IN THIS EDITION
Patient INR Self Testing

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NATIONAL ALLIANCE FOR
THROMBOSIS & THROMBOPHILIA

## *Letter from the President*

The Centers for Disease Control and Prevention (CDC) has awarded NATT $675,000 for our "Stop the Clot" educational initiative and for a new program to train health professionals on how to improve care for people with thrombosis and thrombophilia. This funding is for the first year of a two year cooperative agreement. Congratulations to the NATT team for an excellent application and many thanks to CDC for its continued support for NATT!

Most of us who have experienced clotting disorders are probably way too familiar with the prothrombin time (PT) test and regular visits to the lab. If your life is anything like mine, the lab's schedule and yours seldom cooperate, so PT testing becomes another of life's little hassles. Nonetheless, testing is a critical part of managing anticoagulation therapy and staying clot free until someone comes up with an effective substitute for warfarin.

In this newsletter we explore PT testing and the International Normalized Ratio (INR) fully, with an emphasis on self testing. There is growing interest in home testing, both for convenience and for improved compliance. The articles in this newsletter look at how to do it, whether it is right for you and the experiences of people who have used home testing.

We think this issue is timely since Medicare is currently reviewing its own standards for home testing to determine whether or not they should be expanded.

Presently, Medicare limits cover-

*Continued on page 6.*

# Owning My Coagulation Health Management

*By David Henry, Bear, Delaware*

Like many of you who are reading this, I am a Warfarin 'lifer.' Also, like many of you, I have experienced the frequent delays and inconvenience of waiting at busy lab sites for the brief procedure resulting in my PT-INR ratios. As a busy professional, I felt a growing need to challenge this 'traditional' approach. I found my answer in taking ownership of my coagulation health management through patient self-testing.

Patient self-testing involves using a device similar to those used for testing blood glucose levels. I learned that I could do my PT-INR testing at home, on my schedule and with highly accurate results. Knowing this, I turned to the Internet to research how I could make this work.

I learned about coagulation monitors on manufacturer websites. When I could not locate a local 'in-network' DME (Durable Medical Equipment) provider, I chose one via the Web. This DME provider became a one-stop source for the coagulation monitor, supplies, physician coordination, 3rd party insurance reimbursement and training.

Initially, I experienced some reimbursement delays due to lost files and a time-consuming approval process. Eventually, however, my insurance plan agreed to cover all of my DME equipment and supplies and processes it as 'in-network'. I have also developed my own Excel spreadsheet with charts to log and manage my coagulation levels. I coordinate my testing results and dosage adjustments with my specialist by phone.

Patient self-testing may not be appropriate for everyone. However, I like the flexibility and satisfaction that I now have from owning my coagulation health management. The key is in making the patient self testing process easier for all who desire the benefits of this approach. I challenge NATT to lead the advocacy charge in overcoming obstacles with public and private 3rd party payers and in documenting the health and economic benefits.

## SALT LAKE CITY SEMINAR A GREAT SUCCESS!

*Members of the Salt Lake City Stop the Clot Forum patient panel (L-R) - Moderator Matt Rondina, MD, Laurie Fife, First Lady of Utah Mary Kaye Huntsman (seated), Mary Anne Huntsman and Andrew Peterson. These participants or family members shared their experiences with blood clots and how they have dealt with their different situations.*

# UPDATES FROM THE EDUCATION COMMITTEE

*Elizabeth Varga, Education Committee Chair*

As 2007 is coming to a close, it is my pleasure to report on the activities of the Education Committee. As part of our new "Stop the Clot" education program, we held our first Stop the Clot Forum on November 10, 2007 in Salt Lake City, Utah. We had almost 100 attendees, primarily from the Salt Lake area but from surrounding states as well. I believe our speaker panel was one of the best yet, and again, we received resoundingly positive feedback about how informative and helpful the event was! We are always so inspired to know that our seminars make a difference. Our next scheduled event is on March 1, 2008 in Durham, NC. See the NATT website for details.

We are also in the process of finalizing two of our pediatric brochures which we hope will be available soon to educate parents and families about stroke and blood clots in kids. Two new brochures on "Life on Warfarin" and "Heparin Induced Thrombocytopenia" are underway.

With our Stop the Clot Initiatives we will have the opportunity to print and distribute many of our education brochures and we will have multi-media offerings (such as education videos and web-based learning tools) and support resources. Our committee is already tackling projects related to these and health care provider oriented initiatives.

As always, we welcome your feedback! Thanks to all of the many volunteers who have helped organize and attend seminars, provided feedback on brochures and developed educational brochures! We could not do any of this without you!

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# Statement Paper of the Board of Directors of the Anticoagulation Forum on INR Home Monitoring

The Anticoagulation Forum (www.acforum.org) is a national network of anticoagulation providers in the U.S. with a membership of over 4,000 health care professionals. These providers represent over 1,350 anticoagulation clinics, which care for over 500,000 individuals on oral anticoagulation therapy; many are Medicare beneficiaries.

Currently, the Centers for Medicare and Medicaid Services (CMS) provides coverage for home INR testing of patients with mechanical heart valves. We believe CMS should also cover the cost of such monitoring for patients who are anticoagulated with warfarin for conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE), and atrial fibrillation.

A number of recent studies have clearly documented that patient home monitoring increases the benefits and reduces the harms of anticoagulant therapy:

1. Ansell J, et al. International Journal of Cardiology, 2004; 99:37-45
2. Fitzmaurice DA, et al. British Medical Journal, 2005; 331(7524): 1057
3. Heneghan C, et al. The Lancet, 2006; 367:404-11
4. Menendez-Jandula B, et al. Annals of Internal Medicine; 2005;142:1-1

Home monitoring offers patients many benefits, including: increased patient safety, increased "time in therapeutic range", improved quality of life, and reduced loss-of-work time.

Unfortunately, many patients do not currently have access to these benefits because CMS and some other 3rd party payers do not provide reimbursement for home testing. We strongly encourage an expansion of the population eligible for coverage of home PT/INR monitoring by CMS to all patients on long-term oral anticoagulants.

David Garcia, M.D.
*President, Anticoagulation Forum (signed on behalf of the Anticoagulation Forum Board of Directors)*
*University of New Mexico, Albuquerque, NM*

*Stephan Moll, MD; University of North Carolina, Chapel Hill, NC*
*Jack Ansell, MD; Boston University Medical Center; Boston, MA*

# INR Self Testing

## 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. Monitoring of the INR is essential because too high an INR puts an individual at risk for bleeding and too low an INR at risk for clotting. 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 an outside 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 and time-consuming way to manage warfarin.

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.

## 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. However, for many people, INR self testing is also a good and attractive option. There are some powerful advantages of INR self testing over routine office-based care.

- Foremost, several studies (summarized in reference 1) have shown that individuals who monitor their own INR have (a) slightly less bleeding and clotting complications, and (b) are more often in the target INR range, i.e. their anticoagulant therapy is better controlled;
- Patient self testing can be more convenient and save you time, as you do not have to go to the physician's office for testing. This can give you more freedom, particularly, if you have to rely on a caregiver for transportation or have a long drive to your physician's office;
- It may give you a sense of security, as you can easily check the INR at times when you suspect that the INR may be too high or too low, such as when you have started a new medication, discontinued a medication, are sick, or have changed your diet. Also, 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 may empower you by having you actively involved in your medical care;
- It allows you to travel without having to track down service providers for INR testing and deal with bureaucracy and language barriers;
- And lastly, 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

*Continued on page 4.*

of care" instrument, the self testing from a finger stick may be a good solution for you.

Thus, there are several good reasons for you to consider self testing and ask your physician about it. Similarly, these same reasons should prompt physicians to make you aware of the possibility to do INR self testing.

## 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.

Appropriate training and consistent quality control of the instrument are key for INR self monitoring to be safe and effective for you.

## 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.

The instruments are small and light, weighing only between 5.3 and 28.8 ounces. For INR testing, only a small amount of blood needs to be applied to a test strip (for CoaguChek®XS and INRatio®) or a cuvette (for ProTime®), only one small to large blood drop. 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.

When trying to decide 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 (IDTF);
- support and education services provided by the company making the instrument or distributing it;
- amount of blood needed for the test strip or cuvette (10 microliter for CoaguChek®XS; 15 microliter for INRatio®; 27 microliter for ProTime®);
- ease of operating the instrument;
- Weight of the instrument may matter to you especially if travelling frequently.

## Do INR home monitoring instruments give reliable INRs?

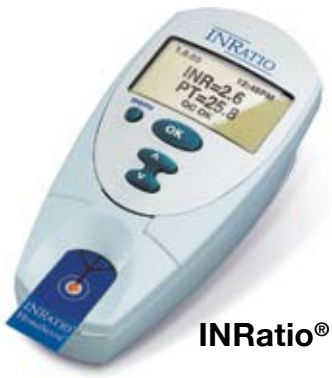
- Yes. INR values obtained with finger stick home monitoring devices are typically very well reproducible and correlate well with INR determinations obtained from blood sticks from a vein and tested in a laboratory. However, INRs above 4.0, discrepancies to INR values obtained with other test methods 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. 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.

## Do insurance companies pay for home monitoring instruments?

- Medicare only pays for these instruments and the testing materials needed (test strips or cuvettes) if the patient is on warfarin because of a mechanical heart valve replacement. Medicaid does not have the same reimbursement guarantees. Medicare does not pay if you are on warfarin for deep vein thrombosis (DVT), pulmonary embolism (PE), irregular heart beat (atrial fibrillation), or other reasons.


**ProTime®**




**INRatio®**

**CoaguChek®XS**

- Other insurance carriers may or may not pay for instrument and testing materials. Some companies pay for them upon submission of the first insurance claim; others may initially deny payment but later agree to pay, if you are persistent and explanatory letters are written (by you and/or your health care provider) and phone calls made.

- CMS (Centers for Medicare and Medicaid Services) is presently considering whether they should expand coverage for these instruments to all patients on warfarin, no matter what the reason is for being treated with warfarin (reference 6). A CMS decision is expected in the next few months.

## 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 prescription for it;
- will need to be available for the continued oral warfarin dose adjustment;
- is medically responsible for your anticoagulation management.

Once a prescription has been written you can contact one of the companies that can help you obtain an instrument (table 2). They are called "independent diagnostic testing facilities" (IDTFs) and are specialized in:
- checking with the insurance companies whether they will pay for the instrument and testing materials;
- filling out the necessary insurance paperwork for you;
- providing you with the instrument and testing materials;
- teaching you how to use it;
- be available to you in the future for answering any questions or assisting you if problems with the testing device arise;
- Some of the IDTFs also have software and methods to help track your INR results and communicate the results to your health care provider.

*Continued on page 6.*

**Table 1: FDA Approved INR home monitoring instruments**

| *Name of Instrument* | *Company* | *Website* | *Phone Number* |
|---|---|---|---|
| CoaguChek® XS | Roche | www.coaguchek.com | 800-852-8766 |
| INRatio® | HemoSense | www.hemosense.com | 877-436-6444 |
| ProTime® | ITC | www.protimesystem.com | 800-631-5945 |

**Table 2: Companies that assist patients in getting an INR home monitoring instrument**

| *Name of company* | *Supported instruments* | *Website* | *Phone number* |
|---|---|---|---|
| In the U.S. | | | |
| BloodRights | INRatio® | www.bloodrights.com | 877-735-3837 |
| QAS | INRatio®<br>Protime®<br>CoaguChek® | www.qualityassuredservices.com<br>www.ptinr.com<br>www.protimetest.com<br>www.coumadintest.com | 800-298-4515 |
| Raytel | INRatio®<br>Protime® | www.inrselftest.com | 800-295-3530 |
| Tapestry Medical | CoaguChek® | www.tapestrymedical.com | 877-262-4669 |
| Zycare | INRatio®<br>Protime® | www.zycare.com | 919-419-7228 |
| In Canada | | | |
| ManthaMed Inc | INRatio® | www.manthamed.com | 905-814-1040 |
| QAS | Protime® | www.ptinr.com<br>www.qualityassuredservices.com | 800-298-4515 |
| Sorin | ProTime® | www.sorin.com | 800-387-4563 (Western Canada);<br>800-268-6552 (Eastern Canada) |

# Dear Friend of NATT:

Thanks to your continued generosity, NATT has made extraordinary progress in promoting awareness among patients, health professionals, and the general public about blood clots and their risks. Since NATT's inception over four years ago, NATT has convened Patient Education Seminars in cities across America. We have stimulated media coverage wherever we go – the beginning of a "wake-up call" to America about the burden of 900,000 venous thromboembolisms (VTE) per year and almost 300,000 deaths.

The added tragedy is that most of these clots and deaths can be prevented. Prevented in the 49 year-old woman in Minneapolis who is having hip replacement surgery; prevented in the 65 year-old Vietnam Veteran from Los Angeles undergoing cancer treatment.

NATT's accomplishments in patient and public education are widely recognized, and most recently by the prestigious U.S. Center for Disease Control and Prevention (CDC). Last month CDC awarded NATT two, year long grants to promote health and wellness among people with clotting disorders and to train health professionals. This will go a long way in our mission to prevent thrombosis, but so much more is needed.

When designating your year-end philanthropic contributions, please consider supporting NATT and its advocacy for thrombosis and thrombophilia awareness and education. All gifts make a difference and can be sent in the enclosed self-addressed envelope.

**THANK YOU!**

## Letter from the President

*Continued from page 1.*

erage of home PT testing to patients with mechanical heart valves who are on warfarin. Medicare received a request to reconsider this policy and expand the population eligible for coverage of home testing to all patients on warfarin. In response to the request, Medicare initiated a review of their current standards.

As part of this process, Medicare solicited comments from the public and NATT submitted a statement strongly endorsing the request. Medicare expects to make a final decision either late this year or in the first quarter of 2008.

A positive decision to expand coverage is important not only for Medicare beneficiaries but also will send a strong message to other health plans, encouraging them to follow the government's lead. For more information on what Medicare is doing, go to www.cms.hhs.gov.

## INR Self Testing *Continued from page 5.*

### What can I tell my health care provider if I am interested in INR self testing?

Your health care provider may be hesitant for you to use an INR home monitoring instrument. He/she may feel left with the work and hassle of phone calls dealing with INRs that have been tested by you at home, giving medical recommendations over the phone, but not receiving appropriate reimbursement for these services. This is a valid concern if you are on an oral anticoagulant for reasons other than a mechanical heart valve and your insurance is through Medicare/Medicaid. However, some other insurance carriers have started to cover such services, even if you are on a warfarin for DVT, PE, irregular heart beat and other reasons. CMS is also presently discussing to expand coverage of home INR testing to indications other than heart valve replacement. A decision is expected early in 2008. At this point, it is probably best for you to:

- discuss your interest in using a home monitor with your health care provider;
- talk to your insurance provider and inquire about their approach to coverage for the instrument, the testing materials (strips or cuvettes) and the health care provider's services.

The easiest route may, however, be to utilize the experience of the IDTFs to help you and your physician navigate the reimbursement issues.

### PATIENT RESOURCES

- www.ismaap.org
- www.nattinfo.org
- www.fvleiden.org
- www.clotcare.com
- www.acforum.org

### REFERENCES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4. *Gardiner C et al. Patient self-testing is a reliable and acceptable alternative to laboratory INR monitoring. Br J Haematol. 2005;128:242-7.*
5. *Perry SL et al. Point-of-care testing of the international normalized ratio in patients with antiphospholipid antibodies. Thromb Haemost. 2005 Dec;94(6):1196-202.*
6. www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=209


### 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

# The Other Side of Nursing

*By Christa Larson, Norwell, Massachusetts*

My name is Christa and I have been a cardiac nurse at South Shore Hospital in S. Weymouth, MA for the past 15 years. My story is not from any of my many years of working in the medical profession but rather of the challenges I came across from the other side of nursing, as the patient. I have been a patient before, conquering bone cancer, rheumatoid arthritis and lupus and the many aches and pains that come along with these diagnoseses and treatments and I consider myself a fighter. I was being passed from doctor to doctor and being put on many different medications and treatment plans, even chemotherapy, and still I felt no better.

It was two years ago that I had the scare of my life. I became the patient again. I was on the other side of the hospital bed now. I could not breath and the pain in my chest was unbearable. I was diagnosed with multiple pulmonary emboli and blood clots in my legs. I was told that I was lucky to be alive. What else could possibly happen to me? It was then that I was taken seriously about my complaints. It was then I tried so hard to understand why this was happening to me and I feared the unknown. My medical background was crushing in on me because I knew all the "possible" things that can happen from blood clotting disorders and lowered immune systems. I felt helpless and out of control. My life was taken over by frequent blood work, doctors visits and blood thinners. Never mind all the side effects. I was determined not to let all this control me or my lifestyle.

The hardest part was to learn to step back and take care of myself first. That is not as easy as it sounds. I was always the care taker, the nurse to my patients and my family. I was always the nurse telling my patients how to make important healthy lifestyle changes. Now it was the other way around. I had to get back on my feet and stop trying to understand why this happened to me, but instead I had to learn ways to accept the new challenges of living with a clotting disorder.

I cut back on my work load at the the hospital. I came off the night shift and changed many of the activities in my life. My diet had to change in order to get the maximum effect of my Coumadin®. Sometimes daily activities, meals, travel and health all depended on how high and low my INR results were. Daily wardrobe depended on how badly I was bruised from lab draws and effects of the blood thinners. I frequently had to wear sunglasses to cover up the broken blood vessels in my eyes. I looked like a battered person. I can only imagine what my patients thought. But that is the life of a person on Coumadin®. I certainly knew the Coumadin® was working.

The hardest hurdle to overcome was the dreaded lab work. Difficult veins to draw blood, frequent long waits in the clinic and endless days waiting for the INR results to finally get back

to me. It could be two days before test results came back and my Coumadin® was adjusted . Again, I felt out of control. I did some research on the computer and looked into home INR monitoring systems. I purchased a Protime Microcoagulation System with the help of my medical insurance company and doctor. I can now check my own INR at home with a simple finger stick and instantly have results. No more waiting or multiple attempts to find a vein at the clinic. I call the results in to the nurse representative for the home monitoring system and she in turn notifies my doctor. My Coumadin® is adjusted instantly. I find that the values of finger sticks are accurate and dependable. I would highly recommend home INR testing to anyone on Coumadin® or blood thinners. I finally got the control back in my life again.

Today I look back at all I have learned and see a whole new outlook on the medical profession and my nursing career. It was an eye opening experience being the patient instead of the nurse. Recovery from the hospital goes far beyond the hospital stay and follow up with your physician. When I get a patient newly diagnosed with a blood clotting disorder and started on blood thinners I can sympathize with their needs, concerns and fears. I can offer guidance not only as a nurse in the medical profession but also on a more personal level. There is still so much to learn about thrombosis and all the complications associated with it. I truly believe it is all in how you accept the diagnosis and move beyond it with a positive outlook. It is up to the medical professionals to educate the patient about clotting disorders and treatments for it. But sometimes it is up to those individuals who have the disorder to increase awareness to others so you do not feel like you are struggling alone with the challenges of clotting disorders.We can survive this and take control of our lives at the same time. I did.

# *Calendar of Events and NATT Happenings*

What events are happening in your area? Find out about the different thrombosis and thrombophilia related events and activities happening in your community. Also, please check our website for more details at www.nattinfo.org/commandevents.htm.

## MARCH is DVT Awareness Month

**NATT Seminar in Chapel Hill, NC**
**March 1, 2008**
Patient education seminar. Hilton Hotel RDU Airport, Durham, NC. Details to follow in January 2008 on www.nattinfo.org.

**2008 Newsletter Topics**
Women's Health and Blood Clots, Cancer and Blood Clots, Psycho-Social Impact: After the Clot, Blood Clots and the Military.

Have a story you'd like to share with NATT that relates to one of these topics? Send an email to nattinfo@yahoo.com!

Know someone who would like to receive NATT's newsletters? Go to www.nattinfo.org to simply sign up.

*The NATT Board of Directors, Washington D.C., June 2007. Front row (from left to right): Stephanie Rice Davis, Pat Koppa, Arla Johnson, Elizabeth Varga, Lori Preston, Lynn Levitt. Back row: Randy Fenninger (half hidden), Alan Brownstein, Stephen Kinsman, Ed Stransenback, Stephan Moll. Not present: Mark Jablonski, Kathy Early and Thomas Hogan.*

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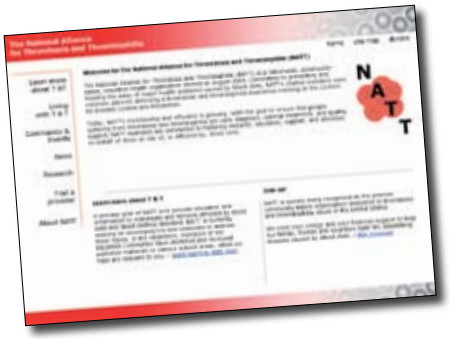

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