTICOAGULATION TESTING STRIPS

AntiCoagulation Europe (ACE) is a charity providing information, advice and support to people on anticoagulation therapy. We are writing to you on behalf of our members in your area, who have expressed to us their dissatisfaction that the test strips needed for their anticoagulation monitors are not currently available on NHS prescription, as they are in many other PCTs throughout the UK. When ACE questioned this matter with the Department of Health, we were informed that any patient thought suitable for self-testing or self-management by their GP should receive their test strips on the NHS.

Anticoagulation self-testing has made a huge difference to the lives of many of our members. We regularly hear from patients whose quality of life has significantly improved by not having the inconvenience of having to attend regular appointments to have their clotting levels monitored. This of course also results in valuable time saved by the healthcare professional team. Many patients also report feeling more reassured and in control of their health, which is important for the majority of anticoagulation patients as they have long-term chronic conditions.

As you may be aware, there are many studies to support the accuracy and reliability of self-testing, for example:

'Patients capable of self-monitoring and self-adjusting therapy have fewer thromboembolic events and lower mortality'

Heneghan C et al. The Lancet, 2006; 367: 404-11*

'Patient self-testing is a safe alternative to attending the hospital clinic and is acceptable to most (94%) of patients.'

MHRA Guidance, 2004*

'Most patients found self-testing straightforward and felt confident with the results they obtained (87%)'

Gardiner C et al. British Journal of Haematology, 2004; 128: 242-247*

'Self-management was found to be a safe and reliable alternative to existing models of care in healthcare systems with high quality routine anticoagulation management. Patient self-management is particularly effective in patients with poor INR control, who are a difficult population to manage and are at risk of adverse events.'

Fitzmaurice DA et al. British Medical Journal, 2005; 331: 1057*

Self-testing is also very much in line with current government initiatives, which aim to encourage patients to take more responsibility for their own health:

"Consider self-monitoring for patients with AF who require long-term anticoagulation if they would prefer it"

NICE Guidance on Atrial Fibrillation, June 2006*

"The DH encourages more patients with long-term conditions to take control of their health"

Self Care – A Real Choice, Department of Health, 2005*

'Give patients the confidence to take responsibility for their own care'

Expert Patient Programme, 2005*

Whilst self-testing has made a big difference to many patients, giving them the freedom and independence to get on with their lives, many can ill afford the ongoing costs of funding their strips.

We would like to request that the funding of test strips in your area is reconsidered and look forward to hearing from you regarding your decision on this matter. Please note that whilst we are supporting patients in this campaign, any correspondence should be sent directly to the patient. However, if you would like more general information regarding anticoagulation please do visit our web-site www.anticoagulationeurope.org or contact us on 020 8289 6875.

Yours sincerely



Eve Knight, Executive Director, AntiCoagulation Europe

*Please contact us if you would like further details of these references.

ANTICOAGULATION THERAPY: THE FACTS

Oral anticoagulation therapy (OAT) refers to medicines prescribed to prevent the formation of clots in blood vessels and the chambers of the heart. Oral anticoagulants may be given following injury or surgery (in particular, heart valve replacement) when there is high risk of clot formation. They are also given as a preventative treatment to people at risk from stroke.

The most common OAT is warfarin. It is estimated that around 950,000 people in the UK are currently taking warfarin¹. The number of patients requiring anticoagulation monitoring is expected to increase by a factor of five over the next decade², due to the ageing population and the increased clinical use of warfarin, primarily for atrial fibrillation, and the associated recommendations within the Coronary Heart Disease National Services Framework (NSF)³.

Conditions that require OAT

People who are prescribed OAT may have one of the following conditions:

- Atrial fibrillation – an irregular, rapid beating of the upper chambers of the heart
- Deep vein thrombosis or pulmonary embolism – a blockage in a vein due to a blood clot
- Congenital heart problems – a defect in the heart that is present from birth
- Artificial heart valves
- Recent myocardial infarction (heart attack) or heart bypass surgery
- Cardiomyopathy/ chronic heart failure
- Thrombophilia – abnormal clotting.

Anticoagulation Monitoring

Warfarin is a very effective treatment. However, there are many factors that can cause patients' clotting levels to fluctuate (e.g. change in diet, travel and/ or physical activity). Too much warfarin may lead to excessive bleeding and too little may allow the formation of clots (thrombosis). Therefore, it is crucial that warfarin treatment is precisely monitored and the dosage adjusted as necessary, to keep potential risks at the lowest possible level. Regular tests must be performed to check the clotting levels of the blood, determined by a scale known as the International Normalised Ratio (INR). Each patient is given a therapeutic INR range by their doctor, which they must stay within to avoid clot formation or excessive bleeding. Studies show that staying within this INR therapeutic range reduces significantly the risk of major complications⁴.

PATIENT CAMPAIGN PACK

The need for regular monitoring can have a significant impact on patients quality of life. Treatment is traditionally monitored and managed by consultants (cardiac surgeons, haematologists or cardiologists). In recent years, with the development of more and more sophisticated and convenient point of care (POC) monitoring devices, there has been an increasing move of this service into primary care. By utilising local services, regular INR monitoring becomes more convenient for patients and allows the local healthcare professionals to work in conjunction with their patients to manage what is often a long-term treatment regime. The Government are encouraging this move by providing considerable financial rewards to practices offering anticoagulation services, offering up to £127.86⁵ per international normalised ratio (INR)-managed patient.

Some patients are able to test their INR levels at home using a POC device and then contact their healthcare professional to receive advice on the dose of warfarin they should take – this is known as patient self-testing (PST). Where appropriate, patients can use a chart to select the dose of warfarin themselves – this is known as patient self-management (PSM). PST/PSM can make a huge difference to patients lives, as they no longer have to attend regular clinic appointments. Tests can be carried out anywhere and at any time, giving patients the freedom and flexibility to get on with their lives and to feel more in control of their condition.

References

1. Gardiner C et al. Patient self-testing is a reliable and acceptable alternative to laboratory INR monitoring. *British Journal of Haematology*. 2004 128: 242-247.
2. Fitzmaurice DA et al. Self-management of oral anticoagulation: randomised trial. *BMJ*. 2005; 331(7524): 1
3. Coronary Heart Disease National Service Framework. www.doh.gov.uk/nsf/coronary.htm. (viewed January 2006)
4. Menendez-Jandula B et al. Comparing self-management of oral anticoagulant therapy with clinic management; *Annals of Internal Medicine*. 2005;142:1-10; ACOA study
5. *Medeconomics*, December 2005

CAMPAIGNING FOR TEST STRIP REIMBURSEMENT: REAL LIFE EXPERIENCES



Linda Murdoch has a history of pulmonary emboli and suffers from the blood clotting disorder Factor V Leiden. In addition she has severe asthma, lupus, osteoporosis and problems with her thyroid. As well as being treated long term with warfarin to prevent her blood from clotting, Linda is also needs to take numerous medications, some of which cause her blood INR levels to change daily.

Four years ago Linda, under the supervision of her GP, purchased a CoaguChek point of care monitor, so that she could test her own INR levels at home. Unfortunately for her, not long after this she was informed that her Primary Care Trust (PCT) would not provide funding for the test strips necessary for her to carry out the tests.

With guidance from AntiCoagulation Europe Linda wrote a number of letters to the head of commissioning at her local PCT. She also looked in her local paper for PCT meetings where she could voice her opinion and gain further support for her campaign.

As a result, Linda campaigned successfully and eventually her PCT agreed to fund her test strips. While this news was a big relief, Linda later found out that other patients in her area had been able to receive funding without any such campaign. This revelation highlighted certain inconsistencies, not just between PCTs (often referred to as the postcode lottery) but also within the PCT.

"It is important to remember that PCTs are just trying to allocate their PCT funds in the best way possible. I would therefore advise a gradual build-up approach to your campaign, keeping in mind that your actions may have an impact on other people also campaigning. If you go through the proper channels and use the help provided by Anticoagulation Europe, obtaining funding is achievable."

Linda describes her move to self-testing as "Absolutely brilliant, self-testing has given me a new lease of life." Because Linda suffers from numerous conditions resulting in her INR levels changing day to day, with self-testing she feels in control of her treatment and being able to check regularly gives her peace of mind. Previously Linda had her INR monitored at a hospital clinic, which meant she found herself travelling regularly to and from her local hospital, which in her current condition would not always be easy or convenient.

Linda has received continual support, training and advice from nurse practitioners at her local haematology clinic. With this she feels sufficiently confident and comfortable with self-testing.

"With self-testing I feel I have absolute control of my own life. Testing at home or out and about with the CoaguChek has given me a freedom which I had not thought possible." Linda describes two recent trips she has had to America: "Self-testing has allowed me to travel away from home without the worry of long flights and lack of access to the local hospital. I still have regular contact with my PCT, but this is now flexible and on my own terms. Before self-testing I really thought trips abroad were a thing of the past."

"As I am on long term warfarin, if I live another twenty-five years, this represents a significant amount of hospital resources to meet my required needs. In reality, the practicalities of being able to self-monitor my warfarin therapy have considerable benefits. If I am taking other medications that do 'interact', I can check my own INR therapeutic range immediately without relying on hospital resources."

"With self-testing I feel I have absolute control of my own life, it has given me a freedom which would not be possible without my self-testing device."

"If you go through the proper channels and use the help provided by AntiCoagulation Europe, obtaining funding is achievable."

PATIENT CAMPAIGN PACK

'TOP TIPS' FROM PATIENTS WHO'VE DONE IT

- Somebody told me to start right at the top and write to the Chief Executive of the Primary Care Trust. I disagreed with this as once you have been to the top you have no where else to go, so I started with my GP and worked upwards.
- Always get the persons name when you are talking on the phone and if possible get them to put everything in writing to you. Remember to keep copies of everything.
- I found it was best to say that I was just trying to understand their decision rather than say I was campaigning and was going to my MP etc.
- It helps to gather as much local information as you can. So I started chatting to the other people waiting at the clinic instead of just sitting in silence. I found someone else who wanted to self-test and we joined forces to support each other.
- I got my local paper involved, albeit in a very small way.
- Find out when your Primary Care Trust is holding one of its meetings in public (they all do this) and attend and ask questions.
- Never be fobbed off. If someone does not return your calls or answer your letters try again perhaps with a registered delivery. If you still get no response involve your local Patient Liaison Advocacy Service (PALS), every trust has one. They can deal with your complaint about not getting a response.
- Never loose your temper no matter how frustrated you feel. Keep calm and keep trying.

POLICY DOCUMENTS

Self-testing is very much in line with current government initiatives, which aim to encourage patients to take more responsibility for their own health:

MHRA Guidance

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. In their guidelines issued in 2004 they recommended PST in appropriate patients, finding PST to be *a safe alternative to attending the hospital clinic and acceptable to most (94%) patients.*

www.mhra.gov.uk

NICE Guidance

The National Institute for Health and Clinical Excellence (NICE) is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.

In June 2006, they published guidelines for healthcare professionals on Atrial Fibrillation (AF), recommending that self-monitoring is considered for patients with AF who require long-term anticoagulation if they would prefer it.

www.nice.org.uk

Self Care – A Real Choice

In 2005, the Department of Health published a document aimed at PCTs and NHS Trusts and at healthcare practitioners to provide information of the developing policy of support for self-care and suggesting practical action that can be taken to deliver this. In this document the DH suggest that more patients with long-term conditions should be encouraged to take control of their health and suggests ways that more individualised support can be offered to help.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4100717

Expert Patient Programme

The Expert Patients Programme (EPP) is a NHS-based training programme that provides opportunities to people who live with long-term chronic conditions to develop new skills to manage their condition better on a day-to-day basis. Set up in April 2002, it is based on research from the US and UK over the last two decades which shows that people living with chronic illnesses are often in the best position to know what they need in managing their own condition. Provided with the necessary 'self-management' skills, they can make a tangible impact on their disease and quality of life more generally.

The EPP is one among a range of new policies and initiatives to modernise the NHS to emphasise the importance of the patient in the design and delivery of services.

www.expertpatients.nhs.uk

SUMMARY OF USEFUL REFERENCES

Clinical Studies

There are many clinical studies which have demonstrated the safety and effectiveness of patient self-testing (PST) and patient self-management (PSM). Some examples are as follows:

- **Ansell J et al. Guidelines for implementation of patient self-testing and patient self-management of oral anticoagulation. International consensus guidelines prepared by International Self-Monitoring Association for Oral Anticoagulation. International Journal of Cardiology, 2005; 99:37-45**

Following a review of the literature and a comparison of results of anticoagulation monitoring in the clinic vs PST/PSM, an international consensus group put forward a series of guidelines for safe and effective PST/PSM for healthcare professionals.

The consensus group agreed that PST and PSM are effective methods of monitoring OAT, providing outcomes at least as good as, and possibly better than, those achieved with an anticoagulation clinic. All patients must be appropriately selected and trained.

Currently available PST/PSM devices give INR results which are comparable with those obtained in laboratory testing. The consensus agreed that there are several points in favour of PST/PSM, such as a higher degree of medical safety, increased patient education, improved response to changes in lifestyle, increased independence for the patient and improved quality of life.

- **Fitzmaurice DA et al. Self-management of oral anticoagulation: randomised trial. British Medical Journal. 2005; 331(7524): 1057.**

This study investigated the clinical effectiveness of PSM compared with routine care in patients on long term OAT. No significant differences were found in percentage of time in the therapeutic range between self-management and routine care.

The study concluded that with appropriate training, PSM is safe and reliable for a sizeable proportion of patients receiving OAT and that it may improve the time spent within the therapeutic range for patients with initially poor control.

- **Gardiner C et al. Patient self-testing is a reliable and acceptable alternative to laboratory INR monitoring. British Journal of Haematology. 2004; 128: 242-247.**

This study was conducted to determine whether patients can achieve accurate INR values through PST, using the CoaguChek S (Roche Diagnostics). The main outcome measurements were: comparability of INR values obtained by PST and the hospital laboratory, patient acceptability as assessed by a questionnaire and anticoagulant control.

84 patients receiving long-term OAT (warfarin), were recruited. Patients were randomised to weekly self-testing or continuing 4-weekly hospital laboratory monitoring of INR. Comparison of INRs showed no significant differences between the

CoaguChek and laboratory testing. There was excellent correlation between the two methods, with 85% of CoaguChek results within 0.5 INR units of the laboratory method.

87% of patients found self-testing straightforward, 87% were confident in the result they obtained and 77% preferred self-testing. It was concluded that PST is a reliable alternative to hospital clinic attendance and is acceptable to the majority of suitably trained patients.

- **Gardiner C et al. A randomised control trial of patient self-management of oral anticoagulation compared with patient self-testing. British Journal of Haematology, 2004; 129 (Suppl. 1): 11.**

This randomised control study was conducted to determine whether the quality of treatment afforded by PSM is superior to that achieved by PST alone. 104 patients aged 22 to 88 years were randomised to PSM or PST. Following satisfactory completion of a nurse-led training course, patients in both groups measured their INR using the CoaguChek S (Roche Diagnostics) every two weeks, or more frequently if required, for a period of six months.

The PST patients telephoned their INR result to a nurse specialist for interpretation and adjustment of warfarin dose, whereas those in the PSM group adjusted their own warfarin dose on the basis of their INR using an algorithm provided by the clinic.

There was no significant difference in median time in target therapeutic range between the two groups and it was concluded that, in the majority of suitably trained patients, the quality of OAT achieved through PSM is comparable to that obtained by self-testing patients managed by a specialised hospital anticoagulation clinic. PSM was therefore found to be an effective model for selected patients.

- **Heneghan C et al. Review: self testing and self management increase the benefits and reduce the harms of anticoagulant therapy. The Lancet, 2006; 367: 404-11**

Carl Heneghan and his colleagues pooled data from 14 randomised trials of PSM. They found that PSM led to a 55% reduction in thromboembolic events, a 39% relative reduction on mortality due to all causes, and 35% relative reduction in major haemorrhage when compared to those who did not self-monitor. They also found that patients who could self-manage had fewer embolic events and lower mortality than those who self-monitor alone.

- **Menendez-Jandula B et al. Comparing self-management of oral anticoagulant therapy with clinic management; Annals of Internal Medicine. 2005;142:1-10; ACOA study**

This study compared the quality of control and the clinical outcomes of OAT in self-managed patients compared to patients receiving conventional management.

The study concluded that, compared with management in an anticoagulation clinic, self-management achieved a similar level of control and that major complications and minor haemorrhages were less common in those self-managing.



www.anticoagulationeurope.org