

# Clarifying misconception of quality and safety in healthcare

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Anna V. Chatzi

*Department of Nursing and Midwifery, Faculty of Education and Health Sciences,  
University of Limerick, Limerick, Ireland, and*

Kyriakos I. Kourousis

*Faculty of Science and Engineering, School of Engineering, University of Limerick,  
Limerick, Ireland and*

*School of Engineering, RMIT University, Melbourne, Australia*

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## Abstract

**Purpose** – Healthcare has undergone multiple phases in gaining understanding, accepting and implementing quality and safety, with the last 3 decades being crucial and decisive in making progress. During that time, safety has always been quoted along with quality, but the cost of error in healthcare (both in human lives and monetary cost) has been continuing to rise.

**Design/methodology/approach** – This article discusses the authors' expert perspective in comparison to the industry's research and practice outputs.

**Findings** – Healthcare has not yet defined quality and safety. This is allowing the misconception that already established quality management systems (QMSs) are fit for safety purposes as well. Even though aviation has acted as a paradigm for healthcare, further alignment in embedding safety management systems (SMS) has yet to be realised.

**Originality/value** – In this paper, the distinct nature of safety and its detachment of quality is being discussed, along with the need for clear and safety specific processes. Setting common language is the first step in establishing appropriate safety processes within SMSs, operating in tandem with QMSs, to promote patient safety successfully.

**Keywords** Quality, Safety, Definitions, Misconception, System, Healthcare

**Paper type** Conceptual paper

## The need to manage quality and safety in healthcare

### Background

High-profile patient harm cases with raised numbers of harmed patients have been making newspaper headlines around the world, while certain medical fields with high exposure, such as anaesthetics, obstetrics and paediatrics, have been putting pressure for action (Back *et al.*, 2024; Waring *et al.*, 2016). Cumulative pressure has led healthcare to intensify activity in the field of patient safety, as healthcare education, regulation and practice have been updated to incorporate aspects of quality and safety.

### Defining the objectives of quality and safety

Quality and safety, even though they complement each other, are also quite different. Quality focuses on reassuring that products and services are becoming more consistent, effective and efficient for clients and/or users. On the other hand, safety is about improving the processes and/or conditions that are in place, to reduce errors and the likelihood of the

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occurrence of adverse events while these products and/or services are produced and/or used (Ladewski and Al-Bayati, 2019). Therefore, quality is all about having better and more efficient services (e.g. low and/or no waiting lists, low and/or no infections, etc.), and safety is having ultimately no adverse events in the meantime (e.g. patient and/or staff injuries, patient deaths, misdiagnoses, etc.) (Ladewski and Al-Bayati, 2019). Nevertheless, in the healthcare sector, quality typically encompasses safety, effectiveness, patient-centeredness, timeliness, equity and efficiency. For example, the World Health Organisation (WHO), based on the previous work of the US Institute of Medicine, defines 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 (World Health Organization, 2024).

#### *Linking patient safety with quality*

Healthcare has gone through multiple phases on gaining understanding, accepting and implementing quality and (patient) safety, with the last 3 decades being crucial and decisive in making progress (Waring *et al.*, 2016). Especially in the late years, quality and safety (in the form of patient safety) have been the centre of research and regulatory activity for healthcare globally, with the WHO leading the way (World Health Organisation, 2011). In 2015, within the European Union (EU), the member states were invited to fully implement EU patient safety recommendations as the totality of member states were (and some still are) not compliant (Pilarska *et al.*, 2020). These recommendations included the provision to establish authorities to regulate and overlook patient safety. The COVID-19 pandemic happened when the global patient safety activity had yet to unfold, a coincidence which posed additional challenges and delays on the process (Grant *et al.*, 2023).

Early healthcare publications integrate quality and safety (Runciman *et al.*, 2006) by presenting safety as one of quality's dimensions. The rationale behind this treatment of safety was that safety should not be dealt on its own, as safety is a prerequisite for good quality outputs (Das *et al.*, 2008). Combining resources utilised for safety management with resources utilised for quality management might prove more cost- and time-effective (Runciman *et al.*, 2006). Since then, safety has always been quoted along with quality, but the cost of error in healthcare (both in human lives and monetary cost) has been continuing to rise (Back *et al.*, 2024; Elliott *et al.*, 2021; Waring *et al.*, 2016), while hospitals still face difficulties in implementing efficiently patient safety and quality control and assurance (McFadden *et al.*, 2015).

This article discusses the common misconceptions existing within healthcare around the link between quality and safety. Other important aspects associated with safety management, such as human factors and safety investigations, are also presented.

### **The paradigm of aviation**

#### *Managing safety and quality in aviation*

Aviation has been the most influential industry when it comes to safety management practices. Safety, as a standalone term, appeared in aviation nearly sixty years ago, along with the term quality management system (QMS), which has been the predecessor of occupational health and safety management systems (SMS) (Stolzer *et al.*, 2015). Through the years, multidisciplinary work has led to the evolvement and standardisation of these initial systems (QMS and SMS) to their current form, as being closely related but both with distinct entities and separate structures and scopes (Stolzer *et al.*, 2015). Quality and safety are governed by a very well-defined regulatory system in an integrated and holistic manner. This system assures airworthiness, namely the capacity of an aircraft to be fit and safe to fly, which is the ultimate goal of the industry.

Quality and safety management in aviation has become an intertwined systematic approach for all technical and non-technical activities, namely across services governing the design, certification, production, maintenance, personnel training and operation of aircraft. Risks in aviation are evaluated, managed, eliminated or mitigated under this (airworthiness) regulatory framework. Risk management also involves the recognition, identification, evaluation and effective management of errors associated with human factors and ergonomics (HFE). Additionally, independent accident and/or incident (safety) investigations, a well-established activity in the aviation industry, continue to have a key role in safety management.

#### *Safety management system (SMS) in aviation*

SMS is a dedicated vehicle for industries to identify, mitigate, observe and eliminate risk (Otitolaiye and Abd Aziz, 2024). As SMS have been standard practice for many high-intensity and complex industries, the adoption of a standardised system can only augment workplace safety (Viswanathan *et al.*, 2024). In aviation, a complex socio-technical system, the positive experience gained from the implementation of SMS for flight operations has driven its wider adoption practically across all activities. Compliance with SMS structure is regulated by law; however, the size and service complexity of each organisation dictate the details of the SMS implementation (Chatzi, 2020). The minimum of the SMS elements that correspond to the legally required four SMS components (Chatzi, 2020) are illustrated in Figure 1.

#### **Healthcare as a follower of aviation**

In the attempt to manage safety, healthcare has been historically following the aviation example (Back *et al.*, 2024; Carayon *et al.*, 2014; Flin, 2007; Leonard *et al.*, 2004; Pronovost *et al.*, 2011). Nevertheless, healthcare has not fully adopted established practices from aviation, as there is the misconception that having a quality system in place is enough to cover safety as well. A common problem is that the metrics of safety record and safety performance are used without distinction or there is an overreliance on the former when it

| Safety Policy and Objectives                                                                                                                                                                                                                                 | Safety Risk Management                                                                                   | Safety Assurance                                                                                                                                                               | Safety Promotion                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• Management commitment and responsibility</li><li>• Safety accountabilities</li><li>• Appointment of key safety personnel</li><li>• Coordination of emergency response planning</li><li>• SMS documentation</li></ul> | <ul style="list-style-type: none"><li>• Hazard identification</li><li>• Safety risk assessment</li></ul> | <ul style="list-style-type: none"><li>• Safety performance monitoring and measurement</li><li>• The management of change</li><li>• Continuous improvement of the SMS</li></ul> | <ul style="list-style-type: none"><li>• Training and education</li><li>• Safety communication</li></ul> |

Source(s): Authors' own work

**Figure 1.**  
The elements of a  
safety management  
system (SMS)

comes to evaluating the effectiveness of healthcare services. Both safety record and safety performance can be measured, with the latter being a key element in SMS (under safety assurance – see [Figure 1](#)). An acceptable safety record (i.e. achieving less than X fatalities occurring from misdiagnosed cervical checks) cannot reveal underlying issues affecting safety performance (i.e. number of near misses, admin staff clerical errors, organisational gaps, risky behaviours, etc.). A problematic safety performance will eventually lead to fatalities, namely to a poor safety record. It is, therefore, necessary to monitor safety performance if one wishes to achieve and maintain an acceptable safety record in the long run.

Nearly all healthcare publications contain and use interchangeably the two terms “quality” and “safety” when the topic of the publication is, in essence, either on quality or safety. Analyses and publications on factors, principles and processes and/or models strengthening quality and safety in healthcare have been multiplied in the late years ([Back et al., 2024](#); [Carayon et al., 2014](#); [McFadden et al., 2015](#); [Runciman et al., 2006](#); [Waring et al., 2016](#)); however, the distinction between quality and safety is still not clear ([Back et al., 2024](#); [McFadden et al., 2015](#)).

Interestingly, even in aviation, there is a debate around the confusion of the QMS and SMS, as service users find it difficult to accept that a product and/or service that meets quality standards may still appear to be unsafe in the context of airworthiness ([Federal Aviation Administration, 2021](#)). It appears that there is a similar misconception within healthcare services that having a quality system in place, without having to have any specific safety-related provisions and/or processes in place, serves safety adequately as well ([Back et al., 2024](#); [Waring et al., 2016](#)). For example, we have been witnessing the emergence of integrated patient safety and quality directorates, units, etc. within healthcare providers and regulatory bodies. It is the lack of understanding about the importance of independence between the quality and the safety assurance functions that typically leads to this integrated approach. Healthcare lacks the rigour of aviation’s regulatory structure and practice, as the equivalent of an “airworthiness” regulatory system does not exist in healthcare. In turn, the regulators in healthcare are not sufficiently independent from the regulated parties, which creates a series of competing interests (i.e. common senior management for healthcare services and quality and safety directorates and/or units, safety investigations being performed by staff from the investigated organisation, etc.).

## Discussion

### *SMS as a quality enabler*

By having a quality system in place, healthcare organisations can meet the requirements of working and progressing with the advancement of their processes. Safety is indeed part of these processes, as quality systems are primarily focused on creating a safe environment for patients and employees. The promotion of safety is evident here through the relevant policies, aims, strategies, processes, etc. However, for safety to be thoroughly implemented, an SMS is required. When looking at safety through the prism of a structure like SMS, it is understood that isolated actions, through the prism of a quality system, are not fit for purpose in the case of safety ([Back et al., 2024](#)).

Relevant research in the area has supported that quality and safety initiatives can co-exist and produce positive outcomes. This statement comes with the condition that quality initiatives are used for quality purposes and safety initiatives are used for the safety ones; none of them can be used for the purposes of the other, as they are of different nature with different objectives and processes ([McFadden et al., 2015](#)). Leadership is the key element in organising and implementing QMS and SMS ([McFadden et al., 2015](#)). As the misconceptions of quality and safety terms among the healthcare sector have been recognised, leadership’s

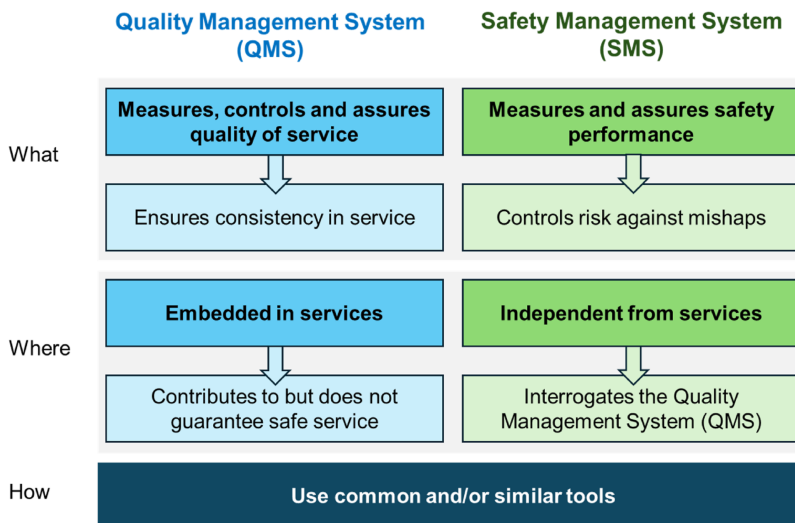
role in establishing common language and setting a safety system within this frame is of importance when it comes to improving healthcare practice.

Despite SMS being widely adopted by various safety-critical industries, in healthcare, SMSs are still non-existent (Niv and Tal, 2024). For SMS to be applied within a healthcare organisation, there are certain structures that need to be in place for safety actions to be completed successfully, such as safety auditing, data collection and analysis, restorative actions and management review. The lack of clarity for personnel's safety roles and responsibilities, the identification and management of risk, elimination or mitigation and communication of risk and safety assessment are some aspects that sole quality systems fail to address completely (Back *et al.*, 2024). For this reason, quality systems need to have these required structures in place to support fully functional and efficient SMS.

The differentiators and common aspects of QMS and SMS are illustrated in Figure 2. With a focus on output, QMS is embedded in healthcare services, aiming to ensure consistency (quality) in the delivery of the services. Nevertheless, quality itself cannot guarantee safety. Patient safety can be achieved by linking QMS with SMS. SMS not only measures and assures safety performance by controlling and mitigating risks but also interrogates the QMS independently. When it comes to implementation, both QMS and SMS share common and/or similar tools (i.e. quantitative analysis methodologies, trend analysis techniques, etc.).

#### *Human factors and ergonomics (HFE)*

HFE principles are applicable to the healthcare system as a whole, with patient safety and quality of care being included (Carayon *et al.*, 2014). In this publication, quality and safety are treated as separate entities, and even though HFE principles are applicable to both, each one of them includes different processes and is addressed individually (Carayon *et al.*, 2014). For HFE principles to be effective, the consideration of the unique elements of healthcare is important. These unique features include the human aspect, tasks, the specialised equipment and technologies, the physical environment and the organisational structure, which find



Source(s): Authors' own work

**Figure 2.**  
Differentiators and common aspects of quality management system (QMS) and safety management system (SMS)

themselves at the centre of the HFE principles (Carayon *et al.*, 2014). In regard to the human aspect of the system, healthcare is compiled of many different specialities, with different training and cultures working together.

Another unique feature is that even though the nursing subgroup compiles the majority of the total workforce in healthcare, it is the medical group's culture that dominates among all (Chatzi and Malliarou, 2023; Waring *et al.*, 2016). This is a very important element in understanding the unique features of healthcare, as traditionally quality and safety have been considered primarily to be the physician and/or the care giver's duty (Waring *et al.*, 2016). In the course of quality and safety advancements in healthcare, the parallel legal aspect of the issue, particularly in the USA with rising numbers of malpractice suits against healthcare providers, was also affecting its course (Waring *et al.*, 2016). Among the rising number of litigations, rising costs coming from adverse healthcare events, political scandals and pressure in the Western world, quality and safety shifted to be considered a systematic problem (Waring *et al.*, 2016).

### *Safety investigations*

Only recently, the United Kingdom, through their recently established independent Health Services Safety Investigations Body (HSSIB), is starting to consider the use of SMSs in healthcare (Back *et al.*, 2024). SMSs are designed to incorporate four components that work together in promoting safety: safety policy and objectives, safety risk management, safety assurance and safety promotion (Back *et al.*, 2024; Chatzi, 2020). HSSIB's combined experience under their previous form and structure, spans over seven years. This experience has led them to the realisation that:

- (1) Safety needs clear and dedicated structure, as existing quality structure does not efficiently serve safety, and
- (2) Healthcare has not yet provided and/or adopted clear common definitions on safety management-related activities (Back *et al.*, 2024).

The HSSIB findings are very important within the healthcare sector as their experience and output has inspired other EU countries, such as Norway, to establish the Norwegian Healthcare Investigation Board (Ukom) with relevant legislative reform.

### **Conclusion**

Legally required SMSs have been a reality for aviation for many decades now. Air travel has been synonymous to safe travel for millions of travellers around the globe with flights, destinations and complexity constantly augmenting. Aviation, a socio-technical system, acts as a paradigm due to the nature of the operations and the complexity of the roles, structures and regulatory constructs. Unfortunately, one cannot say that healthcare takes a similar stance on people, as high-profile mishaps still make newspaper headlines and the toll of human life remains high. The discussion of both quality and safety in healthcare began about 20 years ago. This was a good start, but it is time now to distinguish the two and develop two separate systems (QMS and SMS) for patient safety yet to pick up.

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**Corresponding author**

Anna V. Chatzi can be contacted at: [anna.chatzi@ul.ie](mailto:anna.chatzi@ul.ie)

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