Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Two regimens, adjusted-dose subcutaneous unfractionated heparin (SC heparin) versus conventional inpatient heparin, in the initial management of deep venous thrombosis (DVT).

Type of intervention
Treatment; secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Patients aged 18 years or older with lower extremity DVT. Patients were excluded if: more than 48 hours had passed since the time of diagnosis, they presented a massive DVT involving all three proximal veins, bilateral or iliac DVT, current or prior pulmonary embolism (PE), history of two or more DVTs, active bleeding or hematocrit <25%, platelet count <100,000, history of allergy to heparin, inability to tolerate warfarin, or pregnancy. Additionally, patients were excluded if requiring hospitalisation of more than 48 hours for reasons other than DVT.

Setting
Hospital. The study was carried out in Boston, MA, USA.

Dates to which data relate
The effectiveness and resource use data were collected between 1993 and 1994. The price date was not stated.

Source of effectiveness data
Effectiveness data were taken from a single study.

Link between effectiveness and cost data
The costing was undertaken retrospectively on a different patient sample from that used in the effectiveness study.

Study sample
Of 18 patients enrolled in the intervention group (23% of the original 78 patients screened), 16 (89%) completed the protocol. Fifty six patients received the conventional therapy. Power calculations were not used to determine the sample size.
Study design
Although the analysis of patient satisfaction (and length of stay) used a control group, the effectiveness analysis was based on a case series study design. The study was based on a single centre. The follow-up period was 6 weeks. Two patients, originally screened for inclusion, were unable to return for follow-up study (10% of a total of 20 patients who would have been included had they been able to return).

Analysis of effectiveness
Whilst the principle of analysis used in the effectiveness study was not relevant given the study design, the rest of the analysis of the clinical study was based on treatment completers only. Outcomes considered in the study were the rate of completion of the treatment protocol (those stopping the SC injections were to be converted to intravenous heparin). Additionally, length of stay, percentage of patients within the activated partial thromboplastin time (aPTT) therapeutic range (from 55 to 80 seconds), and patient satisfaction were estimated (only the first and the last outcome measures compared the results of the intervention group with those for control groups of 37 and 56 patients using the conventional option, respectively). A questionnaire was used to evaluate patient satisfaction (n=14 patients for the intervention group). The patient groups were not shown to be comparable in terms of demographic characteristics or prognostic factors.

Effectiveness results
Two patients were unable to continue with the established treatment. Hospital length of stay was 2 days in protocol patients and 5 days for patients receiving the conventional therapy. At any given aPTT assay (performed daily), 0.33% to 25% of the intervention group were in the target range. Three patients were never in the target range. No bleeding complications occurred despite the high proportion of patients with supratherapeutic values (by the fifth heparin dose more than 50% of patients had such values). No patient in the intervention group had DVT extension or symptomatic pulmonary embolism. The follow-up ultrasound examination showed no change in thrombus extent in 25% of patients (n=4), whereas clot regression was observed in the remaining 12 patients. Satisfaction was excellent for the patients using SC heparin with a mean score of 1.4 (+/- 0.6; p=0.48) and for the conventional therapy, mean scores 1.3 (+/- 0.7; p=0.48). A greater satisfaction with the efficiency of the discharge process for the patients using SC heparin was reported; the mean score was 1.0 (+/- 0.0) compared to 0.1 (+/- 1.0) for the comparator (p=0.001).

Clinical conclusions
Adjusted-dose subcutaneous heparin was administered safely on an outpatient basis with daily laboratory monitoring.

Measure of benefits used in the economic analysis
The measure of benefits in the economic analysis was the number of additional patients successfully discharged home.

Direct costs
Apart from the length of hospital stay (and the total drug dosage used in the intervention group) the quantities of resource use and costs were not reported separately. Hospital costs were estimated. The data was obtained from the database of Brigham and Women’s Hospital. Those data were originally in the form of charges, and were subsequently converted to costs by using cost-to-charge ratios from the institution. The price date was not stated. Data on costs for the comparator were derived from resource use of 37 patients admitted during 1993 for inpatient treatment of uncomplicated DVT and discharged at day 6 at the latest. Although outpatient follow-up costs were mentioned in passing, they were not considered in the total figures reported.

Statistical analysis of costs
The Wilcoxon Rank sum test was used to analyse the differences in costs between groups.

Currency
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
Two patients in the intervention group did not complete the protocol. After discontinuation of the subcutaneous injections, intravenous heparin was initiated in those patients.

**Cost results**
The median hospital cost for subcutaneous heparin regimen with early discharge was $2,273 and for inpatient intravenous heparin was $4,520.

**Synthesis of costs and benefits**
Costs and benefits were not combined.

**Authors’ conclusions**
The study has demonstrated that an outpatient approach is feasible, but until regimens requiring less frequent laboratory monitoring and dosing changes (such as, perhaps, low-molecular-weight heparin) have been validated, continuous intravenous infusions of unfractionated heparin should remain the standard of care for initial DVT management.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of comparator, inpatient heparin, is clear as it was the current conventional therapy in the authors' setting.

**Validity of estimate of measure of benefit**
The sample size of the patients using SC heparin was small, which limited the power of the study and the accuracy of the effectiveness results. Moreover, the lack of a proper control group renders the effectiveness results questionable.

**Validity of estimate of costs**
A clearer explanation of the quantities and costs of the intervention group and comparator would have been useful in order to assess whether all the relevant costs were considered in the analysis. Only the length of hospital stay was reported separately from the costs.

**Other issues**
The issue of generalisability was not addressed in the study.

**Source of funding**
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