ABSTRACT

Background: Implementing venous thromboembolism (VTE) risk assessment guidance on admission to hospital has proved difficult worldwide. In 2010, VTE risk assessment in English hospitals was linked to financial sanctions. This study investigated possible barriers and facilitators for VTE risk assessment in medical patients and evaluated the impact of local and national initiatives.

Setting: Acute Medical Unit in one English National Health Service university teaching hospital.

Methods: This was a mixed methods study; National Research Ethics Service approval was granted. Data were collected over four 1-week periods; November 2009 (1), January 2010 (2), April 2010 (3) and April 2011 (4). Case notes for all medical patients admitted during these periods were reviewed. Thirty-six staff were observed admitting 71 of these patients; 24 observed staff participated in a structured interview.

Results: 876 case notes were reviewed. In total, 82.1% of patients had one or more VTE risk factors and 25.3% one or more bleeding risks. VTE risk assessment rose from a baseline of 6.9–19.6%, following local initiatives, and to 98.7% following financially sanctioned government targets. A similar increase in appropriate prescribing of prophylaxis was seen, but inappropriate prescribing also rose. No staff observed in period 1 conducted VTE risk assessment, risk-assessment forms were largely ignored or discarded during period 2; and electronic recording systems available during period 3 were not accessed. Few patients were asked any VTE-related questions in periods 1, 2 or 3. Interviewees’ actual knowledge of VTE risk was not related to perceived knowledge level. Eight of the 24 staff interviewed were aware of national policies or guidance: none had seen them. Principal barriers identified to risk assessment were: involvement of multiple staff in individual admissions; interruptions; lack of policy awareness; time pressure and complexity of tools.

Conclusions: National financial sanctions appear effective in implementing guidance, where other local measures have failed.
INTRODUCTION
Venous thromboembolism (VTE) was first described in 1676 and its association with surgery recognised in 1866.1 During the 20th century, accumulating evidence of risk factors for VTE, especially those associated with surgery, led to the first consensus statement for preventing VTE and pulmonary embolism (PE) in 1986.2 The link between inflammation and increased VTE risk was first proposed in the 1970s3 and the increased risk of VTE associated with medical conditions which have an inflammatory component, such as respiratory disease and acute infection, is now recognised.4 Not surprisingly, the proportion of patients developing VTE increases with the number of risk factors present,5 but over 80% of medical patients admitted to hospital have at least one risk factor.6 The risk of deep vein thrombosis (DVT) in hospitalised medical patients if no thromboprophylaxis is given was approximately 20% in a meta-analysis of 17 randomised clinical trials.8 Prophylaxis with low-molecular-weight heparin (LMWH) reduces the number of hospital-acquired VTEs in medical patients by up to 60%.9,10 Increased international awareness of VTE risks is shown by studies assessing current practice in Europe,11 the USA14,15 and Canada.16 In England and Wales this awareness has been seen at government level, through the commissioning of reports in 200417 and 2007,18 the National Institute For Health and Clinical Excellence (NICE) published guidance on risk assessment (RA) in 201019 and most recently mandatory collection of VTE RA figures as part of the National Health Service (NHS) Outcomes Framework in June 2010.20 This top down approach has had limited success, with uptake of VTE RA guidance slow and many NHS hospitals struggling with its implementation.6–23

METHODS
A triangulated mixed methods approach was used involving review of case notes, observation of the admission process and interviews with healthcare staff. There were four 1-week study periods: November 2009 (1), January 2010 (2), April 2010 (3) and April 2011 (4). Case note review and direct observation of a sample of admissions was carried out for all four study periods. Interviews were undertaken with all admitting staff observed during periods 1, 2 and 3. The data collection periods were selected to assess the impact of both local and national initiatives occurring during the study and also to avoid the weeks when junior doctors change jobs to minimise bias due to lack of familiarity with the role (figure 1).

1. November 2009—All Party Parliamentary Thrombosis Group—Audit of acute trusts (National)
2. 24 November 2009—Trust RA forms placed with medication charts on AMU (Local)
3. 27 January 2010—NICE guidance—national press & TV coverage (National)
4. 15 February 2010—Thrombosis nurse employed (Local)
5. 26 February 2010—VTE Grand round (1)—launch of Trust VTE policy (Local)
6. March 2010—Department of Health (DH) RA tool (V.2) (National)
7. 21 March 2010—DH letter—Collecting of VTE RA data to be mandatory (National)
8. 1 April 2010—electronic VTE RA (Local)
Local initiatives were introduced to increase staff awareness of and facilitate the implementation of national guidance and included both education and provision of RA tools. A thrombosis nurse was recruited to provide ward based training for nursing staff and education sessions were provided for medical staff at two of the weekly Grand rounds. Paper RA forms were initially based on the available literature and those used by other local hospitals. These were modified during the course of the study in line with comments received from staff and to comply with the revised DH RA tool introduced in March 2010. The initial electronic RA tool introduced in April 2010 was very cumbersome as it required a yes/no answer to each VTE risk and each bleeding risk. This was later simplified to electronic confirmation that VTE RA had been completed and whether or not the assessment had taken place within 24 h of admission.

Ethical approval

The study was approved by the National Research Ethics Service (Liverpool Central REC Ref 09/H1005/67), Liverpool John Moores University Ethics Committee (approval no 09/PBS/015); Research Governance approval from Royal Liverpool University Hospital (study no 3862) and was carried out in the Acute Medical Unit (AMU) of an English university teaching hospital.

Case note review

Case notes for patients admitted during each study period were reviewed retrospectively, following discharge or death, to establish the frequency of VTE RA and prescribing of prophylactic LMWH, evidence of VTE risk factors and bleeding risks to assess the appropriateness of prescribing and DVTs, PEs, deaths or episodes of bleeding during hospitalisation.

A power calculation was performed to determine the number of records required for detecting a difference of 15% in the proportion of patients risk assessed between study periods, with a power of 99%. Using a baseline proportion of documented RAs of 5%, derived from an earlier case note audit, 200 patient records per study period were required. Assuming that 20% of patients have a contraindication to treatment and using a baseline proportion of 30% patients receiving appropriate prophylaxis, proportions again derived from earlier data, 160 patients per study period would provide 96% power to detect an increase of 20% in patients treated appropriately.

In accordance with Trust policy all patients requiring pharmacological DVT prophylaxis should receive LMWH; those with renal impairment (eGFR <30 ml/min) receive a lower dose. Inappropriate prescribing of LMWH was defined as ‘prescribing for patients with at least one known bleeding risk’ and was assessed by an expert panel of four AMU consultant physicians. Each consultant independently reviewed a case summary for each patient with at least one bleeding risk who was prescribed LMWH and indicated that LMWH was either appropriate or inappropriate. If there was consensus among all four consultants the decision was accepted. Where there was initial disagreement, all four consultants debated the cases until consensus was reached.

Observations

Staff gave informed consent for observations; patients or their carers could exclude the researcher at any time. Patients observed were purposively selected to maximise both the range of staff observed and variation in time and day of admission. Staffs were aware that the study related to the hospital admission process but not specifically to VTE RA. During observations, data relating to VTE RA and prescribing of prophylactic therapies were recorded on a standard form with additional field notes. The pharmacist researcher had only social interaction with staff, but was able to identify any inappropriate clinical management with the potential to seriously adversely impact on patient care and intervene if required.

Interviews

Interviews with staff took place as soon as practical following observations, using a structured questionnaire to ascertain their knowledge, perceived knowledge, training experiences and views on implementing VTE RA.

Data analysis

Data from the observations and interviews were coded into themes where necessary. Descriptive analysis was carried using SPSS V.17; statistical tests (t tests and \( \chi^2 \) tests treating the groups as simple categories) were carried out using Minitab V.16. Where case notes and/or prescription charts were missing these cases were excluded from the relevant analyses.
Table 1  Demographic details of patients included in case note reviews and observations

| Characteristic | Case note review | Observations |
|----------------|-----------------|--------------|
| Number         | 930             | 71           |
| Case notes available | 876       | 67           |
| Sex: male (%)  | 381 (43.5%)     | 28 (39%)     |
| Age range (mean) | 16–98 (64) years | 16–98 (68) years |
| Average length of stay (mean) | 1–182 (9.9) days | 1–54 (8.7) days |
| Main causes of admission (descending order of occurrence) | | |
| Infection | (285; 32.5%) | (15; 22%) |
| Pain | (72; 8.2%) | (8; 12%) |
| Cardiac cause | (60; 6.8%) | Abnormal biochemistry* (8; 12%) |
| Shortness of breath | (54; 6.2%) | Possible VTE (7; 10%) |
| Abnormal biochemistry* (51; 5.5%) | | Shortness of breath (5; 7%) |
| Possible VTE (46; 5.3%) | | Vomiting or diarrhoea (5; 7%) |

*Results outside of the normal range for haemoglobin, glucose, thyroid hormones, sodium, potassium, magnesium or calcium.

RESULTS

Case note review
The demographic details of the patients admitted during the study are shown in table 1.

A total of 1015 patients were recruited, 930 (91.6%) were followed up. In 54 cases the relevant admission documentation was not available in records, leaving 876 cases suitable for analysis. The prescription chart was missing for a further 72 cases resulting from their exclusion from the analysis relating to prescription of prophylaxis. Statistical analyses showed that there were no significant differences between the patients whose case notes were reviewed and the remainder in terms of gender ($\chi^2$ test; $p=0.534$) or length of stay (t test; $p=0.326$). Observed patients were slightly older than those not observed (t test; $p=0.045$) and the main causes of admission were broadly similar (table 1). The numbers of patients reviewed in each study period are shown in table 2, together with details of risk factors present.

Of the 876 patients, 719 (82.1%) had at least one VTE risk factor and 222 (25.3%) had at least one bleeding risk on admission. Almost a fifth of all admissions (171; 19.5%) had risk factors for both VTE and bleeding (table 2), therefore 23.8% of the patients admitted with a VTE risk factor also had a bleeding risk, requiring clinical judgement before prescribing prophylaxis.

There was an increase in the proportion of patients who had both VTE and bleeding risk factors during the course of the study however this did not reach statistical significance ($\chi^2$ test; $p=0.170$). Over the period of the study there was a gradual increase in the complexity of patients treated as bed pressures resulted in more patients with minor conditions receiving ambulatory care which may explain this trend.

The proportion of patients with a documented completed VTE RA rose from 6.9% in study period 1 to 18.5% and 19.6% in periods 2 and 3, respectively, following local initiatives, but to 98.7% in period 4 following the imposition of payment-related government targets (table 3). These changes were statistically significant ($\chi^2$ test; $p<0.001$). Three subanalyses showed that comparisons of periods 1 to 2 and 3 to 4 both gave $p<0.001$ and these were therefore statistically significant even when the Bonferroni correction was applied. The comparison of period 2 to 3 was non-significant ($p=0.884$).

Table 2  Frequency of VTE risk factors and bleeding risks

| Study period | November 2009 (1) | January 2010 (2) | April 2010 (3) | April 2011 (4) | Totals |
|--------------|------------------|-----------------|--------------|--------------|--------|
| Total admitted | 265             | 255             | 239          | 256          | 1015   |
| Case notes available | 232/265 (87.5%) | 216/255 (84.7%) | 204/239 (85.4%) | 224/256 (87.5%) | 876/1015 (86.3%) |
| At least 1 VTE risk factor* | 192/232 (82.8%) | 172/216 (79.6%) | 161/204 (78.9%) | 195/224 (87.1%) | 719/876 (82.1%) |
| 95% CI | (77.3% to 87.4%) | (73.6% to 84.8%) | (72.7% to 82.3%) | (82.9% to 91.1%) | (79.4 to 84.6%) |
| At least one bleeding risk factor* | 44/232 (19.0%) | 62/216 (28.7%) | 53/204 (26.0%) | 63/224 (28.1%) | 222/876 (25.3%) |
| 95% CI | (14.1% to 24.6%) | (22.8% to 35.2%) | (20.1% to 32.6%) | (22.3% to 34.5%) | (22.5% to 28.4%) |
| Risk factors for both VTE and bleeding* | 34/232 (14.7%) | 44/216 (20.4%) | 43/204 (21.1%) | 50/224 (22.3%) | 171/876 (19.5%) |
| 95% CI | (10.4% to 19.9%) | (15.2% to 26.4%) | (15.7% to 27.3%) | (17.0% to 28.3%) | (16.9% to 22.3%) |
| VTE risk and no bleeding risk* (LMWH indicated) | 158/232 (68.1%) | 128/216 (59.3%) | 118/204 (57.8%) | 145/224 (64.7%) | 549/876 (62.7%) |
| 95% CI | (61.7% to 74.1%) | (52.4% to 65.9%) | (50.7% to 64.7%) | (58.1% to 71.0%) | (59.4% to 65.9%) |

*No significant difference between study periods.

LMWH, low-molecular-weight heparin; VTE, venous thromboembolism.
Thirty-three patients had at least one bleeding risk, but received LMWH. Independent review of all 33 case summaries by four AMU consultants achieved consensus agreement in 24 cases, with the remaining nine requiring discussion before consensus was reached. In six cases it was agreed that LMWH was appropriate, but was inappropriately prescribed in the remaining 27.

Patients taking oral anticoagulants on admission are included in those for whom LMWH was contraindicated (table 3). Six patients were prescribed antiembolism stockings and no patients used foot pumps during the study. The proportion of patients appropriately prescribed prophylaxis with LMWH (those with VTE risks but no bleeding risks) rose from 49.7% in period 1 to 61.7% and 67.8% in periods 2 and 3, then to 92.6% in period 4 (table 3). The change was statistically significant between periods 3 and 4 ($\chi^2$ test; $p<0.001$). There was also a statistically significant increase in the proportion of patients who were prescribed LMWH inappropriately in period 4 compared with the three earlier study periods ($\chi^2$ test $P=0.002$). Three subanalyses of periods 1, 2 and 3 to period 4 were carried out with Bonferroni correction. Comparison of periods 1 to 4 and 3 to 4 were statistically significant ($p=0.002$ and 0.006, respectively). The comparison of period 2 to 4 was non-significant ($p=0.117$).

### Observations

During the four data collection periods a total of 71 patient admissions were observed, involving 35 doctors (four consultant/specialist registrar, four specialist trainee year 4/5, nine specialist trainee year 1/2 and 18 foundation) and one advanced nurse practitioner. Patient details are shown in table 1.

The numbers of observations, plus numbers of RAs performed and appropriate VTE prophylaxis prescribed are shown in table 3. No RA forms were completed in period 1, and while this increased in periods 2 and 3, a greater change was noted between periods 3 and 4. Placement of RA forms with medication charts prior to period 2 resulted in only seven of 21 being completed, five being actively removed and nine being ignored. An electronic RA form implemented prior to period 3 was not used by staff, with only four of the 14 admissions assessed using this process. Over the first three study periods, only 8 of the 51 patients (16%) observed were asked questions relating to previous personal or family history of VTE or warfarin use, three of significant ($p=0.002$ and 0.006, respectively). The comparison of period 2 to 4 was non-significant ($p=0.117$).

### Table 3: Frequency of VTE risk assessment and appropriate prescribing of LMWH

| Study period | November 2009 (1) | January 2010 (2) | April 2010 (3) | April 2011 (4) |
|--------------|------------------|-----------------|----------------|---------------|
| Total admitted | All admissions | 265 | 255 | 239 | 256 |
| Case notes available | 232/265 (87.5%) | 216/255 (84.7%) | 204/239 (85.4%) | 224/256 (87.5%) |
| VTE risk assessment completed* | 16/232 (6.9%) | 40/216 (18.5%) | 40/204 (19.6%) | 221/224 (98.7%) |
| Prescription charts and case notes available | 205/265 (77.4%) | 201/255 (78.8%) | 189/239 (79.1%) | 209/256 (81.6%) |
| LMWH indicated | 147/205 (71.7%) | 115/201 (57.2%) | 115/189 (60.8%) | 135/209 (64.6%) |
| 95% CI | (65.0% to 77.8%) | (50.1% to 64.3%) | (53.5% to 67.8%) | (57.7% to 71.1%) |
| LMWH prescribed appropriately* (patient has VTE risk factors and no bleeding risks) | 73/147 (49.7%) | 71/115 (61.7%) | 78/115 (67.8%) | 126/136 (92.6%) |
| 95% CI | (41.3% to 58.0%) | (35.1% to 56.7%) | (54.0% to 64.3%) | (86.9% to 96.4%) |
| LMWH contra indicated | 32/205 (15.6%) | 49/201 (24.4%) | 39/189 (20.6%) | 43/209 (20.6%) |
| 95% CI | (10.9% to 21.3%) | (8.6% to 30.9%) | (4.6% to 27.1%) | (5.3% to 26.7%) |
| LMWH prescribed inappropriately** | 1/32 (3%) | 9/49 (18%) | 3/39 (8%) | 14/43 (33%) |
| 95% CI | (0% to 16%) | (5% to 32%) | (2% to 21%) | (19% to 49%) |
| Number of admissions observed | 16 | 21 | 14 | 20 |
| VTE risk assessment completed | 0/16 (0%) | 7/21 (33%) | 4/14 (29%) | 15/20 (75%) |
| 95% CI | (0% to 17%) | (15% to 60%) | (8% to 58%) | (51% to 91%) |
| LMWH prescribed appropriately | 9/16 (56%) | 12/21 (57%) | 7/14 (50%) | 12/20 (60%) |
| 95% CI | (30% to 80%) | (34% to 78%) | (23% to 77%) | (36% to 81%) |
| LMWH prescribed inappropriately | 0/16 (0%) | 2/21 (10%) | 0/14 (0%) | 1/20 (5%) |
| 95% CI | (0% to 17%) | (1% to 30%) | (0% to 19%) | (0% to 25%) |

Significant differences between study periods *$p<0.001$; **$p=0.002$. LMWH, low-molecular-weight heparin; VTE, venous thromboembolism.
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whom had presented with symptoms suggestive of VTE, whereas in period 4, 6 of the 20 observed (30%) were asked VTE-related questions, only one of whom presented with symptoms suggestive of VTE.

Interviews
All 24 healthcare staff observed during periods 1, 2 and 3 were interviewed; (three consultant/specialist registrar, two specialist trainee year 4/5, six specialist trainee year 1/2, 12 foundation and one advanced nurse practitioner), of whom 13 (58%) had undergone VTE training. There was no correlation between staff receiving training and whether or not VTE RA was completed ($\chi^2$ test, $p=0.106$). Self-rated knowledge of VTE RA was ‘good’ in nine (38%), ‘average’ in 14 (58%) and ‘below average’ in 1 (4%). The number of spontaneously listed VTE risk factors ranged from 3 to 8 of a possible 18 and of bleeding risks, 1 to 3 of 12. There was no statistically significant evidence of any difference in actual knowledge between staff with below average or average perceived knowledge or those with good perceived knowledge (Mann-Whitney test, $p=0.210$). Staff perceptions of the proportion of medical patients with VTE risk factors ranged from 30% to 90%, only 13 believed that over 80% would be at risk, while the majority (20/24; 83%) estimated that less than 20% of patients would have both VTE and bleeding risks.

Only eight staffs were aware of any national policies or guidance on VTE RA, although the DH working group report was published in 2007 and the first DH VTE RA tool was published in September 2008, none of the interviewees had actually seen these documents. The majority of staffs (22; 88%) felt that responsibility for VTE RA should fall to the clerking doctor or nurse, but 15 (63%) felt the actual responsibility was unclear. Open questions elicited suggestions that the involvement of multiple staff in individual admissions, interruptions, lack of awareness, time pressures and the lack of user-friendliness of the tools provided may contribute to failure to conduct the assessment. Recommendations for improving performance related mainly to increasing training and raising awareness, the need for strong leadership and empowerment of nurses.

DISCUSSION
During the first three observation periods, from November 2009 until April 2010, VTE RAs were not routinely carried out during the hospital admission process and on occasion staff made a deliberate decision not to complete an assessment, as shown by forms being discarded. There was no evidence that staff who had received VTE training were any more likely to carry out RA. Despite this, the majority of the staff interviewed felt that the admitting doctor or specialist nurse was the most appropriate person to conduct the VTE RA due to the complexity of data needed and the clinical interpretation necessary for safe, appropriate prophylaxis.

The dramatic increase in both the number of patients risk assessed for VTE and the number appropriately treated with LMWH in period 4, April 2011, followed the introduction of national mandatory data collection in June 2010. There was an associated increase in the number of patients who received LMWH inappropriately. However, as there were a minimum of three initiatives between each of the data collection periods it is difficult to attribute the changes to any particular intervention. The apparent impact of national mandatory data collection may have been as a result of increased uptake of local initiatives.

Comparison with other studies
The patients in our study differed in the most common causes for admission from those in a large international study;25 due to the local policy of directing patients with acute cardiac conditions to a Heart Emergency Centre, however we believe this was unlikely to affect staff behaviour.

Implementing guidelines in practice is recognised as being difficult.25-27 The staff interviewed in this study considered that the admitting doctor was the most suitable person to carry out the VTE RA and prescribing, which concurs with the findings of a study conducted in the USA.26 Various systematic reviews have examined the difficulties of implementing guidelines, one concluding that there is no ‘magic bullet’ in terms of the most effective strategy for implementation in hospitals.27 Barriers identified to guideline implementation have been classified into three broad categories; knowledge, including lack of familiarity and awareness; attitudes, including failure to believe that the intervention will have the desired outcome and behavioural factors, such as lack of time.28 The interviews in the present study identified similar factors; doctors were unaware of local and national guideline, they lacked motivation, they were unaware of the risks of VTE and commented that the time taken to carry out a RA was an issue. Small group training with active participation has been found to be effective in policy implementation in contrast to courses alone which had mixed effects.29 In our study, just over half of admitting staff had received training in VTE RA, which was in lecture format whether provided at medical school or at the hospital, which may contribute to the lack of association between training in and carrying out RAs.

A meta-analysis of strategies to improve VTE prophylaxis carried out in 2005 found that passive dissemination of guidelines was generally ineffective30 which supports our findings that the initiatives prior to June 2010 resulted in limited improvement. Other work has demonstrated the value of opinion leaders in guideline implementation,31 which was most likely the reason for the significant improvement achieved in the last study period. Following the introduction of mandatory data collection, government targets and associated financial penalties in June 2010, VTE RA became consultant-led.
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as a result of pressure from Trust managers. This, together with continuous reminders during ward rounds, emphasised the importance of VTE RA to junior staff and the target of at least 90% of patients having a RA performed on admission was exceeded. In addition, a Trust requirement for RA to be completed by a senior doctor in the event of its omission during initial admission resulted in almost 100% of patients having been assessed within 24 h. An American study published in 2012\(^3^2\) has shown that introduction of a mandatory computerised decision support tool had a similar significant beneficial effect on both VTE RA and prescription of appropriate prophylaxis.

VTE RA was one of the first quality standards with a financial sanction to be issued by the DH in 2010. While the results show that the 90% VTE RA target was achieved in April 2011, this standard will need to be maintained in a culture of organisational change and additional targets. Financial targets are a relatively new concept in secondary care in the NHS: they have been used more widely in primary care. A recent Cochrane review\(^3^3\) found that there was little evidence either for or against their use in primary care and it has been suggested that there may be unintended consequences.\(^3^3\) 34

In addition, an analysis of CQUIN targets in London published this year showed that only 38% of London Trusts achieved the full payment for the VTE CQUIN in 2010/11 and that performance in a CQUIN indicator does not always correlate with other quality indicators.\(^3^5\) A checklist has recently been published\(^3^6\) to help decide whether a financial incentive is appropriate in a particular clinical scenario and if so provide some guidance for the development of a successful initiative.

CONCLUSION

This study shows that a national financial sanction resulting in a consultant-led approach was associated with effective implementation of guidance. However, it remains to be seen whether the level of achievement can be maintained as new targets are added in a culture of organisational change.

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Contributors

AJB, JK, AM, TDK were responsible for the planning and design of the study; AJB was responsible for data collection and analysis. AJB wrote the first draft; all authors read and approved the final manuscript.

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Competing interests

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Provenance and peer review

Not commissioned; internally peer reviewed.

Data sharing statement

Participants gave informed consent for data sharing in publications. Consent was not obtained for the sharing of the dataset but the presented data are anonymised and the risk of identification is low; dataset available from the corresponding author at A.Basey@2009.ljmu.ac.uk

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