



## Extended Research Article

# The implementation of Safety Management Systems in healthcare: a systematic review and international comparison

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Published March 2025  
DOI: 10.3310/QPLF8546

## Scientific summary

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Health and Social Care Delivery Research 2025; Vol. 13: No. 7  
DOI: 10.3310/QPLF8546

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# Scientific summary

## Background

In health care, failures or errors could have serious consequences for patients, staff or the environment. Safety incidents in health care include medication errors, wrong site surgery and lack of a timely response to deterioration in a patient's condition. Despite efforts to improve patient safety, harm still occurs to patients each year. For example, in 2020, it was estimated that 237 million medical errors occur annually in England, contributing to more than 1700 deaths.

Safety in a healthcare setting is the prevention or avoidance of harm and is normally considered to be a component of the provision of quality health care. Quality health care is defined by the World Health Organization as health care or services which are effective, safe, people-centred, timely, equitable, integrated and efficient. The aim of quality health care is to achieve the desired health outcomes.

Other industries where safety is a priority, such as aviation, have improved safety by taking a systems approach operationalised in the form of a safety management system (SMS). A SMS is an organised approach to managing safety and is generally considered to have four key components:

1. leadership commitment and safety policy – an expressed leadership commitment to safety with documentation of responsibilities and processes for safety within an organisation
2. safety risk management – the identification of hazards and risk, and assessment of how to mitigate these
3. safety assurance – monitoring and measuring safety within the organisation and ensuring continuous improvement
4. safety promotion and culture – training, education and communication of safety to staff at all levels.

Safety management systems take a performance-based approach, with the underlying theory being that by focusing on monitoring and achieving desired outcomes rather than being based solely on compliance with policies or standards, they facilitate improvement. A systematic review published in 2012 of SMS in three safety-critical industries – aviation, marine and rail – concluded that the approach led to improvements in safety (e.g. reduced accident rates).

While the basic principles of a SMS are transferrable, the details need to be context-specific to be effective. Evidence on the use of SMS in health care is therefore needed to support their effective implementation.

## Objectives

The purpose of the review was to inform UK NHS patient safety policy and practice, by drawing on the experience of other countries where a SMS approach, or some of its principles, have been implemented in the context of health care, focusing on how this can be influenced or co-ordinated nationally. The review aimed to answer the following question:

In selected countries, to what extent and in what ways is patient safety policy and strategy based on a SMS approach and what is the evidence supporting implementation and impact?

Within this broad research question, we aimed to answer three specific questions:

- How are the components of SMS reflected in the healthcare policy documents of selected countries (see below), or their regional healthcare systems?
- What research or other relevant evidence is available regarding the effectiveness, implementation or experience of SMS within health care?
- What does existing research and other relevant evidence from the included countries tell us about the effectiveness, implementation or experience of SMS within health care?

## Methods

We conducted a systematic review of evidence from English-speaking countries, or countries where most of the key policy documents and research papers are available in English. We included only high-income countries that have publicly funded healthcare systems with universal coverage, as the evidence from such countries is most relevant to the UK context. The following countries were included: Australia, Canada, Ireland, New Zealand and the Netherlands. The UK was not included as the review aimed to inform NHS policy and practice by drawing on the experience of other countries.

We searched the websites of, and contacted, national patient safety organisations from these countries to identify key policy documents and evidence that might not be captured through database searches. Online meetings with experts from the respective countries were held to understand the context within each country and identify further sources of evidence. We also searched MEDLINE (in December 2023) and EMBASE (via Ovid), Cumulative Index to Nursing and Allied Health Literature (EBSCO) and Web of Science (WoS): Core collection (in February 2024). Two reviewers independently screened all identified records at title/abstract level and the full texts of the records selected in the first round. We included policy documents, research and other relevant evidence relating to the effectiveness, implementation or experience of the SMS or safety approach in the respective healthcare system.

Data were extracted from each included publication by one reviewer and checked by a second reviewer. No formal, standardised quality appraisal was carried out, but we examined and reported the risk of bias in studies evaluating impact.

We reviewed policy documents and research papers from high-risk industries (focusing on aviation, oil and gas and nuclear energy) and developed an analytical framework to guide data extraction and narrative synthesis. We adopted a case-study approach whereby the patient safety approach in each country was described and analysed separately. Draft descriptions of the patient safety approach taken in each country were shared with experts from the respective countries for comment. We then carried out a cross-national comparison of the SMS or safety approach in health care as the final step of the analysis.

## Results

Fifty-three publications were included, from Australia (5), Canada (7), Ireland (8), New Zealand (9) and the Netherlands (24). Twenty-five of those were research or evaluations; the rest were policy (26) or other (2) types of documents.

Of the five included countries, the Netherlands was the only country which had introduced a National Patient Safety Programme (2008–12) explicitly based on a high-risk industry SMS approach. The programme was based on two pillars: all Dutch hospitals were required to have a certified SMS and to implement patient safety recommendations focusing on 10 high-priority themes (e.g. medication safety). The scope of the SMS was gradually extended to make the system more comprehensive. Specific objectives were set for each theme; an overarching target of reducing hospital-based, potentially preventable adverse events and mortality by 50% by 2013 was also agreed.

Multiple studies evaluated the implementation and impact of the programme. Of note, a longitudinal review of patient records called Healthcare-related Harm Monitor (Monitor Zorggerelateerde Schade in Dutch) was conducted every 4 years to capture the impact on potentially preventable adverse events and mortality at a national level. The scope of the Monitor was gradually expanded to include specific topics of interest (e.g. technology-related adverse events, medication safety, vulnerable older people and the quality of patient records). Another longitudinal study measured the impact of the programme on safety culture. An in-depth evaluation of the implementation of the themes was carried out in the last year of the programme (2011–2). Additional evaluations were conducted after 2012 focusing on specific themes, some of which were carried out from both a Safety-I and Safety-II perspective and included interventional elements.

Analysis of data from 2011 to 2012 showed a 45% decrease in the proportion of patients experiencing potentially preventable adverse events (out of all hospital admissions): from 2.9% [95% confidence interval (CI) 2.3% to 3.7%] in 2008 to 1.6% (95% CI 1.1% to 2.2%) in 2011–2 ( $p < 0.001$ ). Potentially avoidable hospital deaths (out of all hospital

deaths) decreased by 53% from 5.5% (95% CI 4.5% to 6.6%) in 2008 to 2.6% (95% CI 2.0% to 3.4%) in 2011–2. Expressed in absolute numbers and extrapolated to all Dutch hospitals, this was a decrease from approximately 1960 deaths (95% CI 1600 to 2360) in 2008 to 970 deaths (95% CI 738 to 1274) in 2011–2. The programme was considered successful in achieving its overarching target of reducing preventable adverse events and mortality in the Dutch hospitals by 50%. However, further analysis correcting for clustering of data and changes in the patient mix between measurements resulted in a more moderate 30% decrease in preventable adverse events, from 2.0% (95% CI 1.5% to 2.8%) in 2008 to 1.4% (95% CI 0.9% to 2.0%) in 2011–2, which was no longer statistically significant ( $p = 0.10$ ). Insufficient sample size was considered a potential explanation for the lack of statistical significance. Further Monitor analyses of 2015–6 and 2019 data showed no further decrease in preventable adverse events and mortality when compared to the uncorrected results from 2011 to 2012.

Considerable variation in the success of implementation was observed across themes and between hospitals and departments. While progress was made with most of the themes, the targets were met for only a small number of subthemes (e.g. treatment of severe sepsis). Focused evaluations of the lagging themes conducted after 2012 showed further progress but for most of the themes, the objectives remained unmet, and some recommendations required updating. Improvement was also found in safety culture, although the rating of some domains (e.g. 'Adequate staffing') decreased.

A number of staff-related, organisational and topic-specific factors were found to affect the success of the programme, with broader socio-historical processes also playing a role (e.g. other quality and safety improvement initiatives). Staff-related factors included the perceived need for the implementation of the clinical topic and factors that concerned the implementation team and its leader, such as enthusiasm and management skills. Organisational factors related to the availability of people and resources, management involvement, a clear approach to implementation (e.g. an action plan), and the availability of recording systems to monitor progress. Topic-related factors concerned the perceived complexity of a theme and its connection with existing projects or guidelines.

None of the other four countries included in the review explicitly used a SMS approach but the main components of a SMS were identified, to varying extents, in their patient safety policies and initiatives. Although there were differences in implementation, similarities were seen in their patient safety approaches relating to:

- leadership commitment
- national patient safety policy (separately or as part of a wider quality improvement policy)
- retrospective incident reporting and analysis with a linked feedback and learning system to ensure continuous improvement
- prospective risk management
- monitoring of patient safety performance
- focus on developing a safety culture
- patients' and families' involvement in policy development and safety at the local level.

There was variation between the countries, particularly relating to the scope of the patient safety approach. In most cases, patient safety was considered alongside quality improvement, although in the Netherlands it was separate. Implementation of policies varied from national to regional, and their application to all or specific healthcare settings (e.g. hospital care only). A consideration of health inequalities was evident in all countries to some extent, through the targeting of at-risk groups, though this was most clear in Australia, Canada and New Zealand. Additionally, a range of concepts from high-risk industries and safety science more broadly (e.g. Safety-II, human factors) had influenced the patient safety approach of different countries.

As the Netherlands was the only country which explicitly used a SMS approach, and the SMS elements were seen and adopted differently across the other four countries, it is difficult to compare the effectiveness of adopting 'a SMS approach' between countries. Australia and Ireland conducted national evaluations of their patient safety approach; both found improvements for certain aspects of patient safety. Some of these were in areas (e.g. medication safety) in which the Netherlands also saw improvement. Similarly, there were factors which these countries identified as facilitating patient safety, such as strong governance.

Although we followed best practice for conducting a systematic review, some limitations should be acknowledged:

- The review is focused on patient safety in selected high-income, English-speaking countries with healthcare systems broadly comparable to that in the UK.
- We did not conduct formal study quality appraisal, but the risk of bias in studies evaluating impact was examined.
- We tried to mitigate the risk of partial understanding (due to the review being based mostly on policy documents) by talking to experts from each country.

The following areas of patient safety policy could benefit from further research. Patient safety policies are growing increasingly complex and multidimensional. Realist evaluation methods – primary research and systematic reviews – could be used to understand the causal mechanisms by which patient safety initiatives and their components are expected to work, the evidence supporting such assumptions, and the contextual factors that affect their performance. This could be linked to research on methods used to evaluate the impact of such programmes. Monitoring and evaluation are an integral part of a systems approach to safety improvement, and there are a number of methods and indicators which could be, and are being, used to assess the impact of patient safety approaches in different countries. However, valid, reliable and theory-based methods for evaluating the impacts of such systemic, incremental and multilevel changes in health care and policy require further development. Additionally, evaluations of the impact of different patient safety approaches should be expanded beyond hospital care, where they have currently been focused, to other settings, especially primary and community care. Research in these areas will allow better understanding of how and to what extent SMS approaches, or other concepts from high-risk industries and safety science, work in specific circumstances, and allow better comparison within and between countries.

## Conclusions

Only the Dutch patient safety programme was explicitly based on a SMS approach. Multiple studies evaluated its implementation and impact over a period of more than 10 years after its launch. There is enough evidence to support the claim that the programme, directly and indirectly (e.g. by initiating a large movement for improving patient safety), has contributed to the improvement of some aspects of patient safety in the Dutch hospitals. The importance of implementing a certified SMS in all Dutch hospitals, relative to work on the specific themes, is difficult to judge from the reviewed evidence except indirectly (e.g. through improvements in safety culture). Progress was made with the implementation of the theme-specific recommendations, including after the end of the programme, and improvement in some outcomes was observed; at the same time, considerable challenges were encountered leading to variability in implementation and outcomes and failure to meet the initial targets for most of the themes. Furthermore, some of the guidelines and objectives needed updating to reflect new evidence and understanding.

Process safety as conceptualised in high-risk industries had some influence on the patient safety approach in the other countries, but this was less systematic and explicit. Approaches to patient safety in all countries also draw on a range of concepts from the broader safety science, reflecting a shift from the view that health care needs to adopt high-risk industries' approach to safety, and increasing awareness that for initiatives to be successful, they need to be context-specific.

## Study registration

This study is registered as PROSPERO CRD42023487512.

## Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research programme (NIHR award ref: NIHR136105) and is published in full in *Health and Social Care Delivery Research*; Vol. 13, No. 7. See the NIHR Funding and Awards website for further award information.

# Health and Social Care Delivery Research

ISSN 2755-0079 (Online)

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*Health and Social Care Delivery Research* (HSDR) was launched in 2013 and is indexed by Europe PMC, DOAJ, INAHTA, Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA), NCBI Bookshelf, Scopus and MEDLINE.

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Editorial contact: [journals.library@nihr.ac.uk](mailto:journals.library@nihr.ac.uk)

This journal was previously published as *Health Services and Delivery Research* (Volumes 1–9); ISSN 2050-4349 (print), ISSN 2050-4357 (online)

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## This article

The research reported here is the product of an HSDR Evidence Synthesis Centre, contracted to provide rapid evidence syntheses on issues of relevance to the health service, and to inform future HSDR calls for new research around identified gaps in evidence. Other reviews by the Evidence Synthesis Centres are also available in the HSDR journal.

The research reported in this issue of the journal was funded by the HSDR programme or one of its preceding programmes as award number NIHR136105. The contractual start date was in July 2023. The draft manuscript began editorial review in April 2024 and was accepted for publication in September 2024. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HSDR editors and production house have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

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