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Clinical Pharmaceutical Safety and Healthcare Systems Management- An Updated Review Article For Pharmacists, Health Securities, and Medical Maintenance Specialists

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Abstract

Background: Healthcare is a safety-critical industry where preventable harm remains a major public health concern. Learning from high-risk sectors like aviation and nuclear power, safety management systems (SMS) offer a proactive, systematic framework for managing safety through organizational structures, risk management, and continuous improvement.

Aim: This review was commissioned to inform the development of the NHS England's patient safety policy. It aims to synthesis evidence on SMS in healthcare to address three key questions: the attributes of a successful NHS SMS, the links between an SMS and quality management, and the next steps for safety management in the NHS.

Methods: The study conducted a comparative review of national patient safety approaches, analyzing systems in the Netherlands, Australia, Canada, Ireland, and New Zealand, with a focus on the integration of SMS principles.

Results: The Netherlands was the only country with a mandatory, certified SMS for hospitals, which was associated with a reduction in preventable adverse events. Other countries embedded core SMS components—such as leadership, risk management, and safety assurance—within national standards and accreditation frameworks but did not mandate a formal SMS. Evidence from the Dutch programme showed improvements, though outcomes were influenced by contextual factors like implementation support and concurrent initiatives.

Conclusion: Core SMS principles are transferable to healthcare and can contribute to improved safety outcomes. However, successful implementation requires significant contextual adaptation, strong leadership, and robust supporting infrastructure, rather than simply adopting a generic model.

Keywords: Patient Safety, Safety Management Systems, Healthcare Quality, Risk Management, NHS England, Comparative Health Systems..

Introduction

Health care is widely recognized as a ‘safety-critical industry’, comparable to sectors such as aviation, offshore oil, and nuclear power, where even a single failure or error can have profound consequences for individuals, organizations, and society at large [1]. In such environments, adverse events may lead not only to loss of life or serious injury but also to long-term environmental damage and substantial harm to infrastructure and resources [1]. Within the healthcare domain, safety is therefore conceived as a central dimension of practice and policy, commonly defined as the avoidance, prevention and amelioration of adverse outcomes or injuries arising from the delivery of care, rather than from the underlying disease or condition itself [2]. This perspective emphasizes that harm is often a consequence of complex processes and systems rather than isolated individual mistakes. Patient safety incidents in health care encompass a range of events including, but not limited to, medication errors, wrong-site surgery, failures in equipment maintenance, and delayed recognition or response to clinical deterioration [1]. The landmark Institute of

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Medicine report "To Err is Human" served as a pivotal moment in drawing global attention to the magnitude and systemic nature of medical error, illustrating that such harm is frequently rooted in organizational processes rather than personal negligence [3]. Subsequent research continues to demonstrate that, despite substantial investment in safety initiatives, preventable harm persists as a major public health concern. For example, estimates from 2020 suggested that hundreds of millions of medication-related and other clinical errors occur annually, contributing to avoidable morbidity and mortality in high-income health systems [4].

Within contemporary health policy discourse, safety is typically conceptualized as an integral component of healthcare quality, rather than as a separate or isolated goal [1]. The World Health Organization characterizes high-quality care as effective, safe, people-centred, timely, equitable, integrated and efficient, underscoring that safety must be pursued in conjunction with these other dimensions to achieve optimal outcomes [5]. In parallel with other high-risk industries, health care has increasingly shifted from a narrow focus on counting and reacting to discrete incidents toward a more proactive approach that identifies, monitors and manages the underlying conditions that generate hazards [6]. This evolution is closely linked to systems thinking, which views safety as emerging from the dynamic interactions between social, organizational and technological elements, where small misalignments can propagate into major events [6,7]. Some determinants of safety, such as physical infrastructure or formal organizational structures, may change only slowly, whereas more fluid mediating factors—including staff morale, interprofessional teamwork and individual performance—can often be modified more rapidly, offering important leverage points for sustainable improvement in patient safety [6].

Defining safety management systems

Within safety-critical industries, the systems approach to safety has been formalized through the development and implementation of safety management systems (SMS), defined as 'a systematic approach to managing safety, including the necessary organizational structures, accountabilities, responsibilities, policies and procedures' [8]. This definition highlights that safety is not an adjunct activity but a core organizational function that must be embedded in governance structures, operational processes and everyday practice. Rather than relying on reactive responses to adverse events, an SMS emphasizes proactive and preventive strategies, creating a structured framework through which hazards are identified, risks are assessed and mitigated, and performance is continually monitored and improved [1,8]. A systematic review conducted in 2012 examining SMS in aviation, marine and rail industries found that the implementation of such systems was associated with tangible improvements in safety performance, including reductions in accident rates and near-miss events [9]. Although there is debate about the adequacy of accident rates as indicators of SMS effectiveness—given that such events are relatively rare and may not fully capture underlying system resilience—these findings nonetheless suggest that SMS can contribute meaningfully to safer operations in domains where risk is inherent and consequences are severe [10]. Beyond outcome measures, SMS provide a conceptual and practical scaffold for integrating diverse safety activities—such as training, incident reporting, equipment maintenance, and emergency preparedness—into a coherent, organization-wide strategy [1]. They clarify lines of accountability, ensuring that responsibilities for safety are explicitly allocated from senior leadership to frontline staff, and that communication channels support upward reporting of hazards and concerns [8]. Furthermore, SMS typically incorporate mechanisms for data collection and analysis, enabling organizations to learn from incidents, near misses and routine operations, and to adapt policies and procedures accordingly [9,10]. By encouraging a performance-based approach that focuses on monitoring and achieving defined safety objectives, rather than merely complying with prescriptive regulations, SMS foster continuous improvement and support the development of a positive safety culture [1]. These characteristics make SMS highly transferable and relevant to other high-risk sectors, including health care, where complex socio-technical interactions demand structured, system-level approaches to safety management [1,8].

History of safety management systems

The evolution of safety management systems did not occur through a single, planned reform but rather emerged gradually as safety became recognized as a strategic management responsibility rather than solely a regulatory obligation [10]. In many high-risk industries, safety was historically governed through external regulation, with compliance focused on adherence to technical standards and inspection regimes. This paradigm began to shift in the 1970s, following a series of catastrophic accidents that exposed the limitations of purely prescriptive regulatory approaches and underscored the need for organizations themselves to assume explicit responsibility for managing risk [9,10]. Major events that catalyzed this reorientation included the 1976 Seveso disaster in Italy's chemical industry, which resulted in widespread dioxin contamination; the Three Mile Island nuclear accident in 1979; the Chernobyl disaster in 1986; and the Piper Alpha offshore oil and gas platform explosion in 1988 [10]. Investigations into these disasters consistently revealed systemic failures—such as inadequate risk assessment, poor communication, weak organizational oversight and

deficient safety culture—rather than isolated technical faults or individual errors [9,10]. In response, regulatory frameworks in several jurisdictions began to mandate the adoption of SMS, particularly in industries where low-probability, high-consequence events posed unacceptable societal risks [9]. Although the detailed structure and documentation requirements of SMS vary across sectors and countries, the underlying theory is consistent: safety should be achieved and continuously improved through a structured, cyclical process that defines responsibilities, identifies hazards, analyses data, assesses and manages risks, and reviews performance [1,8]. This approach aligns closely with broader quality and risk management philosophies, emphasizing learning, feedback, and iterative refinement of systems over time. By shifting emphasis from compliance with static rules to a performance-based orientation—where organizations are required to demonstrate that they understand their risks and are effectively controlling them—SMS frameworks encourage innovation and contextual adaptation [1]. Crucially, the historical development of SMS also reflects a growing appreciation of socio-technical complexity. As investigations into major accidents highlighted how interactions between human, organizational and technological factors could combine in unexpected ways, the systems perspective gained prominence as a necessary lens for understanding and managing safety [10]. SMS thus embody these systems thinking by integrating technical safeguards with organizational processes, leadership commitment and workforce engagement [1,8]. Over time, this model has influenced not only traditional high-hazard sectors but has also informed emerging discussions about how to structure safety management in complex fields such as health care, where similar patterns of distributed responsibility, technological dependence and potential for catastrophic harm are increasingly recognized [1].

Examples of safety management systems in the aviation, oil and gas, and nuclear industries

Aviation

In aviation, safety management systems are embedded within what is often described as a ‘total systems approach’, in which the aviation sector as a whole is conceptualized as an overarching system and each individual organization, with its own SMS, forms a subsystem within this broader network [8]. This framing underscores the interdependence of airlines, aerodromes, air navigation service providers, regulators and maintenance organizations, and highlights that safety is produced collectively rather than by any single actor. At the international level, the International Civil Aviation Organization (ICAO) has developed safety management guidelines and offers a widely used definition of SMS that emphasizes structured processes, clear lines of accountability and continuous improvement [8]. States that are contracting members of ICAO are obligated to establish and maintain a national State safety programme, which specifies detailed requirements for safety management tailored to different categories of aviation organizations, such as aerodromes, air operators and air traffic service providers; for example, the UK Civil Aviation Authority’s National Aviation Safety Plan 2022–4 sets out national priorities and performance targets for safety [11]. Within this overarching framework, each organization is required to design and operate its own SMS, with a primary focus on process safety and the integrity of operational activities. Although effective process safety should contribute indirectly to the personal safety of employees, occupational health and safety are generally treated as distinct domains, often governed by separate legislation and management systems.

The way SMS boundaries are conceived in aviation further illustrates the breadth of responsibility attached to safety management. When aviation organizations procure services from external providers that are not themselves subject to SMS requirements—for instance, ground handling, catering or certain maintenance functions—the potential hazards introduced by such arrangements are considered to remain within the risk remit of the contracting organization, and must therefore be addressed and controlled through its own SMS [8]. Internally, aviation SMS are expected to give explicit attention to the interfaces between functional units, such as operations, engineering, finance and commercial departments, because misalignments at these boundaries can generate latent conditions for failure [8]. This expectation has led to an emphasis on integrating the SMS with other organizational systems, including quality management and environmental management, so that policies, procedures and feedback mechanisms are coherent rather than fragmented [8]. Australian civil aviation safety guidance explicitly notes that, while there are overlaps with quality management and related approaches, a SMS goes beyond these frameworks by foregrounding how people, and particularly their decisions, behaviours and interactions, contribute to both the creation and control of risk [12]. Consequently, aviation SMS place considerable weight on safety culture, training, reporting systems and human factors, seeking to ensure that technical and procedural controls are complemented by organizational and behavioural safeguards [8,12].

Nuclear power

In the nuclear power industry, safety management systems have developed under the influence of both international guidance and robust national regulatory regimes. At the international level, bodies such as the International Nuclear Safety Advisory Group provide high-level advice on nuclear safety issues of global relevance and articulate shared

concepts, including the core features of a SMS [13]. These universal features are described as 'those arrangements made by the organization for the management of safety in order to promote a strong safety culture and achieve good safety performance' (p. 2), emphasizing that the SMS is not merely a set of documents or procedures but an integrated management framework that shapes attitudes, priorities and behaviours across all levels of the organization [13]. Nonetheless, nuclear safety is fundamentally regarded as a national responsibility, with individual states bearing ultimate accountability for the safe operation of their nuclear facilities [14]. In the UK, for example, the Office for Nuclear Regulation (ONR) serves as the independent nuclear regulator, setting expectations and assessing duty holders' performance. Unlike in aviation, where explicit SMS implementation guidance is often centralized, the ONR does not publish a single, prescriptive SMS standard; instead, expectations relating to safety management are embedded across multiple guidance and assessment documents, allowing for sector- and site-specific interpretation and application [14].

As in aviation, nuclear SMS are primarily directed toward 'operational safety', focusing on the safety of processes, plant operations and the control of radiological and other industrial hazards [13]. However, the way external boundaries are conceptualized differs slightly. While it is recognized that effective safety management requires coordination with external entities such as contractors, suppliers and emergency responders, these organizations are not necessarily required to be formally encompassed within the licensee's SMS [13]. Rather, the nuclear operator is expected to ensure that interfaces are well managed—through robust contract management, specification of safety requirements, and oversight of contractor performance—so that risks associated with outsourced or supplied activities remain controlled. Internally, nuclear SMS guidance stresses that safety cannot be managed as a separate or parallel activity, detached from the rest of the business. Instead, safety management should be embedded within broader management processes and is often implemented as part of, or closely aligned with, the organization's quality management systems [13]. The specific organizational form of the SMS, including reporting lines, committee structures and documentation, will depend on context, such as the size, complexity, lifecycle stage and culture of the organization [13,14]. Across these variations, however, the underlying principle remains that nuclear safety must be systematically planned, resourced and reviewed, with leadership commitment and a strong safety culture recognized as critical determinants of effective performance [13,14].

Oil and gas

In the oil and gas sector, safety management has often been framed through the concept of an operating management system (OMS), which functions as a comprehensive framework to help companies identify, assess and control safety risks within the broader context of business performance and stakeholder expectations [15]. Rather than treating safety as a standalone objective, the OMS explicitly situates risk management alongside the pursuit of operational efficiency, reliability and value creation, reflecting the commercial realities of this capital-intensive, high-hazard industry [15]. The term 'operating' is interpreted broadly, extending to all upstream and downstream activities—such as exploration, production, refining, transportation and retail—and spanning the entire lifecycle of assets and products from design and construction through operation, modification and ultimately decommissioning [15]. This lifecycle perspective highlights that critical decisions with major safety implications are often made at early project stages, and that the OMS must therefore provide a structured approach to risk management throughout planning, execution and closure phases.

With respect to external boundaries, an OMS normally applies wherever the company retains direct management control over activities or facilities [16]. When work is undertaken by contractors or joint venture partners, where direct control is attenuated, the emphasis shifts towards ensuring clarity of roles and responsibilities, establishing minimum safety expectations, and verifying that appropriate risk controls are in place at the relevant organizational level [16]. However, as in the nuclear industry, risks associated with activities not directly managed by the company are not always considered to fall fully under the remit of the company's own SMS or OMS, even though failures in these areas can significantly affect overall safety performance [16]. Internally, the OMS framework typically encompasses a wide array of operational domains, including process safety, personal safety, environmental protection, security, and aspects of social responsibility and quality management [15]. It sets out principles, expectations and processes for topics such as risk assessment, management of change, competence and training, incident reporting and learning, emergency preparedness, and asset integrity. Financial control, accounting systems and commercial risk management are generally excluded from the formal scope of the OMS, reflecting a distinction between operational and financial governance [15]. Nonetheless, in practice, organizations may choose to integrate financial and commercial considerations more closely with the OMS, recognizing that budgetary decisions, contracting strategies and investment choices can have significant safety implications [15]. By providing an overarching structure within which these diverse elements can be aligned, the OMS supports consistent implementation of safety policies

across geographically dispersed and technically complex operations, and encourages continuous improvement through systematic monitoring, audit and review [15,16].

Overview of safety management systems structure and relationship between components
A safety management system (SMS) is commonly conceptualized as an integrated, organizational-wide framework that brings together four interdependent components: leadership commitment and safety policy, safety risk management, safety assurance, and safety promotion, including the cultivation of a positive safety culture [1,8]. These components do not operate in isolation; rather, they form a dynamic and mutually reinforcing structure through which safety is planned, enacted, monitored and continuously improved. Leadership commitment and safety policy serve as the foundation of the entire SMS, providing strategic direction, articulating organizational responsibilities and establishing the values that guide decision-making. Without explicit leadership support, the SMS lacks the authority and resources necessary to function effectively, as policies and procedures must be embedded within governance structures, operational priorities and managerial expectations [8]. Building on this foundation, safety risk management provides the operational architecture for identifying hazards, assessing associated risks and determining appropriate controls. This component is crucial for translating high-level commitments into meaningful action by ensuring that risks are systematically assessed and managed throughout the organization's activities [1]. Safety assurance, in turn, creates a feedback loop, allowing the organization to evaluate whether risk controls are effective, whether emerging hazards are being detected and whether safety performance is improving over time. This involves monitoring, auditing and analysis of safety data, enabling continuous refinement of policies and practices. Safety assurance thus functions as the evaluative backbone that links organizational intent with real-world performance [1].

The fourth component, safety promotion and culture, ensures that the principles of the SMS permeate everyday practice. It focuses on training, communication, and the development of attitudes and behaviours aligned with safety, emphasizing that safe operations depend not only on systems and procedures but also on the engagement, competence and shared values of the workforce [8]. A strong safety culture supports open reporting, collaborative problem-solving and learning from events, thereby enhancing both risk management and safety assurance. Although industries differ in how they categorize or prioritize subcomponents—reflecting sector-specific hazards, regulatory requirements and organizational structures—there are clear commonalities across aviation, nuclear power and oil and gas. Each relies on a coherent SMS that integrates strategic leadership, structured risk management, performance monitoring and cultural reinforcement. These elements operate as an interconnected system in which leadership establishes expectations, risk management operationalizes them, safety assurance verifies their effectiveness and safety promotion ensures sustained engagement and organizational learning.

Why it is important to do this review

This review of research and other evidence was commissioned by the National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research (HSDR) programme on behalf of the NHS Patient Safety Team and the Department of Health and Social Care. Its primary purpose is to inform the ongoing development and refinement of NHS England's patient safety policy and practice, as articulated in the NHS Patient Safety Strategy 2019 and associated policy documents [17]. The Strategy sets out an ambitious programme of work designed to reduce avoidable harm, strengthen safety culture and embed more systematic approaches to learning from incidents. However, as with any complex, system-wide initiative, sustained progress depends on drawing together the best available evidence, understanding how different components interact in practice and identifying where gaps remain. A focused review of safety management systems (SMS) is therefore an essential step in ensuring that the NHS Patient Safety Strategy continues to evolve on a sound conceptual and empirical footing [1,7,10,17].

The project brief identified three overarching policy questions that this review seeks to address: first, what are the key attributes of a successful SMS for the NHS in England (Q1); second, what are the links between a SMS and a quality management system (Q2); and third, what should be the next steps for safety management in the NHS in England (Q3). These questions are not purely academic; they go to the heart of how safety is organized, governed and operationalized within a large, complex national health system. Evidence is beginning to emerge that can start to answer these questions, particularly following the implementation of the NHS Patient Safety Strategy 2019 [17]. For example, work led by the National Patient Safety Team is estimated to be saving around 160 lives per year, suggesting that coordinated national interventions can have measurable impact on outcomes [18]. Similarly, evaluation of the Patient Safety Incident Response Framework (PSIRF) early adopter programme indicates that the new approach has contributed to improvements in safety culture, more effective learning from incidents and the identification of more robust risk-reduction strategies in participating organizations [18]. At the same time, the evaluation has surfaced important implementation

challenges, such as the lack of sufficiently detailed and practical guidance on how to undertake systems-based Patient Safety Incident Investigations, underscoring the need for further conceptual clarity and operational support [18,20].

A recent report by the Health Services Safety Investigation Body (HSSIB) has sought to address some of these issues by drawing on evidence from high-risk industries, including aviation, oil and gas, and nuclear power, to describe high-level attributes of SMS and to propose recommendations for further development of a SMS approach in the NHS [1]. This cross-sectoral view is valuable in illustrating that a number of core SMS principles—such as clear leadership accountability, systematic hazard identification, risk assessment, performance monitoring and continuous improvement—appear to be transferable across domains [7,10]. However, the HSSIB report, by design, provides a broad conceptual overview rather than a detailed, health-system-specific implementation blueprint [1]. Experience from other industries indicates that, while overarching principles may travel well, the detailed design of accountability frameworks, governance arrangements and organizational processes must be tailored to contextual features if they are to function effectively [19]. In health care, this implies the need to understand how SMS concepts can be adapted to the specific structures, cultures and regulatory arrangements of the NHS in England, and how they can be aligned with existing efforts to identify and manage recognized patient safety risks [20].

Moreover, the implementation of SMS in other high-risk sectors has typically involved the interaction of international standards, national regulatory frameworks and organizational-level systems. For example, in aviation and nuclear power, international bodies articulate broad safety principles and expectations, national regulators translate these into enforceable requirements, and individual organizations develop local SMS that comply with and operationalize these standards [1,8,13,14]. The NHS, by contrast, is itself a national health system, with NHS England and related bodies playing both strategic and, in some cases, commissioning roles. This raises distinctive questions about how a national organization can best influence, support or coordinate the implementation of a SMS approach across a heterogeneous set of provider organizations, each with their own governance arrangements, cultures and resource constraints. Understanding the levers available at system level, and the potential interactions between national policy, regional structures and organizational practice, is therefore crucial. The present review deliberately focuses on this system-level perspective, rather than on the internal operation of individual organization-level SMS, to reflect the strategic concerns of NHS England and the Department of Health and Social Care [1,17].

There is also increasing international interest in applying SMS principles to health care, with some countries taking explicit steps to embed such approaches at national level. National patient safety strategies or frameworks exist in many health systems and can be understood as partial expressions of SMS concepts [7]. Notably, the Netherlands has been developing and promoting an explicit SMS approach in health care, offering a concrete example of how national policies, regulatory expectations and organizational practices can be aligned around a structured, system-wide view of safety [21]. Examining such experiences provides an opportunity for cross-national learning, allowing NHS England to consider how similar or adapted approaches might be used to strengthen coherence and effectiveness in the English context. At the same time, differences in organizational structures, funding mechanisms, regulatory regimes and historical trajectories mean that policy transfer cannot be assumed to be straightforward; insights from other systems must be interpreted and tested against the specific realities of the NHS [19,21]. Against this backdrop, the review aims to provide a focused synthesis of evidence on SMS in health care, with particular emphasis on how they have been conceptualized, implemented and evaluated in different countries. By comparing experiences across systems, the review seeks to clarify which elements of SMS appear to be essential, which are more context-dependent, and how different configurations interact with existing quality management systems and regulatory structures [1,7,10,19]. The findings are intended to offer critical contextual information to inform future primary research addressing the three policy questions outlined above and to support deliberation about whether, and if so how, NHS England's current patient safety policies, processes and practices could be further developed into a comprehensive SMS. In doing so, the review contributes to a more evidence-informed dialogue about the future direction of safety management in the NHS in England, helping to ensure that any move towards a fuller SMS approach is grounded in both international experience and a realistic appreciation of the opportunities and constraints inherent in the current system [17–21].

Findings

The review found that the Netherlands was the only country to have implemented a national Patient Safety Programme (PSP) that explicitly required healthcare organizations to adopt a certified safety management system (SMS) as a strategic, system-wide approach. Elements of an SMS, such as leadership commitment, risk management, incident reporting and safety culture, were visible in the patient safety policies of Australia, Canada, Ireland and New Zealand, but none of these countries mandated an organization-level SMS in the way the Netherlands did. To reflect this difference, the review focuses first on the Dutch experience, then

summarizes the patient safety approaches in the other four countries and finally compares their main features [22-30].

The Netherlands

In the Netherlands, the PSP "Prevent harm, work safely" was introduced into a context where quality and safety had already been the subject of sustained national and local interventions. Bal and Wagner describe the PSP as one in a series of programmes that had collectively prepared the ground for large-scale change in Dutch hospitals [31]. The Better Faster programme (2004–8) was particularly important. It established national quality and safety indicators under the Dutch Healthcare Inspectorate, stimulated debate via inquiries and reports informed by high-risk industries, and created a quality collaborative involving 24 hospitals that tested a broad range of professional and organizational interventions [31, 32]. By the mid-2000s, Dutch patient safety policy had been heavily influenced by methods originating in high-risk industries, including incident reporting and analysis, risk management tools, surgical checklists and safety culture assessments [33,46,51,81]. Senior leaders from these industries contributed directly to PSP design. A key turning point was advice from former Shell president Rein Willems, whose report on risk management in hospitals recommended the implementation of a certified SMS in all Dutch hospitals [33]. This recommendation became a core requirement of the PSP, launched in 2008 and running until 2012, which aimed to reduce potentially preventable adverse events and deaths in hospitals by 50% over five years [21,34]. The PSP covered all general hospitals (but not other care sectors) and rested on two main pillars: mandatory implementation of an SMS, and implementation of clinical guidelines for ten high-priority patient safety themes, such as medication reconciliation, high-risk parenteral medications, early recognition of deteriorating patients, prevention of line sepsis, surgical site infection, and safety for vulnerable elderly people [21]. The programme assumed that meaningful outcome improvement would only follow changes in organizational structures and processes: without a functioning SMS and changes in day-to-day clinical work, reductions in avoidable harm were unlikely [21].

The basic SMS requirements were specified in a technical agreement, NTA 8009 (2007), which defined SMS as part of a hospital's overall management system used to achieve patient safety policy by systematically identifying and controlling risks [29]. Implementation followed a staged "growth model". Phase 1 specified core elements such as leadership and management, staff roles, patient participation, prospective and retrospective risk assessment, and improvement processes, and suggested methods drawn from high-risk industries, including Bow-Tie analysis and Dutch root cause analysis (SIRE) [29]. Phase 2 added further requirements on communication, third-party management and control measures [29,33]. The latest version, NEN 8009 (2018/19), reframed SMS using a Safety-II and resilience engineering perspective, redefining it as a proactive, systematic approach that learns not only from incidents but also from everyday successful practice [30,82]. This "positive" perspective sought to complement, not replace, the existing SMS framework, but provided less operational detail on how to implement the new ideas in practice [30]. Across both versions, explicit lines of responsibility are central. The Board of Directors (BoD) is given ultimate responsibility for embedding patient safety within multi-year strategy, setting SMART safety objectives, agreeing patient safety policy with key stakeholders, ensuring resources, promoting safety culture and sharing learning with other organizations [30]. The latest iteration places additional emphasis on "bottom-up" improvement, encouraging frontline staff to identify opportunities and propose changes, with safety culture viewed as both a leadership responsibility and an expected outcome of SMS implementation [29,30]. Implementation was supported by extensive infrastructure. The PSP produced structured guides describing recommended structures, processes and indicators for each of the ten themes, created expert groups, organized national theme conferences, and provided tools and patient-facing materials via a dedicated website [21]. The programme was initially adult-focused but later extended paediatric versions of six themes. Quality and safety were embedded in medical education, while regional training and learning networks helped hospitals share experience and maintain momentum [31,32].

Impact and evaluation evidence from the Netherlands

The Dutch PSP and SMS were evaluated through several complementary studies. The core outcome evaluation was the national longitudinal Healthcare-related Harm Monitor (Monitor Zorggerelateerde Schade), using retrospective patient record review. Baseline data from 2004 informed the decision to launch a national PSP, while subsequent measurements in 2008 and 2011–12 assessed overall impact [35,38,39]. Initial analyses suggested a 53% decline in potentially avoidable hospital deaths, from 5.5% of all in-hospital deaths in 2008 to 2.6% in 2011–12, equivalent to a reduction from about 1960 to 970 deaths per year across all Dutch hospitals [38,39]. Potentially preventable adverse events among admitted patients fell from 2.9% to 1.6%, a 45% reduction [39]. Re-analysis by Baines et al. applied multilevel modelling to adjust for clustering and changes in patient mix across the three measurement points (2004, 2008, 2011–12). After these corrections, the estimated prevalence of

preventable adverse events was 1.9% in 2004, 2.0% in 2008 and 1.4% in 2011–12, a 30% decrease between 2008 and 2011–12 that no longer reached statistical significance [33]. Subgroup analyses suggested improvements particularly in older patients and in surgical care, consistent with PSP themes and with parallel initiatives such as greater regulatory focus on operative processes and widespread adoption of surgical checklists [21,33]. The authors concluded that it was plausible that the PSP had contributed to the observed reductions but emphasized the limitations of observational record-review studies, including low event rates, methodological changes over time and unmeasured confounding [33]. Later Monitor cycles (2015–16 and 2019) restricted analyses to deceased patients. These showed reduction in overall adverse events between 2011–12 and 2015–16 but no further decline in preventable harm or mortality, and a subsequent rise in overall healthcare-related events by 2019, likely influenced by changes in patient demographics (older, more multimorbid) and care processes (greater technological intensity, workforce pressures, more networked care) [40,49].

A large evaluation of the ten PSP themes, conducted in 2011–12, found that a "broad movement" in patient safety had been initiated but no theme had been fully implemented across all hospitals [21]. Implementation levels and progress varied widely by theme and by hospital. Some themes, such as early recognition and treatment of acutely ill patients and prevention of contrast-induced renal failure, showed strong uptake and sustained performance, with almost universal pre-contrast renal function checks [21]. Others, such as medication reconciliation, improved but fell short of ambitious targets, and some, such as patient identification and time-out procedures, showed inconsistent gains [21]. Hospitals frequently reported that the number of themes was overwhelming, leading them to prioritize some and neglect others; hospitals performing well on one theme often lagged on another. Qualitative interviews highlighted staff- and organization-related factors influencing success: perceived urgency of the topic, the enthusiasm and competence of local leaders and teams, resource availability, management involvement, clear implementation plans and supportive information systems [21]. Topic characteristics, such as complexity, alignment with existing projects and strength of evidence, also mattered. Working in networks and informal initiatives (for example, local campaigns and symbolic activities) were valued as facilitators. Subsequent evaluations focused on selected themes where implementation lagged. A 2015–16 study found further progress but continued variability. Targets such as 100% compliance with medication processes were not achieved and were questioned as realistic or even desirable, given the need for clinical judgement [37]. Prevention of surgical site infection and line sepsis showed notable improvements, particularly in intensive care, but non-ICU areas remained problematic [37]. A third series of evaluations (2020–21) used Safety-I and Safety-II perspectives and the Functional Resonance Analysis Method (FRAM) to compare "work-as-imagined" in guidelines with "work-as-done" in practice for selected processes such as discharge medication reconciliation and second checks for high-risk medicines [41,45,50,102]. These studies, implemented during the COVID-19 pandemic, did not find measurable compliance improvements but generated rich insights into local adaptations and system constraints and produced recommendations for further improvement.

Safety culture was treated as an expected outcome of the PSP rather than a direct intervention target. Surveys using the Hospital Survey on Patient Safety Culture (HSOPS) showed statistically significant improvements across almost all dimensions between 2005–07 and 2012, particularly in overall perceptions of safety and incident reporting, though staffing concerns persisted [47,51]. A 2020 survey suggested modest further gains in teamwork, non-punitive response to error and learning from mistakes, but stable or worsening scores for interdepartmental collaboration, communication and staffing; limited participation precluded strong statistical conclusions [44]. Although comprehensive, the Dutch PSP and SMS focused on hospital care. The review found no equivalent, national, SMS-type programme in primary care, despite evidence that patient safety is a significant concern in these settings. Possible spill-over benefits from hospital safety improvements into primary care, for example through better cross-boundary communication or shared themes such as vulnerable elderly, were not documented.

Overview of the patient safety approach in the other countries

Australia, Canada, Ireland and New Zealand have all developed national or federal structures for patient safety and quality, but none require healthcare organizations to implement a certified SMS. Instead, they employ standards, frameworks, incident systems, accreditation and governance mechanisms that collectively embody many SMS elements. In Australia, the Australian Commission for Safety and Quality in Health Care leads a national approach underpinned by the National Safety and Quality Health Service (NSQHS) Standards, first issued in 2012 and updated in 2017 and 2021 [53,56]. These standards, enforced through external accreditation, require healthcare organizations to implement systems for clinical governance, partnering with consumers, infection prevention, medication safety, comprehensive care, communication for safety, blood management and recognizing and responding to deterioration [53]. Supporting frameworks, including a national clinical governance model and condition-

specific clinical care standards, provide more detailed guidance [52,56]. Organizations must maintain incident management and open disclosure systems, monitor specified indicators and report performance, with some measures linked to funding [53,56]. Concepts drawn from high-risk industries (such as checklists and human factors) have influenced specific interventions, but an explicit SMS framework is not used [56]. Evaluations of the first NSQHS edition reported improvements in several safety domains, including healthcare-associated infection, antimicrobial stewardship, documentation of adverse drug reactions, blood management and recognition and response to deterioration, while highlighting ongoing challenges in open disclosure, incident investigation, consent, complaints handling, safety culture and role clarity [55,56].

In Canada, responsibilities are divided between federal, provincial and territorial levels, creating variation in patient safety arrangements. The Canadian Quality and Patient Safety (CQPS) Framework, launched in 2020, aims to align legislation, regulation, standards and organizational policies around five goals: people-centred, safe, accessible, appropriate and integrated care [59]. It emphasizes incident reporting and learning, adherence to regulatory and professional standards, accreditation (usually via Accreditation Canada), and audit and feedback processes [58,59]. A discussion guide developed by Healthcare Excellence Canada reflects a shift towards a broader, system-oriented view of safety, influenced by the Measurement and Monitoring of Safety Framework (MMSF) [61,63]. It stresses co-production with patients and families, recognition of diverse forms of harm (including psychological and inequitable care), learning from routine success as well as failure, and the need for action at multiple levels [61]. Canada draws on lessons from high-risk industries but has not adopted a formal SMS approach. Evaluation evidence is mainly from specific initiatives, including a large learning collaborative using the MMSF, which found the framework useful but challenging to implement at scale without extensive support and systems thinking [62,63].

Ireland's patient safety architecture centres on the Health Information and Quality Authority (HIQA), an independent statutory body created to promote safety and quality across health and social care [64,71]. National Standards for Safer Better Healthcare, issued in 2012 and subsequently replaced by a more principles-based approach, provide expectations for service providers [64,65]. The Health Service Executive (HSE) has a national patient safety strategy setting commitments on patient and staff engagement, risk anticipation, harm reduction, data use, and leadership and governance, with specific actions such as workforce planning, promotion of safe culture and implementation of national clinical guidelines [67]. Providers are required to report incidents into a national system, undertake internal and external audits, and maintain formal risk-management processes that integrate with strategic and operational planning [68–70]. The Patient Safety (Notifiable Incidents) Bill mandates open disclosure for serious incidents [71]. Irish policy increasingly incorporates systems thinking, human factors and simulation-based training, influenced by high-risk industries [67,92,93]. HIQA's monitoring reports show improvements in infection prevention and control, antimicrobial stewardship and medication safety, driven partly by stronger governance and leadership, but also identify barriers such as resource constraints and infrastructure deficits [71].

New Zealand has recently undergone major structural reform, replacing district health boards with a single entity, Health New Zealand (Te Whatu Ora), under the Pae Ora (Healthy Futures) Act 2022 [72]. The Te Tāhū Hauora Health Quality & Safety Commission, established in 2010, leads work on quality and safety indicators, public reporting, improvement support and consumer engagement [72,76]. The 2017 Clinical Governance framework treated quality improvement and patient safety as a single theme and required organizations to prioritize safety, manage clinical risks, operate incident systems, nurture just culture and involve patients and whānau [76]. A draft 2024 framework, "Collaborating for Quality", builds on this but is explicitly tailored to New Zealand's cultural context, particularly the needs and rights of Māori and other underserved groups [77]. It introduces domains focused on consumers and whānau as partners, a culturally safe workforce, effective services, and system safety and learning. Cultural safety is emphasized as requiring healthcare professionals and organizations to examine the impact of their own cultures on care interactions [73,77]. New Zealand's national adverse events policy, first introduced in 2012 and updated as "Healing, Learning, and Improving from Harm" in 2023, frames responses to harm around three themes: healing, learning and improving [79,80]. It embeds Māori worldviews, restorative practice and whānau-centred engagement, aiming to balance system safety with human experience. The policy has moved from root cause analysis towards a "learning review" method originally developed for US Forest Service firefighting incidents, grounded in human factors, system safety and resilience thinking and designed for adaptive complex systems such as health care. New Zealand uses a set of quality and safety markers, an atlas of healthcare variation, and summary indicators to monitor performance, with threshold targets (often 90%) for process measures such as falls risk assessment or infection prevention. The current transformation of the system means that

comprehensive evaluation evidence is not yet available.

Comparison

Across the five countries, only the Netherlands has a formal, mandatory SMS framework with defined components and certification requirements for hospitals [30]. Nonetheless, all four core SMS components described earlier—leadership and policy, risk management, safety assurance and safety culture/promotion—are recognizable, to varying degrees, in the patient safety arrangements of Australia, Canada, Ireland and New Zealand. Leadership commitment and national or federal patient safety policy are present everywhere. All systems employ some form of retrospective incident reporting and analysis with feedback and learning mechanisms, and all specify prospective risk-management expectations through standards, guidelines or clinical programmes. Monitoring of safety performance using indicators is common at national level, though local-level use is less consistently described. All emphasize the importance of safety culture and the involvement of patients and families, though approaches differ in scope and depth. There are, however, important variations. The Netherlands' PSP and SMS were hospital-focused, whereas the other four countries generally frame patient safety across all healthcare sectors, even if implementation is uneven or evolving. Governance arrangements differ, from the Netherlands' national hospital focus to Australia and Canada's federated structures with strong provincial or state roles, to Ireland's and New Zealand's national systems, the latter currently in transition. Approaches to incident investigation diverge root cause analysis and systems analysis in Australia and Ireland, learning reviews in New Zealand, and a mix of traditional and newer methods in the Netherlands. The level of attention to inequalities also varies, with Australia, Canada and New Zealand more explicitly targeting social and ethnic inequities, while the Netherlands' PSP emphasized older people but gave less guidance on broader equity dimensions.

High-risk industries and contemporary safety science have influenced all five systems, but in different ways and to different depths. The Netherlands stands out for having directly imported a certified SMS concept, co-designed with senior leaders from industries such as oil and gas, and embedding specific tools like Bow-Tie analysis and formal root cause methodologies into national SMS requirements [29,33]. Other countries have taken a more selective route, adopting discrete tools (for example, checklists, early warning scores, human-factors training) and broader concepts like system safety, resilience and restorative practice, without formalizing a comprehensive SMS framework. Because only one country has implemented a full SMS, and because evaluation designs and contexts differ, it is not possible to make robust cross-national claims about the comparative effectiveness of "SMS vs non-SMS" approaches. Nonetheless, national evaluations in the Netherlands, Australia and Ireland show improvements in specific aspects of patient safety, especially in areas such as infection prevention and control, medication safety and management of deterioration [21,33,55]. Common enablers include strong governance and leadership, clear policy frameworks, meaningful measurement, and mechanisms for learning and improvement. Together, the findings suggest that while the SMS concept is transferable in principle, its effective realization in health care requires careful contextual adaptation of structures, accountability arrangements and implementation strategies.

Conclusion:

This review concludes that while the concept of a safety management system (SMS) is transferable from high-risk industries to healthcare, its effective implementation is highly context-dependent. The Dutch experience demonstrates that a mandatory, certified SMS can form the backbone of a national patient safety strategy and is plausibly associated with reductions in preventable harm. However, its success was contingent on extensive supporting infrastructure, phased implementation, and alignment with specific clinical safety themes. Other nations have achieved progress by integrating core SMS components—leadership, risk management, safety assurance, and culture—into broader quality and governance frameworks without a formal SMS mandate. The key insight is that the structural form of the SMS may be less critical than the underlying principles it embodies proactive risk identification, clear accountability, continuous learning, and strong safety leadership. For the NHS in England, this suggests that the next steps should focus on further embedding these principles into existing governance and quality management systems, rather than pursuing a standalone, prescriptive SMS model. Success will depend on tailoring the approach to the unique, complex structure of the NHS, ensuring practical support for frontline organizations, and fostering a culture that learns from both successes and failures.

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