



Clinical paper

Defining clinical deterioration[☆]Daryl Jones^{a,b,c,*}, Imogen Mitchell^d, Ken Hillman^{e,f}, David Story^{b,g,h,i}^a DEPM Monash University, Australia^b Austin Health, Australia^c Department of Surgery, University of Melbourne, Australia^d The Canberra Hospital, Australia^e University of New South Wales (SWS Clinical School), Clinical Academic, Intensive Care, Liverpool Hospital, Australia^f The Simpson Centre for Health Services Research affiliated with the Australian Institute of Health Innovation, University of New South Wales, Australia^g Department of Anaesthesia, Austin Health, Australia^h The University of Melbourne, Australiaⁱ Centre for Anaesthesia, Perioperative and Pain Medicine, The University of Melbourne, Australia

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ABSTRACT

Objectives: To review literature reporting adverse events and physiological instability in order to develop frameworks that describe and define clinical deterioration in hospitalised patients.

Methods: Literature review of publications from 1960 to August 2012. Conception and refinement of models to describe clinical deterioration based on prevailing themes that developed chronologically in adverse event literature.

Results: We propose four frameworks or models that define clinical deterioration and discuss the utility of each. Early attempts used retrospective chart review and focussed on the end result of deterioration (adverse events) and iatrogenesis. Subsequent models were also retrospective, but used discrete complications (e.g. sepsis, cardiac arrest) to define deterioration, had a more clinical focus, and identified the concept of antecedent physiological instability. Current models for defining clinical deterioration are based on the presence of abnormalities in vital signs and other clinical observations and attempt to prospectively assist clinicians in predicting subsequent risk. However, use of deranged vital signs in isolation does not consider important patient-, disease-, or system-related factors that are known to adversely affect the outcome of hospitalised patients. These include pre-morbid function, frailty, extent and severity of co-morbidity, nature of presenting illness, delays in responding to deterioration and institution of treatment, and patient response to therapy.

Conclusion: There is a need to develop multiple-variable models for deteriorating ward patients similar to those used in intensive care units. Such models may assist clinician education, prospective and real-time patient risk stratification, and guide quality improvement initiatives that prevent and improve response to clinical deterioration.

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1. Introduction

In-hospital clinical deterioration may relate to the presenting condition, a new problem, or a complication of the health care provided. Deterioration not promptly responded to can result in patient morbidity and/or mortality. Accordingly, systems have been developed to respond to deterioration in many countries

including the United Kingdom,¹ United States,² New Zealand and Australia.³

A major challenge with recognising and responding to clinical deterioration is the lack of a consensus definition as to what constitutes a deteriorating patient or clinical deterioration. In this article we compare and contrast four ways that clinical deterioration has been described (Table 1). We highlight that traditional frameworks have used retrospective studies and focussed on the **end result** of clinical deterioration; the **adverse event**, as well as the influence of **iatrogenesis** and **medical neglect** on those events. More recently there has been a move to examine the utility of abnormal vital signs and observations to **predict** in real time the subsequent risk of patient morbidity. There are now attempts to define clinical deterioration using variables other than just abnormal vital signs and observations. There is a need to develop and validate assessment

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Table 1
Comparison of four models for defining deteriorating patients.

Basis and context of framework	Description of framework	Advantages of framework	Disadvantages of framework
Contribution of negligence and iatrogenesis in causing adverse events. Studied between 1960 and 2000.	Adverse events due to medical care and not due to underlying medical condition.	Semi-quantitation of harm due to iatrogenesis. Can audit and assess contributing factors. Important for indemnity purposes.	Retrospective. Variable level of agreement on degree of preventability. Does not inform clinicians <i>prospectively</i> that a patient is at increased risk.
Defined clinical adverse events. Studied since 1998 in the context of post-operative surgical complications and Rapid Response Systems.	Clinical events are defined as adverse events e.g. myocardial infarction, thrombo-embolism, renal failure. Other adverse events used include cardiac arrest and unplanned ICU admission.	Clearly defined end-points. Does not just consider iatrogenesis, but also considers clinical factors. Identified antecedent instability prior to the event. Still useful in research to investigate the effectiveness of system interventions.	Also retrospective. Does not reliably inform clinicians <i>prospectively</i> which patients are at risk.
Presence of physiological instability. Studied since 1994.	Patient fulfils RRT criteria (single parameter trigger). OR Summed MEWs score (aggregate track and trigger system).	Real time, semi-objective and easy to measure. Can follow response to therapy. Can be linked with an expected institutional response. Some degree of validation as predictor of risk (death).	Requires deterioration to be detected through reliable measurement of vital signs. Not completely validated. Only considers vital signs and not other factors that may predict risk and affect outcome in an individual.
Integrated model for prospective risk stratification.	Considers organisational and system factors, patient factors, physiological factors that change over time, and in response to therapy.	Deranged vital signs are placed in context of patient reserve, presenting disease, and setting in which they are being treated. Stratifies risk sequentially during hospital admission.	Although individual components are validated, the overall model is not. Requires validation with complex mathematical modelling.

RRT: rapid response team; MEWS: modified early warning score.

tools that **prospectively** risk-stratify patients who are thought to be deteriorating. Ultimately, such tools may provide individualised and sequential assessment of risk, to guide pro-active and reactive strategies for deteriorating patients.

2. Methods

2.1. Search strategy for literature review

We searched Medline (1960–August 2012) using the following medical subject heading search terms: “adverse event and hospitalisation”, “complication and hospitalisation”, “rapid response team”, “rapid response system”, “track and trigger”, “clinical deterioration and hospitalisation” and “early warning score”. The search was restricted to adults. Additional articles relating to commonly used scoring systems for acute and chronic illness were also included based on author consensus.

2.2. Development of models defining clinical deterioration

The four models were conceived by the principal author and revised by all authors in a series of electronic communications and teleconferences. The first three models were based on the prevailing themes perceived to be present in chronologically published literature. The fourth model was theoretical, and was developed based on patient-, disease- and organisational (system)-factors associated with adverse patient outcomes. The final presentation of the model was designed to reflect model variables, as they would be assessed clinically and develop during the hospital admission and course of clinical deterioration.

3. Results

3.1. Definitions based on iatrogenesis and medical neglect

The first framework to assess the magnitude and consequences of in-hospital deterioration evolved in the United States and

focused on iatrogenesis and medical neglect. In 1964 Schimmel reported that 20% of 1014 patients admitted over eight months suffered a “noxious response to medical care”.⁴ Two subsequent US studies, involving expert panel review subsequently reported lower adverse event incidences of 3.7% and 2.9%.^{5–7}

Wilson et al. subsequently reported that 17% of 14,179 patients in 28 Australian hospitals suffered an adverse event, defined as “*unintended injury or complication that resulted in disability, death or prolonged hospital stay and was caused by the health care management rather than by the underlying disease process*”.⁸ Others used this definition to assess more than 25,500 patient records in New Zealand,^{9,10} the UK,¹¹ and Canada¹² revealing that 8–17% of hospital admissions were associated with adverse events, of which 37–51% were thought to be preventable and 7–19% resulted in long term disability or death.

Interestingly, these studies defined an adverse event not related to the admitting diagnosis as being iatrogenic. This framework drove the initial patient safety agenda, estimated the burden of harm attributable to iatrogenesis, and stimulated the search for factors contributing to morbidity. Although probably unintended, this framework also began to define the concept of clinical deterioration.

While an important first step, this approach is time consuming, retrospective in design, sometimes includes adverse events attributable to pre-hospital care, and does not consider whether deterioration was part of the natural dying process. In addition, assessment and adjudication of preventability is subjective and inter-observer agreement may be poor.¹³ More importantly, the approach describes the epidemiology of patients who **have deteriorated**, and does not prospectively help clinicians reviewing patients who are **possibly deteriorating** (Table 1).

3.2. Definitions based on discrete clinical complications

The next framework that evolved to describe clinical deterioration defined adverse events as one or more discrete complications; e.g. pulmonary embolism or severe sepsis.^{14,15} These events are

Table 2
Examples of studies assessing incidence and antecedents to discrete complications.

Study design and patient cohort	Nature of complications	Major findings
Bellomo et al. 1998–1999. 1125 patients undergoing major surgery in a single hospital in Victoria, Australia.	AMI, PE, APO, unscheduled tracheostomy, respiratory failure, cardiac arrest, stroke, severe sepsis, acute renal failure, emergency ICU admission, death.	16.9% had at least one complication. Patients older than 75 yo and undergoing unscheduled surgery had 20% mortality.
Prospective observational study. Story et al. – REASON study. 4148 patients aged >70 yo in 23 hospitals in Australia and New Zealand.	AMI, cardiac arrest, re-intubation, APO, pulmonary embolism, stroke, systemic inflammation, wound infection, unplanned return to operating room, acute renal impairment, unplanned ICU admission, death.	30 day mortality was 5%. 20% had suffered complications. 9.5% were admitted to the ICU.
Prospective observational study. McQuillan et al. Portsmouth and Southampton UK.	100 consecutive unplanned ICU admissions.	54% of patients received suboptimal care from lack of organisation and knowledge, failure to appreciate urgency, or failure to seek advice.
Prospective observational study. Hodgetts et al. 1999.	118 cardiac arrests compared to 132 controls.	Risk factors for arrest included abnormal respiratory rate, breathing heart rate, systolic blood pressure, chest pain and hypoxia.
Retrospective observational study. Buist et al. January–December 1997. Single hospital in Victoria, Australia. Retrospective observational study.	42 cardiac arrests and 79 unplanned ICU admissions.	75% of patients had instability for at least one hour. Haemodynamic instability more common than respiratory instability or abnormal laboratory results.

AMI: acute myocardial infarction; PE: pulmonary embolism; APO: acute pulmonary oedema; ICU: intensive care unit; yo: years old.

more clinically focussed, and consider both the patient's clinical condition as well as complications of provided care. They developed in the context of studies of post-operative complications and trials of critical care outreach effectiveness. For example, approximately 20% of surgical patients admitted for more than 24 h suffered at least one discrete clinical complication during their admission (Table 2).^{14,15}

Other studies within this framework focussed on in-hospital cardiac arrest, unplanned admission to the intensive care unit (ICU) or unexpected death (Table 2).^{16–18} In addition, these studies attempted to more objectively assess adverse event preventability by reporting the proportion of patients with **more objective signs** of deterioration prior to the complication. Combined, these studies revealed that up to 84% of events were preceded by a new problem and/or derangements in a patient's vital signs that were often present for several hours before the event. This framework informs clinicians that patients suffering an adverse event may have a period of clinical instability prior to the event. However, these studies are also mostly retrospective and also describe patients who have **deteriorated**. As such, they do not prospectively inform the clinician of the likelihood a patient who has abnormal vital signs will **subsequently** develop an event. These frameworks of deterioration remain useful in research as outcome measures when assessing the effectiveness of quality improvement and patient safety initiatives.

3.3. Definitions based on deranged vital signs

The discovery that adverse events were preceded by abnormal vital signs led to the development of **objective criteria** to assist clinicians to identify clinical deterioration in real time. Concurrent with the evolution of this framework came several important principles. The first is the concept of risk stratification, whereby clinicians and researchers **prospectively** attempt to “predict” the subsequent risk of morbidity based on the **degree** of physiological derangement. Second, clinicians and investigators increasingly distinguished between “unexpected deaths” and “expected deaths” (a death with a limitation of medical therapy such as a DNR).¹⁹ Finally, and most importantly, when patients fulfil or breach these objective criteria, there will be an expected institutional response in the form of expert and expeditious patient review.^{20,21}

The simplest and most studied **objective criteria** are single parameter rapid response team (RRT) calling criteria which provide upper and/or lower limits of vital signs and other observations that should trigger RRT review.^{19–21} Other studies have examined the utility of aggregate scores and modified early warning scores (MEWS) in which a score (0–3) is assigned for each vital sign, depending on the degree of their derangement.²² Individual scores are then summed to produce an aggregate score which then provides a framework for graded escalation of care.

In a prospective study of a newly implemented RRT service, Buist et al. found that 9% of 6300 patients admitted to five wards over seven months fulfilled RRT call criteria which was associated with a seven fold increase in mortality.²³ In a hospital without an RRT, Bell and co-workers revealed that 5% of 1100 patients fulfilled RRT criteria during one set of vital sign measurements. The mortality in this group was 25%, compared with 4% in patients who did not fulfil RRT criteria.²⁴

Similarly, studies of hospitals with well established RRTs show that 3–6% of admissions are associated with RRT activation and that the in-hospital mortality of such patients is 24–34%.²⁵ A major limitation of single parameter activation systems is the substantial inter-hospital variation in thresholds for activation, such that a deteriorating patient may fulfil activation criteria in one hospital but not another.²⁶ Furthermore, not all patients who breach criteria will subsequently develop an adverse event.

Many calling criteria include triggers such as airway obstruction, altered conscious state and seizures. They often contain a ‘worried’ criterion permitting bedside clinicians to use clinical judgement in the escalation of care for deteriorating patients, even when vital signs are within normal limits.^{19,20,26} In well established systems, up to half of RRT calls may be the result of ‘concern’ or a ‘worried’ criterion, emphasising that clinician intuition needs to be considered when designing response systems to clinical deterioration.

A limitation of all objective criteria is that they do not take into account other important patient-, disease-, or organisational-related factors that might also influence morbidity and mortality.

3.4. Future definitions of clinical deterioration

In attempting to further explore the nature of factors influencing clinical deterioration, we propose the following definition: “**A deteriorating patient is one who moves from one clinical state**

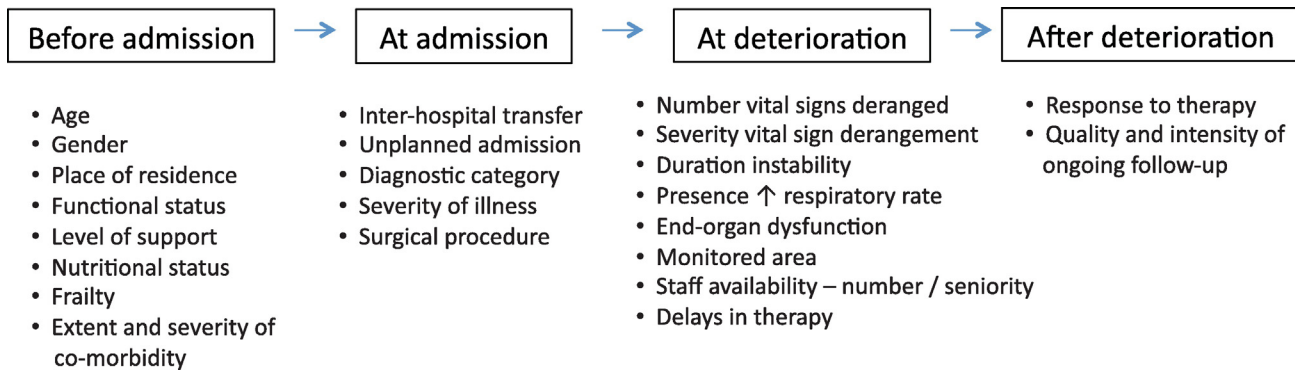


Fig. 1. Model for sequentially stratifying risk of deteriorating patients during hospitalisation.

Table 3

Proposed domains for integrated and sequential model for risk stratifying deteriorating patients.

Low risk patient	Factor influencing risk	High risk patient
Initial assessment in emergency room	<i>Patient location/situation</i> 1. Monitored area 2. Position in relation to usual ward	Three days post-operatively. Outlier; not on usual ward.
18 yo female No co-morbidities Plays regular sport Normal Fully independent No restriction activity	<i>Patient factors</i> 1. Age and gender 2. Prior co-morbidity 3. Physiological reserve 4. Pre-admission Albumin 5. Functional status 6. Frailty	85 yo male Angina, Hypertension, emphysema, renal impairment Short of breath at rest, Cr 175 $\mu\text{mol l}^{-1}$ Low House bound and needs help with personal care Poor strength, tires easily
No Yes Loose bowel actions after eating salad	<i>Disease factors</i> 1. Inter-hospital transfer 2. Emergency admission 3. Prognosis of presenting complaint	Yes Yes Large bowel obstruction due to newly diagnosed sigmoid colonic cancer
Four clear bowel actions without blood in last 24 h	4. Severity of presenting complaint	Bowel perforation and four quadrant peritonitis found at laparotomy. Now has discharging abdominal wound
HR 100 bpm, SBP 90 mmHg, Temp 38.5 °C, SpO ₂ 96% Normal SBP 100 mmHg Three No <2 h Stable	<i>Vital sign factors</i> 1. Degree of derangement 2. Derangement compared to baseline 3. Number of vital signs deranged 4. Presence of increased respiratory rate 5. Duration of derangement 6. Course of vital signs with time	HR 100 bpm, SBP 90 mmHg, Temp 38.5 °C, SpO ₂ 96% Normal SBP 145 mmHg Three No 4 h Worsening
Normal Reduced Warm and well perfused Within normal range	<i>Presence of end organ dysfunction</i> 1. Conscious level 2. Urinary output 3. Peripheral circulation 4. Laboratory tests (Cr, U, lactate, HCO ₃ , base deficit)	Normal Reduced Cold and clammy Cr 250 $\mu\text{mol l}^{-1}$, lactate 4 mmol l ⁻¹ , HCO ₃ 19 mmol l ⁻¹ , base deficit 5.2 mmol l ⁻¹ New onset ST depression V1–V5
Not performed	5. ECG	
Improves with 2 L crystalloid therapy Breathing room air	<i>Therapy factors</i> 1. Response to therapy 2. Intensity of other therapy	No response to 3 L crystalloid On 10 L oxygen via face mask
11 am 1:4 Senior ED nurse, ED consultant is present in department Tertiary referral ICU bed available	<i>Organisational (system) factors</i> 1. Time of day 2. Nursing staff ratios 3. Staff skill mix 4. Hospital type 5. ICU access 6. RRT activation criteria thresholds 7. Seniority of RRT staff 8. Ongoing monitoring and review	3 am 1:6 Senior nurse sick, patient being cared for by agency nurse, resident medical cover in operating room Secondary referral No ICU bed available

ED: emergency department; yo: year old; Cr: creatinine; U: urea; L: litres; bpm: beats per minute; ECG: electrocardiogram.

to a worse clinical state which increases their individual risk of morbidity, including organ dysfunction, protracted hospital stay, disability, or death." As we learn more about patient centred systems for the early detection of deteriorating patients it is likely factors in addition to vital sign derangement and observations will be considered when stratifying degrees of risk of morbidity. The importance of the dynamic and changing nature of a patient's condition and risk level will also need to be recognised (Fig. 1).

The most validated system for risk-stratifying acutely unwell patients against in-hospital mortality is the APACHE system for ICU admissions. It contains both **Acute Physiological and Chronic Health Evaluation** components including the presence of pre-defined chronic health problems, as well as the worst readings in vital signs and haematological and biochemical investigations in the first 24 h of ICU admission.^{27,28} However, this system is only validated for patients after they have been admitted to ICU, and not for patients deteriorating on hospital wards not admitted to ICU.

Increasingly, patients admitted to acute hospitals have multiple co-morbidities,²⁹ and may present with multiple clinical problems. In the future it may be possible to develop an evidence-based integrated framework for risk stratifying deteriorating ward patients that considers the interactions of chronic health status, presenting condition and post-admission course (Fig. 1; Table 3). To illustrate this, we contrast two deteriorating patients with identical vital sign abnormalities (Table 3). Ideally, the importance of each variable should be validated statistically in a multiple variable model, as was done for the APACHE model.

Several factors affect the baseline (**pre-hospital**) physiological reserve of patients including age,^{14,15,27,28,30} the number and extent of organ dysfunctions,^{27,28} and pre-morbid functional status.^{31–33} The concept of frailty reflects a patient's physiological reserve and recent research is has revealed it is strongly linked to patient outcome.^{34,35}

Factors known to affect risk **at hospital admission** include an unplanned admission,^{14,15,30} requirement for inter-hospital transfer,³⁰ as well as the diagnostic category³⁰ and severity of the presenting complaint. Increasingly, scoring systems for individual clinical conditions are available; e.g. community acquired pneumonia³⁶ and subarachnoid haemorrhage³⁷. A confounding problem is that patients may present to hospital with multiple concurrent conditions.

Patient risk and outcome once **deterioration is detected** on the general wards will be influenced by the number and severity of vital sign derangements,^{27,28,38,39} the presence of increased respiratory rate,⁴⁰ whether appropriate intervention is delayed,^{41,42} as well as the presence of end-organ dysfunction.^{27,38,39} Much less studied is the influence of the responsive to initial resuscitative efforts, and the amount of therapeutic support provided during deterioration. Perhaps least studied of all is the effect of **organisational factors**, such as availability of appropriately skilled staff, awareness and support of the system across the organisation, and access to monitored or critical care beds.

A validated framework for risk stratification would serve several uses. It would increase awareness of deterioration and guide clinician education in the area. It would also permit prospective risk stratification based on available information at various phases of the hospital admission (Fig. 1), and guide acquisition of further information to improve stratification. It may also facilitate research around how to improve and refine factors that influence the early detection and response to deterioration. Furthermore, a validated framework for risk stratification may guide geographic placement in the hospital, levels of monitoring, staffing ratios, required skill set and mix of attending clinicians, and finally, graded interventions based on level of risk. Finally, in an era of increasing financial restrictions, risk stratification may permit focus of expensive and

resource intense interventions on patients most at-risk, without loss of overall treatment quality or patient safety. Although each component has been individually validated, the major limitation of the integrated framework is the need for evaluating individual and collective contributors to patient deterioration, most likely in a multiple variable model.

3.5. Consideration of end of life care issues

A major disadvantage of using death as an indicator of patient safety systems is the difficulty in distinguishing between deaths that are potentially avoidable, and deaths that are a natural part of end of life.⁴³ In the former patient, early identification, recognition and response to deterioration may permit aggressive intervention to reduce risk, disability and death. In the latter, it may be inappropriate and a different pathway including relief of distressing symptoms and pain may be more appropriate. Accordingly, alternate outcome measures such as new disability and functional status in survivors may need to be explored.

4. Conclusion

Despite improvements in hospital care, a minority of hospital admissions are associated with clinical deterioration. Early attempts to define deterioration were retrospective and used chart review to focus on the end result of deterioration (adverse events) and iatrogenesis. We currently use systems that identify deterioration real time, and are associated with an expected institutional response. More sophisticated frameworks are required to prospectively and sequentially risk-stratify patients throughout hospital admission to inform education strategies and models of care for the prevention, identification, recognition and care escalation for clinical deterioration. We have provided a definition of a deteriorating patient that supports these ideas.

Conflict of interest statement

No conflicts of interest to declare.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.resuscitation.2013.01.013>.

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