PREVENTION OF

Venous Thromboembolism

The Australia & New Zealand Working Party
on the Management and Prevention
of Venous Thromboembolism.

Best Practice Guidelines for
Australia & New Zealand

4th Edition

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The Australia & New Zealand Working Party on the Prevention of Venous Thromboembolism consists of a group of experts dedicated to promoting best practice in the prevention, treatment and management of venous thromboembolism. They are:

Professor John Fletcher (Chairman)
Professor of Surgery,
University of Sydney,
Westmead Hospital, Sydney

Professor Donald MacLellan
Director of Surgery,
NSW Health,
North Sydney

Assoc Prof Ross Baker
Consultant Haematologist,
University of Western Australia,
Royal Perth Hospital, Perth

Professor Beng Chong
Professor of Medicine,
University of NSW,
St.George Hospital, Sydney

Dr Charles Fisher
Vascular Surgeon,
Royal North Shore Hospital,
Sydney

Dr Damian Flanagan
General Practitioner,
Mornington Peninsula,
Victoria

Professor Alex Gallus
Professor of Haematology,
Flinders Hospital,
Adelaide

Assoc Prof Harry Gibbs
Vascular Physician,
Princess Alexandra Hospital,
Brisbane

Dr Geoff Matthews,
Vascular Physician,
Austin & Repat. Med. Centre,
Melbourne

Professor Hatem Salem,
Professor of Medicine,
Monash University,
Alfred Hospital, Melbourne

Professor Michael Stacey,
Professor of Surgery,
University of Western Australia,
Fremantle Hospital, Fremantle

Professor Andre Van Rij
Professor of Surgery,
University of Otago Med School,
Dunedin, New Zealand.

INTRODUCTION

These updated guidelines have been developed by the Australia and New Zealand Working Party to assist in the identification and treatment of patients at risk of developing venous thromboembolism (VTE). The recommendations are based on the International Union of Angiology (IUA) and American College of Chest Physicians (ACCP) consensus statements adapted to Australia and New Zealand conditions. The recommendations issue from evidence based practice using the highest level of evidence available.

There are many clinical situations where the literature provides little information to direct recommendations for VTE prophylaxis. In these circumstances, the Australia and New Zealand Working Party has applied recommendations based on expert judgement and experience. These recommendations are the combined views of surgeons and physicians expert in thrombosis management and reflect their interpretation of available evidence as well as their subjective opinions about the relative effectiveness, hazard and cost of alternatives.

The members of the Australia and New Zealand Working Party hope that this booklet will encourage more appropriate and frequent VTE prophylaxis and treatment and in so doing reduce both patient suffering and health care costs.

1 IMPORTANCE OF PREVENTION

Although there is extensive evidence to guide proper prophylaxis and treatment of VTE, several surveys show that the evidence is not always being followed. One reason for this is that current approaches tend to focus on the acute management of deep venous thrombosis (DVT), rather than on its prevention and chronic sequelae.

Symptomatic VTE is a major health problem with an annual incidence of 160 per 100,000 for DVT, 20 per 100,000 for symptomatic non-fatal pulmonary embolism (PE) and 50 per 100,000 for fatal autopsy detected PE. The need for prevention applies regardless of ethnicity.

One of the sequelae of VTE is chronic venous insufficiency (CVI), a significant problem throughout the world. CVI decreases quality of life, increases health care costs by causing chronic oedema, cellulitis and recurrent venous ulceration and may cost the Australian Health Care system over $200 million annually. Venous ulcers develop in 300 per 100,000 population and the proportion due to DVT is approximately 25%.

DVT occurs in over 50% of some categories of hospitalised patients if prophylaxis is not used (Table 1) although many are asymptomatic. It prolongs the length of hospital stay, increases drug and laboratory costs and causes potentially fatal PE. PE remains the commonest cause of preventable death; 1% of all hospital admissions will die from this.

Table 1. Incidence of DVT* without prophylaxis

Patient Group	
Stroke	56%
Elective hip replacement	51%
Multiple trauma	50%
Total knee replacement	47%
Hip fracture	45%
Spinal cord injury	35%
General surgery	25%
Myocardial infarction	22%
Neurosurgery	22%
Gynaecological surgery	14-22%
General medicine	17%

* DVT detected by screening – includes symptomatic & sub-clinical DVT.

2 ASSESSMENT FOR PROPHYLAXIS

For effective VTE prophylaxis of surgical and medical patients, it is important to treat patients according to their individual VTE risk, their clinical condition, the bleeding risk and the appropriateness of the prophylaxis for the individual patient. The assessment for VTE prophylaxis should occur on admission to hospital and prophylaxis should commence without undue delay and be re-assessed on a regular basis to ensure prophylaxis remains appropriate. In hospital patients with a prolonged stay prior to surgery, prophylaxis should be commenced during the pre-operative period. Continued encouragement of ambulation and adequate hydration are important principles in all patients regardless of risk category.

3 VTE PROPHYLAXIS

3.1 Duration of Prophylaxis

The optimum length of VTE prophylaxis and treatment requires further research. Decisions regarding time of commencement and duration of prophylaxis should be made for each patient individually. However, in most studies, prophylaxis was used for at least 10 days in high-risk patients, 10 days or more in patients with knee replacement and 28-35 days in patients with hip replacement or hip fracture. In medical patients, prophylaxis should continue until resolution of their acute medical illness or hospital discharge.

3.2 Day Surgery & Minor Surgery or Procedures

The risk of developing VTE when undergoing day surgery or minor surgery is considered to be generally low. However, in some day surgery including laparoscopic and arthroscopic surgery, the intra-operative procedures can be relatively prolonged or the patient is already at high risk. In either circumstance, full VTE prophylaxis should be considered.

There are also a number of types of trauma or procedures where there is an association with VTE but the risk is low. However, additional factors unique to the patient may increase their risk and emphasise the need for individual assessment for VTE prophylaxis.

The following sections include information on common methods of prophylaxis. Section 7 provides recommendations for VTE prophylaxis in a wide variety of clinical situations.

4 PHARMACOLOGICAL AGENTS

Studies have confirmed the effectiveness of subcutaneous low-dose unfractionated heparin (LDUH), low molecular weight heparin (LMWH) and the pentasaccharide fondaparinux for preventing VTE. While dosage recommendations have been included in this booklet, there is a requirement for hospital protocols and individual doctors to select the dose, dosage interval and brand of prophylactic agents having referred to full product information.

Aspirin may have at best a weak protective effect against DVT in some people and therefore is not recommended for this purpose. Adjusted dose warfarin has a role in some high risk surgical patients but requires regular monitoring of its effect. Newer agents, e.g. oral thrombin or Factor Xa inhibitors, may have a role in prophylaxis in the future.

4.1 Out of Hospital & Extended Prophylaxis

Many trials were based on inpatients remaining in hospital for 7-10 days. Increasingly, fewer patients stay as long as 10 days and after discharge may spend a considerable amount of time recuperating at home. They may not be truly ambulant and thus may be at increased risk of VTE.

There is no conclusive evidence to form recommendations for ambulatory patients. Nevertheless, it is important to be cautious with early discharge patients as they may still be at risk and may need continued prophylaxis during their convalescence. Patient groups where the value of extended prophylaxis has been demonstrated and where prophylaxis should be continued for 28-35 days include patients following hip fracture or hip replacement surgery and possibly major curative surgery for cancer.

4.2 Neuraxial Block (Epidural/Spinal)

The use of epidural/spinal anaesthesia has been increasing in recent times. While the incidence of DVT may be reduced by neuraxial anaesthesia, the requirement is still high for appropriate prophylaxis.

The risk of DVT and the importance of prophylaxis is not diminished with the use of neuraxial anaesthesia. However, anaesthetists have become increasingly concerned about the development of the complication of epidural haematoma in patients who are receiving pharmacoprophylaxis.

It is important for the individual patient that the risk of VTE is weighed against the risk of an epidural haematoma and discussions between the anaesthetist and the surgeon should take place early enough for appropriate planning of prophylaxis. While not being able to provide definitive recommendations from the literature, options for the management of such patients would include delaying systemic pharmacological anticoagulants until after the insertion of the epidural catheter or ensuring that pharmacological anticoagulant agents are not administered within 12 hours prior to the insertion or 6 hours following withdrawal of an epidural catheter (see American Society of Regional Anesthesia and Pain Medicine (ASRA) guidelines www.asra.com/).

4.3 Bleeding Risk

Bleeding is the major complication of anticoagulant treatment and the relative risks for bleeding versus VTE must be considered when commencing anticoagulation. Pharmaceutical interactions must also be considered as they can contribute to unstable anticoagulation and can increase the risk for bleeding.

5 MECHANICAL DEVICES

Two main types of mechanical devices are widely used in the prevention of VTE – Graduated Compression Stockings (GCS) and Intermittent Pneumatic Compression (IPC).

5.1 Graduated Compression Stockings

GCS reduce the incidence of DVT. Studies have generally involved full-length stockings. Although it is anticipated that below knee stockings should also provide a degree of protection against DVT, there are few comparative studies.

There are two distinct and non-interchangeable types of GCS, one for DVT prophylaxis and the other for treatment of CVI. In order to achieve optimal benefit from the use of GCS, some general recommendations are provided in Table 2.

Table 2. General recommendations for the use of graduated compression stockings for DVT prophylaxis

- Should be worn continuously during the period of immobility to the return of full ambulation
- Patient compliance is essential eg. ensuring stockings not rolled down
- Are contraindicated in critical limb ischaemia
- Should be measured and fitted for the individual patient

Surgical VTE Prophylaxis Guide

For ALL patients undergoing surgery or when surgery is imminent

STEP 1 — Assess Patient Risk

HIGH RISK

- Hip or knee arthroplasty
- Major trauma

- Hip fracture surgery
- Other surgery with prior VTE and/or active cancer

- Major surgery* age > 40 years

LOWER RISK

- All other surgery

STEP 2 — Assess for Anticoagulant Prophylaxis

Are there any contraindications to anticoagulant prophylaxis? (see below)

NO → Prescribe: enoxaparin 40mg daily
or dalteparin 5000U daily
or for orthopaedic surgery fondaparinux 2.5mg daily (commence 6-8 hrs post-op)
Duration 5-10 days EXCEPT 28-35 days for hip arthroplasty

YES → No anticoagulant

Are there any contraindications to anticoagulant prophylaxis? (see below)

NO → Prescribe: enoxaparin 40mg daily
or dalteparin 5000U daily
or LDUH 5000 TDS
or for hip fracture surgery fondaparinux 2.5mg daily (commence 6-8 hrs post-op)
Duration 5-10 days EXCEPT 28-35 days for hip fracture surgery

YES → No anticoagulant

Are there any contraindications to anticoagulant prophylaxis? (see below)

NO → Prescribe: enoxaparin 20mg daily
or dalteparin 2500U daily
or LDUH 5000 BD or TDS
Duration 5-10 days

YES → No anticoagulant

Are there any contraindications to anticoagulant prophylaxis? (see below)

NO → Consider LMWH or LDUH if additional risk factors †
Duration until hospital discharge

YES → No anticoagulant

STEP 3 — Assess Mechanical Prophylaxis

Are there any contraindications to mechanical prophylaxis? (see below)

NO → Apply IPC and/or GCS

YES → Observe closely for VTE

Are there any contraindications to mechanical prophylaxis? (see below)

NO → Apply GCS and/or IPC

YES → Observe closely for VTE

Are there any contraindications to mechanical prophylaxis? (see below)

NO → Apply GCS and/or IPC

YES → Observe closely for VTE

Are there any contraindications to mechanical prophylaxis? (see below)

NO → Consider GCS

YES → Observe closely for VTE

***Major surgery:** intra-abdominal surgery or any surgery > 45 minutes duration

† Additional VTE Risk Factors
immobility, thrombophilia, oestrogen therapy, pregnancy or puerperium, active inflammation, strong family history of VTE and/or obesity.

Contraindications to anticoagulant prophylaxis
Active bleeding / high risk of bleeding eg. haemophilia, thrombocytopenia (platelet count <50 x 10⁹/L), history of GI bleeding
Severe hepatic disease (INR > 1.3) / adverse reaction to heparin
On current anticoagulation
Other eg. very high falls risk and palliative management

Renal impairment with LMWH - see manufacturer's product information

Contraindications to mechanical prophylaxis
Severe peripheral arterial disease: Recent skin graft
Severe peripheral neuropathy: Severe leg deformity

LMWH - Low Molecular Weight Heparin
LDUH - Low Dose Unfractionated Heparin
GCS - Graduated Compression Stockings
IPC - Intermittent Pneumatic Compression
VTE - Venous Thromboembolism

There are a wide variety of GCS available in Australian and New Zealand. However, there are no Australian standards regulating their manufacture and clinical performance. Ideal characteristics for GCS are set out in Table 3.

Table 3. Ideal characteristics for the selection of GCS stockings for DVT prophylaxis

- Evidence of clinical efficacy
- Pressure of 16mmHg to 20mmHg at the ankle in the supine position with graduated compression to the knee or above
- Appropriate and individual sizing for each patient
- Sizing range should be suitable for a large percentage of the population and the window of coverage should be clearly defined
- Washing and reuse guidelines should be provided
- Appropriate manufacturing standards to ensure quality control
- Independent testing and compression profile of each stocking brand using internationally accepted methods

5.2 Intermittent Pneumatic Compression

IPC reduces the incidence of DVT and is more effective than GCS in high risk patients in combination with anticoagulants or when anticoagulants are contraindicated. In Orthopaedic surgery, foot impulse technology (FIT) can be used with GCS if IPC is not possible.

The use of IPC devices for DVT prophylaxis is similar to the GCS recommendations in that they should be used during the period of immobility to the return of full ambulation.

5.3 Pharmacological & Mechanical Combinations

Combinations of agents (for example, subcutaneous heparin with GCS and/or IPC) may be more effective than single interventions alone. Although studies have generally been too small to draw strong conclusions for prophylaxis in high-risk patients, a combination of pharmacological & mechanical therapy is recommended (see Table 5 & 6).

5.4 Precautions

Success in the use of GCS is dependant on proper fitting and continuous use during the VTE risk period. Improper fitting can be due to a limitation in the range of available stocking sizes as well as due to poor limb measurement for sizing. Incorrectly fitting stockings invariably do not provide the graduated compression required for prophylaxis.

Reported complications with GCS and IPC are rare but include compartment syndrome, skin ulceration and common peroneal nerve palsy. Importantly, they should not be used in limbs with severe or critical ischaemia.

6 ADDITIONAL CONSIDERATIONS

There are a number of other conditions worthy of consideration when determining the risk of VTE.

6.1 Pregnancy & Postpartum

Several factors increase the risk of VTE during pregnancy including Caesarean section, obesity, advanced maternal age and thrombophilia. Although there is insufficient data on optimal timing and dosage, LDUH or LMWH are commonly considered for use in pregnant women with a history of idiopathic proximal VTE, thrombophilia or other high-risk factors. In these patients thromboprophylaxis should be continued for four weeks post-partum. Women undergoing Caesarean section should receive thromboprophylaxis as long as there are no contraindications for anticoagulant therapy.

6.2 Oestrogen Preparations

It is considered prudent to stop hormone replacement therapy (HRT) and the oral contraceptive pill pre-operatively if the patient is in the high risk category. In the absence of other risk factors, there is insufficient evidence to support routine pre-operative cessation of oral contraceptives or HRT. Appropriate prophylaxis should be used when these agents have not been stopped. Ideally, the oral contraceptive pill should be ceased the cycle before planned surgery and other methods of contraception considered. HRT should cease six weeks before planned surgery.

6.3 Thrombophilia

There are many types of thrombophilia (Table 4) but the presence of thrombophilic factors alone does not greatly increase the risk of VTE. However, patients with thrombophilia and a strong family history of VTE, recurrent DVT, or documented unexplained thrombosis before the age of 40 years are at

increased risk of VTE and should receive prophylaxis during any surgical or medical condition. Screening for thrombophilia before surgery is not required and specialist advice should be sought before screening is considered.

Table 4. Causes of thrombophilia

Higher Level of Risk:
- Antithrombin III deficiency
- Protein S deficiency
- Protein C deficiency

Lower Level Risk:
- Activated protein C resistance (Factor V Leiden)
- Prothrombin gene mutation
- Hyperhomocysteinaemia
- Lupus anticoagulant
- Antiphospholipid antibodies
- Hyperhomocysteinaemia
- Myeloproliferative disease

7 RISK STRATIFICATION AND APPROPRIATE PROPHYLAXIS

This section provides recommendations for VTE prophylaxis in a wide variety of clinical situations. Surgical patients at high risk for VTE are divided into two groups dependant on the recommendations for their prophylaxis.

7.1 Hip or Knee Arthroplasty and Major Trauma

Hip or knee arthroplasty and major trauma are high risk for VTE. Recommendations on the management of these patients is summarised in Table 5. Routine ultrasound screening for DVT is not justified in most trauma patients but selective screening might be of benefit in high-risk patients who are unable to receive prophylaxis due to bleeding risk or inability to use mechanical prophylaxis.

With the advent of newer technology of retrievable filters and with the option of bedside insertion under ultrasound guidance, there are some who advocate insertion of a prophylactic inferior vena cava filter for trauma patients considered to be at very high risk for VTE and bleeding. However, their routine use is not advised due to lack of evidence of efficacy or cost-effectiveness.

Table 5.

RISK	FEATURES	PROPHYLAXIS	DURATION	DOSAGE
HIGH	- Hip or knee arthroplasty - Major trauma	- LMWH or Fondaparinux* AND - IPC# &/or GCS	5-10 days EXCEPT 28 - 35 days for hip arthroplasty	Enoxaparin 40mg/day OR Dalteparin 5000U day OR Fondaparinux* 2.5mg/day (commence 6-8 hours post-op)

* Fondaparinux for orthopaedic surgery only
# Foot Impulse Technology (FIT) with GCS may be used if IPC not possible

7.2 Hip Fracture Surgery, Major Surgery age > 40years and Other Surgery with prior VTE and /or active cancer.

In hip fracture surgery and in major surgery in patients over 40 years of age, the duration (>45 minutes) and type of operation (intra-abdominal or intra-thoracic versus non-body cavity surgery) are most important and these features constitute a substantial risk for VTE.

A prior history of VTE and/or active cancer are significant predictors for the development of VTE post-operatively whether major or other types of surgery.

Additional risk factors for VTE development include immobility, the use of oestrogen containing preparations, the presence of thrombophilic factors, pregnancy or puerperium, active inflammation, strong family history of VTE and/or obesity.

The risk classification based on international best evidence is shown in Table 6.

Table 6.

RISK	FEATURES	PROPHYLAXIS	DURATION	DOSAGE
HIGH	- Hip fracture surgery - Other surgery with prior VTE &/or active cancer	- LMWH or LDUH or Fondaparinux# AND - GCS &/or IPC	5 – 10 days EXCEPT 28-35 days for hip fracture surgery	Enoxaparin 40mg/day OR Dalteparin 5000U/day OR LDUH 5000U TDS OR Fondaparinux# 2.5mg/day (commence 6-8 hours post-op)
HIGH	- Major surgery* age > 40 years	- LMWH or LDUH AND GCS &/or IPC	5-10 days	Enoxaparin 20mg/day OR Dalteparin 2500U/day OR LDUH 5000U BD or TDS

Fondaparinux for orthopaedic surgery only
* Major surgery: intra-abdominal surgery or surgery > 45 minutes duration

7.3 All Other Surgery

The requirement for prophylaxis for all other surgery is dependant on any additional VTE risk factors that the patient may carry including immobility, thrombophilia, oestrogen therapy, pregnancy or puerperium, active inflammation, strong family history of VTE and/or obesity. These factors if present will require consideration for prophylaxis. Otherwise, there are no specific recommendations regarding prophylaxis other than the option of GCS use (Table 7).

Table 7.

RISK	FEATURES	PROPHYLAXIS	DURATION	DOSAGE
LOWER	All other surgery	- Consider GCS - Consider LMWH or LDUH if additional risk factors†	Until hospital discharge	If additional risk factors: Enoxaparin 20mg/day OR Dalteparin 2500U/day OR LDUH 5000U BD or TDS

† Additional VTE risk factors: immobility, thrombophilia, oestrogen therapy, pregnancy or puerperium, active inflammation, strong family history of VTE and/or obesity.

7.4 Medical Patients

Up to 75% of fatal PE in general hospitals occur in non-surgical patients immobilised by medical illness, yet there are fewer trials on VTE prophylaxis for hospitalised medical patients compared to surgical patients. Available data suggest that prophylaxis can prevent approximately two thirds of VTE in medical patients, a reduction rate similar to prophylaxis in surgical patients.

Patients suffering an acute stroke with paralysis of a lower limb, a history of VTE, active cancer, decompensated cardiac failure, acute on chronic lung disease, acute on chronic inflammatory disorders or age over 60 years are at highest risk of VTE (Table 8). Medical patients with additional risk factors should also be considered for prophylaxis.

Table 8.

RISK	FEATURES	PROPHYLAXIS	DURATION	DOSAGE
HIGH	- Ischaemic stroke# - History of VTE - Active cancer - Decompensated cardiac failure - Acute on chronic lung disease* - Acute on chronic inflammatory disease - Age >60 years*	LMWH or LDUH	Until resolution of acute medical illness or until hospital discharge	Enoxaparin 40mg/day OR Dalteparin 5000U/day OR LDUH 5000U BD or TDS
LOW	None of above features	Nil		

Favour LMWH over LDUH *While patients aged over 60 years are currently classified as high risk, those who are otherwise well and ambulant and younger patients with acute on chronic lung disease may may not be at high risk for VTE in the absence of other risk factors.

7.5 Travel Related VTE

The risk of travel related DVT is not confined to air travel. There is little information available in the literature with recent studies indicating that the incidence of travel related PE appears to be small and is estimated to be about 1:1 million arrivals although possibly increasing to 1:70,000 arrivals for flights longer than 12 hours. Further studies are required to fully define the risk of travel related VTE. However, based on current information and knowledge, the majority of the travelling public are at low risk of developing a DVT and some common sense suggestions should be followed:

- Ensure adequate hydration by drinking sufficient fluids
- Regularly mobilise ankles, massage the calves and exercise leg muscles when seated for prolonged periods
- Avoid combining sedatives with excess alcohol
- Wear non-restrictive clothing
- Exercise eg. walking, before and after travel and during stop-overs.

Considered at high risk are those travellers with a history of previous VTE, those with known pro-thrombotic states, recent surgery, significant medical illness or with multiple risk factors. In these patients the administration of prophylactic LMWH and use of properly measured and fitted GCS (20-25mmHg) is suggested. Lower compression (e.g 16-20mmHg) does not offer adequate

protection when the legs are in a dependent position. Non-graduated stockings are not recommended.

Aspirin is not likely to be appropriate as at best it may have a weak protective effect and in some people excess bleeding may negate any benefit.

8 COST EFFECTIVENESS OF VTE PROPHYLAXIS

Currently recommended prophylactic methods have been demonstrated to be cost effective in patients at high risk of VTE due to the high cost of diagnosis and treatment of VTE in these patients. There are no data on the cost effectiveness of prophylaxis in low risk groups. Effective VTE prophylaxis and treatment should also reduce the costs of managing the post-thrombotic syndrome and its consequences, especially chronic venous leg ulcers.

9 DIAGNOSIS AND TREATMENT OF VTE

Best Practice Guidelines for the diagnosis and treatment of VTE have been published in booklet form by the Australia and New Zealand Working Party.

In summary, the clinical diagnosis of DVT and PE is inaccurate and if suspected, should be confirmed by objective investigations although treatment may be commenced in the meantime. The current recommendation is to perform venous duplex ultrasound scanning for suspected DVT. For the diagnosis of suspected PE, ventilation perfusion scanning, CT angiography or pulmonary angiography is recommended according to local practice. Reliance on D-Dimer without pre-test probability assessment is not recommended.

Swift and effective diagnosis and treatment of active VTE helps to prevent thrombus extension, leg swelling, potentially fatal PE and the development of the post-thrombotic syndrome. Therapeutic heparin is required (usually low molecular weight heparin). Oral anticoagulants should overlap heparin therapy for at least 2 days. Thrombolysis, thrombectomy or insertion of an IVC filter may be required in selected patients.

Following a DVT, consideration should be given for the use of long term GCS (>20mmHg). Several studies have shown that GCS can reduce the incidence of post-thrombotic syndrome by up to 50%, yet many patients do not receive GCS.

10 IMPLEMENTATION OF BEST PRACTICE VTE PROPHYLAXIS GUIDELINES

There are a number of studies in the literature that suggest inpatient VTE prophylaxis is sub-optimal. A major challenge, therefore, is to implement appropriate systems and policies in hospitals that ensure compliance with best practice guidelines. Further recommendations include:

- VTE prophylaxis should be used routinely
- Hospital policies should include VTE prophylaxis guidelines
- VTE prophylaxis guidelines should be included in clinical pathways, ward and specialist unit guidelines and staff manuals.
- Hospitals should undertake regular audit of the extent and quality of VTE prophylaxis
- Clinicians should ensure that individual patients have a VTE risk assessment documented in the case notes
- The application and use of mechanical methods of prophylaxis should be recorded
- Familiarisation of VTE prophylaxis guidelines should be included in senior and junior medical staff orientation, hospital grand rounds and hospital newsletters
- Liaison should occur with community care physicians particularly for patients receiving extended prophylaxis out of hospital

11 REFERENCES

The recommendations for the prevention of VTE are based on the internationally accepted guidelines. The full lists of references supporting these recommendations are to be found in the following articles:

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NOTES