Government Response to the House of Commons Health Committee Report on the Prevention of Venous Thromboembolism in Hospitalised Patients – Second Report of Session 2004–05

Presented to Parliament by
the Secretary of State for Health
by Command of Her Majesty
July 2005

Cm 6635

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This Command Paper sets out the Government's response to the Health Committee Report on the Prevention of Venous Thromboembolism in Hospitalised Patients.

The Government welcomes the Committee's report as an important milestone for Government to get a clear insight into the issue of preventable deaths from venous thromboembolism (VTE) in hospitalised patients and to ensure there is an effective and systematic approach to tackle VTE in the future.

Patient safety

Patients have a right to expect that every effort is made to ensure that their care and treatment is both safe and effective. We have already achieved a great deal with the spread of clinical governance throughout the NHS. Clinicians and managers have worked hard to achieve a NHS that is dedicated to creating a modern, caring, high-quality, patient-centred service which puts the needs of the public first.

We recognise that there is a need to ensure that there are strong safety mechanisms embedded in the working practices and systems to minimise the chances of an adverse event occurring and the risk to patients. In 2000, the report *An organisation with a memory*, published by the Department of Health, set out the findings of a working group, chaired by the Chief Medical Officer, which reviewed learning from adverse healthcare events in the NHS. The report concluded that the NHS has no consistent system for detecting, reporting, analysing and learning from these adverse healthcare events and made ten recommendations to improve safety mechanisms in the NHS. These include an overall system for analysing and disseminating lessons, better use of existing information and action to ensure quick implementation. We believe that clinical guidelines are an important part of improving patient safety. Added to this is effective implementation of such guidance, including monitoring the improvement in outcome, in order to embed a high-quality patient safety approach for venous thromboembolism.

VTE in hospitalised patients

The Government agrees with the Committee's statement that much more needs to be done and that there are currently far too many preventable deaths from venous thromboembolism in hospitalised patients. The Committee's estimation of 25,000 deaths a year due to VTE is a serious issue which requires rapid and comprehensive action and we welcome the advice and information the Committee has provided to help the Government tackle this issue.

Government action

We recognise that there is no systematic approach to identifying and treating those patients at risk from VTE in hospitals and that there is significant room for improvement.

Clinical knowledge is advanced in this area, therefore spreading good practice is a key next stage. As a first step it is important to take stock of all the work which the Government and the NHS have done to date before building on this further. For example, there are already some authoritative guidelines on VTE and further guidance is being developed.

We are also commissioning guidelines from the National Institute for Health and Clinical Excellence (NICE) and promoting demonstration thrombosis committees. We will also ask the Healthcare Commission to inspect hospitals for compliance with best practice. But the key will be for clinical staff locally to take steps to identify and systematically treat those at risk of VTE. More immediately, the Chief Medical Officer has written to all doctors to remind them of the guidance that does exist and we will ensure that clinical leaders are fully engaged in developing future and more effective guidelines.

It is not just people at risk from developing VTE in hospitals that we need to ensure are subject to robust risk assessment but also people with existing VTE conditions.

As the Committee notes, patients can often develop a deep vein thrombosis after being discharged from hospital.

As part of the Government's approach to VTE we therefore intend to develop a comprehensive strategy that includes both treatment and prevention. At the heart of this we feel it is essential to set up an independent expert working group inviting all the key stakeholders (Royal Colleges, relevant associations and societies, the National Patients Safety Authority, the Healthcare Commission, the National Institute for Health and Clinical Excellence and patient representation). We will ask the expert working group to:

- quickly assess the guidance that is available;
- consider the work already being done on VTE such as the Venous Thromboembolism Registry and the existing thrombosis committees in hospitals in England;

- recommend what action can be taken immediately, in the medium term, and what can wait for the NICE guidance on the prevention of venous thromboembolism in patients undergoing orthopaedic surgery and other high-risk surgical procedures in 2007. NICE's consultation on the first draft of the VTE clinical guideline will take place in 2006. Our plans are to establish an independent expert working group as soon as possible. We are aiming for the first meeting to be in the autumn with a view to making their final recommendations by summer 2006 at the latest and earlier if possible;
- specifically consider the appropriateness of promoting more widely existing guidance on the use of mechanical devices (foot-pumps) or pharmacological preparations (namely heparin or other anti –Xa agent) and to clarify the issue of use of aspirin;
- make recommendations on how to develop the existing thrombosis committees into demonstration sites looking at prevention as well as treatment of VTE in hospitalised patients and consider how this approach can be rolled out nationally including the appropriate resourcing at both local and national level;
- consider better monitoring systems to improve data on deaths from VTE in hospitalised patients.

In summary we are taking the following action to deal with this serious issue:

- The Chief Medical Officer has written to all doctors to remind them of the guidance that does exist and we will ensure that clinical leaders are fully engaged in developing future and more effective guidance.
- We will establish an independent expert working group to quickly assess the guidance that is available; consider the work already being done on VTE such as the Venous Thromboembolism Registry and the existing thrombosis committees in hospitals in England; recommend what action can be taken immediately, in the medium term, and what can wait for the NICE guidance.
- Once the independent expert working group has assessed the current guidance on VTE, the Department will ask that the Healthcare Commission look to seek conformity with this good practice guidance and signal that it intends to include VTE as part of its annual inspection guidance, particularly core standard C2 and developmental standards D1 and D2 as set out in *Standards for Better Health*.*
- NICE will be publishing its first consultation on its draft VTE clinical guidelines in December 2006. The final guidance is due in summer 2007.
- We will discuss with NICE the possibility of producing a separate clinical guideline covering the groups currently excluded from the scope of this guidance – medical patients and patients undergoing low-risk procedures who are themselves at high risk from VTE.
- We will ask the independent expert working group we intend to establish to look at the experiences of the existing thrombosis committees and the current Blood Transfusion team arrangements with a view to mainstreaming this work into existing structures and to make recommendations on identifying appropriate resources needed to underpin their development.

**Standards for Better Health*, Department of Health, 2004.

- The Chief Medical Officer will be writing to the relevant bodies involved in the curricula for undergraduate and postgraduate medical education, including NHS Trusts, asking them to consider any changes they can make as a result of the Committee's report.

We will now respond to each of the Committee's recommendations in the order they were made.

1. We are concerned that the number of post mortems being performed has decreased since Alder Hey. As a result the true cause of death is not being determined in many cases. We recommend that the Department encourage the increased use of post mortems where appropriate. This would enable accurate identification of the cause of death in more patients and more reliable assessment of the current incidence of death through VTE, thereby providing a base from which to monitor progress.

The Department for Constitutional Affairs is leading on reforming the coroner and death certification service and the Department of Health is working closely with them on this. Proposals for reform came out of the recommendations of the Independent Fundamental Review of coroner and death certification systems and from the Third Report of the Shipman Inquiry.

With this new framework we will also aim to encourage pathologists and clinicians to work more closely together to ensure that the causes of deaths are better understood and that this knowledge is used to benefit future patients and improve standards of treatment and care. Whilst this already happens in many hospitals, we will continue to champion best practice to encourage NHS Trusts to review their procedures so that best practice in this important and sensitive area is followed.

There is also a programme of work about improving communications with bereaved families around post mortems (and improving support for bereaved families generally). The Department has produced a DVD as a training tool for the NHS called 'Respect for the dead, care for the living', which explains the differences between a consented post mortem and a coroner's one. All coroners have been given copies.

The newly formed Human Tissue Authority's (HTA) consultation on codes of practice will run from 12th July to 4th October 2005. This includes codes of practice on post mortem and consent.

The removal, retention and use of human tissue and organs is important for the public good through transplantation, medical and scientific research and education. The aim of the HTA is to create an environment where the public can have confidence in the framework in which these activities take place. Consent is central to the legislation and the code of practice addresses communication and consultation with patients and families across this range of activities. The HTA would hope therefore that, as confidence builds, this should lead to more consented post mortems. This should in turn increase the accuracy of identifying deaths from VTE.

2. Many surgeons and physicians are not aware of the incidence of VTE, especially in recently discharged patients and, therefore, are not administering thromboprophylaxis. We recommend that when a patient who has recently been discharged from hospital develops VTE the original surgeon and/or physician should be notified by letter of the incident. Notification should be made by either the primary care physician treating the recently discharged patient, or if the patient is re-admitted to hospital, by the secondary care physician. Notification should also be made in the case of death through PE of a recently discharged patient.

We will be asking the independent expert working group we intend to establish to look at raising awareness of the incidence of VTE, to review what guidance is available and how best practice and awareness of VTE should be communicated widely within the NHS. There is already work underway in the NHS as part of treating people with a deep vein thrombosis as outpatients. We wish to build on this to ensure that both prevention and treatment issues are mainstreamed.

3. We recommend a review of the tariffs to ensure that they do not act as a barrier to the appropriate use of thromboprophylaxis.

We do not believe that the current payment by results system should prevent the use of appropriate thromboprophylaxis measures. The uplift applied to the national tariff to take account of pay and prices and other cost pressures includes provision for quality improvement in the form of efficiency savings of 1%. This is part of the 2.7% annual target for efficiency savings within the NHS for 2005/6 to 2007/8 set by the Gershon review. Of this, only 1.7% is cash releasing, leaving 1% available for quality improvements. Evidence suggests that the cost of the preventive measures is relatively low compared with the total cost of the procedures and so appropriate thromboprophylaxis measures should have a minor impact given the overall provision within the national tariff. In time, the additional costs will be reflected in the national tariff as the underlying cost of undertaking treatments change.

We do however note from existing guidelines that the use of aspirin in the treatment and prevention of VTE and the use of stockings (as opposed to foot-pumps) when used alone do not contribute to the prevention of VTE in hospitalised patients. We will therefore ask the independent expert group we are intending to establish to specifically consider the appropriateness of promoting more widely existing guidance on the use of mechanical devices (foot-pumps) or pharmacological preparations (namely heparin or other anti –Xa agent) and to clarify the issue of the lack of effectiveness of aspirin.

4. We note that the ACCP has recently produced its seventh revision of guidelines and SIGN introduced their guidelines in 1995. It is astonishing that there has been no development of national guidelines in England and Wales.

The recent guidelines produced as a result of the seventh American College of Chest Physicians Consensus Conference on Antithrombotic Therapy were developed with input by UK clinical specialists.

There is a range of authoritative advice on VTE in England and Wales from professional bodies such as the British Thoracic Society and the Royal College of Obstetricians and Gynaecologists which has issued a series of guidelines which are followed by the obstetric community. Lifeblood in their evidence to the Committee stated that *'In the UK we should congratulate ourselves on leading the world in prevention of venous thromboembolism in pregnancy.'*

Also, the British Committee for Standards in Haematology have issued guidelines on the use of Heparins, which will cover prevention of venous thromboembolism, and will be producing two additional guidelines on thromboprophylaxis (in surgery and medicine) to include mechanical methods by the end of this year.

5. The current variations in the administration of thromboprophylaxis indicate that surgeons and physicians are unaware of the extent of VTE and how readily and safely it can be prevented.

The proposed independent expert working group will be asked to assess the VTE guidance that is available as a matter of priority with a view to raising awareness of VTE amongst the profession and all relevant professional bodies.

The independent expert working group will need to take account of experience of work already being done in the existing thrombosis committees.

The Chief Medical Officer has written to all doctors to remind them of the guidelines that do exist and we will ensure that clinical leaders are fully engaged in developing future and more effective guidance.

6. We recommend that VTE and its prevention, including the implementation of, and adherence to, guidelines relating to thromboprophylaxis, counselling and risk assessment, be given more prominence in undergraduate medical education, Continuing Professional Development (CPD), and other relevant aspects of medical and paramedical training. We further recommend that the Royal Colleges bring forward proposals to this end as well as to raise awareness of the problems of VTE. In addition, NHS Trusts should ensure that all physicians and surgeons receive training about the subject. We make recommendations about the role of the Healthcare Commission in audit and implementation below.

The curricula for undergraduate and postgraduate medical education are the responsibility of the General Medical Council and the Specialist Training Authority of the Medical Royal Colleges respectively. The Postgraduate Medical Education and Training Board takes over from the Specialist Training Authority on 30 September 2005. Continuing Professional Development is a matter for individuals and their employers with support from the Royal Colleges.

In addition to our plans to raise awareness of VTE across the profession, the Chief Medical Officer will write to all relevant bodies, including NHS Trusts, asking them to consider any changes they can make as a result of the Committee's report. We will continue to encourage the profession to work in a culture which promotes new learning and change as necessary.

7. The scope of the guidelines for VTE which NICE is preparing are too limited. Many groups of patients who are at considerable risk of VTE are excluded. We recommend that NICE extend the scope of the current project to include both medical patients and patients undergoing low-risk procedures who are themselves at high risk from VTE. If NICE considers that surgical and other patients should not be covered by the same set of guidelines, we recommend that the Department commission NICE to develop guidelines for the excluded groups in parallel with its current work.

We agree with the Committee's recommendation. We will discuss with NICE the best way of taking this recommendation forward in the light of competing demands on NICE to produce a new clinical guideline to cover those groups excluded from the current scope of NICE's VTE clinical guidelines. This area of work will focus on medical patients and patients undergoing low-risk procedures who are themselves at high risk from VTE.

8. In view of the urgency of the situation that leads to more than 25,000 deaths, many of them avoidable, it is unacceptable to wait until 2007 for any attempts to reduce deaths from VTE. We therefore recommend that the currently accepted consensus guidelines are circulated by the relevant bodies including the Royal Colleges, the British Orthopaedic Association, hospital specialist thrombosis teams and Trust Drug and Therapeutics Committees to clinicians so that they can seriously consider whether to implement them immediately.

The Chief Medical Officer has written to all doctors to remind them of the guidance that does exist and we will ensure that clinical leaders are fully engaged in developing future guidance.

The membership of the independent expert working group which we intend to establish will include relevant bodies and will:

- quickly assess the (fairly comprehensive) guidance that is available;
- consider the work already being done on VTE such as the Venous Thromboembolism Registry and the existing thrombosis committees in hospitals in England;
- recommend what action can be taken immediately, in the medium term, and what would be more effectively addressed in the NICE guidance on the prevention of VTE in patients undergoing orthopaedic surgery and other high-risk surgical procedures due to be published in May 2007. The group will be asked to make its recommendations in summer 2006 – a year before the NICE clinical guidelines are due to be published. NICE will be invited to join the membership of this group to ensure there is as much relevance as possible between these two complementary processes;
- make recommendations on how to develop the existing thrombosis committees into demonstration sites looking at prevention as well as treatment of VTE in hospitalised patients and consider how this approach can be rolled out locally and nationally, including identifying appropriate resources.

9. We recommend that procedures for counselling both medical and surgical patients be supported by hospital specialist thrombosis teams and included in the VTE guidelines developed by NICE.

The independent expert working group which we intend to establish will look at the work already being done on the assessment and management of VTE in the NHS, particularly the work of the VTE Registry and the toolkit being developed as part of the Better Blood Transfusion work.

We will also ask the expert working group to consider opportunities to align prevention procedures for already being treated for VTE as outpatients or being admitted to hospital with a pre-existing VTE condition.

NICE will be invited to be part of the independent expert working group. While the expert group will assess current VTE guidance, NICE will be developing new guidelines and will consider all evidence including the Committee's report and this response.

10. We recommend that all patients, both medical and surgical, who are admitted to hospital undergo a risk assessment for venous thrombosis.

There is work already underway within the existing thrombosis committees in NHS hospitals looking at risk assessments for VTE. The independent expert working group will look at whether these committees can be extended to cover risk assessment and the prevention of VTE specifically in hospitalised patients.

11. Systems must be put in place to ensure that the NICE VTE guidelines are implemented. We reiterate the recommendations we made in our inquiry into the National Institute of Clinical Excellence in 2001–02 that the Government should: a) institute practical systems and structures to improve the NHS's capacity to implement NICE guidance, including the possibility of designated individuals within the NHS Trusts and strategic health authorities to liaise with NICE to facilitate implementation of the guidelines; and b) ensure the systematic monitoring of the implementation of NICE guidance.

In order to help the Committee we have responded to the points raised in Recommendation 11 in three parts (11, 11a and 11b).

As we said in response to the Committee's inquiry in 2001–02, we agree in principle with the recommendations on the implementation by the NHS of guidance from the National Institute for Health and Clinical Excellence.

There have been a number of key developments since we made our response to the 2001–02 inquiry aimed at tackling variations in the uptake of NICE guidance. In tackling these variations, the barriers to implementation need to be fully understood.

There is now a growing body of evidence on the uptake of NICE guidance. The National Cancer Director's report (published in June 2004) addressed variations in prescribing practice for NICE-approved cancer drugs. His report found that, whilst the use of cancer drugs generally increases following a positive appraisal from NICE, the reasons for variations are complex and do not appear to be associated with direct funding restrictions on the use of cancer drugs. The main impacts appear to be constraints in service capacity and differences in clinical practice. Issues raised in his report are being followed up. Local action is being overseen by strategic health authorities.

NICE has now established a director-level post with responsibility for implementation and has also developed its website to include a section on implementation. This gives details of current initiatives and also case studies of good practice.

On 14 June 2004, Department of Health Ministers announced a programme of action to aid faster uptake of NICE guidance. However, action to support the implementation of NICE guidance does not fall to one body alone. What is needed is a broad partnership to ensure that patients get ready access to the quality of care recommended by NICE.

The programme of action is being pursued on a number of different fronts by:

(a) the Department of Health – in aligning NICE's work programme as closely as possible to local NHS priorities and developing reports to compare local performance with national distributions;

(b) NICE – in offering advice to support local implementation, reviewing its methods for disseminating guidance to appropriate clinical audiences and developing further information for patients and patient groups; and

(c) the local NHS – in preparing and planning for implementation, assessing local uptake of guidance and using comparative information to challenge and improve local performance.

NICE guidance features both within the core and developmental standards that have been developed for the NHS and published in *Standards for Better Health*. NICE guidance on technology appraisals and interventional procedures are part of the 'core' standards. Clinical guidelines have been included within the developmental standards. The Chief Executive of the Healthcare Commission has confirmed that assessing the implementation of NICE guidance is one of its key priorities. The Commission has published its new ratings and review system which takes into account *Standards for Better Health* and therefore includes adherence to NICE guidance.

11(a). We also recommend that computer reminders are built into the electronic prescribing system of the National Programme for Information Technology to aid physicians in the prescription of thromboprophylaxis and to remind them of guidelines for the prevention of VTE.

The National Programme for Information Technology, now known as Connecting for Health, has recognised the need to provide decision support to assist clinicians in management of conditions such as venous thromboembolism. This includes access to management guidelines and the ability to provide alerts to the possible existence of underlying clinical conditions such as venous thromboembolism, or the lack of thromboprophylaxis. The appropriate functionality has been included in the specifications for Connecting for Health systems that are being implemented across the NHS in England. The pace of implementation will need to take into account local progress across the NHS and the development of appropriate clinical protocols for the use of automated decision support. Development of specific guidelines will need to take place in conjunction with NICE as the organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

11(b). We further recommend that the Healthcare Commission undertake, as part of its audit process, an investigation into the availability and use of venous thromboembolism prevention protocols in each hospital, including appropriate counselling and risk assessment. It should also audit the training for and awareness of thromboprophylaxis and venous thrombosis in hospitals.

Standards for Better Health was published in July 2004 and has at its basis the development of safe high-quality care as we continue to make progress in developing a modern NHS.

The standards set out to achieve two important aims. First, they will set the foundations for a common high quality of healthcare throughout England. Second, they have helped clarify what the NHS can do and should be ambitious in what it can achieve for both staff in the NHS and the public.

The improvements in the quality of care against which the standards will be supported by the Healthcare Commission's assessment framework. The Healthcare Commission will be invited to be part of the independent expert working group and we have asked the group to advise us quickly on the issue of the Healthcare Commission taking this on as part of a two-stage process. Once the group has assessed the current guidance on VTE, the Department will ask the Commission to seek compliance with this. The intended outcome of these standards is that patient safety is enhanced by the use of healthcare processes, working practices and systematic activities that prevent or reduce the risk of harm to patients.

Core standard C3 sets out that healthcare organisations protect patients by following NICE interventional procedures guidance. Development standard D1 is aimed at healthcare organisations to ensure that they continuously and systematically review and improve all aspects of their activities that directly affect patient safety, and D2 at ensuring that patients receive effective treatment and care that conforms to nationally agreed best practice, including NICE guidance.

12. We recommend that a thrombosis committee be established in each hospital, with a specialist thrombosis team. They should be modelled on the existing Blood Transfusion teams and committees. So that these teams are established and operate effectively, a basic standard of expectation (skeleton) should be issued by the Department pending the publication of NICE guidelines.

We will ask the independent expert working group which we intend to establish to look at the experiences of both the existing thrombosis committees and the current Blood Transfusion team arrangements with a view to mainstreaming this work into existing structures. In order to broaden these existing committees to cover both prevention and treatment, we will also be asking them to make recommendations on how to transform the existing thrombosis committees into fully developed demonstration sites. This will include looking at prevention as well as treatment of VTE in hospitalised patients and how this approach can be rolled out nationally, including identifying the appropriate resourcing at both local and national level.

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