Preventing venous thromboembolism in hospitalised patients: Using implementation science to close the evidence-practice gap

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PREVENTING VENOUS THROMBOEMBOLISM IN HOSPITALISED PATIENTS: USING IMPLEMENTATION SCIENCE TO CLOSE THE EVIDENCE-PRACTICE GAP

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A thesis submitted in total fulfilment of the requirements of the degree of

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January 2013
STATEMENT OF AUTHORSHIP

This thesis contains no material extracted in whole or in part from a thesis by which I have qualified for or been awarded another degree or diploma.

No parts of this thesis have been submitted towards the award of any other degree or diploma in any other tertiary institution.

No other person’s work has been used without due acknowledgment in the main text of the thesis.

All research procedures reported in the thesis received the approval of a Human Research Ethics Committee.

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ACKNOWLEDGEMENTS

Thank you to my two academic supervisors, Professors Kim Walker and Abdullah Omari who challenged, encouraged and inspired me. I am proud to call them my mentors and friends and I look forward to many more years of collaboration.

I am grateful for the support of my employer, St Vincent’s Private Hospital, and my many colleagues. In particular, I wish to thank Professor Jose Aguilera, Director of Nursing and Clinical Services.

The St Vincent Clinic Foundation and the Curran Foundation provided funding for my research and I thank them both for their ongoing patronage of nursing research at St Vincent’s Private Hospital, Sydney.

To my family and friends, thank you for your unwavering love and support during this important chapter of my life.
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ABSTRACT

Venous thromboembolism (VTE) is the umbrella term covering deep vein thrombosis, pulmonary embolism and a group of associated chronic conditions. This vascular disease process is a common, yet serious adverse complication of hospitalisation that results in significant mortality, morbidity, and healthcare resource expenditure. VTE in hospitalised patients is preventable and there is a robust evidence base supporting the use of prophylactic therapies for at-risk patients. Unfortunately, despite the evidence, research and clinical audit reveal that these therapies are frequently underutilised or inconsistently applied. The substantial VTE prevention evidence-practice gap has been identified internationally as a priority patient safety issue.

Implementation science is a relatively new field of research focused on closing evidence-practice gaps by translating research findings into routine clinical practice. This PhD thesis contains five publications from a linked series of four implementation science studies aimed at improving the uptake of research evidence on VTE prevention in hospitalised patients. The studies were conducted at St Vincent’s Private Hospital, a 270 bed acute care facility in Sydney, Australia.

Evidence Implementation

The first two publications in this thesis report on two evidence implementation, also known as knowledge translation, studies. Evidence implementation uses a dynamic, iterative improvement method to identify, analyse, and overcome barriers to the provision of evidence-based care. They use multifaceted change strategies tailored to the locally identified barriers and based on the best available evidence on behaviour change
interventions. Both papers are exemplars of pragmatic, clinician initiated evidence implementation and provide a valuable resource for nurses attempting to change practice at the local level.

Study one used audit and feedback; patient and provider education; and decision support aids to improve the management of warfarin therapy - a common yet potentially dangerous drug used for the prevention and treatment of VTE. The study had a repeated measures design and improvement was evaluated with statistical process control charts. The implementation strategy resulted in a non-significant improvement in compliance with recommended warfarin loading doses (42% to 54%) and a significant improvement in the proportion of patients receiving education on warfarin prior to discharge (31% to 85%).

Study two identified four local barriers to the uptake of VTE prevention guidelines: A lack of motivation to change; a lack of systems support; a knowledge or awareness deficit; and disputed evidence. The interventions selected to overcome these barriers were audit and feedback; documentation aids; staff education initiatives; collaboratively developed hospital VTE prevention policy; alert stickers and other reminders. Clinician compliance with evidence-based recommendations was evaluated by clinical audits before and after the intervention roll out. The implementation strategy resulted in a 19% (49% to 68%, p=0.02) improvement in VTE prophylaxis for both surgical and medical patients and a 35% (0% to 35%, p=<0.001) improvement in VTE risk assessment rates. On completion of the study, it was noted that, despite improvements, medical patient prophylaxis rates remained suboptimal (83% prophylaxis rates for surgical patients compared to 45% for medical).
Implementation research

Decision tree analytic modelling was used in the third study to identify if improvements in pharmacological VTE prophylaxis achieved in study two translated into cost savings and improved clinical outcomes. The decision tree model incorporated local treatment algorithms, national Diagnostic Related Group information, and data from clinical trials and meta-analyses. The modelled simulation estimated the incidence of symptomatic VTE, adverse events, and treatment costs. Significant clinical and economic benefits were identified over twelve months including 103 fewer symptomatic VTEs, 512 fewer bed days, 13 fewer deaths, and an overall cost saving of $245,439. The study concluded that there was significant benefit to patients and the health care system in preventing VTE in hospitalised patients.

The final two publications in this thesis are from a piece of implementation research which evaluated the acceptability, utility and clinical impact of Educational Outreach Visiting (EOV) on the provision of VTE prophylaxis to medical patients. EOV has been shown to be a successful change strategy but its use in the acute care setting, and in particular on VTE prevention practices, had not been well studied. Both doctors and nurses felt the EOV was an acceptable and effective change strategy. The intervention had a significant impact on doctors’ prescribing behaviour (16% improvement, 95% CI 5 to 26, p=0.004) but no measurable effect on nurses’ provision of mechanical prophylaxis (-0.3% improvement, 95% CI -13.4 to 14, p=0.96). This study was the first to document the considerable resource investment required for this intervention. It was found that every one minute of face-to-face intervention time required 5 minutes of preparation. The study could not discern the reason for the disparity in results between nursing and medical staff and made
recommendations for future research based on marketing research methods and informed by stage of change theory.

Together, these four studies and five publications inform our understanding of the state of implementation science in Australia and more generally. The work supports the need for greater investment in this emerging new field to ensure effective and efficient translation of evidence into practice. This includes a greater investment in implementation research, research training, facilitator training, and essential knowledge infrastructure.
CHAPTER 1. INTRODUCTION

The disease process, venous thromboembolism (VTE), was first described by the pathologist, Rudolf Virchow, in the early 19th century. He recognised that blood clots being found in the pulmonary artery were actually originating from venous thrombi (Dalen, 2002). Since this discovery the body of evidence on the causes, prevention and treatment of VTE has grown significantly. It is now over 50 years since the first published study showing that symptomatic and fatal VTE could be reduced with the use of thromboprophylaxis (Sevitt & Gallagher, 1959) and over 25 years since the first publication of an evidence-based guideline recommending the routine use of prophylaxis for at-risk hospitalised patients (Geerts, 2009).

Despite the overwhelming evidence that prophylaxis is safe and effective, there continue to be large gaps in the provision of this key patient safety intervention. Research and clinical audit reveal that up to half of all hospitalised patients at-risk of VTE are not receiving evidence-based prophylaxis (Bergmann et al., 2010; National Institute of Clinical Studies, 2008a; Rothberg, Lahti, Pekow, & Lindenauer, 2010). The failure to translate research evidence into clinical practice means that pulmonary embolism remains, today as it was 50 years ago, the single biggest preventable cause of in-hospital mortality (Access Economics, 2008; MacDougall, Feliu, Boccuzzi, & Lin, 2006; Morrell & Dunnill, 1968). In Australia, it is estimated that VTE results in up to 5000 deaths annually (Access Economics, 2008), with approximately half being directly related to current or recent hospitalisation (Geerts, 2009).
The difficulty in translating evidence into practice is not unique to the area of VTE prevention. In a frequently cited paper Grol and Grimshaw (2003) report that 30–40% of all patients do not receive healthcare based on current evidence and up to 20–25% of all patients actually receive harmful or unnecessary care. Implementation science is the relatively new and evolving area of research concerned with addressing the gap between evidence and practice. The field has developed a growing body of knowledge on effective strategies and methods for translating research findings into practice.

The objective of this thesis, and the individual studies that comprise it, was to apply the methods and strategies of implementation science to help close the VTE prevention evidence practice gap at an acute care private hospital in metropolitan Australia (St Vincent’s Private Hospital, Sydney). Specifically, the thesis aimed to:

- Improve VTE prevention at St Vincent’s Private Hospital, Sydney; and
- Contribute to the body of evidence on strategies to promotion the uptake of evidence on VTE prevention in hospitalised patients.

The thesis comprises four interrelated implementation science studies which are reported in five manuscripts (see Table 1). The manuscripts that are either published, in press, or under review (see Appendix A for details) are presented in this thesis as chapters. They have been placed in chronological order to maintain a logical flow and a prologue has been added to provide the reader with background on how the studies are linked. Each manuscript has been written and formatted in the style of the journal it was submitted to; however, for ease of reading and continuity the numbering of tables and figures has been kept continuous and the referencing changed to the American Psychology Association.
style. The thesis concludes with a discussion which examines the implications of the findings and makes recommendations for future research. As per university requirements, a comprehensive list of cited references is provided at the end of the thesis.

In order to provide the reader with some pertinent background information, the rest of this introduction chapter contains details on the facilitator of the four studies (the candidate), the context in which the studies were conducted and the evidence base that informed them.

Table 1 Details of the studies included in this thesis

<table>
<thead>
<tr>
<th>Study name (period)</th>
<th>Publication</th>
<th>Chapter</th>
</tr>
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<tbody>
<tr>
<td>Warfarin Management Evidence Implementation Study (2008-9)</td>
<td>Improving the safety and efficacy of warfarin therapy in a metropolitan private hospital: A multidisciplinary practice improvement project</td>
<td>2</td>
</tr>
<tr>
<td>VTE Prevention Evidence Implementation Study (2009-10)</td>
<td>Translating VTE prevention evidence into practice: A multidisciplinary evidence implementation project</td>
<td>3</td>
</tr>
<tr>
<td>Clinical &amp; Economic Outcomes of Improved Pharmacological VTE Prophylaxis (2010-11)</td>
<td>Prevention of VTE in hospitalised patients: Analysis of reduced cost and improved clinical outcomes</td>
<td>4</td>
</tr>
<tr>
<td>Peer-on-Peer Education for Better VTE Prevention (2011-12)</td>
<td>Educational outreach visits to improve nurses’ use of mechanical VTE prevention in hospitalised medical patients: A prospective before-and-after intervention study</td>
<td>5</td>
</tr>
</tbody>
</table>
<pre><code>                                                                               | Educational outreach visits to improve VTE prevention in hospitalised medical patients: A prospective before-and-after intervention study | 6       |
</code></pre>
1.1 The Candidate

Facilitation is an important concept in evidence implementation and it is included in a number of evidence implementation theories (Harvey et al., 2002). The Promoting Action on Research Implementation in Health Services (PARIHS) framework, for example, states that successful research implementation is a function of the relationship between evidence, context, and facilitation (Rycroft-Malone, 2004). Facilitation has been defined as “a technique by which one person makes things easier for others” (Kitson, Harvey, & McCormack, 1998, p. 152). The role of the facilitator in evidence implementation is to help individuals and teams to understand what they need to change and how they need to change it (Kitson, et al., 1998).

In order to provide the reader with some insight into the facilitation of these studies, I provide the following information on my current and past employment, education, and project management style.

I am a registered nurse with 15 years’ experience working in Australia and the United Kingdom. The bulk of this experience has been in the areas of critical care and perioperative nursing where I have held a number of clinical and academic positions including clinical nurse educator, practice development facilitator, and undergraduate unit coordinator.

I have continued to advance my skills and knowledge in nursing through postgraduate education, completing a graduate diploma in critical care nursing in 2000; a certificate in workplace training and assessment in 2007; and a masters in nursing leadership in 2008. These formal qualifications were supplemented with numerous professional development
courses in relevant areas such evidence-based practice, staff and student facilitation, and research methods.

My involvement in VTE prevention started in 2008 when I was seconded to the position of facilitator for a whole-of-hospital study promoting evidence-based warfarin management. As I explain in the prologue to chapter 2, this study led on to the VTE prevention evidence implementation study, which in turn, led to the other studies contained in this thesis.

I am currently the inaugural clinical research fellow at St Vincent’s Private Hospital, Sydney. This role was developed to promote evidence-based practice within the organisation through practice development and clinical research. Practice Development and clinical research are two approaches at either end of the research continuum. Practice Development employs an emancipatory, organic approach to change (McCormack, Manley, & Garbett, 2004); whereas clinical research uses a far more structure methodology.

These different approaches often require differing facilitation styles. Facilitation styles range on a continuum from taking a task driven approach to being more holistic focused (Kitson et al., 2008). On reflection, I believe my personal facilitation style falls at the holistic end of this continuum as I aim to help people analyse, reflect on and change their own clinical practices. However, I do also argue that good facilitators need to adapt their approach to fit the specific circumstances of each project or within various phases of a given project.
The primary objectives of my position are:

- To develop, test, and implement strategies to improve the uptake of evidence into practice;
- To design and conduct research that contributes to improved patient outcomes and is in line with the mission and values of the sisters of charity;
- To promote research and evidence-based practice;
- To mentor staff in evidence-based practice, evidence implementation and research;
- To communicate the successes of St Vincent’s Private Hospital through publications and presentations.

The body of work contained in this thesis has been an important vehicle for achieving these objectives.

The following section of this chapter describes key contextual characteristics of the facility in which the studies were conducted.
1.2 The Context

It is unadvisable to report implementation research studies without first accurately describing the context to which the evidence is being applied (Eccles et al., 2009). Robust evidence implementation models such as the Knowledge to Action (Graham et al., 2006) and PARIHS (Kitson, et al., 1998) frameworks recognise that factors in the context of healthcare settings significantly impact on the implementation and uptake of evidence. In fact, it is said that the success or failure of evidence implementation interventions is highly dependent on the social, economic and political context in which they are developed and operated (Armstrong et al., 2008).

Identifying, understanding, and making changes to the processes and structures of care are essential to evidence implementation studies. It is therefore necessary to provide the reader with an understanding of the context of the thesis to assist them in their interpretation of the findings. Reporting guidelines, such as the Standards for Quality Improvement Reporting Excellence (SQUIRE) (Davidoff, Batalden, Stevens, Ogrinc, & Mooney, 2008) and Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) (Des Jarlais, Lyles, & Crepaz, 2004) now mandate the reporting of context.

The following description provides the reader with an insight into the culture, the leadership and the systems and process of the hospital where the studies contained in this thesis were conducted.

The studies were conducted at St Vincent’s Private Hospital (SVPH), a 270 bed acute-care private hospital in Sydney, Australia. SVPH is part of St Vincents & Mater Health Sydney, the NSW based arm of St Vincent's Health Australia, the nation’s largest not-for-profit,
non-government healthcare provider. The hospital’s mission, consistent with the values and healthcare of the Sisters of Charity, is to preserve a Catholic identity in healthcare and to provide excellent holistic services through value-based team work, commitment and technology.

SVPH is acknowledged as a world-class medical and surgical facility providing overnight and day-only care across a broad spectrum of specialty areas for patients from the local community, rural areas, interstate and overseas. The hospital is an associated medical and teaching hospital of the University of NSW and the University of Notre Dame Australia. There are also undergraduate nursing partnership agreements with Australian Catholic University, University of Tasmania and the University of Notre Dame, Australia.

A wide range of medical practitioners are accredited to the hospital, with specialist services provided in all the major fields of medicine and surgery with the exception of obstetrics and paediatrics. Over 300 specialist consultants are accredited to admit patients to the hospital. SVPH has become a leader in many areas including cardiac care; cancer; neurosurgery; orthopaedics; head, neck, and reconstructive surgery; laser and laparoscopic; and robotic assisted surgery.

The hospital prides itself on providing excellent nursing care and this was recognised in 2011 when the hospital was awarded Magnet recognition by the American Nurses Credentialing Centre (see Walker & Aguilera, 2011). Magnet recognition is awarded to healthcare organisations for quality patient care, nursing excellence and innovations in professional nursing practice. The process involves a two year developmental period where evidence was collated against a strict set of criteria. These criteria fall within four key
domains: Transformational leadership; structural empowerment; exemplary professional practice; new knowledge, innovations & improvements. At present there are only two other hospitals in Australia with Magnet recognition, both being public sector facilities.

Effective leadership and good governance structures have been identified as predictive factor of successful evidence implementation (Cummings, Estabrooks, Midodzi, Wallin, & Hayduk, 2007). A hallmark of Magnet facilities is transformational leadership and the empowerment of staff at all levels of the hospital. SVPH has a shared governance model which affords staff at all levels the opportunity to engage with day-to-day operations and, more importantly, the strategic directions of the hospital. The six governing councils include the Quality and Safety Council; Clinical Policy and Procedure Council; Practice Development and Research Council; Clinical Management Council; Education, Training and Development Council which all report to the Executive Council.

Another component of an organisation’s context said to influence readiness for implementation is the concept of evaluation (Rycroft-Malone, 2004). Organisations with experience in evaluation and measurement tend to be more receptive to change. SVPH has a long history of data driven management. In 2005, the hospital implemented the Balanced Scorecard clinical governance framework. The Balanced Scorecard is a program for turning strategy into practice. It helps managers systematically map key strategic objectives, measures, targets, initiatives and accountabilities to progress the delivery of clinical care (Aguilera & Walker, 2008). Each unit and department, as well as the aforementioned governance councils at SVPH has a strategic plan based on the Balanced Scorecard framework, with a strategy map, individual objectives, measures, targets,
initiatives and accountabilities. The scorecard is regularly populated with patient outcome, processes of care and patient and staff satisfaction data.

Patient and staff satisfaction are regularly assessed by external organisations. National patient satisfaction data, collected by Press Ganey, has placed the hospital in the 96th percentile for the last three quarters when benchmarked with peer hospitals while Best Practice Australia reported in their latest survey that 75% of staff felt that the hospital was a truly great place to work. Best Practice Australia has also found that the hospital has been in a culture of success, with over 60% staff engagement, in each survey since 2005.

Like all accredited hospitals in Australian, SVPH is regularly audited against national healthcare standards by an external body, the Australian Council on Healthcare Standards (ACHS). In the most recent accreditation SVPH attained its best ever result receiving five awards of Outstanding Achievement (denoting that the hospital is a leader in a particular standard); 26 awards of Extensive Achievement; and 12 awards of Marked Achievement across the 46 standards. The ACHS accreditors made the following comment in their final report:

“St Vincent’s Private has a culture that assists the provision of excellent patient care. Overall there is very strong evidence that patient safety and clinical care is of a very high standard - in fact the survey team believes the hospital is one of the best in Australia.”

Finally, it is important to note that the hospital leadership has made a significant, ongoing commitment to the pursuit of clinically-focussed, outcomes-based research as the studies reported in this thesis attest. The commitment is manifest in a number of positions
dedicated to practice development, professional development and in my own appointment as clinical research fellow. We also have a professor of healthcare improvement with whom I work very closely. It would be not unreasonable to claim that there would be very few, if any, private hospitals in Australia to have made a similar investment.

SVPH, on any measure therefore, is clearly a quality hospital. The above information was not presented to promote the facility but rather to provide the reader with a contextual lens to view the findings of the studies contained within this thesis.
1.3 The Evidence

Two distinct knowledge bases have informed the studies contained in this thesis; the evidence on VTE and its prevention and the evidence on methods and strategies for promoting the uptake of research findings into clinical practice. The following narrative is not an exhaustive review of these two knowledge bases but rather a summary of evidence relevant to the scope and conduct of the studies included in this thesis.

1.3.1 Venous thromboembolism

This review begins with a broad description of the pathophysiology and epidemiology of VTE before the discussion is narrowed to VTE in hospitalised patients. The recommendations of evidence-based VTE prevention guidelines are summarised including risk assessment, and pharmacological and mechanical prophylaxis methods. Finally, the literature documenting the current gap between evidence and clinical practices is reviewed. Specific search terms used to retrieve articles were *venous thromboembolism (VTE), deep vein thrombosis (DVT), pulmonary embolism (PE), prophylaxis, guidelines, protocol, policy, implementation, clinical practice, hospital* in CINAHL, MEDLINE, EMBASE, and PubMed databases.

*Pathophysiology*

VTE occurs when red blood cells, fibrin, platelets, and leukocytes form a mass within an intact vein. A pulmonary embolism may result when a piece of thrombus detaches from the vein wall, travels up to the lungs and lodges within the pulmonary arteries (Emadi & Streiff, 2011). More than 70% of all pulmonary emboli originate in this way (Blann & Lip,
The causes of venous thromboembolic disease were first described in 1859 by the Austrian physician, Rudolf Virchow (Kakkar & Haas, 2007). Virchow outlined the three physiological changes that he believed contributed to the occurrence of VTE: 1) venous stasis; 2) endothelial injury; and 3) hypercoagulable states (Dickson, 2004). These three changes, now known as Virchow’s triad, can help explain the identified risk factors for VTE (Anderson Jr & Spencer, 2003). Table 2 lists the risk factors for VTE and their relationship to Virchow’s triad.

Table 2 Physiological changes that contribute to VTE

<table>
<thead>
<tr>
<th>Endothelial injury</th>
<th>Venous stasis</th>
<th>Hypercoagulable states</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>Advancing age</td>
<td>Cancer</td>
</tr>
<tr>
<td>Prior DVT</td>
<td>Immobilisation</td>
<td>Oestrogen use</td>
</tr>
<tr>
<td>Venous access devices</td>
<td>Cord injury</td>
<td>Family history</td>
</tr>
<tr>
<td>Trauma</td>
<td>Heart or lung failure</td>
<td>Sepsis</td>
</tr>
<tr>
<td>Sepsis</td>
<td>Hyperviscosity</td>
<td>Heparin Induced Thrombocytopenia</td>
</tr>
<tr>
<td>Vasculitis</td>
<td>Obesity</td>
<td>Thrombophilies</td>
</tr>
</tbody>
</table>

Epidemiology

The incidence of first-episode VTE in the Australian population is estimated at 100 per 100,000 (National Institute of Clinical Studies, 2005a). The mortality associated with these events is considerable with death occurring in approximately 6% of DVT cases and 12% of PE cases within one month of diagnosis (White, 2003). The estimated survival rate at one year is 63.6%, dropping to 53.5% after five years, and to 47.5% after eight years (Ageno,
Squizzato, Garcia, & Imberti, 2006). The ongoing mortality risk is associated, in part, with the significant risk of recurrence. People who suffer an idiopathic VTE event have a 25% reoccurrence rate (Hansson, Sörbo, & Eriksson, 2000).

The dramatic and ongoing mortality risk results in approximately 5000 deaths from VTE in Australia each year (Access Economics, 2008) and this number may be an underestimation given the fact that VTE is often under-diagnosed. Australian mortality estimates appear conservative when compared to per capita estimates that are 50% higher in the United Kingdom (25,000 estimated deaths annually) (House of Commons Health Committee, 2005) and four times higher in the United States (300,000 estimated deaths annually) (Heit, 2005).

Morbidity from VTE for survivors can also be substantial: One-third of patients with DVT will develop post-thrombotic syndrome; characterised by persistent lower limb oedema, pain, inflammation, and ulceration (Kakkar & Haas, 2007); and 5% of those suffering PE will go on to develop chronic pulmonary hypertension, a debilitating cardiorespiratory disease (Pengo et al., 2004). This disease profile has led some to refer to VTE as a chronic disease punctuated with periods of acute exacerbation (Hansson, et al., 2000; Mason, 2009).

**VTE in Hospitalised Patients**

The incident of VTE for hospitalised patients is 100 times greater than for the average member of the community (Heit et al., 2001). This is because almost all hospitalised patients have at least one of the above mentioned risk factors for VTE and approximately 40% have three or more risk factors (Qaseem, Chou, Humphrey, Starkey, & Shekelle,
Without any form of prophylaxis 10 to 40% of medical and general surgical patients and 40 to 60% of major orthopaedic surgery patients will acquire a DVT (Geerts et al., 2008b). VTE is a leading cause of inpatient mortality. The Australian Institute of Health and Welfare data reveal that 7% of all hospital deaths are due to VTE (Access Economics, 2008) and some post-mortem studies put that number as high as 10% (MacDougall, et al., 2006). For this reason, VTE prevention in hospitalised patients has been internationally identified as the number one opportunity to significantly improve patient safety (Shojania, Duncan, McDonald, Wachter, & Markowitz, 2001).

**VTE Prevention**

In comparison to other patient safety practices the prevention of VTE is relatively simple, inexpensive and supported by a substantial evidence base (Agency for Healthcare Research and Quality, 2001; Shojania, et al., 2001). There is a large body of level one evidence supporting the use of pharmacological and mechanical prophylaxis measures for those patients at-risk of VTE and this evidence has informed a number of well-developed and well regarded evidence-based guidelines. These include two Australian developed guidelines; the 5th edition of Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism best practice guidelines (2010) and the National Health and Medical Research Council’s clinical practice guideline for the prevention of venous thromboembolism (2009). Two other international bodies who have published guidelines of particular note are the American College of Chest Physicians (Falck-Ytter et al., 2012; Gould et al., 2012; Kahn et al., 2012) and the United Kingdom’s National Institute of Health and Clinical Excellence (National Institute of Health and Clinical Excellence, 2010). The national guideline contains over 30 Grade 1A
recommendations based on meta-analysis or large multisite RCTs. To follow is a summary of the major recommendations from the guidelines. Figure 1 depicts the physiological causes of VTE and the associated preventative therapies.

![Figure 1 Physiological causes of VTE and associated preventative therapies](image)

**Risk Assessment**

A key recommendation in the guidelines is the necessity for clinicians to undertake a systematic assessment of all patients, weighing their risk of VTE against any risk of bleeding (Gould, et al., 2012; National Health and Medical Research Council, 2009; National Institute of Health and Clinical Excellence, 2010; The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2010). There are a number of published risk assessment tools available (RAM) (Caprini & Hyers, 2006; Cohen, Alikhan, & Arcelus, 2003; Kucher, Koo, & Quiroz, 2005). The tools consist of lists of exposing risk factors (presenting illness or procedure) and predisposing
risk factors (genetic and clinical characteristics) which are each assigned a relative risk score. Scores for each risk factor are summed to produce a cumulative score and this is used to classify a patient into a risk stratum (high or low) which, in turn, is used to determine the onset, intensity, type, and duration of the recommended prophylaxis. Several studies in recent years have validated the Caprini (2006) risk assessment model and linked the score to the eventual development of clinically relevant VTE events up to 60 days post discharge (Bahl et al., 2010; Pannucci et al., 2011; Seruya, Venturi, Iorio, & Davison, 2008).

\textit{Pharmacological prophylaxis}

The recommendations for pharmacological and mechanical prophylaxis are stratified by clinical procedure e.g. total hip replacement, general surgery, or gynaecological surgery; or by medical condition e.g. stroke, myocardial infarction, or sepsis. Evidence-based pharmacological options vary according to patients’ risk strata. Table 3 lists the various drug classes and drugs which are included in the guidelines. It is worth noting that, despite each of the guidelines reporting to be based on the best available evidence, there is some obvious discrepancy between them. For example, the United Kingdom (2010) and Australian (2009) guidelines recommend against the use of warfarin or aspirin for VTE prophylaxis while the United States CHEST (2012) guideline supports their use.
Table 3 Pharmacological prophylaxis options

<table>
<thead>
<tr>
<th>Drug class</th>
<th>Drug name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heparins</td>
<td>Low molecular weight heparin</td>
</tr>
<tr>
<td></td>
<td>Unfractionated heparin sodium</td>
</tr>
<tr>
<td>Selective Factor X inhibitor</td>
<td>Fondaparinux</td>
</tr>
<tr>
<td>Heparinoid</td>
<td>Danaparoid</td>
</tr>
<tr>
<td>Vitamin K antagonist</td>
<td>Warfarin</td>
</tr>
<tr>
<td>Platelet aggregation inhibitor</td>
<td>Aspirin</td>
</tr>
<tr>
<td>Direct thrombin inhibitor</td>
<td>Dabigatran</td>
</tr>
<tr>
<td>Direct Factor Xa inhibitor</td>
<td>Rivaroxaban</td>
</tr>
</tbody>
</table>

*Mechanical prophylaxis*

Mechanical prophylaxis methods listed in the guidelines focus on reducing venous stasis and blood stagnation by promoting venous blood flow through external compression. Mechanical prophylaxis options include thigh, or knee-length graduated compression stockings, and pneumatic venous pumping devices that intermittently compress the leg muscles or feet (National Health and Medical Research Council, 2009; National Institute of Health and Clinical Excellence, 2010; The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2010). There is also some discrepancy between the various guidelines on the use of mechanical prophylaxis measures. For example, the United States CHEST guideline (Kahn, et al., 2012) does not recommend the use of mechanical prophylaxis for at-risk medical patients while the Australian (2009) and United Kingdom (2010) guidelines do. The inconsistency between
the various guidelines can be explained by the limited amount of research, particularly level one research, in the area of mechanical prophylaxis (Morris & Woodcock, 2010).

Evidence-practice gap

Research and clinic audit reveal that prophylactic therapies are underutilised and inconsistently applied (Clavijo-Alvarez, Pannucci, Oppenheimer, Wilkins, & Rubin, 2011; Cohen et al., 2008). The ENDORSE study (2008) audited 70,000 patients from 32 countries, including Australia, and found that only 50% of all at-risk patients (n=35,329) were receiving appropriate VTE prophylaxis. Australian data were slightly higher with a compliance rate of 57% (n=804) (Cohen, et al., 2008). A more recent Australian study which audited 485 patients and 1860 clinical encounters had a similar finding (58% appropriate prophylaxis rate, 95% CI 53.3-63) (Runciman et al., 2012). It is difficult to generalise these results as there is a considerable variation in practices between individual Australian hospitals (National Institute of Clinical Studies, 2005b, 2008a).

Despite the fact that between 50 and 80% of all hospital related VTE cases occur in medical patients (Alikhan, Peters, Wilmott, & Cohen, 2004; Goldhaber & Tapson, 2004) this group of patients continues to receive suboptimal thromboprophylaxis (Bergmann, et al., 2010; Rothberg, et al., 2010; Vardi, Dagna, Haran, & Duckit, 2011). An audit of 37,356 at-risk medical inpatients found that less than 40% were receiving recommended prophylaxis (Bergmann, et al., 2010).
Conclusion

There is a robust body of research evidence on the causes of VTE and the methods for prevention it in hospitalised patients. There is also considerable evidence from large multi-site international studies and clinical audits that patients are not routinely receiving evidence-based prophylaxis.
1.3.2 Implementation science

The following review begins by defining key concepts in implementation science before discussing the various theories (or models) that can be used to develop and explain successful implementation. A taxonomy of clinician behaviour change strategies and their documented effectiveness, in general, and more specifically for VTE prevention, will then be explored. Finally, the methods and designs used in implementation research will be summarised and discussed in respect of their relevance to the studies reported in this thesis. Specific search terms used to retrieve articles were implementation science, implementation research, knowledge translation, dissemination, diffusion, guidelines, research utilisation, and knowledge transfer in CINAHL, MEDLINE, EMBASE, and PubMed databases.

Definitions

Broadly speaking, implementation science is concerned with the application of research findings into clinical practice. In the literature, the term implementation science is often used interchangeably to describe both the study of implementation methods and the practical application of these methods. The evolving and sometimes conflicting nature of the terms and definitions used in implementation science is a consequence of this being a relatively new field and one that crosses a number of health and related disciplines. For the purpose of this review, these two different but interrelated areas of implementation science are referred to as evidence implementation and implementation research. Table 4 describes the major differences between evidence implementation and implementation research.
Evidence implementation, also known as knowledge translation, is ‘the dynamic and iterative process that includes the synthesis, dissemination, exchange and application of knowledge to improve health, health services and the healthcare system’ (Straus, Tetroe, & Graham, 2011, p. 3). Evidence implementation and the evidence-based healthcare movement are two interrelated and interdependent areas. It is now widely accepted by clinicians, the community, and regulatory agencies that clinical care should be based on the best available research evidence. It is also now widely accepted that the translation of research evidence into practice requires more effort than the simple dissemination of research findings (Morris, Wooding, & Grant, 2011). There are numerous models of evidence implementation, which will be discussed below, but the common theme to all of these models is their systematic, evidence informed approach to facilitating the translation of research evidence to clinical practice.

Implementation research is the scientific study of methods to promote the systematic uptake of research findings into routine practice to improve the quality and effectiveness of health services and patient care (Wallin, 2009). Historically, evidence implementation strategies were chosen based on personal beliefs or hunches rather than theoretical or empirical knowledge about what changes provider behaviour (Grol, Baker, & Moss, 2004). Early leaders in the field of implementation science called for change declaring that ‘evidence-based medicine should be complemented by evidence-based implementation’ (Grol & Grimshaw, 1999, p. 503). Today, implementation research has developed into an important subset of health services research which is building a body of knowledge on the different models and strategies for implementing research evidence into clinical practice.
Table 4, below, describes the differences between evidence implementation and implementation research as I have come to understand them through the conduct of this PhD.

Table 4 Differences between evidence implementation and implementation research

<table>
<thead>
<tr>
<th>Component</th>
<th>Evidence implementation</th>
<th>Implementation research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim</td>
<td>Brings about improvement</td>
<td>Tests a hypothesis</td>
</tr>
<tr>
<td>Intervention(s)</td>
<td>Applies proven intervention(s)</td>
<td>Tests intervention(s)</td>
</tr>
<tr>
<td>Design</td>
<td>Iterative pragmatic design</td>
<td>Classical research design</td>
</tr>
<tr>
<td>Protocol</td>
<td>Flexible adaptive protocol</td>
<td>(more) Rigid protocol</td>
</tr>
<tr>
<td>Results</td>
<td>Context specific</td>
<td>(more) Generalisable</td>
</tr>
</tbody>
</table>

*Implementation science theories*

The factors that predict ease of implementation are highly complex and numerous theories have been proposed in an attempt to explain the variation. Michie et al (2008) describe the following three reasons for advocating the use of theory in designing interventions. Firstly, interventions are more likely to be effective if they target causal determinants of behaviour and behaviour change. Secondly, theory can only be tested and developed if interventions and their evaluations are theoretically informed. Finally, theory-based interventions facilitate an understanding of what works, or doesn’t work, which provide the basis for further developments.

The key theories used to explain evidence implementation are described below but first it is important to define what is meant by the term theory. Theory has been defined as ‘an
organised, heuristic, coherent, and systematic articulation of a set of statements related to significant questions that are communicated in a meaningful whole’ (ICEBeRG Group, 2006, p. 3). This definition covers both the relatively broad abstract theories and those with more operational detail. In evidence implementation, these two different types of theories (abstract and operational) have been categorised as impact and process theories (Grol, Bosch, Hulscher, Eccles, & Wensing, 2007). These two categories are further divided into subgroups based on the scope or focus of the given theory (Table 5).

Table 5 Classification of evidence implementation theories

<table>
<thead>
<tr>
<th>Category</th>
<th>Group</th>
<th>Subgroup</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact theories</td>
<td>Individual level</td>
<td>Education theories</td>
<td>Adult learning theory</td>
</tr>
<tr>
<td></td>
<td>Group level</td>
<td>Social influence theories</td>
<td>Rogers diffusion of innovation model</td>
</tr>
<tr>
<td></td>
<td>Organisational level</td>
<td>Complexity theories</td>
<td>Complex adaptive systems theory</td>
</tr>
<tr>
<td>Process theories</td>
<td>Action focused</td>
<td></td>
<td>Implementation of change model</td>
</tr>
<tr>
<td></td>
<td>Context focused</td>
<td></td>
<td>PARIHS framework</td>
</tr>
<tr>
<td></td>
<td>Individual focused</td>
<td></td>
<td>Stetler model</td>
</tr>
</tbody>
</table>

Impact theories

Impact theories describe hypotheses and assumptions about how a specific intervention will facilitate a desired change, as well as the causes, effects, and factors determining success (or the lack of it) in improving healthcare (Grol, et al., 2007). These theories come from a wide variety of disciplines and scientific areas such as the educational, social, and
organisational sciences. They can be broadly categorised into three main subgroups; individual level, group level, and organisational level impact theories. An example of a theory from each of the three subgroups is discussed, below.

Individual level impact theories focus on the individual professional and the way they make decisions, their knowledge or skills, their attitudes and motivation, or their routines and habits of daily professional life (Grol, et al., 2007). Educational theories are an example of individual impact level theories. A lack of knowledge in an area of research is often identified as a barrier to effective practice and educational interventions are frequently applied to enhance a clinician’s understanding, knowledge and ability to apply the evidence to practice (Hutchinson & Estabrooks, 2011). Educational theories help to explain the effectiveness of educational interventions and inform the development of frameworks to design and evaluate them (Laidley & Braddock, 2000). A number of systematic reviews have found educational interventions to be an effective strategy for changing clinician behaviour and improving patient care (Farmer et al., 2008; Forsetlund et al., 2009; O’Brien et al., 2007). The extent to which educational theory was used in the individual studies in these reviews, however, is not known.

The group level impact theories are based on social interaction and describe the determinants of change in relation to the interaction between individual professionals (Grol, et al., 2007). The influence of opinion leaders, participation in social networks and the role of leadership are a focus for this type of theory. Social influence theory is a good example as it assumes that the performance of daily routines is not based on conscious considerations of the advantages or disadvantages of a given action but rather on the social norms of the practice community to which they belong (Grol, Wensing, Hulscher, &
Eccles, 2005). Social influence theory can help to explain the impact of opinion leaders on clinical practice. Opinion leaders represent the social norms within the practice community and others trust them to take on the task of evaluating innovations with regard to the existing norms and local situation (Grol, et al., 2007). The effectiveness of opinion leaders in evidence implementation has been mixed however, with significant variation both within and between studies (Flodgren et al., 2011).

Several theories outline the opportunity for improvement in patient care in terms of structural or organisational reforms. These organisational level impact theories focus on areas such as better organisation of care processes, different division of tasks and roles, change in workplace culture and improved inter-professional collaboration (Grol, et al., 2007). Complexity theory, as an example, asserts that, because healthcare is increasingly complex, it is necessary to observe and improve systems as a whole rather than in parts or components (Grol, et al., 2005). This level of theory is also particularly helpful for understanding the influence of contextual factors on change strategies and enables greater understanding of the organisational factors that may facilitate or hinder implementation (Rycroft-Malone & Bucknall, 2011).

Process theories

Process theories refer to the preferred implementation activities: how they should be planned, organised, and scheduled in order to be effective and how the target group will utilise and be influenced by the activities (Grol, et al., 2007). There are numerous process theories, also known as models, for the active transfer of knowledge into practice that have emerged from a variety of healthcare related fields (Mitton, Adair, McKenzie, Patten, &
Sudsawa (2007) broadly categorises process theories into three main subgroups; action focused, context focused, and individual focused. An example of a theory from each of the three subgroups is discussed below.

Action focused process theories consist of ‘a set of logical interrelated concepts that explain, in a systematic way, the means by which planned change occurs, that predict how various forces in an environment will react in change situations, and that help planners or change agents control variables that increase or decrease the likelihood of the occurrence of change’ (Graham, Tetroe, & KT Theories Group, 2011, p. 185). The Implementation of Change model by Grol and Wensing (2004) is an example of an action focused process theory. The steps in the process include the identification of a problem; the development of a proposal; analysis of current performance; development/selection of change strategies; execution of the implementation plan; and evaluation and adaptation (where necessary). A systematic review and thematic analysis of action focused process models found that most of them contain very similar steps (Ward, House, & Hamer, 2009).

Context focused process theories can be used to understand the contextual factors that play important roles in the success or failure of evidence implementation efforts. Promoting Action on Research Implementation in Health Services (PARIHS) is an example of a context focussed theory (Kitson, et al., 1998; Rycroft-Malone, 2004). According to the model, a successful implementation of research into practice is a function of the relationship between three key elements: 1) the level and nature of the evidence to be used; 2) the context or environment in which the research is to be placed; and 3) the method by which the research implementation process is to be facilitated. Strengths of the PARIHS
framework include its flexibility, intuitive appeal, and its more expansive view of what can and should constitute ‘evidence’ (Helfrich et al., 2010).

The Stetler Model of Research Utilisation is an example of an individual focused process theory (Stetler, 2001). It is used by individual practitioners as a procedural and conceptual guide for the application of research in practice. The model is based on six basic assumptions: 1) The formal organisation may or may not be involved in an individual’s utilisation of research; 2) utilisation may be instrumental, conceptual, and/or symbolic; 3) other types of evidence and/or non-research-related information are likely to be combined with research findings to facilitate decision making or problem solving; 4) internal and external factors can influence an individual’s or group’s view and use of evidence; 5) research and evaluation provide us with probabilistic information, not absolutes; and 6) lack of knowledge and skills pertaining to research utilisation and evidence-based practice can inhibit appropriate and effective use (Sudsawad, 2007). The Stetler model is comprehensive and provides procedures to help guide practitioners through all steps in the research use process while taking into consideration the practical aspects of clinical decisions.

For the purpose of brevity only one example has been given here for each of the impact and process theory subgroups. There are, in fact, numerous implementation theories to choose from with a recent review identifying 61 process theories, alone (Tabak, Khoong, Chambers, & Brownson, 2012). One critique of implementation theories is that they are not evidence-based and without evidence there is little information to support the use of one theory over another (Mitton, et al., 2007; Ward, et al., 2009).
A variation on the concept of using theory to inform implementation comes from the world of evaluation science. This field of social science research emphasises the importance of identifying a ‘program theory’ of change which explicitly states the assumed mechanisms of action of a program (or improvement strategy in the case of implementation science). Evaluators are encouraged to clearly specify the hypotheses and assumptions that inform programs, especially those concerning how the program is likely to bring about the desired outcomes (Rogers, Petrosino, Huebner, & Hacsi, 2004). There are a number of different methods described in the literature for developing a program theory but all are pragmatic in nature, relying on the experience of the researcher and influenced by the relevant literature and particular context (Dixon-woods, Bosk, Aveling, Goeschel, & Pronovost, 2011; Leeuw, 2003; Rogers, et al., 2004).

Evidence implementation strategies

The literature contains many different ways of influencing clinician behaviour and changing clinical practice. They can vary greatly from simply sending out printed material in the mail to intensive one-to-one coaching sessions. The strategies have been described and classified in a number of different ways. In this thesis, I use the Cochrane Effective Practices of Care (EPOC) group’s taxonomy of strategies targeted at professionals to improve practice (EPOC Group, 2012). The EPOC group organises high quality systematic reviews of the literature on the effectiveness of methods to implement guidelines or introduce change to healthcare. The various strategies and their evidence base are summarised in Table 6.
The EPOC website (2012) defines audit and feedback as any summary of clinical performance of healthcare over a specific period of time used to change clinicians’ behaviour on objectively measured practices or patient outcomes. Multivariable meta-regression indicates that feedback may be more effective when baseline performance is low; the source is a supervisor or colleague; it is provided more than once; it is delivered in both verbal and written formats; and when it includes both explicit targets and an action plan. In addition, the effect size varied based on the clinical behaviour targeted by the intervention (Ivers et al., 2012).

Educational meetings are defined as the participation of healthcare providers in conferences, lectures, workshops or traineeships (EPOC Group, 2012). Educational meetings are another commonly used strategy because it is relatively inexpensive and generally feasible (Grimshaw, Eccles, Lavis, Hill, & Squires, 2012). The systematic review by Forsetlund et al (2009) found that strategies to increase attendance at educational meetings, using mixed interactive and didactic formats, and focusing on outcomes that are likely to be perceived as serious, may increase the effectiveness of educational meetings. They concluded that educational meetings alone are not likely to be effective for changing complex behaviours.
<table>
<thead>
<tr>
<th>Intervention</th>
<th>Trials</th>
<th>Improvement</th>
<th>Authors conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit &amp; Feedback (Ivers, et al., 2012)</td>
<td>140</td>
<td>Median absolute improvement 4.3 (IQR 0.5 to 16)</td>
<td>Generally leads to small but potentially important improvements in professional practice</td>
</tr>
<tr>
<td>Computer reminders (Shojania et al., 2009)</td>
<td>28</td>
<td>Median absolute improvement 4.2 (IQR 0.8 to 18.8)</td>
<td>Generally achieve small to modest improvements in provider behaviour</td>
</tr>
<tr>
<td>Education meetings (Forsetlund, et al., 2009)</td>
<td>81</td>
<td>Median absolute improvement 6 (IQR 1.8 to 15.9)</td>
<td>Alone or combined with other interventions, can improve professional practice and healthcare outcomes</td>
</tr>
<tr>
<td>Educational outreach (O’Brien, et al., 2007)</td>
<td>69</td>
<td>Median absolute improvement 5.6 (IQR 3 to 9)</td>
<td>Has an effect on prescribing that is relatively consistent and small, but potentially important. The effect on other types of professional performance vary from small to modest improvements</td>
</tr>
<tr>
<td>Local opinion leaders (Flodgren, et al., 2011)</td>
<td>18</td>
<td>Median absolute improvement 12 (IQR 6 to 14.5)</td>
<td>May successfully promote evidence-based practice, but effectiveness varies both within and between studies</td>
</tr>
<tr>
<td>Printed educational materials (Farmer, et al., 2008)</td>
<td>23</td>
<td>Median absolute improvement 4.3 (IQR -8 to 9.6)</td>
<td>May have a beneficial effect on process outcomes but not on patient outcomes.</td>
</tr>
<tr>
<td>Tailored interventions (Baker et al., 2010)</td>
<td>26</td>
<td>Pooled OR 1.54 (95% CI, 1.16 to 2.01)</td>
<td>Interventions tailored to prospectively identified barriers are more likely to improve professional practice than no intervention or dissemination of guidelines.</td>
</tr>
</tbody>
</table>

IQR= Inter Quartile Range. CI= Confidence Interval.
Educational outreach, also known as academic detailing, uses a trained person to meet with providers in their practice setting and give information with the intent of changing the providers’ practice (EPOC Group, 2012). Typically, the detailer aims to give three to four messages during a 15 minute meeting with a healthcare provider. They will tailor their approach to the characteristics of the individual and use other social marketing techniques to reinforce their message (Robertson & Jochelson, 2007). It has been shown to have effects on prescribing that are relatively small but consistent while the effects on other types of professional performance vary from small to modest (O’Brien, et al., 2007).

Local opinion leaders is defined as the use of providers nominated by their colleagues as educationally influential (EPOC Group, 2012). Opinion leaders target the knowledge, attitudes, and social norms of their peer group and thus the success of this intervention is said to depend on intact functional professional networks (Grimshaw, et al., 2012). Although this is a frequently used strategy, in most studies the role of the opinion leader is not clearly described which makes it difficult to identify potential ways for optimising the strategy (O’Brien, et al., 2007).

Printed education materials as a strategy is defined as the distribution of published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials and electronic publications (EPOC Group, 2012). The use of printed education material as an implementation strategy is common because of its low cost and overall feasibility (Grimshaw, et al., 2012). However, its effectiveness compared to other interventions is uncertain and there is insufficient information in the literature about how it may be optimised (Farmer, et al., 2008).
Tailored interventions are strategies to improve professional practice that are planned taking account of prospectively identified barriers to change (EPOC Group, 2012). Although this approach seems logical, it is often not the case in practice. It has been observed that it is common for people to become attached to a familiar strategy which they apply in all situations (Grol & Wensing, 2005b). A systematic review by Baker et al (2010) found that tailored interventions are more likely to improve professional practice than no intervention or dissemination only. Further research was suggested to determine the effectiveness of tailored interventions in comparison with other strategies.

The EPOC group (2012) defines multifaceted interventions as any intervention including two or more components. Multifaceted interventions potentially target different barriers to evidence uptake. Grimshaw et al (2004) analysed the dose response curve in their frequently cited systematic review and found that effect size did not increase with the number of component parts of an intervention. They suggested that when using multifaceted interventions, it is important to carefully consider the components likely to have maximum benefit to avoid a ‘kitchen sink’ approach (Grimshaw, et al., 2012).

There is now a substantial (if incomplete) body of evidence to inform the selection of interventions targeting clinician practice. As illustrated in Table 6, the effect of the various interventions rage from 4-12% absolute improvement in processes of care. This relatively modest improvement illustrates how difficult it is to influence clinician behaviour and change clinical practice.
Evidence implementation strategies for VTE prevention

There are two systematic reviews on interventions to improve VTE prophylaxis in hospitalised patients (Mahan & Spyropoulos, 2010; Tooher et al., 2005). Combined, the reviews included 76 studies published from 1996 to 2008. The quality of the included studies was reported to be poor to average with the majority being single site uncontrolled before and after designs. There were no randomised trials identified by either review.

The strategies in the included studies were audit and feedback, provider education, reminders, and decision support tools. Both reviews found that active implementation strategies were effective, and a number of active strategies used in combination were more effective than any single active strategy used in isolation (Mahan & Spyropoulos, 2010; Tooher, et al., 2005). Mahan et al (2010) recommended a multifaceted, integrated intervention involving risk assessment tools, decision support, electronic alert systems, hospital wide education, and audit and feedback to ensure that all healthcare professionals comply with VTE prevention policies and initiatives. Further investigation of more complex active strategies, such educational outreach visiting, was suggested.

Implementation research designs

As healthcare has become ever more complex, so too have the interventions used to improve practice. The development and evaluation of complex behavioural change interventions can pose a considerable challenge and require a substantial investment of time. A complex intervention consists of a number of components that may act both independently and inter-dependently (Campbell & Murray, 2007). A framework has been developed by the United Kingdom Medical Research Council (UKMRC) which
emphasises the importance of a phased approach to intervention development, using a variety of research designs as appropriate (Craig et al., 2008). The phases of the Medical Research Council framework are depicted in Figure 2 and described below.

Figure 2 UKMRC complex intervention development framework

The pre-clinical (theoretical) phase of the Medical Research Council framework entails establishing the ‘theoretical’ basis for the intervention. The literature and the evidence surrounding the intervention are assessed, including an evaluation of formal behaviour change theories as well as informal evidence of beliefs and attitudes (Blackwood, 2006). This evidence is then used to develop a conceptual map or conceptual pathway of the intervention. The map attempts to describe the mechanism or pathways by which the intervention is predicted to have its desired action (Campbell & Murray, 2007).
This mapping is useful in the next phase (modelling phase) to identify ways of optimising the intervention, or overcoming potential barriers to successful implementation. Barriers are factors that potentially impair the effectiveness of an intervention (Campbell & Murray, 2007). It has been suggested that studies identifying and addressing these barriers have a greater chance of successfully improving and maintaining practice change (Grimshaw, et al., 2004; Grol & Wensing, 2005a).

Phase one (modelling phase) is used to develop a greater understanding of a complex intervention. The aim of this phase is to optimise the component parts identified in the conceptual map/pathway in order to improve the overall effectiveness of the intervention. Here the term component includes both program components (i.e. aspects of the intervention program itself) and delivery components (i.e. aspects of the implementation plan). Modelling a complex intervention before a full-scale evaluation provides important information about the design of both the intervention and the evaluation. The modelling process may comprise a series of smaller studies which progressively help refine the design before embarking on full-scale evaluation.

Phase two (pilot phase) is where all the evidence gathered through modelling is evaluated in an exploratory pilot. The exploratory pilot provides an evaluation of intervention effectiveness as well as valuable process evaluation data (Blackwood, 2006). Process evaluation is an important tool that can help describe an intervention, the actual exposure to the intervention, and the experience of those exposed (Eccles, Grimshaw, Campbell, & Ramsay, 2004). There has been criticism of implementation research that only reports on outcomes and fails to report on process evaluation (Dombrowski, Sniehotta, Avenell, & Coyne, 2007; Paterson, Baarts, Launsa,, & Verhoef, 2009; Stetler et al., 2006b; Thomson,
2009). The importance of process evaluation in implementation research is summarised as follows:

‘Evaluative information is needed beyond clinical impact of the change effort and beyond discovering whether a chosen adoption strategy worked. Implementation researchers need to answer critical questions about the feasibility of implementation strategies, degree of real-time implementation, status and potential influence of contextual factors, response of project participants, and any adaptations necessary to achieve optimal change.’ (Stetler, et al., 2006b, p. 1)

The process and outcome data gathered in this phase can then be used to inform a definitive trial, such as an Randomised Control Trial (RCT) or Cluster-Randomised Control Trial (C-RCT) (phase three of the framework). In fact, the Medical Research Council guidelines refer to this phase as a ‘crucial stage’ prior to any RCT involving complex interventions (Craig, et al., 2008).

The remaining phases include phase three which constitutes the definitive trial, usually a multisite RCT or C-RCT. This phase is described as the central step in this framework (Craig, et al., 2008). The final phase, phase four, establishes the long-term implementation and sustainability of the intervention. This also requires a separate study design, usually incorporating observational studies or audits (Campbell & Murray, 2007).

Conclusion

The body of literature that underpins implementation science comes from a variety of disciplines. As a consequence the knowledge base appears somewhat disjointed and the
terminology is sometimes contradictory or confusing. There is also an abundance of theories which purport to explain and predict implementation but most have not been subject to rigorous evaluation. There is, however, a growing body of rigorously conducted research on the effectiveness of various implementation strategies which is informing evidence implementation.
CHAPTER 2. IMPROVING THE SAFETY AND EFFICACY OF WARFARIN THERAPY IN A METROPOLITAN PRIVATE HOSPITAL: A MULTIDISCIPLINARY PRACTICE IMPROVEMENT PROJECT

2.1 Prologue

The impetus for this evidence implementation study came after a senior vascular physician raised concerns about the management of patients commenced on warfarin therapy at SVPH. Warfarin is a common, yet potentially dangerous anticoagulant which is frequently prescribed for the treatment and secondary prevention of VTE. The drug has a narrow therapeutic window and numerous drug-drug and drug-food interactions which necessitate specific precautions such as regular blood tests and special diets. The physician described an incident where a patient, who had recently been commenced on warfarin, was discharged home without receiving appropriate education on the management of the drug or referral for follow-up monitoring. This was seen by all those concerned as a significant error and one with potentially devastating consequences.

At about the same time, the NSW Clinical Excellence Commission and the NSW Therapeutic Advisory Group asked the hospital to pilot the Medication Safety Self-Assessment for Antithrombotic Therapy (MSSA-AT). The tool, adapted from an American instrument, required a multidisciplinary team to rate the organisation’s compliance with current best practice principles for antithrombotic therapy management. After completing the tool, and considering the concern of the senior physician, it was clear that the hospital was presented with a number of opportunities to improve the management of warfarin therapy and improve VTE prevention.
A practice improvement method which engaged stakeholders to identify and overcome local barriers to practice change was selected (NSW Health Department, 2003). This model was chosen because it was perceived to be a simple and practical tool for translating evidence into practice. The study used a repeated measures design with statistical process control (SPC) charts. The SPC chart was a useful tool at this early stage of my PhD journey as it enabled the analyses of data without advanced statistical skills.

The study commenced in July 2008 and concluded twelve months later in July 2009. The study was funded by a $25,000 St Vincent’s Clinic Foundation multidisciplinary patient-focused research grant which was used to backfill my clinical position so that I could be released to facilitate the study two days a week for a twelve month period. As project facilitator I had carriage of the project activities including developing the education material and decision support tool; undertaking the audit, and analysing the data; and drafting the manuscript.

Other key members of the stakeholder team included Ms Anne Fallon, Manager Education Training & Development; Ms Edel Murray, Wound Management Clinical Nurse Consultant; Dr Abdullah Omari, Vascular Physician; Mr Adam Wardell, Chief Pharmacist; Mr Ian Davidson, Consumer; Dr Joanne Joseph, Haematologist; and Prof Kim Walker, Professor of Nursing. These people were invited to participate because they were identified as opinion leaders in their chosen fields.

A version of this paper was published in 2010 in a special issue of the journal, *Contemporary Nurse* (IF 0.67). The issue was titled Advances in Contemporary Modelling of Clinical Nursing Care and it was dedicated to papers illustrating nurses’ ability to
positively change practice and improve patient care. A prominent theme in the issue was a desire by nurses to improve patient care by applying evidence from research and scholarly activity. The results of the study have also been presented in a paper at the Joanna Briggs Institute International Convention in Adelaide, and a poster at the National Medicines Symposium in Canberra.

As you will read, the implementation strategy was highly successful and resulted in significant improvements in patient care. The study received two national awards, the Australian Council of Healthcare Standards Quality & Safety Award, and the Australian Private Hospital’s Association Award for Clinical Excellence. This recognition was well received by the team members and the organisation, ensuring an enormous amount of support for the subsequent VTE evidence implementation study.

As discussed in the paper, the warfarin process and outcomes indicators were delegated to the Pharmacy Department for ongoing monitoring and are reporting to the hospital Pharmaceutical and Therapeutics Committee. I am pleased to report that the improvements achieved in this study have been maintained overtime.
2.2 Abstract

Background: Warfarin is a very complex, high risk therapy and one that carries the potential for severe adverse events. The aim of this study was to improve warfarin management through the application of the best available evidence. The study was undertaken in a 250 bed acute care metropolitan private hospital.

Interventions: A suite of evidence-based interventions was used including audit and feedback, patient and provider education, and decision support aids.

Measures: This study used the ongoing collection of warfarin process and outcome clinical indicator data to measure improvement.

Results: Compliance with loading protocol increased by 12% (42% to 54%); patient education prior to discharge increased by 54% (31% to 85%); INR’s > 5 decreased by 2.6% (3.7% to 1.1%); and abnormal bleeds fell by 1.2% (1.2% to 0%).

Conclusion: This multifaceted bundle of interventions was successful in influencing clinician behaviour and improving compliance with evidence-based warfarin guidelines.

2.3 Introduction

Warfarin therapy is widely prescribed for the prevention and treatment of venous and arterial thrombosis and embolism (Gallus, Baker, Chong, Ockelford, & Street, 2000; Hirsh, Guyatt, Albers, Harrington, & Schünemann, 2008; Maddali et al., 2006). In our organisation we have seen the number of inpatients on warfarin significantly increase over the last 10 years. This is in part due to strong evidence of its benefit for patients with atrial
fibrillation (Gallus, et al., 2000; Hirsh, et al., 2008; Maddali, et al., 2006). This has led to warfarin now being one of the top 20 most prescribed drugs in Australia with over 2 million prescriptions issued each year (Department of Health and Aging, 2008).

Although effective, warfarin therapy is very complex to manage. The average daily dose required can differ dramatically from person to person varying from 0.5mg/day to 15mg/day (Gallus, et al., 2000). This wide gap in individual responses to dosage requirements can be due to a number of factors including age, weight, cardiac or liver impairment, diet, or drug interactions (Maddali, et al., 2006). In order to manage warfarin safely it must be closely monitored and titrated to avoid under or over-dosage. Indeed, it is potentially a very hazardous drug with reports suggesting major bleeding in approximately 1-2% of people and intracranial bleeding in 0.1-0.5% (Gallus, et al., 2000).

This combination of a potentially dangerous drug with a complex therapeutic regimen considerably increases the likelihood of adverse events. In a systematic review of the literature, Runciman et al (2003) identified that between 2-4% of all hospital admissions in Australia are related to adverse drug events and that anticoagulant medication, such as warfarin, is the second most common drug class implicated (second only to chemotherapy agents). Warfarin is also one of the top five medications most cited in NSW Public Hospital clinical incident reports (Clinical Excellence Commission, 2006).

The impetus for this study started when the organisation was invited by the NSW Therapeutic Advisory Group (TAG) and the NSW Clinical Excellence Commission (CEC) to trial their new Medication Safety Self-Assessment for Antithrombotic Therapy (MSSA-AT). This tool was initially developed in the United States by the Institute of Safe
Medication Practices and had recently been adapted for the Australian context by NSW TAG and the CEC (Clinical Excellence Commission, 2007b). The self-assessment required a multidisciplinary team to rate the organisation’s compliance with best practice initiatives, discussing each initiative until a consensus was reached on the level of organisational implementation (from not implemented to fully implemented). On completion of the self-assessment our overall score was calculated at only 44% (of the maximum possible score). From the MSSA-AT results it was clear that warfarin management was the priority area for further improvement.

Aim

The primary study aim was to improve the safety and efficacy of warfarin therapy through the application of the best available evidence on warfarin management. A number of secondary objectives were set in order to achieve this aim: 1) comprehensively audit current warfarin therapy management practices against evidence-based best practice; 2) benchmark these results with comparable organisations; 3) identify and prioritise areas for practice improvement and; 4) sustain practice change.

2.4 Method

It was decided that the study would use a very pragmatic, yet systematic approach in order to achieve effective and enduring change. Consequently, the study employed a practice improvement methodology. This methodology was first used to monitor and improve processes in the manufacturing industry but has subsequently been adopted by many other industries including the healthcare sector (Wilson & Harrison, 2002). It is a process that recognises clinicians are best able to improve practice systematically through trial and
error based on practical experience of what works and what doesn’t. This approach acknowledges that clinical practice is an inherently messy terrain.

Using the practice improvement methodology, the study followed a sequence of steps starting with the identification and diagnosis of the problem; measuring the size and scope of the problem; identifying the most appropriate interventions for our particular context; implementation of the interventions and finally, a re-measurement of the baseline indicators to ascertain if the interventions had been effective (NSW Health Department, 2003). This sequence is represented graphically in Figure 3, the Shewart-Nolan Practice Improvement model (as cited in NSW Health Department, 2003).

Ethical issues

This is an evidence implementation study and like other such studies it is considered to be of low or negligible ethical risk (Hutton, Eccles, & Grimshaw, 2008). However, an ethics self-assessment checklist for quality improvement projects was completed, as required by organisational policy, and this confirmed that there were no identifiable ethical issues that would require full ethics review.
Figure 3 The Shewart-Nolan Practice Improvement model

Setting

The study ran over a twelve month period in a 250 bed acute care private hospital in metropolitan Australia. The hospital has over 20,000 separations annually and caters for all surgical and medical specialties excluding maternal and paediatric care. The case mix is 70% surgical and 30% medical and 45% of the patient population is over 65 years of age. Given that warfarin is a complex therapy, requiring coordinated interdisciplinary care, the target population for the study interventions included all nursing, pharmacy and medical staff.
**Measures**

A number of process and outcome indicators were used as study measures. The measurement of process indicators is based on the premise that when a process is evidence-based it can be assumed that an improvement in compliance with the process will result in a subsequent improvement in patient outcomes (Clinical Excellence Commission, 2007a). The warfarin process indicators from the Quality Use of Medicines in Australian Hospitals indicator set (Clinical Excellence Commission, 2007a) were selected and include:

- Percentage of patients with an international normalised ratio (INR) above 4 whose dosage has been adjusted or reviewed prior to the next warfarin dose;
- Percentage of patients with atrial fibrillation who are discharged on warfarin;
- Percentage of patients discharged on warfarin who receive written information regarding warfarin management prior to discharge;
- Percentage of patients prescribed hospital initiated warfarin whose loading doses are consistent with hospital approved protocol.

Warfarin specific outcome indicators from the Australian Council of Healthcare Standards (Australian Council on Healthcare Standards, 2008) clinical indicator set were also selected. The four outcome indicators relevant to warfarin therapy from this set are:

- Percentage of patients receiving warfarin who experience abnormal bleeding;
- Percentage of patients receiving warfarin who experience a cerebral haemorrhage;
- Percentage of patients receiving warfarin with an INR greater than 5;
- Percentage of patients receiving warfarin who die as a result of an adverse event.
Planning the intervention

The study was made feasible by the appointment of a part-time facilitator) whose position was funded through a multidisciplinary research grant. The facilitator was a clinical nurse specialist (CNS) who was supported and mentored by a senior nursing academic also employed by the hospital.

A multidisciplinary team of doctors, pharmacists, managers and academics as well as a consumer representative was formed to address the problem. The inclusion of a consumer representative was particularly important. It provided a patient perspective which significantly helped in shaping the way the study was conceived and implemented, enhancing the study’s chance of success. Bringing together the multidisciplinary team ensured ‘buy in’ from each of the professional groupings and enabled a shared vision and goal to be articulated and confirmed by all. This was pivotal to the study’s realisation and established a much higher degree of confidence in the likelihood of its success than would otherwise have been the case.

The team then set out to identify and diagnose the potential barriers to the provision of evidence-based warfarin therapy in our organisation. This involved collection of baseline audit data and the conducting of structured brainstorming sessions with medical, nursing and pharmacy clinical staff. The focus of these sessions was to identify the factors influencing the safe and effective use of warfarin at St Vincent’s Private Hospital. The results were then organised and collated by the research team into a cause and effect diagram, otherwise known as a fishbone diagram (see Figure 4). This information was used to help identify specific interventions that would overcome our identified barriers.
Specific Aims

After review of the diagnostic data (baseline audit results and brainstorming sessions) the research team identified three specific aims for the study, namely:

- Increase the percentage of patients who receive warfarin education prior to discharge to 100%;
- Increase the percentage of patients whose loading dose is consistent with approved protocol by 10% and;
- Maintain adverse outcomes below the ACHS benchmark level.
Study Interventions

In order to achieve these aims the team developed a multifaceted intervention specifically targeted at improving clinician compliance with best practice. The implementation science literature was used to inform the selection of these interventions. Implementation research is the scientific study of interventions to promote the systematic uptake of clinical research findings into routine clinical practice (Schünemann et al., 2004). A number of beneficial interventions have previously been studied including educational outreach, reminders, educational meetings, audit and feedback, and the provision of educational materials (Grimshaw, et al., 2004; Grol & Wensing, 2005a; Ostini et al., 2009; Schünemann, et al., 2004). The strategies selected for this study are listed and discussed below:

Decision support tools

Two decision support tools were trialled and implemented to assist clinicians in making informed, evidence-based choices regarding their patients’ warfarin management. The first decision support tool -for medical staff- was an evidence-based nomogram to aid in the selection of loading doses for patients commencing on warfarin therapy. Nomograms have been shown to decrease the incidence of bleeding associated with warfarin commencement whilst achieving therapeutic levels in a comparable time to that seen with unaided physician prescribing (Maddali, et al., 2006). It was decided that the uptake of the nomogram by medical staff would be maximised if it was placed on the reverse of the current warfarin chart (Appendix B), effectively putting it directly in the hands of every warfarin prescriber. Bereznicki and colleagues (2007) note that this strategy is especially useful in increasing prescriber compliance with dosing guidelines.
The second tool was directed at nursing staff and came in the form of an evidence-based 
electronic clinical pathway for patients on warfarin (Appendix C). The hospital is fortunate 
to have a sophisticated electronic patient records system which includes electronic clinical 
pathways. The research team worked with the information technology department to 
develop a new evidence-based electronic clinical pathway for patients commencing on 
warfarin. This pathway consisted of a checklist of interventions and reminders for clinical 
staff. The interventions and reminders are automatically triggered as the patient passes 
predetermined clinical milestones. For example, the reminder to send an INR each morning 
is automatically cancelled when the patient has achieved therapeutic levels for more than 
two consecutive days. This simple, yet effective intervention is supported by the literature 
which demonstrates that the use of checklists and reminders in clinical pathways 
significantly improves compliance with evidence-based guidelines (Wolff, Taylor, & 
McCabe, 2004).

Education initiatives

Education initiatives were divided into patient and staff specific initiatives. A review of our 
patient education processes was undertaken by the facilitator in consultation with clinicians 
and following this a number of changes were initiated.

The highest priority for clinicians was the reintroduction of the ‘warfarin booklet’. The 
patient education booklet supplied by the pharmaceutical manufacturer had recently been 
discontinued and replaced with two loose-leaf sheets of paper. Although the information 
provided on these sheets was similar, patients and staff felt that the loose-leaf sheets were 
easily misplaced or damaged. As well, these sheets did not contain a place to record the
patient’s INR results, whereas the booklet did. A major challenge and subsequent achievement of the study was the petitioning of the pharmaceutical manufacturer and successful reinstatement of the previous warfarin education booklet. Staff also expressed the need for the warfarin booklet to be available in languages other than English; accordingly it was translated into the most common languages of our patient population. A warfarin patient education DVD was also purchased as an optional education tool.

A formal patient education process was developed to assist staff in providing and assessing warfarin education. The process incorporated the use of two tools. The first tool was a set of warfarin patient education learning objectives adapted with permission from Liverpool Hospital, Sydney (Liverpool Hospital, 2006) (Appendix D). Having these objectives helped standardise patient education sessions and prevent the omission of important information. The list of objectives enabled staff to record and track patients’ warfarin education accurately thus making it possible to stagger the process of information giving over the course of a patient’s admission. Having the objectives in the patient notes also reminded other staff to reinforce the information at every opportunity.

The second tool assisted clinicians to assess their patients’ warfarin knowledge as well as their self-confidence in their ability to manage the therapy on discharge (Appendix E). Although it has not been unequivocally established in the research that these two factors directly influence patient outcomes, the literature suggests that an association between them can nevertheless be inferred (Newall, Monagle, & Johnston, 2005). The form also has an area for the documentation of a ‘medicines discharge plan’. This plan contains information on patient follow-up. Follow-up options differed between patients based on
their knowledge, self-confidence and ability to achieve their learning objectives. Patients could be followed-up by phone or through our extended care home visiting program.

In relation to staff education, the research team agreed with research findings that didactic lectures have little impact on changing clinician behaviour (Grimshaw, et al., 2004; Schünemann, et al., 2004). It was therefore decided that the staff education initiative would comprise a self-paced online information package. This type of approach is described as ‘just in time’ education, where learners can access information as it is needed and when it is relevant (Kitzmiller, Sproat, & Hunt, 2004). This approach was less resource intensive than traditional ward in-services and was also sustainable beyond the life of the study.

Audit and feedback

Process and outcome indicators were monitored throughout the course of the study by monthly chart audits. This served two important functions; firstly, it provided a measure of the impact of the various interventions; and secondly, it enabled regular feedback to the various clinicians, providing an ongoing motivation to change. Audit and feedback is one of the most effective strategies for producing behavioural change in clinicians both on its own and when used, as in this study, as part of a multifaceted approach (Grimshaw, et al., 2004; Schünemann, et al., 2004; Tooher, et al., 2005).

Opinion leaders

Opinion leaders have been well demonstrated to have an influence on the clinical practice of their peers (Grimshaw, et al., 2004; Schünemann, et al., 2004; Tooher, et al., 2005). Practice improvement initiatives require championing by key stakeholders. In our study it
was important to secure the support and input from senior physicians, nurses, educators and managers. Consequently, key opinion leaders were recruited onto the research team. These included an influential vascular physician, the nurse unit managers and educators of the vascular and cardiac wards, and the director of nursing.

**Data Collection and Analysis**

The baseline and ongoing collection of process and outcome clinical indicator data was collated in monthly retrospective chart audits of all patients identified as being on warfarin therapy. Patients on warfarin therapy were identified from a number of sources including pathology, pharmacy and patient health history records. The audits were conducted by an experienced registered nurse following audit guidelines set out by the CEC and ACHS.

The audit results were displayed in statistical process control (SPC) charts. There are a number of different types of SPC charts but all are based on observing the variability of data in relation to the mean. In SPC charts a central line is plotted on the graph representing the mean and then upper and lower control limits (UCL & LCL) are plotted at three standard deviations from that mean (Benneyan, Lloyd, & Plsek, 2003). Theoretically, 99.74% of all data should fall within these control limits and thus, these boundaries are used to help define the threshold for ‘special cause’ variation and statistical significance (Portney & Watkins, 2009).

A number of other criteria for defining special cause variation are also common and include: Any one point that falls outside the three standard deviation control limits; two out of the last three points falling outside the two standard deviation limit; Four out of the last five points falling outside the one standard deviation limit; eight or more consecutive
points all above or all below the mean, also called a ‘run’; and six or more consecutive points moving up or down across the mean, also called a ‘trend’ (National Health Services Scotland, 2008; Portney & Watkins, 2009).

2.5 Results

Baseline

The baseline audit of process indicators showed that there was 100% compliance with reviewing patients with INRs >4 prior to their next dose. It also showed that 94% of all patients with AF were being discharged on warfarin. In light of these good results the research team decided to concentrate on the two indicators with the poorer compliance rates; namely, the percentage of patients who receive written information prior to discharge (baseline compliance 31%) and the percentage of patients whose initial dose is consistent with approved protocol (baseline compliance 42%).

At the time of the baseline audit none of the ACHS adverse warfarin outcomes were identified. There were no major bleeds, cerebral haemorrhages, deaths, or INRs >5 in the month audited. However, the research team acknowledged that these events are rare and therefore not easily detected in a single audit. Consequentially, it was decided to maintain the ongoing monitoring of these indicators over the course of the study.

Process indicators

Prescriber compliance with the hospital-approved loading protocol increased over the course of the study by 12% from 42% to 54%. These results are not statistically significant evidenced by no special cause rule violation (see Figure 5) but they do suggest that the
multifaceted intervention was, at least in part, effective. This 12% improvement is greater than the study target which was set at 10%. This conservative target was chosen based on the extensive literature which describes the difficulty in modifying doctors’ prescribing practices (Dartnell, 2001; Ostini, et al., 2009).

Figure 5 Patients prescribed hospital initiated warfarin whose loading dose was consistent with approved protocol

The number of patients receiving education prior to discharge increased dramatically over the course of the study from 31% to 85% (a 55% increase). This was a statistically significant improvement as seen by the two special case rule violations evident in Figure 6. Although a significant improvement it does fall short of the ACHS benchmark of 88% and our own target of 100%.
Outcomes indicators

The percentage of patients with an INR > 5 decreased over the course of the study falling from 3.7% to 1.1%. This was below the ACHS benchmark level of 3.5%. This is an important clinical improvement given patients are much more likely to suffer a serious adverse event if levels are not contained within the recommended range of 2 to 3 (Gallus, et al., 2000). The percentage of patients who experienced abnormal bleeding fell from 1.2% to 0% over the course of the study, again staying below the ACHS benchmark level which was 1.4%. The percentage of patients who experienced a cerebral haemorrhage and the percentage of patients who die as a result of an adverse reaction to warfarin remained unchanged throughout the course of the study at 0%. This was equal to or better than the ACHS reported figures of 0.12% and 0%, respectively.
Figure 7 Patients receiving warfarin with an INR >5

An unexpected result identified on analysis of the SPC charts was the dramatic decline in all measures during the December audit. The percentage of patients receiving written information prior to discharge decreased in that month, returning to almost baseline levels of 39%. A significant decline was also seen in the percentage of patients whose loading dose was consistent with approved protocol (note the LCL violation in Figure 6). This indicator fell to 20% which was 25% below the initial baseline level. In this same month there was also a significant spike (note the UCL rule violation in Figure 7) in the number of INRs >5, increasing from 4% to 14% of all cases.

The decline in these process indicators may reflect operational changes common in most private hospitals during the holiday season. Routinely during this period there are ward closures and extensive levels of staff leave (annual and recreational) or are relocated
outside their ‘home’ unit and this can potentially result in patients being cared for by nursing and medical staff who are unfamiliar with warfarin therapy management procedures. The increase in INR outcome indicator may also be influenced by the holiday season. At this time of year many patients experience significant changes to their normal routine including changes to their diet and their alcohol consumption which can lead to fluctuations in INR levels (Gallus, et al., 2000; Hirsh, et al., 2008; Maddali, et al., 2006).

2.6 Discussion

Prior to this study, the lack of a coordinated multidisciplinary approach to warfarin therapy had proven the major obstacle to achieving safe and effective practice in our organisation. Increasingly, nurses are taking on the role of clinical leaders, modifying and transforming policy and practice within the multidisciplinary environment (Davidson, Elliott, & Daly, 2006). The success of this study is directly attributable to the depth and breadth of the multidisciplinary collaboration which was achieved from nursing leadership. The study was facilitated and led by a CNS working within a model of interdisciplinary team leadership. This approach focuses on the joint success of the team rather than any single individual’s performance (McCallin, 2003). Because nurses are many, and their skills varied, they are very well placed to work across the multidisciplinary team.

The increasing emphasis on the consumer and consumer participation has been said to have helped empower nurses to take the lead in clinical practice issues (Davidson, et al., 2006). This study had a strong consumer focused approach and from the outset the study team agreed to adhere to a Quality Use of Medicines (QUM) philosophy. One of QUM’s guiding principles is the primacy of the consumer (Department of Health and Ageing,
Consumers bring a different perspective to a study providing a constant reminder that the true aim of any evidence implementation study is ultimately to improve patient outcomes. The inclusion of a consumer representative was so successful that it has since been adopted into subsequent hospital projects.

This study was also one of the first in Australia to use the MSSA-AT which had only recently been contextualised for our healthcare sector by NSW TAG and the CEC. This tool was useful to the study in a number of ways. Firstly, it required a multidisciplinary group to gather and discuss anticoagulation management and this in itself was seen as a benefit. Secondly, the group rated our organisation against the best practice initiatives in the MSSA-AT. The results of the self-assessment provided us with a baseline measure of our current anticoagulation practices and enabled us to benchmark ourselves with hospitals of comparable demographics.

It has long been known that the best science often fails to influence clinical practice (Duffy, 2005; Ginexi & Hilton, 2006; Green & Seifert, 2005; Lang, Wyer, & Haynes, 2007; Lenfant, 2003; Sussman, Valente, Rohrbach, Skara, & Pentz, 2006). This so-called evidence-practice gap has received significant attention in academic debate (Ousey, 2000; Rooks, 2006; Segaric & Hall, 2005; Walker, 2007). As many commentators now well understand, the process of transferring the results of empirical research into clinical practice is fraught with complexity (Doran & Sidani, 2007; Gerrish & Mawson, 2005; Graham & Tetroe, 2007; Lang, et al., 2007). The key to enduring and positive cultural change is embedding changed attitudes, values and behaviours into everyday organisational life. A major component of this is ‘hard wiring’ these changes into institutional policy, procedure and practice.
We believe this was achieved in this study in a number of ways: First, two protocols (a warfarin commencement and warfarin reversal protocol) were developed and endorsed by the organisation. The protocols were then posted on the clinical website and incorporated into hospital policy, procedure and processes. Second, the new warfarin clinical pathway was successfully integrated into existing processes and now sits within the organisation’s computerised clinical pathway system used by all clinicians as part of their everyday practice. Third, the use of an online self-paced education module provided sustainability, enabling ongoing staff education on warfarin therapy well beyond the life of the study. Finally, in an effort to maintain improvements, the warfarin process and outcomes indicators have been delegated to the Pharmacy Department for ongoing monitoring and are now included in routine hospital reporting.

One particular challenge encountered during auditing was the difficulty of identifying those patients on warfarin therapy. Warfarin therapy is not limited to one patient group, nor is there a specific medical coding allocated to their record. The identification of these patients required the collation of information from a number of different sources. The hospital pharmacy system reported patients who had been dispensed warfarin but this did not cover those patients who had brought in their own medication; the electronic patient medical record reported patients who were on warfarin prior to admission but this did not capture patients who had just commenced treatment; and the pathology system reported patients who had an INR but not all patients had or required an INR. Using all three data sources, however, we were able to identify the patients.
2.7 Conclusion

This multidisciplinary evidence implementation study used clinical indicator data and a practice improvement methodology to transfer knowledge of best practice warfarin therapy. The multidisciplinary team achieved some significant progress in warfarin management and patient outcomes including a 12% improvement in compliance with warfarin initiation guidelines; a 48% improvement in patients receiving warfarin education prior to discharge and; and an incidence of adverse events maintained well below the ACHS benchmark. The study has not only improved patient outcomes but has also helped increase the interest and acceptance of nurse-led, multidisciplinary, evidence-based practice improvement initiatives within the organisation.
CHAPTER 3. TRANSLATING VENOUS THROMBOEMBOLISM PREVENTION EVIDENCE INTO PRACTICE: A MULTIDISCIPLINARY EVIDENCE IMPLEMENTATION PROJECT.

3.1 Prologue

On completion of the warfarin evidence implementation study it was clear to the entire multidisciplinary study team that the prevention of VTE in hospitalised patients was a highly complex problem that warranted further attention. At about this time, the National Institute of Clinical Studies (NICS), a national body tasked with improving healthcare by translating evidence into practice, invited the hospital to participate in their private hospital VTE prevention evidence implementation program. The ‘Stop the Clot’ program, as it was called, had previously been run at a number of public hospitals across Australia with significant improvements in compliance with best practice guidelines achieved. The SVPH hospital executive and the multidisciplinary research team agreed that this was the perfect opportunity to improve VTE prevention at SVPH. The study commenced in August 2009 and concluded twelve months later in August 2010.

The research team applied for and received a total of $48,000 in research grants from a range of hospital and industry sources including St Vincent’s Clinic Foundation, St Vincent’s and Mater Health Sydney, and Sanofi-Aventis. The grants funded my facilitator position two days a week for twelve months plus the travel and accommodation costs associated with sending the research team to two NICS training workshops in Melbourne.

As the project facilitator, I was responsible for the development and implementation of the project interventions including the audits, education, documentation aids and policy. This
was done in collaboration with a stakeholder team including Mr Adam Wardell, Chief Pharmacist; Ms Chris Robinson, Quality Coordinator; Mrs Ingrid Tartu, Clinical Risk Manager; Dr Abdullah Omari, Vascular Physician; Adjunct Prof Jose Aguilera, Director of Nursing; Dr Michael McGrath, Vascular Physician; Prof Sandy Middleton, Professor of Nursing; and Prof Kim Walker, Professor of Nursing.

A version of this paper was published in a special issue of the journal, *World Views on Evidence Based Nursing* (IF 1.239). The issue was dedicated to papers on the use of evidence to improve patient safety and the quality of healthcare. The results were also presented at the annual scientific meeting of the Australian and New Zealand Society for Vascular Surgery in the Cold Coast.

The study was a finalist in the 2010 St Vincent’s Health Australia Quality Awards. A video clip filmed as part of the nomination process can be seen at the following address [http://youtu.be/rrBG_8bSnPo](http://youtu.be/rrBG_8bSnPo). Although the study did not win the award, the nomination was seen as recognition of the important improvements in patient care that had been achieved.

As you will read, the study resulted in significant improvements in VTE risk assessment and prophylaxis rates. It also identified the need for a targeted intervention to address the significant disparity between the prophylaxis rates of medical patients compared to surgical patients.
3.2 Abstract

Background: VTE is an important patient safety issue resulting in significant mortality, morbidity, and healthcare resource expenditure. Despite the widespread availability of evidence-practice guidelines on VTE prevention we found that only 49% of our patients were receiving appropriate prophylaxis.

Aim: To improve healthcare professionals’ compliance with evidence-based guidelines for VTE prevention in hospitalised patients.

Design: A practice improvement methodology was employed to identify, analyse, and overcome practice problems. Pre and post intervention audits were used to evaluate performance measures.

Setting: The study was took place in a 250 bed acute care private hospital in metropolitan Sydney, Australia.

Intervention: A change plan was developed which attempted to match organisational barriers to VTE guideline uptake with evidence-based implementation strategies. The strategies used included audit and feedback; documentation aids; staff education initiatives; collaboratively development hospital VTE prevention policy; alert stickers and other reminders.

Results: The proportion of patients receiving appropriate VTE prophylaxis increased by 19% from 49% to 68% (p=0.02). Surgical patient prophylaxis increased by 21% from 61% to 83% (p=0.02) while medical patient prophylaxis increased by 26% from 19% to 45%
(p=0.05). The proportion of patients with a documented VTE risk assessment increased from 0% to 35% (p<0.001).

Conclusion: The intervention resulted in a 19% overall improvement in prophylaxis rates which is a considerable achievement given the difficulty of changing clinician behavioural change. There is, however, still a significant discrepancy between surgical and medical patient prophylaxis rates which clearly warrants further attention.

3.3 Introduction

Venous thromboembolism (VTE) prevention in hospitalised patients has been widely acknowledged in Australia and internationally as a major opportunity to improve patient safety (Agency for Healthcare Research and Quality, 2001; National Health and Medical Research Council, 2009; Shojania, et al., 2001). VTE is one of the single most common preventable causes of hospital deaths (National Institute of Clinical Studies, 2003) with ten percent of all hospital fatalities attributed to pulmonary embolism (PE) (MacDougall, et al., 2006). In Australia, VTE has been estimated to result in 5000 deaths annually (Access Economics, 2008) and in the United Kingdom (UK) it causes 25,000 deaths annually (House of Commons Health Committee, 2005). These numbers are possibly underestimations considering VTE is often under-diagnosed (Access Economics, 2008; National Institute of Health and Clinical Excellence, 2008).

Morbidity from VTE for survivors can also be substantial: One-third of patients with deep vein thrombosis (DVT) will develop post-thrombotic syndrome which is characterised by persistent lower limb oedema, pain, inflammation, and ulceration (Kakkar & Haas, 2007); 25% of patients will experience a recurrence of their DVT (Hansson, et al., 2000); and 5%
of patients who survive a PE will develop chronic pulmonary hypertension (Pengo, et al., 2004). The combination of these factors has led to calls for VTE to be reclassified as a chronic disease process with periods of acute exacerbations (Hansson, et al., 2000; Mason, 2009).

Unfortunately, without appropriate prophylaxis the incidence of objectively confirmed, hospital-acquired DVT is approximately 10% to 40% among medical or general surgical patients and 40% to 60% following major orthopaedic surgery (Geerts, et al., 2008b). There is, however, strong research evidence supporting the use of both pharmacological and mechanical measures for VTE prevention and this research has informed a number of evidence-based clinical guidelines (Geerts, et al., 2008b; International Consensus Statement, 2006; The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2007).

Importantly, despite the ready availability of these guidelines the universal application of this evidence has not been forthcoming. A recent UK survey has reported that 71% of hospitalised patients judged to be at moderate or high-risk of VTE did not receive any form of prophylaxis (National Institute of Health and Clinical Excellence, 2008) and an international audit of 70,000 patients found that only 50% of at-risk patients were receiving appropriate prophylaxis (Cohen, et al., 2008). Similar results were demonstrated in our hospital with a local audit identifying appropriate prophylaxis in only 62% of surgical patients and 19% of medical patients.

Implementation research is the study of interventions to promote the systematic uptake of clinical research findings into routine clinical practice (Schunemann et al., 2004). A
systematic review by Tooher et al (2005) identified 30 studies that examined the impact of various implementation strategies on VTE prophylaxis in hospitalised patients. The types of strategies employed in these studies included passive dissemination, audit and feedback, decision aids, documentation aids, continuing education, advertising, appointment of specific implementation staff, and recruitment of local change agents or opinion leaders.

The effectiveness of individual strategies was found to be highly variable but in general a single active strategy, such as audit and feedback, was consistently more effective than passive dissemination of guidelines alone. It was concluded, however, that rather than any single strategy used in isolation, the most effective approach for improving VTE prophylaxis in hospitalised patients was the combination of multiple strategies (Tooher, et al., 2005).

To aid in the selection of appropriate strategies for our organisation an assessment of barriers to VTE guideline uptake was undertaken. Barriers are factors that potentially impair the effectiveness of professional practice and it has been suggested that studies that identify and address these barriers have a greater chance of successfully improving and maintaining practice change (Grimshaw, et al., 2004; Grol & Wensing, 2005a).

**Setting**

The study was conducted over a twelve month period in a 250 bed acute care private hospital in metropolitan Sydney, Australia. The hospital has approximately 20,000 separations annually and provides a full range of surgical and medical services, excluding maternal and paediatric care. The case mix is 70% surgical/ 30% medical; 45% of the patient population is over 65 years of age.
Aim

To improve healthcare professionals compliance with evidence-based VTE prevention guidelines in surgical and medical inpatients. Specific study objectives included the development of a hospital-wide VTE prophylaxis policy; development of a sustainable system to support routine VTE risk assessment and VTE prophylaxis management; and a standardised approach to documenting these.

3.4 Method

Target population

The prevention of VTE in our organisation is a multidisciplinary concern requiring the contributions and collaboration of a number of healthcare professionals. Interventions were specifically targeted at nurses (n=360), doctors (n=210), and hospital pharmacists (n=6).

Ethics

Ethical approval was obtained from the Human Research Ethics Committee of the hospital.

Design

A systematic, iterative practice improvement method was used which incorporated both qualitative and quantitative approaches to identify, analyse, and overcome practice problems. The steps in the process are represented in Figure 8.
Figure 8 Implementation of Change model adapted from Grol et al
Change strategies

The practice improvement approach employed requires the engagement of clinicians to identify barriers to evidence uptake and then design specific interventions to overcome them (Grol & Wensing, 2005a). Participants in this process included three nurses, a doctor, an academic, a clinical manager, and a consumer. The group reviewed the literature on strategies to improve VTE prophylaxis in hospitals and then brainstormed possible barriers to guideline uptake in our organisation.

Four barriers to the uptake of VTE prevention guidelines were identified: A lack of motivation to change; a lack of systems support; a knowledge or awareness deficit; and disputed evidence. Subsequently, four strategies for change were selected based on their perceived effectiveness at overcoming these particular barriers (Grimshaw, et al., 2004; Tooher, et al., 2005):

- **Audit and feedback:** The results of the baseline audit and of a midpoint snapshot audit were fed back to the clinicians in short presentations.

- **Documentation and decision support aids:** A tool for assessing VTE risk and choosing appropriate prophylaxis measures was developed and printed in the medication chart (see Figure 9). A system where VTE risk alert stickers are placed on the medication chart was also implemented.

- **Provider education:** A series of education sessions was delivered to all departments to raise VTE awareness. This was complemented by an in-house multidisciplinary VTE prevention conference with expert speakers invited from across the country (Appendix F).
- Policy/procedure: A hospital-wide policy on VTE prevention which clearly outlined roles and responsibilities was developed and promulgated (Appendix G)

Figure 9 Tool for assessing VTE risk and choosing appropriate prophylaxis
Table 7 Change plan showing alignment of interventions to known barriers

<table>
<thead>
<tr>
<th>Perceived barrier</th>
<th>Strategy for change</th>
<th>Intervention</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of motivation to change</td>
<td>Audit and feedback</td>
<td>Baseline and snapshot audit</td>
<td>Stratified random sample of inpatients’ audited against national guideline.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feedback presentations</td>
<td>20 min presentation of benchmarked baseline results to all wards and specialties.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feedback letter</td>
<td>To Nursing Unit Managers and Directors of medical specialties feeding back results</td>
</tr>
<tr>
<td>Lack of system support</td>
<td>Documentation aides</td>
<td>VTE Risk alert sticker</td>
<td>A ‘high’ or ‘low risk’ VTE sticker placed on the medication chart communicating risk.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decision support tool</td>
<td>Collaboratively developed evidence-based decision support tool incorporated into medication chart.</td>
</tr>
<tr>
<td>Knowledge/awareness deficits</td>
<td>Provider education</td>
<td>Mock newspaper</td>
<td>Mock newspaper containing a collection of recent news articles from local, national and international media on VTE (Appendix H).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Awareness presentations</td>
<td>2 x 20 min awareness sessions conducted on each clinical ward.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VTE conference</td>
<td>Full day VTE awareness conference with presentations from local and national experts (Appendix F).</td>
</tr>
<tr>
<td></td>
<td>Reminders</td>
<td>Monthly posters</td>
<td>Novel posters using slogans, eye catching pictures and pop culture references (Appendix I).</td>
</tr>
<tr>
<td>Disputed evidence</td>
<td>Regulation and policy</td>
<td>Whole of hospital policy</td>
<td>Hospital-wide policy collaboratively developed (Appendix G).</td>
</tr>
</tbody>
</table>
Key measures of improvement

Data on appropriate risk assessment and prophylaxis rates pre and post intervention were collected.

- Proportion of adult inpatients receiving appropriate VTE prophylaxis
- Proportion of adult inpatients who are assessed for their risk of VTE

These measures were chosen because they have previously been used in national and international VTE studies (Cohen, et al., 2008; Tooher, et al., 2005).

Data collection

Measures were collected in prospective patient audits (n= 149). This sample size provided power (80%) to detect a 20% change at 5% alpha (two-tail). A stratified (by ward) random sample of patients was audited against the Australian and New Zealand Best Practice Guidelines (2007). An audit tool (Appendix J) which had been used in previous national VTE prevention projects (National Institute of Clinical Studies, 2008b) was used to standardise the process. The audits were conducted by two senior registered nurses who had received training in the use of the tool. The medical records were reviewed to determine appropriateness of the prescribed pharmacological prophylaxis and patients were observed to establish the presence or absence of mechanical prophylaxis therapies. Prophylaxis was deemed appropriate if it conformed to the locally endorsed evidence-based guidelines (The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2007) with consideration given to individual’s VTE risk status and contraindications to either pharmacological or mechanical therapies.
The auditors had access to a consultant vascular physician to provide expert clinical advice as required.

Data Analysis

Pre and post intervention audit results were entered into SPSS version 17 and analysed using Chi Square or Fisher’s exact tests. The P value for statistical significance was set at 5% (0.05).

3.5 Results

Audited patients

The admitting specialties and the clinical units of the patients audited pre and post intervention were comparable. Table 8 provides a comparison of the clinical units of the audited patients at baseline and follow-up and Table 9 provides a breakdown of the admitting specialties. Twenty nine percent (n=21) of audited patients were medical and 71% (n=52) surgical pre intervention compared to 39% (n=29) medical and 61% (n=46) surgical post intervention.

Table 10 documents the significant improvements in the study measures. Both the proportion of patients being assessed for their VTE risk and the proportion of patients receiving appropriate prophylaxis increased post intervention.
Table 8 Comparison of the audited population by clinical unit

<table>
<thead>
<tr>
<th>Clinical unit (number of beds)</th>
<th>Baseline audit n (%)</th>
<th>Follow-up audit n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensive Care (12)</td>
<td>3 (4.1)</td>
<td>4 (5.3)</td>
</tr>
<tr>
<td>Orthopaedics (50)</td>
<td>21 (28.8)</td>
<td>21 (28)</td>
</tr>
<tr>
<td>General medical/orthopaedic (34)</td>
<td>10 (13.7)</td>
<td>10 (13.3)</td>
</tr>
<tr>
<td>Cardiac/cardiothoracic (38)</td>
<td>10 (13.7)</td>
<td>10 (13.3)</td>
</tr>
<tr>
<td>Vascular/colorectal (38)</td>
<td>9 (12.3)</td>
<td>10 (13.3)</td>
</tr>
<tr>
<td>Urology/genecology (38)</td>
<td>10 (13.7)</td>
<td>10 (13.3)</td>
</tr>
<tr>
<td>Plastics/head &amp; neck/neo (38)</td>
<td>10 (13.7)</td>
<td>10 (13.3)</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>75</td>
</tr>
</tbody>
</table>

Proportion of patients being assessed for their VTE risk

The proportion of all patients assessed for their VTE risk increased by 35% (95% CI 23 to 45, p<0.001). When analysed by category (medical or surgical), the majority of improvement resulted from a 54% increase in surgical patients' risk assessment rates compared to only a 3.4% increase for medical patients.

Proportion of patients receiving appropriate prophylaxis

The proportion of all patients who received appropriate VTE prophylaxis significantly increased by 19% (95% CI 2.8 to 33, p=0.02). A similar significant improvement was observed among both surgical and medical patients with a 21% (95% CI 3.1 to 37, p=0.02) increase for surgical patients and a 26% (95% CI 0.0 to 46, p=0.05) increase for medical
patients. When low-risk patients were excluded from the analysis the improvement for medical patients fell to 16% (95% CI -9.0 to 41, p=0.12) and was no longer statistically significant.

Table 9 Comparison of the audited population by specialty

<table>
<thead>
<tr>
<th>Specialties (number of specialists)</th>
<th>Baseline audit n (%)</th>
<th>Follow-up audit n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiology (9)</td>
<td>5 (6.8)</td>
<td>9 (12)</td>
</tr>
<tr>
<td>Cardiothoracic (5)</td>
<td>9 (12.3)</td>
<td>8 (10.7)</td>
</tr>
<tr>
<td>Colorectal (6)</td>
<td>6 (8.2)</td>
<td>7 (9.3)</td>
</tr>
<tr>
<td>General Medicine (10)</td>
<td>11 (15.1)</td>
<td>8 (10.7)</td>
</tr>
<tr>
<td>General Surgery (1)</td>
<td>1 (1.4)</td>
<td>0</td>
</tr>
<tr>
<td>Gynaecology (3)</td>
<td>5 (6.8)</td>
<td>0</td>
</tr>
<tr>
<td>Haematology (1)</td>
<td>1 (1.4)</td>
<td>0</td>
</tr>
<tr>
<td>Neurosurgery (6)</td>
<td>8 (11)</td>
<td>12 (16)</td>
</tr>
<tr>
<td>Orthopaedics (12)</td>
<td>19 (26)</td>
<td>16 (21.3)</td>
</tr>
<tr>
<td>Plastics (2)</td>
<td>0</td>
<td>2 (2.7)</td>
</tr>
<tr>
<td>Urology (4)</td>
<td>6 (8.2)</td>
<td>8 (10.7)</td>
</tr>
<tr>
<td>Vascular (2)</td>
<td>2 (2.7)</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>73*</td>
</tr>
</tbody>
</table>

*Medical/surgical specialty missing from two audits
Table 10 Changes in VTE prophylaxis and risk assessment rates

<table>
<thead>
<tr>
<th>Measures</th>
<th>Baseline n/total (%)</th>
<th>Follow-up n/total (%)</th>
<th>Improvement % (95% CI)</th>
<th>P=</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate prophylaxis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>36/73 (49.3)</td>
<td>51/75 (68)</td>
<td>18.6 (2.8 to 33.3)</td>
<td>0.02</td>
</tr>
<tr>
<td>Medical</td>
<td>4/21 (19)</td>
<td>13/29 (44.8)</td>
<td>25.7 (0.0 to 46.7)</td>
<td>0.05</td>
</tr>
<tr>
<td>Surgical</td>
<td>32/52 (61.5)</td>
<td>38/46 (82.6)</td>
<td>21.0 (3.1 to 37.9)</td>
<td>0.02</td>
</tr>
<tr>
<td>Appropriate prophylaxis (high risk)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>30/67 (44.8)</td>
<td>37/58 (63.8)</td>
<td>19.0 (1.5 to 34.9)</td>
<td>0.03</td>
</tr>
<tr>
<td>Medical</td>
<td>3/20 (15)</td>
<td>6/19 (31.6)</td>
<td>15.7 (-9.0 to 41.0)</td>
<td>0.12</td>
</tr>
<tr>
<td>Surgical</td>
<td>27/47 (57.4)</td>
<td>31/39 (79.5)</td>
<td>22.0 (2.1 to 39.2)</td>
<td>0.02</td>
</tr>
<tr>
<td>Documented risk assessment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>0/73 (0)</td>
<td>26/75 (34.7)</td>
<td>34.7 (23.7 to 45.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Medical</td>
<td>0/21 (0)</td>
<td>1/29 (3.4)</td>
<td>3.4 (-12.3 to 17.2)</td>
<td>0.58</td>
</tr>
<tr>
<td>Surgical</td>
<td>0/52 (0)</td>
<td>25/46 (54.3)</td>
<td>54.3 (38.6 to 67.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Appropriate mechanical prophylaxis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>53/73 (72.6)</td>
<td>54/75 (72)</td>
<td>-0.6 (-13.7 to 14.8)</td>
<td>0.54</td>
</tr>
<tr>
<td>Medical</td>
<td>11/21 (52.4)</td>
<td>19/29 (65.5)</td>
<td>13.1 (-13.3 to 37.8)</td>
<td>0.30</td>
</tr>
<tr>
<td>Surgical</td>
<td>46/52 (88.5)</td>
<td>41/46 (89.1)</td>
<td>0.6 (-12.9 to 13.6)</td>
<td>0.59</td>
</tr>
<tr>
<td>Appropriate pharmacological prophylaxis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>45/73 (61.6)</td>
<td>61/75 (81.3)</td>
<td>19.6 (5.1 to 33.2)</td>
<td>0.01</td>
</tr>
<tr>
<td>Medical</td>
<td>11/21 (52.4)</td>
<td>19/29 (65.5)</td>
<td>13.1 (-13.3 to 37.8)</td>
<td>0.26</td>
</tr>
<tr>
<td>Surgical</td>
<td>34/52 (65.4)</td>
<td>42/46 (91.3)</td>
<td>25.9 (9.5 to 40.4)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

The proportion of all patients receiving appropriate pharmacological prophylaxis increased by 20% (95% CI 5.1 to 33, p=0.01). Of this, surgical patient pharmaco-prophylaxis rates increased by 26% (95% CI 9.5 to 40, p=0.002) while medical patients’ rates increased by 13% (95% CI 13 to 37, p=0.26).
For mechanical prophylaxis, the proportion of patients receiving appropriate prophylaxis was not significant and in fact decreased by 0.6% (95% CI -13 to 14, p=0.54). There was no significant difference in the proportion of medical (13% improvement, 95% CI -13 to 37, p=0.30) and surgical (0.6% improvement, 95% CI -12.9 to 13.6, p=0.59) patients receiving appropriate mechanical prophylaxis when analysed separately.

3.6 Discussion

The data on the associated mortality and morbidity of VTE are very compelling and the research team found all levels of hospital staff and management were prompt to accept VTE prevention as an organisational priority. This enthusiasm may help to explain the significant increase in prophylaxis rates. The change observed in this study (19% improvement in all patients receiving appropriate prophylaxis) is nearly two times greater than the median improvement (10%) identified in a systematic review of 235 guideline dissemination and implementation strategies (Grimshaw, et al., 2004).

The change strategy exercised a positive effect on both medical and surgical specialties with improvements of 26% and 21% respectively. However, medical prophylaxis rates remained considerably lower post intervention when compared to surgical rates (45% and 83% respectively). There was also a noteworthy difference between the rates of improvement for pharmacological and mechanical prophylaxis measures. Appropriate pharmacological prophylaxis increased dramatically (20%) while appropriate mechanical prophylaxis failed to show any improvement (-0.6%). In our organisation, medical staff are responsible for pharmacological prophylaxis while the nursing staff are responsible for managing mechanical prophylaxis. The variation in the improvement between
pharmacological and mechanical prophylaxis in this study indicates that the intervention was more effective on medical staff than on the nursing staff.

The research team decided that the VTE risk assessments would be conducted by the nursing staff. This decision was made after considering the local context and available evidence (Collins, MacLellan, Gibbs, MacLellan, & Fletcher, 2010). Risk documentation involved the application of a high or low-risk sticker on the medication chart at admission. The intervention was much more effective in promoting risk assessment in surgical cases than in medical cases (54.3% compared to 3.4%). This result may be explained by the fact that the majority of surgical cases in our organisation are elective and therefore have a more coordinated and systematic admission which usually includes a preadmission visit. This is in contrast to our medical patients which are often emergency admissions. Further strategies are required to capture patients who enter the hospital in this way.

The introduction of sustainable solutions to the problem of VTE prevention was one of the study’s main objectives. Sustainability was structured into the study by embedding interventions into existing clinical practice. For example, VTE prevention roles and responsibilities were clarified in the hospital-wide policy and this policy was endorsed and disseminated throughout the hospital. The development and introduction of a decision support tool was also ‘hard wired’ into practice by having it printed into the inpatient medication chart. Evidence of the sustained effectiveness of these strategies will need to be collected in further follow-up audits.
Limitations

Due to the concurrent roll-out of interventions it is impossible to evaluate the effectiveness of each of the individual strategies used in the improvement plan. This could have been overcome through the inclusion of a process evaluation in the study design which would have enabled greater insight into the mechanisms responsible for the changes observed (Hulscher, Laurant, & Grol, 2004). A cost benefit analysis would also further evaluate this multifaceted change strategy.

The uncontrolled before-and-after design is also a limitation of the study. This quasi experimental design was chosen for pragmatic reasons as it was not possible to randomise the intervention without significant target population contamination. Unfortunately, this design is vulnerable to the influence of fluctuating trends which makes it difficult to attribute improvements solely to the intervention. There is also some evidence to suggest that the results of uncontrolled before and after studies over-estimate the effects of interventions (Grimshaw, Campbell, Eccles, & Steen, 2000).

3.7 Conclusion

A multifaceted improvement strategy including audit and feedback; documentation and decision support aids; provider education; and policy development can result in significantly improved rates of VTE prophylaxis and risk assessment in adult hospitalised patients. There remains, however, a need to address the discrepancy between medical and surgical prophylaxis rates. A specifically targeted intervention may be required to improve medical patient prophylaxis.
CHAPTER 4. PREVENTION OF VENOUS THROMBOEMBOLISM IN HOSPITALISED PATIENTS: ANALYSIS OF REDUCED COST AND IMPROVED CLINICAL OUTCOMES.

4.1 Prologue

Following the success of the previous VTE evidence implementation study (Duff, Walker, & Omari, 2011) the research team was interested in identifying if the improvements in the prophylaxis rates translated into cost savings and better clinical outcomes. Too frequently this type of work (practice improvement) is seen as a cost to the organisation rather than a benefit and we were very keen to demonstrate the impact that evidence implementation has on important outcomes such as mortality, morbidity, and healthcare costs.

The inclusion of clinical and economic outcome measures in the original VTE evidence implementation study was not feasible because of the expense and difficulty in undertaking the extended post discharge follow-up required to obtain a true VTE event rate. However, using outcomes data from previous research on pharmacological prophylaxis and decision tree analytic modelling (Pettiti, 2000) we were able to determine the theoretical improvements in economic and clinical outcomes.

The research team I led included Prof Kim Walker, Professor of Healthcare Improvement; Prof Abdullah Omari, Vascular Physician; and Mr Charles Stratton, Health Outcomes Economist. The model we developed incorporated local hospital data (June 2010 to June 2011), epidemiological data, and data from the meta-analyses of clinical trials. Unfortunately, the model had to be limited to pharmacological prophylaxis because of the limited available level one evidence on mechanical prophylaxis measures.
A version of this manuscript is in press with the *Journal of Vascular Nursing*, the official journal of the American Society of Vascular Nursing. The results have also been presented at the International Society for Pharmacoeconomics and Outcomes Research Asia-Pacific Conference in Phuket, Thailand and the International Forum on Quality and Safety in Healthcare in Paris, France.

### 4.2 Abstract

The impact of implementing a guideline on venous thromboembolism (VTE) prophylaxis was evaluated in a metropolitan private hospital with a before and after intervention study. This subsequent study aimed to identify if improved prophylaxis rates translated into cost savings and improved clinical outcomes. A conceptual decision tree analytical model incorporating local treatment algorithms and clinical trial data was used to compare prophylaxis costs and clinical outcomes before and after the guideline implementation. The study analysed data from 21,942 medical and surgical patients admitted to a 250 bed acute care private hospital in Sydney, Australia. The modelled simulation estimated the incidence of symptomatic deep vein thrombosis (DVT) and pulmonary embolism (PE) as well as adverse events such as heparin-induced thrombocytopenia (HIT), post-thrombotic syndrome (PTS), major bleeding, and mortality. The costs of prophylaxis therapy and treating adverse events were also calculated. The improvement in prophylaxis rates following the implementation of the guideline was estimated to result in 13 fewer deaths, 84 fewer symptomatic DVTs, 19 fewer symptomatic PEs, and 512 fewer hospital bed days. Improved adherence to evidence-based prophylaxis regimens was associated with overall cost savings of $245,439 over 12 months. We conclude that improved adherence to
evidence-based guidelines for VTE prophylaxis is achievable and is likely to result in fewer deaths, less VTE events, and a significant overall cost saving.

4.3 Introduction

Venous thromboembolism (VTE) is the collective term used to describe deep vein thrombosis (DVT) and pulmonary embolism (PE). It is a complex vascular condition which poses a considerable challenge to the healthcare system, resulting in significant mortality, morbidity, and healthcare resource expenditure. Although the exact incidence of VTE is unknown it is believed there are approximately 1 million cases of VTE in the United States each year resulting in 300,000 deaths annually (Heit et al., 2002). VTE is also linked to the development of a number of debilitating chronic cardiopulmonary and vascular health conditions such as pulmonary hypertension and post thrombotic syndrome (PTS) (Mason, 2009). The economic burden of the disease is also considerable, costing the healthcare system in the United States an estimated $1.5 billion/year (Dobesh, 2009).

VTE is primarily a problem for hospitalised or recently hospitalised patients. The reported incidence of VTE in the hospital population is 100 times greater than the general community (Heit, et al., 2001). In fact, studies reveal that without any form of VTE prophylaxis the rate of objectively confirmed, hospital-acquired VTE is approximately 10% to 40% in medical and general surgery patients and 40% to 60% in major orthopaedic surgery patients (Geerts, et al., 2008b). Ten percent of all in-hospital deaths are attributed to VTE making it the single most preventable cause of hospital-related mortality (MacDougall, et al., 2006). For this reason, VTE is now internationally recognised as the
number one priority patient safety issue (National Health and Medical Research Council, 2009).

VTE in hospitalised patients is almost entirely preventable when the appropriate prophylaxis is provided to those at-risk (Geerts, et al., 2008b; National Health and Medical Research Council, 2009; National Institute of Health and Clinical Excellence, 2010; The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2007). There are a number of national and international guidelines (Geerts, et al., 2008b; National Health and Medical Research Council, 2009; National Institute of Health and Clinical Excellence, 2010; The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2007) which provide evidence-based recommendations for the use of chemoprophylaxis such as low molecular weight heparin (LMWH), or low-dose unfractionated heparin (LDUH), however, these guidelines are often not adhered to in clinical practice. An international audit of 70,000 patients identified that only 50% of at-risk patients were receiving the appropriate prophylaxis (Cohen, et al., 2008).

A significant evidence practice gap was identified in our own private hospital in Sydney, Australia. We found that only 62% of surgical patients and 19% of medical patients were receiving the recommended VTE prophylaxis. In an effort to improve prophylaxis rates our organisation undertook a hospital-wide evidence implementation study (Duff, et al., 2011). Following that study, we used a conceptual decision tree analytical model to determine whether the changes brought about by the evidence implementation study translated into cost savings and improved clinical outcomes. Decision tree analytical models offer a systematic quantitative approach for assessing the relative value of one or more healthcare
interventions and is commonly used to help determine healthcare policies that provide the best outcomes and the most value in certain clinical settings (Pettiti, 2000).

*Overview of the evidence implementation study*

The implementation study was conducted in a 250 bed acute care private hospital in Sydney Australia. The hospital has approximately 20,000 admissions annually with a case mix of 70% surgical and 30% medical patients. Forty five percent of the patient population is over 65 years of age. The hospital does not offer maternity, paediatric, or trauma services but all other major medical and surgical specialties are provided.

The aim of the study was to implement an evidence-based VTE prevention guideline and improve VTE prophylaxis rates for all medical and surgical inpatients. An iterative practice improvement method based on the model described by Grol et al (2005a) was employed (see Figure 10). This method uses qualitative and quantitative approaches to identify, diagnose, and overcome local barriers to evidence-based care.

Structured brain storming sessions were conducted with a multidisciplinary group of clinicians (medical, nursing, pharmacy, allied health) and managers to identify local barriers to the implementation of the guideline and to identify possible change strategies to overcoming these barriers. Four barriers were identified during the session and included a lack of motivation to change; a lack of systems support; a knowledge and awareness deficit; and disputed evidence. Evidence-based change strategies were selected from the literature on effective guideline implementation (Grimshaw, et al., 2004; Tooher, et al., 2005) and incorporated into a multifaceted intervention.
Figure 10 Implementation of Change model adapted from Grol et al
The strategies selected in the multifaceted intervention were:

- Audit and feedback: The results of the baseline audit and of a midpoint ‘snapshot’ audit were fed back to the clinicians in short presentations.
- Documentation and decision support aids: A tool for assessing VTE risk and choosing appropriate prophylaxis based on the national VTE prevention guideline (2007) was developed and printed in the medication chart. A reminder system incorporating VTE risk alert stickers was also implemented.
- Provider education: A series of education sessions was delivered to all departments to raise VTE awareness and train staff in the use of the risk assessment and decision support tool. This was complemented by an in-house multidisciplinary VTE prevention conference with expert speakers invited from across the country.
- Local policy and procedure: A hospital-wide policy on VTE prevention which clearly outlined roles and responsibilities was developed and promulgated.

The proportion of orthopaedic, general surgical and medical patients receiving appropriate prophylaxis prior to the guideline implementation and 12 months following implementation was assessed in clinical audits by an experienced registered nurse. The primary study measure was the percentage of patients receiving appropriate VTE prophylaxis. The audit results were entered into SPSS version 18 and compared using Chi square or Fisher’s exact test.

The study resulted in significant changes from baseline to follow-up. The proportion of all patients who received appropriate VTE prophylaxis increased by 19% (95% CI 2.8 to 33, p=0.02) from 49% at baseline to 68% at follow-up. The improvement was similar for both
surgical and medical patients with a 21% (95% CI 3.1 to 37, p=0.02) increase for surgical patients and a 26% (95% CI 0.0 to 46, p=0.05) increase for medical patients. The proportion of all patients receiving appropriate pharmacological prophylaxis increased by 20% (95% CI 5.1 to 33, p=0.01) from 61% at baseline to 81% at follow-up. Of this, surgical patients’ prophylaxis rates increased by 26% (95% CI 9.5 to 40, p=0.002) while medical patients’ rates increased by only 13% (95% CI -13 to 37, p=0.26).

The results of this study were then evaluated using a decision tree analytic economic model which incorporated local audit data, national VTE associated Diagnostic Related Group costing data and freely available clinical trial data to determine how the improvement in prophylaxis rates translated into cost savings and improved clinical outcomes.

4.4 Method

Clinical and economic modelling

A conceptual decision tree analytical model was used to evaluate the impact on cost and clinical outcomes of changes in VTE prophylaxis regimens (LMWH, LDUH, or no prophylaxis) resulting from the implementation of a VTE prophylaxis guideline. The model was validated by thirty clinicians across Australia to ensure that the structure, inputs and outputs of the model were relevant to the Australian clinical setting.

Data on the prophylaxis regime of medical, general surgical and orthopaedic patients admitted to our hospital between January 2010 and January 2011 was entered into the model (n=21,942). The efficacy and safety of the prophylaxis regimens included in the model were assessed via a mixed treatment comparison of publicly available clinical trial
data (Bell & Simon, 1982; Dalen & Alpert, 1975; Gordois et al., 2003; Gould, Dembitzer, Doyle, Hastie, & Garber, 1999; Greinacher et al., 1999; Prandoni et al., 1996). This method enabled the comparison of prophylaxis regimes that have not been directly compared in head-to-head studies (Petrou & Gray, 2011). This data were also used to estimate the incidence of VTE (symptomatic DVT and PE) and costs of prophylaxis as well as adverse events such as HIT, PTS, prophylaxis and treatment related major bleeding, and mortality. Treatment costs in relation to DVT, PE, major bleeds, HIT, and PTS were based on the Australian register of Diagnosis Related Groups for private hospitals that are associated with treatment for VTE related events as well as hospital specific costs for the included prophylaxis regimens (National Hospital Cost Data Collection, 2008).

Structure of the decision tree

Our decision tree consisted of three pathways, one for each prophylaxis option (LMWH, LDUH, and no prophylaxis). The decision tree begins at the far left with the initial decision node (represented by the circle). Decision nodes represent the points at which alternative actions can be selected, with each alternative action represented by a separate branch of the decision tree. Possible outcomes resulting from a particular intervention are defined at chance nodes (represented by a rectangle). Each event emanating from a given chance node is assigned a value which represents the probability of that event occurring. The sum of the probabilities for all possible events from the same chance node must equal one, as all events must be mutually exclusive and exhaustive. For example, in Figure 11, patients will either die (probability 0.3) or survive (probability 0.7) their asymptomatic PE.
The end of a branch of the decision tree is represented by a terminal node (represented by a side-house). Pay-offs (costs) were assigned to each branch of the decision tree based on data from the Australian register Diagnosis Related Groups for Private Hospitals.
Analysis of the decision tree

The cost-effectiveness of VTE prophylaxis following the implementation of the guidelines was analysed via a ‘folding back and averaging’ process. The weighted average net value for each decision node of the three pathways was calculated starting from the terminal node of each branch working backwards to the initial node. The weighted average net value is the sum of the pay-offs (costs) weighted by the probability of their occurrence. This process was repeated working backwards to the initial node for each branch of the decision tree and then comparing the expected results from each of the three pathways (LMWH, LDUH, and no prophylaxis). This process of folding back and averaging is standard for decision-tree analysis (Pettiti, 2000).

4.5 Results

Actual study outcomes

The proportion of orthopaedic, general surgical and medical patients receiving a particular prophylaxis regimen (either LMWH, LDUH, or no prophylaxis) prior to the guideline implementation and 12 months following implementation are shown in Table 11. There was an increase in the percentage of orthopaedic patients who received no prophylaxis at follow-up (21% to 25%). This was related to a decrease in patients receiving LDUH (5% at to 0%) which was not countered by an equivalent increase in patients receiving LMWH (74% to 75%).

There was a decrease in the percentage of general surgical patients who received no prophylaxis (68% to 52%) which was attributable to an increase in the use of both LDUH
(20% to 31%) and LMWH (12% to 17%). Medical patients provided no prophylaxis also decreased from 95% at baseline to 80% at follow-up. This was related to an increase in both LDUH (0% to 5%) and LMWH (5% to 15%) prophylaxis regimes.

Table 11 The proportion of patients receiving prophylaxis at baseline and follow-up

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Prophylaxis regimen</th>
<th>Baseline (%)</th>
<th>Follow-up (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopaedics</td>
<td>LMWH</td>
<td>74</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>LDUH</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>No prophylaxis</td>
<td>21</td>
<td>25</td>
</tr>
<tr>
<td>General surgery</td>
<td>LMWH</td>
<td>12</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>LDUH</td>
<td>20</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>No prophylaxis</td>
<td>68</td>
<td>52</td>
</tr>
<tr>
<td>Medical</td>
<td>LMWH</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>LDUH</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>No prophylaxis</td>
<td>95</td>
<td>80</td>
</tr>
</tbody>
</table>

PTS= post thrombotic syndrome, HIT= heparin-induced thrombocytopenia, PE= pulmonary embolism, DVT= deep vein thrombosis, LMWH= low molecular weight heparin, LDUH= low-dose unfractionated heparin.

Projected clinical outcomes

Table 12 shows the projected change in clinical outcomes following the introduction of the VTE prevention guideline. The economic modelling estimated that there were 13 fewer deaths (183 to 170), 84 fewer symptomatic DVTs (865 to 781), 19 fewer symptomatic PEs (177 to 158), 48 fewer PTS events (455 to 407) and 512 fewer hospital bed days (11,119 to
10,607) over baseline, across medical and surgical patients. The model also estimated 34 more major bleeding events (392 to 426) and 22 more episodes of HIT (44 to 66).

Table 12 Estimated health outcomes at baseline and follow-up

<table>
<thead>
<tr>
<th>Clinical outcomes</th>
<th>Baseline (A)</th>
<th>Follow-up (B)</th>
<th>Incremental (=A–B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic DVT</td>
<td>865</td>
<td>781</td>
<td>-84</td>
</tr>
<tr>
<td>Symptomatic PE</td>
<td>177</td>
<td>158</td>
<td>-19</td>
</tr>
<tr>
<td>Deaths</td>
<td>183</td>
<td>170</td>
<td>-13</td>
</tr>
<tr>
<td>Major bleeding events</td>
<td>392</td>
<td>426</td>
<td>34</td>
</tr>
<tr>
<td>HIT</td>
<td>44</td>
<td>66</td>
<td>22</td>
</tr>
<tr>
<td>PTS</td>
<td>455</td>
<td>407</td>
<td>-48</td>
</tr>
<tr>
<td>Hospital days</td>
<td>11,119</td>
<td>10,607</td>
<td>-512</td>
</tr>
</tbody>
</table>

PTS= post thrombotic syndrome, HIT= heparin-induced thrombocytopenia, PE= pulmonary embolism, DVT= deep vein thrombosis.

Projected economic outcomes

The projected change in economic outcomes following the guideline’s introduction is shown in Table 13. According to the modelled analysis, improved adherence to evidence based prophylaxis regimens was associated with overall cost savings of $245,439 over 12 months ($5,078,522 to $4,833,083). Inpatient prophylaxis costs were estimated to increase by $38,553 from $107,311 to $142,864. The costs for LMWH were estimated to increase by $20,982 ($71,313 to $92,295) whilst costs for heparin were estimated to rise by $17,571 ($32,998 to $50,569). The model estimated that costs associated with the treatment of DVT
would be reduced by $231,765 ($2,375,532 to $2,143,767), that costs associated with the
treatment of PE reduced by $50,104 ($470,284 to $420,180), and that costs associated with
the treatment of PTS reduced by $130,735 ($1,247,732 to $1,116,997). The model also
estimated that the cost of treating major bleeds increased by $66,920 ($762,057 to
$828,977) and that the costs of treating HIT increased by $61,693 ($118,605 to $180,298).

Table 13 Estimated costs at baseline and follow-up

<table>
<thead>
<tr>
<th>Clinical costs</th>
<th>Baseline (A)</th>
<th>Follow-up (B)</th>
<th>Incremental (=A–B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total costs</td>
<td>$5,078,522</td>
<td>$4,833,083</td>
<td>-$245,439</td>
</tr>
<tr>
<td>Prophylaxis</td>
<td>$104,311</td>
<td>$142,864</td>
<td>$38,553</td>
</tr>
<tr>
<td>LMWH</td>
<td>$71,313</td>
<td>$92,295</td>
<td>$20,982</td>
</tr>
<tr>
<td>LDUH</td>
<td>$32,998</td>
<td>$50,569</td>
<td>$17,571</td>
</tr>
<tr>
<td>DVT treatment</td>
<td>$2,375,532</td>
<td>$2,143,767</td>
<td>-$231,765</td>
</tr>
<tr>
<td>PE treatment</td>
<td>$470,284</td>
<td>$420,180</td>
<td>-$50,104</td>
</tr>
<tr>
<td>Major bleeds</td>
<td>$762,057</td>
<td>$828,977</td>
<td>$66,920</td>
</tr>
<tr>
<td>HIT</td>
<td>$118,605</td>
<td>$180,298</td>
<td>$61,693</td>
</tr>
<tr>
<td>PTS</td>
<td>$1,247,732</td>
<td>$1,116,997</td>
<td>-$130,735</td>
</tr>
</tbody>
</table>

PTS=post thrombotic syndrome, HIT=heparin-induced thrombocytopenia, PE=pulmonary embolism, DVT=deep vein thrombosis, LMWH=low molecular weight heparin, LDUH=low-dose unfractionated heparin. All values are in Australian dollars.

4.6 Discussion

Our modelling demonstrated that the positive improvements in VTE prevention practices following the introduction of the evidence-based guideline were estimated to result in 13 fewer deaths, 84 fewer symptomatic DVTs, 19 fewer symptomatic PEs, 512 fewer hospital
bed days, and a saving of $245,439 over 12 months. These findings are comparable to similar studies conducted in European (Ferrando et al., 2009) and North America (Amin, Lin, Johnson, & Schulman, 2010b).

There are a number of important characteristics about this disease process which help explain why relatively small changes in clinical practice resulted in such dramatic improvements in clinical and economic outcomes. The combination of a high incidence rate, significant mortality and morbidity, and costly treatment are all characteristics of VTE that contribute to its significant burden. The most insidious characteristic, however, is the extended natural history of the disease process (Hansson, et al., 2000). Heit et al found the incidence of recurrent VTE was 10% at six months, 13% after one year, and 30% after 10 years (Heit, 2008). Decision tree analytic modelling is the perfect tool for demonstrating the compounding costs associated with each VTE event. As illustrated in Figure 2, all patients who survive VTE are at a significant ongoing risk of a recurrent event which in turn places them at risk of experiencing serious adverse clinical outcome (death, major bleed, PTS, or HIT) (Iorio et al., 2010). The sequelae of serious adverse events following VTE helps to explain why relatively small changes in practice result in such dramatic improvements in clinical and economic outcomes.

*Strengths and limitations*

Decision tree analytic economic modelling helps healthcare providers and funders to make informed decisions regarding the cost-effectiveness of alternative treatment options. Decision trees are the simplest form of analytical economic modelling, providing a relatively simple and transparent economic evaluation of the options available for a
healthcare problem (Petrou & Gray, 2011). A tailored economic model, such as the one used here, ensures that the treatment pathways and costs reflect the environment to which the model is applied which adds to the validity of the economic evaluation.

The decision tree model used in this analysis was designed exclusively for the assessment of pharmacological VTE prophylaxis. As such it is limited to drawing conclusions surrounding the pharmacologic aspects of the guideline implementation. The underlying data in the model, while being sourced from a robust and extensive mixed treatment comparison of published VTE prophylaxis data, only reflects the outcomes likely to be achieved by adherence to best practice and are not necessarily representative of the local hospital context. The analysis of cost-effectiveness could be further tailored by including more local hospital data such as VTE, major bleeding and HIT event rates.

4.7 Conclusion

Improved adherence to evidence-based guidelines for VTE prophylaxis in the Australian clinical setting is achievable and can result in significant improvements in clinical and economic outcomes. Practice improvement initiatives such as these are likely to result in fewer deaths, VTE events and significant overall healthcare cost savings.
CHAPTER 5. EDUCATIONAL OUTREACH VISITS TO IMPROVE NURSES’ USE OF MECHANICAL VENOUS THROMBOEMBOLISM PREVENTION IN HOSPITALISED MEDICAL PATIENTS: A PROSPECTIVE BEFORE-AND-AFTER INTERVENTION STUDY.

5.1 Prologue

Although there was an overall improvement in VTE prevention following the evidence implementation study there remained a significant difference between the prophylaxis rates of surgical and medical patients. The study concluded that ‘a specifically targeted intervention may be required to improve VTE prophylaxis for our medical patients’. The hospital executive, buoyed by the results of the clinical and economic modelling, agreed with this conclusion and approved this subsequent study. The study commenced in July 2011 and concluded in October 2012.

The previous study had used a multifaceted intervention that comprised a suite of strategies previously shown to be effective at improving the uptake of VTE prevention guidelines. The research team decided to take this opportunity to evaluate a strategy that had not previously been used to improve VTE prevention. Educational Outreach Visits (EOV) was known to be effective at guideline implementation in other areas of clinical practice but there was a clear gap in the evidence on its impact on VTE prevention in the acute care setting.

The design of the study was influenced by the United Kingdom Medical Research Council’s recommendations for the development and evaluation of complex interventions. We did not wish to conduct the definitive trial of EOV in this particular context; instead,
we aimed to conduct an evaluation that described the intervention, the actual exposure to the intervention, and the experience of those exposed.

A nursing Honours student working with the research team trialled EOV in her honours research study (see Li, Walker, McInnes, & Duff, 2010) which provided some valuable information on clinical impact and feasibility. Following this trial, it was immediately clear that we needed to source specialised training on EOV for the intervention to be successful. The National Prescribing Service, a non-government organisation that frequently uses EOV to promote the quality use of medicines, was contacted and generously agreed to run a two day workshop on persuasive communication and facilitation skills.

The research team I led included A/Prof Liz McInnes, Senior Research Fellow; Ms Edel Murray, Clinical Nurse Consultant Wound Management; Ms Belinda Johnston, Chief Pharmacist; A/Prof Jose Aguilera, Director of Nursing & Clinical Services; Prof Kim Walker, Professor of Healthcare Improvement; Prof Abdullah Omari, Vascular Physician; and Prof Sandy Middleton, Professor of Nursing. We were awarded a $25,000 St Vincent’s Clinic Foundation multidisciplinary patient-focused research grant which was used to secondment of a senior Registered Nurse, Ms Brid Flyne, and a Vascular Medicine Fellow, Dr Kiernan Hughes, conduct the visits with participants.

The overall aim of the study was to improve pharmacological and mechanical VTE prophylaxis for medical patients. The study involved two distinct targets groups; the nursing staff who initiate the mechanical prophylaxis and the medical staff who prescribe the pharmacological prophylaxis. This chapter reports on the nursing arm of the Peer-on-Peer Education for better VTE Prevention study. A version of this manuscript has been
accepted for publication in the *Journal of Vascular Nursing*, the official journal of the American Society of Vascular Nursing.

### 5.2 Abstract

**Background:** Venous thromboembolism is a significant cause of morbidity and mortality in hospitalised medical patients. The cost of treating non-fatal VTE and its related chronic conditions is also a considerable burden to the healthcare system. Evidence-based guidelines exist for preventing VTE but unfortunately these guidelines are not always adhered to by clinicians.

**Objective:** To evaluate the acceptability, utility and clinical impact of an Educational Outreach Visit (EOV) on nurses’ provision of mechanical prophylaxis to hospitalised medical patients.

**Design:** A prospective uncontrolled before-and-after intervention study.

**Context:** The study was conducted at a 250 bed acute care private hospital in Sydney, Australia.

**Intervention:** Nurses received a one-to-one EOV on mechanical VTE prevention from a trained nurse facilitator. The intervention was designed by a multidisciplinary group of healthcare professionals using social marketing theory.

**Results:** Eighty five of 120 eligible nurses (71%) received an EOV. The median length of each visit was 11.5 minutes (IQ range 10-15). The median time spent arranging and conducting each visit was 63 minutes (IQ range 49-85). Seventy five (97.4%) participants
felt that the EOV was effective or extremely effective at increasing their knowledge of mechanical VTE prevention and 84 (98.8%) of the 85 gave a verbal commitment to trial the new evidence-based mechanical VTE prevention practices. There were, however, no measurable improvements in the proportion of patients assessed for their risk of VTE (-1.7% improvement, 95% CI -7.0 to 10.3, p=0.68) or the proportion of patients provided appropriate mechanical prophylaxis (-0.3% improvement, 95% CI -13.4 to 14, p=0.96) following the intervention.

Conclusions: Participants reported that the EOV was effective at increasing their knowledge and addressing their concerns about providing VTE prophylaxis for medical inpatients. They also expressed a willingness to adopt the new practices following the EOV but this did not translate into measurable improvement in patient care. The intervention was resource intensive requiring four and a half minutes of preparation for every minute spent face-to-face with participants. Further research into the specific mechanism of action is required to explain the variability in clinical effect seen with this intervention.

5.3 Introduction

It is internationally acknowledged that hospitalised medical patients receive suboptimal thromboprophylaxis (Bergmann, et al., 2010). Evidence-based guidelines exist for the prevention of VTE but unfortunately these guidelines are not always adhered to by clinicians (Rothberg, et al., 2010). The challenge of translating evidence into routine clinical practice is not unique to venous thromboembolism (VTE) prevention; it is a growing problem faced by healthcare in general (Palmer, Lancaster, Kramlich, & Gallant, 2011). Implementation science is the relatively new field of research which studies
strategies to promote the systematic uptake of research findings into routine clinical practice (Wallin, 2009). Educational Outreach Visits (EOV) is an implementation strategy which is not widely used to improve VTE prevention practices in acute care. The aim of this study was to evaluate the acceptability, utility and clinical impact of EOV on nurses’ provision of mechanical VTE prophylaxis to hospitalised medical patients.

*Venous thromboembolism*

Deep vein thrombosis (DVT) and pulmonary embolism (PE) are two components of the one disease process known as venous thromboembolism. VTE is a serious vascular condition which is responsible for approximately 5000 deaths in Australia (Access Economics, 2008); 25,000 deaths in the United Kingdom (National Institute of Health and Clinical Excellence, 2010); and 300,000 deaths in the united States (Heit, et al., 2002) each year. VTE is also associated with chronic cardiovascular conditions such as post thrombotic syndrome which is characterised by persistent lower limb oedema, pain, inflammation, and ulceration; and thromboembolic pulmonary hypertension, a rare but debilitating condition featuring elevated pulmonary artery systolic pressures (Mason, 2009).

Hospitalised patients are particularly vulnerable to VTE. Within the acute inpatient population, VTE accounts for 10% of all deaths making it the single most preventable cause of hospital related mortality (Access Economics, 2008). Spencer et al (2007) estimate that approximately 50% of all VTE related deaths in the community are directly attributable to a recent hospital admission.
In the last 50 years there has been a great deal of research on the prevention of VTE in hospitalised patients. This research has identified pharmacological and mechanical prophylactic therapies which, when applied appropriately, significantly reduce the incidence of hospital related VTE (The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2010). Pharmacological therapies recommended by the guidelines are anticoagulants that target the clotting cascade. The classes of drugs include the unfractionated and low molecular weight heparins, heparinoids, factor x inhibitors, and direct thrombin inhibitors. The recommended mechanical therapies, such as graduated compression stockings and pneumatic venous pumping devices, focus on reducing venous stasis through external compression (National Health and Medical Research Council, 2009).

Research and clinic audit reveal that prophylactic therapies are underutilised and inconsistently applied (Clavijo-Alvarez, et al., 2011; Cohen, et al., 2008; Duff, et al., 2011). One patient group that consistently receives suboptimal thromboprophylaxis is hospitalised medical patients (Bergmann, et al., 2010; Rothberg, et al., 2010; Vardi, et al., 2011). An international audit of 37,356 medical patients’ across 32 countries found that less than 40% of at-risk hospitalised medical patients were receiving the recommended prophylaxis (Bergmann, et al., 2010). This is despite the fact that between 50 and 80% of all hospital related VTE cases occur in the medical inpatient population (Alikhan, et al., 2004; Goldhaber & Tapson, 2004).
**Educational Outreach Visits**

Several strategies to improve VTE prevention in hospitalised patients have been studied (Amin & Deitelzweig, 2009; Tooher, et al., 2005). On the whole, the research demonstrates that active strategies such as continuing education are more effective than passive strategies such as simple guideline dissemination. EOV is an active implementation strategy that has been used to change clinician behaviour and improve compliance with evidence-based practice. There is evidence that it is particularly effective at influencing prescribing behaviour but has a more variable effect on other clinical practices (O’Brien, et al., 2007).

EOV consists of a one-to-one educational visit by a trained facilitator to a health professional in their own clinical setting (Soumerai & Avorn, 1990). This type of face-to-face visit has also been referred to as university-based educational detailing, academic detailing, and educational visiting (O’Brien, et al., 2007). This strategy is one that is widely used by the pharmaceutical industry to influence the prescribing practices of doctors (Avorn & Choudhry, 2010).

EOV has a social marketing framework which differentiates it from other types of education-based implementation strategies (Soumerai & Avorn, 1990). There is little argument that commercial marketing has been highly effective at influencing consumer behaviour (Morris & Clarkson, 2009). Social marketing attempts to apply this highly successful approach to the promotion of socially desirable behaviours (Morris & Clarkson, 2009). Most social marketing efforts in healthcare, to date, have targeted consumers and focused primarily on disease prevention. The intervention, for example, has been widely
used to improve immunisation rates in the general community (Szilagyi et al., 2004). There has been an increasing interest in the ability of social marketing to influence clinician behaviour and improve compliance with evidence-based practice (Luck et al., 2009; O’Brien, et al., 2007).

Social marketing applies the psychology of persuasion. This form of educational intervention focusses as much on the delivery of the message and the recipient’s response as it does on the content (Evans & McCormack, 2008). Opel et al (2009) point out that this is, in fact, a 2000 year old approach first proposed by the Greek philosopher, Aristotle. Aristotle argued that persuasion required not only a reasonable argument and supporting data (logos), but also a messenger who is trustworthy and attentive to the audience (ethos) and a message that resonates with the audience’s emotions (pathos). This ancient theory of persuasion now has a substantial body of modern social science research to support it (Cialdini, 2001).

The Canadian Agency for Drugs and Technologies in Health’s (CADTH) Rx for Change database (Canadian Agency for Drugs and Technologies in Health, 2012) identified 31 systematic reviews that evaluated the effectiveness of EOV at changing healthcare practices or improving patient outcomes. Only five of the 31 reviews were assessed as being of a high quality (AMSTAR score >7) (Faulkner et al., 2003; Forsetlund, et al., 2009; Nkansah et al., 2010; O’Brien et al., 2004; O’Brien, et al., 2007). Of these, two reviews (Nkansah, et al., 2010; O’Brien, et al., 2007) found that EOV was generally effective for improving healthcare practices while the other three reviews had an insufficient number of studies to draw conclusions about the effectiveness of the intervention. The Cochrane systematic review by O’Brien et al (2007) included 69 studies
involving more than 15,000 health professional. The authors reported that EOV was consistently effective for prescribing but varied for other types of professional performance. Potential explanatory factors (baseline compliance, complexity, number of visits, study quality, number of clinicians per visit, seriousness of topic) could not explain the variation in adjusted risk difference.

Although there is a growing body of research on the use of EOV to promote evidence-based practices there have only been two single-site studies which have used this strategy to improve VTE prevention (Grupper et al., 2006; Roberts & Adams, 2006). Both studies reported a moderate to large improvement in VTE prophylaxis rates (14 & 21% respectively). The target population in both studies, however, was junior medical officers. To date, there has been no research examining the impact of this intervention on nurses’ compliance with mechanical VTE prevention practices.

5.4 Method

Design

A prospective uncontrolled before-and-after intervention study with process evaluation using pre and post intervention clinical audits and self-administered surveys.

Context

The study was conducted in a 250 bed Magnet designated private hospital in Sydney, Australia. The hospital employs 400 nurses who care for approximately 20,000 patients annually. The hospital has seven acute inpatient units which cater for most major medical
and surgical specialties except paediatric and maternity care. The case mix is 70% surgical, 30% medical.

This study built on a previous VTE evidence implementation study which was conducted at the hospital (Duff, et al., 2011). In this study a planned action implementation science model developed by Grol et al (2005a) was used to identify, analyse, and overcome barriers to practice change. The intervention included audit and feedback; policy development; alerts and reminders; and documentation aids. The study resulted in a 13% improvement in the proportion of medical patients receiving appropriate mechanical prophylaxis (52% to 65%). There remained, however, a significant disparity between the mechanical prophylaxis rates of surgical and medical patients on completion of this study (90% compared to 65%).

Target population

The target population for this study was nursing staff who care for medical inpatients. The following inclusion criteria were used to define the target population: Nurses working two or more shifts per week on an acute medical unit, or a unit where >30% of admissions are medical patients.

Eligible medical units were identified by the medical records manager using hospital admissions data. The managers of these units were contacted to gain permission to conduct the study in their department and to gain a list of eligible nurses. The facilitator then negotiated a convenient time and location to conduct the EOV with the consenting participants.
Target behaviours

There were two behaviours targeted by this intervention; the assessment of VTE risk and the provision of appropriate mechanical VTE prophylaxis. At the study site there was a policy governing VTE prevention which clearly defined the roles and responsibilities of nursing staff. The policy stated that nursing staff were responsible for the assessment of VTE risk and the provision and management of mechanical prophylaxis.

Intervention

EOV was chosen as an implementation strategy by the research team because it uses social marketing principles to overcome individual clinicians’ obstacles to practice change (Morris & Clarkson, 2009). The intervention used in the previous evidence implemented study targeting organisational barriers to VTE prevention and it was hypothesised that this would be complemented by the addition of EOV.

The protocol (Table 14) for the EOV was developed by a multidisciplinary group of healthcare professionals with expertise in VTE, clinical education, healthcare improvement science, and research. The group included a vascular physician, vascular medicine fellow, nurse educator, clinical nurse specialist, pharmacist, professor of healthcare improvement, and clinical research fellow. A Cochrane systematic review (O’Brien, et al., 2007) and the social marketing literature (Cialdini, 2001; Morris & Clarkson, 2009; Opel, et al., 2009) informed the protocol development process.
Table 14 Educational Outreach Visit protocol

<table>
<thead>
<tr>
<th>EOV component</th>
<th>Element</th>
</tr>
</thead>
</table>
| Plan the visit         | Contact the nurse unit manager to gain access to the unit  
Contact the target population by email, phone, or in person to gain consent  
Negotiate a convenient time and location for the visit  
Reconfirm arrangements with prior to the visit  
Discuss with the research team any difficulties with recruitment |
| Set the scene          | Ensure appropriate space for the discussion  
Engage in small talk to place the participant at ease  
Explain the purpose of the visit  
Negotiate the session length (approximately 20 minutes)  
Introduce the four key messages and identify participants specific needs |
| Build trust, credibility and likability | Mention the key opinion leaders in support of the study  
List the study’s academic and clinical affiliations  
Highlight your own clinical expertise in the area  
Attempt to uncover personal similarities between the participant and yourself  
Offer genuine praise where appropriate |
| Promote two-sided communication | Ask open ended questions  
Use minimal encouragement techniques  
Paraphrase and reflect on the participants comments  
Anticipate and acknowledge controversial issues  
Overcome any objections and handle challenging responses |
<table>
<thead>
<tr>
<th>EOV component</th>
<th>Element</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliver key message(s)</td>
<td>VTE is an important healthcare issue</td>
</tr>
<tr>
<td></td>
<td>Assess individual patient risk</td>
</tr>
<tr>
<td></td>
<td>Provide evidence-based VTE prophylaxis and patient education</td>
</tr>
<tr>
<td></td>
<td>Monitor and reassess each patient during their hospital stay</td>
</tr>
<tr>
<td>Wrap-up and reflect</td>
<td>Reflect on the discussion</td>
</tr>
<tr>
<td></td>
<td>Reiterate the key message(s) discussed</td>
</tr>
<tr>
<td></td>
<td>Give the participant the printed resource material to keep</td>
</tr>
<tr>
<td></td>
<td>Gain commitment to trial the new practices</td>
</tr>
<tr>
<td>Provide follow-up</td>
<td>Follow-up via email, phone, or in person</td>
</tr>
<tr>
<td></td>
<td>Fulfill any commitments made during the visit</td>
</tr>
</tbody>
</table>

A registered nurse with expert knowledge in VTE was recruited to the role of EOV facilitator. This person was a senior staff member in the hospital with over twenty years’ experience. The EOV facilitator and other members of the research team attended a two day intensive workshop on social marketing and persuasive communication techniques (Appendix K). The workshop was run by an independent, not-for-profit organisation (National Prescribing Service) that uses this intervention extensively to promote the quality use of medicines in Australia. The training involved role play, peer review, and self-reflection techniques. The specific learning objectives of the workshop were:

- To outline the context in which educational outreach visiting occurs;
- To identify and describe strategies that are effective in promoting behaviour change;
- To demonstrate specific skills development in:
- One-to-one communication techniques;
- Relating information clearly;
- Addressing issues and concerns;
- Gaining commitment to trialling new practices.

The content of the EOV was limited to four key messages: 1) VTE is an important healthcare issue which results in significant mortality, morbidity and resource expenditure; 2) patients must have their VTE risk assessed including clotting risk, bleeding risk, and contraindications to prophylaxis; 3) patients must receive appropriate prophylaxis based on their risk assessment; and 4) patients must be monitored for signs of VTE or prophylaxis related adverse events. These verbal messages were supported by a concise graphic educational resource (Appendix L) given to the participant by the facilitator during the EOV.

The study budget enabled the facilitator to be seconded to the study for a total of 120 hours over the two month intervention period. Two trial visits were conducted prior to the intervention period to identify potential issues and familiarise the facilitator with the protocol. The trial visits were conducted with clinicians working on units that were not participating in the study. During the intervention period, the facilitator received support from the research team in weekly debriefing sessions.

**Objective**

To evaluate the acceptability, utility and clinical impact of an EOV on nurses’ provision of mechanical prophylaxis to hospitalised medical patients.
Outcomes measures and data collection

Outcome (clinical impact) and process (acceptability and utility) measures were incorporated into the design of this study. Process measures were included to help provide a greater understanding of this complex intervention which is known to have variable effectiveness (O’Brien, et al., 2007).

Acceptability

The acceptability of the EOV was measured in post intervention participant and facilitator surveys (Appendix M). The participants’ survey and self-addressed envelope were left by the facilitator at the completion of the EOV. The survey contained eight questions in total. Six questions related to the effectiveness of the EOV at increasing the participants’ knowledge and addressing their concerns about VTE prophylaxis for medical inpatients. These questions were answered on a five point Likert scale (extremely ineffective to extremely effective). Two questions asked how likely was it that they would participate in a program such as this in the future, and how likely was it that the intervention would influence their clinical practice. These questions were answered on a five point Likert scale (extremely likely to extremely unlikely). The EOV facilitator also completed a post intervention survey appraising the participants’ perceived level of interest, participation and comprehension. These three questions were answered on a five point Likert scale (very low to very high).
Utility

Descriptive data on each EOV were recorded on a data collection form by the facilitator (Appendix N). The recorded data included the demographic information of participants; the time and effort spent arranging the EOV; the time spent conducting the EOV; the number of interruptions and the time spent on them; the location of the EOV; and whether or not a commitment was gained from the participant to trial the new practices. The facilitator’s self-assessed level of adherence to all of the elements of the study protocol was also collected. The structured protocol (Table 14) acted as a checklist to aid the reflection process.

Clinical impact

Two measures were used to assess the clinical impact of this intervention: 1) the proportion of medical inpatients with a documented VTE risk assessment; and 2) the proportion of medical patients who received appropriate mechanical VTE prophylaxis. The data were collected in pre and post intervention audits. A stratified (by unit) sample of 192 consecutive medical inpatients was audited before and after the two month EOV intervention period. The following exclusion criteria were used for patient selection: Planned or prior (previous 30 days) surgery this admission; admitted <24 hours previously; medical record or patient unavailable; inadequate documentation to complete the risk assessment.

The audits were conducted using an audit tool based on national VTE prevention guidelines (The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2010) (Appendix J). These guidelines had been
endorsed by the hospital and formed the basis of the hospital VTE prevention policy. The audit tool had been trialled by the researchers in a prior evidence implementation study (Duff, et al., 2011). The audits were conducted by a registered nurse who had been trained by the researchers in the use of the tool. The auditor recorded each eligible patient’s VTE risk status and contraindications to prophylaxis before observing them to determine the presence or absence of appropriate mechanical prophylaxis measures. The appropriateness of the prophylaxis was assessed against the above mentioned VTE prevention guidelines. Depending on the patient’s risk status ‘appropriate prophylaxis’ was either no prophylaxis (low risk and ambulatory); graduated compression stockings (higher risk and ambulatory); or graduated compression stockings and intermittent pneumatic compression device (higher risk and non-ambulatory). The auditor had access to expert adjudication from a consultant vascular physician when required.

Sample size

The study was designed to detect a 10% (50% to 60%) improvement in the proportion of medical inpatients receiving appropriate mechanical prophylaxis. An apriori power calculation was performed (Faul, Erdfelder, Lang, & Buchner, 2007) and a sample size of 180 patients was required to power the study at 80% with a significance level of 5%.

The literature provided limited assistance in estimating the sample size because of the variation in published effect sizes. A pilot study conducted by the researchers enabled a more accurate estimate of the potential effect size in this particular context (Li, et al., 2010). The pilot study resulted in a 16% (59% to 75%) improvement in the proportion of medical patients who received mechanical VTE prophylaxis.
Statistical methods

The data were entered into SPSS version 18 for analysis. Continuous data were summarised as median and interquartile range and categorical data were summarised as number and percentage. For comparisons between groups, the Chi-square test was used for dichotomous variables (appropriate prophylaxis, risk assessment, risk factors, sex, specialty unit, admitting specialty, staff designation) and the Mann-Whitney U test was used for non-parametric continuous variables (age, number of years post registration). The differences in pre and post intervention prophylaxis and risk assessment rates were calculated with 95% confidence intervals. The p value for statistical significance was set at <0.05.

5.5 Results

Target population

Of the 400 nurses employed by the hospital, 120 were identified as members of the target population based on the inclusion criteria. Of the eligible nurses, 85 (71%) agreed to participate in the intervention and 35 (29%) declined or were unavailable. The intervention was conducted over a two month period from August to September 2011. Of the 85 participants who received an EOV intervention, 76 (89.4%) returned the post intervention participant survey. There were no significant differences in sex, number of years post registration, and professional designation between nurses who received the intervention and those who declined it. The number of nurses who declined the intervention differed significantly between units. Three units had 11% to 14% of the nurses decline the EOV
while one unit (cardiothoracic/ respiratory) had 63% decline (adjusted residual 5.9) (see Table 15).

**Audited patients**

The 192 patients who met the criteria were audited before (n=98) and after (n=94) the EOV intervention period. There were no differences between the two groups in age, sex, admitting specialty, and inpatient unit. The overall risk status was comparable with 86 (87.8%) patients at high-risk pre intervention compared to 87 (92.6%) post intervention. The pre intervention group had significantly more patients with two or more additional risk factors (30% to 14%, p=0.01) while the post intervention group had more patients with active cancer (7% to 16%, p=0.03). There were no other differences between the two samples of patients (see Table 16 & Table 17).
Table 15 Characteristics of the target population

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Received the intervention (n=85)</th>
<th>Declined or unavailable (n=35)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Median (IQ range) 29 (25-35)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Years post registration</td>
<td>5 (2-9)</td>
<td>8 (3-15)</td>
<td>0.069*</td>
</tr>
<tr>
<td>Sex</td>
<td>Number (%)</td>
<td></td>
<td>1.0^</td>
</tr>
<tr>
<td>Male</td>
<td>12 (14)</td>
<td>5 (14)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>72 (86)</td>
<td>30 (86)</td>
<td></td>
</tr>
<tr>
<td>Specialty unit</td>
<td></td>
<td></td>
<td>&lt;0.001^</td>
</tr>
<tr>
<td>Neurology/ oncology</td>
<td>24 (28)</td>
<td>4 (11)</td>
<td></td>
</tr>
<tr>
<td>Vascular/ gastroenterology</td>
<td>26 (31)</td>
<td>4 (11)</td>
<td></td>
</tr>
<tr>
<td>Cardiothoracic/ respiratory</td>
<td>9 (10)</td>
<td>22 (63)</td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>26 (31)</td>
<td>5 (14)</td>
<td></td>
</tr>
<tr>
<td>Designation</td>
<td></td>
<td></td>
<td>0.275^</td>
</tr>
<tr>
<td>Registered Nurse</td>
<td>67 (79)</td>
<td>23 (66)</td>
<td></td>
</tr>
<tr>
<td>Enrolled Nurse</td>
<td>1 (1)</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Clinical Nurse Specialist</td>
<td>17 (20)</td>
<td>11 (31)</td>
<td></td>
</tr>
</tbody>
</table>

Percentages may not add up to 100 due to missing data. N/A= not available. *Mann-Whitney U test. ^Pearson Chi-square.
## Table 16 Characteristics of the audited patients

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Pre intervention (n=98)</th>
<th>Post intervention (n=94)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Median (IQ range)</td>
<td>72 (58-82)</td>
<td>75.5 (63.5-85)</td>
<td>0.15*</td>
</tr>
<tr>
<td>Sex Number (%)</td>
<td></td>
<td></td>
<td>0.19^</td>
</tr>
<tr>
<td>Male</td>
<td>43 (43.9)</td>
<td>50 (53.2)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>55 (56.1)</td>
<td>44 (46.8)</td>
<td></td>
</tr>
<tr>
<td>Admitting specialty</td>
<td></td>
<td></td>
<td>0.67^</td>
</tr>
<tr>
<td>Cardiac</td>
<td>36 (36.7)</td>
<td>32 (34)</td>
<td></td>
</tr>
<tr>
<td>Cardiacal/ respiratory</td>
<td>9 (9.2)</td>
<td>7 (7.4)</td>
<td></td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>7 (7.1)</td>
<td>12 (12.8)</td>
<td></td>
</tr>
<tr>
<td>Oncology</td>
<td>11 (11.2)</td>
<td>14 (14.9)</td>
<td></td>
</tr>
<tr>
<td>Neurology</td>
<td>16 (16.3)</td>
<td>11 (11.7)</td>
<td></td>
</tr>
<tr>
<td>Renal</td>
<td>11 (11.2)</td>
<td>7 (7.4)</td>
<td></td>
</tr>
<tr>
<td>Vascular</td>
<td>8 (8.2)</td>
<td>11 (11.7)</td>
<td></td>
</tr>
<tr>
<td>Inpatient unit</td>
<td></td>
<td></td>
<td>0.99^</td>
</tr>
<tr>
<td>Neurology/ oncology</td>
<td>25 (25.5)</td>
<td>23 (24.5)</td>
<td></td>
</tr>
<tr>
<td>Vascular/ gastroenterology</td>
<td>25 (25.5)</td>
<td>24 (25.5)</td>
<td></td>
</tr>
<tr>
<td>Cardiacal/ respiratory</td>
<td>25 (25.5)</td>
<td>25 (26.6)</td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>23 (23.5)</td>
<td>22 (23.4)</td>
<td></td>
</tr>
</tbody>
</table>

Percentages may not add up to 100 due to missing data. IQ= Inter Quartile range. *Mann-Whitney U test. ^Pearson Chi-square.
Table 17 VTE risk factors

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Pre intervention (n=98)</th>
<th>Post intervention (n=94)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>High risk of VTE</td>
<td>86 (87.8)</td>
<td>87 (92.6)</td>
<td>0.26^</td>
</tr>
<tr>
<td>Risk factors present</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischaemic stroke</td>
<td>10 (10.2)</td>
<td>17 (18.1)</td>
<td>0.11^</td>
</tr>
<tr>
<td>History of VTE</td>
<td>29 (29.6)</td>
<td>20 (21.3)</td>
<td>0.18^</td>
</tr>
<tr>
<td>Active cancer</td>
<td>7 (7.1)</td>
<td>16 (17)</td>
<td>0.03^</td>
</tr>
<tr>
<td>Decompensated heart failure</td>
<td>17 (17.3)</td>
<td>20 (21.3)</td>
<td>0.49^</td>
</tr>
<tr>
<td>Acute on chronic lung disease</td>
<td>11 (11.2)</td>
<td>9 (9.6)</td>
<td>0.7^</td>
</tr>
<tr>
<td>Age &gt; 60 years and immobile</td>
<td>73 (74.5)</td>
<td>62 (66)</td>
<td>0.19^</td>
</tr>
<tr>
<td>Acute inflammatory disease</td>
<td>6 (6.1)</td>
<td>12 (12.8)</td>
<td>0.11^</td>
</tr>
<tr>
<td>Multiple additional risk factors</td>
<td>30 (30.6)</td>
<td>14 (14.6)</td>
<td>0.01^</td>
</tr>
<tr>
<td>Additional risk factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immobility</td>
<td>26 (26.5)</td>
<td>25 (26.6)</td>
<td>0.99^</td>
</tr>
<tr>
<td>Familial history of VTE</td>
<td>12 (12.2)</td>
<td>9 (9.6)</td>
<td>0.55^</td>
</tr>
<tr>
<td>Oestrogen therapy</td>
<td>1 (1)</td>
<td>2 (2.1)</td>
<td>0.53^</td>
</tr>
<tr>
<td>Obesity</td>
<td>7 (7.1)</td>
<td>9 (9.6)</td>
<td>0.54^</td>
</tr>
<tr>
<td>Thrombophilia</td>
<td>1 (1)</td>
<td>1 (1.1)</td>
<td>0.97^</td>
</tr>
<tr>
<td>Active inflammation</td>
<td>6 (6.1)</td>
<td>4 (4.3)</td>
<td>0.56^</td>
</tr>
</tbody>
</table>

Percentages may not add up to 100 due to missing data. IQ= Inter Quartile range. *Mann-Whitney U test. ^Pearson Chi-square.
Table 18 Acceptability of the Educational Outreach Visit

<table>
<thead>
<tr>
<th>How effective was the Educational Outreach Visit in...</th>
<th>Extremely Effective n (%)</th>
<th>Ineffective n (%)</th>
<th>Unsure n (%)</th>
<th>Effective n (%)</th>
<th>Extremely Ineffective n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increasing or refreshing your knowledge about VTE prophylaxis for medical patients?</td>
<td>37 (48.7)</td>
<td>2 (2.6)</td>
<td>0 (0)</td>
<td>40 (52.6)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td>Addressing concerns you have had about providing VTE prophylaxis to medical patients?</td>
<td>34 (44.7)</td>
<td>2 (2.6)</td>
<td>0 (0)</td>
<td>42 (55.3)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td>Providing information about the significance of VTE as a healthcare issue?</td>
<td>42 (55.3)</td>
<td>2 (2.6)</td>
<td>0 (0)</td>
<td>28 (36.8)</td>
<td>4 (5.3)</td>
</tr>
<tr>
<td>Providing information about VTE risk assessment for medical patients?</td>
<td>43 (57.3)</td>
<td>1 (1.2)</td>
<td>1 (1.2)</td>
<td>29 (38.7)</td>
<td>1 (1.2)</td>
</tr>
<tr>
<td>Providing information about selecting appropriate VTE prophylaxis for medical patients?</td>
<td>35 (46.7)</td>
<td>2 (2.7)</td>
<td>0 (0)</td>
<td>36 (48)</td>
<td>2 (2.7)</td>
</tr>
<tr>
<td>Providing information about the ongoing monitoring of patients risk and response to prophylaxis?</td>
<td>34 (45.3)</td>
<td>1 (1.2)</td>
<td>2 (2.7)</td>
<td>37 (49.3)</td>
<td>1 (1.2)</td>
</tr>
</tbody>
</table>

Percentages may not add up to 100 due to missing data.
Table 19 Acceptability of the Educational Outreach Visit

<table>
<thead>
<tr>
<th>How likely is it that...</th>
<th>Extremely unlikely n (%)</th>
<th>Unlikely n (%)</th>
<th>Unsure n (%)</th>
<th>Likely n (%)</th>
<th>Extremely likely n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>You will participate in another educational program such as this one in the future?</td>
<td>1 (1.2)</td>
<td>0 (0)</td>
<td>1 (1.2)</td>
<td>34 (44.7)</td>
<td>40 (52.6)</td>
</tr>
<tr>
<td>This educational visit will influence your clinical practice?</td>
<td>1 (1.2)</td>
<td>0 (0)</td>
<td>1 (1.2)</td>
<td>28 (36.8)</td>
<td>46 (60.5)</td>
</tr>
</tbody>
</table>

Percentages may not add up to 100 due to missing data.

Table 20 Acceptability of the Educational Outreach Visit

<table>
<thead>
<tr>
<th>What was the participants perceived level of ...</th>
<th>Very low n (%)</th>
<th>low n (%)</th>
<th>Average n (%)</th>
<th>high n (%)</th>
<th>Very high n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interest in the topic presented?</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>4 (4.8)</td>
<td>45 (54.2)</td>
<td>34 (41)</td>
</tr>
<tr>
<td>Participation during the visit?</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>4 (4.8)</td>
<td>45 (54.2)</td>
<td>34 (41)</td>
</tr>
<tr>
<td>Comprehension of the information provided?</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>12 (14.5)</td>
<td>26 (31.3)</td>
<td>45 (54.2)</td>
</tr>
</tbody>
</table>

Percentages may not add up to 100 due to missing data.

**Acceptability**

Of the 76 nurses who returned the post intervention evaluation, 74 (97.4%) felt that the EOV was effective or extremely effective at increasing their knowledge and addressing their concerns about VTE prophylaxis for medical inpatients. The participants also agreed that the EOV was effective at providing information on the four key messages outlined in
the study protocol: Seventy (92.1%) participants reported that the EOV was effective or extremely effective at communicating the significance of VTE; 72 (96%) felt that the importance of VTE risk assessment was effectively or extremely effectively communicated; and 71 (94.7%) agreed that the EOV was effective or extremely effective at providing information on the selection and ongoing monitoring of appropriate prophylaxis. When asked how likely it would be that they would participate in another EOV, 74 (97.4%) participants reported that it would be likely, or extremely likely. The same number (n=74, 97.4%) felt that the EOV was likely, or extremely likely to influence their clinical practice. When the EOV facilitator was asked to rate the participants’ perceived interest, participation and comprehension in the EOV, she reported that 79 (95.2%) of the participants had a high or very high level of interest and participation, and 71 (85.5%) had a high to very high level of comprehension (Table 18, Table 19, Table 20).

Utility

Table 21 provides data on the EOV intervention. The median number of times it was necessary to make contact with the participant to arrange an EOV was 2 (IQ range 1-2) and the median number of cancellations was 0 (IQ range 0-1). The median time spent on each EOV was 63 minutes (IQ range 49-85) which was made up of time spent arranging the EOV (median 20 minutes, IQ range 15-20); customising the material (median 10 minutes, IQ range 10-15); waiting for the participant (median 20 minutes, IQ range 0-30) and conducting the EOV (median 11.5 minutes, IQ range 10-15). The majority of visits was conducted in an office or education room (n=35, 41.2%). The rest were split evenly between the clinical area (n=25, 29.4%) and other public areas (n=25, 29.4%). At the completion of the EOV, 84 (98.8%) of the 85 participants gave a verbal commitment to
trial the new evidence-based mechanical VTE prevention practices. The facilitator’s self-reported adherence to the EOV protocol was 90% (IQ range 87.5-92.5).

Table 21 Utility of the Educational Outreach Visit

<table>
<thead>
<tr>
<th>Number of contacts to arrange each EOV</th>
<th>Median (IQ range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contacts needed to arrange the visit</td>
<td>2 (1-2)</td>
</tr>
<tr>
<td>Cancelled visits prior to the visit</td>
<td>0 (0-1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time spent arranging and conducting each EOV</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Arranging the visit</td>
<td>20 (15-20)</td>
</tr>
<tr>
<td>Customising material</td>
<td>10 (10-15)</td>
</tr>
<tr>
<td>Waiting for the participant</td>
<td>20 (0-30)</td>
</tr>
<tr>
<td>Conducting the EOV</td>
<td>11.50 (10-15)</td>
</tr>
<tr>
<td>Time spent on interruptions</td>
<td>0 (0-0)</td>
</tr>
<tr>
<td>Total time spent on the EOV</td>
<td>63 (49-85)</td>
</tr>
</tbody>
</table>

| Percentage of protocol elements delivered to participant               | 90 (87.5-92.5)    |

<table>
<thead>
<tr>
<th>Location of the EOV</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical area</td>
<td>25 (29.4)</td>
</tr>
<tr>
<td>Office or education room</td>
<td>35 (41.2)</td>
</tr>
<tr>
<td>Other public area</td>
<td>25 (29.4)</td>
</tr>
<tr>
<td>Other private area</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome of the EOV</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant agreed to trial the new practices</td>
<td>84 (98.8)</td>
</tr>
</tbody>
</table>
Clinical impact

There was no measurable improvement in the proportion of patients with a documented VTE risk assessment following the intervention period (-1.7% improvement, 95% CI -7.0 to 10.3, p=68). There was also no improvement in the proportion of patients who received appropriate mechanical VTE prophylaxis (-0.3% improvement, 95% CI -13.4 to 14, p=0.96). Removing patients who were at low-risk of VTE from the analysis made no significant difference to this result (3.0% improvement, 95% CI -11.0 to 17.1, p=0.68) (see Table 22).

Table 22 Clinical impact of the Educational Outreach Visit

<table>
<thead>
<tr>
<th>Measures</th>
<th>Pre intervention n (%)</th>
<th>Post intervention n (%)</th>
<th>% Improvement (95% CI)</th>
<th>P value^</th>
</tr>
</thead>
<tbody>
<tr>
<td>VTE Risk assessment</td>
<td>10 (10.2)</td>
<td>8 (8.5)</td>
<td>-1.7 (-7.0 to 10.3)</td>
<td>0.68</td>
</tr>
<tr>
<td>Appropriate mechanical prophylaxis</td>
<td>42 (42.9)</td>
<td>40 (42.6)</td>
<td>-0.3 (-13.4 to 14.0)</td>
<td>0.96</td>
</tr>
<tr>
<td>Appropriate mechanical prophylaxis (high-risk)</td>
<td>32 (37.2)</td>
<td>35 (40.2)</td>
<td>3.0 (-11.0 to 17.1)</td>
<td>0.68</td>
</tr>
</tbody>
</table>

^Chi square or Fishers exact test. CI= Confidence Interval.

5.6 Discussion

Improving VTE prophylaxis in hospitalised patients is a particularly challenging task. Our study has produced new knowledge on the acceptability, utility and clinical impact of EOV on nurses’ provision of mechanical prophylaxis to hospitalised medical patients. We found
that there were no measurable improvements in VTE prevention practices despite the use of this highly targeted implementation strategy. In fact, the proportion of medical inpatients assessed for their risk of VTE decreased by 1.7% and the proportion of medical patients provided appropriate mechanical prophylaxis decreased by 0.3% following the intervention period. These results are indicative of the variability in effectiveness of EOV reported in the literature (O’Brien, et al., 2007). The adjusted difference in compliance with desired practices in the Cochrane systematic review by O’Brien et al (2007) ranged from -3% to 64%. The authors concluded that EOV is an intervention of varying effectiveness with outcomes highly dependent on the specific targeted population and target behaviour.

Studies examining the use of EOV for VTE prevention clearly demonstrate this variability in effectiveness. Two previous studies (Grupper, et al., 2006; Roberts & Adams, 2006) which both reported significant improvements, targeted the prescription of pharmacological prophylaxis by junior doctors, while our study targeting nurses’ use of mechanical prophylaxis, found no significant improvement in practice. It is difficult to fully explain the reason for this significant variation in effect, although it is clear from our results that it is not related to the perceived acceptability of the intervention to nurses. O’Brien (2007) recommends that future studies on EOV integrate a process evaluation into the design to provide greater insight into this complex intervention.

There has been much criticism of implementation science studies which have not included process evaluation (Glasziou et al., 2010). A strength of our study was that it incorporated a process evaluation which was based on United Kingdom Medical Research Council guidance on evaluation of complex interventions (Craig, et al., 2008). Stetler (2006a, p.
a nurse and implementation researcher describes the importance of process evaluation in implementation research:

‘Evaluative information is needed beyond clinical impact of the change effort and beyond discovering whether a chosen adoption strategy worked. Implementation researchers need to answer critical questions about the feasibility of implementation strategies, degree of real-time implementation, status and potential influence of contextual factors, response of project participants, and any adaptations necessary to achieve optimal change’.

The data collected in the process evaluation enabled a much greater assessment of the effectiveness of the intervention in this particular context. An important point and one that will benefit clinicians and researchers who wish to use this strategy, is our finding that four and a half minutes of organisation and preparation was required for every minute spent face-to-face with participants. The data also revealed that the median time spent with each participant was only 11.5 minutes (IQ range 10-15) and not the 20 minutes proposed in the protocol. The exposure of the participants to the intervention was therefore considerably less than expected which may have had a bearing on the overall results. Importantly, although there was no discernible improvement in patient care, our study did find that nurses felt the intervention was an acceptable evidence implementation strategy which would positively influence their clinical practice. They felt the EOV was effective at increasing their knowledge and addressing their concerns about VTE prophylaxis for medical inpatients.
Having both process and outcome data should inform researchers’ and clinicians’ assessment of the overall benefit of a particular intervention in a given context (Glasziou, et al., 2010). The disparity between the process and outcome results in this study does potentially complicate this task. Barry (1987) points out, in his history of the evolution of marketing theory, that commercial marketing has similarly struggled with assessing the benefit of marketing campaigns. To directly measure the improvement in sales and profits produced by marketing is highly complex, if indeed, possible at all. Instead, marketers have contended that the effectiveness of a marketing campaign should be measured by its impact on a hierarchy of positive responses such as the ability to recognise brand names, recall main copy points, generate positive attitudes, or change an image.

The ‘hierarchy of effects’ model has been used by marketers as a framework for assessing the overall benefit of a campaign. The model describes the six stages a person moves through when making a purchase. The stages are awareness; knowledge; liking; preference; conviction; and purchase (Barry, 1987). A marketing campaign may, for example, progress a consumer group from the awareness stage to the liking stage and this may well be considered a beneficial outcome.

The ‘hierarchy of effects’ model is similar to a number of stages of change models theorised by implementation researchers (Grol, 1992; Pathman, Konrad, Freed, Freeman, & Koch, 1996; Prochaska, Redding, & Evers, 1997). Pathman’s (1996) ‘awareness-to-adherence’ model, for example, describes four very similar stages a clinician moves through when adopting a new clinical practice. These stages are awareness; agreement; adoption; and adherence. With these models in mind, an implementation strategy could be said to have a positive effect on evidence uptake without necessarily producing a
measurable improvement in clinical practice. For example, an intervention may successfully shift a target population from an awareness stage to an agreement stage of change. Stages of change theory may help explain the results of this study and the variability in the effectiveness of EOV in general. This theory should be included in the design and evaluation of future studies that include social marketing based interventions such as EOV.

**Strengths and limitations**

Due to the resource-intensive nature of this implementation strategy participants were only able to receive one EOV during the intervention period. Previous studies have reported a greater clinical impact when multiple visits were performed with the same participants (O’Brien, et al., 2007). Future studies in this field should evaluate the accumulative effect of multiple visits to this target population and include a more in depth follow up of the nursing staff to better understand why the intervention did or did not change practice.

The uncontrolled before and after design is another potential weakness as it is known to be vulnerable to the influence of fluctuating trends or sudden organisational changes which make it difficult to attribute improvements solely to the intervention. Having only one post-implementation data point also means that it is unknown whether the observed improvements in practice would be sustained or improved upon over time. There is also some evidence to suggest that the results of uncontrolled before and after studies may overestimate the effects of interventions (Grimshaw, et al., 2000) although there is no evidence of that in this study.
Our study was limited by the fact that it was conducted at one site, a metropolitan private hospital. As a result, it is difficult to ascertain how these results were influenced by previous VTE implementation efforts undertaken at the hospital. What can be said is that in this context it is clear that the EOV provided no additional benefit over and above the improvements produced by previous implementation efforts. This could be addressed by repeating the study at a number of sites using a cluster randomised controlled design which is the gold standard method for evaluating implementation strategies (Eccles, et al., 2004). This trial should also include an evaluation of the ongoing sustainability of the intervention.

While the study was limited in size (the number of sites and participants) it did include a process evaluation which provided an extra degree of depth to the research. Future research should include qualitative methods to follow up the nursing staff to better understand why the intervention did or did not change practice.

5.7 Conclusion

This is an original piece of research. It is one of only a three studies to evaluate the use of EOV to improve VTE prophylaxis and it is the only published study to focus specifically on medical inpatients and nurses use of mechanical prophylaxis. This study has established that nurses find EOV to be an acceptable strategy for the promotion of evidence-based mechanical VTE prevention practices for medical inpatients. A majority of nurses were willing to participate in the EOV and felt that it was effective at increasing their knowledge and addressing their concerns about providing prophylaxis. Importantly, they also expressed a willingness to adopt the new evidence-based practices. Of course, the
acceptability of an intervention should also be considered in relation to its utility and clinical impact. Our study confirmed the resource intensive nature of EOV: Four and a half minutes of preparation was required for every minute of time spent face-to-face with participants. We also found that, despite the participants’ willingness to trial the new practices there was actually no measurable improvement in patient care following the EOV. However, we suggest that the measurement of clinical outcomes in isolation provides only a rudimentary evaluation of effectiveness. We therefore suggest that future research using EOV include process measures which are informed by stage of change theory.
CHAPTER 6. EDUCATIONAL OUTREACH VISITS TO IMPROVE VENOUS THROMBOEMBOLISM PREVENTION IN HOSPITALISED MEDICAL PATIENTS: A PROSPECTIVE BEFORE-AND-AFTER INTERVENTION STUDY

6.1 Prologue

This chapter reports on the medical arm of the Peer-on-Peer Education for better VTE Prevention study described as discussed in the prologue to chapter 5. A version of this manuscript has been accepted for publication in the journal, *BMC Health Services Research* (IF 1.66).

6.2 Abstract

Background: Despite the availability of evidence-based guidelines on venous thromboembolism (VTE) prevention, clinical audit and research reveals that hospitalised medical patients frequently receive suboptimal prophylaxis. The aim of this study was to evaluate the acceptability, utility and clinical impact of an educational outreach visit (EOV) on the provision of VTE prophylaxis to hospitalised medical patients in a 270 bed acute care private hospital in metropolitan Australia.

Method: The study used an uncontrolled before-and-after design with accompanying process evaluation. The acceptability of the intervention to participants was measured with a post intervention survey; descriptive data on resource use was collected as a measure of utility; and clinical impact (prophylaxis rate) was assessed by pre and post intervention clinical audits. Doctors who admit >40 medical patients each year were targeted to receive the intervention which consisted of a one-to-one educational visit on VTE prevention from
a trained peer facilitator. The EOV protocol was designed by a multidisciplinary group of healthcare professionals using social marketing theory.

Results: Nineteen (73%) of 26 eligible participants received an EOV. The majority (n=16, 85%) felt the EOV was effective or extremely effective at increasing their knowledge about VTE prophylaxis and 15 (78%) gave a verbal commitment to provide evidence-based prophylaxis. The average length of each visit was 15 minutes (IQ range 15 to 20) and the average time spent arranging and conducting each visit was 92 minutes (IQ range 78 to 129). There was a significant improvement in the proportion of medical patients receiving appropriate pharmacological VTE prophylaxis following the intervention (16% improvement, 95% CI 5 to 26, p=0.004).

Conclusions: EOV is effective at improving doctors’ provision of pharmacological VTE prophylaxis to hospitalised medical patients. It was also found to be an acceptable implementation strategy by the majority of participants; however, it was resource intensive requiring on average 92 minutes per visit.

6.3 Introduction

Venous thromboembolism (VTE) is a common and potentially devastating complication of hospitalisation. Failure to provide appropriate VTE prophylaxis can result in serious adverse outcomes including symptomatic deep vein thrombosis (DVT) or pulmonary embolism (PE), post-thrombotic syndrome, chronic pulmonary hypertension, recurrent VTE, or fatal PE. Each year in the United States there are an estimated one million cases of VTE resulting in approximately 300,000 deaths annually (Heit, et al., 2002). Together, the
combined morbidity and mortality associated with this disease process result in an estimated economic burden to the nation of $1.5 billion/year (Dobesh, 2009).

People who are hospitalised with acute medical illness are particularly at risk of VTE. Without effective prophylaxis 10-20% of medical patients will develop an objectively diagnosed VTE which, in turn, has the potential to result in fatal PE. Within the acute patient population, fatal PE accounts for 10% of all deaths making it the single most preventable cause of hospital related mortality (Access Economics, 2008). Contrary to common held perceptions, a significant proportion of these deaths occur in the medical patient population. A retrospective evaluation of 6833 autopsies found that 80% of the fatal PEs occurred in medical (nonsurgical) patients (Alikhan, et al., 2004).

VTE in hospitalised medical patients is preventable. Evidence-based guidelines recommend the use of low molecular weight heparin (LMWH), low dose unfractionated heparin (LDUH), or fondaparinux for patients deemed to be at increased risk of VTE (Kahn, et al., 2012; The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2010). Risk factors for VTE in medical patients include active cancer, previous VTE, reduced mobility, known thrombophylic condition, increased age, heart and/or respiratory failure, myocardial infarction, ischaemia stroke, acute infection or rheumatologic condition, obesity, and ongoing hormonal treatment (Kahn, et al., 2012; The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2010). A number of tools have been developed and validated to aid in the assessment of VTE risk and help determine the onset, intensity, type, and duration of recommended prophylaxis (Caprini & Hyers, 2006; Cohen, et al., 2003; Kucher, et al., 2005).
Despite the widespread availability of evidence-based guidelines on VTE prevention hospitalised medical patients still receive suboptimal prophylaxis (Amin et al., 2010a; Bergmann, et al., 2010; Rothberg, et al., 2010; Tapson et al., 2007). One international study, the ENDORSE study, found that only 40% of at risk medical patients (n=37,356) were receiving the recommended prophylaxis (Bergmann, et al., 2010; Geerts et al., 2008a). Numerous strategies to improve VTE prevention in hospitalised patients have been studied with varying degrees of success (Amin & Deitelzweig, 2009; Kakkar, Davidson, & Haas, 2004; Merli, 2010; Michota, 2007; Tooher, et al., 2005). The evidence suggests that active implementation strategies which engage the target population are more effective than passive strategies at changing clinician behaviour and improving prophylaxis rates (Mahan & Spyropoulos, 2010; Merli, 2010; Michota, 2007; Tooher, et al., 2005).

An educational outreach visit (EOV) is an active implementation strategy that entails a structured one-to-one educational visit conducted in the clinical setting of the participant by a trained facilitator (Soumerai & Avorn, 1990). This intervention is also known as university-based educational detailing, academic detailing, and educational visiting (O’Brien, et al., 2007). An EOV is based on social marketing theory. It relies on the psychological principles of persuasion to influence clinician behaviour and promote evidence-based practices (Morris & Clarkson, 2009). A Cochrane systematic review of this implementation strategy concluded that EOVs, alone or in combination with other interventions, are consistently effective at influencing prescribing practices (O’Brien, et al., 2007). There have been few studies, however, examining the clinical impact of EOVs on the provision of VTE prophylaxis to medical patients and no previous studies on its acceptability or utility.
6.4 Method

Objective

To evaluate the acceptability, utility and clinical impact of an EOV on doctors’ provision of pharmacological VTE prophylaxis to hospitalised medical patients.

Target population

The target population was doctors who regularly admit medical (nonsurgical) patients to the study site. ‘Regular’ was defined as being in the top two quartiles of admitters which equated to a minimum of 40 admissions per year.

Setting

The study site is a 270 bed acute care private hospital in Sydney, Australia. It provides services in all major fields of medicine and surgery with the exception of obstetric and paediatric care. The hospital has 20,000 admissions annually, with approximately 30% admitted for acute medical illness.

Intervention

A vascular medicine physician with expertise in VTE prevention was recruited to the role of EOV facilitator and was responsible for arranging and conducting each visit. The facilitator followed a strict protocol which was collaboratively developed by a multidisciplinary team of healthcare professionals (Table 23). A Cochrane systematic review (O’Brien, et al., 2007) and social marketing literature (Cialdini, 2001; Morris & Clarkson, 2009; Opel, et al., 2009) informed the development of the protocol.
### Table 23 Educational Outreach Visit protocol

<table>
<thead>
<tr>
<th>EOV component</th>
<th>Element</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning the visit</td>
<td>Contact by email, phone, or in person to gain consent</td>
</tr>
<tr>
<td></td>
<td>Negotiate a convenient time and location for the visit</td>
</tr>
<tr>
<td></td>
<td>Reconfirm arrangements prior to the visit</td>
</tr>
<tr>
<td></td>
<td>Discuss with the research team any recruitment difficulties</td>
</tr>
<tr>
<td>Setting the scene</td>
<td>Ensure appropriate space for the discussion</td>
</tr>
<tr>
<td></td>
<td>Engage in small talk to place the participant at ease</td>
</tr>
<tr>
<td></td>
<td>Explain the purpose of the visit</td>
</tr>
<tr>
<td></td>
<td>Negotiate the session length (approximately 20 minutes)</td>
</tr>
<tr>
<td></td>
<td>Introduce the four key messages and identify participants specific needs</td>
</tr>
<tr>
<td>Building trust, credibility and</td>
<td>Mention the key opinion leaders in support of the study</td>
</tr>
<tr>
<td>likability</td>
<td>List the study's academic and clinical affiliations</td>
</tr>
<tr>
<td></td>
<td>Highlight your own clinical expertise in the area</td>
</tr>
<tr>
<td></td>
<td>Attempt to uncover personal similarities between participant and yourself</td>
</tr>
<tr>
<td></td>
<td>Offer genuine praise where appropriate</td>
</tr>
<tr>
<td>Promoting two-sided communication</td>
<td>Ask open ended questions</td>
</tr>
<tr>
<td></td>
<td>Use minimal encouragement techniques</td>
</tr>
<tr>
<td></td>
<td>Paraphrase and reflect on the participants comments</td>
</tr>
<tr>
<td></td>
<td>Anticipate and acknowledge controversial issues</td>
</tr>
<tr>
<td></td>
<td>Overcome any objections and handle challenging responses</td>
</tr>
<tr>
<td>EOV component</td>
<td>Element</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Delivering key message(s)</td>
<td>VTE is an important healthcare issue</td>
</tr>
<tr>
<td></td>
<td>Assess individual patient risk</td>
</tr>
<tr>
<td></td>
<td>Provide evidence-based VTE prophylaxis and patient education</td>
</tr>
<tr>
<td></td>
<td>Monitor and reassess each patient during their hospital stay</td>
</tr>
<tr>
<td>Wrapping up</td>
<td>Reflect on the discussion</td>
</tr>
<tr>
<td></td>
<td>Reiterate the key message(s) discussed</td>
</tr>
<tr>
<td></td>
<td>Give the participant the printed resource material to keep</td>
</tr>
<tr>
<td></td>
<td>Gain commitment to provide evidence-based prophylaxis</td>
</tr>
<tr>
<td>Providing follow-up</td>
<td>Follow-up via email, phone, or in person</td>
</tr>
<tr>
<td></td>
<td>Fulfil any commitments made during the visit</td>
</tr>
</tbody>
</table>

The EOV facilitator and research team received training on social marketing and persuasive communication techniques in a two day workshop run by an independent not-for-profit organisation (the National Prescribing Service) with extensive experience in the use of EOVs for the promotion of the quality use of medicine in the Australian healthcare system.

The multidisciplinary group also developed the content to be delivered by the facilitator during the EOV. The content was limited to four key messages: 1) VTE is an important healthcare issue which results in significant mortality, morbidity and resource expenditure; 2) patients must have their risks assessed including clotting risk, bleeding risk, and contraindications to prophylaxis; 3) patients must receive appropriate prophylaxis based on
their risk assessment; and 4) patients must be monitored for signs of VTE or prophylaxis related adverse events. A concise graphic educational resource was developed to accompany and reinforce the verbal message. Two trial visits were conducted prior to the intervention period to identify potential issues and familiarise the facilitator with the protocol.

Outcome measures and data collection

Acceptability

Acceptability was measured with post intervention participant and facilitator surveys (Appendix M). The participants’ survey and self-addressed envelope were given to the participants by the facilitator following the EOV. The survey contained eight questions in total; six questions related to the doctor’s beliefs about the effectiveness of the EOV at increasing knowledge and addressing concerns about VTE prophylaxis for medical patients. The remaining two questions asked participants how likely it was that they would participate in a program such as this in the future, and how likely it was that the intervention would influence their clinical practice. The EOV facilitator was also asked to complete a post intervention survey (Appendix N) appraising the participants’ level of interest, participation and comprehension. All survey questions were answered on a five point Likert scale.
Utility

Descriptive data on the practical application and utility of the intervention were recorded on a data collection form by the EOV facilitator (Appendix N). The information included the time and effort spent arranging the EOV, the time spent conducting the EOV, the number of interruptions and the time spent on them, the location of the EOV, the facilitator’s self-assessed adherence to the elements of the study protocol, and whether or not the participant committed to provide evidence-based prophylaxis.

Clinical impact

Clinical impact was assessed by auditing the proportion of medical patients receiving appropriate pharmacological VTE prophylaxis before and after the EOV intervention. The following exclusion criteria were used for patient selection: Planned or prior (previous 30 days) surgery on that admission; admitted for less than 24 hours; and inadequate documentation to complete a risk assessment. The audits were conducted using an audit tool (Appendix J) based on national VTE prevention guidelines (The Australian and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 2010). A registered nurse trained in the use of the tool conducted each audit with expert adjudication from a consultant vascular physician when required.

Sample size

The study was designed to detect a change in prescribing practice of 15% (from 50% to 65% appropriate prophylaxis). This estimate of effect was based on two previous studies which had used EOVs to improve VTE prophylaxis in the acute care setting (Grupper, et
al., 2006; Roberts & Adams, 2006). A total sample size of 300 patients (150 pre and 150 post intervention) was necessary to power the study at 80% with a significance level of 5%.

Data analysis

Data were entered into SPSS version 18 for analysis. Categorical data were summarised as number and percentage and contiguous data were summarised as median and interquartile (IQ) range. For comparisons between groups, the T test, or Mann-Whitney U test, was used for continuous variables (age, number of years post registration) and the Chi-square test was used for dichotomous variables (appropriate prophylaxis, risk factors, sex, specialty unit, admitting specialty). The difference in pharmacological prophylaxis rates before and after the intervention was calculated with 95% confidence intervals. The p value for statistical significance was set at <0.05.

6.5 Results

Characteristics of the target population

Of the 26 doctors who met the inclusion criteria 19 (73%) agreed to participate in the intervention and seven (27%) declined or were unavailable. The demographic characteristics of the target population are shown in Table 24. The median age of the participants was 54 years (IQ range 42-65) and their median number of years post registration was 30 years (IQ range 18-41). Fifteen (79%) were male and four (21%) female. The clinical specialties of the doctors were cardiology (n=8, 42%); neurology (n=4, 21%); nephrology (n=1, 5.3%); medical oncology (n=1, 5.3%); immunology/
rheumatology (n=2, 10%); thoracic medicine (n=2, 10%); and gastroenterology (n=1, 5.3%). There was no statistical difference in sex, number of years post registration, or specialty between doctors who received the intervention and those who declined or were unavailable.

Table 24 Characteristics of the target population

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Received intervention (n=19)</th>
<th>Declined intervention (n=7)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Median (IQ range) 54 (42-65)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Years post registration</td>
<td>30 (18-41)</td>
<td>26 (23-33)</td>
<td>0.93*</td>
</tr>
<tr>
<td>Sex</td>
<td>Number (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>15 (79)</td>
<td>7 (100)</td>
<td>0.18^</td>
</tr>
<tr>
<td>Female</td>
<td>4 (21)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Specialty</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>8 (42)</td>
<td>3 (43)</td>
<td></td>
</tr>
<tr>
<td>Neurology</td>
<td>4 (21)</td>
<td>1 (14)</td>
<td></td>
</tr>
<tr>
<td>Nephrology</td>
<td>1 (5.3)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Medical oncology</td>
<td>1 (5.3)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Immunology/rheumatology</td>
<td>2 (10)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Thoracic medicine</td>
<td>2 (10)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>1 (5.3)</td>
<td>3 (43)</td>
<td></td>
</tr>
</tbody>
</table>

Percentages may not add up to 100 due to missing data. IQ= Interquartile range; N/A= not available; *Mann-Whitney U test; ^Chi-square.
Characteristics of the audited patients

A total of 300 consecutive patients who met the inclusion criteria were audited before (n=150) and after (n=150) the two month EOV intervention period. The demographic characteristics of the audited patients are summarised in Table 25 and Table 26. There were no statistical differences between the two groups in age, sex, admitting specialty, or risk profile. The mean age of the groups was 70.8 (SD 14.4) and 72.4 (SD 13.9) years respectively. The majority of patients in both groups were admitted by a cardiologist (n=91, 60% and n=90, 60%). The overall risk status was comparable with 126 (84%) patients identified as high risk pre intervention compared to 116 (77%) post intervention.

Acceptability

Table 27, Table 28 and Table 29 depict the results of the participant and facilitator post intervention surveys. Sixteen (94%) of the 17 participants who returned the post intervention survey reported that the EOV was effective or extremely effective at increasing their knowledge and 15 (88%) felt that it was effective or extremely effective at addressing their concerns about VTE prophylaxis for medical patients. The participants also agreed that the EOV was effective at providing information on the four key messages outlined in the study protocol: 16 (94%) participants reported that the EOV was effective or extremely effective at communicating the significance of VTE and the importance of VTE risk assessment; 15 (88%) agreed that the EOV was effective or extremely effective at providing information on selecting appropriate VTE prophylaxis; and 10 (59%) felt that the EOV was effective or extremely effective at providing information about ongoing monitoring.
Table 25 Characteristics of the audited patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Pre intervention (n =150)</th>
<th>Post intervention (n =150)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Mean (SD)</td>
<td>70.8 (14.4)</td>
<td>72.4 (13.9)</td>
</tr>
<tr>
<td>Sex</td>
<td>Number (%)</td>
<td>84 (56)</td>
<td>83 (55.3)</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>66 (44)</td>
<td>67 (44.7)</td>
</tr>
<tr>
<td>Admitting specialty</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>91 (61)</td>
<td>90 (60)</td>
<td>0.98^</td>
</tr>
<tr>
<td>Oncology</td>
<td>3 (2)</td>
<td>3 (2)</td>
<td></td>
</tr>
<tr>
<td>Thoracic medicine</td>
<td>6 (4)</td>
<td>5 (3.3)</td>
<td></td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>11 (7.3)</td>
<td>8 (5.3)</td>
<td></td>
</tr>
<tr>
<td>Nephrology</td>
<td>9 (6)</td>
<td>9 (6)</td>
<td></td>
</tr>
<tr>
<td>Neurology</td>
<td>13 (8.7)</td>
<td>12 (8)</td>
<td></td>
</tr>
<tr>
<td>Rheumatology</td>
<td>1 (0.3)</td>
<td>1 (0.3)</td>
<td></td>
</tr>
<tr>
<td>Cardiac investigations</td>
<td>12 (8)</td>
<td>18 (12)</td>
<td></td>
</tr>
<tr>
<td>Immunology</td>
<td>4 (2.7)</td>
<td>4 (2.7)</td>
<td></td>
</tr>
</tbody>
</table>

Percentages may not add up to 100 due to missing data. SD= Standard Deviation; *T test; ^Chi-square.
Table 26 VTE risk factors

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Pre intervention (n =150)</th>
<th>Post intervention (n =150)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-risk of VTE</td>
<td>126 (84)</td>
<td>116 (77)</td>
<td>0.14^</td>
</tr>
<tr>
<td>Risk factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischaemic stroke</td>
<td>7 (4.7)</td>
<td>3 (2)</td>
<td>0.19^</td>
</tr>
<tr>
<td>History of VTE</td>
<td>15 (10)</td>
<td>18 (12)</td>
<td>0.58^</td>
</tr>
<tr>
<td>Active cancer</td>
<td>4 (2.7)</td>
<td>4 (2.7)</td>
<td>1.0^</td>
</tr>
<tr>
<td>Decompensated heart failure</td>
<td>42 (28)</td>
<td>29 (19)</td>
<td>0.7^</td>
</tr>
<tr>
<td>Acute on chronic lung disease</td>
<td>10 (6.7)</td>
<td>10 (6.7)</td>
<td>1.0^</td>
</tr>
<tr>
<td>Age &gt; 60years and immobile</td>
<td>107 (71)</td>
<td>108 (72)</td>
<td>0.89^</td>
</tr>
<tr>
<td>Acute inflammatory disease</td>
<td>6 (4)</td>
<td>1 (0.7)</td>
<td>0.5^</td>
</tr>
<tr>
<td>Multiple additional risk factors</td>
<td>21 (14)</td>
<td>10 (6.7)</td>
<td>0.33^</td>
</tr>
<tr>
<td>Additional risk factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immobility (&lt;60 years)</td>
<td>1 (0.7)</td>
<td>1 (0.7)</td>
<td>0.98^</td>
</tr>
<tr>
<td>Familial history of VTE</td>
<td>1 (0.7)</td>
<td>0 (0)</td>
<td>0.31^</td>
</tr>
<tr>
<td>Oestrogen therapy</td>
<td>2 (1.4)</td>
<td>1 (0.7)</td>
<td>0.55^</td>
</tr>
<tr>
<td>Obesity</td>
<td>10 (6.8)</td>
<td>7 (4.7)</td>
<td>0.43^</td>
</tr>
<tr>
<td>Thrombophilia</td>
<td>1 (0.7)</td>
<td>0 (0)</td>
<td>0.313^</td>
</tr>
<tr>
<td>Active inflammation</td>
<td>6 (4.1)</td>
<td>2 (1.4)</td>
<td>0.09^</td>
</tr>
</tbody>
</table>

Percentages may not add up to 100 due to missing data. SD= Standard Deviation; T test; Chi-square.
### Table 27 Acceptability of the Educational Outreach Visit

<table>
<thead>
<tr>
<th>How effective was the Educational Outreach Visit in...</th>
<th>Extremely Ineffective n (%)</th>
<th>Ineffective n (%)</th>
<th>Unsure n (%)</th>
<th>Effective n (%)</th>
<th>Extremely Effective n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increasing or refreshing your knowledge about VTE prophylaxis for medical patients?</td>
<td>0 (0)</td>
<td>1 (5.3)</td>
<td>0 (0)</td>
<td>11 (58)</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Addressing concerns you have had about providing VTE prophylaxis to medical patients?</td>
<td>0 (0)</td>
<td>1 (5.3)</td>
<td>0 (0)</td>
<td>13 (68)</td>
<td>2 (11)</td>
</tr>
<tr>
<td>Providing information about the significance of VTE as a healthcare issue?</td>
<td>0 (0)</td>
<td>1 (5.3)</td>
<td>0 (0)</td>
<td>11 (58)</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Providing information about VTE risk assessment for medical patients?</td>
<td>0 (0)</td>
<td>1 (5.3)</td>
<td>0 (0)</td>
<td>11 (58)</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Providing information about selecting appropriate VTE prophylaxis for medical patients?</td>
<td>0 (0)</td>
<td>1 (5.3)</td>
<td>1 (5.3)</td>
<td>11 (58)</td>
<td>4 (21)</td>
</tr>
<tr>
<td>Providing information about the ongoing monitoring of patients risk and response to prophylaxis?</td>
<td>0 (0)</td>
<td>3 (16)</td>
<td>4 (21)</td>
<td>7 (37)</td>
<td>3 (16)</td>
</tr>
</tbody>
</table>
Table 28 Acceptability of the Educational Outreach Visit

<table>
<thead>
<tr>
<th>How likely is it that...</th>
<th>Extremely unlikely n (%)</th>
<th>Unlikely n (%)</th>
<th>Unsure n (%)</th>
<th>Likely n (%)</th>
<th>Extremely likely n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>You will participate in another educational program such as this one in the future?</td>
<td>1 (5.3)</td>
<td>0 (0)</td>
<td>3 (16)</td>
<td>11 (58)</td>
<td>2 (11)</td>
</tr>
<tr>
<td>This educational visit will influence your clinical practice?</td>
<td>1 (5.3)</td>
<td>0 (0)</td>
<td>3 (16)</td>
<td>11 (58)</td>
<td>2 (11)</td>
</tr>
</tbody>
</table>

Table 29 Acceptability of the Educational Outreach Visit

<table>
<thead>
<tr>
<th>What was the participants perceived level of...</th>
<th>Very low n (%)</th>
<th>Low n (%)</th>
<th>Average n (%)</th>
<th>High n (%)</th>
<th>Very high n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interest in the topic presented?</td>
<td>2 (11)</td>
<td>3 (16)</td>
<td>3 (16)</td>
<td>6 (32)</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Participation during the visit?</td>
<td>1 (5.3)</td>
<td>1 (5.3)</td>
<td>4 (21)</td>
<td>3 (16)</td>
<td>10 (53)</td>
</tr>
<tr>
<td>Comprehension of the information provided?</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>2 (11)</td>
<td>7 (37)</td>
<td>10 (53)</td>
</tr>
</tbody>
</table>

Percentages may not add up to 100 due to missing data.

When asked how likely it was that they would participate in another EOV, 12 (71%) participants reported that it would be likely, or extremely likely. The same number (n=12, 71%) felt that the EOV was likely, or extremely likely to influence their clinical practice.

When the EOV facilitator was asked to rate the participants’ (n=19) perceived interest, participation and comprehension in the EOV he reported that 11 (58%) participants had a
high or very high level of interest; 13 (68%) had a high or very high level of participation; and 17 (89%) had a high or very high level of comprehension.

**Utility**

Table 30 shows the descriptive data on the practical application and utility of the intervention. The median number of times it was necessary to make contact with participants to arrange the EOV was 3 (IQ range 1 to 4). The median time spent on each EOV was 92 minutes (IQ range 78 to 129) which was made up of time spent arranging the EOV (median 10 minutes, IQ range 10 to 20); customising the material (median 45 minutes, IQ range 45 to 60); waiting for the participant (median 5 minutes, IQ range 0-20) and conducting the EOV (median 15 minutes, IQ range 15 to 20). The majority of visits were conducted in the doctor’s office (n=10, 53%). The remainder were held in the clinical area (n=6, 32%); other public area (n=2, 10%); or other private area (n=1, 5%). At the completion of the EOV 15 (78%) of the 19 participants gave a verbal commitment to provide evidence-based prophylaxis. The facilitator’s self-reported adherence to all of the elements of the EOV protocol was 80% (IQ range 70-85).

**Clinical impact**

There was a significant improvement in the proportion of medical patients who received appropriate pharmacological VTE prophylaxis following the intervention (54% to 70%, 16% improvement, 95% CI 5 to 26, p=0.004). Removing patients who were at lower risk of VTE from the analysis made no difference to the significance of the result (47% to 63%, 16% improvement, 95% CI 3 to 27, p=0.01).
Table 30 Utility of the Educational Outreach Visit

<table>
<thead>
<tr>
<th>Number of contacts to arrange each EOV</th>
<th>Median (IQ range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contacts needed to arrange the EOV</td>
<td>3 (1-4)</td>
</tr>
<tr>
<td>Cancelled visits prior to the EOV</td>
<td>0</td>
</tr>
</tbody>
</table>

Time spent arranging and conducting the EOV (min)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Median (IQ range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arranging the visit</td>
<td>20 (10-20)</td>
</tr>
<tr>
<td>Customising material</td>
<td>45 (45-60)</td>
</tr>
<tr>
<td>Waiting for the participant</td>
<td>5 (0-20)</td>
</tr>
<tr>
<td>Conducting the EOV</td>
<td>15 (15-20)</td>
</tr>
<tr>
<td>Time spent on interruptions</td>
<td>0</td>
</tr>
<tr>
<td>Total time spent on the visit</td>
<td>92 (78-129)</td>
</tr>
</tbody>
</table>

Protocol adherence

| Percentage of protocol elements delivered to participant | 80 (70-85) |

Location of the EOV

<table>
<thead>
<tr>
<th>Location of the EOV</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical area</td>
<td>6 (32)</td>
</tr>
<tr>
<td>Office</td>
<td>10 (53)</td>
</tr>
<tr>
<td>Other public area</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Other private area</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>

Outcome of the EOV

| Participant agreed to provide evidence-based prophylaxis | 15 (79) |

IQ= Interquartile.
6.6 Discussion

VTE is a major health and financial burden on the community (Access Economics, 2008). Unfortunately, despite the availability of evidence-based guidelines, VTE prophylaxis is still frequently underutilised. Our study found that at baseline only 54% of medical patients were receiving evidence-based VTE prophylaxis. This confirms the evidence-practice gap described in the international literature (Amin, et al., 2010a; Bergmann, et al., 2010; Rothberg, et al., 2010; Tapson, et al., 2007). Numerous strategies to improve VTE prevention in hospitalised patients have been studied but none have been successful at addressing all the barriers to the provision of evidence-based care (Amin & Deitelzweig, 2009; Kakkar, et al., 2004; Merli, 2010; Michota, 2007; Tooher, et al., 2005).

The barriers to the provision of appropriate medical patient prophylaxis have been documented in a number of recent studies (Lloyd et al., 2012; Vardi, et al., 2011). Known barriers include a lack of awareness of the importance of VTE prophylaxis and of the presence of evidence-based guidelines; a lack of knowledge on the indications for VTE prophylaxis and on appropriate prophylaxis options; and a lack of agreement and acceptance of current evidence-based recommendations (Lloyd, et al., 2012; Vardi, et al., 2011). EOVs acknowledge and address each participant’s barriers to change with the aim of facilitating increased compliance with evidence-based practice (Soumerai & Avorn, 1990). Few studies have examined the clinical impact of this intervention on the provision of VTE prophylaxis to medical patients and no previous studies have reported on its acceptability or utility.
Our results strongly suggest that EOVs are an acceptable implementation strategy for doctors working in the acute care setting. Nineteen (73%) of the 26 doctors eligible to participate agreed to receive an EOV. This was a greater than expected uptake given the established difficulty in providing hospital delivered education to senior doctors who, in the Australian private system, are consultant practitioners and not employees of the hospital (Koczwara et al., 2006). It was also encouraging to find that following the intervention 71% (n=12) of participants who provided feedback reported that they would participate in another EOV in the future.

By reporting descriptive data on the practical application and utility of the intervention we hope to provide valuable information for anyone wishing to use this intervention in an acute care hospital setting. Of particular note was the considerable time (92 minutes) required to organise, prepare and deliver each EOV. This study is one of a very few published studies to report the total time required for each EOV and the only study set in an acute care hospital setting.

Of the 19 participants who received the intervention 79% (n=15) gave a verbal agreement to provide evidence-based VTE prophylaxis to their medical patients. Importantly, this commitment translated into a 16% (95% CI 5 to 26, p=0.004) improvement in prophylaxis rates above baseline. This clinical impact is much larger than that reported in a Cochrane systematic review on the effectiveness of EOVs (O’Brien, et al., 2007). The review found that the median adjusted risk difference in compliance with prescribing practices was only 4.8% (IQ range 3.0% to 6.5%). The findings are similar, however, to two previous studies which used EOVs to improve doctors’ compliance with evidence-based VTE prevention practices in the acute care hospital setting. Roberts and Adams (2006) observed a 14.2%
(52.8% to 67%, p=0.004) improvement in prophylaxis rates in medical patients while Grupper et al (2006) reported a 21% (29% to 50%, p<0.001) improvement in a surgical population.

A limitation of our study was the use of a before-and-after design which may be subject to methodological limitations. There is some evidence to suggest that uncontrolled before and after studies over-estimate the effect of interventions (Grimshaw, et al., 2000). Having only one post-implementation data point also means that it is unknown whether the observed improvements in practice would be sustained or improved upon over time. Future research is recommended that examines the clinical impact of EOVs on VTE prophylaxis using a cluster randomised controlled trial which includes an evaluation of the ongoing sustainability of the intervention.

6.7 Conclusion

This study confirms that EOVs are effective at improving doctors’ provision of pharmacological VTE prophylaxis to hospitalised medical patients. In addition, it provides evidence of the acceptability of the intervention as an implementation strategy in the acute care setting, as well as valuable data on the practical application and utility of EOVs for those wishing to use this intervention in the future.
CHAPTER 7. DISCUSSION AND RECOMMENDATIONS

This chapter will discuss some of the key implementation science concepts that have influenced this thesis and make recommendations for future research. This is an addition to the discussion on the findings of the individual studies which is found at the conclusion of each chapter.

Although there is growing agreement that theory should be used to inform evidence implementation, there is currently no consensus among the implementation science community on the optimal theory (Grol, et al., 2007; Michie, et al., 2008). In fact, there is some question as to whether there can or should be such a thing as a single overarching implementation theory (Estabrooks, Thompson, Lovely, & Hofmeyer, 2006). A systematic review of implementation studies found that only 22.5% (53 of 235) were based, implicitly or explicitly, on a theory or theories. It was noted that the 53 studies that were based on theory cited 25 different theories (Davies, Walker, & Grimshaw, 2010, p. 3).

The conduct of the evidence implementation studies contained in this thesis was informed by two separate action focused process theories. This type of theory is useful for explaining, in a systematic way, how planned change should occur; how various forces in an environment will react to change; and how to control the variables to increase the likelihood of change’ (Graham, et al., 2011, p. 185).

The Steward-Nowlan Practice Improvement model (Langley et al., 2009; NSW Health Department, 2003) and the Implementation of Change model by Grol et al (2005a).were used in this thesis. They were chosen by the research team based on previous experience and personal preference. As an experienced facilitator, I would agree with Graham et al’s
(2011) observation that, although impact theories are informative and helpful for identifying the determinants of change, generally speaking, administrators and clinicians tend to prefer the more practical action focused process theories.

From a practical perspective, there was very little difference between the two theories except for the fact that the Implementation of Change model had a specific emphasis on guideline implementation. In fact, there appears to be very little observable difference between most of the process theories. The Improved Clinical Effectiveness through Behavioural Research Group (ICEBeRG) include 31 process theories in their knowledge translation database (ICEBeRG Group, 2012) which all comprise very similar component steps. The most common steps are: 1) identify the problem; 2) review the evidence; 3) assess the barriers to change; 4) select tailored interventions; 5) implement the change; 6) evaluate the impact; 7) maintain the change; and 8) disseminate the results (Graham, et al., 2011).

There is very little by the way of evidence to inform theory selection. It is not clear from the literature when and why a person would select one theory over another. In fact, there is not even strong evidence that the use of theory is beneficial to outcomes. A common criticism of many process theories is that they are not based on rigorous evidence and have not been subject to empirical evaluation. Grol et al (2007) note that there is a striking lack of scientific evidence underpinning even the most popular models for change. Presumably, Grol was also referring to his own model when making this comment, for there is also very little evidence of the effectiveness of his Implementation of Change model. One recent case control study did compare the use of the model, as adapted in this thesis (Duff, et al., 2011), with simple guideline dissemination and found significantly greater compliance.
with recommended practice in the intervention (Implementation of Change model) group compared to the control (Velligan et al., 2012). This was a single-site small study with a number of methodological limitations. More rigorous evaluation of this and other process theories is needed and should be of a type that assists end-users to select the most appropriate theory for their particular circumstance. Advancing evidence implementation through research, such as this, has been identified as the single biggest priority for implementation science (Holmes, Scarrow, & Schellenberg, 2012; Mitton, et al., 2007).

The process of selecting implementation strategies has been described as an ‘art’ informed by science because the task requires a mix of context specific experience and creativity (Wensing, Bosch, & Grol, 2011). Most process theories are based on the premise that planned evidence implementation is more likely to be successful if an assessment of the likely barriers informs the choice of implementation strategy (Graham, et al., 2006; Grol & Grimshaw, 2003). The warfarin and VTE evidence implementation studies both selected interventions ‘tailored’ to the local barriers to practice change, as identified by the target group. The research team used conceptual mapping to align the barriers with a specific implementation strategy (see Table 7) (Campbell & Murray, 2007). As yet, there is insufficient evidence on the most effective approaches to tailoring, including how barriers should be identified and how interventions should be selected to address the barriers (Baker, et al., 2010). The authors of a Cochrane systematic review on the effectiveness of tailored interventions reported that many of the included studies lacked any detail on how barriers were assessed and in what way this assessment informed the selection of interventions (Baker, et al., 2010). Further research comparing the effectiveness of various
methods for selecting interventions is needed. This research should include how different stakeholders, including patients, are best involved in the development of interventions.

There is a growing push for the involvement of consumers and the community health research (National Health and Medical Research Council, 2005). The method for consulting patients and consumers varied between the studies included in this thesis. The warfarin evidence implementation study had a consumer on the research team who participated in the development of the protocol and selection of interventions whereas the VTE prevention study consulted with consumers on an ad hoc basis when input was required. The rational for using two different approaches was based on the different focus of the two studies. A consumer was put on the warfarin study from the outset because we were aware that the project would address patient education needs. On the other hand, in the VTE study, we were not expecting to target patients with any of the interventions. In both instances the research team managed to elicit a great deal of input from consumers. On reflection, perhaps it was less important how consumers are engaged, and more important that they were engaged at all.

The three clinical studies contained in this thesis have shown significant variability in the effectiveness of their interventions between the target groups (nurses and doctors). The warfarin evidence implementation study was highly effective at improving the percentage of patients who received pre discharge education by nursing staff but was less effective at improving the prescribing of appropriate loading doses by doctors. In contrast, the VTE prevention evidence implementation study and the Peer-on-Peer Education for Better VTE Prevention study significantly improved doctors’ prescribing of pharmacological prophylaxis but was less effective at influencing nurses’ use of mechanical prophylaxis.
Variability in the effectiveness of behaviour change interventions is well documented. (Baker, et al., 2010; Grimshaw, et al., 2012). The reason for the variation is not as well understood, however. The findings from this thesis imply that strategies proven to be effective in one context with one target group may not necessarily be effective in another context or with another target group. This means that until we have a greater appreciation of the mechanism of action of the various implementation strategies each strategy will need to be rigorously evaluated whenever it is used in a new context or with each new target group.

Stame (2004) comments that without a clear account of what an intervention comprises, how it links to outcomes, and how the context and intervention interact, its mechanism of action remains a ‘black box’. Without this understanding, when a strategy fails to achieve the desired result, it is difficult to know if this is due to a failure of theory, failure of implementation, or a combination of both. Trying to understanding what is inside the ‘black box’ is especially important in implementation science where large variations in effectiveness are frequently observed. The Peer-on-Peer Education for Better VTE Prevention study included measures of acceptability, utility and intervention fidelity. The process evaluation did not completely explain the reason for the observed variation in effectiveness but it did identify that it was not related to a difference in the perceived acceptability of the intervention between the two target groups. The process evaluation was also crucial in accurately describing the resource intense nature of the intervention.

The concurrent roll-out of interventions in the two evidence implementation studies made it difficult to identify the cause of variation in effectiveness between the target groups. A process evaluation may have helped quantify the mechanisms responsible for the observed
changes by describing the intervention, the exposure of the participants, and their experiences (Hulscher, et al., 2004; Hulscher, Laurant, & Grol, 2005). Formal process evaluation is not an explicit part of either of the action focused process theories used in this thesis. Instead, the theories recommend that the component parts of multifaceted interventions are trialled and tested before full scale implantation (Grol & Wensing, 2005a; Langley, et al., 2009). Future research should focus on improving the method and design of process evaluation in evidence implementation.

Evidence implementation, of the kind presented in this thesis, requires a facilitator with an understanding of the local context and ability to coordinate and engage key stakeholder groups. The quality of the facilitation is therefore a major contributing factor in the success or failure of evidence implementation. It is surprising then, that most published evidence implementation studies contain little or no detail of the facilitation model used or the facilitator (Seers et al., 2012). Various facilitation models suitable to evidence implementation have been described in the literature. They are usually represented along a continuum from a largely task-focused approach to a more holistic-enabling approach (Harvey, et al., 2002). Seers et al (2012) point out that given the complex nature of implementing and the need to address stakeholder and organisational needs, it is reasonable to expect a good facilitator to be able to move across different points of this continuum as required during different stages of a study.

Facilitation is a difficult role that most people are ill prepared to undertake. It requires a sophisticated range of knowledge and skills, yet, there is no clarity on how these are developed and refined (Harvey, et al., 2002; Seers, et al., 2012). I have seen many staff attempt to introduce practice change only to fail due to a lack of facilitation skills. Units on
research methods and evidence-based practice are common components of most nursing and medical curricula but it is a rarity for undergraduate health professional to receive education on implementing change and improving clinical practice (Kovner, Brewer, Yingrengreung, & Fairchild, 2010). The Institute for Healthcare Improvement, in the United States, and the Joanna Briggs Institute, in Australia, are two examples of organisations that have identified the need to provide training to healthcare professionals in methods for practice improvement. Both organisations use self-directed online training and face-to-face intensive education sessions, alone or in combination. Research is needed on the optimal method for training the health workforce in order to increase their ability to implement new knowledge and facilitate practice change. Future studies should also aim to develop a common taxonomy or set of descriptors to enable the consistent and accurate communication of the facilitation model used.

Although there is a growing body of work on assessing context in evidence implementation (Estabrooks, Squires, Cummings, Birdsell, & Norton, 2009; McCormack, McCarthy, Wright, & Coffey, 2009), the concept continues to lack clarity in the literature. There are many issues with the way it is characterised and there is limited evidence on the consequences of working with different contexts (Grimshaw, et al., 2012; McCormack et al., 2002). St Vincent’s Private has a number of organisational characteristics that facilitate evidence implementation and practice change but it has been difficult to communicate the exact nature of these traits because of a lack of a common descriptors.

The organisation has made a significant invested in human and material resources to promote evidence-based care. As clinical research fellow, I develop, test, and implement strategies to improve the uptake of evidence into routine clinical practice. I work closely
with the hospital’s practice development facilitator and professor of healthcare improvement to achieve this aim. These positions are supported by knowledge infrastructure which facilitate research use such as a medical library and librarian, online research databases, and internet access (Flodgren, Rojas-Reyes Maria, Cole, & Foxcroft David, 2012). There are calls for all hospitals to take a proactive approach to knowledge translation by making substantial investment in knowledge infrastructure (Ellen, Lavis, Ouimet, Grimshaw, & Bedard, 2011).

Cultural factors also have had a positive impact on evidence implementation at St Vincent’s Private. During the period that these studies were conducted the hospital applied and was awarded Magnet status which is awarded by the American Nurse Credentialing Centre to hospitals that can demonstrate a robust nursing culture. During the Magnet journey we surveyed the practice environment using a validated tool, the Practice Environment Scale (Warshawsky & Havens, 2011). The survey found that the hospital had a nursing culture that was equivalent or better than Magnet designated facility in the United States (Walker, Middleton, Rolley, & Duff, 2010). The Practice Environment scale was a simple and effective tool for quantifying culture. Future studies should aim to develop other tools to enable the consistent and accurate measurement of the contextual environment in which studies are conducted.

The conduct of these implementation studies has had a reciprocal beneficial effect on organisational culture. Although only anecdotal, from my perspective, the attitude of staff to evidence based practice and research has significantly improved over the last five years. The studies brought together multidisciplinary teams to solve complex healthcare problems using a systematic evidence based approach and this has had a beneficial effect on doctor
nurse relations and nurse empowerment. This is not a unique finding to our hospital, it is well documented that there is an associated benefit to organisational culture when staff are empowered to positively influence practice (McCormack, et al., 2004).

There has been some criticism in the past of the design and conduct of implementation research. Some interventions have been carefully developed, but poorly evaluated, or elegant trial designs have been used to evaluate poorly specified interventions (Grol, et al., 2004; Hardeman et al., 2005). The United Kingdom Medical Research Council (UKMRC) framework for developing and evaluating complex interventions recommends the use of a number of difference phases of study which employ a variety of different methodologies with the aim of building a more comprehensive picture of the intervention including its mechanism of action and acceptability to participants. Some authors believe that the term complex intervention is over used (Thomson, 2009), but considering the number of modifiable elements of most evidence implementation strategies it is hard to negate their complexity. For example, in evidence implementation the content, intensity, method, duration and context of a specific strategy can be modified in ways that can dramatically change the strategy (ICEBeRG Group, 2006).

Although the development and evaluation of complex evidence implementation strategies appears well suited to the phased method described by the UKMRC, there is little evidence in the literature that this approach is being widely used. A scan of the implementation research literature reveals that it is weighted heavily towards studies that are evaluative in nature using designs such as the C-RCT. It is important that we not only know if an intervention worked or didn’t work but we should also know its mechanisms of action, scope, and limitations. There are much fewer developmental studies as represented in
phase one (theoretical) and phase two (modelling) of the UKMRC framework. More developmental studies, such as the ones contained in this thesis, are needed to help us better understand the practical application of evidence implementation interventions. Future research should describe effective methodologies for the development of implementation strategies.

Implementation science is a relatively new field of research and thus it has an evolving and developing scientific language. Unfortunately, to the frustration of the beginning researcher, there are frequent inconsistencies in the way the language is used and a tendency to substitute one term for another without explanation (Kitson, et al., 2008). Interventions are also frequently described using the same label in different studies, yet they contain none, or few, of the same elements, or are delivered in very different ways (e.g. educational outreach visiting) (ICEBeRG Group, 2006). Implementation science studies are also known for their poor description of exactly what the strategy comprises. A review of nearly 1,000 behaviour change studies found that the interventions were described in detail in only 5% to 30% of studies (Michie, Fixsen, Grimshaw, & Eccles, 2009). Thankful, in recent years, a number of guidelines have been developed which specify the component parts of interventions that are required to be reported in publications (Boutron, Moher, Altman, Schulz, & Ravaud, 2008; Davidoff, et al., 2008; Des Jarlais, et al., 2004). More research around the terminology of implementation science and the conceptual framework for classifying interventions is needed.

Although the implementation science field is growing rapidly, it is clear from this work that a greater investment is needed to improve our effectiveness and efficiency at translating evidence into practice. The Cochrane collaboration has over 350,00 RCTs in
clinical medicine of which only 2,400 are trials of interventions to improve healthcare delivery (Bhattacharyya & Zwarenstein, 2011). More implementation research is necessary but a greater investment in implementation research training, facilitator training, and essential knowledge infrastructure is also required.
CHAPTER 8. CONCLUSION

This thesis has achieved the dual aims of improving VTE prophylaxis at St Vincent’s Private Hospital while contributing to the body of knowledge on strategies to promote the uptake of evidence on VTE prevention in hospitalised patients.

Evidence implementation studies

The warfarin evidence implementation study identified multiple nursing, medical, patient and evidence related factors that hinder the safe and effective use of warfarin- a complex, high risk therapy widely prescribed for the prevention and treatment of venous thromboembolism. A multifaceted intervention- consisting of audit and feedback, patient and provider education, and decision support aids- was found to significantly improved the level of pre-discharge patient education provided by nursing staff but have a lesser effect on the prescribing practice of doctors’. The findings illustrated that the prevention of VTE in hospitalised patients is a complex healthcare problem.

The subsequent VTE prevention evidence implementation study identified four barriers to effective practice which included a lack of motivation to change; lack of systems support; knowledge and awareness deficit; and lack of consensus with the evidence. A multifaceted intervention- consisting of audit and feedback, documentation aids, staff education initiatives, collaboratively development hospital VTE prevention policy, alert stickers and other reminders- significantly improved the prescribing of pharmacological prophylaxis by doctors but did not improve the provision of mechanical prophylaxis by nurses. The study also identified the need for a targeted intervention to address the significant disparity between the prophylaxis rates of medical patients compared to surgical patients.
Implementation research studies

Decision tree analytic modelling was used to analyse the clinical and economic impact of the VTE prevention evidence implementation study. The study demonstrated the substantial effect that evidence implementation has on important outcomes such as mortality, morbidity, and healthcare costs. The model revealed that a moderate improvement in adherence to VTE prevention guidelines results in fewer deaths, symptomatic DVTs, symptomatic PEs, and hospital bed days which in turn contribute to considerable cost savings.

The acceptability, utility and clinical impact of Educational Outreach Visits (EOV) as an implementation strategy to improve VTE prophylaxis for medical patients was examined in the Peer-on-Peer Education for better VTE Prevention study. Nurses and doctors reported that EOV was an acceptable strategy for the promotion of evidence-based VTE prevention practices and yet, the intervention had a variable impact on clinical practice between the two target groups. There was a significant improvement in the prescribing of pharmacological prophylaxis by doctors but no measurable improvement in the provision of mechanical prophylaxis by nurses following the intervention. This study was the first to document the resources required to undertake this intervention in the acute care setting. It was found that every one minute of face-to-face intervention time required 5 minutes of preparation.
Recommendations for future research

Changing clinician behaviour and improving clinical practice is a complex task which requires further research to enhance our understanding. Specific areas for further research which have emerged from thesis include:

- Two implementation models were used in this thesis and both were selection for pragmatic reasons. Future research should aim to develop a tool to assist in the selection of an implementation theory appropriate to various settings and contexts.

- The studies contained in this research selected interventions based on perceived barriers but there is very little research to inform this decision making process. Future research should compare the effectiveness of various methods for selecting interventions and understanding how different stakeholders, including patients, are best involved in the process.

- Process evaluation- understanding what was really happening during implementation- was an important part of the studies contained in this thesis. Future research should identify appropriate methods and designs for process evaluation in evidence implementation.

- The effectiveness of interventions, as measured by clinical impact, have been evaluated in this thesis but future research should describe the mechanism of action of the various implementation strategies.

- Facilitation is a difficult role and healthcare professionals are often ill equipped at undertaking it. Future research should ascertain the optimal method for training the health workforce in order to increase their ability to implement new knowledge.
- Context is clearly an important component of the evidence implementation equation, yet it is poorly described in most reports. Future research should develop a taxonomy or common set of descriptors to enable the consistent and accurate communication of the contextual environment and facilitation model.

- Published implementation research is predominantly cluster randomised trials but this thesis has demonstrated that other more pragmatic designs can offer a great deal of information. Future research should describe effective methodologies for the development of implementation strategies.

VTE prevention has received an increasing amount of attention and resources in Australia over the past few years, yet it remains a significant burden to individuals, hospitals, and the healthcare system. At St Vincent’s Private Hospital, despite the significant efforts to improve practice, substantial numbers of patients still fail to receive appropriate prophylaxis. This thesis has illustrated the difficulty in closing the VTE prevention evidence-practice gap and provides evidence of the need for greater investment in implementation research, evidence implementation, and knowledge infrastructure.

There is now a substantial (if incomplete) evidence base to guide the choice of evidence implementation activities targeting healthcare professionals. It should no longer be acceptable to base the selection of interventions on ones beliefs, rather than evidence about the likely effectiveness of different approaches. Grol and Grimshaw (1999) challenged healthcare systems to develop and use a robust evidence base to support the choice of knowledge translation strategies. While we are some way from achieving this goal, there are grounds for optimism.
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Retrieved from


multinational survey from member countries of the european federation of internal medicine. *Thrombosis research, 129*(5), 573-576.


APPENDIX A: RESEARCH PORTFOLIO
PERMISSION

I warrant that I have obtained, where necessary, permission from the copyright owners to use any third-party copyright material reproduced in this thesis, and to use any of my own published work in which the copyright is held by another party.

Name       Jed Duff
Date       23/01/2013
ETHICS
Guideline

Title: Quality Improvement and Ethics Review: A Practice Guide for NSW

Improving the Safety and Efficacy of Warfarin Therapy

THE CHECKLIST

Use of this Checklist is optional in NSW public hospitals. It is designed to assist in identifying when a proposed QI activity entails ethical risks. For more detailed information related to each statement, please see Considerations for reviewing QI activities. This Checklist may be modified for use with local HREC.

Section 1: ISSUES THAT MAY REQUIRE CONSENT

1. The project involves direct contact with patients, consumers, or members of the public.
2. The project poses additional risks or burdens to the patient beyond their routine care.
3. The data to be collected is of a sensitive nature or application.
4. The purpose of the activity is not 'directly related' to the patient's disease, illness or its management.
5. The data will be used or available in such a way that may identify individuals.

If the response to any of the above statements is "true", you should contact your nominated HREC delegate or designated institutional body to discuss. Informed consent is usually required. If approval is required, you will need to provide a project outline, including a description of how you intend to gain consent, as well as a participant information statement.

Section 2: PRIVACY and CONFIDENTIALITY

6. There is no process for de-identification of data.
7. Access to personal information will extend beyond those who are members of the clinical care team, or to others who normally do not have access to the patient’s record, or to other data sets.
8. The project involves rare conditions or a small community.
9. Data will be selected or identified by:
   • Aboriginal or Torres Strait Islander status;
   • Ethnic, religious or minority group.
10. Data will be collected beyond that which is normally collected in routine care.

If the response to any of the above statements is "true", you will need to provide more information and you may need full Ethics Committee approval. Please provide a brief explanation and a description of the consent process with your application, and contact your nominated HREC or QI delegate to discuss.

Section 3: OTHER IMPLICATIONS

11. The project uses "new" interventions, protocols or equipment.
12. The project will involve allocation of patients to groups to enable comparisons.
13. The project will involve genetic testing.
14. The project may potentially infringe the rights, privacy or professional reputation of carers, health professionals or institutions.
15. The project involves use of placebo.

If the response to any of the above statements is "true", you will need to provide more information and it is highly likely you will need full Ethics Committee approval for your project. Contact your HREC representative.

If responses to all of the above statements in the checklist are "false", then no ethical risks have been identified with this project and no ethics review is required.

205
26 May 2009

Prof Kim Walker
St Vincent's Private Hospital
406 Victoria St
Darlinghurst NSW 2010

Dear Kim

SVH File Number: 09/072
Project Title: National Institute of Clinical Studies (NICS) Private Hospital Venous Thromboembolism (VTE) Prevention Program

Thank you for submitting the above project for review. Based on the information you have provided and in accordance with the following NHMRC guidelines, National Statement 2007 – Section 5 Institutional Responsibilities and “When does quality assurance in health care require independent ethical review?” (2003), this project has been assessed as low risk and is therefore exempt from full HREC review.

I am pleased to advise that the on 25 May 2009 the HREC Executive on behalf of the Executive Director granted authorization for the above project to commence at St Vincent's Private Hospital.

The documents approved for this project are:
- VTE Prevention Program Project Plan 2008

Please note the following conditions of approval:

1. This approval is valid for five years, and the Committee requires that you furnish it with annual reports on the project’s progress beginning in May 2010. Please notify the HREC Executive in writing when this project is completed.

2. The investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by participants regarding the conduct of the project.

3. Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the HREC Executive for review, in the specified format.

4. The HREC Executive will be notified, giving reasons, if the project is discontinued before the expected date of completion.

5. Projects that are undertaken by investigators holding an academic appointment (including conjoint appointments) or by students as part of a University course are required to provide a copy of the application form, all approved documents and a copy of this letter to the relevant University HREC for ratification.

Please note that for multi-site projects authorisation needs to be obtained from each participating institution.

Continuing the Mission of the
Sisters of Charity
SVH File Number: 11/051
Project Title: Peer on peer education for better venous thromboembolism prophylaxis

Thank you for submitting the above project for review. Based on the information you have provided and in accordance with the NHMRC National Statement 2007 and NSW Health Policy Directive PD2010_056 Ethical and Scientific Review of Human Research in NSW Public Health Organisations, this project has been assessed as low/negligible risk and is therefore exempt from full HREC review.

This Lead HREC is constituted and operates in accordance with the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the HREC Executive, at a meeting on 2 May 2011, has granted ethical and scientific approval of the above single-site project.

The project is approved to be conducted at St Vincent's Private Hospital.

The following documents have been approved:
- Protocol PoPE Study Version 2 dated 5 May 2011
- Participant Information Sheet and Consent Form – Medical /Nursing Version 2 dated 5 May 2011
- PoPE Post Visit Checklist Version 2 dated 5 May 2011
- PoPE Visit Record Version 2 dated 5 May 2011
- Participant Post Intervention Survey Version 2 dated 5 May 2011
- PoPE Audit Tool Version 2 dated 5 May 2011

You are reminded that this letter constitutes ETHICAL and SCIENTIFIC approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Please note the following conditions of approval:

- This approval is valid for five years, and the Committee requires that you furnish it with annual reports on the projects progress beginning in May 2012. Please notify the HREC Executive in writing when this project is completed.
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by participants regarding the conduct of the project.
- Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the HREC Executive for review, in the specified format.

Continuing the Mission of the
Sisters of Charity
• The HREC Executive will be notified, giving reasons, if the project is discontinued before the expected date of completion.

• Projects that are undertaken by investigators holding an academic appointment (including conjoint appointments) or by students as part of a University course are required to provide a copy of the application form, all approved documents and a copy of this letter to the relevant University HREC for ratification.


Yours sincerely

[Signature]
Kerry McFarland (Research Office)

Sarah Charlton
HREC Executive Officer
Research Office
L6 deLacy Building

CC: Jed Duff
D/2011/0019
CONTRIBUTION OF OTHERS
STATEMENT OF CONTRIBUTION BY OTHERS

Improving the safety and efficacy of warfarin therapy in a metropolitan private hospital: A multidisciplinary practice improvement project.

I, Jed Duff, acknowledge that my contribution to the above mentioned paper was eighty (80) percent.

Name  Jed Duff
Date   28/10/2017

I, Kim Walker, acknowledge that my contribution to the above mentioned paper was twenty (20) percent.

Name  Kim Walker
Date   29/10/2017
STATEMENT OF CONTRIBUTION BY OTHERS

Translating venous thromboembolism prevention evidence into practice: A multidisciplinary evidence implementation project.

I, Jed Duff, acknowledge that my contribution to the above mentioned paper was seventy (70) percent.

Name: Jed Duff
Date: 28/1/2012

I, Kim Walker, acknowledge that my contribution to the above mentioned paper was twenty (20) percent.

Name: Kim Walker
Date: 29/10/2012

I, Abdullah Omari, acknowledge that my contribution to the above mentioned paper was ten (10) percent.

Name: Abdullah Omari
Date: 21/10/2012
STRICTMENT OF CONTRIBUTION BY OTHERS

Prevention of venous thromboembolism in hospitalised patients: Analysis of reduced cost and improved clinical outcomes.

I, Jed Duff, acknowledge that my contribution to the above mentioned paper was sixty (60) percent.

Name  Jed Duff
Date  29/10/2012

I, Kim Walker, acknowledge that my contribution to the above mentioned paper was ten (10) percent.

Name  Kim Walker
Date  29/10/2012

I, Abdullah Omari, acknowledge that my contribution to the above mentioned paper was ten (10) percent.

Name  Abdullah Omari
Date  31/10/2012

I, Charlie Stratton, acknowledge that my contribution to the above mentioned paper was twenty (20) percent.

Name  Charlie Stratton
Date  22/10/2012
STATEMENT OF CONTRIBUTION BY OTHERS

Educational Outreach Visits to improve nurses’ use of mechanical venous thromboembolism prevention in hospitalised medical patients: A prospective before-and-after intervention study.

I, Jed Duff, acknowledge that my contribution to the above mentioned paper was sixty (60) percent.
Name: Jed Duff
Date: 29/10/2012

I, Kim Walker, acknowledge that my contribution to the above mentioned paper was ten (10) percent.
Name: Kim Walker
Date: 29/10/2012

I, Abdullah Omari, acknowledge that my contribution to the above mentioned paper was ten (10) percent.
Name: Abdullah Omari
Date: 31/10/2012

I, Sandy Middleton, acknowledge that my contribution to the above mentioned paper was ten (10) percent.
Name: Sandy Middleton
Date: 29/10/2012

I, Elizabeth McInnes, acknowledge that my contribution to the above mentioned paper was ten (10) percent.
Name: Elizabeth McInnes
Date: 29/10/2012
STATEMENT OF CONTRIBUTION BY OTHERS

Preventing venous thromboembolism in hospitalised medical patients: Evaluating the acceptability, utility and clinical impact of educational outreach visits.

I, Jed Duff, acknowledge that my contribution to the above mentioned paper was sixty (60) percent.

Name  Jed Duff
Date  29/10/2012

I, Kim Walker, acknowledge that my contribution to the above mentioned paper was ten (10) percent.

Name  Kim Walker
Date  29/10/12

I, Abdullah Omari, acknowledge that my contribution to the above mentioned paper was ten (10) percent.

Name  Abdullah Omari
Date  2/10/12

I, Sandy Middleton, acknowledge that my contribution to the above mentioned paper was ten (10) percent.

Name  Sandy Middleton
Date  2/10/12

I, Elizabeth Melness, acknowledge that my contribution to the above mentioned paper was ten (10) percent.

Name  Elizabeth Melness
Date  29/10/12
OTHER RELATED PUBLICATIONS
PEER REVIEWED PUBLICATIONS


OTHER PUBLICATIONS


PEER REVIEWED PUBLISHED ABSTRACTS


**PEER REVIEWED CONFERENCE PAPERS**


**PEER REVIEWED CONFERENCE POSTERS**


RELATED GRANTS & AWARDS
GRANTS


AWARDS

2011 Australian Catholic University Competitive Research Symposium Finalist.

2010 St Vincent’s Campus Excellence Award for Clinical Research (Emerging Researcher).


2010 Finalist, St Vincent’s Health Australia Quality Awards: Translating Venous Thromboembolism Prevention Evidence into Practice.

2009 Highly Commended, St Vincent’s Campus Excellence Award for Clinical Research.

2008 Australian Private Hospitals Association Baxter Quality and Safety Award: Improving the Safety and Efficacy of Warfarin Therapy.
APPENDIX B: WARFARIN PRESCRIPTION CHART
# Warfarin Therapy Chart

<table>
<thead>
<tr>
<th>Allergies/ADR’s</th>
<th>Education needs assessed by</th>
<th>Name:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target INR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date commenced</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected Duration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warfarin Brand</td>
<td>Booklet provided</td>
<td></td>
<td>Date:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INR</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

INR Required/ Attended ✔
Caution!/Marevan
Dose (mg): 
Route: PO PO PO PO PO PO PO PO PO PO PO PO PO PO

Time Due
Doctors Signature
Doctors Name
Phone Order Nurse 1
Phone Order Nurse 2
Nurse Administering
Nurse Checking
Time Given

See the SVH Guidelines for the management of anticoagulation INR.
St Vincent’s Private Hospital
GUIDELINES FOR INITIATING WARFARIN THERAPY

- If indicated, commence heparin (UF or LMW) concurrently for a minimum of five days and until INR>2 for two consecutive days.
- Assess each patient for bleeding risk factors*.
- High starting doses, such as 10mg, should not be used.
- Monitor INR daily and adjust dose using the protocol below.
- Restart patients on previous dose; considering new bleeding risk factors*.
- There are many drug interactions with warfarin; consult pharmacy or a drug database. Check INR two days after starting or stopping any drug.
- Coumadin® is the preferred brand for initiating warfarin at St Vincent’s Private.
- Note: Marevan® and Coumadin® are not bioequivalent and thus not interchangeable.
- This tool is an aid only; clinical judgement should always be exercised.

*Bleeding Risk Factors
- ‘Frail’ elderly
- Low body weight
- Reduced oral intake
- Baseline INR > 1.4
- Abnormal LFT’s/ albumin
- Uncontrolled hypertension
- Hx of GI bleed/ peptic ulcer
- Recent trauma/ Hx of falls
- Excessive alcohol intake
- Cognitive deficit
- Anaemia/ thrombocytopenia
- Renal failure
- Severe heart failure
- Potential drug interactions
- History of recent stroke/ MI

<table>
<thead>
<tr>
<th>Age and Risk Factor Adjusted Warfarin Initiation Protocol</th>
<th>For Target INR Range 2-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day</td>
<td>INR</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>One</td>
<td>&lt;1.2</td>
</tr>
<tr>
<td>≥1.2</td>
<td>If baseline INR ≥1.2- seek specialist physician advice</td>
</tr>
<tr>
<td>Two</td>
<td>&lt;1.6</td>
</tr>
<tr>
<td>≥1.6</td>
<td>3</td>
</tr>
<tr>
<td>Three</td>
<td>&lt;1.8</td>
</tr>
<tr>
<td>1.8-2</td>
<td>3</td>
</tr>
<tr>
<td>2.1-2.5</td>
<td>2</td>
</tr>
<tr>
<td>2.6-3</td>
<td>1</td>
</tr>
<tr>
<td>3.1-3.5</td>
<td>0</td>
</tr>
<tr>
<td>&gt;3.5</td>
<td>0</td>
</tr>
<tr>
<td>Four</td>
<td>&lt;1.6</td>
</tr>
<tr>
<td>1.6-1.9</td>
<td>5</td>
</tr>
<tr>
<td>2.2-3</td>
<td>3</td>
</tr>
<tr>
<td>2.7-3.5</td>
<td>1</td>
</tr>
<tr>
<td>3.6-4</td>
<td>0</td>
</tr>
<tr>
<td>&gt;4</td>
<td>0</td>
</tr>
<tr>
<td>Five +</td>
<td>Dose adjustment depends on clinical judgement; use response to previous doses and day four protocol</td>
</tr>
</tbody>
</table>

Modified from: St Vincents Hospital Guidelines for Initiating Warfarin Therapy
Endorsed by: St Vincent’s Private Hospital Pharmacy Committee February 2008
APPENDIX C: WARFARIN PATIENT CARE GUIDE
1. Oral anticoagulant therapy care guide integrated into the electronic clinical pathway

2. Links to warfarin self-management & knowledge assessment; risk of bleeding assessment; and warfarin education & discharge management documents.
APPENDIX D: WARFARIN EDUCATION & DISCHARGE TOOL
St Vincent's Private

Warfarin Education and Discharge Management

Please ensure that the following education objectives are met by every patient that is commenced on warfarin. If a knowledge deficit is identified please refer to a clinical pharmacist.

Prior to discharge the patient will be able to:

1. Indicate that he/she has a warfarin education booklet □ Yes □ No
2. State that he/she has read the booklet and/or viewed the warfarin video □ Yes □ No
3. Updates their latest INR and warfarin dose in the booklet □ Yes □ No
4. Explain the action of warfarin
   - Anticoagulant drug, used to prevent or treat thrombosis by decreasing the clotting power of the blood. □ Yes □ No
5. Answer the following questions regarding warfarin
   - Are you aware there are two brands of warfarin? (Yes) □ Yes □ No
   - State the brand that you are on (Marevan / Coumadin). □ Yes □ No
   - Are the two brands the same? (No) □ Yes □ No
   - Can you swap between brands? (No) □ Yes □ No
6. State: (a) Why he/she is taking warfarin □ Yes □ No
   - The length of time they are required to take warfarin □ Yes □ No
   - Target INR □ Yes □ No
7. Identify the 3 manufactured doses of Warfarin brand he/she is taking:
   - Coumadin 1 mg - Light Tan; 2 mg - Lavender; 5 mg - Green □ Yes □ No
   - Marevan 1mg - Brown; 3mg - Blue; 5mg - Pink □ Yes □ No
8. State: (a) When to take warfarin
   - With the evening meal every day - use a calendar. □ Yes □ No
   - Why it is important to take the drug at the same time every day □ Yes □ No
   - To maintain consistency for checking of INR. □ Yes □ No
9. Outline the steps to take if they forget to take their evening dose of warfarin
   - If patient remembers within two to three hours they can take Warfarin. □ Yes □ No
   - If longer don’t take warfarin, take next dose when it is due and tell your doctor or laboratory □ Yes □ No
10. Identify significant signs of bleeding
   • Obvious bleeding i.e. cuts, nosebleed, bleeding gums. □ Yes □ No
   • Less obvious bleeding – urine, faeces, vomit and coughing. □ Yes □ No

11. State what he/she will do in the event of signs of bleeding
   • Call the GP promptly. □ Yes □ No

12. Identify other medications that may interfere with the way that warfarin works
   • Prescription medications and over the counter medications eg. aspirin, paracetamol or other pain medications, rubs, liniments, cold or cough preparations. □ Yes □ No
   • Antacids, laxatives, multi-vitamins (may contain Vitamin K). □ Yes □ No
   • Herbal medications. □ Yes □ No

13. Identify illnesses that require reporting to their GP
   • Diarrhoea, vomiting. □ Yes □ No
   • Infection or fever. □ Yes □ No
   • Pain, swelling or discomfort. □ Yes □ No

14. Understand significant dietary facts
   • Maintain a well-balanced and consistent diet – Avoid crash dieting and binge eating. □ Yes □ No
   • Stabilise intake of vitamin K. This includes green leafy vegetables. □ Yes □ No
   • If taking vitamin or herbal supplements discuss with GP or pharmacist. □ Yes □ No
   • Take alcohol in moderation. □ Yes □ No

15. Understands the discharge plan and follow-up
   • Follow up date with GP and of next INR blood test □ Yes □ No
   • Warfarin dose to take until follow up □ Yes □ No
   • Hospital staff may follow up by phone (Identify best contact number) □ Yes □ No

Staff member(s) signature:

Date:
APPENDIX E: WARFARIN SELF-MANAGEMENT ASSESSMENT TOOL
There are two key indicators of a patient's potential for non-compliance with Warfarin therapy; their Warfarin knowledge and their reported self-management confidence.

**KNOWLEDGE ASSESSMENT**

You can briefly assess a patient's medication knowledge with the following questions.

- Do you know anything about Warfarin?  
  - If yes;  
  - How does Warfarin work?  
  - How and when should Warfarin be taken?  
  - Does Warfarin have any side effects?  
  - What else do you know about Warfarin?  

If a knowledge deficit is assessed, please make a referral to pharmacy for medication counseling.

**SELF-MANAGEMENT QUESTIONNAIRE**

Ask your patient the following questions to assess their self-management confidence.

- How confident are you that you can take Warfarin tablets correctly?
- How confident are you that you can recognise serious bleeding side effects which need medical help?
- How confident are you that you can self manage your Warfarin at home? (Especially with regard to diet/alcohol)
- How confident are you that you know and understand the information given to you about warfarin?
- Are you worried about taking Warfarin?
- If yes; what is it about taking Warfarin that worries you?

If a self-management deficit is assessed, please make a referral to pharmacy for medication counseling.
APPENDIX F: VTE WORKSHOP FLYER
VENOUS THROMBOEMBOLISM (VTE) PREVENTION

Deep vein thrombosis (DVT) and pulmonary embolus (PE) are collectively referred to as venous thromboembolism (VTE). It has been estimated that VTE causes between 2000-5000 deaths in Australia each year, with many more people suffering ongoing medical complications.

We now know that with risk assessment and appropriate prophylaxis a great deal of these deaths and complications can be prevented.

We invite all health professionals to a one day conference on this important health and patient safety issue.

Date: 3rd April 2009
Time: 8.30 - 4.30
Cost: Free
Venue: St Vincent’s Private Hospital, Sydney
Level 4 Function Room
406 Victoria Street
Darlinghurst
NSW 2010
Phone: Email: Web: www.svph.com.au
Inaugural Multidisciplinary VTE Conference

An overview of Venous Thromboembolism.

VTE risk assessment: How, when, & why.

Stop the clot: The NICS VTE prevention program.

The Queensland experience: What can be gained from a VTE nurse advocate?

VTE prevention in NSW: A state wide approach.

Panel discussion.

VTE- More than just a clot!

Let's get physical: Mechanical prophylaxis measures.

Chemoprophylaxis: drugs, drugs & more drugs.

Guideline implementing: What you need to know.

Please fax this registration form to (02) 8382 6442

Dr Abdullah Omari
Vascular Physician, St Vincent’s campus

Jed Duff
St Vincent’s Private Hospital, VTE Project Facilitator

Tanyth de Gooier
Assistant Director, Research Implementation Program
National Institute of Clinical Studies

Renea Collins
Clinical Nurse Consultant, VTE, Princess Alexandra Hospital, Brisbane

Prof Donald MacLellan
Program Director (Surgery), NSW Health

Prof Kim Walker
Professor of Nursing, St Vincent’s Private Hospital

Edel Murrey
Clinical Nurse Consultant, Wounds, St Vincent’s Private Hospital

Helen Devenish
Clinical Nurse Educator, Orthopaedics, St Vincent’s Private Hospital

Katrina Kelleher
VTE Pharmacist, St Vincent’s Private Hospital

Prof Sandy Middleton
Professor of Nursing, St Vincents & Mater Health, Sydney

Name

Address

Phone

Organisation

Email
APPENDIX G: VTE PREVENTION POLICY
ST. VINCENT’S PRIVATE HOSPITAL

CLINICAL POLICY AND PROCEDURE MANUAL

POLICY PNA/01/01/55/00/00

Subject: Venous Thromboembolism Prevention Policy
Area: Clinical
Classification: Patient Care
Effective Date: August 2009
Review Date: August 2012
Approved by:
Signature: .......................... Date: ...................
Director of Nursing

Signature: .......................... Date: ...................
Consultant of Vascular Medicine

Signature: .......................... Date: ...................
Chair of the pharmacy committee

Primary Responsibility
Registered Nurses
Endorsed Enrolled Nurses
Medical Officers

Co-ordinating Responsibility
Nursing Unit Managers
Clinical Practice & Policy Council
Director of Pharmacy
Director of Nursing

Distribution: All Clinical Areas

Key Words: Venous thromboembolism prophylaxis
Deep vein thrombosis
Pulmonary embolus

Policy Statement
Venous thromboembolism (VTE) is the collective term for deep vein thrombosis (DVT) and pulmonary embolism (PE). Each patient will be assessed for venous thromboembolism (VTE) risk within 24 hours of admission and receive appropriate prophylaxis based on this risk assessment. This policy provides guidelines for the assessment of VTE risk and for thromboprophylaxis and are based on Best Practice Guidelines for Australia and New Zealand.
Blood clots cost Australia $1.72 billion

Deadly blood clots kill more than 5,000 hospitalised Australians each year and cost the country about $1.7 billion, mostly from lost productivity, a new report shows.

An Access Economics report estimates venous thromboembolism (VTE) will be responsible for 5,285 preventable deaths this year, more than lung and breast cancer combined.

More than 80 per cent of the $1.72 billion financial cost of the condition was caused by productivity lost due to premature death. Direct health costs accounted for just nine per cent.

Hospital Patients' Blood Clot Risk High

But study finds many aren't getting preventive treatments.

More than half the patients in hospitals worldwide risk developing dangerous blood clots known as venous thromboembolisms, yet many aren't receiving treatments that could prevent the condition, a large international study shows.

"Venuous thromboembolism has long been recognized to be one of the most common avoidable causes of death associated with hospital stay," said study co-author Dr. Ajay Kakkar, a professor of surgical sciences at Barts and the London School of Medicine and Dentistry in the United Kingdom. "What was interesting from this study was how commonly risk factors for blood clots are found in patients admitted to hospital and the variations in the provision of preventative measures."

The study, published in The Lancet, covered 358 hospitals in 32 countries and included all hospital inpatients over 40 admitted to a medical ward and those aged 18 or over admitted to a surgical ward.

Participants were assessed for VTE risk based on a review of their hospital charts.
Blood clots cost Australia $1.72 billion

Lynne Pezzullo of Access Economics said VTE, or blood clots that form in the veins, caused more deaths than all transport accidents and falls combined.

"It is a bigger killer than bowel or breast cancer," Ms Pezzullo said.

"The findings of this report are surprising and present an immediate call to action."

The report was commissioned by a trans-Tasman VTE expert group that has been lobbying governments to make blood clot assessments of every patients compulsory on arrival at hospital.

An international study published in The Lancet in February found fewer than half of inpatients at risk were receiving preventive treatments.

NSW and Queensland have adopted guidelines laid down by the Australia and New Zealand Working Party on VTE, but the chair, Professor John Fletcher, said there was a clear need for risk assessments to be introduced across all states.

"This report adds to the growing body of evidence which shows that VTE prevention in hospitals in sub-optimal and results in significant, unnecessary loss of life," Prof Fletcher said.

"The ultimate goal now is for all states to introduce VTE incidence and risk assessments as key performance indicators on which hospitals are measured."

Blood clot danger for bed-ridden patients

By Hannah Davies

TWO in three Australians are at risk of developing potentially fatal blood clots while in hospital, a new study has revealed.

The figure is much higher than the global average of one in two and has prompted doctors to call for a nationwide strategy to tackle the problem.

The condition, known as deep vein thrombosis (DVT), is often referred to as "Economy Class Syndrome", because it can be caused by long-distance flights.

Hospital patients are 135 times more likely to develop it than air travellers, because of long periods of inactivity and conditions such as strokes.

Research shows one in 10 hospital deaths is the result of DVT - caused by a clot travelling from the vein to the lungs.

Dr Harry Gibbs, director of the department of vascular medicine at Brisbane's Princess Alexandra Hospital, said lack of awareness of the condition was a problem in most Australian hospitals.

"The study has shown this condition to be a serious problem throughout the world, and all hospitals need to be taking action to change this," he said.

Preventive measures include nurses encouraging patients to take walks and advising doctors on administering blood-thinning drugs and compression stockings.

Dr Gibbs said other hospitals across the state urgently needed to follow suit.

"We have been proactive to try to improve it," he said.

"Now the same measures need to be rolled out across the state and the rest of Australia."

Patients most at risk from DVT are cancer sufferers, those having major surgery - particularly if over 40 - and stroke victims.
SVPH Patients at risk of blood clots (VTE)

A recent audit of patients at St Vincent’s Private Hospital has shown that over half of patients are not receiving the recommended VTE prophylaxis.

75 patients were selected randomly and their VTE prophylaxis measures were audited against the Australian & New Zealand Best Practice Guidelines.

The Audit revealed that 55% of patients were not meeting best practice guidelines, with 45% of surgical patients and over 80% of medical patients lacking appropriate prophylaxis.

Formal VTE risk assessment was also found to be lacking, with no recorded assessments identified.

This is an excellent opportunity for SVPH to improve patient outcomes, points out Prof Kim Walker, of the SVPH VTE project.

St Vincent’s Private improves VTE compliance

St Vincent’s Private has improved its compliance with Venous Thromboembolism Prevention measures thanks to the ‘STOP THE CLOT’.

This program has used a number of interventions to help promote the uptake of the best practice VTE guidelines.

Percentage of High Risk patients on appropriate prophylaxis & Percentage of patients risk assessed

- High Risk (Sept)
- High Risk (March)
- Risk Assessed (Sept & March)

All Patients  Surgical Patients  Medical Patients
Hanson brother has operation for blood clot

A member of the pop group Hanson underwent surgery Thursday in Dallas to remove a blood clot in his lungs after suffering chest and shoulder pain following a concert this week, the band’s publicist said.

Isaac Hanson, 26, was diagnosed with venous thoracic outlet syndrome, said spokesman Ken Phillips. Also known as Paget-Schröetter syndrome, the potentially fatal ailment occurs when a blood clot forms in a deep arm or shoulder vein.

Dr. Bradley Grimsley, Hanson’s surgeon, said he expected the guitarist to make a full and swift recovery, Phillips said in a news release.

Phillips said Hanson has had similar problems in the past, but not to this extent. Hanson was taken to Baylor University Medical Center Tuesday night after a show at the House of Blues.

Hanson and his doctor were to discuss the surgery at a news conference Friday. Phillips said Hanson may be released from the hospital then.

Hanson cancelled shows in Tulsa, Okla., St. Louis and Kansas City, Mo. The band expects to resume its tour Oct. 8 in Knoxville, Tenn.

The group is best known for the 1997 hit single, MMMBop.

NEW YORK - Darryl "DMC" McDaniels of the legendary rap group Run-DMC was scheduled to undergo surgery at a New Jersey hospital Friday to remove two major blood clots in his left arm.

McDaniels, 44, had been suffering from pain and swelling in his arm when doctors discovered the clots, his publicist Tracey Miller told The Associated Press.

Miller did not know when McDaniels would be released, and said he had canceled a planned performance over the weekend.
Jesus died from a blood clot

Jesus died from a blood clot caused by his immobilisation on the cross, says a researcher, who challenges the popular belief that Jesus died of blood loss.

The clotting condition, known as pulmonary embolism, sometimes kills and is now more commonly linked with long-haul air travel.

Professor Benjamin Brenner writes in the *Journal of Thrombosis and Haemostasis* that Jesus' death, traditionally believed to have occurred 3 to 6 hours after crucifixion began, was probably caused by a blood clot.

Such pulmonary embolisms, leading to sudden death, can stem from immobilisation, multiple trauma and dehydration, says Brenner.

"This fits well with Jesus' condition and actually was in all likelihood the major cause of death by crucifixion," he writes in the article, based on religious and medical texts.

A 1986 study in the *Journal of the American Medical Association* mentions the possibility that Jesus suffered a blood clot but concluded that he died of blood loss.

But Brenner says research into blood coagulation has made significant strides over the past two decades.

He says recent medical research has linked immobility among passengers on lengthy air flights to deep vein thrombosis, popularly known as 'economy-class syndrome' in which potentially fatal blood clots can develop, usually in the lower legs.

Brenner notes that Jesus was flogged before crucifixion, but the researcher concludes that "the amount of blood loss by itself" would not have killed him.

Simple measures can cut blood-clot deaths

TENS of thousands of patients in NSW hospitals are to be given mandatory clot prophylaxis in a bid to prevent unnecessary deaths.

A new policy to assess patients at risk will be implemented throughout the state to combat the 10,000 deaths each year in hospitals from venous thromboembolism (VTE). This is despite the availability of simple, cost-effective preventative measures such as blood-thinning medications and compression stockings.

The condition, which refers to deep vein thrombosis (DVT) and pulmonary embolism (PE), takes more lives than lung and breast cancer combined every year. A recent international study showed 60 per cent of Australian hospital patients were at risk of VTE but, of those, 40 per cent did not receive effective prophylaxis.

Professor Beng Chong, a hematologist at St George Hospital and head of the Department of Medicine at the University of NSW, said many hospitals did not assign the task of VTE risk assessment to particular doctors or nurses while many simply "forget".

Evidence shows the risk of blood clots drops from 50 per cent to 10 per cent if the patient is given an injection of heparin or another blood-thinning agent.

"All patients should be given the prophylaxis. It's very cheap, it's very safe and it's very effective," he said.
Stop The Clot Program- Reducing Blood Clot Risk For Hospital Patients

A new national prevention program to stop potentially lethal blood clots developing in private hospital patients was launched in Canberra by Minister for Health and Ageing, Nicola Roxon.

Blood clots kill at least 2,000 people each year. Around 30,000 Australians are hospitalised each year due to blood clots. Hospital patients are at 25 times greater risk of developing a clot than air travellers.

Titled Stop the Clot, this program was developed by the National Health and Medical Research Council’s National Institute of Clinical Studies (NICS) and successfully implemented in over 40 public hospitals nationally.

The Australian Government is committed to working with both public and private hospitals to raise standards and improve safety. Ms Roxon has made clear that accountability measures in the new Australian Health Care Agreements will apply to both public and private hospitals.

Minister Roxon stressed the urgent need to better manage high risk patients in a bid to cut the VTE toll. “For those that survive, there are significant long term consequences and costs,” Minister Roxon said. “Patients with VTE require diagnostic tests, treatment with blood thinning drugs, a longer hospital stay and lifelong tests and treatment.”

According to Prof. Warwick Anderson, Chief Executive Officer of the National Health and Medical Research Council, the Stop the Clot program uses a world first whole of hospital approach to minimise the risk of blood clots.

“The key is identifying at risk patients and managing them throughout their entire hospital stay from admission to discharge and even post-discharge,” he said.

“Simple management measures, such as the use of blood thinning drugs and compression stockings, systematically used across all departments can have a big impact.

“We know what we have to do to prevent blood clots occurring, but the challenge has been changing hospitals’ systems and procedures to address the issue across the board.”

[Image of group of people with text: SVaMH Sydney ‘Stop the Clot’ program team members (l to r).]

Helen Devenish SVPH
Jed Duff SVPH
Katrina Kelleher SVPH
Margaret Sheehan TMH
Paul Morgan TMH
Prof Kim Walker SVPH
Simple measures can cut blood-clot deaths

Chairman of the Australian and New Zealand Working Party on the Prevention and Management of VTE, Professor John Fletcher called for a national prevention strategy.

He said the Rudd Government's $150 million commitment to fund an extra 25,000 surgical procedures could see the deaths or hospital re-admissions of up to 1000 patients if the VTE policy is not implemented.

He said VTE incidence and risk assessment rates should be a key performance indicator under the next Australian Health Care Agreement.

A recent study in The Lancet medical journal concluded that VTE was a critical safety issue because there was a "clear gap" between official strategies for dealing with the problem and what actually happened in hospitals across the globe.

Australia performs better than the UK and America when it comes to protecting at-risk patients but lags behind European countries such as Germany. Some countries operate an automatic alert system so that a doctor is reminded to assess a patient and administer treatment the first time they examine them.

Hospital Patients' Blood Clot Risk High

But study finds many aren’t getting preventive treatments.

Out of a total of 68,183 patients, only 58.5 percent of at-risk surgical patients and 39.5 percent of at-risk medical patients received recommended preventive treatments.

The consistency of risk reported throughout the countries studied was surprising, according to the study's lead author, Dr. Alexander Cohen, an honorary consultant and vascular physician at King's College London.

But, he added, "the great variation in prevention use and the fact that all countries were suboptimal, with the U.K. somewhere in the middle, were not surprising."

In the study, the proportion of at-risk medical patients receiving the appropriate treatment varied by country, with Germany (70 percent), Spain (64 percent) and Colombia (64 percent) rating the highest, and Bangladesh (3 percent), Thailand (4 percent) and Romania (18 percent) at the bottom.

In the United States, 48 percent of at-risk medical patients received the appropriate care.

Germany scored the highest for at-risk surgical patients (92 percent), along with Hungary (87 percent) and Spain (82 percent). Bangladesh and Thailand (both 0.2 percent) were the low rankers again, along with Pakistan (10 percent). In this category, the United States scored 71 percent.

VTE can result in blockage of blood vessels in the leg (deep vein thrombosis) or a pulmonary embolism, the blockage of a lung artery that can sometimes be fatal.

VTE is common during and after hospitalization, and is considered the most common preventable cause of in-hospital death. Studies have linked pulmonary embolism to up to 10 percent of in-hospital sudden deaths.

Guidelines for prevention of VTE in hospitals have been available for more than 15 years, yet are underused. Such treatments include blood-thinning drugs, as well as pneumatic compression and compression stockings.

According to an accompanying commentary in the journal, preventive medications can reduce the risk of pulmonary embolism by 75 percent in general surgical patients and by 57 percent in medical patients.

One U.S. expert agreed that steps can be taken to reduce the danger to patients. Dr. Joel Horowitz, director of the division of general surgery at Maimonides Medical Center in New York City, noted that some hospitals are using a computer-order entry system in which all hospital orders have to be recorded on the computer, not written.

"At our hospital, doctors can't escape that screen, so 97 percent of patients admitted to surgery are prescribed prophylaxis," he said.

But a recent study of U.S. hospital patients found that, despite these guidelines, half the patients were not getting preventive treatment for VTE.

"Identifying those at risk of developing a blood clot is straightforward and should happen at the time of hospital admission. For those at risk, preventative measures should be initiated immediately," Kalkkar said.
Dr Omari is a vascular physician, specialising in VTE prevention and treatment and Karen Dewsnap is the vascular nurse educator at SVPH.

Dear Dr Omari,
How can I tell if my patient has developed a DVT?

Patients with deep venous thrombosis (DVT) can present with leg discomfort, commonly a fullness or tightness, in conjunction with limb swelling and discoloration. These symptoms worsen during standing and improve upon sitting or lying down.

Unfortunately, some patients, especially those undergoing surgical procedures, develop asymptomatic DVT. These DVT’s can still lead to potentially fatal Pulmonary Embolus (PE) and this is the reason why rigorous VTE risk assessment and prophylaxis is essential.

Dear Karen,
Recently I have had a couple of very large patients and the calf compessor sleeves and anti-embolic stockings wouldn’t fit. What can I do in this situation?

Thanks for that great question. It’s very important that these patients’ receive appropriate prophylaxis as obesity is a risk factor for developing VTE.

Did you know that the calf compessor sleeves and anti-embolic stockings now come in large and extra large sizes? They are now available from stores.

If the extra large sizes still won’t fit, then maybe you should consider using the new foot compessor available from CSD.
APPENDIX I: EXAMPLE VTE POSTER
APPENDIX J: VTE AUDIT TOOL
## VTE Audit Tool

<table>
<thead>
<tr>
<th>Step one: Demographic data</th>
<th></th>
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<tbody>
<tr>
<td>Admitting specialty:</td>
<td>Admitting doctor:</td>
</tr>
<tr>
<td>Date of admission:</td>
<td>Clinical unit:</td>
</tr>
<tr>
<td>Date of audit:</td>
<td>Study Number:</td>
</tr>
<tr>
<td>Reason for admission:</td>
<td>Age: Sex:</td>
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</table>

### Step two: Medical or Surgical patient?

| Surgical                  | Planned or prior (past 30 days) surgery this admission |
| Medical                   | No planned or prior (past 30 days) surgery this admission |

### Step three: Exclusion criteria?

| Yes                        | Planned stay less than 24 hours  |
|                           | Medical record unavailable for audit |
|                           | Patient unavailable for audit |
|                           | Inadequate documentation to complete audit |
| No                        | No exclusion criteria |

### Step four: VTE Risk factors present?

#### Medical patients

| Yes                        | Ischaemic stroke  |
|                           | History of VTE  |
|                           | Active cancer  |
|                           | Decompensated heart failure  |
|                           | Acute on chronic lung disease  |
|                           | Acute inflammatory disease  |
|                           | Age >60 years (with reduced mobility)  |
|                           | Additional risk factors  |
| No                        | None of the above |

#### Surgical patients

<p>| Yes                        | Hip arthroplasty  |
|                           | Knee arthroplasty  |
|                           | Major trauma  |
|                           | Hip fracture surgery  |
|                           | Other surgery with prior VTE &amp;/or active cancer  |
|                           | Major surgery and &gt;40 years  |
|                           | Additional risk factors  |
| No                        | None of the above |</p>
<table>
<thead>
<tr>
<th>Step five: Additional risk factors present?</th>
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<tbody>
<tr>
<td>Yes</td>
<td>Immobility</td>
</tr>
<tr>
<td></td>
<td>Family history</td>
</tr>
<tr>
<td></td>
<td>Oestrogen therapy</td>
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<tr>
<td></td>
<td>Obesity</td>
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<tr>
<td></td>
<td>Active inflammation</td>
</tr>
<tr>
<td></td>
<td>Thrombophilia</td>
</tr>
<tr>
<td>No</td>
<td>No additional risk factors</td>
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<table>
<thead>
<tr>
<th>Step six: VTE risk documented?</th>
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<tbody>
<tr>
<td>Yes</td>
<td>On Delacy</td>
</tr>
<tr>
<td></td>
<td>On the medication chart</td>
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<td>No</td>
<td>No documentation</td>
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<tr>
<th>Step seven: Contraindications to prophylaxis present?</th>
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<tbody>
<tr>
<td>Mechanical</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
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<tr>
<td>Periperal arterial disease</td>
<td></td>
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<tr>
<td>Periperal neuropathy</td>
<td></td>
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<tr>
<td>Severe lower limb oedema</td>
<td></td>
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<tr>
<td>Severe leg deformity</td>
<td></td>
</tr>
<tr>
<td>Recent skin graft</td>
<td></td>
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<tr>
<td>Other-please state</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>No contraindications to mechanical prophylaxis</td>
</tr>
<tr>
<td>Chemical</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Active bleeding</td>
<td></td>
</tr>
<tr>
<td>High risk of bleeding</td>
<td></td>
</tr>
<tr>
<td>Severe hepatic disease (INR &gt; 1.3)</td>
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<tr>
<td>Adverse reaction to heparin (HIT)</td>
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<tr>
<td>On therapeutic anticoagulation</td>
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</tr>
<tr>
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<td></td>
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<tr>
<td>No</td>
<td>No contraindications to chemical prophylaxis</td>
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### Step eight: Prophylaxis present?

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<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Enoxaparin (LMWH) 40mg/day</td>
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<td>Enoxaparin (LMWH) 20mg/day</td>
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<tr>
<td>Rivaroxaban 10mg/daily</td>
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<tr>
<td>LDUH 5000 units/TDS</td>
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<td>LDUH 5000 units/BD</td>
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<tr>
<td>Other chemical prophylaxis-please state</td>
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<table>
<thead>
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<tr>
<td>Graduated compression stockings</td>
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<tr>
<td>Intermittent pneumatic compression</td>
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<td>Other mechanical-please state</td>
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<td>No</td>
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### Step nine: Appropriate prophylaxis provided?

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<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>On appropriate prophylaxis for risk category</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>At risk but not on any prophylaxis</td>
<td></td>
</tr>
<tr>
<td>Missing mechanical prophylaxis</td>
<td></td>
</tr>
<tr>
<td>Missing chemical prophylaxis</td>
<td></td>
</tr>
<tr>
<td>Mechanical prophylaxis inadequate</td>
<td></td>
</tr>
<tr>
<td>Chemical prophylaxis inadequate</td>
<td></td>
</tr>
<tr>
<td>Chemical and mechanical prophylaxis both inadequate</td>
<td></td>
</tr>
<tr>
<td>On prophylaxis but not indicated</td>
<td></td>
</tr>
</tbody>
</table>

### Step ten: Data entry

<table>
<thead>
<tr>
<th>Name:</th>
<th>Date entered:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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251
## Audit Tool Clarifying Information

### Notes for medical risk stratification

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischaemic stroke</td>
<td>Acute, confirmed by CT or MRI and unable to walk unassisted because of motor impairment</td>
</tr>
<tr>
<td>Active cancer</td>
<td>Currently receiving or recommended active therapy/treatments for cancer</td>
</tr>
<tr>
<td>History of VTE</td>
<td>Previous PE or DVT</td>
</tr>
<tr>
<td>Decompensated heart failure</td>
<td>Symptoms of heart failure that occur with minimal activity or at rest</td>
</tr>
<tr>
<td>Acute on chronic lung disease</td>
<td>Respiratory failure or exacerbation of respiratory disease</td>
</tr>
<tr>
<td>Acute inflammatory disease</td>
<td>E.g. rheumatoid arthritis, systemic lupus erythematosus</td>
</tr>
<tr>
<td>High risk of bleeding</td>
<td>E.g. haemophilia, thrombocytopenia (platelet count &lt;50 x 10^9/L), history of GI bleeding</td>
</tr>
<tr>
<td>Major surgery</td>
<td>Intra-abdominal surgery or any surgery &gt;45 min duration</td>
</tr>
</tbody>
</table>

### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GCS</td>
<td>Graduated compression stockings</td>
</tr>
<tr>
<td>IPC</td>
<td>Intermittent pneumatic compression device, including calf and foot pumps</td>
</tr>
<tr>
<td>LDUH</td>
<td>Low dose unfractionated heparin</td>
</tr>
<tr>
<td>LMWH</td>
<td>Low molecular weight heparin</td>
</tr>
</tbody>
</table>
APPENDIX K: EOV WORKSHOP FLYER
How to influence clinician behaviour and change practice:

One-on-one educational visits & small group facilitation training workshop

The challenges in changing clinician behaviour are well known. Two approaches that are effective include one-on-one educational visits and facilitated small group education. In this two day workshop trainers from the NPS will guide participants through the use of these exciting techniques.

On day one participants will observe a visit being conducted by an experienced NPS facilitator. Multiple strategies for achieving a successful visit will be explored, and participants will have opportunities to practice the necessary skills in a supportive small group environment.

The focus of the second day will be on small group facilitation skills. Participants will be guided through the processes necessary to promote small group discussion and learning.

This workshop is perfect for all health professionals faced with the challenge of influencing clinician behaviour and changing clinical practice.

Enrolment NOW OPEN for this two day Workshop. Numbers are limited. Applications close 25th February 2011

St Vincent’s Private
APPENDIX L: EOV PRINTED MATERIAL
More Information
More information on VTE prevention can be found at the following locations:

- The St Vincent's Private Hospital (SVPH) VTE prevention resources available on the SVPH Clinical Workstation
- The St Vincent's Private Hospital VTE prevention policy PNA/01/01/55/00/00 available on the SVPH Clinical Workstation

Acknowledgements
This brochure was developed by the St Vincent's Private VTE Prevention Working Group. The brochure summarises the hospital's VTE prevention policy and prophylaxis protocol which are based on the Australian & New Zealand Best Practice Guidelines for the Prevention of Venous Thromboembolism 4th ed.

Preventing Venous Thromboembolism (VTE) in Hospitalised Medical Patients
VTE in hospitalised medical patients is a significant health problem resulting in considerable death and disability.

Ten percent of all hospital deaths are due to pulmonary embolism and 75% of these deaths are in acutely ill medical patients.

VTE also causes debilitating and costly chronic health complications such as pulmonary hypertension and post-thrombotic syndrome.

VTE is largely preventable and effective prophylaxis is available but inconsistently applied. Less than half of all medical patients at risk of VTE are receiving the recommended prophylaxis.

Is your patient at risk?
ASSESS, PROVIDE & MONITOR your patients’ VTE prophylaxis
**Clotting Risk**
Medical inpatients are at high risk of VTE if they are aged over 60 years or have:
- Heart failure or a recent MI
- History of VTE
- Ischemic stroke
- Active cancer
- Acute on chronic lung disease

**Bleeding Risk**
When prescribing or administering chemical prophylaxis consider the following potential contraindications:
- Active bleeding or at high risk of bleeding
- Thrombocytopenia (plts<50x10^9/L)
- Severe hepatic disease (INR>1.3)
- Renal impairment
- Weight <45kg or >120kg

**Contraindications**
Contraindications to the use of mechanical prophylaxis include:
- Peripheral arterial disease
- Peripheral neuropathy
- Recent skin graft to area
- Severe leg deformity

**Chemical Prophylaxis**
For medical patients at high risk of VTE and with no contraindications to anticoagulation the recommended chemical prophylaxis is:
- Enoxaparin 40mg daily subcut or Heparin 5000units bd/ts subcut for the duration of the hospital stay

**Mechanical Prophylaxis**
The recommended mechanical prophylaxis for high risk patients is:
- Graduated compressions stocking (knee or thigh length) for the full duration of their hospital stay
- Intermittent pneumatic compression should be considered if additional risk factors are present

**Patient Education**
Patients should always be informed of their VTE risk and the preventative therapies they are receiving.

**Risk Status**
Patients should have a VTE risk assessment on admission and their risk status and preventative therapies should be documented in their medical record. Risk status should be reassessed when a patient's medical condition changes.

**Signs of VTE**
VTE is very often asymptomatic; however, possible signs and symptoms include:
- Pain or tenderness; swelling; increased warmth; oedema; erythema; and dilated veins
- Dyspnoea; tachypnoea; and pleuritic chest pain

**Adverse Reactions**
Chemical and mechanical prophylaxis therapies are not without risk and patients should be observed for any adverse reactions or adverse events including:
- Chemical therapies
  - Bleeding
  - Heparin Induced Thrombocytopenia (HITTs)
- Mechanical therapies
  - Pressure and friction sores
  - Trips or falls
APPENDIX M: POST EOV PARTICIPANT SURVEY
Participant Post Intervention Survey

Thank you for participating in the venous thromboembolism educational outreach sessions. We would appreciate your feedback on the program’s effectiveness and usefulness to you. Please answer the following questions. When complete please post your responses to the Nursing Research Institute using the addressed envelope provided.

<table>
<thead>
<tr>
<th>Question</th>
<th>Extremely ineffective</th>
<th>ineffective</th>
<th>unsure</th>
<th>effective</th>
<th>Extremely effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How effective were the educational visits in increasing or refreshing your knowledge about VTE prophylaxis for medical patients?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. How effective were the educational visits in addressing concerns you have had about providing VTE prophylaxis to medical patients?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. How effective were the educational visits in providing information about the significance of VTE as a healthcare issue?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. How effective were the educational visits in providing information about VTE risk assessment for medical patients?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. How effective were the educational visits in providing information about selecting appropriate VTE prophylaxis for medical patients?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. How effective were the educational visits in providing information about the ongoing monitoring of patients risk and response to prophylaxis?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Extremely unlikely</th>
<th>unlikely</th>
<th>unsure</th>
<th>likely</th>
<th>Extremely likely</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. How likely is it that you will participate in another educational program such as this one in the future?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8. How likely is it that these educational visits will influence your clinical practice?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

POPE Study
Participants post intervention survey_v2 5-May-11
APPENDIX N: EOV VISIT RECORD
PoPE Post Visit Checklist

Please complete this checklist at the completion of every Educational Outreach Visit. The checklist is an important data source in the process evaluation of this project. The tool helps identify the component parts of the EOV intervention that were successfully delivered. Please make a comment on why certain strategies were not/ could not be employed.

<table>
<thead>
<tr>
<th>Planning</th>
<th></th>
<th></th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forwarded letter of support from hospital executive and opinion leaders to clinician</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contacted clinician to arrange convenient time/ location for visit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirmed arrangements prior to visit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussed with project team strategies to gain access to particular clinician</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Objectives (please enter specific clinician specific objectives)

<table>
<thead>
<tr>
<th>Comments:</th>
</tr>
</thead>
</table>

Introduction

<table>
<thead>
<tr>
<th>Ensured an appropriate space for discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Started with small talk</td>
</tr>
<tr>
<td>Explained the purpose of the visit</td>
</tr>
<tr>
<td>Negotiated the session length</td>
</tr>
<tr>
<td>key messages introduced (assess, provide, monitor VTE prophylaxis)</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
</tbody>
</table>

Trust, credibility and likability

<table>
<thead>
<tr>
<th>Mentioned the project ’s affiliated with campus working party, St Vincent’s Clinic Foundation etc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Listed key opinion leaders in support of the project</td>
</tr>
<tr>
<td>Highlighted own clinical expertise in the area of VTE</td>
</tr>
<tr>
<td>Attempted to uncover personal similarities with clinician</td>
</tr>
<tr>
<td>Offered genuine praise where appropriate</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
</tbody>
</table>

Two-sided communication

| Used open ended questions to get the clinician talking                                     |
| Used minimal encouragement techniques to keep clinician talking                            |
| Paraphrased and reflected on clinicians comments                                              |
| Identified the clinicians needs |          |
| Tailored message based on clinician needs |          |
| Anticipated and acknowledged controversies in their particular area |          |
| Overcame any objections and handled challenging responses |          |

**Comments:**

<table>
<thead>
<tr>
<th>Key messages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledge that VTE is an important healthcare issue:</td>
</tr>
<tr>
<td>a. Mortality</td>
</tr>
<tr>
<td>b. Morbidity</td>
</tr>
<tr>
<td>c. Resource expenditure</td>
</tr>
</tbody>
</table>

| Assess individual patient risk: |
| a. Clotting risk |
| b. Bleeding risk |
| c. Contraindications |

| Provide evidence-based VTE prophylaxis and patient education: |
| a. Mechanical |
| b. Chemical |
| c. Patient education |

| Monitor and reassess each patient during their hospital stay: |
| a. Risk status |
| b. Signs of VTE |
| c. Signs of adverse reactions |

**Comments:**

<table>
<thead>
<tr>
<th>Wrapping-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reflected on discussion</td>
</tr>
<tr>
<td>Reiterated the key messages discussed</td>
</tr>
<tr>
<td>Presented clinician with brief printed graphical resource material</td>
</tr>
<tr>
<td>Gained commitment from clinician to trial new practice(s)</td>
</tr>
<tr>
<td>Gained commitment from clinician for subsequent visit</td>
</tr>
</tbody>
</table>

**Comments:**

<table>
<thead>
<tr>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up email or phone call attended</td>
</tr>
<tr>
<td>Fulfilled all commitments made to clinician i.e. provided copy of research paper, as requested</td>
</tr>
</tbody>
</table>

**Comments:**

---

PoPE Study
PoPE post visit checklist_v3 5-May-11
APPENDIX O: STUDY TIMELINES
WARFARIN MANAGEMENT EVIDENCE IMPLEMENTATION STUDY

VTE PREVENTION EVIDENCE IMPLEMENTATION STUDY
PEER-ON-PEER EDUCATION FOR BETTER VTE PREVENTION STUDY

![Diagram of project timeline]

- Recruit visitors
- Visitor training
- Content development
- Pilot visits
- Pre visit audits
- Intervention
- Post visit audits
- Data analysis