The incidence, cost and risk factors for inhospital adverse events are well documented.1-4 Failure to comply with clinical protocols, and in particular failure of communication to ensure the most appropriate timely clinical response, have been shown to be significant causative factors associated with inhospital adverse events.5-7

With the availability of reliable and robust information communication technologies, it is possible for bedside clinical observations to be analysed and appropriate alerts raised automatically.8,9 With the incorporation of decision-making algorithms into computer software, reliability in clinical care and outcomes has been demonstrated in areas such as medication prescribing,10,11 weaning from mechanical ventilation,12,13 insulin therapy14 and anticoagulation therapy.15 However, despite the sophistication of such systems, they are still dependent on a human response that requires interpretation of the presented data.16

In an attempt to introduce more reliability into the interpretation of data, overcome non-attendance, and deliver the most appropriate intervention to individual patients, we developed an intelligent alert response system (Patientrack, Sydney, NSW) to track the clinical response, and if inappropriate, unsuccessful, or absent, repeat the alerting process to a series of predefined clinical responses indefinitely until the clinical situation is resolved. Additionally, this system, with the patient observation data, the associated clinical alerts, and electronic record of the clinical responses, is able to construct the “patient black box” for any particular clinical situation.

The Early Warning Score (EWS) protocol (Figure 1 and Table 1) developed by the Central Manchester University Hospitals National Health Service Foundation Trust (CMFT) in the United Kingdom is designed to ensure that patients in an unstable condition are responded to in a timely fashion with appropriate alleviation of the clinical emergency.

In this study, we aimed to determine whether automated clinical alerts increase compliance with the CMFT EWS protocol and improve outcomes of patients with acute critical conditions.

Methods
Study design and setting
The study was a historically controlled study of the Patientrack intervention.

ABSTRACT

Background: Failure to comply with clinical protocols and failure of communication to ensure delivery of the most appropriate timely clinical responses to patients whose conditions are acutely deteriorating have been shown to be significant causative factors associated with inhospital adverse events.

Objective: To determine whether automated clinical alerts increase compliance with an Early Warning Score (EWS) protocol and improve patient outcomes.

Methods: We performed a historically controlled study of bedside electronic capture of observations and automated clinical alerts. The primary outcome measure was hospital length of stay (LOS); secondary outcome measures were compliance with the EWS protocol, cardiac arrest incidence, critical care utilisation and hospital mortality.

Results: Between baseline and intervention, 1481 consecutive patients were recruited generating 13 668 observation sets. There was a reduction in hospital LOS between the baseline and alert phase (9.7 days v 6.9 days, \(P < 0.001\)). EWS accuracy improved from 81% to 100% with electronic calculation. Clinical attendance to patients with EWS 3, 4 or 5 increased from 29% at baseline to 78% with automated alerts (\(P < 0.001\)). For patients with an EWS > 5, clinical attendance increased from 67% at baseline to 96% with automatic alerts (\(P < 0.001\)).

Conclusions: Electronic recording of patient observations linked to a computer system that calculates patient risk and then issues automatic graded alerts can improve clinical attendance to unstable general medical ward patients.

The CMFT is a group of five university teaching hospitals in the UK that acts as a district general hospital to its inner-city population. There are 900 adult beds and all specialties are provided except plastic surgery and neurosurgery. To limit the geographical area of the study, the medical assessment unit (MAU) and one of the general medical wards of the Manchester Royal Infirmary (one of the CMFT group of hospitals) constituted the study setting. This replicated the normal
pathway of non-specialty medical patients through the hospital (ie, emergency department to MAU to general medical ward). Haematology, cardiology and nephrology patients are admitted to specialty-specific ward areas. The MAU admits about 500 patients each month.

Approval to conduct this study was granted by the Central Manchester Research Ethics Committee (no. 07/Q1407/23).

Intervention

Patientrack was implemented on a central web server with an underlying data repository. The web server provides several services that manage and monitor the data, and manages EWS scores and alerts. A set of configurable business rules determined how the system reacted to the inputs provided. For this study, the rules were based on the CMFT EWS protocol that had been in place since 2000 (Figure 1).

It is possible, however, to define the rules to determine baseline frequency of clinical observations by clinical area and patient groups, adjust observation frequency on an individual patient and introduce modified alert and escalation pathways for each clinical area. Rules can be configured to set EWS scoring, alert recipients, alert escalation and other clinical system requirements.

Study timeline

The study had three phases.

The first phase entailed baseline data capture.

The second phase involved implementation of the electronic observation capture and EWS calculation. Patient bedside observations were taken manually and the results were entered into a personal digital assistant (PDA). The PDA was connected to a wireless network that allowed the results to be presented as a whole-of-ward view. Both the PDA and the whole-of-ward views displayed, for each patient, the time and date of all observations, the EWS score, and the time for next set of observations to be performed. Doctors were alerted by the traditional systems (ie, nurse call, switchboard to page doctors, or personal notification).

The third phase was the alert phase — electronic observation capture (as above) with automated electronic alerts to doctors. The alert engine of the Patientrack system was configured using existing doctor rosters. A software interface was constructed to enable direct communication from the nurse PDA to the doctor pager system. The rules on alerting the doctors followed the CMFT EWS protocol. The roster was constructed to align anticipated clinical compe-

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Table 1. The Early Warning Score system used in the Central Manchester University Hospitals National Health Service Foundation Trust

<table>
<thead>
<tr>
<th>Score</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate, beats/min</td>
<td>101–110</td>
<td>111–130</td>
<td>&gt; 130</td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure, mmHg</td>
<td>71–199</td>
<td>&gt; 200</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory rate, breaths/min</td>
<td>9–14</td>
<td>15–20</td>
<td>21–29</td>
<td>&gt; 30</td>
</tr>
<tr>
<td>Temperature, °C</td>
<td>38.0–38.9</td>
<td>&gt; 39.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central nervous system response</td>
<td>Alert</td>
<td>Verbal</td>
<td>Pain</td>
<td>Unresponsive</td>
</tr>
</tbody>
</table>

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Figure 1. The Central Manchester University Hospitals National Health Service Foundation Trust Early Warning Score (EWS) protocol

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tendencies associated with grade of doctor or nurse to anticipated need of patients as defined by the EWS.

Outcome measures
The primary outcome measure was length of stay (LOS); secondary outcome measures were compliance with the EWS protocol, cardiac arrest incidence, critical care utilisation, and hospital mortality.

Data collection and statistical analysis
During each phase, all consecutive patients admitted to the study wards were recruited. Patients were advised that they were entitled to withdraw from the study at any time. Patients discharged within 24 hours were excluded from data collection a priori, as they were unlikely to trigger an EWS score greater than 2. Parallel paper records of observation data continued throughout the study.

During the baseline phase, the observation charts and patient medical records were checked manually each day by a single investigator (M M) to determine the accuracy of the EWS score and the compliance with the CMFT EWS protocol (Figure 1). Accuracy of the EWS in the baseline phase was determined by checking the score calculation based on the recorded observations and the EWS table of values (Table 1). A second investigator (S J) checked 10% of the documentation to ensure validity of entry.

During the alert phase, all data were collected and assessed electronically from the Patientrack system. For patients who triggered an EWS alert, compliance was checked retrospectively by a medical record review.

Patient hospital outcome and LOS was collected retrospectively from the hospital patient administration system. LOS in either the intensive care or high dependency unit was determined by review of the medical record. Cardiac arrest incidence was determined from data maintained by the resuscitation committee.

Sample size determination and statistical analysis
Determining a sample size in this study was difficult as there were no previous data using this or any similar system. When the EWS protocol was implemented at CMFT in 2000, there was a reduction in LOS by about 2 days. This introduction in 2000 was accompanied by significant educational initiatives and compliance with the EWS protocol was excellent. Subsequent annual auditing demonstrated high compliance with taking observations, but unreliable clinical response. It was hoped that a structured automated alerting system that directed clinical “calls” to the most appropriate clinician would not only eliminate redundancy in inappropriate calls for assistance, but would enhance patient care and again reduce LOS of patients with acute medical conditions. It was anticipated that the implementation of this system might bring about a similar change. Accepting this and using a $P < 0.05$ seeking a power of 80%, it was calculated that 500 patients were required in each group.

Data were analysed independently using SAS, version 9.1 (SAS Institute, Cary, NC, USA). Group comparisons were performed using Student t tests for normally distributed outcomes, $\chi^2$ test for equal proportion or non-parametric tests for non-normally distributed outcomes. Normally distributed outcomes are reported as means (standard error). A two-sided $P$ of 0.05 was considered statistically significant.

To ensure that observed difference in LOS was not due to increased age, a multivariate linear regression was used with the LOS log transformed to ensure that the underlying assumption for linear regression of normality was met. In accordance with reporting results from log-linear regression, the adjusted LOSs were reported as geometric means with 95% confidence intervals.

Results
The baseline data collection took place over 47 consecutive days between November and December 2007, during which 705 patients generated 7820 observations. The alert phase data collection took place over 38 consecutive days between August and September 2008, during which 776 patients generated 5848 observations. No patients removed themselves from the study. There was over-recruitment in the baseline period and it was decided to match this in the subsequent phases.

Demographic data are shown in Table 2. Age distributions of patients in the baseline and alerting phases are shown in Figure 2.

Primary outcome
There was a significant reduction in the hospital LOS of patients recruited in the alert phase (9.7 days v 6.9 days; $P < 0.001$).

Secondary outcomes
Several results measured compliance with the CMFT EWS protocol.

Early Warning Score accuracy
Table 3 shows the results of the accuracy of EWS calculation by ward staff during the baseline phase. Overall, they calculated 81% of EWSs correctly. The errors in calculation produced both overestimates (false positives) and underestimates (false negatives) of the EWSs. There were 12 instances where the recorded score was underestimated and the actual score would have triggered a clinical response as per the EWS protocol.
Timeliness of observation recheck when initial Early Warning Score was 3, 4 or 5

There was no difference between the baseline and alert phase time interval to recheck an EWS 3, 4 or 5 within 1 hour. This only occurred in 27% and 22% of instances in the baseline and alert phase, respectively (P=0.07). Both the baseline and alert phase groups continued to have non-compliance of 9% and 10%, respectively, up to 4 hours later.

Clinical response for Early Warning Score 3, 4 or 5

The documentation of a clinical response to a patient with an EWS of 3, 4 or 5 (on recheck as per the CMFT EWS protocol) increased from 29% at baseline to 78% in the alert phase (P<0.001). Complete compliance with the CMFT EWS protocol for EWS 3, 4 or 5 (ie, recheck EWS within 1 hour and if still EWS 3, 4 or 5 then clinical response within the next hour) could not be determined in the baseline group due to poor documentation of attendance times in the medical record. In contrast, the electronic system automatically documented both the time EWS data entry and the times of any clinical response to the patient.

Clinical response for Early Warning Score greater than 5

Timelines could not be determined accurately at baseline due to poor documentation in the paper record. Overall, at baseline these patients were responded to at some time in 67% of instances during the baseline phase and in 96% of instances during the alert phase (P<0.001).

Other secondary outcomes

Secondary results are shown in Table 4. The number of patients admitted to critical care and corresponding LOS in critical care during the study periods were 14 patients (51 bed-days) and five patients (26 bed-days), respectively (P=0.04). The other secondary outcomes — cardiac arrest incidence and mortality — did not reach statistical significance.

Discussion

This study demonstrated significant benefits associated with electronic capture of observations at the bedside and implementation of automated clinical alerts to an acutely ill, unselected medical emergency population.

Adherence to the taking of observations at predefined time points and accurate summation of the aggregated score was an immediate benefit from the electronic bedside software.

Similar benefits in the reliability of the recording of observations have been reported from other electronic systems, such as VitalPAC (TLC, London, UK). However, achieving improvements in outcome for acutely ill patients requires more than just the recording of observations. An appropriate clinical response requires communication of the need for attendance, attendance at the bedside and the initiation of appropriate clinical care. Electronic solutions can communicate the need for attendance to clinicians using predetermined logic, and can be designed to escalate the alert.

This study is the first to demonstrate significant improvement to clinician attendance to acutely ill patients with EWSs of 3 and above associated with alert logic software. The Patientrack alert logic rules engine not only issues alerts as per the hospital EWS protocol, but reissues reminders for non-response and non-attendance. If these reminders fail, a system escalates the alert to more senior doctors, such as a specialist registrar or consultant, until the EWS alert is managed. Such alert escalation provides the assurance that clinical attendance to acutely ill patients will occur.

Translating clinician attendance to improved patient outcome requires matching of attending staff’s skills and knowledge to the clinical needs of individual patients. The use of electronic solutions with inherent alerting logic provides a
hospital with the ability to redesign their clinical pathway for acutely ill patients, thereby matching clinical competency as determined by grade of clinician to an individual patient’s clinical condition and risk of deterioration as measured by their EWS. Consequently, there is an opportunity to not only improve attendance at the bedside, but also hasten the delivery of clinical intervention due to the elimination of the time lag that is inherent in clinical pathways frequently in use throughout the UK. In this later model, the historical pathway involves junior members of staff attending in the first instance and thereafter seeking senior support as and when they feel it is appropriate. In our study, senior medical attendance was achieved in 96% of occasions for the highest-risk group of patients (EWS ≥ 6) in the alert phase, compared with 67% in our baseline phase.

Translating improvements in clinical care to better outcomes in such a heterogeneous casemix of patients can be challenging. Previously, the hospital used LOS as a measure of an effective clinical pathway. We demonstrated a reduction in LOS in the study population. Coupled to the implementation of the electronic solution, the hospital implemented additional acute illness training to the nurses in the wards used for the study. Assessing the direct influence of this initiative will not be possible, but the coupling of educational actions to operational improvements will maximise the benefit of any initiative.

Other clinical outcomes that have historically been used in this area of research where the population is not homogeneous have been number of critical care admissions and associated bed-day use, and number of cardiac arrests. Our study reported a significant reduction in critical care admissions and associated bed-day use, which was surprising for the relative small size of the cohort compared with annual throughput. No cardiac arrests were reported during the alert phase. Historically, the hospital had recorded 360 cardiac arrests in 2006.

Hospitals will benefit from the publication of real-time process and clinical outcome data by being able to deliver clinicians with accurate details of the performance of this clinical pathway. Such an approach, when coupled to educational initiatives, should allow clinical teams to avoid alert fatigue, which has befallen some electronic health care systems.17,18 Further research is required to identify casemix-relevant clinical outcomes that do not rely on the clinical pathway

| Table 3. Early Warning Score (EWS) accuracy* |  |
|---|---|---|
| Actual EWSs | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Recorded EWSs | 3 | 7 | 25 | 23 | 4 | 25 | 2 | 1 | 0 | 0 | 0 |
| 4 | 0 | 5 | 12 | 13 | 0 | 10 | 2 | 1 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 1 | 5 | 51 | 8 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 | 1 | 28 | 2 | 2 | 0 | 0 | 0 |
| 7 | 0 | 0 | 0 | 0 | 0 | 1 | 5 | 0 | 1 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 5 | 0 | 0 | 0 |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 |

* Black cells indicate correct EWS calculations by staff. Grey cells indicate incorrect calculations, either through misallocation of a number or a summation error. Grey squares to the left of the black cells were overestimated scores. Grey squares to the right of the black cells were underestimates.

| Table 4. Early Warning Score (EWS) protocol compliance before and after the implementation of Patientrack and outcomes |
|---|---|---|
| Traditional hospital manual referral system | Patientrack electronic alert system | P |
| No. of patients | 705 | 776 | |
| No. of observations | 7820* | 5848† | |
| Observations sets with EWS 3–5, no. (%) | 518 (6.6%) | 515 (8.8%) | <0.001 |
| Clinical attendance per EWS protocol for EWS 3–5, no. (%) | 150 (29.0%) | 401 (78.0%) | <0.001 |
| Observations with EWS > 5, no. (%) | 48 (0.6%) | 27 (0.5%) | 0.28 |
| Clinical attendance per EWS protocol for EWS > 5, no. (%) | 32 (67.0%) | 26 (96.2%) | 0.003 |
| No. of patients with cardiac arrest (%) | 3 (0.4%) | 0 | 0.21 |
| No. of critical care bed/hospital bed-days (admissions) | 51/10 802 (14 admissions) | 26/9222 (5 admissions) | 0.04 |
| Deaths in study population (%) | 67 (9.5%) | 59 (7.6%) | 0.19 |
| Hospital length of stay in days, median (IQR) | 9.7 (4.7–19.8) | 6.9 (3.3–13.9) | <0.001 |

IQR = interquartile range. * Estimate from paper observation charts. † Actual as counted by computer.
failing and a cardiac arrest being the end point. The availability of electronic software solutions linked to automated alerting logic affords this opportunity.

Limitations

Our study had limitations. Historically controlled interventions like this, even ones where the baseline data are collected prospectively, are always subject to confounders. In this case, it was impossible to control for external factors that may have influenced LOS. This is particularly pertinent to any seasonal influence and internal adjustments in the hospital’s pathway for acute medical admissions.

Calculating a sample size in this situation was difficult, given the nature of the study and the lack of other data. As such, we could be criticised for the methods used to calculate the group sizes. Additionally, we significantly over-recruited in the baseline collection phase. This was because it took longer than anticipated to acquire the hardware and for our single trainer to train all the relevant staff in its use. Once we had done this for the baseline group, we set out to make the sample groups of equal size.

The study was designed in consecutive phases — baseline, implementation of PDA software, and activation of alerting software. As a consequence, the three phases occurred at different times of the year. The influence of seasonal illness may therefore have contributed to the longer LOS in the baseline phase.

Conclusions

Bedside entry of electronic clinical observations and matching of aggregated EWS score to automated alerting logic using the Patientrack system significantly improves timely clinical attendance to acutely ill adult medical patients with EWS scores greater than 3. An associated reduction in critical care use was also reported.

Acknowledgements

This project was part funded by a grant from TrusTECH the North West NHS Innovation Hub. The balance of funding was from the CMFT.

Competing interests

Michael Buist is a shareholder and founding director of Patientrack. He is a board member of Patientrack and his institution has received monies for consultancy, employment, expert testimony, gifts, grants, honoraria, payment for manuscript preparation and payment for development of educational presentations, including service on speakers’ bureaus.

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