Bedside electronic capture — methodological concerns

Christian P Subbe

To the Editor: I read the article by Jones and colleagues about bedside electronic capture of clinical observations and automated clinical alerts[1] with great interest. As a proof of concept, this is an important piece of work that demonstrated increased compliance with call-outs by automating part of the process, thus reducing scope for error.

However, as a physician currently working in two medical admissions units in the United Kingdom, I have great reservations about one claim made in the article — that the introduction of this tool on only two wards reduced hospital length of stay from 9.7 to 6.9 days.

Given the small number of abnormal observations (in a possibly even smaller number of patients) who triggered a score of 3 or more (7.2% in the control and 9.3% in the intervention group compared with over 15% in our data from a study that used, in essence, the same scoring tool[2]) this needs further explanation. Is it possible that with the Early Warning Score (EWS) protocol, patients were identified earlier for palliative care and therefore died earlier? What was the breakdown of length of stay in the different EWS bands? And was the reduction of length of stay due to shorter length of stay among patients who survived or died, or among younger or older patients?

I would also like the authors to reflect on the changes in service delivery in acute medicine that occurred in central Manchester in 2007 and 2008. The number of 500 admissions per months seems small for a hospital of this size, suggesting that some medical patients were admitted through other services, thus influencing casemix. In our experience, length of stay among older patients is largely dependent on the establishment of rehabilitation facilities and social services.[3] Again, I believe that there have been changes to services in Manchester and I would be grateful if the authors could expand on the impact they think this might have had on delivery of shorter length of stay.

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Bedside electronic capture — difficult to study, but valid results

Steve Jones, Jane M Eddleston and Michael Buist

In reply: We thank Subbe and Smith and colleagues for their thoughtful comments on the conduct of the trial of Patientrack alert logic software at the Central Manchester University Hospitals NHS Foundation Trust (CMFT).[1] We agree with both correspondents about the limitations of the use of hospital length of stay (LOS) as a study end point, particularly with the seasonal variability and the ever-changing efforts by organisations to reduce LOS. That said, the major aim of this study, as stated in the title, was to provide proof of concept of whether an electronic system of alerting doctors improved compliance with a standard Early Warning System (EWS)/deteriorating patient protocol. Clearly, in terms of that end point, the study results were positive. This then raises the research question of why this should be the case. Despite the limitations that are exhaustively listed by Smith et al, we maintain that it was reasonable to report LOS.

With respect to the other issues raised by Smith et al, we respond as follows. First, we accept that the outcomes of study patients are only reported for the baseline and full implementation phase of the Patientrack system. There was a considerable and unplanned delay in adapting the state-of-the-art Patientrack system to the legacy "bleep" paging system used to communicate with doctors. We also agree with the suggestion that our reported results may be due to the improvement in documentation that occurs with the implementation of electronic systems. We are not sure that such an improvement in documentation is a bad outcome. With particular reference to the issues raised about Table 2, we gave "basic" demographic comparisons between the baseline and intervention groups of patients, as stated in the table's title. Table 2 was never intended to be a results table with outcome data. We agree, however, that better under-

standing of how the Patientrack system derives its benefits could have been obtained by comparing the LOS data of groups of EWS alerting patients. This level of detail was not an aim of our proof-of-concept study. However, with increased implementation of such electronic systems, it will become possible to perform this type of analysis in real time.

Second, we accept that there are minor differences in the data and results that we presented in an abstract poster in 2009[3] from those published in the Journal in 2011[1] (indeed, we are flattered that these correspondents have been so intensely focused on our work). Not surprisingly, the differences are explained by the normal research process where, after initial data collection and analysis, we had the statistics office of the Australian and New Zealand Intensive Care Society Clinical Trials Group reorganise, revalidate and reanalyse the original data, and these reprocessed data were presented in the Journal.

Finally, on the issue of alleged conflict of interest; clearly, Patientrack has a commercial arrangement with the CMFT. The agreement reflects TrusTECH and CMFT's funding, resource and intellectual development of the product. However, only Professor Buist, as the inventor and patent holder of Patientrack, stands to have a pecuniary interest in any way in the outcome of this study. This interest is declared. All other authors, individually or collectively, have no financial interest in Patientrack or the outcome of this study.

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Are we neglecting extra-vascular pressures?

Adrian Regli and Bart De Keulenaer

To the Editor: We read with great interest Groombridge and colleagues' article comparing central venous pressure at the superior vena cava and femoral vein sites.[1] We completely agree with the conclusions drawn by the authors that superior vena cava pressure (SVCP) and femoral venous pressure (FVP) are two different pressure entities altogether.

Unfortunately, despite examining the influence of positive end-expiratory pressures (PEEP) and intra-abdominal pressures on SVCP and FVP, the authors did not point out how important it is to assess potential extra-vascular pressures when interpreting SVCP or FVP correctly when caring for critically ill patients.

When extra-vascular pressures such as intra-abdominal pressures are minimal, FVP and SVCP are comparable.[2-4] This helps explain why some authors have previously found comparable FVP and SVCP readings.

However, extra-vascular pressures should not be neglected. For example, PEEP is transmitted to the SVCP by around 50%, whereas intra-abdominal pressure is transmitted to the FVP by nearly 100%.[2]

Although FVP is not currently recommended as a tool to measure intra-abdominal pressures because of a relatively high level of agreement between FVP and bladder pressure, FVP correlates well with intra-abdominal pressures.[2,5]

We therefore recommend that bladder pressures should be measured to assess intra-abdominal pressures,[6] so that elevated FVP can be correctly interpreted. Knowing the intra-abdominal pressure is essential to differentiate between the presence of intra-abdominal hypertension or elevated SVCP. These conditions each require a different diagnostic and therapeutic approach.

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Extra-vascular pressures are also crucial

Christopher J Groombridge and Warwick Butt

In reply: We completely agree with the recommendation of Regli and De Keulenaer that "bladder pressures should be measured to assess intra-abdominal pressures, so that elevated FVP [femoral venous pressure] can be correctly interpreted".

In our article, we stated

> We also examined the effect of intra-abdominal pressure (as measured by bladder pressure) on these two measurements. We obtained intra-abdominal pressure values between 4 and 22 mmHg. We found a statistically significant increase in the FVP (PE, 0.498; SE, 0.154; $P=0.003$), and the difference (FVP – [central venous pressure]) with increasing intra-abdominal pressure (PE, 0.264; SE, 0.091; $P=0.007$).[1]

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A novel approach to obtaining informed consent from the person responsible: telephone, email and text message

Glenn M Eastwood

To the Editor: Many readers will be acutely aware that sufficient, timely enrolment of participants is vital for successful clinical trial completion. Indeed, investigators often go to great lengths to judiciously select eligibility criteria that will facilitate participant recruitment.

In my experience, the process of obtaining informed consent can, at times, be an additional hurdle. As such, any attempt to expedite this aspect of process is desirable. In accordance with Victorian law (*Guardianship and Administration Act 1986* [Vic]) a "person responsible" can give consent for a patient to take part in medical research if the patient is unable to do so.

Recently, I was involved in an informed consent process that I feel may benefit other investigators and research coordinators. Once trial eligibility was confirmed, and with the assent of the treating intensivist, I sought consent from the daughter (next-of-kin) of a patient in our intensive care unit. Initial contact was made by telephone, and it was established that she was unable to attend the hospital that day. Due to a time restriction for trial enrolment (< 24 hours of ICU admission), a delay in obtaining informed consent would exclude the patient from the study. The daughter wished to know more, so the "person responsible information and consent form" was sent to her nominated email address. After a period of consideration by the daughter, I received a text message from her that read: "you have my consent to enrol [name of patient] in the [name of] study", which was date and time marked.

Participant randomisation swiftly ensued, and the study intervention was commenced shortly thereafter. Written informed consent was obtained from the daughter the next day, and the process was documented in the patient's medical record. The patient's subsequent participation in the trial was uneventful.

This example describes the use of telephone, email and text messaging as a means of facilitating and providing informed consent. Thus, I urge other research coordinators or those in a position of obtaining informed consent from a person responsible, to consider such an approach where permissible. Although this approach may be infrequently used, I feel that it provides an additional means of enrolling participants, which would be appreciated by persons responsible and investigators alike.

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