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# Towards appropriate prevention and treatment of venous thromboembolism

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# ABSTRACT

## Introduction

The prevention and management of venous thromboembolism (VTE) is often at variance with guidelines, despite its prevalence, cost, morbidity and mortality. The CareTrack Australia (CTA) study reported that appropriate care (in line with evidence- or consensus-based guidelines) is being provided for VTE at just over half of eligible encounters. Here, we report indicator-level CTA findings for VTE.

## Methods

Indicators were extracted from Australian VTE clinical practice guidelines and ratified by experts. A sample designed to be representative of the Australian population was recruited. Participants' medical records from 2009 and 2010 were retrospectively reviewed and analysed for compliance with 38 VTE indicators. The main outcome measure was the percentage of eligible healthcare encounters with documented compliance with indicators of appropriate care for VTE.

## Results

Of the 35,145 CTA encounters, 1,078 (3%) were eligible for scoring against VTE indicators. There were 2 - 84 eligible encounters per indicator at 27 hospitals. Overall compliance with indicators for VTE was 51%, and ranged from 34 - 64% for aggregated sets of indicators. Of the 70 VTE patients discharged on anti-coagulant therapy, 46% had a documented discharge plan and a date for cessation of treatment.

## Discussion

The prevention and management of VTE was appropriate for only half of the at-risk patients in our sample. There is a need for national agreement on clinical standards, indicators and

tools to guide, document and monitor care for VTE, and for measures to increase their uptake, particularly in areas where deficiencies have been identified.

# INTRODUCTION

Each year in Australia about 1 in every 1,000 people develop a first episode of venous thrombo-embolism (VTE), manifesting as deep venous thrombosis (DVT) and/or pulmonary embolism (PE).(1, 2). This amounts to about 20,000 cases, of which 80% occur during or soon after an admission to hospital.(1, 2) Including loss of productivity, total costs amount to well over AUS$1 billion per year.(3)

There is evidence that the appropriate use of pharmacological and mechanical prophylaxis in orthopaedic, general surgical and medical patients can reduce the incidence of VTE,(4-6) although a recent paper has questioned use of pharmacological prophylaxis in lower risk medical patients.(7) Clinical practice guidelines (CPGs) have been developed, in Australia(8, 9) and elsewhere,(10, 11) to prevent VTE and to standardise the management of DVT and PE. Several initiatives have been undertaken to promote and facilitate their uptake, including implementation guides,(12) templates,(13) learning modules,(14) hospital medication self-assessments,(15) and patient information pamphlets.(16) However, despite these initiatives and the considerable harm from VTE, much of the care provided for VTE is not in line with CPGs.(17)

As healthcare is facing an affordability crisis, there is an urgent need to move towards being able to monitor the appropriateness of care (“care in line with evidence- or consensus-based guidelines”).(18) The CareTrack Australia (CTA) study was designed to establish baseline estimates of the appropriateness of care delivered, at a population level, by a range of practitioners in real-world settings, and to determine what would be needed to monitor the ongoing appropriateness of care.(19) CTA showed that adult Australians received appropriate care for 22 common conditions at 57% of eligible healthcare encounters during 2009 and 2010; VTE compliance was reported at 58%.(20) Here we present and discuss the detailed CTA results for VTE.

# METHODS

The CTA methods have been described in detail elsewhere.(19, 20) Some aspects of relevance to VTE are summarised here.

## Development and ratification of indicators

An initial list of 15 indicators (with 54 sub-criteria) was sourced from the National Health and Medical Research Council guidelines(8, 9) and sent to three practising specialist haematologists who were Heads of Departments, asking them to comment on and rate each on a scale of 1 to 9 for appropriateness(21) in the Australian context during 2009 and 2010. This resulted in 39 indicators being accepted as appropriate: 31 relating to pharmacological and mechanical prophylaxis and eight to risk assessment, discharge care and management of DVT or PE (see Table 1).

## Recruitment of participants and healthcare providers

A sample designed to be representative of the Australian adult population was used. Households were randomly selected from a phone directory (the Telstra White Pages) from defined regions within New South Wales and South Australia.(19, 20) One adult was randomly selected from each household and recruited over the phone. Those who agreed were sent a mail package containing information about the study and a consent form to allow access to their medical records. Participants who provided consent were called back and asked if they had been admitted overnight to a hospital or had one or more of the CTA conditions, and which healthcare providers they had seen for these in 2009 and 2010. Hospitals identified by the participants were contacted and asked to provide their consent for medical record access. Human Research Ethics Committee (HREC) approval was obtained from Hunter New England Local Health District as the lead HREC and other relevant bodies and local sites.(20)

## Review of medical records

Medical record reviews were undertaken for the 1,154 consenting participants whose healthcare providers had also provided consent. Healthcare encounters were deemed eligible for scoring of VTE indicators if a participant had been admitted overnight during 2009 and/or 2010.

Experienced registered nurses were recruited and trained as surveyors to conduct the medical record reviews using a web-based tool for on-site encrypted data collection. They were provided with formal training and received a manual with detailed criteria for inclusion, exclusion and scoring of indicators.

Estimates of compliance were measured as the percentage of eligible encounters for the VTE indicators that were answered 'yes'.(19, 20) The inclusion criteria for the indicators for VTE prophylaxis were specific to particular types of surgery (e.g. hip fracture surgery or abdominal surgery) or medical conditions (e.g. decompensated cardiac failure or acute on chronic lung disease).(8, 9) As the CTA study was designed to measure the overall appropriateness of the healthcare delivered for 22 conditions and was not powered for significant results at indicator level, the number of eligible encounters for many indicators was low. To address this, indicators were aggregated into broader, clinically meaningful categories. For example, orthopaedic conditions with pharmacological prophylaxis (indicators 45-48) were grouped and included hip arthroplasty, hip fracture surgery, knee arthroplasty, and lower limb fractures (see Table 1).

Data relating to documentation of VTE risk assessment (indicator 42) was not included in the analysis reported here, as a review of surveyor practices revealed that some had assumed that a risk assessment had been carried out whenever appropriate prophylaxis had been prescribed, whether or not explicit documentation of an assessment was found. This was in breach of the criteria for this indicator, and these data were thus excluded.

## Statistical analysis

Mean compliance and associated 95% confidence intervals (using a modified version of the Clopper–Pearson (exact) method) were obtained using the SURVEYFREQ procedure in SAS version 9.3 for Windows (SAS Institute, Cary, NC, USA). To address biases arising from the study design (including adjustment for non-response), two different weighting options and five version of weights (three based on approaches used in the similar US study(21)) were used to generate weighted estimates of compliances. These were not significantly different to unweighted compliances overall or for any condition (including VTE). Hence, unweighted compliances were used for this analysis.(20) Appendix 2 of the CTA study outlines the detailed methodology and overall results.(20)

# RESULTS

Of the 1,154 CTA participants, 481(42%) were admitted overnight to hospital at least once, with a total of 751 admissions eligible for assessment against the VTE indicators. There were 279 females (58%), and the mean age was 64 years (6% were aged 18 – 39, 17% 40 – 54, 56% 55 – 74 and 21% were over 70 years of age).

Of the 35,145 CTA encounters (with duplicates and the risk indicator removed), 1,078 (3%) were eligible for scoring against VTE indicators; the number of eligible encounters per indicator ranged from 2 - 84. Records were reviewed at 33 hospitals, with 27 having eligible encounters. Eight of the hospitals had 50 or more eligible encounters.

Overall compliance with the VTE indicators was 51% (CI 95%: 47-54%), with results for aggregated sets of indicators ranging from 34 - 64% (Table 1). Omission of the risk assessment indicator from the overall score reduced compliance from the 58% reported originally(20) to the 51% reported here. For the eight hospitals with 50 or more eligible encounters, compliance ranged from 45 - 70%.

Table 1: CTA indicators (and aggregated sets of indicators) by compliance

| **Indicator Number** | **Indicator and sets of indicators** | Eligible encounters (N) | Compliant encounters (N) | Compliance* (%) | 95% confidence limits† (%) |
|---|---|---|---|---|---|
| **45-48** | **Patients undergoing certain orthopaedic procedures or care received appropriate pharmacological anticoagulant therapy** | **55** | **34** | **62** | **48 - 75** |
| 45 | Patients who had a hip arthroplasty have received anticoagulant therapy for up to 35 days‡ | 22 | 12 | Insufficient data to report | |
| 46 | Patients who had hip fracture surgery have received anticoagulant therapies for up to 35 days§ | 2 | 2 | Insufficient data to report | |

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| 47 | Patients who had a knee arthroplasty received anticoagulant therapies for up to 28 days‖ | 24 | 16 | Insufficient data to report | |
| 48 | Patients who had a lower limb fracture received anticoagulant therapies for at least 5 days or until fully mobile§ | 7 | 4 | Insufficient data to report | |
| **62, 68-70, 73-75** | **Patients undergoing certain orthopaedic procedures or care received appropriate mechanical anticoagulant therapy** | **104** | **49** | **47** | **37 - 57** |
| 62 | Patients having a total hip replacement have been prescribed graduation compression stockings | 20 | 19 | Insufficient data to report | |
| 68 | Patients having a total hip replacement have been prescribed an intermittent pneumatic compression device | 18 | 11 | Insufficient data to report | |
| 69 | Patients having hip fracture surgery have been prescribed an intermittent pneumatic compression device | 3 | 1 | Insufficient data to report | |
| 70 | Patients having a total knee replacement have been prescribed | 21 | 15 | Insufficient data to report | |

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| | an intermittent pneumatic compression device | | | | |
| 73 | Patients having a total hip replacement have been prescribed a foot pump | 18 | 1 | Insufficient data to report | |
| 74 | Patients having a total knee replacement have been prescribed a foot pump | 22 | 2 | Insufficient data to report | |
| 75 | Patients having hip fracture surgery have been prescribed a foot pump | 2 | 0 | Insufficient data to report | |
| **49-54** | **Patients undergoing non-orthopaedic surgical procedures (general, gynaecological, abdominal, cardiac, thoracic or vascular, trauma or spinal surgery) or who had cancer and underwent surgery received appropriate pharmacological anticoagulant therapy** | **226** | **76** | **34** | **27 - 41** |
| 49 | Patients who had a general surgical procedure received anticoagulant therapies (unless contraindicated) until hospital | 55 | 19 | 35 | 22 - 49 |

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| | discharge or fully mobile¶ | | | | |
| 50 | Patients who had gynaecological surgery received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 26 | 5 | Insufficient data to report | |
| 51 | Patients who had abdominal surgery received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 61 | 29 | 48 | 18 - 78 |
| 52 | Patients who had cardiac, thoracic or vascular surgery received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 31 | 12 | 39 | 16 - 66 |
| 53 | Patients who had trauma or spinal surgery received anticoagulant therapies commenced after primary haemostasis was established (unless contraindicated) until hospital discharge | 18 | 0 | Insufficient data to report | |

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| | or fully mobile¶ | | | | |
| 54 | Patients who have cancer that underwent surgery received one of the following anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 35 | 11 | 31 | 5 - 74 |
| **63-67, 71-72** | **Patients undergoing non-orthopaedic surgical procedures received appropriate mechanical anticoagulant therapy** | **294** | **176** | **60** | **52 - 67** |
| 63 | Patients having general surgery have been prescribed graduated compression stockings | 72 | 63 | 88 | 78 - 94 |
| 64 | Patients having gynaecological surgery have been prescribed graduation compression stockings | 28 | 21 | Insufficient data to report | |
| 65 | Patients having abdominal surgery have been prescribed graduation compression stockings | 66 | 48 | 73 | 46 - 91 |
| 66 | Patients having cardiac, thoracic or vascular surgery have been | 52 | 17 | 33 | 2 - 85 |

| | | | | | |
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| | prescribed graduation compression stockings | | | | |
| 67 | Patients having neurosurgery have been prescribed graduation compression stockings | 13 | 11 | Insufficient data to report | |
| 71 | Patients having cardiac, thoracic or vascular surgery have been prescribed an intermittent pneumatic compression device | 50 | 7 | 14 | 2 - 41 |
| 72 | Patients having neurosurgery have been prescribed an intermittent pneumatic compression devices | 13 | 9 | Insufficient data to report | |
| **55-61** | **Medical patients admitted to hospital with certain conditions received appropriate pharmacological anticoagulant therapy** | **167** | **77** | **46** | **36 - 57** |
| 55 | Medical patients admitted to hospital with ischemic stroke received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 5 | 1 | Insufficient data to report | |

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| 56 | Medical patients admitted to hospital with myocardial infarct (where full anticoagulant is not in use) received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 15 | 6 | Insufficient data to report | |
| 57 | General Medical patients admitted to hospital assessed as being at risk of VTE received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 84 | 43 | 51 | 40 - 62 |
| 58 | Medical patients admitted to hospital with active cancer received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 23 | 8 | Insufficient data to report | |
| 59 | Medical patients admitted to hospital with decompensated cardiac failure received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 7 | 3 | Insufficient data to report | |

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| 60 | Medical patients admitted to hospital with acute on chronic lung disease received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 31 | 15 | 48 | 30 - 67 |
| 61 | Medical patients admitted to hospital with acute on chronic inflammatory disease received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 2 | 1 | Insufficient data to report | |
| **76-80** | **Patients with suspected PE/DVT were managed with appropriate investigations, or had anticoagulant therapy commenced as soon as clinically suspected; or if PE/DVT confirmed, were managed appropriately** | **89** | **57** | **64** | **51 - 76** |
| 76 | Patients with a suspected DVT had a venous duplex ultrasound performed | 12 | 10 | Insufficient data to report | |
| 77 | Patients with a suspected PE had investigations performed‡‡ | 21 | 17 | Insufficient data to report | |

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| 78 | Patients with a suspected DVT or PE where ultrasound was delayed, had anticoagulant therapy commenced (unless contraindicated) as soon as clinically suspected | 10 | 8 | Insufficient data to report | |
| 79 | Patients with a confirmed DVT / PE received anticoagulant therapies[A] | 6 | 3 | Insufficient data to report | |
| 80 | Patients who were administered heparin therapy had it continued until the *International Normalized Ratio* (INR) had been therapeutic for 48 hours (INR range 2.0 - 3.0) | 40 | 19 | 48 | 26 - 70 |
| **Patients discharged on anticoagulant therapy have an appropriate documented care plan including details on the intended duration of treatment AND a review date[B]** | | 70 | 32 | 46 | 31 - 61 |
| 43 | Patients who are discharged on anticoagulant therapy have a documented care plan that includes details on the intended duration of treatment | 73 | 43 | 59 | 46 - 71 |

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| 44 | Patients who are discharged on anticoagulant therapy have a documented care plan that includes a review date | 70 | 35 | 50 | 29 - 71 |

Footnote:

† compliance and % compliance were not calculated for <30 encounters

‡ enoxaparin 40mg/day; dalteparin 5000u/day; low dose unfractionated heparin (LDUH) 5000u TDS; fondiparinux 2.5mg/day [commenced 6 – 8 hours post op]; rivaroxaban[PO]; dabigatran [PO]

§ enoxaparin 40mg/day; dalteparin 5000u/day; LDUH 5000u TDS; fondiparinux 2.5mg/day [commenced 6 – 8 hours post op]

|| enoxaparin 40mg/day; dalteparin 5000u/day; LDUH 5000u TDS; fondiparinux 2.5mg/day [commenced 6 – 8 hours post op]; rivaroxaban[PO]; dabigatran [PO]

¶ enoxaparin 20mg/day; dalteparin 2500U/day

†† enoxaparin 40mg/day; dalteparin 5000U/day; LDUH 5000U BD or TDS; assumed implicit and explicit risk assessments included.

‡‡ One of: ventilation perfusion scan; CT angiography; pulmonary angiography

A heparin administered together with warfarin for at least 5 days; unfractionated heparin IV (Activated Partial Thromboplastin Time (APTT)) or subcutaneous (dose/kg); Low Molecular Weight Heparin (LMWH) subcutaneously at least once daily.

B

Compliance for this aggregated indicator was both indicators 43 and 44 were compliant for a participant in an episode of hospitalisation. In other aggregated indicators, compliance was measured by adding each individual encounter as each episode of hospitalisation was an independent event.

# DISCUSSION

Despite the prevalence, cost, morbidity and mortality associated with VTE, prophylaxis and treatment is often not in line with CPGs. This analysis of CTA data has shown that our sample of 481 Australian adults in 27 hospitals received appropriate care for VTE during 2009 and 2010 at 51% of eligible healthcare encounters.

CTA patients who had surgery received appropriate pharmacological or mechanical anticoagulant therapy on only 39% and 57% of occasions respectively (aggregations from Table 1). The ENDORSE study, a multi-national cross-sectional survey, also examined the proportion of at-risk patients who received effective prophylaxis.(17) It found, for 804 patients from eight Australian hospitals studied in 2006-07, that 82% of at-risk surgical patients received appropriate prophylaxis. This study did not separate pharmacological and mechanical prophylaxis.(17) Baseline (pre-intervention) compliances for surgical patients were also higher than CTA compliances in two single hospital studies (65 and 74% for pharmacological prophylaxis and 89 and 64% for mechanical prophylaxis).(22, 23) Possible reasons for the lower CTA compliances are that CTA was a population-based study at 27 hospitals which were effectively randomly selected, whilst ENDORSE mainly collected data from prominent teaching hospitals, and the two single hospital studies were about to start an intervention for VTE prophylaxis, possibly raising awareness of the problem.

In contrast, the CTA compliance for at-risk medical patients at 46% (aggregations from Table 1) was similar to those in the eight Australian ENDORSE hospitals and a regional hospital (51%, and 64%, respectively).(17, 23) No equivalent Australian studies could be found for indicators associated with management of suspected or confirmed DVT or PE (CTA compliance 64%), or patients with a documented discharge plan and a date for cessation of treatment (CTA compliance 46%), but it would seem reasonable to conclude that both of these areas of practice also require attention.

The risk assessment indicator was studied in two Australian single-hospital studies which both found 0% compliance at the pre-intervention stage, with modest post-intervention increases to 28 and 36%.(22, 24)

The poor compliances with VTE indicators in Australia are consistent with the lack of a system-wide approach. Compliance measures or outcomes are not publicly reported at hospital level,(25) VTE is not included in national standards,(26) nor is it a national health care goal,(27) Australian clinicians have identified that setting agreement on clinical guidelines and standards (agreement on risk categories, risk assessment tools, mandatory actions and protocols, provision of summaries), decision-support tools, and reporting results are enablers to delivering appropriate VTE care.(28, 29) The fact that compliance ranged from 45% to 70% between hospitals suggests that some facilities are faring better than others at managing VTE appropriately.

## Strengths and weaknesses

The key strength of the CTA study is that it is designed to be representative of the Australian population rather than a convenience- or purposive-based sample. However, an unavoidable consequence of this strategy, coupled with finite research funds, is that the number of participants and/or eligible encounters are low for some indicators. The review of medical records, while costly and difficult, allowed compliance to be measured in a real world setting and avoided the limitations inherent in asking health care providers to respond to clinical vignettes(30, 31) or questionnaires.(32) Accordingly CTA provides some baselines against which progress on the provision of appropriate care for VTE could be compared and tracked.

The approach used was associated with a high rate of attrition of potential participants and several sources of possible bias. However, weighting using two methods and five different options made no significant difference to the overall compliance

percentage, or that for VTE;(20) this is consistent with providers not altering their clinical practices for patients of different ages, gender, or socio-economic or health literacy status.

Commentators have raised issues with respect to the levels of evidence, choice of indicators, effects of comorbidities, inter-rater reliability, and the possibility of care having been provided but not recorded.(33, 34) These have all been addressed:(20, 35) compliance was shown to be no different for consensus-based and evidence-based recommendations; the CTA indicators were designed to be clinically relevant but not affected by comorbidities; inter-rater reliability was moderate, but was in line with other studies using implicit medical record review;(35) and the effect on overall compliance of care received but not documented is thought to be no more than 10%.(21, 36, 37)

## CONCLUSION

Our analysis of the VTE indicators from the CTA study show that compliance is modest at 51%, despite resources and guidelines being available, and the high associated cost and burden of disease. This is consistent with the lack of a system-wide focus on VTE. In line with recommendations arising from the overall CTA study and feedback from clinicians, the challenge is to now move towards agreement on national clinical standards and on the development of indicators and tools to guide, document and monitor the appropriateness of care for VTE. An inclusive, national wiki-based process for achieving this has been proposed.(18) VTE data could then be monitored at hospital level and the data aggregated at national level to track progress and inform policy.

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## COMPETING INTERESTS

The authors have no competing interests.

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STROBE Statement—checklist of items that should be included in reports of observational studies

| | Item No | Recommendation | |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | We have described a retrospective medical review in the Methods of the Abstract. |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | The abstract outlines the key definition of the dependent variable used, the indicator review process, sampling aim, medical record review, data collection timeframe; and the abstract results outlining the quantum of data collected, overall result and range. |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | See Introduction with particular attention to the third paragraph. |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | See last paragraph of the Introduction. |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | See Methods section including sub-sections Development and ratification of indicators, Recruitment of participants and healthcare providers, Review of medical records, and Statistical analysis. More detail is provided in the referenced protocol paper and main CareTrack Australia results paper (references 19 and 20). |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | Settings, locations, and relevant dates – see sub-section Recruitment of participants and healthcare providers in the Methods. Data collection – see Review of medical records in the Methods. More detail is provided in the referenced protocol paper and main CareTrack Australia results paper (references 19 and 20). |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>*Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of | Cross-sectional study – the eligibility criteria, sources and methods of selecting participants is outlined in the sub-section "Recruitment of participants and healthcare |

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| | | cases and controls<br>*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants | providers" in the Methods. More detail is provided in the referenced protocol paper and main CareTrack results paper (references 19 and 20). |
| | | (*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed<br>*Case-control study*—For matched studies, give matching criteria and the number of controls per case | Not applicable |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | See Table 1 for descriptions of the indicators used. |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | The sub-section Development and ratification of indicators in the Methods outlines the process for developing the indicators. The sub-section Review of medical records in the Methods outlines the assessment method. |
| Bias | 9 | Describe any efforts to address potential sources of bias | Potential sources of bias are outlined in the Strengths and Weaknesses section of the Discussion. Weighting is discussed in the sub-section Statistical Analysis in the Methods. |
| Study size | 10 | Explain how the study size was arrived at | See first paragraph of the sub-section Review of medical records in the Methods. More detail is provided in the referenced protocol paper. |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | See third paragraph of the sub-section Review of medical records in the Methods for explanation of how the variables were aggregated. These variables are reported in Table 1. |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | See Statistical Analysis in the Methods. |
| | | (*b*) Describe any methods used to examine subgroups and interactions | Not applicable. |
| | | (*c*) Explain how missing data were addressed | See second paragraph of the Results. |

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| | | (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed<br>*Case-control study*—If applicable, explain how matching of cases and controls was addressed<br>*Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy | See Statistical Analysis sub-section in the Methods for weighting process. See Appendix 2 of the CareTrack Australia study (reference 20) for a detailed description of the methodology and results of the weighting process. |
| | | (*e*) Describe any sensitivity analyses | See Statistical Analysis sub-section in the Methods for weighting process. See Appendix 2 of the main CareTrack Australia study (reference 20) for a detailed description of the methodology and results of the weighting process. |

Continued on next page

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| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | See first two paragraphs of the Results section. More details are available in the Results section of the CareTrack Australia study (reference 20). |
| | | (b) Give reasons for non-participation at each stage | See first paragraph of the Results section. More details are available in the Results section of the CareTrack Australia study (reference 20). |
| | | (c) Consider use of a flow diagram | Flow diagrams are provided in the protocol paper (reference 19) regarding stage design and the CareTrack Australia study (reference 20) for non-participation. |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | See first paragraph of the Results section. |
| | | (b) Indicate number of participants with missing data for each variable of interest | Not applicable |
| | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | Not applicable |
| Outcome data | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time | Not applicable |
| | | *Case-control study*—Report numbers in each exposure category, or summary measures of exposure | |
| | | *Cross-sectional study*—Report numbers of outcome events or summary measures | See Results. |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | See Results. |
| | | (*b*) Report category boundaries when continuous variables were categorized | Not applicable |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | Not applicable |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | See Statistical Analysis sub-section in the Methods for weighting process. See Appendix 2 of the CareTrack Australia study (reference 20) for a detailed description of the methodology and results of the weighting process. |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study | See first paragraph of the Discussion. |

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| | | objectives | |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | See Strengths and Weaknesses sub-section of the Discussion. |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | See first paragraph of the Results and the Conclusion for interpretation of results; in the second, third, and fourth paragraphs of the Discussion, our results are compared with other Australian studies and potential reasons for differences. |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | Firstly, we have compared at indicator or aggregated indicator level, our results with other Australian results in the second, third, and fourth paragraphs of the Discussion; we have discussed broader policy developments and their limitations related to our results in the fifth paragraph of the Results. Despite our sample being collected from a large number of hospitals (27), we have been cautious in generalising to the wider population. |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | See Funding section. |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

# Towards appropriate prevention and treatment of venous thromboembolism

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# Full title: Towards appropriate prevention and treatment of venous thromboembolism

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# ABSTRACT

## Objectives

The prevention and management of venous thromboembolism (VTE) is often at variance with guidelines. The CareTrack Australia (CTA) study reported that appropriate care (in line with evidence- or consensus-based guidelines) is being provided for VTE at just over half of eligible encounters. The aim of this paper is to present and discuss the detailed CTA findings for VTE as a baseline for compliance with guidelines at a population level.

## Setting

The setting was 27 hospitals in two states of Australia.

## Participants

A sample of participants designed to be representative of the Australian population was recruited. Participants who had been admitted overnight during 2009 and/or 2010 were eligible. Of the 1,154 CTA participants, 481(42%) were admitted overnight to hospital at least once, comprising 751 admissions. There were 279 females (58%), and the mean age was 64 years.

## Primary and secondary outcome measures

The primary measure was compliance with indicators of appropriate care for VTE. The indicators were extracted from Australian VTE clinical practice guidelines and ratified by experts. Participant's medical records from 2009 and 2010 were analysed for compliance with 38 VTE indicators.

## Results

Of the 35,145 CTA encounters, 1,078 (3%) were eligible for scoring against VTE indicators. There were 2 - 84 eligible encounters per indicator at 27 hospitals. Overall compliance with indicators for VTE was 51%, and ranged from 34 - 64% for aggregated sets of indicators.

## Conclusions

The prevention and management of VTE was appropriate for only half of the at-risk patients in our sample; this provides a baseline for tracking progress nationally. There is a need for national agreement on clinical standards, indicators and tools to guide, document and monitor care for VTE, and for measures to increase their uptake, particularly where deficiencies have been identified.

# ARTICLE SUMMARY

## Strengths and weaknesses of this study

- The study is designed to be representative of the Australian population rather than a convenience- or purposive-based sample.
- The review of medical records, while costly and difficult, allowed compliance to be measured in a real world setting.
- Numbers of participants and/or eligible encounters are low for some indicators.
- There was a high rate of attrition of potential participants and several sources of possible bias. However, weighting using two methods and five different options made no significant difference to the compliance percentage.

# INTRODUCTION

Each year in Australia about 1 in every 1,000 people develop a first episode of venous thrombo-embolism (VTE), manifesting as deep venous thrombosis (DVT) and/or pulmonary embolism (PE).(1, 2). This amounts to about 20,000 cases, of which 80% occur during or soon after an admission to hospital.(1, 2) Including loss of productivity, total costs amount to well over AUS$1 billion per year.(3)

There is evidence that the appropriate use of pharmacological and mechanical prophylaxis in orthopaedic, general surgical and medical patients can reduce the incidence of VTE,(4-6) although a recent paper has questioned use of pharmacological prophylaxis in lower risk medical patients.(7) Clinical practice guidelines (CPGs) have been developed, in Australia(8, 9) and elsewhere,(10, 11) to prevent VTE and to standardise the management of DVT and PE. Several initiatives have been undertaken to promote and facilitate their uptake, including implementation guides,(12) templates,(13) learning modules,(14) hospital medication self-assessments,(15) and patient information pamphlets.(16) However, despite these initiatives and the considerable harm from VTE, much of the care provided for VTE is not in line with CPGs (17) in both the developed (18) and developing worlds (19).

As healthcare is facing an affordability crisis, there is an urgent need to move towards being able to monitor the appropriateness of care ("care in line with evidence- or consensus-based guidelines").(20) The CareTrack Australia (CTA) study was designed to establish baseline estimates of the appropriateness of care delivered, at a population level, by a range of practitioners in real-world settings, and to determine what would be needed to monitor the ongoing appropriateness of care.(21) CTA showed that adult Australians received appropriate care for 22 common conditions at 57% of eligible healthcare encounters during 2009 and 2010; VTE compliance was reported at 58%.(22) The aim of this paper is to present and discuss the detailed CTA findings for VTE as a baseline for

compliance with guidelines at a population level, from which to track progress resulting from future interventions.

# METHODS

The CTA methods have been described in detail elsewhere.(21, 22) Some aspects of relevance to VTE are summarised here.

## Development and ratification of indicators

An initial list of 15 indicators (with 54 sub-criteria) was sourced from recommendations within the National Health and Medical Research Council guidelines(8, 9) and sent to three practising specialist haematologists who were Heads of Departments, asking them to comment on and rate each on a scale of 1 to 9 for appropriateness(23) in the Australian context during 2009 and 2010. A two-round review process was used and a formal process was employed for managing discrepancies between specialists.(21) Opinions of other specialists were not canvassed for logistical reasons. This resulted in 39 indicators being accepted as appropriate: 31 relating to pharmacological and mechanical prophylaxis and eight to risk assessment, discharge care and management of DVT or PE (see Table 1).

## Recruitment of participants and healthcare providers

A sample designed to be representative of the Australian adult population was used. Households were randomly selected from a phone directory (the Telstra White Pages) from defined regions within New South Wales and South Australia and contacted using a Computer-Assisted Telephone Interview (CATI).(21, 22) One adult was randomly selected from each household and was asked to participate. Those who agreed were sent a mail package containing information about the study and a consent form to allow access to their medical records. Participants who provided consent were called back and asked if they had been admitted overnight to a hospital or had one or more of the CTA conditions, and which

healthcare providers they had seen for these in 2009 and 2010. Hospitals identified by the participants were contacted and asked to provide their consent for medical record access. Human Research Ethics Committee (HREC) approval was obtained from Hunter New England Local Health District as the lead HREC and other relevant bodies and local sites.(22)

## Review of medical records

Medical record reviews were undertaken for the 1,154 consenting participants whose healthcare providers had also provided consent. Healthcare encounters were deemed eligible for scoring of VTE indicators if a participant had been admitted overnight during 2009 and/or 2010.

Experienced registered nurses were recruited and trained as surveyors to conduct the medical record reviews using a web-based tool for on-site encrypted data collection. They were provided with formal training and received a manual with detailed criteria for inclusion, exclusion and scoring of indicators.

Estimates of compliance were measured as the percentage of eligible encounters for the VTE indicators that were answered 'yes'.(21, 22) The inclusion criteria for the indicators for VTE prophylaxis were specific to particular types of surgery (e.g. hip fracture surgery or abdominal surgery) or medical conditions (e.g. decompensated cardiac failure or acute on chronic lung disease).(8, 9) As the CTA study was designed to measure the overall appropriateness of the healthcare delivered for 22 conditions and was not powered for significant results at indicator level, the number of eligible encounters for many indicators was low. To address this, indicators were aggregated into broader, clinically meaningful categories. For example, orthopaedic conditions with pharmacological prophylaxis (indicators 45-48) were grouped and included hip arthroplasty, hip fracture surgery, knee arthroplasty, and lower limb fractures (see Table 1).

Data relating to documentation of VTE risk assessment (indicator 42) was not included in the analysis reported here, as a review of surveyor practices revealed that some had assumed that a risk assessment had been carried out whenever appropriate prophylaxis had been prescribed, whether or not explicit documentation of an assessment was found. This was in breach of the criteria for this indicator, and these data were thus excluded.

## Statistical analysis

Mean compliance and associated 95% confidence intervals (using a modified version of the Clopper–Pearson (exact) method) were obtained using the SURVEYFREQ procedure in SAS version 9.3 for Windows (SAS Institute, Cary, NC, USA). To address biases arising from the study design (including adjustment for non-response), two different weighting options and five versions of weights (three based on approaches used in the similar US study(23)) were used to generate weighted estimates of compliances. These were not significantly different to unweighted compliances overall or for any condition (including VTE). Hence, unweighted compliances were used for this analysis.(22) Appendix 2 of the CTA study outlines the detailed methodology and overall results.(22)

# RESULTS

Of the 1,154 CTA participants, 481(42%) were admitted overnight to hospital at least once, with a total of 751 admissions eligible for assessment against the VTE indicators. There were 279 females (58%), and the mean age was 64 years (6% were aged 18 – 39, 17% 40 – 54, 56% 55 – 74 and 21% were over 70 years of age).

Of the 35,145 CTA encounters (with duplicates and the risk indicator removed), 1,078 (3%) were eligible for scoring against VTE indicators; the number of eligible encounters per indicator ranged from 2 - 84. Records were reviewed at 33 hospitals, with 27 having eligible encounters. Eight of the hospitals had 50 or more eligible encounters.

Overall compliance with the VTE indicators was 51% (CI 95%: 47-54%), with results for aggregated sets of indicators ranging from 34 - 64% (Table 1). Omission of the risk assessment indicator from the overall score reduced compliance from the 58% reported originally(22) to the 51% reported here. For the eight hospitals with 50 or more eligible encounters, compliance ranged from 45 - 70%.

Table 1: CTA indicators (and aggregated sets of indicators) by compliance

| Indicator Number | Indicator and sets of indicators | Eligible encounters (N) | Compliant encounters (N) | Compliance* (%) | 95% confidence limits† (%) |
|---|---|---|---|---|---|
| **45-48** | **Patients undergoing certain orthopaedic procedures or care received appropriate pharmacological anticoagulant therapy** | **55** | **34** | **62** | **48 - 75** |
| 45 | Patients who had a hip arthroplasty have received anticoagulant therapy for up to 35 days‡ | 22 | 12 | Insufficient data to report | |
| 46 | Patients who had hip fracture surgery have received anticoagulant therapies for up to 35 days§ | 2 | 2 | Insufficient data to report | |

| | | | | | |
|---|---|---|---|---|---|
| 47 | Patients who had a knee arthroplasty received anticoagulant therapies for up to 28 days‖ | 24 | 16 | Insufficient data to report | |
| 48 | Patients who had a lower limb fracture received anticoagulant therapies for at least 5 days or until fully mobile§ | 7 | 4 | Insufficient data to report | |
| **62, 68-70, 73-75** | **Patients undergoing certain orthopaedic procedures or care received appropriate mechanical anticoagulant therapy** | **104** | **49** | **47** | **37 - 57** |
| 62 | Patients having a total hip replacement have been prescribed graduation compression stockings | 20 | 19 | Insufficient data to report | |
| 68 | Patients having a total hip replacement have been prescribed an intermittent pneumatic compression device | 18 | 11 | Insufficient data to report | |
| 69 | Patients having hip fracture surgery have been prescribed an intermittent pneumatic compression device | 3 | 1 | Insufficient data to report | |
| 70 | Patients having a total knee replacement have been prescribed an intermittent pneumatic compression device | 21 | 15 | Insufficient data to report | |

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| 73 | Patients having a total hip replacement have been prescribed a foot pump | 18 | 1 | Insufficient data to report | |
| 74 | Patients having a total knee replacement have been prescribed a foot pump | 22 | 2 | Insufficient data to report | |
| 75 | Patients having hip fracture surgery have been prescribed a foot pump | 2 | 0 | Insufficient data to report | |
| **49-54** | **Patients undergoing non-orthopaedic surgical procedures (general, gynaecological, abdominal, cardiac, thoracic or vascular, trauma or spinal surgery) or who had cancer and underwent surgery received appropriate pharmacological anticoagulant therapy** | **226** | **76** | **34** | **27 - 41** |
| 49 | Patients who had a general surgical procedure received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 55 | 19 | 35 | 22 - 49 |

| | | | | | |
|---|---|---|---|---|---|
| 50 | Patients who had gynaecological surgery received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 26 | 5 | Insufficient data to report | |
| 51 | Patients who had abdominal surgery received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 61 | 29 | 48 | 18 - 78 |
| 52 | Patients who had cardiac, thoracic or vascular surgery received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 31 | 12 | 39 | 16 - 66 |
| 53 | Patients who had trauma or spinal surgery received anticoagulant therapies commenced after primary haemostasis was established (unless contraindicated) until hospital discharge or fully mobile¶ | 18 | 0 | Insufficient data to report | |
| 54 | Patients who have cancer that underwent surgery received one | 35 | 11 | 31 | 5 - 74 |

| | | | | | |
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| | of the following anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | | | | |
| **63-67, 71-72** | **Patients undergoing non-orthopaedic surgical procedures received appropriate mechanical anticoagulant therapy** | **294** | **176** | **60** | **52 - 67** |
| 63 | Patients having general surgery have been prescribed graduated compression stockings | 72 | 63 | 88 | 78 - 94 |
| 64 | Patients having gynaecological surgery have been prescribed graduation compression stockings | 28 | 21 | Insufficient data to report | |
| 65 | Patients having abdominal surgery have been prescribed graduation compression stockings | 66 | 48 | 73 | 46 - 91 |
| 66 | Patients having cardiac, thoracic or vascular surgery have been prescribed graduation compression stockings | 52 | 17 | 33 | 2 - 85 |
| 67 | Patients having neurosurgery have been prescribed graduation compression stockings | 13 | 11 | Insufficient data to report | |

| | | | | | |
|---|---|---|---|---|---|
| 71 | Patients having cardiac, thoracic or vascular surgery have been prescribed an intermittent pneumatic compression device | 50 | 7 | 14 | 2 - 41 |
| 72 | Patients having neurosurgery have been prescribed an intermittent pneumatic compression devices | 13 | 9 | Insufficient data to report | |
| **55-61** | **Medical patients admitted to hospital with certain conditions received appropriate pharmacological anticoagulant therapy** | **167** | **77** | **46** | **36 - 57** |
| 55 | Medical patients admitted to hospital with ischemic stroke received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 5 | 1 | Insufficient data to report | |
| 56 | Medical patients admitted to hospital with myocardial infarct (where full anticoagulant is not in use) received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 15 | 6 | Insufficient data to report | |

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| 57 | General Medical patients admitted to hospital assessed as being at risk of VTE received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 84 | 43 | 51 | 40 - 62 |
| 58 | Medical patients admitted to hospital with active cancer received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 23 | 8 | Insufficient data to report | |
| 59 | Medical patients admitted to hospital with decompensated cardiac failure received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 7 | 3 | Insufficient data to report | |
| 60 | Medical patients admitted to hospital with acute on chronic lung disease received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 31 | 15 | 48 | 30 - 67 |
| 61 | Medical patients admitted to hospital with acute on chronic inflammatory disease received anticoagulant therapies until | 2 | 1 | Insufficient data to report | |

| | | | | | |
|---|---|---|---|---|---|
| | resolution of the acute medical illness or until hospital discharge†† | | | | |
| **76-80** | **Patients with suspected PE/DVT were managed with appropriate investigations, or had anticoagulant therapy commenced as soon as clinically suspected; or if PE/DVT confirmed, were managed appropriately** | **89** | **57** | **64** | **51 - 76** |
| 76 | Patients with a suspected DVT had a venous duplex ultrasound performed | 12 | 10 | Insufficient data to report | |
| 77 | Patients with a suspected PE had investigations performed‡‡ | 21 | 17 | Insufficient data to report | |
| 78 | Patients with a suspected DVT or PE where ultrasound was delayed, had anticoagulant therapy commenced (unless contraindicated) as soon as clinically suspected | 10 | 8 | Insufficient data to report | |
| 79 | Patients with a confirmed DVT / PE received anticoagulant therapies[A] | 6 | 3 | Insufficient data to report | |

| | | | | | |
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| 80 | Patients who were administered heparin therapy had it continued until the *International Normalized Ratio* (INR) had been therapeutic for 48 hours (INR range 2.0 - 3.0) | 40 | 19 | 48 | 26 - 70 |
| **Patients discharged on anticoagulant therapy have an appropriate documented care plan including details on the intended duration of treatment AND a review date[B]** | | 70 | 32 | 46 | 31 - 61 |
| 43 | Patients who are discharged on anticoagulant therapy have a documented care plan that includes details on the intended duration of treatment | 73 | 43 | 59 | 46 - 71 |
| 44 | Patients who are discharged on anticoagulant therapy have a documented care plan that includes a review date | 70 | 35 | 50 | 29 - 71 |

Footnote:

† compliance and % compliance were not calculated for <30 encounters

‡ enoxaparin 40mg/day; dalteparin 5000u/day; low dose unfractionated heparin (LDUH) 5000u TDS; fondiparinux 2.5mg/day [commenced 6 – 8 hours post op]; rivaroxaban[PO]; dabigatran [PO]

§ enoxaparin 40mg/day; dalteparin 5000u/day; LDUH 5000u TDS; fondiparinux 2.5mg/day [commenced 6 – 8 hours post op]

|| enoxaparin 40mg/day; dalteparin 5000u/day; LDUH 5000u TDS; fondiparinux 2.5mg/day [commenced 6 – 8 hours post op]; rivaroxaban[PO]; dabigatran [PO]

¶ enoxaparin 20mg/day; dalteparin 2500U/day

†† enoxaparin 40mg/day; dalteparin 5000U/day; LDUH 5000U BD or TDS; assumed implicit and explicit risk assessments included.

‡‡ One of: ventilation perfusion scan; CT angiography; pulmonary angiography

A heparin administered together with warfarin for at least 5 days; unfractionated heparin IV (Activated Partial Thromboplastin Time (APTT)) or subcutaneous (dose/kg); Low Molecular Weight Heparin (LMWH) subcutaneously at least once daily.

B Compliance for this aggregated indicator was both indicators 43 and 44 were compliant for a participant in an episode of hospitalisation. In other aggregated indicators, compliance was measured by adding each individual encounter as each episode of hospitalisation was an independent event.

# DISCUSSION

Despite the prevalence, cost, morbidity and mortality associated with VTE, prophylaxis and treatment is often not in line with CPGs. This analysis of CTA data has shown that our sample of 481 Australian adults in 27 hospitals received appropriate care for VTE during 2009 and 2010 at 51% of eligible healthcare encounters.

CTA patients who had surgery received appropriate pharmacological or mechanical anticoagulant therapy on only 39% and 57% of occasions respectively (aggregations from Table 1). The ENDORSE study, a multi-national cross-sectional survey, also examined the proportion of at-risk patients who received effective prophylaxis.(17) It found, for 804 patients from eight Australian hospitals studied in 2006-07, that 82% of at-risk surgical patients received appropriate prophylaxis. This study did not separate pharmacological and mechanical prophylaxis.(17) Baseline (pre-intervention) compliances for surgical patients were also higher than CTA compliances in two single hospital studies (65 and 74% for pharmacological prophylaxis and 89 and 64% for mechanical prophylaxis).(24, 25) Possible reasons for the lower CTA compliances are that CTA was a population-based study at 27 hospitals which were effectively randomly selected, whilst ENDORSE mainly collected data from prominent teaching hospitals, and the two single hospital studies were about to start an intervention for VTE prophylaxis, possibly raising awareness of the problem.

In contrast, the CTA compliance for at-risk medical patients at 46% (aggregations from Table 1) was similar to those in the eight Australian ENDORSE hospitals and a regional hospital (51%, and 64%, respectively).(17, 25) Lower compliances for medical than surgical patients in the ENDORSE study and the regional hospital are consistent with the more complex indications in medical patients, and have been noted elsewhere.(26) No equivalent Australian studies could be found for indicators associated with management of suspected or confirmed DVT or PE (CTA compliance 64%), or patients with a documented discharge

plan and a date for cessation of treatment (CTA compliance 46%), but it would seem reasonable to conclude that both of these areas of practice also require attention.

The risk assessment indicator was studied in two Australian single-hospital studies which both found 0% compliance at the pre-intervention stage, with modest post-intervention increases to 28 and 36%.(24, 27)

The poor compliances with VTE indicators in Australia are consistent with the lack of a system-wide approach. Compliance measures or outcomes are not publicly reported at hospital level,(28) VTE is not included in national standards,(29) nor is it a national health care goal.(30) Australian clinicians have identified that setting agreement on clinical guidelines and standards (agreement on risk categories, risk assessment tools, mandatory actions and protocols, provision of summaries), decision-support tools, and reporting results are enablers to delivering appropriate VTE care.(31, 32) The fact that compliance ranged from 45% to 70% between hospitals suggests that some facilities are faring better than others at managing VTE appropriately.

## Strengths and weaknesses

The key strength of the CTA study is that it is designed to be representative of the Australian population rather than a convenience- or purposive-based sample. However, an unavoidable consequence of this strategy, coupled with finite research funds, is that the numbers of participants and/or eligible encounters are low for some indicators; 25 of 38 had insufficient data to report. Findings for these must be disregarded or interpreted with caution. The review of medical records, while costly and difficult, allowed compliance to be measured in a real world setting and avoided the limitations inherent in asking health care providers to respond to clinical vignettes(33, 34) or questionnaires.(35) Accordingly CTA provides some baseline estimates for compliance against which progress on the provision of appropriate care for VTE could be compared and tracked.

The approach used was associated with a high rate of attrition of potential participants and several sources of possible bias. However, weighting using two methods and five different options made no significant difference to the overall compliance percentage, or that for VTE;(22) this is consistent with providers not altering their clinical practices for patients of different ages, gender, or socio-economic or health literacy status.

Commentators have raised issues with respect to the levels of evidence, choice of indicators, effects of comorbidities, inter-rater reliability, and the possibility of care having been provided but not recorded.(36, 37) These have all been addressed:(22, 38) compliance was shown to be no different for consensus-based and evidence-based recommendations; the CTA indicators were designed to be clinically relevant but not affected by comorbidities; inter-rater reliability was moderate, but was in line with other studies using implicit medical record review;(38) and the effect on overall compliance of care received but not documented is thought to be no more than 10%.(23, 39, 40)

## CONCLUSION

Our analysis of the VTE indicators from the CTA study show that compliance is modest at 51%, despite resources and guidelines being available, and the high associated cost and burden of disease. This is consistent with the lack of a system-wide focus on VTE. In line with recommendations arising from the overall CTA study and feedback from clinicians, the challenge is to now move towards agreement on national clinical standards and on the development of indicators and tools to guide, document and monitor the appropriateness of care for VTE. An inclusive, national wiki-based process for achieving this has been proposed.(20) VTE data could then be monitored at hospital level and the data aggregated at national level to track progress and inform policy.

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## CONTRIBUTORSHIP STATEMENT

I confirm that all listed authors have contributed substantially to the conception and design of the study, or acquisition of data or analysis and interpretation of the finding. All have also been actively involved in either the drafting of the manuscript or revising it critically for important intellectual content; and have given approval for this version to be published.

Peter D Hibbert was Program Manager for the NHMRC Program Grant who also assisted with the analysis and interpretation of findings and made a substantial contribution to review the literature, synthesising results and findings from other relevant studies, and the drafting of the manuscript.

Natalie A Hannaford was responsible for the selection, development and ratification of all the indicators used in the study and assisted Tamara Hunt with surveyor recruitment and training. She also contributed to the revision of the manuscript.

Tamara D Hooper was the Project Manager for CareTrack and coordinated the data collection for the entire study including the extraction of patient medical records. She also coordinated all the necessary approvals and managed the training and performance of surveyors and contributed to the revision of the manuscript.

Diane M Hindmarsh was the main Statistician for CareTrack and undertook analysis of the CareTrack. She also contributed to the interpretation of the statistical information included in the manuscript.

Jeffrey Braithwaite was involved in the design and conception of CareTrack Australia as the Chief Investigator-A of the NHMRC Program Grant, and extensive editing and revision of the manuscript.

Shanthi Ramanathan developed the initial sampling plan for CareTrack Australia; provided advice for the process of recruiting participants and organised and managed telephone recruiters.

Nicholas Wickham was involved as a CareTrack Australia clinical expert, assisted in the ratification of the SSI indicators and provided clinical input into the editing and revision of the manuscript.

William B Runciman was the primary instigator of CareTrack and responsible for its conception and design. He was also involved in all aspects of the project from data collection to analysis and interpretation of findings. He has been heavily involved in the editing and revision of the manuscript providing invaluable advice and guidance to the corresponding author.

## COMPETING INTERESTS

The authors have no competing interests.

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## DATA SHARING STATEMENT

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STROBE Statement—checklist of items that should be included in reports of observational studies

| | Item No | Recommendation | |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | We have described a retrospective medical review in the Methods of the Abstract. |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | The abstract outlines the key definition of the dependent variable used, the indicator review process, sampling aim, medical record review, data collection timeframe; and the abstract results outlining the quantum of data collected, overall result and range. |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | See Introduction with particular attention to the third paragraph. |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | See last paragraph of the Introduction. |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | See Methods section including sub-sections Development and ratification of indicators, Recruitment of participants and healthcare providers, Review of medical records, and Statistical analysis. More detail is provided in the referenced protocol paper and main CareTrack Australia results paper (references 19 and 20). |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | Settings, locations, and relevant dates – see sub-section Recruitment of participants and healthcare providers in the Methods. Data collection – see Review of medical records in the Methods. More detail is provided in the referenced protocol paper and main CareTrack Australia results paper (references 19 and 20). |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>*Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of | Cross-sectional study – the eligibility criteria, sources and methods of selecting participants is outlined in the sub-section "Recruitment of participants and healthcare |

| | | | |
|---|---|---|---|
| | | cases and controls<br>*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants | providers" in the Methods. More detail is provided in the referenced protocol paper and main CareTrack results paper (references 19 and 20). |
| | | (*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed<br>*Case-control study*—For matched studies, give matching criteria and the number of controls per case | Not applicable |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | See Table 1 for descriptions of the indicators used. |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | The sub-section Development and ratification of indicators in the Methods outlines the process for developing the indicators. The sub-section Review of medical records in the Methods outlines the assessment method. |
| Bias | 9 | Describe any efforts to address potential sources of bias | Potential sources of bias are outlined in the Strengths and Weaknesses section of the Discussion. Weighting is discussed in the sub-section Statistical Analysis in the Methods. |
| Study size | 10 | Explain how the study size was arrived at | See first paragraph of the sub-section Review of medical records in the Methods. More detail is provided in the referenced protocol paper. |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | See third paragraph of the sub-section Review of medical records in the Methods for explanation of how the variables were aggregated. These variables are reported in Table 1. |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | See Statistical Analysis in the Methods. |
| | | (*b*) Describe any methods used to examine subgroups and interactions | Not applicable. |
| | | (*c*) Explain how missing data were addressed | See second paragraph of the Results. |

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| | | (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed<br>*Case-control study*—If applicable, explain how matching of cases and controls was addressed<br>*Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy | See Statistical Analysis sub-section in the Methods for weighting process. See Appendix 2 of the CareTrack Australia study (reference 20) for a detailed description of the methodology and results of the weighting process. |
| | | (*e*) Describe any sensitivity analyses | See Statistical Analysis sub-section in the Methods for weighting process. See Appendix 2 of the main CareTrack Australia study (reference 20) for a detailed description of the methodology and results of the weighting process. |

Continued on next page

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| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | See first two paragraphs of the Results section. More details are available in the Results section of the CareTrack Australia study (reference 20). |
| | | (b) Give reasons for non-participation at each stage | See first paragraph of the Results section. More details are available in the Results section of the CareTrack Australia study (reference 20). |
| | | (c) Consider use of a flow diagram | Flow diagrams are provided in the protocol paper (reference 19) regarding stage design and the CareTrack Australia study (reference 20) for non-participation. |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | See first paragraph of the Results section. |
| | | (b) Indicate number of participants with missing data for each variable of interest | Not applicable |
| | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | Not applicable |
| Outcome data | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time | Not applicable |
| | | *Case-control study*—Report numbers in each exposure category, or summary measures of exposure | |
| | | *Cross-sectional study*—Report numbers of outcome events or summary measures | See Results. |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | See Results. |
| | | (*b*) Report category boundaries when continuous variables were categorized | Not applicable |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | Not applicable |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | See Statistical Analysis sub-section in the Methods for weighting process. See Appendix 2 of the CareTrack Australia study (reference 20) for a detailed description of the methodology and results of the weighting process. |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study | See first paragraph of the Discussion. |

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|---|---|---|---|
| | | objectives | |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | See Strengths and Weaknesses sub-section of the Discussion. |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | See first paragraph of the Results and the Conclusion for interpretation of results; in the second, third, and fourth paragraphs of the Discussion, our results are compared with other Australian studies and potential reasons for differences. |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | Firstly, we have compared at indicator or aggregated indicator level, our results with other Australian results in the second, third, and fourth paragraphs of the Discussion; we have discussed broader policy developments and their limitations related to our results in the fifth paragraph of the Results. Despite our sample being collected from a large number of hospitals (27), we have been cautious in generalising to the wider population. |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | See Funding section. |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

# Assessing the appropriateness of prevention and management of venous thromboembolism in Australia: a cross-sectional study

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# Full title: Assessing the appropriateness of prevention and management of venous thromboembolism in Australia: a cross-sectional study

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# ABSTRACT

## Objectives

The prevention and management of venous thromboembolism (VTE) is often at variance with guidelines. The CareTrack Australia (CTA) study reported that appropriate care (in line with evidence- or consensus-based guidelines) is being provided for VTE at just over half of eligible encounters. The aim of this paper is to present and discuss the detailed CTA findings for VTE as a baseline for compliance with guidelines at a population level.

## Setting

The setting was 27 hospitals in two states of Australia.

## Participants

A sample of participants designed to be representative of the Australian population was recruited. Participants who had been admitted overnight during 2009 and/or 2010 were eligible. Of the 1,154 CTA participants, 481(42%) were admitted overnight to hospital at least once, comprising 751 admissions. There were 279 females (58%), and the mean age was 64 years.

## Primary and secondary outcome measures

The primary measure was compliance with indicators of appropriate care for VTE. The indicators were extracted from Australian VTE clinical practice guidelines and ratified by experts. Participants' medical records from 2009 and 2010 were analysed for compliance with 38 VTE indicators.

## Results

Of the 35,145 CTA encounters, 1,078 (3%) were eligible for scoring against VTE indicators. There were 2 - 84 eligible encounters per indicator at 27 hospitals. Overall compliance with indicators for VTE was 51%, and ranged from 34 - 64% for aggregated sets of indicators.

## Conclusions

The prevention and management of VTE was appropriate for only half of the at-risk patients in our sample; this provides a baseline for tracking progress nationally. There is a need for national and, ideally, international agreement on clinical standards, indicators and tools to guide, document and monitor care for VTE, and for measures to increase their uptake, particularly where deficiencies have been identified.

## ARTICLE SUMMARY

### Strengths and weaknesses of this study

- The study is designed to be representative of the Australian population rather than a convenience- or purposive-based sample.
- The review of medical records, while costly and difficult, allowed compliance to be measured in a real world setting.
- Numbers of participants and/or eligible encounters are low for some indicators.
- There was a high rate of attrition of potential participants and several sources of possible bias. However, weighting using two methods and five different options made no significant difference to the compliance percentage.

# INTRODUCTION

Each year in Australia about 1 in every 1,000 people develop a first episode of venous thrombo-embolism (VTE), manifesting as deep venous thrombosis (DVT) and/or pulmonary embolism (PE).(1, 2). This amounts to about 20,000 cases, of which 80% occur during or soon after an admission to hospital.(1, 2) Including loss of productivity, total costs amount to well over AUS$1 billion per year.(3)

There is evidence that the appropriate use of pharmacological and mechanical prophylaxis in orthopaedic, general surgical and medical patients can reduce the incidence of VTE,(4-6) although a recent paper has questioned use of pharmacological prophylaxis in lower risk medical patients.(7) Clinical practice guidelines (CPGs) have been developed, in Australia(8, 9) and elsewhere,(10, 11) to prevent VTE and to standardise the management of DVT and PE. Several initiatives have been undertaken to promote and facilitate their uptake, including implementation guides,(12) templates,(13) learning modules,(14) hospital medication self-assessments,(15) and patient information pamphlets.(16) However, despite these initiatives and the considerable harm from VTE, much of the care provided for VTE is not in line with CPGs (17) in both the developed (18) and developing worlds (19).

As healthcare is facing an affordability crisis, there is an urgent need to move towards being able to monitor the appropriateness of care ("care in line with evidence- or consensus-based guidelines").(20) The CareTrack Australia (CTA) study was designed to establish baseline estimates of the appropriateness of care delivered, at a population level, by a range of practitioners in real-world settings, and to determine what would be needed to monitor the ongoing appropriateness of care.(21) CTA showed that adult Australians received appropriate care for 22 common conditions at 57% of eligible healthcare encounters during 2009 and 2010; VTE compliance was reported at 58%.(22) The aim of this paper is to present and discuss the detailed CTA findings for VTE as a baseline for

compliance with guidelines at a population level, from which to track progress resulting from future interventions.

# METHODS

The CTA methods have been described in detail elsewhere.(21, 22) Some aspects of relevance to VTE are summarised here.

## Development and ratification of indicators

An initial list of 15 indicators (with 54 sub-criteria) was sourced from recommendations within the National Health and Medical Research Council guidelines(8, 9) and sent to three practising specialist haematologists who were Heads of Departments, asking them to comment on and rate each on a scale of 1 to 9 for appropriateness(23) in the Australian context during 2009 and 2010. A two-round review process was used and a formal process was employed for managing discrepancies between specialists.(21) Opinions of other specialists were not canvassed for logistical reasons. This resulted in 39 indicators being accepted as appropriate: 31 relating to pharmacological and mechanical prophylaxis and eight to risk assessment, discharge care and management of DVT or PE (see Table 1).

## Recruitment of participants and healthcare providers

A sample designed to be representative of the Australian adult population was used. Households were randomly selected from a phone directory (the Telstra White Pages) from defined regions within New South Wales and South Australia and contacted using a Computer-Assisted Telephone Interview (CATI).(21, 22) One adult was randomly selected from each household and was asked to participate. Those who agreed were sent a mail package containing information about the study and a consent form to allow access to their medical records. Participants who provided consent were called back and asked if they had been admitted overnight to a hospital or had one or more of the CTA conditions, and which

healthcare providers they had seen for these in 2009 and 2010. Hospitals identified by the participants were contacted and asked to provide their consent for medical record access. Human Research Ethics Committee (HREC) approval was obtained from Hunter New England Local Health District as the lead HREC and other relevant bodies and local sites.(22)

## Review of medical records

Medical record reviews were undertaken for the 1,154 consenting participants whose healthcare providers had also provided consent. Healthcare encounters were deemed eligible for scoring of VTE indicators if a participant had been admitted overnight during 2009 and/or 2010.

Experienced registered nurses were recruited and trained as surveyors to conduct the medical record reviews using a web-based tool for on-site encrypted data collection. They were provided with formal training and received a manual with detailed criteria for inclusion, exclusion and scoring of indicators.

Estimates of compliance were measured as the percentage of eligible encounters for the VTE indicators that were answered 'yes'.(21, 22) The inclusion criteria for the indicators for VTE prophylaxis were specific to particular types of surgery (e.g. hip fracture surgery or abdominal surgery) or medical conditions (e.g. decompensated cardiac failure or acute on chronic lung disease).(8, 9) As the CTA study was designed to measure the overall appropriateness of the healthcare delivered for 22 conditions and was not powered for significant results at indicator level, the number of eligible encounters for many indicators was low. To address this, indicators were aggregated into broader, clinically meaningful categories. For example, orthopaedic conditions with pharmacological prophylaxis (indicators 45-48) were grouped and included hip arthroplasty, hip fracture surgery, knee arthroplasty, and lower limb fractures (see Table 1).

Data relating to documentation of VTE risk assessment (indicator 42) was not included in the analysis reported here, as a review of surveyor practices revealed that some had assumed that a risk assessment had been carried out whenever appropriate prophylaxis had been prescribed, whether or not explicit documentation of an assessment was found. This was in breach of the criteria for this indicator, and these data were thus excluded.

## Statistical analysis

Mean compliance and associated 95% confidence intervals (using a modified version of the Clopper–Pearson (exact) method) were obtained using the SURVEYFREQ procedure in SAS version 9.3 for Windows (SAS Institute, Cary, NC, USA). To address biases arising from the study design (including adjustment for non-response), two different weighting options and five versions of weights (three based on approaches used in the similar US study(23)) were used to generate weighted estimates of compliances. These were not significantly different to unweighted compliances overall or for any condition (including VTE). Hence, unweighted compliances were used for this analysis.(22) Appendix 2 of the CTA study outlines the detailed methodology and overall results.(22)

# RESULTS

Of the 1,154 CTA participants, 481(42%) were admitted overnight to hospital at least once, with a total of 751 admissions eligible for assessment against the VTE indicators. There were 279 females (58%), and the mean age was 64 years (6% were aged 18 – 39, 17% 40 – 54, 56% 55 – 74 and 21% were over 70 years of age).

Of the 35,145 CTA encounters (with duplicates and the risk indicator removed), 1,078 (3%) were eligible for scoring against VTE indicators; the number of eligible encounters per indicator ranged from 2 - 84. Records were reviewed at 33 hospitals, with 27 having eligible encounters. Eight of the hospitals had 50 or more eligible encounters.

Overall compliance with the VTE indicators was 51% (CI 95%: 47-54%), with results for aggregated sets of indicators ranging from 34 - 64% (Table 1). Omission of the risk assessment indicator from the overall score reduced compliance from the 58% reported originally(22) to the 51% reported here. For the eight hospitals with 50 or more eligible encounters, compliance ranged from 45 - 70%.

Table 1: CTA indicators (and aggregated sets of indicators) by compliance

| Indicator Number | Indicator and sets of indicators | Eligible encounters (N) | Compliant encounters (N) | Compliance* (%) | 95% confidence limits† (%) |
|---|---|---|---|---|---|
| **45-48** | **Patients undergoing certain orthopaedic procedures or care received appropriate pharmacological anticoagulant therapy** | **55** | **34** | **62** | **48 - 75** |
| 45 | Patients who had a hip arthroplasty have received anticoagulant therapy for up to 35 days‡ | 22 | 12 | Insufficient data to report | |
| 46 | Patients who had hip fracture surgery have received anticoagulant therapies for up to 35 days§ | 2 | 2 | Insufficient data to report | |

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| 47 | Patients who had a knee arthroplasty received anticoagulant therapies for up to 28 days‖ | 24 | 16 | Insufficient data to report | |
| 48 | Patients who had a lower limb fracture received anticoagulant therapies for at least 5 days or until fully mobile§ | 7 | 4 | Insufficient data to report | |
| **62, 68-70, 73-75** | **Patients undergoing certain orthopaedic procedures or care received appropriate mechanical anticoagulant therapy** | **104** | **49** | **47** | **37 - 57** |
| 62 | Patients having a total hip replacement have been prescribed graduation compression stockings | 20 | 19 | Insufficient data to report | |
| 68 | Patients having a total hip replacement have been prescribed an intermittent pneumatic compression device | 18 | 11 | Insufficient data to report | |
| 69 | Patients having hip fracture surgery have been prescribed an intermittent pneumatic compression device | 3 | 1 | Insufficient data to report | |
| 70 | Patients having a total knee replacement have been prescribed an intermittent pneumatic compression device | 21 | 15 | Insufficient data to report | |

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| 73 | Patients having a total hip replacement have been prescribed a foot pump | 18 | 1 | Insufficient data to report | |
| 74 | Patients having a total knee replacement have been prescribed a foot pump | 22 | 2 | Insufficient data to report | |
| 75 | Patients having hip fracture surgery have been prescribed a foot pump | 2 | 0 | Insufficient data to report | |
| **49-54** | **Patients undergoing non-orthopaedic surgical procedures (general, gynaecological, abdominal, cardiac, thoracic or vascular, trauma or spinal surgery) or who had cancer and underwent surgery received appropriate pharmacological anticoagulant therapy** | **226** | **76** | **34** | **27 - 41** |
| 49 | Patients who had a general surgical procedure received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 55 | 19 | 35 | 22 - 49 |

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| 50 | Patients who had gynaecological surgery received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 26 | 5 | Insufficient data to report | |
| 51 | Patients who had abdominal surgery received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 61 | 29 | 48 | 18 - 78 |
| 52 | Patients who had cardiac, thoracic or vascular surgery received anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | 31 | 12 | 39 | 16 - 66 |
| 53 | Patients who had trauma or spinal surgery received anticoagulant therapies commenced after primary haemostasis was established (unless contraindicated) until hospital discharge or fully mobile¶ | 18 | 0 | Insufficient data to report | |
| 54 | Patients who have cancer that underwent surgery received one | 35 | 11 | 31 | 5 - 74 |

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| | of the following anticoagulant therapies (unless contraindicated) until hospital discharge or fully mobile¶ | | | | |
| **63-67, 71-72** | **Patients undergoing non-orthopaedic surgical procedures received appropriate mechanical anticoagulant therapy** | **294** | **176** | **60** | **52 - 67** |
| 63 | Patients having general surgery have been prescribed graduated compression stockings | 72 | 63 | 88 | 78 - 94 |
| 64 | Patients having gynaecological surgery have been prescribed graduation compression stockings | 28 | 21 | Insufficient data to report | |
| 65 | Patients having abdominal surgery have been prescribed graduation compression stockings | 66 | 48 | 73 | 46 - 91 |
| 66 | Patients having cardiac, thoracic or vascular surgery have been prescribed graduation compression stockings | 52 | 17 | 33 | 2 - 85 |
| 67 | Patients having neurosurgery have been prescribed graduation compression stockings | 13 | 11 | Insufficient data to report | |

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| 71 | Patients having cardiac, thoracic or vascular surgery have been prescribed an intermittent pneumatic compression device | 50 | 7 | 14 | 2 - 41 |
| 72 | Patients having neurosurgery have been prescribed an intermittent pneumatic compression devices | 13 | 9 | Insufficient data to report | |
| **55-61** | **Medical patients admitted to hospital with certain conditions received appropriate pharmacological anticoagulant therapy** | **167** | **77** | **46** | **36 - 57** |
| 55 | Medical patients admitted to hospital with ischemic stroke received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 5 | 1 | Insufficient data to report | |
| 56 | Medical patients admitted to hospital with myocardial infarct (where full anticoagulant is not in use) received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 15 | 6 | Insufficient data to report | |

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| 57 | General Medical patients admitted to hospital assessed as being at risk of VTE received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 84 | 43 | 51 | 40 - 62 |
| 58 | Medical patients admitted to hospital with active cancer received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 23 | 8 | Insufficient data to report | |
| 59 | Medical patients admitted to hospital with decompensated cardiac failure received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 7 | 3 | Insufficient data to report | |
| 60 | Medical patients admitted to hospital with acute on chronic lung disease received anticoagulant therapies until resolution of the acute medical illness or until hospital discharge†† | 31 | 15 | 48 | 30 - 67 |
| 61 | Medical patients admitted to hospital with acute on chronic inflammatory disease received anticoagulant therapies until | 2 | 1 | Insufficient data to report | |

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| | resolution of the acute medical illness or until hospital discharge†† | | | | |
| **76-80** | **Patients with suspected PE/DVT were managed with appropriate investigations, or had anticoagulant therapy commenced as soon as clinically suspected; or if PE/DVT confirmed, were managed appropriately** | **89** | **57** | **64** | **51 - 76** |
| 76 | Patients with a suspected DVT had a venous duplex ultrasound performed | 12 | 10 | Insufficient data to report | |
| 77 | Patients with a suspected PE had investigations performed‡‡ | 21 | 17 | Insufficient data to report | |
| 78 | Patients with a suspected DVT or PE where ultrasound was delayed, had anticoagulant therapy commenced (unless contraindicated) as soon as clinically suspected | 10 | 8 | Insufficient data to report | |
| 79 | Patients with a confirmed DVT / PE received anticoagulant therapies[A] | 6 | 3 | Insufficient data to report | |

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| 80 | Patients who were administered heparin therapy had it continued until the *International Normalized Ratio* (INR) had been therapeutic for 48 hours (INR range 2.0 - 3.0) | 40 | 19 | 48 | 26 - 70 |
| **Patients discharged on anticoagulant therapy have an appropriate documented care plan including details on the intended duration of treatment AND a review date[B]** | | 70 | 32 | 46 | 31 - 61 |
| 43 | Patients who are discharged on anticoagulant therapy have a documented care plan that includes details on the intended duration of treatment | 73 | 43 | 59 | 46 - 71 |
| 44 | Patients who are discharged on anticoagulant therapy have a documented care plan that includes a review date | 70 | 35 | 50 | 29 - 71 |

Footnote:

† compliance and % compliance were not calculated for <30 encounters

‡ enoxaparin 40mg/day; dalteparin 5000u/day; low dose unfractionated heparin (LDUH) 5000u TDS; fondiparinux 2.5mg/day [commenced 6 – 8 hours post op]; rivaroxaban[PO]; dabigatran [PO]

§ enoxaparin 40mg/day; dalteparin 5000u/day; LDUH 5000u TDS; fondiparinux 2.5mg/day [commenced 6 – 8 hours post op]

|| enoxaparin 40mg/day; dalteparin 5000u/day; LDUH 5000u TDS; fondiparinux 2.5mg/day [commenced 6 – 8 hours post op]; rivaroxaban[PO]; dabigatran [PO]

¶ enoxaparin 20mg/day; dalteparin 2500U/day

†† enoxaparin 40mg/day; dalteparin 5000U/day; LDUH 5000U BD or TDS; assumed implicit and explicit risk assessments included.

‡‡ One of: ventilation perfusion scan; CT angiography; pulmonary angiography

A heparin administered together with warfarin for at least 5 days; unfractionated heparin IV (Activated Partial Thromboplastin Time (APTT)) or subcutaneous (dose/kg); Low Molecular Weight Heparin (LMWH) subcutaneously at least once daily.

B Compliance for this aggregated indicator was both indicators 43 and 44 were compliant for a participant in an episode of hospitalisation. In other aggregated indicators, compliance was measured by adding each individual encounter as each episode of hospitalisation was an independent event.

# DISCUSSION

Our analysis of CTA data has shown that a sample of 481 Australian adults in 27 hospitals received appropriate care for VTE during 2009 and 2010 at only 51% of eligible healthcare encounters, in spite of considerable efforts to promote and facilitate the uptake of CPGs in Australia.(12-16) Thus despite the prevalence, cost, morbidity and mortality associated with VTE and PE, prophylaxis and treatment are still in line with CPGs only half the time. This continues to be a problem in both the developed and developing worlds.(17-19)

CTA patients who had surgery received appropriate pharmacological or mechanical anticoagulant therapy on only 39% and 57% of occasions respectively (aggregations from Table 1). The ENDORSE study, a multi-national cross-sectional survey, also examined the proportion of at-risk patients who received effective prophylaxis.(17) It found, for 804 patients from eight Australian hospitals studied in 2006-07, that 82% of at-risk surgical patients received appropriate prophylaxis. This study did not separate pharmacological and mechanical prophylaxis.(17) Baseline (pre-intervention) compliances for surgical patients were also higher than CTA compliances in two single hospital studies (65 and 74% for pharmacological prophylaxis and 89 and 64% for mechanical prophylaxis).(24, 25) Possible reasons for the lower CTA compliances are that CTA was a population-based study at 27 hospitals which were effectively randomly selected, whilst ENDORSE mainly collected data from prominent teaching hospitals, and the two single hospital studies were about to start an intervention for VTE prophylaxis, and had possibly raised awareness of the problem.

In contrast, the CTA compliance for at-risk medical patients at 46% (aggregations from Table 1) was similar to those in the eight Australian ENDORSE hospitals and a regional hospital (51%, and 64%, respectively).(17, 25) Lower compliances for medical than surgical patients in the ENDORSE study and the regional hospital are consistent with the more

complex indications in medical patients, and have been noted elsewhere.(26) No equivalent Australian studies could be found for indicators associated with management of suspected or confirmed DVT or PE (CTA compliance 64%), or patients with a documented discharge plan and a date for cessation of treatment (CTA compliance 46%), but it would seem reasonable to conclude that both of these areas of practice also require attention.

The risk assessment indicator was studied in two Australian single-hospital studies which both found 0% compliance at the pre-intervention stage, with modest post-intervention compliances of 28 and 36%.(24, 27)

The poor compliances with VTE indicators in Australia are consistent with the lack of a system-wide approach. Compliance measures or outcomes are not publicly reported at hospital level,(28) VTE is not included in national standards,(29) nor is it a national health care goal.(30) Australian clinicians have identified that setting agreement on clinical guidelines and standards (agreement on risk categories, risk assessment tools, mandatory actions and protocols, provision of summaries), decision-support tools, and reporting results are enablers to delivering appropriate VTE care.(31, 32) The fact that compliance ranged from 45% to 70% between hospitals suggests that some facilities are faring better than others at managing VTE appropriately.

## Strengths and weaknesses

The key strength of the CTA study is that it is designed to be representative of the Australian population to minimise selection bias, rather than a convenience- or purposive-based sample. However, an unavoidable consequence of this strategy, coupled with finite research funds, is that the numbers of participants and/or eligible encounters are low for some indicators; 25 of 38 had insufficient data to report. Findings for these must be disregarded or interpreted with caution. The review of medical records, while costly and difficult, allowed compliance to be measured in a real world setting and avoided the limitations inherent in asking health care providers to respond to clinical vignettes(33, 34) or

questionnaires.(35) Errors arising from measurement (information bias) were within acceptable limits for implicit review.(36-38) Accordingly CTA provides some baseline estimates for compliance against which progress on the provision of appropriate care for VTE could be compared and tracked.

The approach used was associated with a high rate of attrition of potential participants and several other sources of possible bias. Although it was not logistically feasible to design sampling so as to eliminate all possible confounders (confusion bias) or have the sample characteristics to exactly match the Australian population, weighting using two methods and five different options made no significant difference to the overall compliance percentage, or that for VTE;(22) this is consistent with providers not altering their clinical practices for patients of different ages, gender, or socio-economic or health literacy status.

Commentators have raised issues with respect to the levels of evidence for and choice of indicators, effects of comorbidities, inter-rater reliability, and the possibility of care having been provided but not recorded.(36, 37) These have all been addressed:(22, 38) compliance was shown to be no different for consensus-based and evidence-based recommendations; the CTA indicators were designed to be clinically relevant but not affected by comorbidities; inter-rater reliability was moderate, but was in line with other studies using implicit medical record review;(38) and the effect on overall compliance of care received but not documented is thought to be no more than 10%.(23, 39, 40)

## CONCLUSION

Our analysis of the VTE indicators from the CTA study show that compliance is modest at 51%, despite resources and guidelines being available, and the high associated cost and burden of disease. This is consistent with the lack of a system-wide focus on VTE in Australia as is the case in most of the rest of the world. In line with recommendations arising from the overall CTA study and feedback from clinicians, the challenge is to now move towards agreement on national clinical standards and on the development of

indicators and tools to guide, document and monitor the appropriateness of care for VTE. An inclusive, national wiki-based process for achieving this has been proposed.(20) VTE data could then be monitored at hospital level and the data aggregated at national and, potentially at international levels to track progress and inform policy.

## ACKNOWLEDGEMENTS

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## CONTRIBUTORSHIP STATEMENT

I confirm that all listed authors have contributed substantially to the conception and design of the study, or acquisition of data or analysis and interpretation of the finding. All have also been actively involved in either the drafting of the manuscript or revising it critically for important intellectual content; and have given approval for this version to be published.

Peter D Hibbert was Program Manager for the NHMRC Program Grant who also assisted with the analysis and interpretation of findings and made a substantial contribution to review the literature, synthesising results and findings from other relevant studies, and the drafting of the manuscript.

Natalie A Hannaford was responsible for the selection, development and ratification of all the indicators used in the study and assisted Tamara Hooper with surveyor recruitment and training. She also contributed to the revision of the manuscript.

Tamara Hooper was the Project Manager for CareTrack and coordinated the data collection for the entire study including the extraction of patient medical records. She also coordinated all the necessary approvals and managed the training and performance of surveyors and contributed to the revision of the manuscript.

Diane M Hindmarsh was the main Statistician for CareTrack and undertook analysis of the CareTrack. She also contributed to the interpretation of the statistical information included in the manuscript.

Jeffrey Braithwaite was involved in the design and conception of CareTrack Australia as the Chief Investigator-A of the NHMRC Program Grant, and extensive editing and revision of the manuscript.

Shanthi Ramanathan developed the initial sampling plan for CareTrack Australia; provided advice for the process of recruiting participants and organised and managed telephone recruiters.

Nicholas Wickham was involved as a CareTrack Australia clinical expert, assisted in the ratification of the SSI indicators and provided clinical input into the editing and revision of the manuscript.

William B Runciman was the primary instigator of CareTrack and responsible for its conception and design. He was also involved in all aspects of the project from data collection to analysis and interpretation of findings. He has been heavily involved in the editing and revision of the manuscript providing invaluable advice and guidance to the corresponding author.

## COMPETING INTERESTS

The authors have no competing interests.

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## DATA SHARING STATEMENT

There are no additional available data to be published

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STROBE Statement—checklist of items that should be included in reports of observational studies

| | Item No | Recommendation | |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | We have described a retrospective medical review in the Methods of the Abstract. |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | The abstract outlines the key definition of the dependent variable used, the indicator review process, sampling aim, medical record review, data collection timeframe; and the abstract results outlining the quantum of data collected, overall result and range. |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | See Introduction with particular attention to the third paragraph. |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | See last paragraph of the Introduction. |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | See Methods section including sub-sections Development and ratification of indicators, Recruitment of participants and healthcare providers, Review of medical records, and Statistical analysis. More detail is provided in the referenced protocol paper and main CareTrack Australia results paper (references 19 and 20). |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | Settings, locations, and relevant dates – see sub-section Recruitment of participants and healthcare providers in the Methods. Data collection – see Review of medical records in the Methods. More detail is provided in the referenced protocol paper and main CareTrack Australia results paper (references 19 and 20). |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>*Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of | Cross-sectional study – the eligibility criteria, sources and methods of selecting participants is outlined in the sub-section "Recruitment of participants and healthcare |

| | | | |
|---|---|---|---|
| | | cases and controls<br>*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants | providers" in the Methods. More detail is provided in the referenced protocol paper and main CareTrack results paper (references 19 and 20). |
| | | (*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed<br>*Case-control study*—For matched studies, give matching criteria and the number of controls per case | Not applicable |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | See Table 1 for descriptions of the indicators used. |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | The sub-section Development and ratification of indicators in the Methods outlines the process for developing the indicators. The sub-section Review of medical records in the Methods outlines the assessment method. |
| Bias | 9 | Describe any efforts to address potential sources of bias | Potential sources of bias are outlined in the Strengths and Weaknesses section of the Discussion. Weighting is discussed in the sub-section Statistical Analysis in the Methods. |
| Study size | 10 | Explain how the study size was arrived at | See first paragraph of the sub-section Review of medical records in the Methods. More detail is provided in the referenced protocol paper. |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | See third paragraph of the sub-section Review of medical records in the Methods for explanation of how the variables were aggregated. These variables are reported in Table 1. |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | See Statistical Analysis in the Methods. |
| | | (*b*) Describe any methods used to examine subgroups and interactions | Not applicable. |
| | | (*c*) Explain how missing data were addressed | See second paragraph of the Results. |

| | | | |
|---|---|---|---|
| | | (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed<br>*Case-control study*—If applicable, explain how matching of cases and controls was addressed<br>*Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy | See Statistical Analysis sub-section in the Methods for weighting process. See Appendix 2 of the CareTrack Australia study (reference 20) for a detailed description of the methodology and results of the weighting process. |
| | | (*e*) Describe any sensitivity analyses | See Statistical Analysis sub-section in the Methods for weighting process. See Appendix 2 of the main CareTrack Australia study (reference 20) for a detailed description of the methodology and results of the weighting process. |

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| | | | |
|---|---|---|---|
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | See first two paragraphs of the Results section. More details are available in the Results section of the CareTrack Australia study (reference 20). |
| | | (b) Give reasons for non-participation at each stage | See first paragraph of the Results section. More details are available in the Results section of the CareTrack Australia study (reference 20). |
| | | (c) Consider use of a flow diagram | Flow diagrams are provided in the protocol paper (reference 19) regarding stage design and the CareTrack Australia study (reference 20) for non-participation. |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | See first paragraph of the Results section. |
| | | (b) Indicate number of participants with missing data for each variable of interest | Not applicable |
| | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | Not applicable |
| Outcome data | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time | Not applicable |
| | | *Case-control study*—Report numbers in each exposure category, or summary measures of exposure | |
| | | *Cross-sectional study*—Report numbers of outcome events or summary measures | See Results. |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | See Results. |
| | | (*b*) Report category boundaries when continuous variables were categorized | Not applicable |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | Not applicable |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | See Statistical Analysis sub-section in the Methods for weighting process. See Appendix 2 of the CareTrack Australia study (reference 20) for a detailed description of the methodology and results of the weighting process. |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study | See first paragraph of the Discussion. |

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| | | objectives | |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | See Strengths and Weaknesses sub-section of the Discussion. |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | See first paragraph of the Results and the Conclusion for interpretation of results; in the second, third, and fourth paragraphs of the Discussion, our results are compared with other Australian studies and potential reasons for differences. |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | Firstly, we have compared at indicator or aggregated indicator level, our results with other Australian results in the second, third, and fourth paragraphs of the Discussion; we have discussed broader policy developments and their limitations related to our results in the fifth paragraph of the Results. Despite our sample being collected from a large number of hospitals (27), we have been cautious in generalising to the wider population. |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | See Funding section. |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.