Rui P. Moreno and Andrew Rhodes

Improving safety in intensive care – What does it mean?

"Primum non nocere"
Galen of Pergamum, Roman physician and philosopher of Greek origin (AD 129–200/217)

Introduction

A 1999 report from the Institute of Medicine (IOM) entitled "To Err is Human: Building a Safer Health System" raised the public profile of patient safety [1]. According to this report, the authors estimated that between 44,000 and 98,000 patients die every year in the United States of America as a result of clinical errors; these numbers make medical error the eighth leading cause of death in the USA, more frequent than those due to motor vehicle accidents (43,458), breast cancer (42,458) and AIDS (16,516). The costs involved in this issue are staggering, estimated to be in excess of US$ 20 billion (just for the USA).

For the purposes of the IOM Report, safety was defined as the absence of clinical error, either by commission (unintentionally doing the wrong thing) or omission (unintentionally not doing the right thing) [2] and error as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim; the accumulation of errors resulting in accidents [1]. Following this report, a series of authors started to use the terms safety and quality of care almost interchangeably, although the IOM defined healthcare quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" [3]. The IOM's definition is, in fact, very close to an old conceptual framework that was proposed by Avedis Donabedian, who reported that measurement of the quality of healthcare could only be made following careful observation of its structure, processes, and outcomes [4]. On top of this he also described seven pillars, or attributes, that also need to be analysed to assess the quality of care:

- Efficacy
- Effectiveness
- Efficiency
- Optimality
- Acceptability
- Legitimacy
- Equity

In other words, patient preferences are as important as social preferences and both must be taken into consideration when assessing the quality of healthcare [4].

Safety and the individual patient

As a consequence of this misperception between quality and safety of care, the awareness of the public, the media and the politicians shifted from the evaluation of the efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy, and equity of medical practices (so from the quality of care) to the identification, quantification and prevention of medical error (or the adverse clinical events arising from a presumed chain of causation are attributed to the last link in that chain, usually a doctor or nurse). This misperception has subsequently been extended to the choices and decisions (or errors) that patients make themselves [5]. Most of the error-reduction efforts in healthcare have therefore focused on the doctor/patient interface, which paradoxically is a minor cause of medical accidents and incidents [6], and neglected the fact that institutional and healthcare system approaches must complement bedside strategies to reduce unsafe acts. This helps to explain why correcting the performance of individual healthcare providers rarely leads to a general improvement in patients' safety throughout a healthcare system [6–7].

Many of these issues are well known to anyone practicing in intensive care and have been repeatedly reported in the medical literature [6–9]. Furthermore it has been shown that not only are these adverse events frequent, they can result in sometimes devastating or fatal consequences [10–11]. This area has therefore become a main focus of attention in recent years with the key issues of decision-making, situation awareness, teamwork, communication, stress management and the effects of workload patterns taking their rightful place in medical journals alongside the more traditional avenues of research and development. An increased understanding of these topics is now leading to significant advances being made. Many authors have reported techniques and therapies to prevent many of the avoidable adverse consequences of critical illness. These include, but are by no means limited to, the prevention of deep vein thrombosis, stress ulceration and hyperglycaemia [12]. Indeed many have advocated that bundles of these interventions should become the standard of practice that others should compare themselves against. In parallel with this has been a greater recognition of the value of registry-type data describing practice, interventions and adverse (or beneficial) consequences. This can be typified by the increased attention paid in recent years to nosocomial infections. Whereas in the past many of these infections, sometimes even fatal, were accepted as a normal consequence of being in hospital, the publication of large-scale multinational registry data has allowed us to understand the extent of the problem and to develop patient-centred interventions [11, 13–16] for preventing it. Nowadays units can provide their own data to a relevant registry and get feedback and benchmarking data that allows the users to quantify their own quality and performance in comparison to other units of similar demographic circumstances [17].

Mr A.R., a 65-old male resident of west London, with antecedents of chronic obstructive pulmonary disease, duodenal ulceration, and a history of colonic cancer treated with surgery and chemotherapy within the last 6 months. He developed malaise and fever two days ago and presented today to the emergency department of the local hospital. On observation, he had rales in his right pulmonary field, was slightly hypotensive (mean arterial pressure 60 mmHg), tachycardic (heart rate 126 beats/minute) and febrile (39° C). He had a mild hypoxaemia (PaO_2 62 mmHg under 50 % oxygen mask), acidosis (pH 7.23), a low $PaCO_2$ (26 mmHg), leukocytosis (WBC 18.00/mm^3) and thrombocytopenia (platelets 13,000/mm^3). The attending physician referred him to the local ICU (which was full), so he was admitted to the ICU of another hospital 8 hours later.

While awaiting transfer he was given some fluid (500 ml of HES) and started on amoxycillin plus clavulanic acid 4 hours after admission.

On admission to the ICU:

Scenario a)

On admission, the patient was in severe respiratory distress; before the clinicians were able to secure his airway he had a cardiac arrest; CPR manoeuvres where immediately performed, with apparent success, a central line was inserted into the right subclavian vein (sub-clavicular approach) but unfortunately the tube was not well positioned (endobronchial in the right main bronchus). Throughout this period

he had a very low oxygen saturation. The physician in charge suspected a pneumothorax – which was present – but no check of the position of tube was done for a further hour. At that time the patient was in deep coma, without measurable oxygen saturation and in shock (mean arterial pressure 35 mmHg). Despite all resuscitation manoeuvres, the patient died 11 hours later. The conclusion from the morbidity and mortality conference done one week later was that the patient died as a direct consequence of an inadequate management of the airway on admission to the ICU.

The family is not happy at all with the ICU team, and is considering whether to proceed with a lawsuit for inadequate care and gross negligence on ICU admission.

Scenario b)

On admission, the patient was in severe respiratory distress; he was immediately intubated, a central line inserted, fluid starts to achieve a CVP of 12 mmHg and then noradrenaline and dobutamine were added to correct the shock. Blood cultures were taken and antibiotic therapy changed to piperacilin/tazobactam due to the existence of immunosuppression and prior structural lung disease. According to an outcome prediction model developed to be used in patients in severe infection, sepsis and shock his probability of death before hospital discharge was 48 % [35].

During the ICU course pseudomonas aeruginosa was identified in the blood cultures and sputum from admission. The ICU course was complicated by an episode of shock due to bleeding from a duodenal ulcer two days after admission that required surgery (the patient was not on enteral nutrition at that time due to the high dose of vasopressor agents, and no prophylaxis for stress ulcer had been given). He required a tracheostomy for long-term ventilator support after a late-onset episode of ventilator-associated pneumonia (VAP) and was discharged seven weeks later to a long-term rehabilitation unit with severe residual morbidities. The family is very happy with the ICU team, who during the period have always tried to do their best.

When the morbidity and mortality conference was performed one week after discharge, several problems were identified, which may have had a significant impact on his prognosis:

- *The initial treatment of the patient in the emergency department was grossly inappropriate, with a wrong estimation of the severity of the situation. This led to an incomplete and inappropriate haemodynamic resuscitation, no attempts to make an early identification of the causal agent and inadequate empirical antimicrobial therapy. Also, there was a significant delay in transferring the patient to an ICU.*
- *The final diagnosis: "Community-acquired pneumonia due to pseudomonas aeruginosa" was correct, but several factors lead to a bad outcome, namely:*
  - *The patient had inadequate antimicrobial therapy for about 8 hours after the beginning of hypotension, which per se increases his chances of death from 30 % to 80 % [36]*
  - *The choice of the inappropriate initial antibiotic therapy probably resulted in an excess in-hospital mortality of 39.1 %. Also, the rate of the risk of nosocomial infection was increased by 16.1 %. Overall, these factors could have resulted in an excess in-hospital mortality was 31.4 % [37]*
  - *Despite being a high-risk patient, no prophylactic therapy was given to prevent stress ulceration, the development of which is associated with a relative risk of death up to 4 times greater and an excess length of ICU stay of approximately 4 to 8 days [38]*
  - *The increase in the length of stay due to the need of prolonged mechanical ventilation was possibly associated with the development of the late VAP, which in itself added an attributable mortality of 25 % [39]*

Are the two cases so different? For the individual patient described in the first case obviously yes. From the scientific point of view, according to the existing standards of practice in the emergency department and in the ICU, the potential prevalence of the mistakes described in the second case – as well as their impact on patient safety – is much more common.

When developing protocols and interventions that are designed with the aim of preventing adverse consequences for our patients, it is important to keep in mind the concept of "primum non

nocere": First, do no harm [18–19]. Although this is one of the fundamental aspects of medical practice – it remains a key component of the Hippocratic Oath sworn by the majority of medical professionals – it is often forgotten. Many interventions have a good and a bad side [20–21]. Mechanical ventilation can both correct respiratory failure and also cause ventilator-induced lung injury or barotrauma. Fluid resuscitation can resuscitate shock but can also cause pulmonary oedema, the so-called circutrauma. Many new therapies or interventions get rushed into practice, with the best of intentions, only to lead to a later awareness of negative effects for some groups of patients and then a reappraisal of the situation.

The dual face of safety in intensive care: From the individual patient to populations

Although the emphasis on individualising therapy for a patient is important, it is vital that we do not forget our duty and responsibility to strive for the best possible results for the whole population of patients that we treat. In order to improve the care of a population of patients we need to identify and make use of consistent, appropriate and effective diagnostic tests and therapeutic interventions, with the aim of reducing the numbers of adverse events. This can be achieved by following strictly the indications and contraindications of the drugs that we use and avoiding where possible their off-label use [22–23].

Modern mantra dictates that we should utilise an evidenced-based doctrine to direct our clinical practice. Although this is perhaps the gold standard approach, it is not always either practical or possible. Indeed in many situations that we are faced with in daily intensive care practice the evidence available to direct our thoughts is sadly lacking in both quantity and/or quality. There are often problems translating research into clinical practice due to alterations in case mix and other methodological issues in the original studies. The end result of this is that although an intervention may be proven to be beneficial in a randomised clinical trial, the effect may not be apparent, or even be sadly lacking, when utilising the same intervention in a wider patient group in normal everyday practice. The best way to summarise the available evidence, without bias, in a systematic and objective fashion remains controversial, although advances are being made [24]. Hopefully this will help close the gap between available knowledge and physicians' behaviors [22], and the understanding of the presence and size of this gap should lead to calls for both future funding and research into this area [23]. Unfortunately this whole area, due to its limitations, is prone to inappropriate influence and bias. This is especially true taking on board the recent controversies surrounding the conduct, analysis and reporting of several well-known products [25–28]. The current move to develop industry-independent corroborating trials [29–30] and also to clearly and transparently delineate the relationships between sponsor, investigator and expert opinion-maker is therefore to be encouraged and will hopefully improve this process [31].

For readers used to appraising research studies and papers it is often relatively easy to understand and quantify a likely beneficial effect on mortality from a given intervention. Indeed there are even many statistical terms that we are all familiar with that can be used to describe this effect. However, the reverse side to this is not so easy. Brennan described in his landmark New England Journal of Medicine paper the difficulties attached with quantifying mortality hazards due to inattention to safety. Without being able to grasp the size of this problem when trying to tackle the issue in our own units, other variables and indicators need to be followed. These include following the available evidence, making small-step changes in performance that can be measured, focusing our initiatives on the strengths of our staff, expecting to expend resources in an effort to improve healthcare quality, recognising the role of incident reporting on improving this quality and finally, recognising that to improve quality we need the input of many other disciplines than just our own [32].

Most of these aims can be achieved only through the development and implementation of cooperative benchmarking organisations, providing comparative feedback of the data and using meaningful endpoints [33]. We are glad that these organisations are becoming more common and foresee the need in the near future for coordination and cooperation amongst them in a common effort to increase the quality of in-

tensive care throughout the world. If we want to perform better than at the time of the IOM report, something that so far we have obviously not achieved [34], we must view safety and effectiveness as complimentary measures, that should be taken together, not be viewed in isolation as together their effect is far more powerful than each on its own.

Finally, we should not forget that our role as physicians includes the duty of assigning available resources for healthcare in both a sensitive and equitable fashion. This is obviously specific to each of our own cultural and geopolitical settings and is therefore very different around the world. It is important to recognise that what we do today may well impact on the future and an understanding of this may help us prevent our interventions having a detrimental impact for and on the next generation of patients.

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A. Safety in Intensive Care Medicine

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Current definitions of patient safety

Introduction

Patient safety is a major global public health concern. In developed countries, it is estimated that up to one in six patients can suffer harm while hospitalised and most of these situations are potentially preventable [1–3]. Each year in Europe, between 8 % and 12 % of patients admitted to hospitals experience care-related harm or injury [3]. In developing countries and countries in economic transition, the probability of patients being harmed in hospitals is much higher than in developed nations [4].

Patients admitted to intensive care units (ICUs) are particularly more vulnerable to suffer from adverse events as a result of severe illness itself and due to the high complexity of critical care and its multiple interventions, among other factors [5–9]. The occurrence of severe adverse events is associated with increased probability of death [8], and the vast majority of incidents occur during routine care [5]. A demand for safer care is the cornerstone of a worldwide discussion involving governmental agencies, medical societies, clinicians, patients and healthcare payers [10–13].

In this scenario, several patient safety initiatives emerged and significant continued efforts were made towards increasing patient safety. However, despite all this effort much work is still needed in the fundamentals of safety. A lack of clear and standardised definitions precludes scientifically sound measurement and evaluation of patient safety [14–15].

The need for standardised terminology and classification

Increasing concerns on patient safety have led to increased use of patient safety reporting systems. Standardised reporting systems makes possible to learn from adverse event and near miss data and to establish research priorities and compare initiatives. In the 2000 report *"To Err is Human: Building a Safer Health System"*, the Institute of Medicine (IOM) recommended that nationwide mandatory reporting systems should be established for the collection of standardised information by states on adverse events that result in death or serious harm [2]. Information and data on patient safety performance can be used to support strategies for making care safer for patients and with different purposes, from accountability to learning. A universally accepted classification of patient safety data is essential to better communicate and share knowledge on risks, hazards and patient safety events. To accomplish this goal

more time and funding for the "basic science" of patient safety are clearly needed [16].

Patient safety is still an emerging field of study and there is a wide variation in definitions, terminology and classification systems used to measure and report patient safety-related issues [17–22]. The lack of an internationally agreed set of patient safety concepts limits comparative analysis of studies in this field across countries. Actually, not only a clear terminology is necessary, but also definitions of measures that identify hazards should be available to improve our ability to evaluate patient safety. In the 2003 IOM report *"Patient Safety: Achieving a New Standard of Care"*, patient safety was defined as "the prevention of harm caused by errors of commission (that result from an action that is taken) and omission (that result from an action that is not taken)" [23]. An adverse event was defined as "an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient" [23]. "Near misses", another important concept, have been defined as "acts of commission or omission that could have harmed the patient but did not cause harm as a result of chance, prevention, or mitigation" [23]. The concept of "near misses" is extremely important as they occur much more frequently than adverse events or incidents. However, near misses have been defined in several ways and inappropriately referred to as synonymous with "potential adverse events" and "close calls", which may contribute to under-reporting.

The IOM also stated that the development of a standardised event taxonomy and common report format for submission of data related to patient safety (near misses and adverse events) is needed to allow clinicians and researchers "to aggregate the data to formulate research priorities, identify trends, and compare various approaches to patient safety" [23].

In 2004, the Dutch Institute for Healthcare Improvement (CBO) in association with several European governmental and non-governmental organisations started the Safety Improvement for Patients in Europe [SIMPATIE] project (http://www.simpatie.org) to establish a common European set of vocabulary, indicators, and reliable internal and external instruments for improving safety in healthcare. The SIMPATIE project was a two-year project starting in February 2005 funded by European Commission on Public Health. The different tasks were set out in various work packages (WP) [24], the fourth WP (WP4) being dedicated to the development of a vocabulary and an internal indicator set for patient safety [25].

Also in 2004, the World Alliance for Patient Safety (WAPS) was created by the World Health Organization (WHO) with the aim to improve patient safety through a global initiative. WHO-WAPS (http://www.who.int/patientsafety/en) is endorsed by several governmental agencies and accrediting organisations and has established a series of priorities including the development of an internationally acceptable taxonomy for patient safety [26].

These two proposed systems to standardise key concepts, definitions and preferred terms used in patient safety issues are summarised in the following sections.

The SIMPATIE project – A European vocabulary of patient safety

In the methodology used in WP4 to develop a European vocabulary of patient safety for the SIMPATIE project, an expert group performed a comprehensive review of existing literature [25]. A list of identified terms was discussed in telephone conferences and during a one-day meeting. A total of 24 patient safety terms were defined in a cross-cultural perspective and divided into four categories: detection of risk, analysis of risk, resulting actions and failure mode [25].

According to the SIMPATIE Project, *patient safety* is defined as "the continuous identification, analysis and management of patient-related risks and incidents in order to make patient care safer and minimise harm to patients". An *adverse event* is "an unintended and undesired occurrence in the healthcare process because of the performance or lack of it of a healthcare provider and/or the healthcare system". *Near misses* are considered "adverse events, with the capacity to cause harm but which do not have adverse consequences, because of, for instance, timely and appropriate identification and correction of potential consequences for the patient". The complete list of terms and definitions used in the "European Vocabulary on Patient Safety" is given in Table 1 [25].

Tab. 1 Definitions of the 24 terms of The SIMPATIE Project – European Vocabulary on Patient Safety.*
[reproduced from Kristensen S, Mainz J, Bartels P. Patient Safety – A Vocabulary for European Application. Aarhus, Denmark: SIMPATIE European Society for Quality in Healthcare – Office for Quality Indicators, 2007. Available at: http://www.simpatie.org]
* Terms in italics are also defined in Table 1.

Category: Detection of Risk	
1.	**Patient Safety**: The continuous identification, analysis and management of patient-related *risks* and *incidents* in order to make patient care safer and minimise *harm* to patients. Safety emerges from interaction of the components of the system. Improving safety depends on learning how safety emerges form such interactions.
2.	**Adverse Event**: An unintended and undesired occurrence in the healthcare process because of the performance or lack of it of a healthcare provider and/or the healthcare system.
3.	**Actual Event**: An *adverse event*, which causes *harm*.
4.	**Near Miss** (sub-event): An *adverse event*, with the capacity to cause *harm* but which does not have *adverse consequences*, because of for instance timely and appropriate identification and correction of potential consequences for the patient.
5.	**Complication**: An unintended and undesired outcome which develops as a consequence of intervention of an already present illness. It may be non preventable under the given circumstances. Please note the related definition of term number 12, "Adverse Outcome".
6.	**Sentinel Even**t: Sentinel reflects the seriousness of the injury and the likelihood that investigation of an event will reveal serious problems in current policies or procedures. Such occurrences signal the need for immediate investigation and response.
7.	**Critical Incident**: Occurrences, which are significant or pivotal, in either a desirable or an undesirable way. Significant or pivotal means that there was significant potential for *harm* (or actual harm), but also that the event has the potential to reveal important hazards in the organisation. In other words, these incidents, whether *near misses* or *events* in which significant *harm* occurred, provide valuable opportunities to learn about individual and organisational factors that can be remedied to prevent similar incidents in the future.
8.	**Complaint**: Each expression of resentment or discontent with the practice, operation or conduct of a healthcare provider made by a potential user or a user of the healthcare services or someone acting on their behalf.
9.	**Reporting System**: A system which is designed to contain reports on *adverse events*. On the basis of reports analysis and communication of known causes and risk situations is possible. The system can contain reports on human and technical errors as well as organisational circumstances, which affects the occurrence of *adverse events* in the healthcare process. Reporting systems include input from all stakeholders – providers and service users.
10.	**Professional Standard**: The standard of performance in particular circumstances taking into account recent insights and evidence-based norms and a standard of practice to be expected of a comparable experienced and qualified prudent practitioner in equal circumstances. Please note the related definition of term number 24, "Negligence".
Category: Analysis of Risk	
11.	**Harm**: Negative consequence experienced by a patient leading to: death, a permanent or temporary impairment of physical, mental or social function or a more intense or prolonged treatment.
12.	**Adverse Outcome**: An unintended and undesired occurrence in the healthcare process which causes *harm* to the patient. Please note related definition of term number 5, "Complication"
13.	**Risk**: The probability or chance that something undesirable will happen. A measure of the probability and severity of potential *harm*.
14.	**Calculated Risk**: A deliberately and consciously taken risk in which the benefits of a treatment are deemed to offset/ countervail the possible burden of serious *harm*.
15.	**Barrier**: Protects people and structures from *adverse events*.
16.	**Situational Awareness**: Refers to the degree to which one's perception of a situation matches reality.