Expert Forum

VTE prevention in New Zealand Hospitals

Making Education Easy

May 2013

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In this review:

Abbreviations used in this issue

CI = confidence interval
CT = computed tomography
DVT = deep vein thrombosis
GCS = graded compression stockings
IPC = intermittent pneumatic compression
KPI = key performance indicator
LMWH = low molecular weight heparin
LV/RV = left/right ventricular
PE = pulmonary embolism
THA/THR/TKA/TKR = total hip/knee arthroplasty/replacement
VTE = venous thromboembolism

Welcome to this review of the recent NZ VTE Experts' Forum in Auckland.

The grand round and expert forum held at Ko Awatea, Middlemore Hospital, Auckland, attracted a wide range of attendees including haematologists, surgeons and administrators from around the country. This publication has been made to provide an overview of presentations and discussions as a record for the attendees and for the benefit of those who could not attend. Professor Alexander Gallus, MBBS, FRACP, FRCPA, a haematologist at Flinders University School of Medicine in Adelaide, Australia, gave three valuable presentations on VTE prevention in hospitalised patients based on his expertise in this area. Representatives for various DHBs around NZ also provided updates on progress that has been made at their respective institutions, and Anne Blumgart from the VTE Prevention Steering Group and co-ordinator of the VTE Prevention National Policy Framework led an important and valuable discussion with the attendees regarding the current status and future of this living document, which was first published on the HQSC's website in June 2012.

MEDICINE GRAND ROUND

With Professor Alexander Gallus

Two case reports – presented by Dr Manali Jain, MBChB, Middlemore Hospital

Two cases were presented that outline the difficulties associated with therapeutic dose anticoagulation.

Case 1: A 67-year-old Caucasian man with a background of osteoarthritis, spinal surgery and atypical chest pain underwent elective left TKR. He developed postoperative dyspnoea and chest tightness, and was consequently investigated for PE. CT pulmonary angiography revealed an isolated right upper lobe posterior segmental branch PE. He was initiated on warfarin therapy with enoxaparin bridging. He was discharged to the community with regular INR monitoring, which showed an INR of 1.1–1.4. He was readmitted 1 week later with increased pain and swelling in his left knee, and was diagnosed with haemarthrosis. Warfarin was reversed and discontinued. He then developed infective complications of the haemarthrosis, requiring multiple washouts in theatre and prolonged antibiotic treatment in the community. His function and recovery were significantly affected by the complications of anticoagulation, which included joint haemarthrosis with infection. He eventually underwent revision of his TKR.

Case 2: A 48-year-old Samoan man with a background of left radial fracture and gout was admitted with pleuritic chest pain and fever. He had no background history, family history or risk factors for VTE. He was clinically hypoxic with an oxygen saturation of 93%, and underwent a CT pulmonary angiogram due to clinical suspicion. This revealed segmental PE involving his right upper lobe and both lower lobes. He also had a left-sided pleural effusion with compressive atelectasis. His echocardiographic findings were normal, despite an elevated troponin level. He was discharged on enoxaparin and warfarin. Two days later, he was readmitted with presyncope. His haemoglobin level had fallen to 118 g/L. A chest x-ray revealed a large left-sided haemothorax, with whiteout of the left lung field. He had a chest drain inserted the following day, which drained 1L of blood and fluid. An inferior vena cava filter was inserted and his chest infection was also treated with antibiotics. Repeat CT pulmonary angiography revealed no residual PE. He was restarted on warfarin 2 weeks later with a planned treatment duration of 3–6 months. He remained clinically well at discharge.

Preventing hospital-related VTE

Prof Gallus presented data published by the Australian National Institute of Clinical Studies on VTE among hospitalised patients in Western Australia.[1] It reported one newly treated VTE each year per 1000 individuals, of which 55% were DVT and 45% were PE, which would extrapolate to 23,000 new cases across Australia in 2013; 40% are expected to occur within 90 days of a medical admission (especially for cancer, cardiovascular, respiratory), 40% within 90 days of surgery (4/1000 procedures, 33/1000 after TKA/THA), and 20% 'idiopathic'. It is also important to remember that nearly 45% of VTEs occurred in people of working age (15–64 years).

The early consequences of VTE are well known. These may be very severe and include multiple sequential complications, as illustrated by the two case reports. In most people with a fatal PE, death occurs within 3 hours of symptoms, and autopsy studies report that up to 70% of fatal PE have been clinically unsuspected or wrongly diagnosed. Late consequences of VTE include: i) recurrence (17%, 24% and 30% at 2, 5 and 8 years, respectively) and post-thrombotic syndrome (25% and 30% at 2 and 5–8 years, respectively) after a first proximal

DVT;[2] and ii) symptomatic pulmonary hypertension after acute PE (1.0%, 3.1% and 3.8% at 6, 12 and 24 months, respectively).[3] Improved and systematic prophylaxis offers the best chance for reducing morbidity and mortality from VTE, with a high cost-benefit balance.

Good clinical quality requires that health units develop and implement protocols for VTE prevention that include, with appropriate documentation, both an early assessment of each adult admission for their risks of VTE and bleeding, plus anticoagulant and/or mechanical prophylaxis (unless contraindicated) for all patients with a sufficiently high risk of developing VTE. Ongoing reviews of uptake and of changing evidence are also necessary. A good example is the National Policy Framework: VTE Prevention in Adult Hospitalized Patients in NZ (June 2012).

Both the predispositions for developing a VTE and the methods used to prevent thrombosis conceptually fit into Virchow's triad for thrombosis, as does prevention (Figure 1).

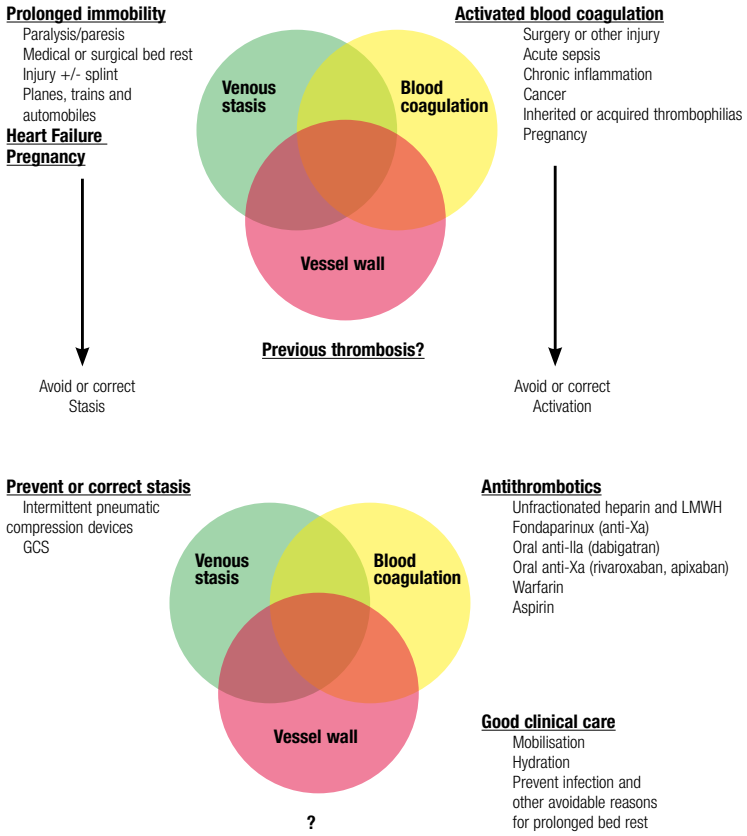


Figure 1. How VTE predispositions and prevention fit with Virchow's triad

There are a number of factors related to hazards, complexity, discomfort and costs that need to be taken into account when considering thromboprophylaxis (Table 1).

Thromboprophylaxis type	Factors
Anticoagulants	
Heparins	Bleeding risk Injection-site reactions Heparin-induced thrombocytopenia Time to inject and teach self-injection
New oral anticoagulants	Bleeding risk Still unfamiliar to most
Stasis prevention	
Compression devices	Clumsy/uncomfortable Poor compliance Short term
GCS	Difficult for obese or unfit patients Blisters Vascular disease Questionable efficacy

Table 1. Factors to take into account when considering thromboprophylaxis

It is important to consider the evidence for proposed interventions. This includes questions like: 'have trials measured clinically valid outcomes and correctly estimated bleeding risk?', and 'how well does the evidence translate into practice?'. Recent clinical practice guidelines have put increasing weight on the demonstrated effects of prophylaxis on symptomatic outcome events (especially nonfatal or fatal PE). Nevertheless, there is consistent evidence of similar relative effects on both subclinical DVT and symptomatic VTE (albeit with smaller absolute reductions of clinical event rates).

Surgical patients

Data from elective general surgical patients show high relative risk reductions of subclinical DVT rates with unfractionated heparin or LMWH (Figure 2).[4] When combined with data on clinical outcomes, the guidance for general surgery is to: i) estimate risks of VTE and of surgical bleeding; ii) give a LMWH for 7–10 days (unless contraindicated), with or without support stockings, and consider extending chemoprophylaxis to 4–6 weeks if patients had surgery for active cancer. There are published VTE risk assessment tools for patients having general surgery – these are often complicated, but perhaps not much superior to clinical judgement.

For hip or knee arthroplasty, there is debate regarding the value of aspirin relative to anticoagulants. Studies with surrogate endpoints suggest that LMWHs are the better option (Figure 2). After examining clinical trials and observational studies to estimate the cumulative risk of symptomatic VTE within 90 days after THA/TKA, the most recent ACCP (American College of Chest Physicians) guidelines suggest a risk reduction from ~4.5% without prophylaxis to ~2–2.5% with LMWHs, with little increase of major bleeding risk.[5] While these guidelines accept the evidence for aspirin, LMWH remains their preferred option, due to greater evidence for effectiveness.

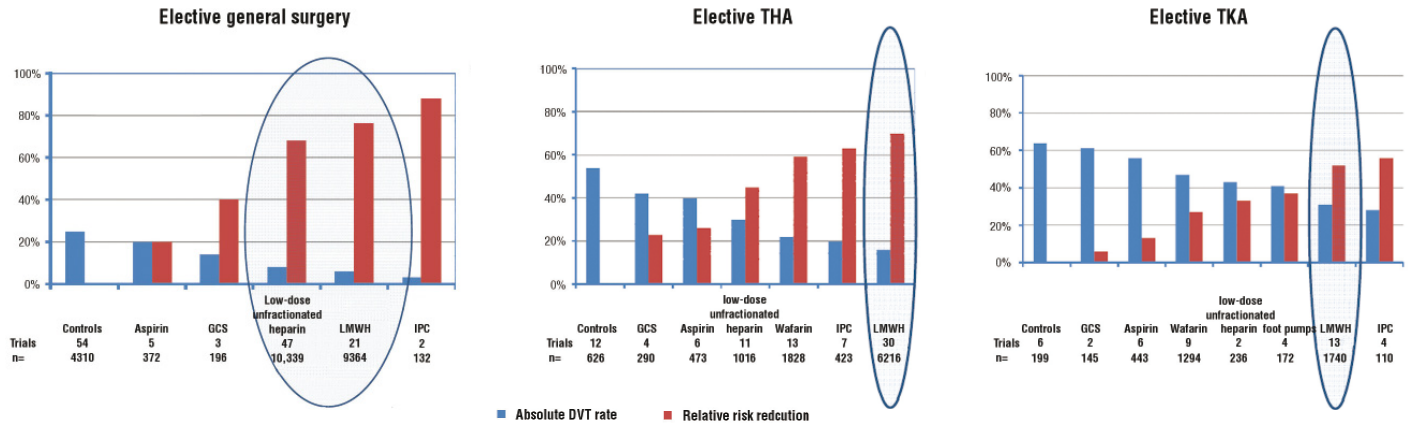


Figure 2. VTE rates and risk reductions of thromboprophylaxis versus untreated/placebo in randomised controlled trials of surgical patients[4]

Medical patients

There have been few placebo-controlled trials of thromboprophylaxis in acute medical patients. There are three with consistent findings of benefit.[6-8] Nevertheless, a practice gap exists, with typical survey results of roughly 50% compliance with guideline recommendations, compared with 80% compliance typical for surgical patients (see following presentation summary – 'Preventing VTE in medical inpatients').

Mechanical thromboprophylaxis

GCS add efficacy when combined with LMWHs after elective general surgery. Despite minimal evidence from nonsurgical patients, the 2012 ACCP guidelines recommend their use for those 'at risk of VTE' who also have high bleeding risk.[5] In addition, GCS are recommended as the minimal intervention for all patients 'at risk of VTE' in the 2010 NICE (UK) guidelines.[9] When considered together, the CLOTS-1 and CLOTS-2 studies suggest some benefit for preventing proximal DVT after an acute stroke (Table 2), but GCS increase the risks of developing skin ulcers or breaks (4–5% with thigh and 3% with calf-length GCS vs. 1% in controls).[10-11] The potential for harm is increased if GCS are poorly fitted, and in patients with peripheral vascular disease. Cost is also a consideration of GCS.

Trial	Proximal DVT			Difference (95% CI)
	Tight GCS	Calf GCS	No GCS	
CLOTS-1	126/1256 (10.0%)		133/1262 (10.5%)	–0.5% (–1.9 to 2.9)
CLOTS-2	98/1552 (6.3%)	138/1562 (8.8%)		–2.5% (–0.7 to –4.4)

Table 2. Proximal DVT outcomes in the CLOTS-1 and CLOTS-2 trials of GCS for thromboprophylaxis in patients with acute stroke[10,11]

Summary points – good clinical quality requires:

- clinical units to develop and implement VTE prevention protocols that include
  - early assessment of adult admissions for risks of VTE and bleeding
  - prophylaxis, unless contraindicated, for all patients who have sufficiently high risk of VTE with an anticoagulant with or without a physical method
  - ongoing reviews of uptake and of changing evidence

A video of the Medicine Grand Round can be viewed at http://vimeo.com/65690462

PREVENTING VTE IN MEDICAL INPATIENTS

Professor Alexander Gallus

VTE in medical patients

Prof Gallus began his presentation with some general observations. Firstly, the wide spectrum of adult medical inpatient admissions means it is not sensible to recommend anticoagulant prophylaxis for all. Secondly, it is important, because there are far fewer data from medical than surgical patients, to accept there is room for valid debate about the relative clinical benefits and harms of anticoagulant prophylaxis in medical patients. Thirdly, debate has been coloured at times by suggestions that some experts recommending a greater uptake of prophylaxis may have been 'conflicted' by their roles in industry-sponsored studies. Industry-sponsored studies have been pivotal to better understanding, but like all clinical study results, theirs must also be interpreted critically. During question time, he reminded the audience that industry-sponsored study design is bound to regulators' requirements, which are usually conservative.

When heparin was discovered in the 1930s, small doses were given after surgery to prevent VTE, and were adjusted to 'normalise' blood clotting tests. However, for anticoagulant prophylaxis to be feasible across the board, it needs to be simple. In the early 1970s, it was found that fixed doses of unfractionated heparin, 5000IU given twice or three times a day, could substantially reduce subclinical thrombosis rates in medical patients (typically elderly with myocardial infarction, respiratory illness, etc).

Medical illnesses contribute about half the hospital-acquired burden of VTE, with an incidence of 1–1.5 per 1000 patients (Figure 3).[12] A potentially important difference of surgical patients, apart from their surgical condition, is that they usually arrive in hospital in a relatively healthy state, which makes the period of increased VTE risk more definable. Medical patients are often clinically more complicated and harder to categorise.

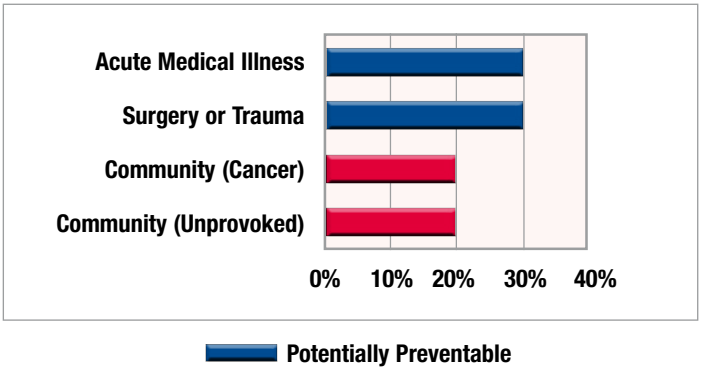


Figure 3. Sources of patients with symptomatic VTE

Estimates derived by applying a risk assessment model to US hospital data show fairly consistent levels of DVT and PE risk levels across most medical conditions, except for stroke where the risk is much greater.[13,14]

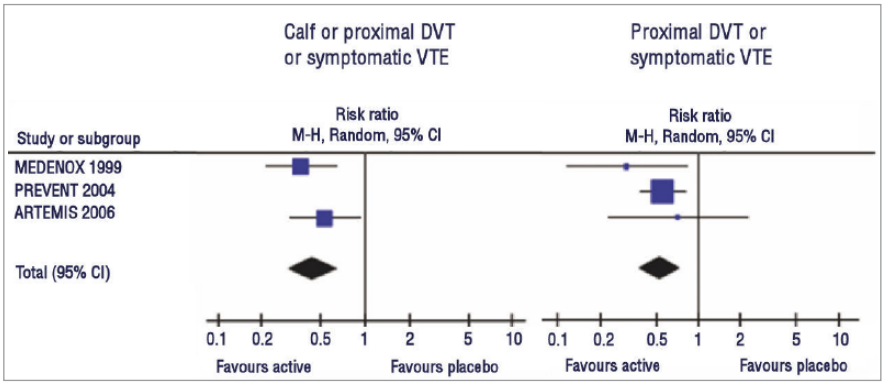
VTE prevention methods

Accepted methods for preventing VTE in medical inpatients include heparins (unfractionated, LMWH), GCS and good clinical care (i.e. mobility, hydration). The best evidence for the use of heparins in VTE prevention comes from three placebo-controlled double-blind trials.[6-8] Thromboprophylaxis in MEDENOX (enoxaparin), PREVENT (dalteparin) and ARTEMIS (fondaparinux) led to similar relative risk reductions of any VTE (all subclinical and symptomatic events) and proximal DVT (see Table 3). Data from these trials, summarised as a forest plot, show a significant reduction in the risks of VTE and a nonsignificant trend towards more bleeding (Figure 4). Sceptics argue the evidence does not include significant reductions of symptomatic events or sufficiently examine effects on bleeding; the studies were not powered for these. They also question if the trial results can be generalised to usual clinical practice (due to restrictions on study entry)? These important reservations need further study, and discussion.

Trial	MEDENOX[6]	PREVENT[7]	ARTEMIS[8]
Heparin	Enoxaparin	Dalteparin	Fondaparinux
Dosage	40 mg/day	5000IU	2.5 mg/day
Duration (d)	6–14	14	16
Assessment method	Venography/ultrasound	Ultrasound (d21)	Venography
Relative risk reduction			
– Any VTE	63%*	44%*	47%*
– Proximal DVT	65%*	54%*	27%

*Statistically significant

Table 3. Placebo-controlled, double-blind trials of VTE chemoprophylaxis in medical patients



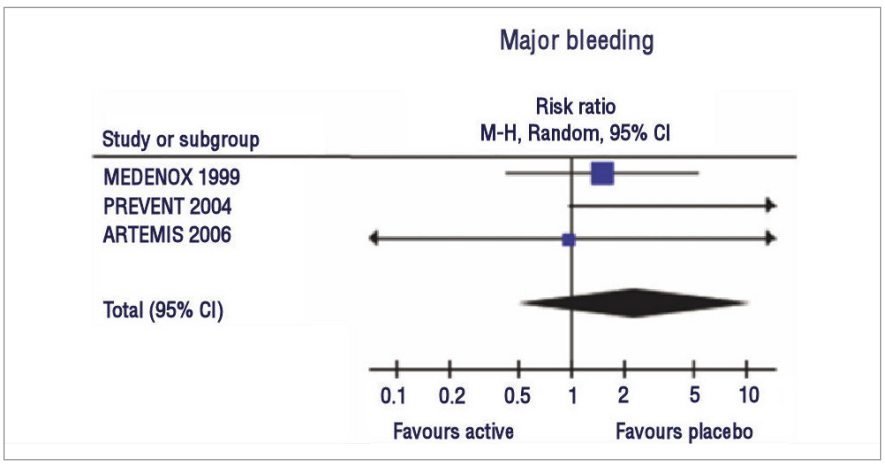


Figure 4. VTE and bleeding risks in the MEDENOX, PREVENT and ARTEMIS placebo-controlled, double-blind trials[6-8]

Is a clinical trial outcome of subclinical DVT relevant to symptomatic outcomes?

The relevance of subclinical DVT (as measured in many VTE prevention trials) to clinically important outcomes has been challenged, and recent guidelines rely more on evidence about symptomatic DVT and PE for their practice recommendations. When considering medical inpatients, the evidence about clinical outcomes is limited, so the basis for recommendations remains less direct. However, there is strong evidence that effects on subclinical DVT rates have meaning. Autopsy studies confirmed that fatal emboli often start as subclinical events, in deep veins of the leg or pelvis. There were consistent relative risk reductions for any DVT, proximal DVT and proximal DVT plus clinical events in pooled data from four randomised controlled trials of enoxaparin versus fondaparinux after joint surgery (see Table 4)[15] (and in more recent studies of new oral agents). Measured effects on subclinical DVT indicate the agent is efficacious; however, they are not enough because they do not provide information on the balance between symptomatic disease and bleeding risk (Figure 5). That clinical balance needs to be ascertained, and can be approximated using sensible assumptions. The latest ACCP guidelines for medical inpatients estimate a significant risk reduction in symptomatic DVT, a trend for risk reduction of nonfatal PE, no mortality effect, and a trend, with very wide CIs, for increased major bleeding (Figure 6).[16]

Efficacy measure	Enoxaparin	Fondaparinux	Common OR (95% CI)
	Relative risk reduction		
Any VTE (venogram plus clinical)	13.7%	6.8%	55.2% (45.8, 63.1)
ACCP (proximal DVT, any clinical VTE, fatal PE)	3.3%	1.7%	49.6%
CPMP (proximal DVT, any clinical VTE, any death)	3.9%	2.1%	48.0%

Table 4. Pooled results of four randomised, double-blind comparisons of enoxaparin (n=2682) and fondaparinux (n=2703)[15]

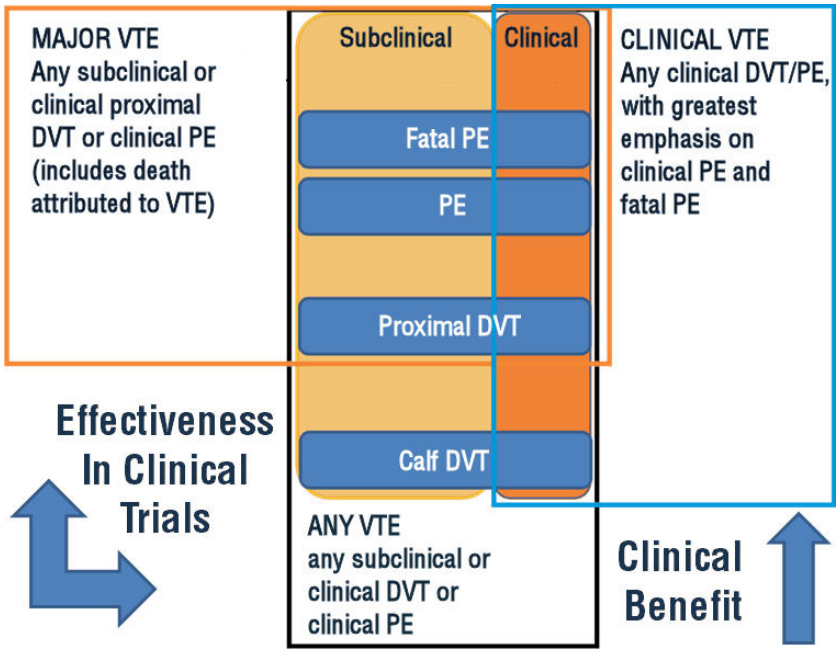


Figure 5. Measuring effectiveness/clinical benefit

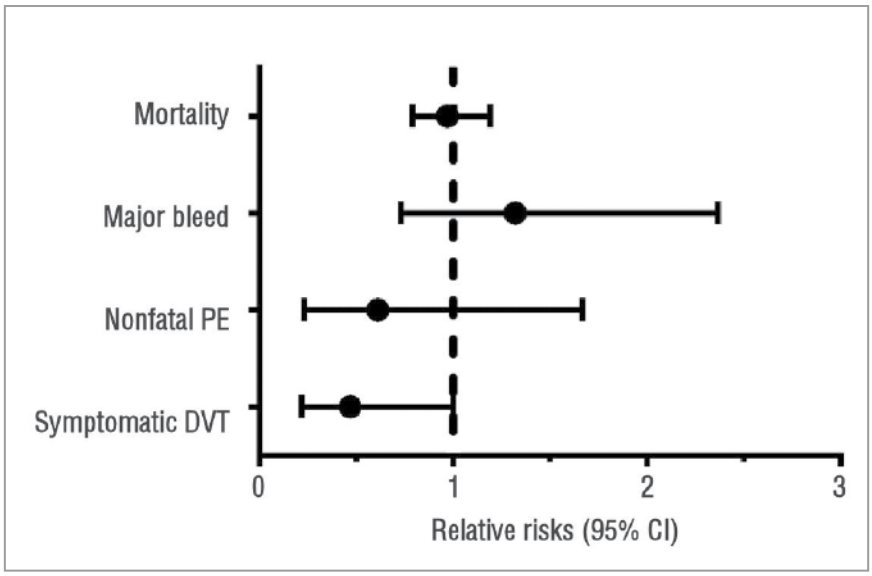


Figure 6. Estimated clinical treatment effects of LMWH or unfractionated heparin versus placebo/no treatment.[16]

How well do the medical in-patients recruited for VTE prevention trials compare with patients from routine hospital practice?

Surveys suggest that ~50% of usual general medical inpatients would match the inclusion and exclusion criteria (e.g. bleeding risks) applied to patients recruited for the VTE prevention trials referenced above.

The ENDORSE study was a global survey of risk for VTE and receipt of prophylaxis in 68,183 inpatients from 358 acute-care hospitals in 32 countries.[17] In the Australian subset of ENDORSE, most at-risk surgical patients received prophylaxis, but only about half of medical patients did (Figure 7).

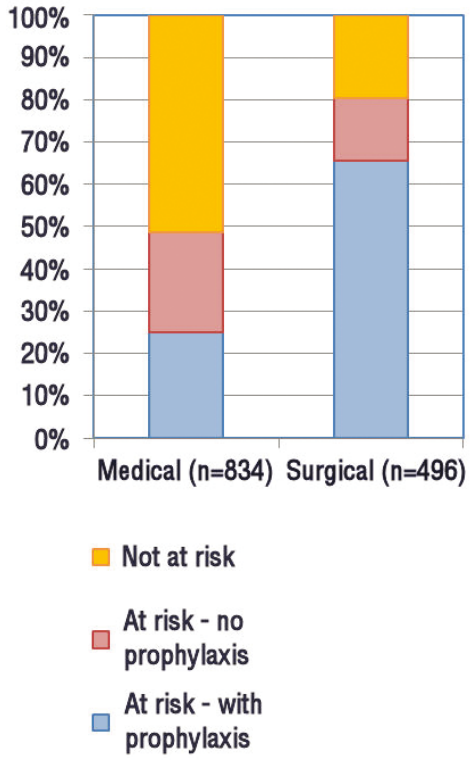


Figure 7. VTE risk and prophylaxis in the Australian subset of ENDORSE study[17]

Matching VTE prophylaxis to the risk of developing VTE

In a Swiss audit of 1091 medical inpatients in eight hospitals, ~60% of high-risk patients received thromboprophylaxis, but so did ~40% who were not at high risk.[18] Furthermore, there was a strong correlation between a hospital's overuse and underuse of VTE prophylaxis (the more overuse in low-risk patients, the more the usage in high-risk patients, and vice versa).

Risk assessment

Risk assessment can be implicit (based on clinical judgment) or explicit (using a tool for risk assessment that applies a weighted list of known and validated risk factors). There has been limited validation of tools recommended for estimating the risks of VTE and of bleeding, but their use is preferable to not performing any risk assessment at all (of course any locally used assessment instrument can be replaced by more accurate, validated tools when they become available). Perhaps the most attractive VTE risk assessment tool is the PADUA prediction score (see next page), which is based on clinical data from 1180 consecutive medical inpatients of one medical service, followed for 90 days.[19] While the score was based on expert opinion, the symptomatic VTE rate among the 186 high-risk patients who received adequate prophylaxis was 2.2%, compared with 11.0% for the 283 high-risk patients who received no or inadequate prophylaxis; the rate among

the 711 low-risk patients, who received 'no or inadequate' prophylaxis, was 0.3%. The presently most attractive bleeding risk assessment tool comes from a multiple regression analysis of data from the multinational IMPROVE registry of 10,866 medical inpatients (see below).[20] Note that several important bleeding risk factors (e.g. older age, active cancer) also contribute to thrombosis risk.

PADUA VTE risk assessment	
Active cancer	3
Previous VTE (not SVT)	3
Reduced mobility (bathroom privileges; >3 days)	3
Known thrombophilia	3
Trauma and/or surgery	2
Aged ≥70 years	1
Heart and/or respiratory failure	1
Acute MI or ischaemic stroke	1
Acute infection/inflammation	1
BMI >30 kg/m^2	1
Hormone therapy	1
Total score ≥4 denotes high risk	

IMPROVE scores and bleeding risk		
Age 40–84 years	1.5	VTE risk in IMPROVE and others[20,21]
Age ≥85 years	3.5	
Current cancer	2	
ICU/CCU admission	2.5	
Rheumatic diseases	2	
Central venous catheter	2	
Liver failure (INR >5)	2.5	Avoid chemoprophylaxis
Platelet count <50	4	
Bleeding ≤3 months	4	
Active gastroduodenal ulcer	4.5	
GFR <30	2.5	
GFR 30–59	1	
Male	1	
Bleeding risk increases exponentially above total score of 7		

Postdischarge thromboprophylaxis

There is good evidence for postdischarge thromboprophylaxis after some types of surgery (arthroplasty, hip fracture, operations for cancer), but not for medical inpatients. There were, in the ARTEMIS, an additional 10 fatal PE events during the 30 days after discharge (regardless of in-hospital treatment with fondaparinux or placebo), compared with five such events while in hospital (all in the placebo arm).[8] This and other similar observations raised the questions of whether late deaths from PE could be prevented by continuing prophylaxis for some time after discharge from hospital. A crude overview of results from three placebo-controlled trials done to address this question (Table 5) found that, although ongoing prophylaxis did reduce VTE rates, it increased the rate of major bleeding, so there was no net clinical benefit (Figure 8).

Trial	**EXCLAIM[22]**	**ADOPT[23]**	**MAGELLAN[24]**
Agent	Enoxaparin	Apixaban	Rivaroxaban
Dosage	40 mg/d	2.5mg twice daily	10mg once daily
Duration (d)	28d*	30d*	35d*
*All postdischarge regimens were preceded by 10±4d of enoxaparin 40 mg/d			

Table 5. Placebo-controlled trials of extended VTE chemoprophylaxis in medical patients

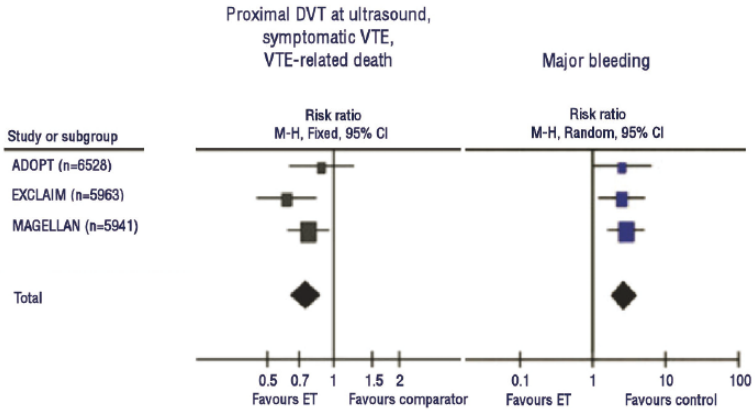


Figure 8. Risk of VTE and major bleeding with in meta-analysis of extended thromboprophylaxis in medical patients

Prof Gallus also briefly discussed GCS, which had been previously discussed in the forum. He noted that the evidence regarding their benefit in medical patients is 'slim to nonexistent' and there is 'pretty good evidence' of harm, and he did not recommend their use.

Take home points – challenges of thromboprophylaxis for medical patients.

- Variable thrombosis and bleeding risk
- Incomplete evidence
  - Uncertain predictors of VTE or bleeding
  - Effectiveness in clinical trials driven by subclinical calf/proximal DVT (underpowered for clinical VTE)
- Protocols should tailor prophylaxis to risk
  - Choose risk assessment models (VTE and bleeding)
  - Choose preferred methods
  - Ensure early start of prevention
  - Check for bleeding risk (platelets, creatinine)
  - Reassess whenever clinical conditions change

A video of 'Preventing VTE in medical inpatients' by Prof Gallus can be viewed at http://vimeo.com/65694654

OPTIMISING UPTAKE OF VTE PREVENTION IN HOSPITALS

Professor Alexander Gallus

The emphasis for this topic was optimising, which can mean different things to different people. Those who interpret clinical trial results sometimes calculate net clinical benefit (e.g. episodes of symptomatic VTE minus episodes of major bleeding). Prof Gallus discussed how the individual patient often defines what an optimal outcome is.

Guidelines

Guidelines are developed to guide clinical practice, and should be a nonbiased and comprehensive source for: i) information about the relative benefits and hazards of clinical interventions; ii) advice on evidence-based clinical practice; and iii) clinical practice protocols and standards. Guidelines now require a comprehensive review of evidence, which is expensive and time and energy consuming. As methodological requirements have evolved, guidelines have become more detailed and more complex, with less specific advice. However, there is awareness that advice that is too specific might invite more medicolegal consequences than are desirable. All VTE prevention guidelines recommend: i) formal VTE prevention protocols; ii) early VTE **and** bleeding risk assessments for all admitted patients; iii) appropriate prophylaxis for patients with a high VTE risk, unless contraindicated; and iv) continuing implementation. There are a number of available guidelines adjusted for emerging evidence and with locally relevant emphasis, etc.

Guidelines also differ in their details. For example, the Scottish guidelines recommend aspirin for preventing surgical VTE; the 2008 ACCP had a 1A recommendation against aspirin; AAOS (American Academy of Orthopaedic Surgeons) guidelines at first recommended no prophylaxis other than aspirin, except in patients at greater than average risk after arthroplasty. In 2011, the AAOS changed their guidance to thromboprophylaxis for all arthroplasty patients, but offered little guidance for choice between modalities. In 2012, the ACCP changed their recommendation against aspirin from 1A to 1B, and gave a 2B/2C recommendation for LMWH over warfarin or aspirin. So, it is not only that evidence does change, but guideline groups may change their opinion/interpretation of evidence. Local protocols therefore require ongoing review to consider changes in evidence and the response of guidelines and stakeholders. The Australian guidelines were based on 2008 ACCP guidelines, but have become obsolete as subsequent international guidelines have evolved.

Implementing protocols

Evidence-based guidance needs to be translated into clinical practice. The ENDORSE study (which looked at VTE risk and prophylaxis on a single day in 358 hospitals from 32 countries) reported lower prophylaxis rates in at-risk medical patients compared with at-risk surgical patients (Table 6).[17] The problem with prophylaxis for low-risk patients is that lower baseline risk is associated with less absolute improvement, while bleeding risk remains, so that bleeding risk can exceed the benefit.

	Medical	Surgical
Patients	37,356	30,827
Low VTE risk*	21,869 (58.5%)	10,985 (35.6%)
Prophylaxis	29%	34%
High VTE risk*	15,487 (41.5%)	19,842 (64.4%)
Anticoagulation contraindicated	10%	9%
Prophylaxis*	39.5%	58.5%
Prophylaxis (Australian subset)*	51%	82%
***ACCP recommended**		

Table 6. VTE risk and prophylaxis rates in the ENDORSE study[17]

The reasons for differing rates of prophylaxis between 'high-risk' medical and surgical patients are uncertain (see below). The processes for optimising VTE prophylaxis in medical and surgical patients are essentially similar. The first steps are consultation with appropriate stakeholders, agreement on protocols and choice of method of prophylaxis (modality and duration). Audit, feedback and review follow, with subsequent adjustment of protocols as needed. It is important to have all admitted adult patients risk assessed for both VTE and bleeding (e.g. PADUA and IMPROVE, respectively – other available risk assessment tools probably do not differ much), have the assessments and decisions about prophylaxis recorded, and regularly review each patient while hospitalised. These processes should be embedded into standard hospital practice.

Elective general surgery	Medical inpatients
Main VTE/bleeding risks start with and relate to surgical procedure Orderly and scheduled process: pre-anaesthesia clinic; surgery; recovery Large, consistent body of evidence Opt out ≫ opt in	Multifactorial, graded risks for VTE/bleeding Unplanned, acute on chronic, reasons to admit Much less extensive evidence More sceptical clinicians? Opt in > opt out

Clinical practice change

The processes for changing clinical practice can be challenging. There are many different ways to improve the uptake of VTE prophylaxis in hospitals, but the task should become much easier once electronic medical records are introduced (see below). Electronic record systems could provide real-time alerts when VTE prophylaxis has not been prescribed and, potentially, a real-time risk assessment. Changing clinical behaviour also requires considerable effort. Just making information available is ineffective, so active strategies are necessary to bring about changes in behaviours. Such strategies include computer-based clinical support systems, audits with feedback and documentation aids.

Before Electronic Records	After Electronic Records
Guidelines → protocols Awareness and information – intranet, pocket cards Medical record stickers/stamps Prescribing chart Audit/feedback/adjust/repeat	Computer-based order entry Clinical support systems Real-time risk assessment Early electronic alerts/reminders

It is vital that a problem is shown to be real and important to the individuals whose behaviour we seek to change. Audits can provide appropriate feedback that is useful for identifying and illustrating problems that otherwise might not be perceived by some individuals. Additional essential components include processes to demonstrate clinical importance and raise understanding, reminders and prescribing aids and, critically, person power. The latter is often the limiting factor, as often people are taken from other jobs, and may be part-time, usually there is insufficient funding, and other priorities compete, so that success depends on juggling many tasks.

Important considerations when assessing impact include the Hawthorne effect, reminder fatigue and reporting KPIs/clinical outcomes. The 'Hawthorne effect' classically describes the way individuals change behaviour when they know they are being observed.

It is also important for achievements to be sustained. Durieux et al conducted a crossover study in which surgeons received an electronic reminder about VTE prophylaxis if they had not included a prophylactic regimen when entering their electronic orders for prescriptions after surgery.[25] There were three 10-week intervention periods, and four 10-week control periods (separated by 4-week washout periods). The results consistently showed improvements in appropriate prescriptions for VTE prophylaxis during each intervention and consistent decreases during each control period (Figure 9).

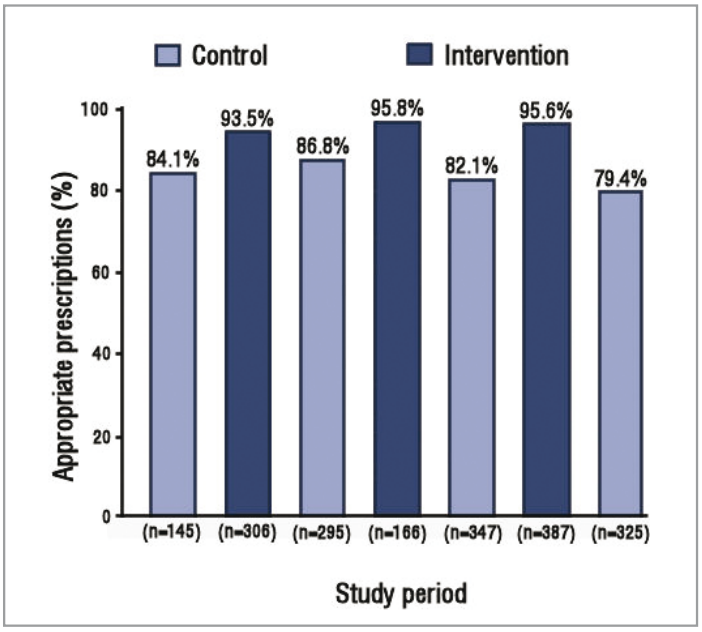


Figure 9. Appropriate prescription rates among surgeons with versus without electronic reminders during postsurgical electronic order entry[25]

A comparison of clinical support systems for VTE prophylaxis in medical inpatients found no benefit from pocket cards and PDAs, and only small benefit with a primitive electronic alert.[26] However, Kucher et al did find an increased rate of appropriate VTE prophylaxis, from 44% to 76% among 1027 medical admissions with the use of a continuously flashing electronic reminder message on ward computers. The reminder activated if the patient was without prophylaxis >6 hours after admission, and was visible to nurses and physicians, but only physicians could deactivate it, and then only if they took appropriate action.[27] Piazza et al reported outcomes as well as VTE prophylaxis rates with use or nonuse of a physician alert in 2493 patients (82% medical).[28] While the alert was associated with a significant improvement in the KPI of appropriate prophylaxis rate (46% vs. 21%; p<0.0001), the decrease seen in the VTE rate did not reach statistical significance (2.7% vs. 3.4%; hazard ratio 0.79 [95% CI 0.5, 1.5]). However, Prof Gallus commented that a study with much greater numbers would be needed to detect a statistically significant difference for this outcome. He concluded that, assuming the difference in VTE outcomes is real and it can be achieved with minimal effort, an improvement of this size (~20%) is worth achieving, noting that far smaller effects are often sought in other fields such as cardiology.

Take home points

- Theory is simple
  - Identify the need (better prophylaxis)
  - Gather consensus
  - Inform, persuade, act → change
- Practice is hard and continuing
- Aim is to safely prevent the preventable

A video of 'Optimising uptake of VTE prevention in hospitals' by Prof Gallus can be viewed at http://vimeo.com/65697436

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UPDATES FROM DHBS

Waitemata

Dr Eileen Merriman

Dr Merriman presented the findings of an audit at North Shore Hospital of VTE rates in patients undergoing major hip and knee joint surgery.

Background: Major orthopaedic surgery is an important risk factor for VTE, although rates are now around 4.3% when no prophylaxis is given, and LMWH prophylaxis is associated with a relative risk reduction in DVT of 50–60%.[1] Data pooled from the RECORD trial showed VTE incidence rates of 0.4% and 0.8% with rivaroxaban and LMWH, respectively.[2] The risk is greatest during the first 2 postoperative weeks, but remains elevated for up to 2 months.[3] VTE is associated with significant mortality and morbidity, and bleeding rates associated with appropriate prophylaxis are low.

Aim: The main aim was to document symptomatic DVT and PE rates within 3 months of major hip and knee joint surgery at Waitemata DHB. Secondary aims included documentation of: i) rates and types of prophylaxis received by these patients; ii) subsequent treatment for acute VTE; iii) all-cause mortality in patients with VTE; and iv) bleeding rates associated with VTE treatment.

Methods: A retrospective audit of prospective database and hospital records on patients undergoing major orthopaedic surgery between Jan 2006 and Dec 2010 who experienced an objectively confirmed VTE within 3 months of surgery. RV strain was defined as evidence of: i) elevated RV pressures; ii) flattening of the interventricular septum in systole (so called D-shaped septum); iii) RV:LV end-diastolic ratio >0.9; iv) RV hypokinesis; or v) RV diameter >90% or greater than the size of the LV diameter. Bleeding was classified as major, clinically relevant nonmajor, nonmajor and minor according to the International Society on Thrombosis and Haemostasis (ISTH) definition criteria.

Results: The audit included 2306, 1481 and 1259 patients with THR, TKR and fractures, respectively, and VTEs occurred within 3 months of surgery in 80, 36 and 56 of them, respectively (Figure 10). The overall 3-month symptomatic VTE rate was 3.41%. The median times from surgery to VTE were 10 days, 6.5 days and 5.5 days for fracture, THR and TKR, respectively. Complications included right heart strain (44% of PEs) and major and minor bleeding (7.5% each). The 3-month all-cause mortality rate was 2.9%, with at least one death attributed to PE.

Discussion: The VTE rates following TKR and fracture surgery are similar to rates reported by the ACCP among patients who receive no prophylaxis. Patients admitted for elective surgery received prophylaxis more consistently. Most VTEs were distal DVTs, but PEs were significant, particularly following TKR and fracture surgery, with nearly half being large-volume PEs.

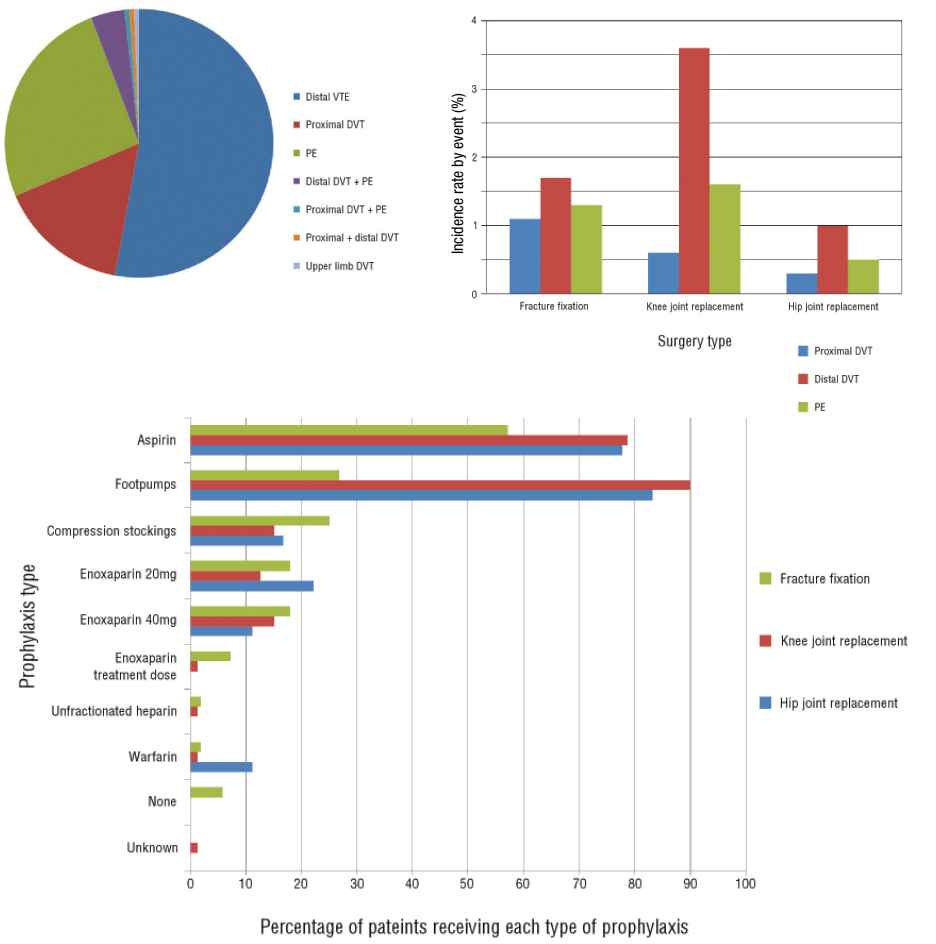

Figure 10. VTE within 3 months of surgery in 5046 orthopaedic patients from the Waitemata DHB

Summary points

- **VTE incidence after major hip/knee joint surgery at Waitemata DHB is high (3.41%)**
- **Prophylaxis with aspirin and foot pumps is suboptimal**
- **Appropriate extended duration prophylaxis is needed to decrease VTE rates, especially in knee joint and hip fracture surgery**
- **Further education is needed, particularly appropriate extended duration prophylaxis and timing of initiating prophylaxis**
- **Outcomes of interventions can be assessed by further audits**

Lakes

Dr Ulrike Buehner

This was an update on key recommendations made to front-line clinicians on VTE prevention at Rotorua hospital. The aims were 100% compliance with routine VTE risk assessment within 24 hours of admission, 100% compliance with evidence-informed thromboprophylaxis, and a reduction in avoidable deaths and disability from hospital-acquired VTE events. Good improvements were seen in all departments after the VTE prevention scheme was introduced (see Table 7). The challenge of maintaining the good outcomes was facilitated by: i) the appointment of a (part-time) VTE prevention nurse/educator to follow-up with new staff, etc; and ii) the classification of VTE prevention as a KPI at a workshop with management and senior medical staff. A trend for improving outcomes has been seen (Figure 11). Correct prescribing rates are particularly good, with 100% for medical, surgery and obstetric departments, and 77% in the orthopaedic department. While VTE prophylaxis compliance is overall excellent among elective orthopaedic patients, trauma patients are an area that has been identified for further improvements. Trauma patients are not considered for VTE chemoprophylaxis until after surgery, and several have experienced postsurgical PE events.

Department	Baseline (June 2011)	Post-VTE prevention scheme (April 2013)
Medicine	40%	95%
Obstetrics	80%	91%
Orthopaedics	35%	90%
Surgery	78%	92%

Table 7. Improvements in compliance with VTE prevention at Rotorua hospital

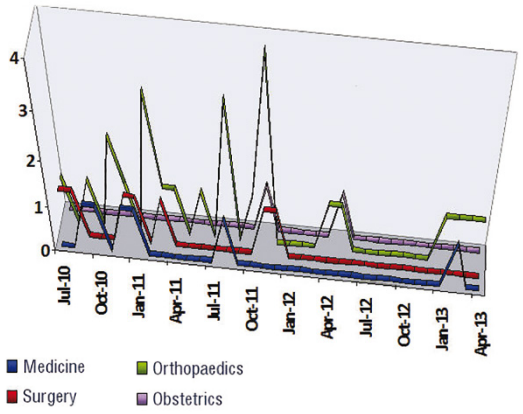

Figure 11. VTE event trends in patients at Rotorua hospital

It was also determined that many patients, particular orthopaedic patients, would have one or more contraindications to mechanical VTE prophylaxis (leg oedema, skin graft, lower leg dermatitis/cellulitis, morbid obesity, peripheral vascular disease, diabetic neuropathy). The following recommendations regarding mechanical VTE prophylaxis for surgical patients were described: i) only if there are no contraindications; ii) below-knee GCS only; iii) size and apply carefully; iv) daily assessment of skin and pressure areas; and v) respect patients' comfort. Contraindications for venous foot pumps are peripheral vascular disease, arterial ulcers and patient discomfort (which results in poor compliance), all of which put patients at increased risk of pressure ulceration of the heel, need for plastic surgery and limb loss.

Learnings obtained from the 'plan-do-study-act' cycles at Rotorua hospital were:

- lower limb trauma patients (including minor), especially with bilateral trauma and other risk factors, require timely VTE chemoprophylaxis
- venous foot pumps cause more harm than good, and are associated with poor patient compliance
- best VTE prevention is obtained by early mobilisation plus chemoprophylaxis in high-risk patients.

The key recommendations that emerged were:

- early mobilisation
- VTE chemoprophylaxis for high-risk patients unless contraindicated
- calf IPCs for immobile patients with contraindications to VTE chemoprophylaxis
- venous foot pumps not to be used (unfavourable risk-benefit/cost analysis)
- no GCS for medical patients
- consider below-knee GCS for surgical patients.

A telephone audit of 20 patients who received extended VTE prophylaxis (enoxaparin, n=15; rivaroxaban, n=5) found that all were compliant with treatment. Ongoing challenges are to: i) provide consistent early VTE prevention measures for (lower limb) trauma patients; ii) maintain and improve the achieved level of VTE prophylaxis standards; and iii) continue educating new staff and patients on VTE prevention.

Canterbury

Anthony Spencer

Christchurch Hospital took a fresh look at the evidence for VTE prophylaxis. The evidence shows a clear benefit for surgical patients, but the evidence in medical patients is less clear. Three meta-analyses (ACCP, Chest and Cochrane Review) include approximately ten studies relevant to medical patients. These studies have quite different criteria for inclusion/exclusion, diagnosis and treatment. The study populations were usually immobile, the length of stay >3 days, there were variations in strict exclusion criteria, DVT was investigated with routine venography in three of eight studies, fibrinogen scans in two and ultrasonography in one, and the participants received prolonged LMWH therapy. The Cochrane meta-analysis concluded that there were significant risk reductions in DVT and PE by 60% and 42%, respectively (these were asymptomatic on the whole); however, this was accompanied by a significant increase in major and minor bleeding risk, and there were no significant reductions in all-cause mortality or fatal PE.[4] This meta-analysis was 'withdrawn' in Jan 2010 after concerns about the 'information regarding fatal PEs'. The more recent meta-analysis for the ACCP reported that heparin prophylaxis in medical patients did not significantly reduce total mortality.[5] While there were fewer PEs, there was evidence of publication bias and an increase in bleeding events. Heparin prophylaxis had no significant effect on any outcome in patients with acute stroke besides an increase in minor bleeding events. The absolute reduction in PE was 3 events per 1000 patients, while the absolute increase in bleeding was 9 events per 1000 patients, four of which were major bleeds. The conclusion was that heparin prophylaxis had no significant effect on mortality, may have reduced PE and led to more bleeding events, thus resulting in little or no net benefit.

The current 'blue book' policy at Christchurch Hospital follows.

- Certain medical conditions, such as stroke, myocardial infarction, heart failure, chronic obstructive pulmonary disease, pneumonia, etc., increase the risk of DVT. Compared with surgical prophylaxis, there are relatively few trials designed to assess this risk and the degree of benefit, if any, associated with prophylactic treatment.
- Recommended prophylaxis schedule
  - SC enoxaparin 40mg daily, provided there are no contraindications (e.g. active bleeding). The dosage may need to be reduced in renal impairment – discuss with consultant.
  - Prophylaxis duration with heparins must be individualised. It should cover the obvious risk period, such as immobilisation, but must be stopped as soon as the perceived increased risk has passed.

Summary points

- ***Primum non nocere* (first, do no harm)**
- **Apply the evidence to the patient population**
- **Not in favour of routine risk stratification for unproven treatment**
- **Ongoing research into subgroups that may benefit**
- **Concern over pharmaceutical industry influence**

Capital Coast

Julia Phillips

Data from the Capital Coast DHB decision support unit, with a catchment population of 360,000, indicate that there were around 278 VTE diagnoses made each year between July 2007 and March 2012, with 115 of these being made after admission to hospital. Specialty distribution analysis showed that 28% were in patients from general medicine, 18% from oncology, 12% from orthopaedics, 8% were aged care and 7% were general surgery. A VTE prevention audit for 100 patients from each of four specialties from Jan 2010 and Jan 2011 showed that the rate of accordance with the DHB's draft VTE prevention guidelines was 45% overall, with some variability between specialties (Table 8); however, it was noted that most accordance with the guidelines was seen for low-risk patients.

Specialty	Accordance
Obstetrics	56%
Medicine	55%
Orthopaedics	40%
General surgery	29%

Table 8. Accordance rates with draft VTE prevention guidelines by specialty at the Capital Coast DHB in Jan 2010 and Jan 2011

The DHB's draft VTE prevention guidelines, which is based on international guidelines and was resubmitted for approval in April 2013, recommends VTE and bleeding risk assessments for all inpatients, with a decision on thromboprophylaxis made and documented in each case. Risk assessment flowcharts were developed for orthopaedics, gynaecology, obstetrics and other surgery, while the medicine and oncology departments have agreed to risk assess patients without the use of a flowchart.

It was noted that use of GCS or IPC devices was inconsistent across a range of medical and surgical settings. In addition, a lot of injuries were observed among patients receiving mechanical VTE prophylaxis, and the DHB was spending $400,000 on mechanical thromboprophylaxis, with $120,000 of that for GCS. After reviewing ACCP guidelines and other literature on mechanical thromboprophylaxis, they found no evidence that GCS are more effective than IPC devices, and that they do increase the risk of skin tears. The DHB's new protocol for mechanical thromboprophylaxis follows.

- Use sequential compression devices:
  - in operating theatre and PACU or ICU if surgery >1 hour
  - in operating theatre and recovery for caesarean section
  - on the ward for major abdominal/orthopaedic surgery until fully mobile
  - in ICU for long-stay patients
- Anti-embolic stockings should be used only in patients with high risks of both thrombosis and bleeding who are not candidates for sequential compression devices.

As a result, fewer stocking injuries, cost savings of >$50,000 per year and no increase in VTE events are anticipated.

Counties Manukau

Gordon Royle

Middlemore Hospital had 210 patients admitted to its thrombosis service over a 6-month period, of which 73 (35%) were VTE that occurred during (n=25) or within 3 months of a hospital admission. Nearly half of the hospital-related VTEs occurred in patients aged 60–80 years, and the rate in females was double that of males. Two-thirds of hospital VTEs occurred in patients of Caucasian ethnicity, even though Caucasians make up less than half (~40%) of the population in the catchment area. Furthermore, 41% of the hospital-associated VTEs were PEs and 21% were proximal DVTs. Orthopaedic patients accounted for 42 of the hospital-associated VTEs, and there were 15 medical patients (9 with cancer) and 16 other surgical patients. The rate of hospital-associated VTEs was 1.8% for all orthopaedic discharges, compared with 0.28% for all medical discharges. According to risk assessment tool criteria, 65 of the 73 hospital-associated VTEs occurred in high-risk patients. Although most of these patients received some form of thromboprophylaxis, 19 received none. Of those who did receive thromboprophylaxis, 19 received enoxaparin (two received suboptimal doses), 13 received aspirin as their only chemoprophylaxis and 25 received mechanical thromboprophylaxis. Using an efficacy rate of 50–90%, 3–6 deaths could be prevented annually. Of possibly greater importance, preventing clots in inpatients could prevent significant morbidity as well as reducing costs associated with caring for patients with DVTs and PEs.

A single risk assessment tool for all patients (surgical and medical) has been developed. It is included in the admission document when patients are admitted acutely, and also in the elective surgery admission pack. It avoids being overly prescriptive to avoid medicolegal issues. It was described as more of a guideline with helpful lists of things to look for. A lanyard card also summarises the basics, while reminding the treating physician not to suspend clinical judgement. Of note, mechanical thromboprophylaxis has been removed from the recommendations, as have the obstetric and stroke subpopulations. The focus for medical patients is on those with a history of active malignancy, thrombophilia or significant obesity.

During question time, Prof Gallus asked if there is a difference in how patients from different ethnicities receive treatment that results in differences between VTE events being detected in hospital versus the community and possibly explaining some of the reported differences. However, this was not felt to be the case to a degree that would account for the observed ethnic differences. The general consensus among attendees was that there are fewer VTE events among individuals of Māori and Pacific Island ethnicities.

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NATIONAL POLICY FRAMEWORK: VTE PREVENTION IN ADULT HOSPITALISED PATIENTS IN NZ – UPDATE AND DISCUSSION

This session began with a brief presentation by Anne Blumgart, coordinator of the National Policy Framework, on the document's development and contents. This was followed by discussion of the Framework on its current place in the prevention of hospital-associated VTE and its future development as a living document. This discussion included issues that had already been raised and discussed to some degree during the day. As such, some of the information included in this section may have only been articulated during previous presentations, particularly during the question times, but is included in this section for contextual purposes.

Funding from the HQSC enabled 6 months to prepare the National Policy Framework, culminating with its publication in June 2012. There was much consultation with many individuals involved in developing the document, with great review processes. The framework is based on best evidence and practice, and incorporates guidance on VTE quality improvement, clinical guidance and examples of resources for sharing. Many groups, including other DHBs, have used the guidance in the framework to develop their own protocols and policies. However, it is important that it remains a living document. An informal meeting with Ian Civil and the HQSC concluded that:

- The National Policy Framework should be cognisant of variation and recognise that there is a range of clinical treatments within various specialities.
- Each unit/hospital should be encouraged to develop appropriate risk assessment guidelines and policy on appropriate prophylaxis. They should then ensure that every patient is being assessed and treated according to that policy. Both risk assessment and treatment should be documented.

- Preventing harm from VTE will be an area of focus for the Perioperative Harm work programme at the HQSC. Initial work will focus on ensuring that all surgical safety checklists across the country have a check for thromboprophylaxis, as this has been shown to improve compliance to thromboprophylaxis guidelines.

Anne reminded the attendees that patient outcomes are the main focus of the framework.

Discussion

The issue of whether national guidelines should be developed was raised. While the framework team acknowledged how useful it would be to have national guidelines, they commented that, at least at this stage of the process, they had been careful not to call the document a guideline, but to still describe the components necessary for an organisation/DHB to formulate its own guideline that takes into account its particular requirements. The main reason given for the approach taken with the framework document was difficulties associated with obtaining buy-in and consensus from each organisation. However, it was considered that a national guideline could be a worthwhile next step from the current achievements, and it was also pointed out that the development of a national guideline would eliminate the multiplication of effort and resources that would occur by each DHB developing their own guideline. The comment was also made that the development of the framework document was led and co-ordinated by a small group of dedicated individuals from local hospitals, while a national guideline is best managed at a governmental level. Prof Gallus added that top-down approaches for clinical protocols tend to not work very well, and that local protocols would be more realistic. There were discussions around what the roles of DHBs' CEOs should be in VTE prevention, along with the comment that KPIs help to keep things progressing at that organisational level, in contrast to the hard outcomes that front-line health professionals tend to seek.

One of the CMOs present pointed out the importance of having a minimum accepted standard of practice and documentation for VTE prevention, particularly for medicolegal reasons. At the top level of organisations, where decisions are made, good risk-to-benefit evidence needs to be available to justify the costs (both monetary and resources) necessary to support and implement a VTE prevention policy, and there was a general feeling among those present at that level that the evidence is still not clear. Prof Gallus made the observation that VTE prevention should not be made too complicated, and administrators tend to associate complication with costs and resource use.

One of the notable areas of disagreement was the need to risk assess all medical patients, and whether an opt-out approach is better than an opt-in one. However, the general consensus was that all medical inpatients should, and in many cases probably are, risk assessed for VTE and bleeding, whether that occurs via a formal risk assessment or a more informal case-by-case clinical judgement basis. Regarding the implementation of formal risk assessments, the attendees were more divided. The haematologists and clinicians in the room tended to favour a more inclusive 'risk assess everyone' approach, while surgeons and administrators appeared to have a more cautious approach stating concerns regarding insufficient or unclear evidence, time pressures and use of resources in an already pressured environment. Proponents of an all-inclusive approach believed that, once established, the process of risk assessing everyone should not require much additional time or administrative procedures if embedded in existing admission processes, as many clinicians are assessing medical patients on an informal basis anyway. With respect to unclear/insufficient evidence, particularly fatal PE, which has not been demonstrated to be reduced to a statistically significant degree (due mainly to insufficient power of the clinical trials to detect such a change), it was pointed out that other clinical outcomes are also important, with the potential for VTE complications (e.g. PTS) to have a significant impact on patients' quality of life for many years beyond their thrombotic event. The individuals involved in developing the framework document were clear that it was not designed to be prescriptive, but to ensure all physicians are considering VTE in all patients, and then for each individual institution to formulate its own policies and processes to minimise the risk of VTE events. Prof Gallus believes about 80% of the desired outcome can be achieved by applying common sense. He described the must-have processes of risk assessments (for clinical and medicolegal reasons) and local protocols.

A representative from a private hospital commented on the importance of ensuring there is buy-in for VTE risk assessment and VTE prevention from both public and private hospitals, given that there is quite a lot of crossover with both patients and staff being transferred between private and public institutions.

Where to next…

One of the plans for the framework document moving forward is to, at the advice of the HQSC, put together an abbreviated 1–2 page version for the surgical perspective. With the importance of embedding risk assessment into everyday clinical practice highlighted throughout the forum, it was noted that some physicians, while still considering a patient's VTE/bleeding risk, are prescribing thromboprophylaxis without any documentation of their VTE and bleeding risks. It was therefore proposed that a national policy defining the minimum standard be developed, which would likely address risk assessment while leaving VTE prophylaxis up to each organisation or physician to exercise clinical judgement. Having clinical VTE events made reportable was also suggested as a way for improving compliance with risk assessments. It was also suggested that letters be sent to the CEO and board of the HQSC to ask for VTE prevention to be officially included in the National Patient Safety Campaign for the coming year, with the key individuals who have been working on the framework document forming the necessary advisory working group. Anne Blumgart also commented that an important deficiency in the current environment is the lack of processes included in day-to-day workflow for following an individual patient's journey, and measures to address this would facilitate processes aimed at reducing hospital-associated VTE. Demonstrating that the number of hospital-associated VTEs is decreasing with interventions targeted at preventing them is also important. It was suggested that all DHBs should be required to report the annual number of hospital-associated VTEs to the HQSC. Also data on the costs of hospital-associated VTE from the ACC could help drive improvements.

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