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From: Gordon McPherson
Sent: Thursday, April 17, 2008 4:38 PM
To: Cochrane FD (Fergus)
Subject: Petition PE1056

Mr Cochrane

Thank you for the opportunity to comment on the responses from NHSQIS,Scottish Government and The National Screening Committee to your letters of January 2008.
If we may we would comment as they were received by yourself.

PE1056G.... Response from NHSQIS dated 28 February and also response dated 16 April to e-mail from ourselves dated 28 March (copy enclosed)

We are pleased to note that "All Health Boards have indicated their agreement with the content of the letter from The Chief Medical Officer and Sir Graham Teasdale dated 26th January by taking action in response to the letter" We would hope that,in say 6 months,a further audit will be carried out to ensure that "policies have either been reviewed and amended or are undergoing review" Although after 6 months it would be hoped that a review would have been completed and all Health Boards are indeed working to the same Protocol and Procedures.
We await the collated information from all Health Boards noted in para.4 letter dated April 16th during May/June 2008.

PE1056H....Response from The Scottish Government dated 5th March

A copy of our e-mail dated 19th March is enclosed to explain the comment made in para.3 page 2 of the letter dated 5th March. We felt,and still feel, that the Scottish Government should be issuing information leaflets and not a Charity (A copy of the General Information leaflet is enclosed for reference)
The balance of the Scottish Government response supports the response from NHSQIS noted previously.

PE1056I....Response from The Chief Medical Officer,Dr Harry Burns,regarding stance of National Screening Committee.

We are pleased at the fact the National Screening Committee will be reviewing the situation regarding screening for factor V Leiden mutation during 2008/2009.
Para. 3 of Dr Burns letter is confusing as he is implying that The American College of Medical Genetics Consensus is the Guideline to whether the National Screening Committee will carry out screening in the U.K.
We put forward the fact that The World Health Organization set up a standard,with the assistance of the National Institute for Biological Standards and Control (NIBSC) in the United Kingdom,in collaboration with colleagues from the National Quality Assessment Schemes for Blood Coagulation and the Royal Hallamshire Hospital in Sheffield,U.K.,for the genetic testing for Factor V Leiden.We

enclose a copy of the World Health Organization report and would draw attention in particular to para.3,4,7,9,and 10.

As per our e-mail of January 14th 2008 (doc PE1056/F) we are pleased with responses received,but would ask that policies are put in place to ensure audits are carried out to ensure continued adherence to existing and new Guidelines.

Gordon,Jane and Steven McPherson

Alan McGhee

From: Gordon McPherson
Sent: 28 March 2008 09:43
To: 'david.steel@nhs.net'
Subject: Management of Deep Vein Thrombosis (DVT)

Dear Dr Steel

Public Petition PE1056

I am writing to ask if,now that the deadline for responses to the Chief Medical Officer`s letter of 26th January 2008 has been reached,you have received responses from all Health Boards in Scotland.
If you have received responses may I enquire if all Health Boards are in agreement with the content of the letter regarding Management of Deep Vein Thrombosis (DVT)?.If so can you advise when the guidelines therein will be implemented and adopted by the Health Boards?
Are there any Health Boards who have not responded or have responded negatively to the said letter from the Chief Medical Officer?
At what date can it be assumed that all Health Boards will be adhering to the same guidelines for DVT i.e. there will no longer be disparage of Protocol and Procedures relating to DVT throughout Scotland?
My reason for writing and asking the above questions is that the Public Petitions Committee will be further considering Petition 1056 and I asked for an extension to allow me to raise the above questions with yourself.A request that Fergus Cochrane,the Clerk to the Committee agreed.
I would be grateful if I could receive a response by 17th April to allow my response to the questions raised and further evidence to be submitted by 21st April.

Regards

Gordon McPherson

28/03/2008

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NHS
Quality Improvement Scotland

Mr G McPherson

April 16, 2008

Dear Mr McPherson

Thank you for your email of 28 March. We have now received responses from all NHS Boards.

All Boards have indicated their agreement with the content of the letter from the Chief Medical Officer and Sir Graham Teasdale dated 26 January 2008 by taking action in response to the letter. They have all reported that their policies have either been reviewed and amended or are undergoing review at this time, in collaboration with a range of healthcare professionals.

Evidence based guidelines form the basis of local policies and protocols, and as you know the SIGN guidelines are currently being revised. This will further help NHSScotland to achieve consistency in approach.

NHS QIS is currently collating the information received from Boards and will provide a detailed response to our Board and to the Chief Medical Officer on the position across NHSScotland in May. This will also be provided to NHS Board Chief Executives to share examples of good practice.

We will be delighted to share this with you.

With kind regards

David R Steel
Chief Executive

Glasgow Office, Delta House
50 West Nile Street, Glasgow G1 2NP

Gordon McPherson

From: Gordon McPherson
Sent: 19 February 2008 08:49
To: 'Craig.Bell@scotland.gsi.gov.uk'
Cc: 'Nicola.Sturgeon.msp@scottish.parliament.uk'; 'FirstMinister@scotland.gsi.gov.uk'
Subject: Katie McPherson DVT

Good Morning Craig

We were disappointed to read the content of the e-mails of yesterdays date between Lifeblood and The Scottish Government regarding the production of the general Information Leaflets covering Signs and Symptoms of DVT. Right from the beginning we have always voiced the opinion that the production of such a leaflet should be the responsibility of the Government and not that of a Charity.
We are disappointed at the apparent break-down in communication which has caused the situation where although we as a family submitted the draft of the leaflet,which as you know was not the easiest of projects we have worked on due to the fact that in our opinion Lifeblood do not understand the variances of the Scottish language regarding the different use of some words against what Lifeblood perceives the definition of the words to be in England.
At the outset of our wish to raise awareness of DVT,we were pleased to see that The Scottish Government apparently wished to assist us in what we are trying to achieve,namely the reduction of deaths due to this condition,now we are as we said earlier disappointed at this delay in producing the leaflet,distributing the leaflet and also the raising of awareness of existence of the leaflet.
A year ago this month we attended a meeting in Glasgow along with NHS24,NHSSCOTLAND,SIGN and Scottish Consumer Council and the impression was that once the draft was submitted to the Scottish Government then the Scottish Consumer Council would take over the printing,publishing,marketing and distribution of the leaflet,i.e.the leaflet would be a Scottish Government Information Leaflet not yet another leaflet from a charity.It was being done that way to carry more weight.
After 5 years since Katie's death we actually felt things were reaching a conclusion.Unfortunately this incident,i.e. the apparent breakdown in communication regarding the Information Leaflet,leads us to conclude we are no further on.
Can you please advise what The Scottish Government intends to do regarding the raising of awareness of DVT.Are you intending to do anything,or has the last 5 years just been a waste of our time and effort,because no matter how hard we as a family push for change,If the Scottish Government do not respond then it is pointless pushing any more.

We look forward to hopefully a positive response

Gordon,Jane & Steven McPherson

LIFEBLOOD
THE
Thrombosis
CHARITY

DEEP VEIN THROMBOSIS (DVT) ADVICE LEAFLET
Are You At Risk of Getting a Blood Clot?

This leaflet is important reading for anyone who :

1 *Is pregnant*
2 *Is over 40 years old*
3 *Is not mobile*
4 *Is going into hospital*
5 *Has cancer*
6 *Is using the combined oral contraceptive pill (OCP) or hormone replacement therapy (HRT)*
7 *Is contemplating long-distance travel*
8 *Is obese*
9 *Has a family history of DVT*
10 *Has had a previous DVT or pulmonary embolism*
11 *Has thrombophilia - blood changes that predispose to DVT*
12 *Has a plaster cast*
13 *Has recently had surgery*
14 *Has no previous history, but has symptoms of DVT*

If you can tick more than one of these boxes your risk of having a thrombosis is greater than average and you should seek medical advice.

What is a DVT?

A *deep vein thrombosis (DVT)* is a clot which has formed in a deep vein, usually in the leg. It most commonly forms in the calf, but can also form in the thigh or in deep veins in other parts of the body. Deep veins are the larger veins that go through the muscles (not the veins you can see just below the surface of the skin) and carry blood towards the heart.

Why do blood clots form in the veins?

Blood normally flows quickly through the veins helped along by movement of the muscles which squeeze the veins and does not usually clot. Occasionally thrombosis sometimes occurs for no clear reason; however, there are certain circumstances which increase the risk of having a DVT e.g. immobility and damage to the vein walls, especially in people who may be more susceptible through genetic history.

What makes you more at risk of developing a DVT?

Pregnancy increases the risk of clotting and about 1 in 1000 pregnant women develop a DVT.
Age: Older people are more likely to have a DVT, particularly if they are immobile or have a serious medical condition such as cancer.
Immobility: Lack of mobility causes the flow of blood in the veins to slow leading to an increased likelihood of clotting.
Going into hospital: A surgical operation which lasts more than 30 minutes increases the risk too, especially in people more susceptible to DVT.
Cancer: Cancer and some chemotherapy drugs can damage the veins. Cancer patients are often less mobile, also increasing the chances of developing a DVT.
"The Pill" or Hormone Replacement Therapy: The oral contraceptive pill (OCP)and hormone replacement therapy (HRT) that contain oestrogen can increase the risk of a DVT.

Long distance travel: Long journeys by plane, train, or car cause a minor increase in the risk of DVT.
Family history: Some inherited conditions, such as Factor V Leiden, which causes the blood to clot more easily, can lead to an increased risk of DVT.
Obesity: Being significantly overweight increases your chances of developing a DVT.

What are the symptoms of a DVT?

The typical symptoms of DVT are pain and tenderness in the calf with a sensation of heat and swelling sometimes associated with skin discolouration, usually in the calf but sometimes the whole leg can be affected, particularly in pregnancy. However, 80% of DVTs produce no symptoms at all and are only diagnosed if a complication such as *pulmonary embolism* occurs.

What tests will I have?

It is often hard for a doctor to be sure of a diagnosis of DVT just from the symptoms, as pain and swelling in the calf can be caused by other reasons such muscle strain or infection for example. If you have a suspected DVT you will normally be advised to have some tests done urgently to confirm the diagnosis. Two commonly used tests are:

a. **The D-dimer test:** This is usually positive in DVT but can be positive in other conditions.
b. **Ultrasound scan:** An ultrasound scan detects a clot in a vein and is used in most patients.

These tests are not 100% conclusive as there is no definitive test for DVT and more detailed tests may be necessary and may include for example a contrast venogram where dye is injected into the vein and then x-rayed to see if the blood flow is interrupted.

Is a DVT serious?

It can be a very serious and potentially life-threatening condition.

Pulmonary embolism (PE): This is when part of a blood clot breaks off and travels in the blood stream. It is called an embolus. The clot will be carried up into the larger veins, through the heart, and becomes lodged in the lung. This is called a pulmonary embolus (PE). Symptoms can include shortness of breath, either sudden or of gradual onset, chest pain which can be worse on breathing in and sudden collapse. The symptoms of DVT (pain, tenderness and swelling) may also be present.

What is the treatment for a DVT?

Treatment for DVT is anticoagulation with either heparin or warfarin, although there will be some new anticoagulant drugs soon. Heparin works by making the body's natural blood thinner work better. Warfarin takes a few days for the warfarin tablets to work fully and so heparin injections are often used for the first few days after diagnosis. You will need regular blood tests whilst you are on warfarin to ensure that the level is right - too much and you risk increased bleeding and too little may not stop more clots forming. If you are pregnant regular heparin injections may be continued in place of warfarin treatment. The length of time you will continue on treatment is usually 3 to 6 months. However, some people continue to have an increased risk of DVT and will need to stay on anticoagulation in the long-term. Your doctor or hospital specialist will advise you accordingly. You may also be advised to use compression stockings to compress the leg veins, which stimulates blood flow.

Preventing or reducing the risk of a DVT

Avoid prolonged periods of immobility such as sitting in a chair for many hours. If possible get up and walk around now and then or, even better, take regular exercise, for example a regular walk for 30-60 minutes a day. When going on long trips on planes, trains or in the car, get up and walk around every so often and perform calf exercises when sitting. Just being unwell and in hospital if you are undergoing surgery, particularly abdominal or orthopaedic, increases your chances of a DVT. You may already be at a higher risk just by your family medical history; this can be checked out by a simple blood test, which may show you have a genetic susceptibility to DVT.

This leaflet is not intended to be a comprehensive patient guide. If in doubt always seek additional information/advice from your GP, NHS 24 (08454242424) or your hospital specialist

This leaflet was produced in conjunction with Lifeblood: The Thrombosis Charity. Further information on venous thrombosis and other thrombosis-related topics and links can be found on their website at www.thrombosis-charity.org.uk

This leaflet was created in memory of Katie McPherson, who tragically died of a pulmonary embolism at the age of 23

World Health Organization

First international standard for common genetic test approved by WHO

17 NOVEMBER 2004 | GENEVA -- The first international standard for a human genetic test was approved by the World Health Organization (WHO) today. Use of the standard will help to improve the accuracy and quality of laboratory results worldwide from a frequently used genetic test. This test identifies a genetic predisposition to thrombosis -- a potentially life-threatening blood condition -- and could therefore enable people to take preventive measures.

"Establishment of the first international standard for a genetic test is an important milestone. Genetic testing procedures are playing a vital and growing part in clinical medicine. This new standard will help to ensure that the tests are giving accurate results worldwide," said Dr David Wood, Coordinator of Quality Assurance and Safety of Biologicals at WHO.

The newly established standard, formally called an International Reference Panel, relates to the testing of patients for a particular genetic mutation known as Factor V Leiden. Discovered in 1994, this mutation is one of the most common genetic risk factors for venous thrombosis (blood clot), and is involved in 20-40% of all cases. Factor V Leiden induces a defect in the natural anti-coagulation system.

The test for Factor V Leiden is one of the most frequent genetic tests carried out in clinical laboratories. It determines the presence or absence of the mutation, which has been shown to result in a seven-fold to 80-fold higher risk of thrombosis depending on whether the individual carries one or two copies of the gene respectively

The new standard was agreed at the 55th session of one of WHO's longest-standing committees, the WHO Expert Committee on Biological Standardization (WHO ECBS) which is meeting from 15 to 18 November in Geneva. It is composed of ten global experts from academia, industry and national regulatory authorities, as well as 25 advisors.

One of WHO's key functions, specified in its Constitution, is to develop, establish and promote international standards with respect to biological and other products. WHO is the world authority on biological standards, and has established more than 300 standards covering vaccines; blood products; therapeutic biological products, such as insulin; and diagnostic tests, such as those that detect HIV in a blood product.

Researchers are currently investigating whether or not there is a link between air travel and deep vein thrombosis. This is one example of a condition which may be more likely as a result of the Factor V Leiden mutation. Having information about their genetic make-up could allow travellers at risk to take additional precautions.

The standard for Factor V Leiden was developed by WHO partner and the leading international laboratory for biological standards, the National Institute for Biological Standards and Control (NIBSC) in the United Kingdom, in collaboration with colleagues from the clinical National Quality Assessment schemes for Blood Coagulation and the Royal Hallamshire Hospital in Sheffield, UK.

"This is an important step in genetic medicine. I am delighted that the NIBSC has taken the international lead in developing the first WHO standard for a genetic test. This will provide information on susceptibility to venous thrombosis, and ultimately will deliver clinical benefits for people at increased risk of developing thrombosis," said Professor Gordon Duff, Chairman of the NIBSC Board. NIBSC is currently developing several other new reference standards to support testing for a range of other clinically important genetic characteristics.

DNA-based genetic testing offers enormous promise for improved disease management by giving doctors better information about patients on which to base diagnosis and decisions about treatment or counselling. It also offers the potential for better targeting of therapies and drugs to those patients most likely to benefit. Hundreds of different genetic tests are currently available.

A recent study estimated that in the European Union alone more than 700 000 genetic tests were performed in 2002; and found that at least 700 laboratories and 900 clinical centres in Europe were carrying out genetic tests.[1] Though the exact number is unknown, it is likely that millions of genetic tests are being carried out worldwide each year.

Setting standards is particularly critical as genetic testing has expanded to more and more laboratories throughout the world. Genetic testing must be done consistently in all laboratories around the world and to high quality standards in order to give confidence in the results.

A standard for a biological product is essentially a yardstick (either on paper or in an ampoule, in which there is a specially prepared

reference material) which enables laboratories around the world to compare results. The work of the WHO Expert Committee on Biological Standardization contributes to global public health in a fundamental way since the written guidance and reference preparations established on its recommendations define international technical specifications for the quality and safety of biological medicines and in vitro diagnostic procedures.

Once a WHO collaborating laboratory physically creates a standard, it is typically evaluated by 15 other top laboratories. The WHO ECBS reviews all the laboratory data and decides to approve or not the proposed standard for international use. The rigorous assessment of the standard for the Factor V Leiden genetic test was carried out by an international panel of investigators in conjunction with the International Society on Thrombosis and Hemostasis (ISTH).

The announcement of the first international standard for the genetic diagnosis of the Factor V Leiden mutation is a significant step forward in the assurance of high quality genetic testing. In the future, the WHO ECBS will likely approve standards for other genetic tests, the increasing use of which will enable prevention and early treatment of genetic disorders, improving quality of life.

[1]Ibarreta, D., Elles, R., Cassiman, J-J., Rodriguez-Cerezo, E., and Dequeker, E. Towards quality assurance and harmonization of genetic testing services in the European Union. *Nature Biotechnology*, 22, 1230-1235 (October 2004).

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