



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

| | |
|---------------------------------|---|
| Journal: | <i>BMJ Open</i> |
| Manuscript ID: | bmjopen-2013-002766 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 20-Feb-2013 |
| Complete List of Authors: | Ward, Alison; University of Oxford, Primary Health Care Greenfield, Sheila; University of Birmingham, Primary care and Clinical Sciences Fitzmaurice, DA; University of Birmingham, Primary Care and General Practice Murray, Ellen; University of Birmingham, Primary care and Clinical Sciences Heneghan, Carl; Oxford University, Primary Health Care Harrison, Sian; Oxford University, Primary Health Care McFarland, Lorraine; University of Birmingham, Primary care and Clinical Sciences |
| Primary Subject Heading: | Cardiovascular medicine |
| Secondary Subject Heading: | Haematology (incl blood transfusion) |
| Keywords: | Thromboembolism < CARDIOLOGY, Anticoagulation < HAEMATOLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PRIMARY CARE |
| | |

SCHOLARONE™
Manuscripts

1
2
3 **ExPeKT: Exploring prevention and knowledge of venous thromboembolism: A two stage,**
4 **mixed method study protocol**
5
6
7
8
9

10 Lead investigators: Dr Alison Ward ²/ Professor Sheila Greenfield¹

11 Co-investigators: Professor David Fitzmaurice (NIHR programme lead)¹

12 Dr Ellen Murray (Programme co-ordinator)¹

13 Dr Carl Heneghan (Co-investigator)²

14 Dr Sian Harrison (Research fellow)²

15 Dr Lorraine McFarland (Research Fellow)¹

16
17
18
19
20 ¹ Primary Care Clinical Sciences, University of Birmingham, Edgbaston, B15 2TT

21
22
23 ² Department of Primary Health Care, University of Oxford, New Radcliffe House, Jericho, Oxford,
24 OX2 6NW

25
26
27 Trial grant number: NIHR RP-PG-0608-10073

28
29
30 Article type: Study protocol

31
32
33 Corresponding author: Professor David Fitzmaurice, Primary Care Clinical Sciences, University of
34 Birmingham, Edgbaston, B15 2TT. Email: D.A.Fitzmaurice@bham.ac.uk . Telephone: 0214147482

35
36
37
38
39
40 **Key words**

41 Venous thromboembolism (VTE), deep vein thrombosis, thromboprophylaxis, prevention, barriers,
42 patient and health care professional knowledge
43
44

45
46
47 Word count 3785
48
49
50
51
52
53
54
55
56
57
58
59
60

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 [1]. However, VTE is a substantial health-care 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 health care professionals and patients followed by interviews with primary health care 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 education initiatives for primary health care professionals and patients to adopt thromboprophylaxis outside of 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. Open-ended responses will be analysed using qualitative thematic methods. The recorded and transcribed semi-structured 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 NHS trusts. Findings will be disseminated at healthcare and academic conferences and written for peer-reviewed publication.

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 health-care problem.

The 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 health care professionals.

Introduction

There is little awareness of venous thromboembolism (VTE) in the public arena. 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 due to VTE after hospital admission is more than 10 times the number caused by *Staphylococcus aureus* (MRSA) 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 (HCPs) also underestimate the extent of VTE [8]. Thus, VTE is a substantial health-care problem, resulting in significant mortality, morbidity, and economic cost [9]. In 2005 VTE was estimated by the Health Select Committee to cost the 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 intervention [9] 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 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 England [14] (19th 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 hours) 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 of 18 years and

1
2
3 over who have been admitted to a hospital and the number who received a VTE assessment [17].
4
5 The Standards are also used for the basis of Commissioning for Quality and Innovation (CQUIN)
6
7 agreements with trusts and as from June 2010 the CQUIN payment framework requires all acute
8
9 trusts in the UK to risk assess 90% of patients admitted for VTE in order to receive 1.5% for their
10
11 funding. Finally, the Care Quality Commission is responsible for monitoring the trusts' performance on
12
13 the new Quality Standards throughout the UK and will be collecting data each month on VTE risk
14
15 assessments as well as visiting the trusts and interviewing staff of their performance.
16
17
18

19
20 Alongside these initiatives, an All Parliamentary Thrombosis Group (APPTG) undertook a survey of
21
22 173 acute NHS hospital trusts in 2007 to elucidate awareness of the problem and what action was
23
24 being taken. The survey found that implementation was poor despite almost universal awareness of
25
26 the guidance [18]. The survey demonstrated that only one third were implementing mandatory risk
27
28 assessments on every patient admitted, only a third were educating patients on admission and
29
30 discharge and only a third were educating staff regarding thromboprophylaxis. A further APPTG
31
32 survey in 2008 showed a marked improvement with 70% of trusts now stating they were undertaking
33
34 risk assessment on all patients. However, this means that one third of trusts are still not risk
35
36 assessing in a structured manner. The survey also showed that patient information around the risk
37
38 factors for VTE is poor. This survey was superseded in 2010 and found a continued low general
39
40 awareness of VTE. The report called for a VTE public awareness campaign. In addition, the majority
41
42 of Trusts were unable to provide monthly data on the percentage of patients at risk of VTE who
43
44 received appropriate prophylaxis [19].
45
46

47
48 The APPTG reports suggested that there is a role for PCTs and that patient and public education will
49
50 play an important role. Primary health care professionals are in a good position to deliver VTE
51
52 education to patients and empower patients with the knowledge to request a risk assessment on
53
54 admission to hospital. However, we do not know patients' attitudes to education and information. Will
55
56 highlighting the need for thromboprophylaxis to patients result in a reduction in events or will it have
57
58 an unfavourable clinical outcome?
59
60

1
2
3
4
5 A study in 2007 of 460 patients, used a standardised questionnaire to determine patients' preferences
6 to consent to low molecular weight heparin (LMWH) prophylaxis following orthopaedic surgery [20].
7
8 The patients were educated concerning the risk of heparin-induced thrombocytopenia (HIT) with
9 LMWH. (HIT is a life-threatening, immune-mediated prothrombotic adverse drug effect that occurs
10 less often with LMWH than with unfractionated heparin (UFH) in orthopedic surgery patients). Patients
11 appreciated receiving information about the potential adverse effects of heparin prophylaxis. The
12 specific information about HIT did not lead to treatment refusal with all patients choosing to receive the
13 drug. Over 90 percent of patients welcomed the information and felt it appropriate to be informed.
14
15
16
17
18
19
20

21
22
23
24 When considering patient barriers to VTE prophylaxis, diabetes studies have shown the desire to
25 avoid injectable drugs and LMWH therapy may therefore introduce concordance issues [21]. Health
26 care professional barriers to initiating VTE prophylaxis may be manifold. Knowledge-to-practice
27 translation issues are extremely important for the successful integration of thromboprophylaxis into
28 the community.
29
30
31
32
33
34
35
36

37 There is little evidence to suggest that care pathways are always successful for disease management.
38 A Cochrane review of in-hospital care pathways stated that there was insufficient evidence to support
39 their routine implementation, no reduction in hospital length of stay was seen [22]. A further evaluating
40 pathways for chronic obstructive airway disease, congestive cardiac failure, myocardial infarction and
41 pneumonia had similar conclusions [23]. There has been no evidence of the use of care plans for
42 prophylaxis in the community. However, one study evaluated a heart failure programme of care in the
43 community using an integrated multidisciplinary team and an educational package for patients
44 including advice on disease recognition and compliance [24]. This study had more positive outcomes
45 in terms of decreased length of stay in hospital and readmission rates.
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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 amongst the range of primary health care 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 amongst primary health care professionals, patients, acute trusts and relevant organisations for the development of educational initiatives to help the adoption of safe practice 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 amongst a range of primary health care professionals and patients
- To assess current practice and the perceived role of primary care in thromboprophylaxis amongst primary health care professionals and patients

- To explore the interface between primary and secondary care in terms of thromboprophylaxis and the perceived role of primary care amongst acute trusts and other relevant organisations
- 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 health care professionals and patients followed by interviews with primary health care professionals, patients, acute trusts and relevant organisations for example Lifeblood and Anticoagulation Europe, both charities involved in supporting patients with thrombo-embolic disease.

Informed consent

All potential participants will be provided with a participant information sheet. Primary health care 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 whilst on the ward or at discharge. All patients will be given at least 24 hours 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' GPs and the Information

1
2
3 Centre for Health and Social Care. Interviewed patients will complete an additional consent form prior
4 to the interview.
5
6
7
8
9

10 **Stage one - Survey**

11
12 The development of the survey was informed by published research and the previous work carried out
13 by the research team.
14
15

16 ***Practitioners and practice nurses***

17
18 A postal survey, containing open and closed questions, will be sent to all of the general practitioners
19 (GPs) (n=728) and practice nurses (PNs) (n=440) in Oxfordshire and South Birmingham PCTs.
20
21
22

23
24 This stage will be used to generate information on their knowledge of VTE risk and
25 thromboprophylaxis, the current use of VTE risk assessment and thromboprophylaxis and information
26 on the education that is currently provided on risk and management of VTE both in terms of the
27 education health care professionals receive and the education they provide. The survey will determine
28 current and potential care pathways and examine any perceived financial or clinical barriers to the use
29 of VTE risk assessment and management and the impact on workload in terms of resources for
30 undertaking the risk assessment and providing education to patients and other health care
31 professionals as well as undertaking the thromboprophylaxis procedure. Topics in the survey include:
32
33
34
35
36
37
38

- 39 • awareness of the guidance into prevention of VTE
- 40 • methods of prophylaxis currently adopted
- 41 • advice currently given to patients with regard to thromboprophylaxis before admission to
42 hospital
- 43 • opinions of how to improve thromboprophylaxis implementation.
44
45
46
47

48 In the survey participants will be asked if they would be willing to participate in a face-to-face interview
49 and a sample will be approached for in-depth interviews.
50
51
52
53
54
55
56
57
58
59
60

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 percent 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 health care professionals following discharge from hospital.

Eligibility criteria

Inclusion criteria

- Patients assessed as being at high risk of venous thromboembolism (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 whilst on the ward post-surgery. The research nurse will discuss the study with potential patients and provide a patient information sheet (PIS). Patients will be given at least 24 hours 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 hours will be provided with information packs (PIS, 2 consent forms and pre-paid 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 in order to calculate response rates and will maintain an anonymised log of the patients that have been issued with the information packs. Upon receipt of the consent form, the research team will immediately send a survey and a further pre-paid 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 patients understanding of information given, 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 health care 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 health care professionals

In depth semi-structured 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]. 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 telephone 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]. 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 added [26] no new insights are obtained, no new themes are identified, and no issues arise regarding a category of data [27]. 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 [28]. Saturation is derived from a coherent and rigorous process of data condensation and interpretation that accounts for all possible explanations [29]. 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 and colleagues [30].

Interviews with high risk patients

Face-to-face semi-structured 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

1
2
3 condition will be taken into account when sampling. The interviews will explore topics elicited from the
4 initial survey and will be carried out at a place of the patient's choosing. The interview schedule topics
5 will include:
6
7

- 8
- 9 • patient awareness of VTE
- 10
- 11 • satisfaction with VTE information and understanding of the information received
- 12
- 13 • adherence to treatment
- 14
- 15 • the need for primary care intervention
- 16
- 17 • issues to increase awareness of VTE.
- 18

19 The interview schedule will be reviewed by two lay-persons to ensure suitability.
20

21 ***Interviews with acute trusts and other relevant organisations***

22

23
24 Interviews will be conducted with a purposive sample of staff in the four acute trusts including; ward
25 managers in medical, surgical and orthopaedic wards, consultants and registrars and a sample of
26 people in relevant organisations such as the Lifeblood Charity and Anticoagulation Europe. These
27 interviews will explore the interface between primary and secondary care in terms of VTE prevention
28 and the perceived role of primary care. Areas to be covered in the interview schedule will include:
29
30

- 31
- 32
- 33
- 34 • the role and current use of VTE risk assessment and thromboprophylaxis in primary care
- 35
- 36 • an examination of interdisciplinary communication
- 37
- 38 • perceived barriers to VTE management
- 39
- 40 • training provision and future requirements for VTE management.
- 41

42 Key informants will be identified to be followed by snowball sampling [25]. The sample is expected to
43 include between 10 and 30 participants.
44

45 **Care pathways**

46

47
48 Potential care pathways for high risk patients admitted to hospital will be explored as well as effective
49 education initiatives to enhance public and primary health care engagement in VTE prevention. The
50 care pathway will be devised utilising data received from the survey and interviews with both primary
51 health care professionals and patients. It will comprise a guide for primary health care professionals to
52 assess patients at high risk of VTE, guidance on how to integrate management of thromboprophylaxis
53 between hospital and the community. Educational resources for both primary health care
54
55
56
57
58
59
60

1
2
3 professionals and patients will be produced to give information and education for patients before and
4 after admission to hospital, with particular reference to compliance and disease recognition.
5
6

7
8 The purpose of the care pathway devised in this body of work will be to provide a mechanism to
9 coordinate care, reduce fragmentation and educate primary health care professionals and patients
10 which will ultimately reduce costs by preventing VTE. The whole package of care plus educational
11 resources will be evaluated in a future randomised controlled trial.
12
13
14

15 16 17 18 **Data analysis** 19

20 Survey data will be analysed using SPSS. Descriptive data will be summarised from the two surveys.
21 Open-ended responses will be analysed using qualitative thematic methods. The recorded and
22 transcribed semi-structured interview data will be analysed using constant comparative methods
23 developed by Glaser [31]. The constant comparative method utilises the skills and sensitivities of the
24 analyst to assist theory generation which is integrated, consistent, plausible and close to the data.
25 Themes and patterns are identified from the data, rather than being imposed on the data and are
26 presented in a clear manner that allows flexibility to aid the creative generation of theory. The method
27 uses theory and empirical data as means of creating hypothesis and a deeper understanding of the
28 phenomena being researched [32].
29
30
31
32
33
34
35
36
37
38

39 Data collection and analysis will be iterative occurring as data collection in the interviews proceeds,
40 with new data being used to challenge and assess or confirm emerging analysis. Key categories and
41 concepts emerging from each of the three interview groups will be considered individually for each
42 group, across the dimensions selected for purposive sampling within groups, between groups where
43 there are areas of communality and across established concepts in existing literature.
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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 amongst primary health care professionals, patients, acute trusts and other relevant organisations.

Secondary Outcomes

- an understanding of the current practice of thromboprophylaxis amongst primary health care professionals and patients
- development of education initiatives for primary health care 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 to understand the barriers to thromboprophylaxis and will identify methods of increasing knowledge of VTE prevention to primary health care professionals needing to educate patients pre and post admission to hospital and as such, through the use of appropriate care pathways and education, to reduce costs by preventing re admission 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 [33].

Author's contribution

DF, EM, SG and AW developed the original idea of the study and submitted the grant application to the NIHR. EM and AW wrote the study protocol and LMcf and SH contributed to the development of the protocol. LMcf produced the first draft of the protocol manuscript. All authors reviewed the draft versions of this paper and approved the final version.

Funding

The research was funded by the National Institute for Health Research (NIHR) programme grant entitled Improving the prevention and treatment of Venous Thromboembolism in Hospital and the Community. The views expressed in this paper are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. The authors declare that they have no competing interests.

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.

Acknowledgments

This paper summarises independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research programme (RP-PG-0608-10073). The views expressed in this paper are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

References

- [1] Torbicki A, van Beek EJR, Charbonnier B, et al: *Task Force Report: Guidelines on the diagnosis and management of acute pulmonary embolism. Eur Heart Journal* 2000;21:1301-1336.
- [2] Anderson FA, Wheeler HB, Goldberg RJ, et al: The prevalence of risk factors for venous thromboembolism among hospital patients. *Arch Intern Med* 1992;152:1660-1664.
- [3] Rosendaal FR. Risk factors for venous thrombotic disease. *Thromb Haemost* 1999;82:610-619.
- [4] Kearon C, Salzman EW, Hirsh J: Epidemiology, pathogenesis, and natural history of venous thrombosis. In *Hemostasis and Thrombosis: Basic Principles and Clinical Practice*. 4th edition. Ed Colman RW, Hirsh J, Marder VJ, Clowes AW, George JN. Philadelphia, PA: JB Lippincott; 2001;1153-1177.
- [5] Heit JA, O'Fallon WM, Petterson TM, et al: Relative impact of risk factors for deep vein thrombosis and pulmonary embolism: a population-based study. *Arch Intern Med* 2002;162:1245-1248
- [6] Anderson FA, Spencer FA: Risk factors for venous thromboembolism. *Circulation* 2003;107:19-116.
- [7] Fitzmaurice DA, Murray E: Thromboprophylaxis for adults in hospital. *BMJ* 2007;334:1017-8.
- [8] Lifeblood Thrombosis Charity: www.thrombosis-charity.org.uk
- [9] Geerts WH, Pineo GF, Heit JA, et al: Prevention of venous thromboembolism. *Chest* 2004;126:338S-400S.
- [10] Cohen AT, Tapson VF, Bergmann JF: Venous thromboembolism risk and prophylaxis in the acute hospital care setting (ENDORSE study): a multinational cross-sectional study. *Lancet* 2008;371(9610): 387-94.
- [11] House of Commons Health Committee: The prevention of venous thromboembolism in hospitalised patients. London: Stationery Office, 2005.
- [12] National Institute for Clinical Excellence: Venous thromboembolism: reducing the risk of thromboembolism (deep vein thrombosis and pulmonary embolism) in inpatients undergoing surgery.

1
2
3 London: NICE, 2007. Available at: www.nice.org.uk/nicemedia/pdf/CG046quickrefguide.pdf (last
4
5 accessed 3 May 2012).

6
7 [13] National Collaborating Centre for Acute Care: Venous thromboembolism: reducing the risk of
8
9 venous thromboembolism (deep vein thrombosis and pulmonary embolism) in inpatients undergoing
10
11 surgery: methods, evidence and guidance. London: National Collaborating Centre for Acute Care,
12
13 2007. Available at: www.nice.org.uk/nicemedia/pdf/VTEFullGuide.pdf (last accessed 3 May 2012).

14
15 [14] Department of Health: Venous thromboembolism (VTE) risk assessment. London: Department of
16
17 Health, September 2008.

18
19 [15] National Institute for Clinical Excellence: Reducing the risk of venous thromboembolism (deep
20
21 vein thrombosis and pulmonary embolism) in patients admitted to hospital. London: NICE, 2010.
22
23 Available at: <http://www.guidance.nice.org.uk/CG92>

24
25 [16] Royal College of Obstetricians and Gynaecologists: Green top Guideline No. 37. Reducing the
26
27 risk of thromboembolism during pregnancy, birth and the puerperium. September 2009.

28
29 [17] National Institute for Clinical Excellence: Draft Quality Standard for Venous Thromboembolism
30
31 (VTE) – prevention. London: NICE, 2009. Available at:
32
33 <http://www.nice.org.uk/media/1DC/4E/VTEPreventionQualityStandard.pdf>

34
35 [18] All-Party Parliamentary Thrombosis Group: Thrombosis: awareness, assessment, management
36
37 and prevention: an audit of hospital trusts. London, 2007.

38
39 [19] All-Party Parliamentary Thrombosis Group. Awareness, Assessment, Management and
40
41 Prevention" Fourth Annual Audit of Acute NHS Trusts' VTE Policies. November 2010. Available at:
42
43 www.kingsthrombosiscentre.org.uk

44
45 [20] Lubenow N, Hinz P, Ekkernkamp A, et al: Should patients be informed about the risk of heparin
46
47 induced thrombocytopenia before prolonged low-molecular weight heparin thromboprophylaxis post
48
49 trauma/orthopaedic surgery? *Eur J Haematology* 2007;79(3):187-190.

50
51 [21] Chancellor J, Aballea S, Lawrence A, et al: Preferences of patients with diabetes mellitus for
52
53 inhaled versus injectable insulin regimens. *Pharmacoeconomics* 2008;26(3):217-34.

- 1
2
3 [22] Kwan J, Sandercock P: In-hospital care pathways for stroke: a Cochrane systematic review.
4
5 *Stroke* 2003;34: 587.
6
7
8 [23] Lee KH, Anderson YM: The association between clinical pathways and hospital length of stay: a
9
10 case study. *J Med Syst* 2007;31(1):79-83.
11
12 [24] Rauh RA, Schwabauer NJ, Enger EL, et al: A community hospital based congestive cardiac
13
14 failure program: impact on length of stay, admission and readmission rates and costs. *Am J Manag*
15
16 *Care* 1999;5(1):37-43 15.
17
18 [25] Vogt WP: Dictionary of Statistics and Methodology: A Nontechnical Guide for the Social
19
20 Sciences. London: Sage. 1999.
21
22
23 [25] Morse JM. Strategies for sampling. In J Morse (Ed.), *Qualitative nursing research: A*
24
25 *contemporary dialogue* (Rev. Ed) Newbury Park, CA: Sage; 1991.
26
27 [26] Charmaz K: Grounded theory: Objectivist and constructivist methods. In NK Denzin, YS Lincoln
28
29 (Eds.), *Strategies of qualitative inquiry*, 2nd ed., Thousand Oaks, CA: Sage Publications. 2003:249-
30
31 291.
32
33 [27] Strauss A. Corbin J: *Basics of Qualitative Research: Grounded Theory Procedures and*
34
35 *Techniques*. Newbury Park, CA: Sage Publications 1990.
36
37 [28] Morse JM: 'The Significance of Saturation'. *Qualitative Health Research*; 1995;5(2):147-9.
38
39
40 [29] Hyde CA: 'Multicultural Organization Development in Nonprofit Human Service Agencies: Views
41
42 from the Field'. *Journal of Community Practice* 2003;11(1):39-59.
43
44 [30] Caelli K, Ray L, Mill J: "Clear as Mud": Toward Greater Clarity in Generic Qualitative Research,
45
46 *International Journal of Qualitative Methods* 2(2): Article 1. 2003 URL:
47
48 <http://www.ualberta.ca/~iiqm/backissues/pdf/caellietal.pdf>
49
50
51 [31] Glaser B: The Constant Comparative Method of Qualitative Analysis. *Social Problems*
52
53 1965;12:4:436-445.
54
55 [32] Glaser BG, Strauss AL: *The Discovery of Grounded Theory: Strategies for Qualitative Research*.
56
57 New York: Aldine De Gruyter. 1967.
58
59
60

1
2
3 [33] Brannen J: NCRM Methods Review Papers, NCRM/005. Mixed Methods Research: A discussion
4
5 paper. 2005. Available at: <http://eprints.ncrm.ac.uk/89/>
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

Research checklist for a mixed methods Study Protocol

O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health services research. *J Health Serv Res Policy*. 2008;13(2):92-8. PMID: [18416914](https://pubmed.ncbi.nlm.nih.gov/18416914/)

Study to title –including study design

Authors, job title and affiliations

Funding number

Key words

Word count

Abstract

- Introduction
- Methods and analysis
- Ethics and dissemination

Article summary

Introduction- review of the literature, rationale

Methods

Aims and objectives

Informed consent

Participants, Recruitment, Inclusion criteria, Sampling strategy, Snowball, Saturation

How –survey / interview

Proposed analysis –SPSS, constant comparison

Outcomes

Discussion

Author's contributions

References

Ethics