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Venous Thrombo-Embolism Risk After Emergency Department and Same Day Emergency Care Discharge: A Retrospective Observational Study of Adult Patients Attending Two Hospital Sites V.2

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Sue Dean[1,2], Dr Rashaad Gossiel[3], Danielle Carroll[2], Paulina Solarz[4]

[1]NIHR Doctoral Fellow; [2]Advanced Practitioner (RN), United Lincolnshire Teaching Hospitals NHS Trust;
[3]Acute Medical Consultant, United Lincolnshire Teaching Hospitals NHS Trust;
[4]Thrombosis Practitioner, United Lincolnshire Teaching Hospitals NHS Trust

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The ED SDEC VTE Study

Sue Dean
University of Nottingham , United Lincolnshire Teaching Hosp...

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Disclaimer

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Abstract

This protocol outlines a retrospective observational study examining venous thromboembolism (VTE) risk in patients discharged from Emergency Department (ED) and Same Day Emergency Care (SDEC) pathways over a three-year period. Data will be obtained under local NHS Trust information governance approvals and data sharing agreements, with case ascertainment following established coding and audit procedures. All data handling will comply with GDPR and NHS governance requirements, with pseudonymised records used for analysis. Ethical approval will be sought from the appropriate NHS Research Ethics Committee. As a retrospective study using routinely collected data, individual patient consent is not required. Patient and public involvement was provided by a contributor with whom one of the researchers had previously collaborated, alongside input from clinical and organisational stakeholders. Together, these perspectives ensured that the study objectives are both patient-centred and operationally meaningful. The study has limitations, including constraints inherent to retrospective design, risks of missing or incomplete data, and limited generalisability beyond a single Trust setting. These will be acknowledged when interpreting results. Dissemination will include a peer-reviewed publication and presentation at a professional conference, alongside local feedback to the host NHS Trust and a plain-English summary for patient and public audiences. The anticipated impact is to inform local policy on VTE risk management in non-admitted emergency pathways and contribute to wider NHS discussions on enhanced SDEC models and VTE surveillance.

Guidelines

STROBE guidelines for reporting will be used (von Elm *et al._, 2007)*.

Background

1 Venous thromboembolism (VTE), comprising deep vein thrombosis (DVT) and pulmonary embolism (PE), remains a leading cause of preventable morbidity and mortality worldwide. Hospital-associated thrombosis (HAT) is defined as VTE occurring during admission or within 90 days of discharge, and accounts for approximately 60% of all VTE cases. Despite improvements in inpatient risk assessment and prophylaxis, post-discharge VTE continues to represent a substantial patient safety burden (Hunt, 2023; Healey *et al.*, 2024).

In England, national surveillance data demonstrate that deaths from VTE-related events within 90 days of discharge decreased from 72 to 62 per 100,000 adult admissions between 2007/08 and 2019/20, yet absolute numbers rose due to increased hospital activity. During the COVID-19 pandemic, rates spiked to 104 per 100,000 before falling again. These figures highlight the persistent risk of VTE beyond the inpatient setting (NHS England, 2025; NHS Digital, 2023). National guidance mandates that all hospital inpatients undergo VTE risk assessment, and in 2018 NICE extended this requirement to medical patients in the Emergency Department (ED) who remain for more than 12 hours without admission (National Institute for Health and Care Excellence, 2018). In practice, however, compliance with this recommendation is inconsistent. Importantly, the guidance does not explicitly address patients managed entirely through SDEC, for whom there is currently no requirement to undertake VTE risk assessment.

Patients may be discharged directly from ED or transferred to SDEC after prolonged ED stays, yet there is no reliable evidence that risk assessment is routinely undertaken in these cohorts. This combined implementation gap and policy omission represents a significant patient safety concern, particularly given
the expansion of ambulatory emergency pathways and sustained pressures on acute care services.
The sustained pressures on emergency care services and the prolonged waits for an admission bed
are well documented (Black, Seaman and Boyle, 2025). Patients may be discharged after extended ED stays without ever being admitted to a ward at all. SDEC pathways are increasingly utilised to reduce inpatient admissions and improve patient flow. SDEC pathways are increasingly utilised to reduce inpatient
admissions and improve patient flow, but whether patients discharged from these pathways face comparable risks of post-discharge VTE remains uncertain.

Some patients spend many hours in ED before transfer to SDEC and subsequent discharge. Both cohorts may exceed the 12-hour threshold for mandated risk

assessment, yet there is no reliable way of determining whether assessment is undertaken.

A recent retrospective study of over 40,000 SDEC episodes reported that 0.9% of patients developed VTE within 90 days, with risk factors including age over 60, prior malignancy, circulatory disease, and repeat attendances. Notably, there was no association with completion of an electronic VTE risk assessment. This incidence is comparable to symptomatic VTE rates in medical inpatients who did not receive prophylaxis (Shapiro *et al.*, 2025).

It therefore remains unclear whether ED and SDEC patients are risk assessed or offered prophylaxis. Given the expansion of ambulatory emergency pathways and the increasing frequency of prolonged ED stays, this omission represents a significant patient safety risk.

Rationale

2 **Clinical importance**

Understanding VTE risk in patients discharged from ED and SDEC pathways is critical for patient safety. These pathways are increasingly utilised to avoid inpatient admission, yet patients may remain at comparable risk of post-discharge VTE.

Evidence gap

While the incidence of VTE in hospital inpatients has been extensively studied, there is limited evidence on post-discharge VTE risk in ED and SDEC cohorts, particularly within real-world NHS practice. This gap leaves uncertainty about whether current strategies adequately protect these populations.

Impact

Findings from this study will directly inform whether existing VTE risk assessment and prophylaxis policies are sufficient for patients discharged from ED and SDEC. While NICE guidance requires risk assessment for medical patients in ED who remain beyond 12 hours, compliance is inconsistent, and there is currently no requirement to assess patients managed entirely through SDEC. By quantifying the incidence of VTE in these cohorts, this study will highlight whether current policy omissions contribute to preventable harm. The results will have implications for NICE guidance, NHS safety frameworks, and resource allocation, supporting evidence-based decisions to extend risk assessment and prophylaxis strategies to ambulatory emergency pathways.

Research contribution

By conducting a retrospective cohort study using routinely collected NHS data, this research will generate robust, audit-traceable evidence. The results will support clinical decision-making, strengthen patient safety initiatives, and contribute to national efforts to reduce hospital-associated thrombosis.

Aim and Objectives

3

Aims and Objectives

Aim:

To determine the incidence of VTE within 90 days of discharge among non-admitted adult patients attending ED and SDEC with ≥ 12 hour waits.

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Objectives:

Primary objective – quantify the incidence of VTE within 90 days of discharge from ED and SDEC.

- Secondary objectives – establish the timing of
- VTE post-discharge and compare incidence between those discharged directly from
- ED and those discharged from SDEC.

Study Design

4

Design: retrospective observational cohort study.

Setting: ED and SDEC units at two hospitals in a single NHS Trust.

Timeframe: Three years of routinely collected records from 1st April 2023 to 31st March 2026

Population (P):

Inclusion criteria: Adult patients (≥16 years)
who attended the ED or SDEC, waited ≥12
hours, and were discharged without inpatient admission.

Exclusion criteria: Admitted patients, prior VTE within 90 days, prior hospitalisation within 90 days, patients diagnosed with VTE within 72 hours of ED/SDEC attendance, patients aged <16 years, waits
<12 hours.

Exposure (I): Discharge from ED or SDEC following initial assessment and management, without hospital admission.

Comparison (C): No direct intervention group (observational study).

Comparisons will be drawn between: ED vs. SDEC discharged cohorts.

Outcome (O): Primary Outcome: Incidence of VTE (deep vein thrombosis or pulmonary embolism) within 90 days of discharge.

Secondary Outcomes:
- o Timing of VTE events within the 90-day follow-up period.
- o Incidence of VTE stratified by discharge pathway (ED vs. SDEC).

Data Quality and Governance

5 Data Quality and Governance: Data will be obtained under local NHS Trust information governance approvals and data sharing agreements. Case ascertainment will follow established Trust coding and audit procedures. All data handling will comply with GDPR and NHS data governance requirements, with pseudonymised records used for analysis.

Ethics

6 This study will be conducted in accordance with the principles of the Declaration of Helsinki and the UK Policy Framework for Health and Social Care Research. Ethical approval will be sought from the appropriate NHS Research Ethics Committee.

As this is a retrospective observational study using routinely collected, pseudonymised data, individual patient consent will not be required. The legal basis for data use will be established under the Health Research Authority (HRA) guidance for secondary use of health data.

Patient and Public Involvement and Engagement (PPIE) and Stakeholder Input

7 PPIE has informed the study design, ensuring that the research questions are relevant to patient safety and service delivery. Risks to participants are minimal, as no direct patient contact or intervention is involved. The potential benefits include improved understanding of VTE risk in ambulatory emergency pathways and informing future policy and clinical practice.

8 PPIE was provided by a contributor with whom one of the researchers had previously collaborated in an earlier study. Their input helped refine the current study focus, emphasising the importance of understanding VTE risk in patients discharged from ED and SDEC without inpatient admission. They supported the use of routinely collected, pseudonymised data to minimise patient burden and highlighted the need for accessible dissemination of findings.

9 In addition, discussions with clinical and organisational stakeholders (including ED and SDEC clinicians and Trust VTE Committee) informed the study design. Stakeholders confirmed the relevance of comparing ED and SDEC discharge pathways and highlighted the potential impact on service delivery and patient safety.

10 Together, PPIE and stakeholder input ensured that the study objectives are both patient-centred and operationally meaningful, and that dissemination plans will address the needs of diverse audiences, including patients, clinicians, and service leaders.

Statistical Analysis Plan

11 Descriptive analysis: Baseline characteristics of the cohort (age, sex, ethnicity, repeat attendances including inpatient stays within the previous 90 days) will be summarised using means, medians, and proportions as appropriate. Differences between ED and SDEC cohorts will be explored using chi-square tests for categorical variables and t-tests for continuous variables.

Primary analysis:
Incidence of VTE within 90 days of discharge will be calculated as the number of events per 100 discharges, with 95% confidence intervals.
Kaplan–Meier survival curves will be used to illustrate time to VTE event, censored at 90 days.

Secondary analyses:
Timing of VTE events:
Median time to event will be reported, with interquartile ranges.
Hazard functions will be plotted to show risk distribution across the 90-day period.

Comparison between ED and SDEC cohorts:
Incidence rates will be compared using rate ratios and chi-square tests.
Cox proportional hazards regression will be used to compare time to VTE between cohorts, adjusting for age, sex, ethnicity, and repeat attendances.

Sensitivity analyses
Exclusion of patients with incomplete records or uncertain diagnostic coding.
Stratification by age group (>65 vs. ≤65), and repeat attendances.

Missing data
Extent and pattern of missing data will be described.
Multiple imputation will be considered if missingness exceeds 5% for key covariates.

Software

12 Analyses will be conducted using R (R Core Team, 2025).

Reporting

13 STROBE guidelines for reporting will be used (von Elm *et al._, 2007).*

Limitations

14 This study has several limitations. First, the retrospective design constrains the ability to establish causal relationships, as analyses are reliant on routinely collected records rather than prospectively defined data.
Second, there is a risk of missing or incomplete data, particularly in diagnostic coding, imaging reports, and prescribing records, which may affect case ascertainment and introduce bias.
Finally, findings are based on data from a single NHS Trust, which may limit generalisability to other settings with different patient populations, service configurations, or coding practices.
These limitations will be acknowledged when interpreting results and considering implications for wider practice.

Dissemination and Impact

15 The findings from this study will be disseminated through a peer-reviewed publication and presentation at a professional conference. A manuscript will be prepared for submission to a journal relevant to emergency medicine, thrombosis, or health services research. In addition, results will be shared as an abstract and poster at a national or international conference, ensuring visibility within both academic and clinical communities.
For patient and public audiences, a plain-English summary will be produced and shared with the PPIE contributor and local patient groups, and via social media. Findings will be communicated in accessible formats such as newsletters, Trust websites, or patient forums, ensuring transparency and relevance to those most affected.
The anticipated impact of this study is to inform local policy on VTE risk management in non-admitted emergency pathways, while contributing to national discussions on

enhanced SDEC models and VTE surveillance. By disseminating findings across academic, clinical, and patient and public audiences, the study will ensure results are translated into practice, accessible to diverse stakeholders, and positioned to influence both local service improvement and wider NHS policy development.

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