COURSEWORK

23rd April 2024

Writing Tips: Story, Style & Sales Pitch

Practical: Writing techniques

1. What immediately obvious thing has been done to help the reader?
2. Find three examples of **ASSERT-JUSTIFY**.
3. Find two examples of where **ASSERT-JUSTIFY** might have been used, but was not. Can you find a sentence in the paragraph that could either be used or adapted for use for this purpose?
4. Find three examples of **priming**
5. Find three examples of **linking**
6. Find three examples of **signposting**
7. Can you identify any **tag-phrases**?
8. In five short bullet points, outline the **argument** being made to reviewers
9. Did you understand the importance of the proposed work?

Background & Rationale Section (Gerry, DRF, 2016)

Developing a new early warning score to more accurately predict which hospital patients are in need of immediate care, using novel dynamic prediction methods

Clinical problem

Severe clinical deterioration of hospital patients is often preceded by changes in their physiological parameters, such as blood pressure, respiratory rate, pulse and level of consciousness.[1-4] Chart reviews and a recent report from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) show that before serious events such as death, cardiac arrest and intensive care unit admission occur, there is often several hours of evidence of clinical deterioration. Many of these serious events could thus be prevented with appropriate action.[3,5-8] Factors associated with failure to prevent deaths in hospital include poor patient monitoring, failure to recognise signs of deterioration, inadequate interpretation of physiological changes, and failure to take appropriate action.[9-12] A recent review estimated that 12,000 deaths could have been prevented in English hospitals in 2009, whilst other sources estimate this number could reach 40,000 per year.[3]

Early Warning Scores are the existing solution

Hospitals need tools to help staff recognise patients at risk of deterioration, enabling them to provide appropriate, timely care and prevent unnecessary serious events. Morgan proposed the Early Warning Score (EWS) as a solution in 1997.[13] Many adaptations of the idea have since been proposed. These simple algorithms usually allocate points for each physiological vital sign, weighted according to the degree of departure from a range perceived as normal, then add up the weighted points to give a total score. The vital signs typically assessed are respiratory rate, systolic blood pressure, temperature, heart rate and level of consciousness. It is the total score that informs care. Particular scores trigger particular actions, such as increasing the frequency of vital sign monitoring, calling more experienced staff or calling a rapid response team. These simple tools can easily be implemented as part of traditional bedside observation charts.

A systematic review published in 2007 found 33 EWS algorithms in use, with a high degree of overlap in the vital signs included, but with considerable variability in the weighting systems used to obtain the score.[14] However, due to numerous deficiencies in the methods used to develop many of these EWSs, the authors concluded that none of the algorithms could be said to ‘perform well’ at identifying patients at increased risk of in-hospital death from those who were not. In the same year, NICE released guideline CG50 on recognising and responding to deterioration using EWSs.[15] Recommendations from the guideline concluded that all adult patients in acute hospital settings should be monitored using an EWS, that there are six key physiological factors that should be included in an EWS, and that they should be used on admission, at least every twelve hours, and more frequently if an abnormal physiology is detected. As a result, NHS hospitals in England could collect around 350 million sets of vital signs observations each year.[16]

In 2012 a group formed by the Royal College of Physicians published recommendations[17] proposing a standardised EWS to be used across the NHS. This led to the development of the National Early Warning Score (NEWS). The NEWS incorporates the six physiological parameters recommended in NICE CG50: respiratory rate, oxygen saturations, temperature, systolic blood pressure, pulse rate and level of consciousness. The weighting for each vital sign is based on a recently developed EWS, called ViEWS[18], and on the clinical consensus of the group. The NEWS is now seen as the gold standard EWS.[17]

Early Warning Scores have been developed using suboptimal methods

Several approaches have been used to develop EWSs. The majority have been based wholly or partly on the clinical expertise of a committee and on a review of the literature. Others have used a 'trial and error' approach[18], in which parameters are manipulated and weights assigned based on those that give the optimal results from a single dataset. This approach leads to 'overfitting' problems: the model fits idiosyncrasies in that particular dataset rather than any underlying generalisable patterns, meaning that the model fails to work in other data.[19] Very few EWS models have been developed using robust statistical regression modelling, which is the most widely recommended approach for developing clinical risk prediction models. The inherent correlation between different vital signs is thus not typically accounted for in current EWS models. In contrast, if a statistical model were used, apparent predictive effects of one vital sign could be explained by other predictive variables, and a more robust and unbiased choice of which predictors to include in the model could be made.

When data-driven methods have been used in the past, over-simplistic assumptions have been made. For example, when datasets have been used in which any one patient may contribute multiple sets of vital signs, these sets have been assumed to be independent. However, measurements are likely to be highly correlated within a patient, and therefore results from these approaches could be biased and over-confident. Further, although the link between vital signs and patient outcomes is of interest, it can often be confounded by treatment interventions. For example, hospital staff may notice that a patient is deteriorating, give appropriate medical care, and therefore prevent a serious event. Ignoring the occurrence of this treatment intervention will modify the apparent relationship between vital signs and outcome.

By definition, a model will generally fit better to the data that it is derived from than most other datasets. Models must therefore be evaluated on another, independent, dataset, which is known as external validation.[20] As there is little evidence that EWSs generally undergo external validation, their performance is largely unknown, which raises questions about whether they should be used.[21] The validation studies that do exist tend to have been poorly designed, conducted and reported, show only limited usefulness, look at a very specific population, or have been carried out on a very similar population to the original derivation dataset.[22,23]

A further weakness of the current EWSs is the way they have been developed and delivered: in many cases the same algorithm is applied to all hospital patients, regardless of their illness (and severity), age or sex.[24] There are a few exceptions, such as the development of paediatric- or antenatal-specific versions.[25,26] However, EWSs are generally applied to highly variable populations. As one would expect different physiological factors to predict poor outcome in different illnesses, a generic algorithm is likely to perform badly in some groups.[24,27] Furthermore, despite their broad target population, most algorithms do not contain patient-specific variables that could 'individualise' the prediction, such as age, sex and medical indication (and severity).[28]

As with all risk prediction algorithms, the aim is to have a system that flags the majority of those actually at risk (sensitivity) and correctly does not flag those not at risk (specificity). Once an algorithm has been chosen, a threshold score at which action will be taken is defined. The threshold creates a trade-off between sensitivity and specificity – improving one is to the detriment of the other. The NEWS has a recommended threshold for calling the critical care team of five points. This threshold results in a specificity of around 80%; 20% of alerts are false alerts[17]. However, the scores are meant to be calculated regularly. A patient who will not ultimately deteriorate has around a 60% chance of being flagged as at risk in any one day, assuming six hourly assessments. This creates a tremendous workload for clinical staff, resulting in protocols often not being followed.[29,30] This may be part of the reason why randomised trials of EWSs have generally shown them to be ineffective in improving health outcomes.[31]

A fundamental problem with current methods for developing EWSs is that only a patient's most recent information is considered. Current EWSs all aim to predict future risk of deterioration based on a single moment in time, the most recent vital signs measured for a particular patient. All observations of that patient made in the past are ignored when calculating the patient's current risk. Any trends (or deterioration) in previous measurements are not captured, which is clearly wasteful. For example, a patient with oxygen saturation readings over the course of a day of 100%, 99%, 97% and 95% is showing a clear downward trend that may well increase their risk of deterioration. However, the most recent value alone, 95%, may not prompt a nurse to take appropriate action.

Electronic systems give the opportunity for next-generation Early Warning Scores

Vital signs have traditionally been recorded on paper observation charts. An assessor, typically a nurse, applies weights to each vital sign and sums them to calculate the total EWS. Unsurprisingly, this approach is errorprone; incorrect scores are assigned to vital signs and individual scores are incorrectly summed.[32] Electronic EWS systems have been developed, partly to mitigate human-error flaws. An electronic system assigns scores to vital signs and computes the EWS automatically.[33] These systems can send alerts, prompt appropriate action and give ward- or hospital-level oversight of the EWS status of all patients.

The Health Secretary delivered a mandate in 2013 that the NHS should be paperless by 2018.[34] A 2013 audit reported that 27% of English NHS trusts were already using electronic systems to monitor vital signs.[35] The majority of hospitals are likely to be using electronic EWS systems soon. As electronic systems become more widely available, they should be the subject of focused research. More sophisticated models can be devised now that scores are calculated automatically. Further, very large numbers of vital sign observations will be recorded. These datasets can be used to develop improved EWSs.

Next-generation scores risk being developed using the same poor statistical methods

Despite their enormous potential, there has been no obvious improvement in the methods used to develop EWSs in the five years since electronic systems became available. There is a real risk that the basic EWS algorithms developed to take into account the restrictions of paper observation charts will continue to be used if no concerted effort is made. In light of the lack of progress in this area, it seems likely that any new EWSs will continue to be developed using the same poor quality methods and will continue to be of little benefit to patients.

My research will provide a better solution

The developments in electronic systems and their increasing use within hospitals present an opportunity and need for robust and novel methods to be applied to EWSs, to take them to the next stage of their development. My proposed research will take this step.

I will use statistical regression modelling techniques that are robust and unbiased, and will more accurately link vital signs to patient outcomes. Other patient characteristics may be included in the models, such as age and medical condition, allowing for individualisation of the risk prediction. Unlike previous attempts, I will not ignore the complexity of the problem. I will take into account the potential for multiple, correlated measurements within each patient. I will also recognise that any treatment interventions that occur could severely modify the relationship between vital signs and outcomes. I will validate any models that I develop using data from different hospitals, allowing for a better test of the models' prediction. Finally, and perhaps most importantly, I will use dynamic prediction modelling methods to build prediction models that use both past and current measurements. This will allow individualised trends to be detected and therefore allow faster recognition of deterioration.