

ExPeKT – Exploring prevention and knowledge of venous thromboembolism: a two-stage, mixed-method study protocol

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ABSTRACT

Introduction: There is little awareness of venous thromboembolism (VTE) in the public arena. Most commonly known causes are—travellers' thrombosis and thrombosis associated with oral contraception, both frequently referred to in the media. However, VTE is a substantial healthcare problem, resulting in mortality, morbidity and economic cost. Most hospitalised patients have one or more risk factors for VTE. Around 60% of people undergoing hip or knee replacement will suffer a deep vein thrombosis without preventative intervention. Studies demonstrate a risk reduction for VTE of up to 70% with preventative medicine for medical and surgical conditions: cancer, orthopaedic surgery, general surgery and acutely ill medical admissions. Results will be used to identify methods of increasing knowledge of VTE prevention and for the development of educational and patient information materials.

Methods and analysis: A two-stage, mixed-method study using surveys with primary healthcare professionals and patients followed by interviews with primary healthcare professionals, patients, acute trusts and other relevant organisations. Survey and qualitative interview data will examine the current practice of thromboprophylaxis, and the knowledge and experience of VTE prevention for the development of education initiatives for primary healthcare professionals and patients to adopt thromboprophylaxis outside the hospital setting. As this is a scientific exploratory study for the generation, rather than testing, of new hypotheses a sample-size analysis is not called for. Survey data will be analysed using SPSS version 20. Open-ended responses will be analysed using qualitative thematic methods. The recorded and transcribed semistructured interview data will be analysed using constant comparative methods.

Ethics and dissemination: Ethics approval has been provided by the National Research Ethics Committee (reference: 11/H0605/5) and site-specific R&D approval granted by the relevant R&D National Health Service trusts. Findings will be disseminated at healthcare and academic conferences and written for peer-reviewed publication.

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ARTICLE SUMMARY

Article focus

- Understanding the current practice of thromboprophylaxis, and the knowledge and experience of venous thromboembolism (VTE) prevention.
- Study protocol using a mixed-methods approach.

Key messages

- VTE is a largely unrecognised as a significant healthcare problem.
- Public and healthcare professionals underestimate the extent of VTE for hospital admissions. Educational and patient information materials will be developed to adopt thromboprophylaxis outside of the hospital setting.

Strengths and limitations of this study

- Survey and interview data from multiple sources will provide a unique insight into the knowledge of, and barriers facing, VTE prevention.
- Workplace demands may limit the response from healthcare professionals.

INTRODUCTION

There is little awareness of venous thromboembolism (VTE) in the public arena.¹ The most commonly known causes are travellers' thrombosis and its association with oral contraception, both frequently referred to in the media. These, however, are uncommon causes of thrombosis compared to the risk associated with hospital admissions for either medical or surgical conditions.¹ Most hospitalised patients have one or more risk factors for VTE.^{2–6} Mortality owing to VTE after hospital admission is more than 10 times the number caused by *Staphylococcus aureus* (MRSA, methicillin-resistant *S aureus*) and is greater than the combined total of deaths from breast cancer, AIDS and road traffic incidents each year in the UK.⁷ Public ignorance is not surprising when healthcare professionals also underestimate the extent of

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VTE.⁸ Thus, VTE is a substantial healthcare problem, resulting in significant mortality, morbidity and economic cost.⁹ In 2005 VTE was estimated by the Health Select Committee to cost the National Health Service (NHS) £640 million a year to manage.

There is evidence to show that around 60% of people undergoing hip or knee replacement will suffer a deep vein thrombosis (DVT) without preventative intervention⁹ and that DVT has a mortality rate of 30% when left untreated.¹ Figures from numerous studies also demonstrate a risk reduction for VTE of up to 70% for medical and surgical conditions: cancer, orthopaedic surgery, general surgery and acutely ill medical admissions.^{10 11} As a result, in April 2007 National Institute for Health and Clinical Excellence (NICE) published a clinical guideline offering best-practice advice for reducing the risk of VTE in inpatients undergoing high-risk surgery and latterly for all surgical procedures.^{12 13} The Chief Medical Officer also announced the publication of a VTE risk assessment tool recommended for all patients admitted to hospital in England¹⁴ (19 September 2008). New NICE guidelines were introduced in January 2010 covering all patients aged 18 years and over admitted to hospital (including day patients).¹⁵ The guidelines include medical, surgical and cancer patients and recommend risk assessment for VTE and risk of bleeding be undertaken for all patients at admission (and repeated after 24 h) and appropriate prophylaxis be provided where indicated.¹⁵ Further, the Royal College of Obstetricians and Gynaecologists produced a Green-top Guideline regarding the prevention of VTE during pregnancy, birth and following delivery.¹⁶ In addition, VTE is one of the four Quality Standards to be developed by NICE. These standards offer quality measures such as the number of patients aged 18 years and more who have been admitted to a hospital and the number who received a VTE assessment.¹⁷ The standards are also used for the basis of Commissioning for Quality and Innovation (CQUIN) agreements with trusts and as from June 2010 the CQUIN payment framework requires all acute trusts in the UK to risk assess 90% of patients admitted for VTE to receive 1.5% for their funding. Finally, the Care Quality Commission is responsible for monitoring the trusts' performance on the new Quality Standards throughout the UK and will be collecting data each month on VTE risk assessments as well as visiting the trusts and interviewing staff of their performance.

Alongside these initiatives, an All Parliamentary Thrombosis Group (APPTG) undertook a survey of 173 acute NHS hospital trusts in 2007 to elucidate awareness of the problem and the action being taken. The survey found that implementation was poor despite almost universal awareness of the guidance.¹⁸ The survey demonstrated that only one-third of the hospital trusts were implementing mandatory risk assessments on every patient admitted, another one third were educating patients on admission and discharge and the remaining one third were educating the staffs regarding

thromboprophylaxis. A further APPTG survey in 2008 showed a marked improvement with 70% of trusts now stating they were undertaking risk assessment on all patients. However, this means that one third of trusts are still not assessing the risk in a structured manner. The survey also showed that patient information around the risk factors for VTE is poor. This survey was superseded in 2010 and found a continued low general awareness of VTE. The report called for a VTE public awareness campaign. In addition, the majority of trusts were unable to provide monthly data on the percentage of patients at risk of VTE who received appropriate prophylaxis.¹⁹

The APPTG reports suggested that there is a role for primary care trusts (PCTs) and that patient and public education will play an important role. Primary healthcare professionals are in a good position to deliver VTE education to patients and empower patients with the knowledge to request a risk assessment on admission to hospital. However, we do not know patients' attitudes towards education and information. Will highlighting the need for thromboprophylaxis to patients result in a reduction in events or will it have an unfavourable clinical outcome?

A study in 2007 of 460 patients, used a standardised questionnaire to determine patients' preferences to consent to low-molecular-weight-heparin (LMWH) prophylaxis following an orthopaedic surgery.²⁰ The patients were educated concerning the risk of heparin-induced thrombocytopenia (HIT) with LMWH. (HIT is a life-threatening, immune-mediated prothrombotic adverse drug effect that occurs less often with LMWH than with unfractionated heparin in orthopaedic surgery patients). Patients appreciated receiving information about the potential adverse effects of heparin prophylaxis. The specific information about HIT did not lead to treatment refusal with all patients choosing to receive the drug. Over 90% of patients welcomed the information and felt it appropriate to be informed.

When considering patient barriers to VTE prophylaxis, diabetes studies have shown the desire to avoid injectable drugs and LMWH therapy may therefore introduce concordance issues.²¹ Healthcare professional barriers to initiating VTE prophylaxis may be manifold. Knowledge-to-practice translation issues are extremely important for the successful integration of thromboprophylaxis into the community.

There is little evidence to suggest that care pathways are always successful for disease management. A Cochrane review of in-hospital care pathways stated that there was insufficient evidence to support their routine implementation, no reduction in hospital length of stay was seen.²² A further evaluating pathways for chronic obstructive airway disease, congestive cardiac failure, myocardial infarction and pneumonia had similar conclusions.²³ There has been no evidence of the use of care plans for prophylaxis in the community. However, one study evaluated a heart failure programme of care in the community using an integrated multidisciplinary team and an educational package for patients including advice on disease recognition and compliance.²⁴ This

study had more positive outcomes in terms of decreased length of stay in hospital and readmission rates.

STUDY RATIONALE

VTE is a recognised risk following inpatient admission. However, with appropriate thromboprophylaxis, risk of VTE can be reduced by up to 70% for medical and surgical conditions. In January 2010, new NICE guidelines were introduced which recommend VTE risk assessment of all patients aged 18 years and over who are admitted to hospital. The new initiatives introduced by the department of health focus on monitoring the risk assessment for VTE in the hospital setting and will document the performance of the hospital trusts. There is a need to transfer awareness, education and management of thromboprophylaxis outside the hospital setting. Currently there is a gap in our knowledge about the role of primary care in thromboprophylaxis. We do not know what information high-risk patients receive prior to hospital admission or what happens to them when they return to the community.

This study will assess current levels of knowledge of VTE risk and current practice of thromboprophylaxis among the range of primary healthcare professionals and patients. This will identify barriers to the implementation of thromboprophylaxis in primary care. Based on these data, effective educational measures will be designed for implementation outside the hospital setting to ensure patients receive the most effective care to prevent VTE.

METHODS

Study aims and objectives

The overriding aim of the study is to explore the existing knowledge and perceived role of primary care in thromboprophylaxis among primary healthcare professionals, patients, acute trusts and relevant organisations for the development of educational initiatives to help the adoption of safe practices outside the hospital setting. This will include the identification of barriers to providing thromboprophylaxis in primary care. The study objectives are as follows:

- ▶ To assess the level of existing knowledge of VTE risk among a range of primary healthcare professionals and patients;
- ▶ To assess current practice and the perceived role of primary care in thromboprophylaxis among primary healthcare professionals and patients;
- ▶ To explore the interface between primary and secondary care in terms of thromboprophylaxis and the perceived role of primary care among acute trusts and other relevant organizations;
- ▶ To explore potential care pathways for high-risk patients prior to hospital admission in terms of assessment for thromboprophylaxis;
- ▶ To design effective education initiatives to ensure public and primary care engagement in VTE preventative measures outside the hospital setting.

STUDY DESIGN

This two-stage, mixed-method study will involve surveys with primary healthcare professionals and patients followed by interviews with primary healthcare professionals, patients, acute trusts and relevant organisations, for example, Lifeblood and Anticoagulation Europe, both charities involved in supporting patients with thromboembolic disease.

INFORMED CONSENT

All potential participants will be provided with a participant information sheet. Primary healthcare professionals completing the postal survey will be asked to complete a written consent form as part of the survey. All professionals taking part in an interview will be asked to complete a written consent form prior to the interview.

All potential patients will be provided with a participant information sheet and consent form either while on the ward or at discharge. All patients will be given at least 24 h to decide whether they would be willing to participate. The participant information sheet will include contact telephone numbers of the research team who will be available to answer any questions. Willing participants will sign two copies of the consent form, one copy of which they will retain.

The participant information sheet has been written for ease of understanding and checked for readability using The Flesch-Kincaid Grade Level readability score (8.3) and Flesch Reading Ease Test (64.5). The patient consent form will ask permission to contact patients' general practitioners (GPs) and the Information Centre for Health and Social Care. Interviewed patients will complete an additional consent form prior to the interview.

STAGE 1: SURVEY

The development of the survey was informed by published research and the previous work carried out by the research team.

Practitioners and practice nurses

A postal survey, containing open and closed questions, will be sent to all of the GPs (n=728) and practice nurses (PNs) (n=440) in Oxfordshire and South Birmingham PCTs.

This stage will be used to generate information on their knowledge of VTE risk and thromboprophylaxis, the current use of VTE risk assessment and thromboprophylaxis and information on the education that is currently provided on risk and management of VTE both in terms of the education healthcare professionals receive and the education they provide. The survey will determine current and potential care pathways and examine any perceived financial or clinical barriers to the use of VTE risk assessment and management and the impact on workload in terms of resources for undertaking the risk assessment and providing education to patients and

other healthcare professionals as well as undertaking the thromboprophylaxis procedure. Topics in the survey include

- ▶ Awareness of the guidance into prevention of VTE;
- ▶ Methods of prophylaxis currently adopted;
- ▶ Advice currently given to patients with regard to thromboprophylaxis before admission to hospital;
- ▶ Opinions of how to improve thromboprophylaxis implementation.

In the survey participants will be asked if they would be willing to participate in a face-to-face interview and a sample will be approached for in-depth interviews.

High-risk patients

A postal survey, using open and closed questions, will be conducted with a sample of high-risk patients (n=600) from Oxfordshire and Birmingham acute trusts. Fifty per cent of the sample will be patients requiring extended thromboprophylaxis (defined using the department of health risk assessment tool). This is a scientific exploratory study for the generation, rather than testing, of new hypotheses. Accordingly, no sample-size analysis is called for. Differing demographic variables will be used to look for patterns of response and to examine associations among the variables. Given the exploratory nature of this study, the sample sizes included are thought to be acceptable for drawing preliminary conclusions about the prevention and knowledge of VTE.

The survey will examine patients' receipt of information and education about risk of VTE and need for thromboprophylaxis prior to hospital admission and will assess their awareness of VTE risk and attitudes to receiving thromboprophylaxis, their experiences of risk assessment for VTE and of thromboprophylaxis during hospital admission and at discharge. In addition, the survey will evaluate the contact that those patients' on extended thromboprophylaxis have with primary healthcare professionals following discharge from hospital.

Eligibility criteria

Inclusion criteria

- ▶ Patients assessed as being at high risk of VTE (requiring or not requiring extended prophylaxis) aged 18 years and over admitted to the identified wards.

Exclusion criteria

- ▶ Patients unable to speak/read English;
- ▶ Patients unable or unwilling to provide informed consent;
- ▶ Patients not assessed to be at high risk of venous thromboembolism;
- ▶ High-risk patients admitted to wards other than those identified for the study.

Recruitment of patients

The patients will be recruited in medical, surgical and orthopaedic wards from acute trusts in Oxfordshire and

Birmingham. Potential patients will be approached by a research nurse while on the ward postsurgery. The research nurse will discuss the study with potential patients and provide a patient information sheet (PIS). Patients will be given at least 24 h to decide whether they would be willing to participate. They will then have the opportunity to further discuss the study with the research nurse who will revisit them on the ward. They can also contact the research team for information. If patients are willing to participate they will be asked to sign two copies of the consent form, one copy of which they will retain and one copy for the research team. Patients who are to be discharged within 24 h will be provided with information packs (PIS, 2 consent forms and prepaid envelope). These patients will be asked to return one copy of the consent form, in the envelope provided, within 2 weeks. The research nurse will inform the research team when consenting patients are discharged. The research nurse will keep a record of all patients approached to calculate response rates and will maintain an anonymised log of the patients who have been issued with the information packs. Upon receipt of the consent form, the research team will immediately send a survey and a further prepaid envelope to those patients not requiring extended prophylaxis. High-risk patients requiring extended prophylaxis will be sent the survey pack to their home address to arrive 28 days after discharge. Topics covered in the patient survey include details of hospital admission, knowledge of thrombosis risk before admission, knowledge and management of thrombosis risk during admission, knowledge and management of thrombosis risk at the end of hospital stay, management of thrombosis risk following hospital stay, the patient's understanding of information given and personal details.

Patients will be asked to indicate on the survey if they would be interested in taking part in an interview. A sample of those indicating interest in the interviews will then be approached for recruitment to the in-depth interviews.

Stage 2

Interviews

The surveys of primary healthcare professionals and high-risk patients will elicit broad concepts and issues which will be developed and explored in more detail in the subsequent interviews.

Interviews with primary healthcare professionals

In-depth semistructured telephone or face-to-face interviews will be undertaken with a purposive sample of approximately 60 GPs and PNs who respond to the survey. The sampling will take into account individual responder characteristics and important issues identified in the survey. In addition, pharmacy leads and PCT commissioners will be identified for interview to be followed by snowball sampling.^{25 26} This will involve identifying a

key informant in each organisation and asking them to recommend other appropriate people for interview.

Topics to be covered in the interview schedule will include

- ▶ An examination of current practice and existing knowledge of VTE;
- ▶ Potential care pathways for high-risk patients prior to hospitalisation;
- ▶ Management of VTE in primary care;
- ▶ Identification of barriers to managing VTE in the community;
- ▶ An exploration of the interface between primary and secondary care.

The option of a telephonic interview or online interview will be offered. An appropriate sample is composed of participants who best represent or have knowledge of the research topic.^{25 26} Our sample will have sufficient knowledge of the research topic to allow the data to reach saturation. Saturation is reached when data is gathered to the point of diminishing returns and nothing new is being added²⁷ no new insights are obtained, no new themes are identified and no issues arise regarding a category of data.²⁸ At this point, the data categories are considered well established and validated. Saturation of each category signifies the stage at which to end the research.²⁹ Saturation is derived from a coherent and rigorous process of data condensation and interpretation that accounts for all possible explanations.³⁰ Clear descriptions of the data saturation process, and the forms in which it was recognised during the analysis, will be provided in the research reports as suggested by Caelli *et al.*³¹

Interviews with high-risk patients

Face-to-face semistructured interviews with a purposive sample of 30 high-risk patients (across the two PCTs) who respond to the survey will be undertaken. 50% of which will be patients requiring extended thromboprophylaxis. Individual characteristics such as age, gender, ethnicity and medical condition will be taken into account when sampling. The interviews will explore topics elicited from the initial survey and will be carried out at a place of the patient's choice. The interviews' schedule topics will include

- ▶ Patient awareness of VTE;
- ▶ Satisfaction with VTE information and understanding of the information received;
- ▶ Adherence to treatment;
- ▶ The need for primary care intervention;
- ▶ Issues to increase awareness of VTE.

The interview schedule will be reviewed by two laypersons to ensure suitability.

Interviews with acute trusts and other relevant organisations

Interviews will be conducted with a purposive sample of staff in the four acute trusts including ward managers in medical, surgical and orthopaedic wards, consultants and registrars and a sample of people in relevant organisations

such as the Lifeblood Charity and Anticoagulation Europe. These interviews will explore the interface between primary and secondary care in terms of VTE prevention and the perceived role of primary care. Areas to be covered in the interview schedule will include

- ▶ The role and current use of VTE risk assessment and thromboprophylaxis in primary care;
- ▶ An examination of interdisciplinary communication;
- ▶ Perceived barriers to VTE management;
- ▶ Training provision and future requirements for VTE management.

Key informants will be identified to be followed by snowball sampling.^{25 26} The sample is expected to include between 10 and 30 participants.

Care pathways

Potential care pathways for high-risk patients admitted to hospital will be explored as well as effective education initiatives to enhance public and primary healthcare engagement in VTE prevention. The care pathway will be devised utilising data received from the survey and interviews with both primary healthcare professionals and patients. It will comprise a guide for primary healthcare professionals to assess patients at high risk of VTE, guidance on how to integrate management of thromboprophylaxis between hospital and the community. Educational resources for both primary healthcare professionals and patients will be produced to give information and education for patients before and after admission to hospital, with particular reference to compliance and disease recognition.

The purpose of the care pathway devised in this body of work will be to provide a mechanism to coordinate care, reduce fragmentation and educate primary healthcare professionals and patients which will ultimately reduce costs by preventing VTE. The whole package of care plus educational resources will be evaluated in a future randomized-controlled trial.

Data analysis

Survey data will be analysed using SPSS. Descriptive data will be summarised from the two surveys. Open-ended responses will be analysed using qualitative thematic methods. The recorded and transcribed semistructured interview data will be analysed using constant comparative methods developed by Glaser.³² The constant comparative method utilises the skills and sensitivities of the analyst to assist theory generation which is integrated, consistent, plausible and close to the data. Themes and patterns are identified from the data, rather than being imposed on the data and are presented in a clear manner that allows flexibility to aid the creative generation of theory. The method uses theory and empirical data as means of creating hypothesis and a deeper understanding of the phenomena being researched.³³

Data collection and analysis will be iterative occurring as data collection in the interviews' proceeds, with new data being used to challenge and assess or confirm emerging

analysis. Key categories and concepts emerging from each of the three interview groups will be considered individually for each group, across the dimensions selected for purposive sampling within groups, between groups where there are areas of communality and across established concepts in existing literature.

Study outcomes

Primary outcome

- ▶ An understanding of the perceived role of primary care in thromboprophylaxis prevention and management and an awareness of the knowledge of thromboprophylaxis among primary healthcare professionals, patients, acute trusts and other relevant organisations.

Secondary outcomes

- ▶ An understanding of the current practice of thromboprophylaxis among primary healthcare professionals and patients;
- ▶ Development of education initiatives for primary healthcare professionals and patients to adopt thromboprophylaxis outside of the hospital setting;
- ▶ Knowledge of the perceived and actual clinical barriers to thromboprophylaxis;
- ▶ Development of care pathways for high-risk patients prior to hospital admission.

DISCUSSION

The results of the surveys and interviews in conjunction with the pathways analysis will inform the design of optimal awareness and educational interventions for VTE prophylaxis. The results will help clinicians understand the barriers to thromboprophylaxis and will identify methods of increasing knowledge of VTE prevention to primary healthcare professionals needing to educate patients preadmission and postadmission to hospital and as such, through the use of appropriate care pathways and education, to reduce costs by preventing readmission to hospital for recurrence of VTE. The combined results of the surveys and interviews in conjunction with the pathways analysis will inform the design of optimal awareness and educational interventions for VTE prophylaxis.³⁴

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Competing interests None.

Ethics approval Ethics approval has been provided by Oxfordshire REC B Research Ethics Committee on 05/05/2011 (reference: 11/H0605/5). R & D

approval has been granted by the following R&D trusts: University Hospital Birmingham, Royal Orthopaedic Hospital Birmingham, Oxfordshire Radcliffe Hospitals, Nuffield Orthopaedic Centre, Oxfordshire and South Birmingham and Oxfordshire PCTs.

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Data sharing statement No additional data are available.

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