EJA

Eur J Anaesthesiol 2020; **37:**1–90

REVIEW ARTICLE

Ten years of the Helsinki Declaration on patient safety in anaesthesiology

An expert opinion on peri-operative safety aspects

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Patient safety is an activity to mitigate preventable patient harm that may occur during the delivery of medical care. The European Board of Anaesthesiology (EBA)/European Union of Medical Specialists had previously published safety recommendations on minimal monitoring and postanaesthesia care, but with the growing public and professional interest it was decided to produce a much more encompassing document. The EBA and the European Society of Anaesthesiology (ESA) published a consensus on what needs to be done/achieved for improvement of peri-operative patient safety. During the Euroanaesthesia meeting in Helsinki/Finland in 2010, this vision was presented to anaesthesiologists, patients, industry and others involved in health care as the 'Helsinki Declaration on Patient Safety in Anaesthesiology'. In May/June 2020, ESA and EBA are celebrating the 10th anniversary of the Helsinki Declaration on Patient Safety in Anaesthesiology; a good opportunity to look back and forward evaluating what was achieved in the recent 10 years, and what needs to be done in the upcoming years. The Patient Safety and Quality Committee (PSQC) of ESA invited experts in their fields to contribute, and these experts addressed their topic in different ways; there are classical, narrative reviews, more systematic reviews, political statements, personal opinions and also original data presentation. With this publication we hope to further stimulate implementation of the Helsinki Declaration on Patient Safety in Anaesthesiology, as well as initiating relevant research in the future.

Published online xx month 2020

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DOI:10.1097/EJA.0000000000001244

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Introduction (Arnal, Preckel)

'Anaesthesiologists have a unique, cross-speciality opportunity to influence the safety and quality of patient care'.[1] The central role of anaesthesiologists in the acute and surgical patient; the safety improvements in anaesthetic practice, with more than 10-fold decrease of anaesthesia mortality since 1970 and the pioneering interest in the topic have made anaesthesiology the leading medical speciality for addressing patient safety issues.[2–4] In the 1999 Institute of Medicine report 'To Err is Human', Anaesthesiology rightly received the recognition it deserved as the original leader in patient safety, and even the source of the term 'Patient Safety' itself.[5] Anaesthesia care has become quite safe: an analysis of national registry data from the United States revealed for the years 1999 to 2005 an estimated rate for anaesthesia-related death of 1.1 per million population per year, and 8.2 per million hospital surgical discharges.[6] However, huge regional differences exist, and anaesthesia-related mortality is much higher in low-income and middle-income countries.[7,8] This difference becomes even more important if we recognise that availability of surgery is unequally distributed in the world, with the expectation that surgery will increase in the lower income countries during the next decades.[9]

Which risks for patient safety do we face in anaesthesiology? today Previous publications have shown that even in high-income countries, 44 to 54% of peri-operative 'adverse events' are preventable. Factors like increased pressure on throughput, along with reduced medical staff, new drugs and devices, sicker patients, as well as more complex procedures all increase the opportunity for errors in our work. Are we now paying the price for the success from previous years? Chantler[10], already in 1999, said that 'Medicine used to be simple, ineffective and *relatively safe*. Now it is complex, effective and *potentially dangerous*'. Surgical and anaesthesia safety was for a long time unrecognised as a public health issue and for numerous safety topics we still lack evidence-based data. For years, medical staff and policy makers failed to use existing safety know-how from industry in healthcare systems.[11]

Patient safety is an activity to mitigate preventable patient harm that may occur during the delivery of medical care. The European Board of Anaesthesiology (EBA)/European Union of Medical Specialists (UEMS) had previously published safety recommendations on Minimal Monitoring and Postanaesthesia Care, but with the growing public and professional interest it was decided to produce a much more encompassing document.[12,13] The EBA and the European Society of Anaesthesiology (ESA) published a consensus on what needs to be done/achieved for improvement of peri-operative patient safety. During the Euroanaesthesia meeting in 2010, taking place in Helsinki, Finland, this vision was presented to anaesthesiologists, patients, industry and others involved in health care as the 'Helsinki Declaration on Patient Safety in Anaesthesiology'.[1]

This Declaration represents a shared opinion of what currently is worth doing and practical to improve patient safety. There are eight 'Heads of Agreement' and seven 'Principal Requirements'.

Helsinki Declaration on patient safety in anaesthesiology

Background

Anaesthesiology shares responsibility for quality and safety in Anaesthesia, Intensive Care, Emergency Medicine and Pain Medicine, including the whole peri-operative process and also in many other situations inside and outside the hospital where patients are at their most vulnerable.[1]

(1) Around 230 million patients undergo anaesthesia for major surgery in the world every year. Seven million develop severe complications associated with these surgical procedures from which one million die (200 000 in Europe).[1] All involved should try to reduce this complication rate significantly.

Anaesthesiology is the key speciality in medicine to take up responsibility for achieving the goals listed below which will notably improve Patient Safety in Europe.

Heads of agreement

(1) Patients have a right to expect to be safe and protected from harm during their medical care and anaesthesiology has a key role to play in improving patient safety peri-operatively. To this end we fully endorse the World Federation of Societies of Anaesthesiologists International Standards for a Safe Practice of Anaesthesia.
(2) Patients have an important role to play in their safe care which they should be educated about and given opportunities to provide feedback to further improve the process for others.
(3) The funders of health care have a right to expect that peri-operative anaesthesia care will be delivered safely and therefore they must provide appropriate resources.
(4) Education has a key role to play in improving patient safety, and we fully support the development, dissemination and delivery of patient safety training.
(5) Human factors play a large part in the delivery of safe care to patients, and we will work with our surgical, nursing and other clinical partners to reliably provide this.
(6) Our partners in industry have an important role to play in developing, manufacturing and supplying safe drugs and equipment for our patients' care.
(7) Anaesthesiology has been a key speciality in medicine leading the development of patient safety. We are not complacent and know there are still more areas to improve through research and innovation.
(8) No ethical, legal or regulatory requirement should reduce or eliminate any of the protections for safe care set forth in this Declaration.

Principal requirements

(1) All institutions providing peri-operative anaesthesia care to patients (in Europe) should comply with the minimum standards of monitoring recommended by the EBA, both in operating theatres and in recovery areas.
(2) All such institutions should have protocols and the necessary facilities for managing the following:
    (a) Pre-operative assessment and preparation
    (b) Checking equipment and drugs
    (c) Syringe labelling
    (d) Difficult/failed intubation
    (e) Malignant hyperpyrexia
    (f) Anaphylaxis
    (g) Local anaesthetic toxicity
    (h) Massive haemorrhage
    (i) Infection control
    (j) Postoperative care, including pain relief

(3) All institutions providing sedation to patients must comply with anaesthesiology recognised sedation standards for safe practice.
(4) All institutions should support the WHO Safe Surgery Saves Lives initiative and checklist.
(5) All departments of anaesthesiology in Europe must be able to produce an annual report of measures taken and results obtained in improving patient safety locally.
(6) All institutions providing anaesthesiological care to patients must collect the required data to be able to produce an annual report on patient morbidity and mortality.
(7) All institutions providing anaesthesiological care to patients must contribute to the recognised national or other major audits of safe practice and critical incident reporting systems. Resources must be provided to achieve this.

Conclusion

This Declaration emphasises the key role of anaesthesiology in promoting safe peri-operative care.

Continuity

We invite anyone involved in health care to join us and sign up to this Declaration.

We will reconvene to review our progress annually to implement this Declaration.

The presidents of EBA/UEMS, ESA and the chairperson of the National Anesthesia Society Committee on behalf of the ESA Member Societies signed the Declaration in Helsinki on 12 June 2010. The Declaration was immediately endorsed by several international and national organisations/societies. Meanwhile, anaesthesia societies all over the world signed the Declaration (https://www.esahq.org/uploads/media/ESA/Files/Downloads/Resources-PatientSafety-MapHelsinkiDeclaration/Resources-PatientSafety-Map%20Helsinki%20Declaration.pdf).

This year, in May/June 2020, ESA and EBA are celebrating the 10th anniversary of the Helsinki Declaration on Patient Safety in Anaesthesiology; a good opportunity to look back and forward evaluating what was achieved in the recent 10 years, and what needs to be done in the upcoming years. Implementation of the Declaration was an objective from the outset and in connection with this in 2011, an issue of the journal Best Practice and Research in Clinical the project consisted of an online survey of ESA members to s.[14] A joint EBA/ESA Task Force was set up to deliver this and produced a number of implementation tools distributed at Euroanaesthesia Congresses and put on the website. A discussion in the Patient Safety and Quality Committee (PSQC) of the ESA has led to engagement in an update of the safety literature, resulting in the present 'Expert Opinion'. This article will go beyond the topics mentioned in the Helsinki Declaration on Patient Safety in Anaesthesiology, and will elaborate on topics, which 10 years ago were not as prevalent as today in the clinical practice. Of course, the list of safety topics covered by the following chapters is not – and cannot be – exhaustive. The reader will learn that there has been enormous progress and developments regarding safety tools, but it will also be mentioned that in given areas we urgently need more valuable research data. Randomised clinical trials are often difficult to perform in safety topics, and newer strategies might offer opportunities.[15] Methods other than clinical trials can also illuminate safety.[16]

As this experts' opinion compilation emanates from the 10th anniversary of the Helsinki Declaration, we start by presenting the state of its implementation and a reflection on the role that the Declaration has meant in the past and can be foreseen in the future. Following this initial chapter, we present a mixture of a selection of Helsinki Declaration principal requirement updates (pre-operative assessment, incident reporting, medication safety (beyond the syringe labelling), monitoring standards and safe sedation) a collection of chapters related to human factors (speak up, multidisciplinary simulation, handovers and cognitive aids, exhibiting the growth of knowledge and relevance of this Helsinki Declaration 'head of agreement' in the last decade); and a compendium of relevant topics to patient safety that have become more relevant since the Declaration was launched and that were not specifically addressed in 2010 but we consider necessary to include in 2020 (Learning from Excellence (LfE), the patient perspective, patient safety teaching, second victim support, failure to rescue and patient blood management (PBM)). Displaying all these chapters in the order just presented would probably send the false message of having old and new topics. We have, therefore, mixed them in a varied and eclectic hierarchy-free distribution.

The experts addressed their specific topic: the reader will find classical reviews, more systematic reviews, political statements, personal opinions and also original data presentation. With this publication we hope to further stimulate implementation of the Helsinki Declaration on Patient Safety in Anaesthesiology in your own hospital, as well as opening the scope of the patient safety strategies to address in the near future.

Chapter 1: Implementation of the Helsinki Declaration on patient safety in anaesthesiology: past activities, current European perspectives and future opportunities (Ffrench-O'Carroll, Smith)

The Helsinki Declaration on patient safety in anaesthesiology

The Helsinki Declaration on Patient Safety in Anaesthesiology (hereafter 'the Declaration') was launched in 2010 by the EBA/UEMS in close co-operation with the ESA.[1] It set out a vision for patient safety in anaesthesiology, together with recommendations for specific activities which could improve safety. It has four distinct elements:

standards for clinical care; protocols for the management of clinical crises in anaesthesiology; critical incident reporting; and an exhortation to engage in audit and the compilation of annual reports about local patient safety as well as morbidity and mortality, to reap the benefits of measurement to improve safety.

The Declaration was signed by all the European societies attending its launch in Helsinki and also by the European Patients' Forum. A number of implementation activities were undertaken to promote the use of the Declaration in practice. A joint EBA/ESA Patient Safety Task Force was set up, and every year this produced materials and resources that were made freely available to every delegate at the Euroanaesthesia Congress. In 2011, a special edition of the journal Best Practice and Research in Clinical Anaesthesiology devoted to patient safety was given out.[14] A survey on syringe labelling and a template for the annual safety report (available from http://html.esahq.org/patientsafetykit/resources/basics.html) were published in 2012.[17] The following year, a manual of algorithms for managing clinical crises in anaesthesiology was issued (available from http://html.esahq.org/patientsafetykit/resources/downloads/05_Checklists/Emergency_CL/Emergency_Checklists.pdf). A 'Patient Safety Starter Kit' on a data stick, containing recorded lectures and other resources, was distributed to participants at the ESA's Euroanaesthesia meeting in June 2014 (available from http://html.esahq.org/patientsafetykit/resources/index.html). Many lectures and presentations were given at anaesthesiology conferences within Europe and beyond and such was the appeal of the Declaration that it has now been signed by approximately three-quarters of national societies worldwide. Despite the widespread endorsement of the Declaration's principles, and the promotional activities described above, there remains some uncertainty regarding its usage and influence in practice, with limited studies performed assessing its impact.[18]

To address this gap, the ESA's PSQC has started a project designed to assess, understand and improve the translation of the Declaration's principles and requirements into clinical practice. As part of this project, the ESA recently commissioned one of us (AFS) to undertake a three-phase investigation (details available from https://www.esahq.org/patient-safety/hd-follow-up-project/) to assess the uptake and use of the Declaration. (The study was funded by ESA, supported by the following industry partners of ESA: Philips Healthcare, Masimo International, Fresenius Kabi and Nihon Kohden Europe. These companies played no role in data collection, analysis or writing of the article.) Phase I OF the project consisted of an online survey of ESA members to determine what aspects of the Declaration had been adopted.[19] Respondents were also asked to express their opinions on the Declaration, its impact on patient safety, and limitations and barriers to embedding its recommendations in daily practice. Phase II sought to learn about patient safety practices and the Declaration's impact in greater detail, by conducting telephone interviews with national leaders in anaesthesiology in a number of European countries. Interviews were semistructured and the resulting qualitative data underwent thematic analysis, with themes developed inductively.[20] Phase III involves site visits to hospitals throughout Europe, to examine patient safety practice 'on the ground'. The three phases thus each aimed to address anaesthesiology practice at various levels (Fig. 1). While the third phase is still continuing at the time of writing (September 2019), the combination of methods used is innovative and has not previously been described in the exploration of patient safety. This chapter thus aims to outline the methodology of this phase of the project, report on the current state of implementation of the Declaration, outline possible future measures for improving its uptake, and reflect on possible implementation approaches that have been, or could be adopted.

Methodology of site visits

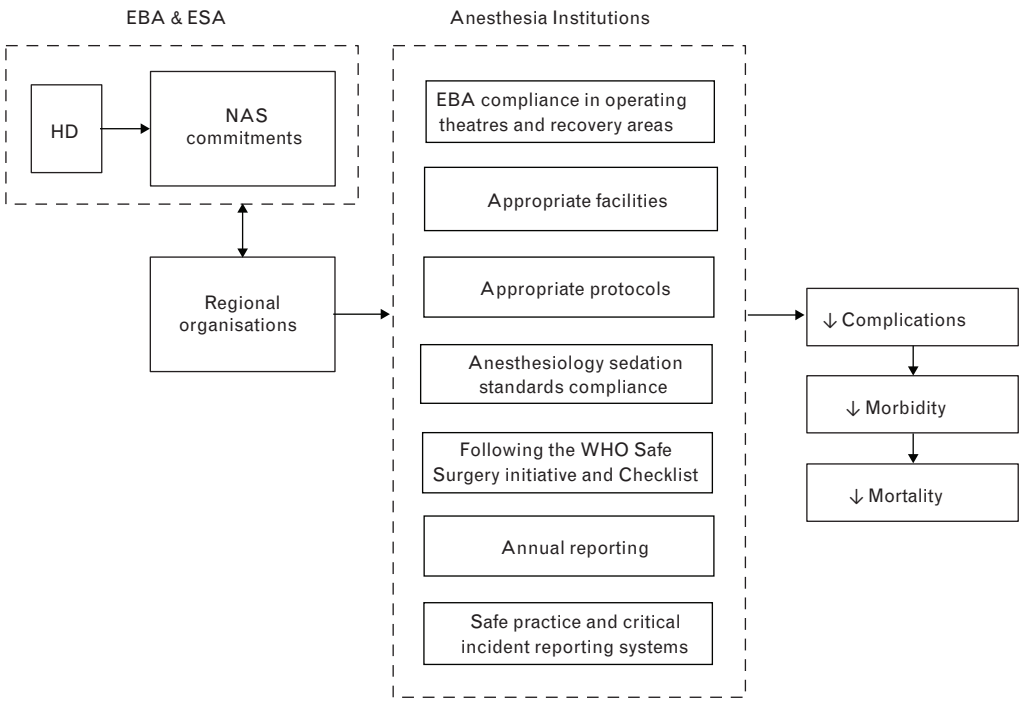
From the beginning of the project, it was clear that, to illuminate the subject properly, the inquiry needed to extend beyond a simple assessment of whether or not the Declaration had been adopted to a broader attempt to set it in the practice context of European anaesthesiology.[21–23] We adopted a case study methodology and a broadly positive stance implying a 'Safety II' framework (i.e., a framework which aims to understand why things go right in health care most of the time) complementing a traditional 'Safety I' framework (i.e., a framework which involves learning from errors).[24–28] Our approach was essentially ethnographic, aiming to build up a picture of safety as practised which was both scientifically rigorous but which also 'made sense' to those under study, recognising the time constraints imposed by the short visit schedule.[29–32]

Country and hospital selection

Six European countries were chosen to reflect varying healthcare systems across Europe. Selection of countries was influenced by practicality and the presence of a 'project champion' (a high-level sponsor, often within the national anaesthesiology society) and a local collaborator, often a senior anaesthesiology trainee or a local consultant with expertise in patient safety. Typically, AFS conducts the first couple of visits in a country with the local collaborator, with subsequent visits being performed by the local collaborator. There are plans for the local contacts to perform visits outside of their home country to gain experience and also share their own experience of visits in different health care settings.

Four or five hospital sites were selected in each country. Methods of selection of these hospitals varied between countries. Generally, a list of hospitals in the target country was identified, then a computer-generated random number sequence was used to identify hospitals, and

Fig. 1



Schematic of the potential impact of the Helsinki Declaration across organisational levels of anaesthesiology practice in Europe. Reproduced with kind permission of Grant Aaron, Masimo Company, Geneva, Switzerland. EBA, European Board of Anaesthesiology; ESA, European Society of Anaesthesiology; HD, Helsinki Declaration; NAS, national anaesthesiology societies; WHO, World Health Organization.

departments of anaesthesia were contacted. If the first department contacted did not wish to take part, then the next hospital on the list was contacted, and so on. In other countries, the hospitals were selected by the local sponsor or collaborator. Hospitals were chosen to represent a mix, both in terms of geographical spread and care provision (district general vs. university vs. private hospitals). Following agreement from the relevant anaesthetic departments, several steps were taken before the visit: included contacting local ethics boards to gain ethical approval and establishing local rules for data sharing and confidentiality.

Data collection

The data collection process was designed to explore themes which emerged from earlier phases of the project. These included pre-operative assessment; checklists (in particular the WHO Safe Surgery Checklist; WHO SSC); patient experience; anaesthesiologists' working conditions and wellbeing the role of protocols; documentation and medication prescribing; postoperative care and critical incident reporting. The streams of data sought are set out in the hospital visit schedule shown in Table 1.

The first, documentary data were collated by the local contact for the project, who completed the annual safety report using the ESA's template mentioned above, and also collected any relevant safety protocols. On the day of the visit, the investigators reviewed the departmental protocols and guidelines with staff anaesthesiologists. Second, we invited members of participating anaesthesiology departments to fill in a questionnaire measuring workplace safety culture. This, the University of Texas Safety Attitudes Questionnaire (SAQ), gauges staff attitudes across six patient safety-related domains and provides a snapshot of safety climate.[33] The local contact person was asked to distribute these among at least 20 anaesthesiologists and theatre nurses prior to the visit. SAQs measure staff attitudes across the domains of teamwork, safety climate, job satisfaction, stress recognition, perceptions of unit management, perceptions of hospital management and working conditions. The questionnaire is a widely used tool, which can be used to measure staff's attitudes to safety at a particular time point, prompt discussion about safety and the introduction of safety interventions, and act as a comparison tool with other organisations.[33–35] The third stream of data was obtained from observation. We undertook a 'walk-through' of the operating theatre department, noting facilities such as drug cupboards, emergency drugs, airway management, other equipment and optional monitoring modalities [apart from ECG, pulse oximetry, noninvasive blood pressure (NIBP)]. Such 'safety walk-rounds' provided the opportunity to engage staff in the project, discuss safety concerns and notable safety

Table 1 Site visit process

Site visit process
1 Practical arrangements
Seek ethical approval for relevant country
Identify contact person in each hospital
Send project briefing summary to contact person
Confirm date when relevant stakeholders available
Establish rules for data sharing and confidentiality
Invite contact person to inform anaesthesiology department and theatre managers of project in advance of visit
Invite contact person to arrange open group meeting to anaesthesiology department on morning of meeting to explain purpose of project and aims of day
2. Preliminary information (by written questionnaire to be completed in advance)
Invite contact person to complete the annual departmental safety report
Further information to be sought by contact person (some contained within safety report)
Establish what staff are responsible for sedation in the hospital
Establish departmental participation in the local/regional/national incident reporting system
Reports of morbidity and mortality meetings if available
Summary of critical incident reports, if available
Are there any additional safety-related materials to guide practice in the hospital?
Establish departmental participation in major audits and local audits
Establish whether existing protocols exist for
Pre-operative assessment and preparation
Checking equipment and drugs
Syringe labelling
Difficult/failed intubation
Malignant hyperpyrexia
Anaphylaxis
Local anaesthetic toxicity
Massive haemorrhage
Infection control
Postoperative care including pain relief
Invite contact person to ask 20 to 30 people to complete SAQ before the visit
Invite contact person to suggest additional areas to explore on the visit in addition to the standard areas of interest below
3. Data collection during visit
Interviews
Two consultant anaesthesiologists (one preferably with a role in patient safety in department), one trainee and an anaesthesiology nurse, as a minimum
Review safety documents above during interview
Semistructured with open ended questions outlined in Fig. 3
Also cover suggested themes and follow-up on the information previously gathered
'Walk-through'
Perform safety 'walk-round' of theatre department
Engage staff in the project
Discuss safety concerns and notable safety practices
Examine drug cupboards, emergency drugs and equipment, optional monitoring modalities (apart from ECG, pulse oximetry, NIBP)
Observation of safety practices
Checklists being performed – WHO checklist, patient check in
Pre-operative visit by anaesthesiologist
Checking of equipment – checking anaesthetic machine
Observe drug checking, preparation and labelling
Observe transfer of patient from theatre to recovery and handover to recovery staff
4. Follow-up
Write letter of thanks to contact person
Prepare report with findings
Send participation certificate

NIBP, noninvasive blood pressure; SAQ, Safety Attitudes Questionnaire.

practices and help towards promoting a safety culture.[36,37] Furthermore, we observed several practices to gain further information around safety, namely WHO Safer Surgery 'time out' procedures, handover between anaesthesiologists and recovery staff, and sometimes drug and equipment checking.[38] The fourth stream of data came from several semistructured interviews. The open-ended guide questions used in the interviews are shown in Table 2. Questions were developed to explore themes mentioned above which emerged from phases I and II of the project, incorporating previous work on patient safety assessment, but also to allow discussion of local safety practices and opinions.[39] Typically two consultant anaesthesiologists (one with a responsibility for safety in the department), one trainee anaesthesiologist and one anaesthetic nurse were interviewed. The interviews were tape recorded, with the respondents' consent.

Follow-up

Following the visit, the investigators prepared a report on their findings. This was sent to the anaesthetic department but not shared more widely, either with other

Table 2 Guide questions for interviews

Guide questions for interviews
Talk me through what happens to a patient when they come in for an elective operation
What do you think it is like to be a patient here? (nurses especially)
How would you describe the 'safety culture' in the department/operating theatres/hospital in general? What does it feel like to work here? What are relationships like between anaesthesiologists, surgeons, nurses etc.? What are the working conditions like (trainee anaesthesiologists especially)
Could you outline the main factors that ensure safety in anaesthesia and perioperative care? What keeps patients safe at present, day to day?
Have you any particular safety or quality 'successes' which others might learn and benefit from? Any particular difficulties/problems? Why have these been difficult?
Are there any 'problem cases' in the department or your own work recently you would like to talk about? How do they show a lack of safety or, conversely, how things were kept safe despite threats to safety?
How reliable do you think the systems of care are in the department/hospital? How could care be kept safe or made safer in the future? What practical steps might help improve patient safety in the hospital?
What sort of education and training opportunities are there for staff here?
Are people responding to opportunities to learn from problems and strengthen good practice?
How do you think the Helsinki Declaration on Patient Safety in Anaesthesiology has influenced your department and hospital? Of all the areas outlined in the Declaration, which are most useful in practice? Which are least useful?
Do you think/is it possible that the Helsinki Declaration on Patient Safety in Anaesthesiology has had any unintended or unforeseen consequences?

participating departments or the project funder. The report included: a summary of the annual safety report; discussion of organisation and staffing issues; analysis of monitoring standards; discussion of departmental policies and protocols; an analysis of the results of the SAQs; qualitative themes from interviews; a list of recent safety initiatives and notable safety practices and notes on areas for consideration for improvement or change. Within the report appendices, there were also links for safety resources and examples of notable safety practices from other institutions, which the department might choose to adopt. We also invited participating hospitals to provide feedback on the visit process by completing an evaluation questionnaire after receiving the report.

Results

Material from online and interview studies

Results from phases I and II of our project provide an insight into current and future implementation of the Declaration (full results from phases I and II have already been published in this journal).[19,20] In summary, the Declaration is perceived variously as a force for good, a standardisation framework and a catalyst for change. It benefits from being broad in scope, with knowledge of the themes of the Declaration being better known than the more specific details. National leaders interviewed felt that it acts as a tool to help advance patient safety, both politically and scientifically. It could be argued too that the Declaration is also an improvement intervention with 44.5% of ESA members surveyed agreeing that it had improved safety. This was felt to be largely through promoting the use of checklists in the areas of pre-operative preparation, and the management of crises during anaesthesia.[19]

Our results suggest that the Declaration's impact is influenced by national practice context and local safety culture. Many respondents commented that safety practices such as monitoring standards have exceeded those set out in the Declaration for many years, especially in Northern Europe. It is possible that the high levels of monitoring as recommended by WHO/World Federation of Societies of Anaesthesiology (WFSA) standards (pulse oximetry: 99.6%, BP: 99.4%, ECG: 98.1% and capnography: 96.0% throughout Europe), would have come about without the Declaration.[40] Thus the potential benefit of the Declaration in enabling change and improvement is greatest in areas where safety practices are less well established (such as in the use of data for improvement, whether they are routinely collected or reporting adverse incidents). The Declaration's impact has also been influenced by recent changes in anaesthesia, with anaesthesiologists throughout Europe reporting greater workloads, more complex patients, and pressures to cut down on pre-operative preparation. This, along with financial austerity and staff shortages (with workforce migration reported by many) have resulted in a perception that more time is spent reacting to patient safety threats as opposed to progressing safety practices.[20] Other factors, namely an organisation's safety culture and staffing issues, have influenced the uptake of the Declaration: for example in the production of annual safety reports and running morbidity and mortality meetings.[19] The hospital visit process described above aimed to explore many of these contextual factors identified in the first two phases of the project.

Survey and interview data suggested that future changes to the Declaration could take account of the challenges mentioned above, as well as the increased role of simulation, human factors and multidisciplinary training in anaesthesiology. But many respondents advocated greater adherence to the existing Declaration rather than changes to the Declaration itself. This could be brought about by introducing a formal checklist of items in the Declaration to guide day-to-day practice, and greater publicity. Efforts could be focused on areas that are less well implemented, such as annual safety reports. The Helsinki Declaration on Patient Safety in Anaesthesiology could be revitalised, by inviting signatories to confirm their continuing commitment on the Declaration's 10-year anniversary in 2020. The existing Declaration could also be translated into languages other than English where this has not already been done. Further safety suggestions stemming from our study results are outlined in Table 3.

Practical aspects of the visits and our experiences

Having performed several site visits at the time of writing, we can now reflect on some of the factors required for

Table 3 Suggestions for further implementation of the Helsinki Declaration on Patient Safety in Anaesthesiology

Suggestions for further implementation of the Helsinki Declaration on Patient Safety in Anaesthesiology
Create and maintain structures for safety education both in training curricula and for established specialist anaesthesiologists
Promote a 'no blame' culture to encourage the reporting and open discussion of threats to patient safety
Greater involvement of patients in the promotion of safe practice
Make the scientific, clinical, humanitarian and economic case for thorough pre-operative assessment
Establish and maintain regional networks within Europe to share practice and solutions appropriate to available resources
Encourage the participatory self/peer evaluation of safety using the site visit methodology and process described in this article. Even simple but repeated measures such as using the annual safety report year on year can allow changes to be made visible and possibly attributable to interventions made
Consider a concurrent, specific evaluation plan if the Declaration is revised and/or relaunched

a successful visit, some of the difficulties we have experienced and the benefits to host departments.

The visits require considerable organisation and planning. Early work involves contacting anaesthesiology departments and requesting their participation. Many departments contacted raised concerns that the visit was an 'inspection', or that data collected might result in negative publicity for the organisation. It was important at this stage to stress that the project is an attempt to learn about safety in everyday anaesthesiology work (especially what is done well) and how the Declaration fits into this, rather than an assessment of compliance with any particular standard. A successful visit depends on close liaison with the local contact person, who will be required to gather protocols, fill out the safety report, distribute the SAQs and inform relevant staff in the hospital of the visit. We are extremely grateful for the enthusiasm and time dedicated by our local hosts.

We found that providing an open education session to the host anaesthesiology department about the project (on the morning of the visit) was useful in engaging staff, many of whom were later keen to chat to us during our theatre walk-through. Ideally this meeting should be multiprofessional, including anaesthesia nurses and theatre managers.

Early feedback suggests several immediate benefits to hospitals from taking part in the project. Staff reported promotion of a safety culture through the planning and execution of the visit. Multidisciplinary staff were keen to complete SAQs, although for some the questionnaires were seen more as an opportunity to express their opinions on problems with the organisation. Anaesthesiology departments learnt much about their safety systems; for example, they identified protocols that needed updating or revision, and they reviewed their position with regard to contributing to national audits of practice. In some cases, the visit provided an impetus to commence new safety projects. The report distributed to departments after the visit contained several recommendations, useful safety references and suggestions from other hospitals. We hope this will serve as a useful tool for departments.

Performing the visit was also a valuable learning experience for the investigators. Trainees taking part gained greater understanding of recommended safety standards, safety culture and research methods; arranging the visits called for a level of communication, leadership and organisation more than is usually necessary in everyday clinical practice.

Discussion

As we mark the 10th anniversary of the launch of the Declaration, we have, with hindsight, an opportunity to ask some fundamental conceptual questions which have not been previously asked but which are relevant to any consideration of the Declaration's impact. The first is, what was (is) the Declaration exactly? Is it a statement of vision or intent, similar, for instance, to a resolution from the United Nations or WHO? Is it a standard of care (it certainly refers to published international standards and invites compliance)? Is it a guideline? (This is more contested perhaps, as the word 'guideline' can encompass care standards too and there are different challenges to uptake).[41] Is it in some sense a care 'bundle' (a set of interventions implemented together for a synergistic effect on outcomes)?[42,43] These questions may seem theoretical, but are important, because how the Declaration is framed will affect how we perceive it, our expectations of what it can achieve, and how it should be evaluated. What is clear, both from the initial documentation at the time of the launch, and from the interview responses and visits so far, is that the Declaration is not explicitly seen as a quality/safety improvement intervention. Maybe this is because it is complex (it has a broad focus and includes drug, equipment, individual and organisational elements). Alternatively, it may simply be that those who met and drafted it did not refer to quality improvement science, although it must be said that this science was neither so well developed, nor so widely applied, as it is today.[44] This is not just conceptually important; viewing the Declaration as an intervention allows us to invoke the science of implementation referred to above, both as an analytical framework but also to enhance future uptake into practice. The text of the original Declaration shows little evidence of planning as to outcomes, timelines or accountability, and only vaguely deals with what change is desired, though even this lacks any prediction of the effect any change might be expected to have.[44]

There is a note that 'we' (not explicitly defined, but possibly the three organisations represented by the signatories in the printed version of the Declaration) would reconvene annually to review progress. This apparent lack of specificity in setting out a framework

for evaluation is not necessarily a problem, especially if the Declaration is conceived as a 'vision statement'. However, if it is seen as a quality improvement tool greater attention to the design of the intervention at the start of its 'lifetime' can help avoid disappointing results later.

The second question is, to what extent can changes in practice be attributed to the Declaration? It is clear from the various streams of data collected during the project that there have been many changes since 2010, and it is not possible to establish fully which have come about as a result of the Declaration and which were happening anyway. (The interview data refer to the latter phenomenon, known in quality improvement science as a 'maturation' effect.[44]) Selection bias in respondents in all three phases of this project could have coloured the data we hold, and this is inevitable. Evidence for maturation could have been captured by repeated measurements over time (an 'interrupted time series design'), had an implementation and evaluation plan for the Declaration been conceived as part of its launch.[44] (A further analytical approach to uptake and coverage of the Declaration, drawing on the basic foundational categories of implementation science, might also be fruitful in the future.[45]) In any case, there was variation in uptake, both of the same elements between countries, but also of different elements of the Declaration. Compliance with essential monitoring standards was very high throughout Europe though there was variable use of other modalities such as bispectral index and neuromonitoring.[46,47] Protocols for pre-operative assessment and preparation were more widely used than those for the management of postoperative pain, but sedation remains problematic.[19,40,48–52] Both 'human factors' elements such as communication, and critical incident reporting were recognised as important throughout Europe, but the degree to which they featured in practice and training varied.[53,54]

The third question deals with the nature of the project we have conducted. Right from the start it was clear to the investigating team that, although the impetus for the ESA was to establish the uptake and impact of the Helsinki Declaration, a wider reaching enquiry was preferable, for two main reasons. Despite the ESA's efforts, we knew that some anaesthesiologists had not heard of the Declaration, and many were not familiar with its contents. Further, any safety initiative needs to fit into the practice context for which it is intended, if it is to be adopted and used.[55] Asking closed questions such as 'does this department of anaesthesiology comply with the Declaration?' yields some information, but less than asking 'why?' (if they do) or 'why not?' (if they do not). Thus the project has been more an attempt to understand the context (or indeed, multiple contexts) of safety in anaesthesiology in Europe.[22] Methodologically, we designed it too as 'action research' right at the beginning (indeed, this is in the title of the project as presented to its funders and various research governance bodies). This entails not only discovering new knowledge and understanding specific problems, but also facilitating action and generating knowledge about that action.[56] This implied a mixed methods approach drawing on both quantitative and qualitative data, which has allowed us to construct an account of patient safety in anaesthesiology, which reflects participants' perceptions of, and meanings attributed to patient safety within the social context of anaesthesiology practice.[57] We believe that this is one of the main strengths of our approach, which falls broadly within the emerging field of sociology of healthcare safety and quality as recently delineated by Allen at al.[55] It was argued that patient safety is not simply about individual or team psychology, but is subject to the sociocultural and political context of healthcare work. According to them, 'a sociological perspective … reveals how these problems might be managed and by whom, as well as the everyday – and often invisible – situated practices through which quality and safety are accomplished'.[55]

A further point on our data collection approach deals with how we conceptualised and presented the project. We did not see it (especially for the hospital site visits) as an 'inspection' in the sense that we were directly assessing 'compliance' with the Declaration's standards (as noted above, there is more to it than this is any case). We introduced it, both in our initial contact with potential sites, and during the briefing at the start of the visit, as an attempt to understand how safety is 'created' in day to day anaesthesiology work, as above, and gauge the role played by the Declaration within this. Patient safety can easily be overshadowed by a strong 'normative' element, with negative moral overtones and intimations of blame and recrimination.[26] Adopting the more positive note of 'Safety II', with its emphasis on understanding how and why things usually go right in safety terms, and seeing safety as a natural part of the anaesthesiologist's professional identity complement this.[27,58]

The action research approach described above also implies that those participating are not simply passive providers of data, but are also being facilitated in further action in the name of promoting patient safety. The project could be said to have had a 'transformative' goal from its inception.[45] Scientific purists might label this 'contamination' or invoke the Hawthorne effect, but as the ultimate aim of the Declaration and its associated activities is to promote patient safety, we do not see this as a shortcoming. We believe that it was possible to find out what was happening but also at the same time to stimulate interest and activity in safety and raise awareness of the Declaration. The project (especially phase III) has indeed promoted the Declaration and patient safety; our initial informal intelligence (supported by the initial postvisit evaluation questionnaires completed by our local contacts) suggests that the mere fact of taking part

in the visits has heightened departments' awareness of patient safety. Sharing of safety practices between hospitals will probably also benefit sites and in the future, we hope that departments may be able to use the visit schedule we have described to perform their own self-assessment of their safety practices. Establishing a network of safety peer-reviewers, who could then potentially cover more sites, as more anaesthesiologists within the network gain experience and confidence with the visit tool, could provide the benefit of having an external view. We hope that such activities will help implement the Declaration in themselves.

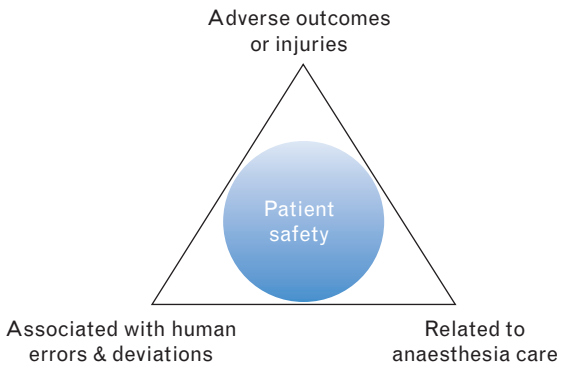
Chapter 2: How to define and adequately measure peri-operative patient safety (Haller)

Since the early development of anaesthesia, manipulating powerful drugs, thereby altering physiological functions, taking control of the circulation as well as the airway in unconscious patients have been recognised as intrinsically challenging to patient safety. As a consequence, the speciality has been at the forefront of many developments, particularly in-patient safety measurement, according to the rule: 'One can only address what one can see'. However, before patient safety is reliably assessed, it first needs to be accurately defined.

Definition of patient safety

Many patient safety definitions exist but all include the presence of adverse outcomes/injuries stemming from the processes of anaesthesia care and are related to errors, or deviations from expected care. Cooper *et al.*[59] defined the concept of patient safety as 'the avoidance, prevention, amelioration of adverse outcomes or injuries stemming from the processes of health care (i.e. anaesthesia care). Patient safety should address events that span the continuum from what may be called errors and deviations to accidents'. This concept can be modelled as a triangle integrating all these three dimensions (Fig. 2).

Fig. 2



Model for the definition for patient safety in anaesthesia.

Several tools have been developed to measure adverse outcomes related to anaesthesia care and human errors and/or deviations. These tools can be divided into traditional safety measurement methods, developed by clinicians, and alternative methods, developed by IT specialists or quality assurance organisations.

Traditional patient safety measurement methods

Anaesthesia-related mortality

Anaesthesia-related mortality refers to any death occurring during or following the care from an anaesthetist. For analysis, cases are extracted from coroners' registries, voluntary reports, surveys and malpractice reports/autopsies.[60–63] Information is usually forwarded to peer review committees of expert practitioners, usually senior anaesthetists. Experts then determine whether adverse outcomes are related to anaesthesia or not, and whether any errors have occurred.

The peer review process is largely based on implicit criteria: individual reviewers determine the standard of care, including their personal opinions regarding what should be defined as an error.

This has been a preferred method since the beginning of the speciality. Some examples include the National Confidential Enquiry into Peri-Operative Deaths in the United Kingdom, the survey of anaesthesia-related death in France, the study of deaths associated with anaesthesia in Taiwan, the review of anaesthesia-related mortality reporting in Australia and New Zealand, and the study of anaesthesia-related mortality in the United States.[6,64–66] In all these studies, reviewers assess whether adverse outcomes are related to anaesthesia or not. They identify which factors contributed to the death of the patient, including human errors and case mismanagement. The latest figures report a mortality rate related solely to anaesthesia of 2.96 per million population per year. Depending on countries and studies, the contribution of error and mismanagement to the number of patients dying as a consequence of anaesthesia has been found to vary between 77 and 97% of cases.[65,67]

Although used over decades, mortality reviews have a number of limitations. The first is a lack of a standardised definition for anaesthesia-related mortality. In a number of studies, mortality includes only cases of intraoperative or immediate postoperative death to which human error of the anaesthesia provider has contributed, while for others anaesthesia-related mortality refers to all potential causes of deaths occurring during or following anaesthesia.[61,62,68] The second limitation relates to peer review as a method to assess the contribution of human error. There is often variability among peer reviewers' opinion on 'preventability' of adverse outcomes and their level of agreement is sometimes only slightly better than chance.[69] The third limitation

relates to the absence of a valid denominator. Because most studies use coroners' registries, voluntary reports, surveys and malpractice claims, these data sources only include cases, while the denominator (number of patients undergoing anaesthesia care) is unknown. Approximations are often used, based on population registries or estimates of discharges from hospitals. Finally, death under or following anaesthesia is a rare event, and therefore patient safety cannot be determined from the sole analysis of anaesthesia-related mortality. Other types of adverse outcomes have to be used. The most popular is anaesthesia-related morbidity.

Anaesthesia-related morbidity

Anaesthesia-related morbidity includes any complication, excluding death, occurring during the peri-operative period.[70] Complications include a whole range of undesirable outcomes, from postoperative nausea and vomiting (PONV) to dental injury, cardiac arrest and permanent neurological disability. Methods to assess safety of care from morbidity data are similar to those used for mortality studies. Data provided by voluntary reports, post anaesthetic follow-up programmes and malpractice reports are analysed by peer review committees which determine whether anaesthesia is implicated, and, if so, whether the anaesthesia-related morbidity is due to an accident or a preventable error.[71–73] Cardiac arrest and coma are the most widely analysed adverse outcomes. The current prevalence of anaesthesia-related cardiac arrest in high-income countries is between 0.7 and 5.8/10 000 procedures and the prevalence of anaesthesia-related brain injuries ranges between 0.02 and 0.05/10 000.[74–78] Less severe complications such as dental injuries or PONV occur more frequently in 0.2 to 1.3/1000 patients for dental injuries, and 10 to 45/100 patients for PONV.[79–82] These figures show that the incidence of different morbidities varies significantly and conclusions regarding the level of patient safety differ accordingly. In addition, there is only a limited number of studies looking at anaesthesia-related morbidity which include both, the identification of anaesthesia-related injuries and a formal peer review assessment that can be considered as formally measuring patient safety.[73,83,84] This is partly based on a lack of consensus in the literature as to what precisely defines anaesthesia-related morbidity. Some studies report events occurring mainly during surgery while others look at events occurring in the recovery room, or both.[85,86] Some studies analyse any event while others consider mainly serious injuries.[87,88] Finally, most large studies analysing anaesthesia-related morbidity take a larger perspective on peri-operative outcomes and do not include a formal assessment of the preventability of complications. These studies mainly focus on patient characteristics and associations with pre-existing risk factors.[89–91] Despite these limitations, anaesthesia-related morbidity is a useful outcome with which to assess the safety of anaesthesia care.

Closed claim studies

While based on mortality and morbidity, closed claims studies represent a distinct category of patient safety measurement tools. This approach is on the basis of the standardised collection and analysis of anaesthetic complications in closed claim files from professional liability insurances or peer review committees from professional organisations. The most well known initiative is the closed claims project of the Committee on Professional Liability of the American Society of Anesthesiologists (ASA) in the United States.[92] Initiated in 1984, this project explores, through a range of successive analyses, more than 4000 claims collected from 35 insurance organisations throughout the United States. Analysed complications include cardiac arrest, major respiratory system events, difficult intubations, nerve injuries, awareness, claims associated with chronic pain management, injuries associated with regional anaesthesia and events during obstetrical anaesthesia.[93–98] A closed claim file typically includes hospital and anaesthesia records, narrative statements of the healthcare personnel involved, chart summaries, experts' opinions, outcome reports, cost of settlements and jury awards. At the start, a practicing anaesthetist reviews the files using a standardised data collection form to assess the cause of injury and appropriateness of care. A second, third and sometimes fourth practitioner is then involved in the file review process to ensure expert agreement on the level of preventability of the injuries.[99]

This method is a comprehensive tool to measure patient safety in anaesthesia. It is highly specific to anaesthesia care. It also systematically includes injuries and a formal assessment of physicians' liability.[100] However, despite its high specificity for patient safety issues, this method cannot be used to measure the true incidence of safety issues in anaesthesia. First, because not all injuries related to anaesthesia care are followed by claims for compensation from insurance companies. Second, because the overall number of anaesthetic procedures performed (denominator) is unknown, the true rate of injuries cannot be calculated. Third, this method is retrospective, and the validity of the performed analysis largely depends on the amount and quality of the available information. Despite these limitations, analysis of these cases can provide interesting information on the trends of the main injuries in anaesthesia care resulting in claims for compensation. For instance, when comparing the period between 1970 to 1989 and 1990 to 2007, analyses showed that oesophageal intubation had nearly disappeared (probably due to the more systematic use of end-tidal capnography) while in contrast inadequate oxygenation and ventilation have risen in nonoperating room locations, mainly due to the development of monitored anaesthesia care. Difficult intubation still represents 27% of adverse respiratory events reported in 1990 to 2007, increasing over the two time periods.[101] This is why

closed claim studies are still performed on a regular basis in many countries.[100,102–105]

Incident reporting

Since the first structured questionnaires measuring critical incidents as part of the Australian Incident Monitoring Study, incident reporting systems have progressively evolved into large and worldwide initiatives of voluntarily reported incidents.[106–109] These are defined as 'unintended or unexpected events which could have or did lead to harm'.[110] As such the definition of incidents includes a wide range of events, from transfusion accidents or near misses, to drug reactions or nosocomial infections.

Staff members or risk managers analyse and classify reported incidents to assess causality and preventability. The analysis can sometimes take the format of an extensive inquiry including staff and patient interviews, which has been formalised and named root cause analysis (RCA).[111] Because this extensive process requires much time and resources, it is mainly used for severe incidents, often part of so-called sentinel events.[108,112] Other incidents are recorded, and crude analysis are performed to spot trends and identify rare or alarming events.

Although the incident reporting is relatively specific to patient safety it still has some limitations. Incident reporting is qualitative by nature,[113] and qualitative methods emphasise description and interpretation rather than quantification.[114] They cannot be used to assess the level of safety of anaesthetic practice since only voluntarily reported incidents are available for analysis. Underreporting is as common, and several studies suggest its magnitude as high as 77 to 94%.[115,116] Incident reporting is also prone to selection and hindsight bias. Clinicians can for instance select the type of incident they will record: these tend to be the most severe ones, those in accordance with individual perspectives of safety, or those likely to carry a message to the health organisation's management.[117] To overcome these limitations, reporting systems are increasingly becoming more standardised and are nowadays accessible through electronic solutions. Some systems use predefined categories of events or are integrated into the electronic patient records routinely used in operating theatres.[118] This integration can improve accuracy and acceptance of the system with a very high level of reporting and with up to 85.1% of incidents documented,[119] thereby reducing its limitation as a patient safety measurement method. Even so, incident reporting systems should not be used to measure patient safety or identify unsafe hospitals or unsafe professionals.

Adverse events

Adverse events refer specifically to iatrogenic injuries resulting from the process of care.[120] They comprise all types of injuries including those occurring during the peri-operative period. Adverse events analysis is the cornerstone of hospital safety assessment. It has been used in many well known studies on healthcare safety measurement such as the Harvard Medical Practice Study, the Quality in Australian Healthcare Study, a total of the Canadian Adverse Events Study, the Adverse Events in British Hospitals study, the ENEIS study and more recently similar studies in Switzerland, Sweden and Norway.[121–129] All except one study on adverse events have used the investigation approach.[121] This method is based on a two-stage analysis process of medical records selected among hospitalised patients. During the first stage, records are selected using predefined screening criteria or trigger tools. These criteria usually involve the presence of identifiable events likely to be associated with adverse events and negligence, such as readmission to the operating theatre, hospital-acquired infection/sepsis or adverse drug reaction. In a second stage, expert reviewers examine the records that screen positive for one of these criteria and confirm the presence of an adverse event and its possible preventability. These studies, in which large samples of hospitalised patients are examined over a period of time, have provided the most comprehensive overview of hospital care-related adverse events and safety issues, including the field of anaesthesia. In the Quality in Australian Healthcare Study, a total of 16.6% of patients included in the study had an adverse event, with 2.2% of the total being anaesthesia related.[124] One third of these events were considered preventable.[122,123,130]

There are also some limitations to the user adverse events for patient safety measurement: they represent mainly iatrogenic injuries associated with permanent or prolonged sequelae. This excludes a range of transitory complications from analysis, which could also be related to safety issues. The final decision as to whether an injury or complication is a real adverse event is left to the peer reviewer. The overall sensitivity of this measurement method largely relies on the quality and availability of information, and missing information can significantly bias the analysis. And finally, although this measurement method captures adverse events related to peri-operative care, it was not specifically designed to capture anaesthesia-related adverse events. In addition, only earlier studies published before 2000 have systematically assessed anaesthesia, and this limits the validity of this approach as a global measure of patient safety in anaesthesia.

Alternative methods of safety measurement

Clinical indicators

Developed initially in the manufacturing industry, indicators have been increasingly implemented in health care to be used as quantifiable surrogates of patient safety.[131] A good example is *an unplanned admission to the Intensive Care Unit within 24 h of a procedure with an anaesthetist in attendance*. This indicator is considered as a valid measure of patient safety because it has been found to be

associated with complication caused by anaesthesia and/or surgery in 87 to 92% of the patients. Furthermore, 74 to 92% of these complications can be considered as being preventable.[132–134] However, like other patient safety measurement methods, clinical indicators have limitations. First, there is a lack of consensus definitions for clinical indicators across healthcare systems and the same clinical indicator can be defined and used in different ways, depending on countries. For example, peri-operative anaesthesia-related mortality can be measured by three different indicators: *death within 48 h of a procedure involving anaesthesia* [Agency for Healthcare Research and Quality (AHRQ) patient safety indicators programme – United States], *death rate associated with procedures involving anaesthesia* (Veterans administration quality indicators programme – United States) or *deaths within 30 days of surgery* (NHS clinical indicators programme – United Kingdom).[134–136] Second, clinical indicators developed for anaesthesia care focus largely on complications but less on preventability and errors. Finally, there appears to be limited academic interest in clinical indicators. As a result, these measurement tools are more often viewed as 'quality improvement tools' and are disregarded as measures of patient safety in anaesthesia. Their validity is often limited and largely based on expert opinion. Even when process indicators which are based on sound scientific evidence are used, it still needs to be demonstrated that compliance with evidence-based best practice systematically results in better patient outcome.[137–139]

Despite these limitations, clinical indicators offer promising perspectives as handy and useful metrics to quantify patient safety on a day-to-day basis. Indicators such as *an unplanned admission to the ICU, surgical site infections, wrong side procedures, death within 30 days of coronary artery bypass surgery, and readmission to hospital following complications* are some examples of straightforward and valid measures of patient safety since, beyond complications, they also exemplify events that are largely preventable through targeted evidence-based practices.[140]

Information technologies

With the development of computing technologies and artificial intelligence, a number of new methods have become available. They are based on electronic tracking, and examples include recognition of nosocomial infections, hazards associated with drugs or wrong patient orders and medical device dysfunctions.[141] To detect errors and complications, methods based on computing technologies use electronic algorithms to analyse hospital administrative databases, patient computerised records or monitoring devices.[142] These algorithms are designed to flag specific adverse events-related codes, for example, iatrogenic pneumothorax, Methicillin-resistant *Staphylococcus aureus* (MRSA) nosocomial infections or drug antidote administration (e.g. Naloxone).[143,144] More advanced algorithms have been designed recently to detect out-of-range signals from monitoring systems, or wrong drug prescriptions. These systems are also able to support decision making on correction strategies to be put in place.[145–148] These computerised systems should not be confused with portable computerised data collection and automatic monitoring systems for physiological data monitoring (i.e. ECG, pulse oximetry, invasive BP) which are not direct patient safety measurement tools.

Information technologies have some limitations: they require advanced and fully implemented information systems at a hospital level, a technology that many hospitals cannot afford. In addition, they are only highly effective in detecting adverse events if these events generate computable and identifiable markers (e.g. a positive MRSA blood culture and absence of antibiotic administration). When adverse events are not documented or simply inappropriately coded, they cannot be captured by these technologies. Finally, no information regarding association with patient care and preventability is provided by these computerised systems. Therefore, further developments are still needed before this method can be used for routine measurement of patient safety in anaesthesia.

Safety culture questionnaires

Largely influenced by analyses of large-scale accidents such as the capsizing of the Herald of Free Enterprise in 1982 or the combustion of the Chernobyl nuclear power plant reactors in 1985, psychologists have developed organisational models of accident analysis.[149,150] All these models consider that accidents occur because of a succession of breeches in the organisation's defence system. Consequently, safety questionnaires are designed to perform a global assessment of the defence system of an organisation. The best defence is considered to be the safety culture of the organisation itself. As a result, safety culture is assessed through formal questionnaires analysing the different dimensions of safety culture. These include levels of staffing, communication and interaction between management and staff members, and overall perception of the level of safety of the organisation. Some examples of organisational safety questionnaires in anaesthesia include the anaesthetists' attitude to teamwork and safety questionnaire, the safety attitude questionnaire and the Hospital Survey on Patient Safety Culture.[33,151,152]

Although promising, the model used to build these questionnaires is based on the assumption that management is at the top of the organisation, defines policies and provides resources that will largely influence work procedures and outcomes at the lower level of the organisation. Tasks and procedures are clearly defined, roles readily identifiable and co-ordination ensured by policies and written rules. Organisational culture is safe whenever there is a harmonious balance between policies, co-ordination of teams and environment. Whether this model

really applies to healthcare organisations remains unclear. A dual line of control characterises healthcare organisations: professional (physicians and other allied health staff) and managerial (hospital administrative management). The influence of management decisions and policies on professionals, particularly physicians, is limited. There are few written rules to coordinate work among different professionals and co-ordination is largely ensured by skills and knowledge. The collaboration between surgeons and anaesthetists offers a good example of such a co-ordination.[153] This makes healthcare organisation a very complex and ambiguous environment and the validity of safety culture questionnaires based on the model of a normalised organisation is still to be demonstrated. Furthermore, evidence of the validity of safety climate questionnaires in all various hospital settings and cultural contexts is largely challenged.[154] These major limitations make the use of this method unsuitable for routine measurement of patient safety in anaesthesia.

Summary of findings and future directions

The current chapter provides an overview of current patient safety measurement tools in anaesthesia. Strengths, weaknesses and prevalence of injuries according to the chosen patient safety measurement method are summarised in Table 4. There is as yet no gold standard for patient safety measurement in anaesthesia. Various methods with different strengths and weaknesses coexist. Analysis of safety levels of anaesthesia care will depend on the type of measurement method used. If anaesthesia-related mortality is used, it can be stated that anaesthesia has reached the 'six sigma' level of reliability (99.99966% free of defects) and is the safest speciality. If morbidity or incident figures are analysed, there is clearly a need for improvement, with a rate of undesirable outcomes ranging between 13.6 and 79%. Furthermore, most measurement methods rely on peer review opinion regarding preventability of recorded complications and unsafe events. This opinion can vary significantly from one reviewer to another. Even when complications that are related more specifically to patient safety issues, such as those defined in the critical incident method by Cooper *et al.*,[3] are analysed, there still is a significant reliance on the interpretative process of reporters.[69]

Despite these limitations, all the different patient safety measurement methods provide a comprehensive picture of anaesthesia-related adverse outcomes and errors. This is particularly true for studies analysing anaesthesia-related mortality and adverse events. These studies include all the different areas of the patient safety definition: adverse outcomes/injuries related to anaesthesia care and associated with errors or deviations. They also all use relatively similar methods for injury collection and analysis, allowing quantitative assessment and comparison over time. These methods can provide a broad overview of the level of safety in anaesthesia throughout different time periods and countries.

The described methods are factual metrics of clinical practice from a physician's perspective. Patients' perceptions are not incorporated into these tools. In a recent systematic review analysing critically ill patients, authors

Table 4 Summary characteristics of patient safety measurement systems

	Strengths	Weaknesses	Number of events, *N*	Proportion preventable (%)
Anaesthesia-related mortality	Widely used Consistent Simple Clear cut-off	Unreliable denominator Inconsistent peer review process Variability in definition Rare event	0.4 to 0.8/100 000	77 to 99
Anaesthesia-related morbidity	Widely used Simple Relatively frequent	Unreliable denominator Inconsistent peer review process Unclear association with anaesthesia	0.15 to 7900/10 000	0.1 to 25
Closed claims	Simple Clear association with anaesthesia	No denominator Restricted to claims Inconsistent peer review process	NA	30 to 76
Incident reporting systems	Comprehensive Simple Widely used	Limited specificity Qualitative/semi quantitative Under-reporting Selection and insight bias	13.6 to 17/100	NA
Adverse events	Specific to safety Comprehensive Comparison between studies possible	Limited specificity Inconsistent peer review Time-consuming	0.7 to 5.5/100	16.6 to 38
Information technologies	Efficient Cost-effective	Limited to specific events Limited to fully IT equipped hospitals	NA	NA
Safety Culture Questionnaires	Broad organisational Perspective	Not validated Difficult to use in routine practice	NA	NA
Clinical indicators	Highly specific to patient safety Usable to benchmark hospitals Cost-effective	Partially validated Inconsistent definition and method Complex	0.7 to 4.5/1000	74 to 92

IT, intelligent technology; NA, not applicable.

found that only 24% of the primary and 22% of the secondary outcomes used in the analysed reports included patient-centred outcomes.[155] These outcomes are defined as 'reflecting how a patient feels, functions or survives'.[156,157] This is why several initiatives have focused on the development of patient-centred outcomes to be used in clinical trials. These include the EuroQol five D, the WHO Disability Assessment Schedule version 2.0 and the one life-impact measure (days alive and out of hospital at 30 days after surgery).[158]

This approach has not yet translated into the area of patient safety measurement. While there are initiatives to include patients through interviews and conversations for safety monitoring in the area of care, these approaches are still largely physician centred (i.e. preventing drug errors, identity confusion).[159,160] Future developments in this area should focus on the development of measures of patients' personal experience of care, looking at the way anaesthetists answer concerns regarding the overall anaesthetic care process and how they ensure continuity of care through drug reconciliation and postoperative follow-up, particularly when complications have occurred.[161] This could be summarised as the ability to provide safe and professional care with empathy and respect for patients' needs.

Chapter 3: Speaking up as a vital part of a safety culture (Brattebø, Whitaker)

Safe and effective communication between team members is a vital part of health care, and this is why communication instruction is seen now as very important in our professional training. Good and open communication is also essential to a safety culture. It is hard to find any adverse event that has no element of communication issues as one of the contributing factors, such as misunderstandings, under-communication or withholding of information. Often, the analysis of such events concludes that someone in the team involved had some relevant information, which possibly could have avoided the event or at least influenced the outcome. The safety challenges span from established safety threats (e.g. lack of hand washing) to more delicate professionalism-related issues.

The big question is why didn't the individuals in the situation speak up and make their voice heard, if that could have prevented possible harm? Do we only need to better train healthcare providers in expressing assertiveness, or are there other action points that also have to be addressed?

The current chapter presents and discusses relevant research on various perspectives of this subject, as well as the challenges of speaking up in relation to factors both inhibiting and encouraging this safety behaviour. Examples of promising ways of building an environment, in which all types of safety threat concerns can be easily aired by anyone without any fear of retributions or other negative actions, will also be presented.

Background

It is always easy to blame the front-line individuals involved in an adverse event. It is also common on an institutional level to decide that, for example, in our department we now urge everyone to speak up for ensuring safety. However, as healthcare professionals we often find ourselves in situations where we observe that safety may be threatened, but find speaking up to be a significant challenge.[162–164]

Issues like culture, professional groupings and organisational socialisation may predispose personnel to avoid speaking up in hierarchies where this might be interpreted as disloyalty, disobedience or disrespect.[165] A recent study among 1800 interns and residents in the United States reported that 47% of the respondents had experienced a patient safety breach during the last month.[166] However, even more interesting, 75% of them had also observed what they saw as examples of unprofessional behaviour.[166] The first type of safety issues are, for example, regarding hand hygiene and handling of medications, while the latter may be bad professional behaviour like hiding adverse events and disrespect for patients. To be able to speak up, an individual healthcare provider must be able to express assertiveness.

Assertiveness can be defined as a form of behaviour characterised by a confident declaration or affirmation of a statement without need of proof; this affirms the person's rights or point of view without either aggressively threatening the rights of another (assuming a position of dominance) or submissively permitting another to ignore or deny one's rights or point of view. Assertive communication respects the boundaries of both oneself and the others, lying between ineffective passive or aggressive responses.[167]

Assertive statements can be used to facilitate speaking up when there is concern for patient safety, and team leaders should try to create an atmosphere in which every medical team member can make their voice heard and their input is valued. Also, their input should be expected in situations that threaten safety. Team members must respect and support the authority of the team leader while at the same time clearly asserting alternative suggestions or communicating concerns.

Challenges and barriers to speaking up

In aviation the problem of failed communication has received extensive focus and empowering crew members to speak up has especially been identified as an important factor for improving flight safety.[168] Studies from aviation, which have been exploring the reasons for remaining silent when actually being concerned about safety, have identified the fear of damaging relationships, of

Table 5 Reasons for not speaking up with corresponding statements[165,169,170]

Reasons for not speaking up	Corresponding statements
Status differences and hierarchy	'I'm only a nurse or a student'
Respect for more experienced colleagues or professionals	'I don't tell a consultant what to do or not'
Fear of damaging relationships	'I don't want to lose this friendship'
Fear of retributions or punishment	'Speaking up might result in problems for me'
Conflict avoidance	'I don't want to start an argument'
Negative evaluation	'I really want to continue working in this department'
Uncertainty	'I might be wrong'
Futility	'It won't help anyway'
Getting a bad reputation	'I don't want to become a pain in the neck'
Conformity	'Nobody else has spoken up about this'
Lack of empowerment	'This is not my responsibility'
Fear of embarrassment of self or others	'What if this is not a real problem?'
Concern over being misjudged	'I do care about safety, but I might be seen as quarrelsome'
Lack of experience in such communication	'I don't know how to say it'
Time pressure	'I don't have the time needed'
Culture	'Not common to make such comments in our department'
	'In this giant organisation I don't know who to speak to'

punishment or high operational pressures as the most common causes. Silence was lowest for captains, while first officers and pursers more often did not speak up.[168] Like in aviation, healthcare personnel may refrain from speaking up due to a number of reasons as listed in Table 5. These factors are real and affect our behaviour, whether we like it or not. Another barrier to speaking up is the individual healthcare provider's ability to use the appropriate wording to communicate their concern or to question a decision or situation that may threaten safety.[169]

Yet another consequence may be that instead of speaking up, individuals may accumulate their concerns over time, and then one day when, 'the glass is full' the resulting cannonade will be aimed in several directions, instead of addressing each specific safety issue. Ende[171] published a valuable article in JAMA many years ago, giving some advice in the art of providing useful clinical feedback. Some of his advice on professional feedback is listed in Table 6. The point of explicitly addressing specific behaviour, decisions and actions, and not generalisations, is important, as well as using descriptive nonevaluative language.

The aviation industry developed the so-called two-challenge rule to empower everyone in a flight team, who often have not met each other before, to feel shared responsibility for safety and that they are required to speak up (even repeatedly) if they observe something that they think may represent a safety hazard. This communication rule is meant to empower all team members to 'stop the line' if they sense or discover an essential safety breach. If an initial assertive statement is ignored, it is the team member's responsibility to assertively voice concern at least two times to ensure that it has been heard. The team member being challenged must acknowledge that concern has been heard. If the safety issue still has not been addressed, the person who raised a concern must take a stronger course of action, and if necessary, utilise a supervisor or chain of command. The US AHRQ has coined the acronym 'CUS' (Fig. 3). This is part of a teamwork system developed jointly by the Department of Defence and the AHRQ to improve institutional collaboration and communication relating to patient safety, called TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety: https://www.ahrq.gov/teamstepps/instructor/essentials/pocketguide.html). This course specifically addresses assertiveness, when a given situation dictates that team members must be assertive and address concerns regarding patient care. Ideally, this should be done in a non-threatening, respectful way to make sure the concern or critical information is addressed. AHRQ has also suggested a constructive approach for managing and resolving conflict; the DESC script (Table 7).

Table 6 Guidelines for giving feedback[171]

Feedback should
be undertaken with the subjects involved working together as allies, with common goals
be well timed and expected
be based on first-hand information
be regulated in quality and limited to behaviour that are remediable
be phrased in descriptive nonevaluative language
deal with specific performances, not generalisations
offer subjective data for the recipient, labelled as such
deal with their actual decisions and actions, rather than assumed intentions and interpretations

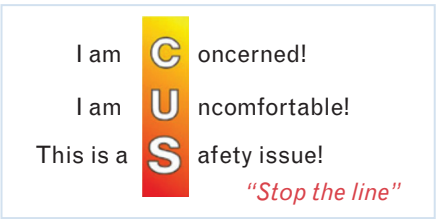
An example from aviation would be the following:

Draw the error to the captain's attention.

I see there is high ground over this way.

If the captain ignores the remark, or fails to make a satisfactory response, the first officer should **express concern in nonconfrontational language**.

Fig. 3



The CUS acronym explained (from:): it involves a five-step process: open the discussion; state the concern; state the problem – real or perceived; offer a solution; obtain an agreement.

I'm concerned that this direction will take us too close to the mountains.

If the captain ignores the remark, or fails to make a satisfactory response, the first officer should **clearly state a preferred alternative**.

Let's turn right to move toward lower ground.

If the captain ignores the remark, or fails to make a satisfactory response, the first officer should **ask the captain why** he/she has decided not to follow the first officer's suggestion.

'Can you please explain why you're not concerned about the high ground?' If the captain ignores the remark, or fails to make a satisfactory response, the first officer should **loudly and clearly make an imperative statement** *that the captain must pay attention to his/her colleague.*

Captain, you must listen!

We are dangerously close to the mountains! We must climb now!

At this point, regardless of what else happens, the captain's career is in jeopardy at a safety-conscious airline.

A respective example from anaesthesia would be:

No Trace = Wrong Place (https://www.youtube.com/watch?v=t97G65bignQ)

After an uneventful operation and extubation the patient deteriorated, has a cardiac arrest on the operating table and is re-intubated. There is no trace on the waveform capnograph.

Table 7 **The DESC Script: a constructive approach for managing and resolving conflict ()**

Feedback should
D: Describe the specific situation or behaviour; provide concrete data
E: Express how the situation makes you feel/what your concerns are
S: Suggest other alternatives and seek agreement
C: Consequences team goals; strive for consensus

Draw the error to the consultants attention

To me there seems to be no trace on the waveform capnograph

If the consultant ignores remark, or fails to make a satisfactory response such as 'well that is what you would expect in a cardiac arrest' the trainee should **express concern in a non confrontational language**

I am concerned that even in cardiac arrest without any CPR if we are ventilating we should still see a capnograph trace. The tube may be in the oesophagus

If the consultant ignores the remark, or fails to make a satisfactory response the trainee **should clearly state a preferred alternative**

Let's re-intubate the tube may in the oesophagus

If the consultant ignores the remark or fails to make a satisfactory response the trainee should **ask the consultant why** they have decided not to follow the first of their suggestions

Can you please explain why you're not concerned about the possibility of an oesophageal intubation. The No Trace = Wrong Place campaign says it means an oesophageal intubationuntil proven otherwise

If the consultant ignores the remark or fails to make a satisfactory response the trainee should **loudly and clearly make an imperative statement** that the consultant must pay attention to their colleague

Consultant you must listen The No Trace = Wrong Place campaign says a flat capnograph trace even in cardiac arrest means an oesophageal intubation until proven otherwise. We must re-intubate now or use a laryngeal mask or the patient will die.

Different perspectives and actors

Usually the value of speaking up is discussed in relation to healthcare providers' roles in ensuring patient safety, but the patients are also valuable partners in this endeavour. While we, as professionals, have the medical knowledge and know the procedures and signs of something that may be a warning signal in a given situation, the patient (and their next of kin) often may be an expert on his/her own disease and treatment/care. Patients may often feel that they should be silent and grateful beneficiaries of the healthcare provided, and not ask questions or be a 'difficult customer'. This attitude will miss a safety opportunity. On the other hand, encouraging and empowering the patients and relatives to speak up if they see something that seems unusual or not according

to what they have been told, for example, concerning medications or procedures, is a valuable source of improving safety that has not been fully utilised.[172]

Students, nurses and other health personnel may also be reluctant to voice concerns towards physicians, managers and seniors if they are raised in or part of a system that does not seem to welcome questions or other input from 'below'. An organisation with a leadership proactively fostering a culture in which both patient advocacy and safety threats are openly invited and positively responded to, is far more likely to experience their staff speaking up about concerns regarding safety issues (https://www.virginiamasoninstitute.org/2014/03/terrible-tragedy-and-powerful-legacy-of-preventable-death/).[162,166] Likewise, reducing the hierarchy among doctors has been repeatedly mentioned as a way of increasing junior doctors' willingness to speak up.[166,173]

The WHO safe surgery checklist section on time-out before surgery is started includes an item where everyone in the operating room is required to introduce themselves and say out loud their name and function.[174] This is a way of empowering every team member to speak up, because the fact that they already have raised their voice to the team increases the likelihood for them to later say something during the procedure if they see something that they feel may represent a safety hazard.

Salazar *et al.*[175] reported an interesting simulation study where they randomly allocated 55 medical students to surgical teams in which the senior surgeon either encouraged or discouraged input from the juniors. During the scenarios, the surgeon made an obvious procedural error, which the student was expected to comment on. The students in the groups where the surgeon welcomed concerns were significantly more likely to speak up (82 vs. 30%). The authors concluded that senior surgeons could improve the safety-related communication between junior and senior staff in the operating room, thereby increasing patient safety. A recent Dutch study of 27 interns also concludes that opinions and actions of supervisors have a considerable influence on residents' decision on speaking up or remaining silent.[171] Seniors with an open and proactive attitude will increase the residents' willingness to speak up.

Useful ways of encouraging speaking up behaviour

The Norwegian patient safety campaign (*In safe hands – 24-7*, https://helsenorge.no/rettigheter/rad-til-deg-som-skal-pa-sjukehus) has included the patients and relatives in the strive for safety by producing a booklet with some examples of questions that they may ask if hospitalised as shown in Table 8. The suggested questions are easy to use for a given patient needing some help to find the appropriate words for their concerns. It is a way of reducing the power-distance between the healthcare provider and the patient, and it also opens up for a more informative dialogue between them. Patients who are unable to speak for themselves or are small children will have to rely on their carer or next of kin.

Table 8 Some examples of questions and concerns patients may be encourged to raise (from the Norwegian patient safety campaign, https://helsenorge.no/rettigheter/rad-til-deg-som-skal-pa-sjukehus)

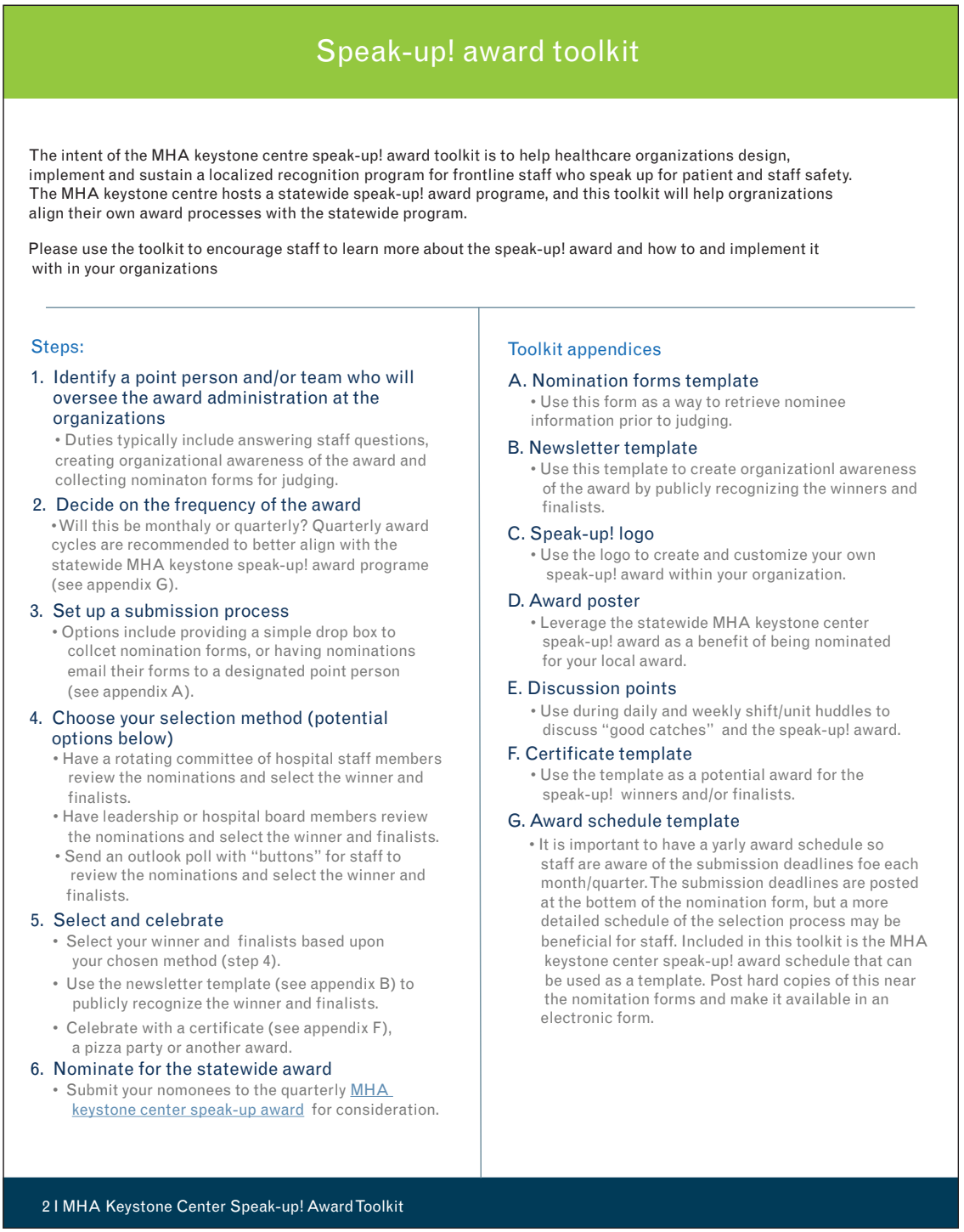
Questions and concerns raised by patients
This is new for me. Can you repeat?
You are using some expressions that I don't understand. Can you explain using other words?
I still have some worries. May I raise them now?
Have I correctly understood you that. . ..? (Then repeat using your own wording)
What is the goal of this examination?
Whom may I contact if I'm feeling unwell or have further questions?
Why should I take this medication?
What should I be aware of?

The Keystone Center in Michigan has published an interesting article on the ethical and financial imperative of making the front line staff in their organisation speak up if they experience quality and safety issues.[176] One novel approach in this project was to ask staff to report when a chain of events, which might have led to an adverse event, was intercepted. In addition, they were asked to suggest an award for those who intervened. An electronic toolkit was developed to collect information of the possible adverse events that were prevented (Fig. 4). The cost savings for each prevented event was then calculated; for every instance of speaking up expenses of 13 000 US dollar was avoided. The author reports that encouraging personnel to speak up may also have a positive financial side.

The EBA recommends that all staff should speak up when they believe that the safety of the patient is compromised (http://www.eba-uems.eu/resources/PDFS/safety-guidelines/EBA-recommemdation-Speaking-up-for-Safety-2016.pdf). A particularly useful technique promoted by Cooper *et al.*[177] is 'to be curious' and start the discussion about something you are concerned about in a nonthreatening way pretending you are not very knowledgeable. For example, ask the operator *Those gallipots have not got any labels on them, like the ones used in Theatre 3*, or *I wonder why you are doing that?*

All grades of staff should be encouraged that, if for a moment they are ever 'wondering' about the safety of what is going on, it is time to speak up! Often, just starting a conversation about safety encourages others present, who may also be concerned, to join in. Investigation of patient safety incidents has shown that other members of staff in the room often have private misgivings about what is happening as colleagues drift away from safety, and someone speaking up will give them confidence to express their unease as well.[177] In health care, physician behaviour is closely observed and imitated, therefore showing leadership in this way may promote a positive culture.

Fig. 4



Speak-up! award toolkit

The intent of the MHA keystone centre speak-up! award toolkit is to help healthcare organizations design, implement and sustain a localized recognition program for frontline staff who speak up for patient and staff safety. The MHA keystone centre hosts a statewide speak-up! award programe, and this toolkit will help orgranizations align their own award processes with the statewide program.

Please use the toolkit to encourage staff to learn more about the speak-up! award and how to and implement it with in your organizations

Steps:

1. Identify a point person and/or team who will oversee the award administration at the organizations
   - Duties typically include answering staff questions, creating organizational awareness of the award and collecting nominaton forms for judging.
2. Decide on the frequency of the award
   - Will this be monthaly or quarterly? Quarterly award cycles are recommended to better align with the statewide MHA keystone speak-up! award programe (see appendix G).
3. Set up a submission process
   - Options include providing a simple drop box to collcet nomination forms, or having nominations email their forms to a designated point person (see appendix A).
4. Choose your selection method (potential options below)
   - Have a rotating committee of hospital staff members review the nominations and select the winner and finalists.
   - Have leadership or hospital board members review the nominations and select the winner and finalists.
   - Send an outlook poll with "buttons" for staff to review the nominations and select the winner and finalists.
5. Select and celebrate
   - Select your winner and finalists based upon your chosen method (step 4).
   - Use the newsletter template (see appendix B) to publicly recognize the winner and finalists.
   - Celebrate with a certificate (see appendix F), a pizza party or another award.
6. Nominate for the statewide award
   - Submit your nomonees to the quarterly MHA keystone center speak-up award for consideration.

Toolkit appendices

A. Nomination forms template
- Use this form as a way to retrieve nominee information prior to judging.

B. Newsletter template
- Use this template to create organizationl awareness of the award by publicly recognizing the winners and finalists.

C. Speak-up! logo
- Use the logo to create and customize your own speak-up! award within your organization.

D. Award poster
- Leverage the statewide MHA keystone center speak-up! award as a benefit of being nominated for your local award.

E. Discussion points
- Use during daily and weekly shift/unit huddles to discuss "good catches" and the speak-up! award.

F. Certificate template
- Use the template as a potential award for the speak-up! winners and/or finalists.

G. Award schedule template
- It is important to have a yarly award schedule so staff are aware of the submission deadlines foe each month/quarter. The submission deadlines are posted at the bottem of the nomination form, but a more detailed schedule of the selection process may be beneficial for staff. Included in this toolkit is the MHA keystone center speak-up! award schedule that can be used as a template. Post hard copies of this near the nomitation forms and make it available in an electronic form.

2 I MHA Keystone Center Speak-up! Award Toolkit

The Keystone Center Speaking up award toolkit[176] (©2019 Thelished by John Wiley & Sons Ltd Published online in Wiley Online Library (wileyonlinelibrary.com) (INK https://onlinelibrary.wiley.com/doi/pdf/10.1002/jhrm.21360).

Some studies have concluded that it is possible to train junior staff to voice their concerns in a clinical setting, and several factors which may increase the likelihood for speaking up have been identified.[166,170,178] A number of these factors are listed in Table 9. However, the challenge remains to create a clinical environment which ensures that speaking up is the norm. On the other hand, one study concluded that speaking-up

Table 9 Factors that may increase the likelihood for speaking up (partly based on Refs.[4,5,10])

Factors positively influencing speaking up
Seniors who encourage input from team members
Small teams and institutions with clear communication lines
Organisations that invite input from employees
Positive experiences of actual results from speaking up
Strong networks and supportive colleagues
An active approach against unwanted hierarchies
Possibilities for anonymous reporting
Expressed organisational protection from retaliations

behaviours seem to be so deeply rooted, meaning that educational interventions alone do not seem to make any change.[165]

Conclusion

Improving healthcare providers' ability for and willingness to speak up is a complex undertaking. Barriers against, and factors enabling speaking up behaviour have been identified. Just offering training in assertiveness and speaking up will fail to improve safety, if it is not accompanied by addressing the culture throughout the organisation. This requires leadership and commitment right from the top down board level to make the entire organisation take ownership and responsibility for ensuring safety, and to make everyone feel that voicing their concerns is encouraged and welcomed. Further, such behaviour should be met with an open attitude, eager to respond by making necessary adjustments or changes to ensure safety. However, we must not expect that changing and maintaining a multiprofessional culture is achieved overnight but will be an ongoing and dedicated effort for any organisation striving for safety.

Chapter 4: Learning from Excellence and Safety-II: reframing patient safety (Plunkett)

The prevailing approach to patient safety is to define safety as the absence of harm. In this paradigm, safety is considered to be a condition in which as few things as possible go wrong. Arguably, this definition is incomplete as it only considers safety from a deficit-based perspective.

Reframing is a cognitive exercise through which concepts are viewed from alternative perspectives. Reframing can be applied to patient safety, allowing safety to be considered from a strengths-based perspective: that is safety can be considered to be a condition where as many things as possible go right. This is the basis of Safety-II and a number of other new approaches to safety, including Learning from Excellence (LfE). Viewing safety from a strengths-based perspective allows new insights to appear through examination of the conditions and characteristics of success, rather than those of failure. Strengths-based approaches are intended to be used as a complementary approach to the prevailing approach.

The aims of this chapter are to put forward a case for reframing safety; to review some of the limitations of the prevailing approach to safety; to introduce the concepts of Safety-II and LfE; to review relevant cognitive considerations related to safety; to provide examples of reframing; and to highlight other strengths-based approaches, including exnovation and positive deviance.

The case for reframing patient safety

The prevailing definition of safety is incomplete

The prevailing approach to improving patient safety is to identify and eliminate harm. This deficit-based approach is on the basis of a paradigm in which safety is defined as the absence of harm. Arguably, the definition is incomplete as it only defines the condition by what it isn't, rather than by what it *is*. It reduces events in health care into two mutually exclusive states: safe and unsafe. In reality, events in health care occur across a wide spectrum from exceptionally poor to exceptionally good. The vast majority of events in this spectrum result in successful outcomes, yet the prevailing approach to safety compels all improvement efforts to be focused on the *minority* of events which lead to failure (i.e. harm or near misses).

Concentrating all efforts to improve safety on events leading to failure results in missed opportunities to learn from events leading to success. Inquiry into success can shed light on the positive aspects by which safety can be defined. Characteristics and properties of healthcare events and interactions which *create* safety come into view, and can be considered alongside those which lead to failure. Thus, strengths-based approaches are intended to be complementary to deficit-based approaches.

Limitations of the deficit-based approach to safety

Assumption of linearity

The deficit-based approach to safety adopts 'find and fix' methodologies, which aim to make systems safer by identifying harm, or potential harm, and then eliminating the causes. Flaws in a system are thus 'patched' or 'repaired'. Methodologies to identify causation of harm in health care are typically based on approaches taken from other safety-critical industries. A common methodology is Root Cause Analysis (RCA), which aims to identify root causes and contributory factors to adverse incidents or episodes of harm. This method was not developed specifically for health care. Its application in complex systems such as health care may be flawed, in part due to its assumptions about linear causation of events.[179,180] RCA requires complex systems to be decomposed to causal chains of events, aligned in a linear fashion, in order for investigators to identify why adverse events happened, and how they may be prevented in the future.

Application of this approach to health care may result in oversimplified representation of complex systems. Health care is a complex adaptive system (CAS), in which conditions and events rarely occur in a simple, predictable linear fashion.[179] Indeed, many conditions and events in health care are emergent properties of the system, and thereby unpredictable.[27]

Work-as-imagined is not the same as work-as-done

The reality of work in a CAS is often significantly different from the protocols and guidelines on which work is *designed*. The latter are often developed away from the 'sharp end' of work, and don't account for the highly variable conditions in which work is carried out. In the Safety-II literature, this protocolised and procedural depiction of work is known as work-as-imagined (WAI); and is contrasted with the real work carried out by front-line staff, known as work-as-done (WAD).[181]

The prevailing approach to investigating safety incidents typically seeks to identify deviations from protocol, by comparing WAD with WAI. Safety investigations often find that protocols and guidelines were not followed, and then assume that this deviation is the reason for the error or harm. In this paradigm, *human error* is frequently identified as a root cause or contributory factor of harm: human fallibility is considered a risk, and human performance variability is identified as something to be mitigated and reduced.[182,183] It follows that recommendations from safety investigations are often designed to reduce the variability of human performance through the introduction of constraints and guardrails. If WAD is not properly understood, the addition of constraints and guardrails may paradoxically make work more difficult, and thus less safe.[181]

Analysis of successful work, on the other hand, reveals that WAD often deviates from WAI across the whole spectrum of work: that is in success as well as failure. Performance variability is often key to create safety, rather than creating harm.[184] Therefore, WAD is often inherently different from WAI. Reconciling this difference is part of the aim of Safety-II and other strengths-based approaches to safety, such as LfE. To do this, proactive, prospective exploration of everyday work (i.e. WAD) is required, including examination of the approximate adjustments and performance variability required to create safety.

There are more opportunities to learn from success than failure

Learning from success is arguably easier than learning from failure in at least two ways: first, success is far more prevalent than failure, and therefore success presents more opportunities for learning than failure.[181] Second, there are fewer paths to success than to failure: a 'thing' can go wrong in a greater number of ways than it can go right. Therefore, understanding the causes of rare failure may yield less actionable intelligence than understanding the causes of frequent success.

Cognitive considerations

Negativity bias

Learning from adverse events is of great importance, especially for the patients and families who have suffered consequential harm. It is arguably equally important to learn from positive events (e.g. unexpected positive outcome), yet the deficit-based approach to safety does not provide a means through which this can be done. This is in part due to an innate *negativity bias*,[185] which is reflected in our (human) tendency to be drawn to the small part of the system in which adverse events occur. We are more sensitive to negative events than to positive ones of equivalent value: thus, errors and harms are simply more obvious to us than success at the other end of the spectrum. Our preoccupation with negativity in health care may be enhanced by the primary aim of health care itself – the intention of medicine is to diagnose and treat illness. This 'diagnose and cure' approach to medicine is analogous to the 'find and fix' approach used in the prevailing approach to safety.

Habituation

An additional relevant feature of human cognition is habituation.[186] Frequently occurring events become habituated in our cognition, and thus become less and less noticeable. The rare, serious adverse event is much more easily noticed against a background of everyday success. Like many features of innate cognition, this phenomenon is useful most of the time: there is simply too much data to notice everything! Through careful inquiry it is possible to temporarily overcome this phenomenon and understand what we take for granted in everyday, successful work. Thus, it is possible to shed light on insights into why things go right most of the time, and conversely, why things occasionally go wrong.

Patternicity

We have a tendency to find patterns and create oversimplified representation of complex systems (e.g. RCA).[187] It is very hard to 'see' complexity in a CAS, and thus safety investigations run the risk of oversimplification of causal chains of events.[180] Modelling systems are available to better illustrate the manifold interactions and interdependencies of multiple functions within a system – for example, the Functional Resonance Analysis Method (FRAM).[188] While these models are still an oversimplification, they have the potential to create a significantly improved depiction of WAD.

These cognitive 'programmes' (e.g. negativity bias, habituation, oversimplification) can be temporarily suspended to recognise and learn from success in everyday work in health care; and thus, significantly open the

aperture of the lens through which we can gain insights from the whole spectrum of work.

How to reframe

General approach

Reframing is an exercise in which concepts can be challenged and viewed from alternative perspectives. It creates an opportunity to scrutinise, and learn from, part of a system hitherto unstudied. Relevant examples of reframing from the patient safety domain are shown in Table 10. The table shows the contrasting, and complementary, lines of inquiry into the same issue, from different frames. This illustrates how a complementary approach can be taken to almost any issue, by revealing a different part of the system to study. In this way, the whole landscape of work, both successful and unsuccessful, can provide learning opportunities.

Practical examples of reframing safety

Safety-II

In recognition of the limitations of the prevailing approach to safety, the concept of Safety-II was introduced by Hollnagel *et al.*[181] They named the prevailing, deficit-based approach to safety, 'Safety-I'. Safety-I was contrasted with the novel, complementary concept of 'Safety-II', in which safety is considered to be a condition in which as many things as possible go right.

The application of this theoretical concept to practical work is challenging, especially if viewed from within the conventional confines of the Safety-I mindset. Reconciling the difference between WAD and WAI is one of the main features of Safety-II. A different approach is required from the backward-looking, exception reporting approach typical of Safety-I. Safety-II methods, therefore, are typically prospective, front-line-based interventions, which focus on understanding how real work is done before recommending and implementing system adjustments.

Safety-II methods seek multiple perspectives on work to appreciate the degree of complexity, along with close participation of front-line workers to gain a good understanding of WAD. Examples include a project in which central venous catheter bundle adherence was improved by redesigning the bundle protocol with insights gained from an in-depth study of WAD.[189] This is an example of combined Safety-I (identifying where bundle adherence was poor) and Safety-II (understanding how WAD actually happens, including variability and adjustments in real work) approaches, to achieve a goal of increased rate of success.

Other Safety-II methods include FRAM,[188] which can be used to create a model of a complex system to share understanding of how the various steps (functions) in a process are related. Rather than creating a linear flow diagram, FRAM results in a map through which the interdependencies of multiple steps can be visualised. Vulnerable or impactful steps can then be identified and potentially modified. An example of the application of FRAM in healthcare safety is illustrated in a study of blood sampling by Pickup *et al.*,[190] in which the authors created a FRAM model of blood sampling to illustrate how the process works successfully. Key steps were identified in which potential downstream consequences of variability were highlighted. Insights from this type of study can be used to add resilience to a complex system.

Learning from Excellence

LfE is a social movement in health care which started in 2014 in a single paediatric ICU.[191] The initiative is based on a strengths-based philosophy with two main aims: first, to gain new insights about safety by identifying and studying excellence; and second, to provide formal positive feedback between staff following excellent practice.

LfE is a complementary approach to the prevailing approach to patient safety. It arose, in part, as a response to a perception of increasing negativity associated with the patient safety industry, for which there was growing concern that healthcare staff were suffering adverse psychological consequences (referred to as second victim). In the LfE model, 'excellence' is not defined a priori, since the initiative aims to capture excellence 'in the wild' as judged by front-line staff. Reports are filed by staff members using

Table 10 Examples of reframing

Domain of health care	Definition/metric from the prevailing safety paradigm:	Safety question	Reframed definition/ metric	Reframed safety question
Health-care associated harm	Rate of HCAI	Why do some patients get HCAI?	HCAI-free patient days	Why do most patients not get HCAI?
Time-critical treatment(s)	Rate of delayed peri-operative antibiotics	Why are some antibiotics delayed?	Rate of successful antibiotic administration	Why are most antibiotics delivered on time?
Hand-hygiene compliance	Rate of failure to comply with hand hygiene protocol	Why do staff sometimes fail to comply with hand hygiene protocols?	Rate of successful adherence to protocol	Why do staff adhere to hand hygiene protocols most of the time?
Safety	A condition in which as few things as possible go wrong	What leads to failure?	A condition in which as many things as possible go right	What leads to success?
Sources of harm/sources of safety	Health care is inherently safe; humans make it unsafe	What are the sources of human error?How can human error be minimised/eliminated?	Health care is inherently unsafe; humans create safety	How can successful work be supported/enhanced/ amplified?

HCAI, healthcare-associated infection.

reporting systems that typically are juxtaposed to adverse incident reporting systems. In some centres, patients also have access to the system. Reports are forwarded privately, but not anonymously, to cited individuals or teams to provide positive feedback, to enhance learning and to improve morale and staff experience. Previous research has established a correlation between staff experience and performance of healthcare organisations, as measured by multiple performance indicators.[192]

Selected reports are investigated in more detail using appreciative inquiry (AI), a strengths-based inquiry method which originated in health care.[193] Insights from these inquiries, which may include innovative practice, are shared with stakeholders and, if practicable, adjustments made to working conditions and systems. In addition to gaining useful insights into successful work, the LfE approach aims to reinforce positive interactions between colleagues by identifying and appreciating pro-social, positive behaviours in the workplace. This unique feature of LfE addresses an important aspect of the initiative, through which a wider organisational culture could be positively influenced, for example, by increasing psychological safety.

Practical example of Learning from Excellence approach

LfE can be easily introduced through a variety of open, voluntary reporting systems. A more focused application of the initiative can also be used to drive change in a quality improvement setting. In a recent proof of concept study, LfE was used to positively reinforce clinician behaviours related to antimicrobial stewardship in a paediatric ICU.[194] Selected positive (i.e. successful) behaviours including prescribing practice and antimicrobial selection and administration were reinforced with LfE reporting and AI interviews over a period of 6 months. Rates of some positive behaviours improved throughout the study, and the primary aim of safe reduction in overall antimicrobial consumption was achieved.

Comparison of Safety-II and Learning from Excellence

A number of Safety-II methods have now been described. While LfE overlaps with Safety-II, the two philosophies also deviate in some respects. Table 11 illustrates some of the similarities and differences between the two philosophies.

Other strengths-based approaches

The current article is not as an exhaustive review of strengths-based approaches to patient safety. Other approaches include exnovation and positive deviance. Exnovation is a process through which 'hidden competence' can be unmasked.[195] The usual method employed in exnovation is observation of practitioners, typically with video ethnography. The participants then review the observations and identify and share how safety is created in daily work. Thus, exnovation is a methodology for capturing successful WAD, and can therefore be employed as a Safety-II methodology. Positive deviance

Table 11 Safety-I, Safety-II and Learning from Excellence

	Safety-I	Safety-II	LfE
Definition of safety	Safety is a condition in which as few things as possible go wrong	Safety is a condition in which as many things as possible go right	
How safety is improved	Reduction of harm, through recognising, understanding and mitigating for adverse events	Increasing successful outcome through reconciliation of WAI with WAD	Improving performance through positive feedback and positive reinforcement
Assumption of causality	Assumes a linear chain of causality ('x' leads to 'y' leads to 'z') Investigations therefore work backwards from an adverse incident	Considers health care to be a CAS, in which causality does not follow a linear, tractable course Many 'causes' are in fact emergent properties of the complex system	
Aim of interventions	Interventions aim to reduce variability, typically through increasing constraints and guardrails	Interventions aim to reconcile WAI with WAD, through sharing intelligence about WAD throughout a team/system	Interventions aim to reinforce excellent practice. Typically focuses more on process (e.g. behaviours/nontechnical skills) than outcome Reconciliation of WAI with WAD is also a feature via AI; which also serves as positive reinforcement
Analysis of successful work	Success is neither investigated nor formally recognised	All work is considered as part of WAD: this includes work leading to successful and failed outcomes	Recognises and reinforces excellent processes rather than outcome per se Excellent processes may be present in failed and successful outcomes; therefore, LfE incorporates the whole system
Tools	Adverse incident reporting Variety of 'error counting' methods – for example, trend analysis and 'rates' of adverse events and harm Investigations typically employ tools adapted from other safety-critical industries – for example, RCA	Direct observation of work-as-done (e.g. ethnographic studies), and interviews with front-line staff to reconcile WAI with WAD Mapping of complex systems using various tools, including FRAM; with the aim to identify opportunities for optimisation of functions within the system	Excellence reporting: peer (and/or patient) reporting system Appreciative Inquiry to further understand the conditions associated with excellent performance, to generate improvement ideas and to reinforce excellence

AI, appreciative Inquiry; CAS, complex adaptive system; FRAM, Functional Resonance Analysis Method; LfE, Learning from Excellence; RCA, root cause analysis; WAD, work-as-done; WAI, work-as-imagined.

is an approach to identify solutions which already exist within a system or community, but have hitherto not been fully appreciated.[196] Individual behaviours, practitioners or teams who are successful, but deviant in their practice (i.e. significantly different from their peers/community) are identified for the purpose of amplifying and spreading their successful practice more widely. This has been applied in several settings, including health care.

Conclusion

The impact of healthcare-associated harm on patients and their families is considerable, but progress on reducing rates of harm has been disappointing.[197] The prevailing approach to patient safety may be inadequate, as it only considers safety from a deficit-based perspective. Reframing allows safety to be considered from a strengths-based perspective and opens the door to alternative methods and tools to improve safety. Strengths-based approaches, such as LfE, can be used to unmask the positive characteristics of safety, many of which are behavioural, cultural and relational. LfE provides a method to recognise, appreciate and reinforce these positive factors. Safety-II is a concept from which stems multiple novel methods to improve safety through reconciliation of WAD and WAI. The challenge for the future is to integrate both perspectives to provide a balanced, holistic approach to safety.

Chapter 5: Safety from the patient's perspective (Mellin-Olsen)

The Helsinki Declaration on Patient Safety in Anaesthesiology highlights the contribution of all actors in health to improve patient safety.[1] In its Heads of Agreements, it states that 'Patients have an important role to play in their safe care which they should be educated about and given opportunities to provide feedback to further improve the process for others'. This statement seems to state the obvious. However, the reality is still different.

In recent years, the paternalistic 'the doctor knows best' attitude has changed into more of an equal partnership between healthcare professionals and patients. The Norwegian author Garborg[198] is credited to have said that *A sick man knows much of which a healthy man has no clue*. Yet, everybody who has been involved in health care for some time knows that there is still some way to go until we have utilised patients' potential to help us provide safe medical care.

There will always be some level of unequal relationship between healthcare providers and patients. Patients must rely on the competence of the healthcare system, the hospital, the physicians, the nurses, the pharma and MedTech industry, and so on, to help them. Although they are invited to make 'informed' decisions regarding themselves when possible, they will still need to rely on advice from experts.

As anaesthesiologists, we are all aware that we are safeguarding the best interests of our patients when they are at their most vulnerable. Patients need to let go of their autonomy and submit themselves to our control when they undergo anaesthetic and surgical procedures, when we care for them in ICUs or in critical emergency medical situations, and in some pain procedures. Such submission significant trust.

This imbalance also requires that the providers invite and encourage active involvement by patients. Yet not all patients are equally able to do that, as demonstrated by Doherty and Stavropoulou.[172] They found that potential barriers for patients' involvement depended on illness severity, cognitive characteristics (including language barriers), poor physician–patient communication and organisational factors (including safety culture).

Barriers for patient involvement

(1) For illness severity, there is not much we can do, except trying to optimise the situation. But we can influence the other elements.
(2) Cognitive characteristics (including language barriers): here, there is a potential to improve; for instance using professional interpreters for patients with language barriers. Family members, particularly children, should not be used as interpreters.[199] Healthcare professionals have to learn how to address patients and their families in lay terms and support them in this learning process.
(3) Poor physician–patient communication affects not only patient safety, but also the choice of appropriate treatment. Gone are the days when most patients listened obediently to doctors' orders, today's physicians more often act as health coaches or advisers to assist patients to make informed decisions on treatment strategies.[200] Patients who want decisions to be taken for them still exist, and it is our duty to identify them. The 'Four Habits' model was launched at Kaiser Permanente as early as 1999.[201] These habits are simple and seem self-evident when one is aware of them. If done correctly and consistently, the Four Habits Model will deepen trust and improve decision making in health care, which in turn will result in better health outcomes, patient satisfaction and improved patient safety (https://www.careinnovations.org/wp-content/uploads/2016/03/four-habits-monograph_new-agenda.pdf).
    (a) The first habit is 'Invest in the beginning'. A negative first impression is hard to change. A friendly handshake, eye contact and an appreciative personal comment work wonders for trust. On the contrary, it still is far too common that the physician has not read the patient's chart before the consultation. The patients should be allowed to speak freely about his condition and concerns. Ospina *et al.*[202] found that in only 20% of

encounters in speciality care did clinicians elicit the patient's agenda. The clinician interrupted the patient at a median of 11 s, yet uninterrupted patients took a median of 6 s to state their concern. If the physician is able to elicit the concern in the beginning, then it is easier to plan the consultation without missing the most important issue.

(b) Next is 'Elicit the Patient's Perspective'. There are three elements of this habit – understand how the patient assesses the condition, his expectations, and how his problems impact his life. Physicians have their own understanding and preconceptions, which might be very different from a patient's point of view. In addition, we might be in for surprises if we ask 'what matters to you' rather than 'what is the matter with you'.[200,203] Patients' trust and satisfaction is dependant not only on the outcome of treatment, but also on the perception of being 'seen' and respected.

(c) The third habit is 'Demonstrate Empathy'. The physician should catch the small hints the patient provides regarding his worries. Support and encouragement are important, but more so is that the patient experiences that the doctor tries to understand and appreciates the patient's situation.[204] We are not all good at this. In a study of consultations with lung cancer patients and their doctors, the patients presented 384 empathic opportunities, but the doctors responded with empathy only in 10% of the cases.[205] Empathy is not to say that 'I know how you feel', but rather to express 'I can see that this distresses you'. Showing empathy can prevent unnecessary visits and treatments. It would also uncover otherwise missed diagnoses, in addition to leading to greater trust and adherence to our recommendations.[206]

(d) Finally, the fourth habit is 'Invest in the End'. The clinician should inform the patients and encourage them to participate in the decision process leading to a common plan. The doctor should give reasons for the recommendations and ensure that the patient understands and agrees with that plan. One problem through the whole patient meeting, and particularly towards the end, is when the doctor is looking at his computer screen, ordering lab tests, writing his findings and so on. Explaining to the patient what he is doing can mitigate that problem.

(4) Organisational factors (including safety culture): The way doctors meet patients does not happen in a vacuum. We depend on the work environment and we are affected by leadership priorities. If leadership rewards behaviour to increase 'number of patients treated' more than behaviour prioritising delivering safe care, then that will affect our attitude. Patient outcome suffer when hospital boards do not make safety a top priority.[207] Patients expect to be treated by personnel that concentrate on them. Personnel should not be distracted by fatigue, unhealthy working conditions and other 'external' factors. Time pressure could also be a factor for less than optimal patient involvement.

Patients not only have a right, but also should actively be encouraged to speak up (see also Chapter 3) when they see that something is not right. As the Berwick report stated in 2013, based on the Mid Staffordshire scandal in the United Kingdom: *Involvement means having the patient voice heard at every level of the service, even when that voice is a whisper*. Patients see things we do not see. By being integral parts of the 'system', we are socialised into getting blind spots.[208] To elicit these blind spots, we should encourage patients to give us feedback on errors and mishaps as well as what is 'just potential for improved service'. One example is the MedStar Health platform 'We want to know', which encourages patients to give feedback.[209,210] Factors that prevent patients from feeding back if not encouraged include fear that voicing concerns will negatively impact their own care. Patients do not want healthcare providers to be blamed, they are focused on getting well, they want to focus on the future. Patients often do not know how to report and sometimes expect that reporting will not help. Yet, input from patients has been shown to improve healthcare personnel's adherence to safety routines, for instance regarding hand hygiene.[211] There are also other useful initiatives on a higher level to encourage feedback from patients, like 'the Care Opinion' in the United Kingdom, Australia and New Zealand (https://www.careopinion.org.uk/info/about). Such initiatives provide opportunities for improvement but must be followed up by optimisation to be of real value.

Patients also have a role in setting the research agenda, which is often driven by researchers' curiosity and interests. These might not overlap with what patients see as important. A consequence could be that relevant questions are not addressed, and areas of potentially useful research are neglected. Therefore, efforts like the 'James Lind Alliance' (http://www.jla.nihr.ac.uk/about-the-james-lind-alliance/) have been established, funded by the National Institute for Health Research in the United Kingdom. This Alliance offers a partnership between all stakeholders including patients and organisations to set research priorities (http://www.jla.nihr.ac.uk/about-the-james-lind-alliance/).

Patients and relatives are often placed in the same category. Relatives often are an important resource and support for the patient. In situations where patients are unable to speak up for themselves, their relatives will often speak on their behalf. Health personnel can turn to

families to understand what would be in the best interest of the patients. Yet, we must respect privacy rules. People do not always share all their personal and private information with their relatives, and we must tread carefully to not reveal information that a patient has kept to himself.

When the worst has happened, and a patient has been harmed, we have a duty to the involved persons to deal with the situation in an appropriate way. This includes open disclosure and learning from the incident to minimise the risk of the same incident being repeated. Vincent *et al.* looked into reasons why people sued doctors.[212] The most important reasons stated were not revenge and monetary compensation, but factors like preventing an incident from happening again. Patients wanted an explanation, to make the doctors realise what they had done and to admit that an error had occurred. Sometimes, doctors think it is better not to disclose everything, as it might create more 'noise': this could be defensive or protective behaviour, sometimes with good intentions. In such cases one should use the 'Australian open disclosure substitution test' described in the world's first nationwide open disclosure standard in 2003, which is now replaced by the 2013 Standard (https://www.safetyandquality.gov.au/sites/default/files/migrated/Australian-Open-Disclosure-Framework-Feb-2014.pdf). The test is simple: 'Imagine the last time something went really, really wrong. Imagine that it concerned your wife, child, mother, father instead. Imagine the conversation you would have wanted to have with the doctor, the team and the management'.

Patients and relatives understand that there is no such thing as a perfect system. What they do not understand is when providers and the system try to hide the truth, do not assume responsibility and do not use the incidents that have happened to learn so that the same thing will not occur again. People sense if something is being hidden from them. They do not like that health personnel blame each other without assuming responsibility. A sincere apology does not mean taking blame. Programmes like the CANDOR (Communication and Optimal Resolution) have proven useful to improve patient safety and satisfaction, as well as reducing legal actions and have led to economic benefit.[213] The US AHRQ states that the key learnings of the CANDOR Toolkit are to engage patients and families in disclosure communication following adverse events, to partner with patients and families on safety solutions, maintain trust with patients and families after harm events, implement a care for the caregiver programme for providers involved in adverse events, analyse an unexpected outcome to learn from it and prevent future adverse events, establish a resolution process for the organisation, enhance joy and meaning for care team members and to provide safer care to everyone (https://www.ahrq.gov/patient-safety/capacity/candor/modules.html).

Patients and healthcare providers share the same goal – that no patient is harmed under our care. Patients want to be our partners in patient safety and can contribute with insights we do not have. One of the initiatives to bring all stakeholders together for a common goal is the Patient Safety Movement Foundation, which brings together all stakeholders. One of their Actionable Patient Safety Solutions is 'Patient and Family Engagement' (https://patientsafetymovement.org/actionable-solutions/challenge-solutions/person-and-family-engagement/). Such initiatives should be utilised by policy makers to empower us together to reach our common goal – zero preventable harm in health care.

Chapter 6: Teaching patient safet the project consisted of an online survey of ESA members to determine what aspects of essional practice (Wacker, Staender)

Ten years ago, the Helsinki Declaration on Patient Safety in Anaesthesiology stated that *Education has a key role to play in improving patient safety*. . ..[1,214] Moreover, it called for improvement through research and innovation.[1] Teaching patient safety aims to improve patient outcomes – but the scientific evidence of such beneficial impact remains sparse.[215] This fact is of particular importance for this chapter, which describes approaches to teaching patient safety to medical students.

For the design and successful implementation of curricula, evidence-based contents are needed. Practical conditions, local structures and limited resources often restrict the optimal realisation of such courses. In due consideration of these limitations, this chapter presents a narrative review of published evidence, and of practical experiences with teaching patient safety. A short perspective on particular aspects of patient safety education beyond medical school is included. Hence, this chapter addresses physicians and other healthcare professionals interested in teaching patient safety to medical students. Articles were identified by searches in PubMed, and complemented by selective searches in Google Scholar as well as by a Web of Science cited reference search for articles citing the latest systematic review on the topic.[215,216] Readers interested in simulation-based skills training are referred to other chapters, and to the specific literature.

Education as a patient safety intervention

The concept of 'patient safety' used in this chapter follows a definition provided by Charles Vincent: *The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare.*[217] Acknowledging that not *all* adverse outcomes or harm may be inevitable, *preventable* harm should be the target of patient safety interventions.[218,219] From a public health perspective, formalised patient safety education programmes or curricula represent patient safety interventions.[220] The target is significant: according to a

recent systematic review, harm occurs in 20% of surgical and 34% of intensive care patients, and about 50% of this harm was considered preventable, in line with earlier reports.[219,221,222]

Origins, advancement and development of dedicated patient safety education

At the turn of the millennium, several national reports pointed to an alarming number of patient harmed in medicine, among them the IOM report 'To Err is Human' published in the United States in 2000, and the report 'An organisation with a memory' published by the UK Department of Health in 2000.[223,224] Consistently, the IOM report identified the need of integrating a curriculum on patient safety into professional training and certification requirements of healthcare professionals.[223] Subsequently, ideas about the contents and teaching formats of such curricula were developed in many countries.[225] The following trendsetting examples are just a small selection from the multitude of initiatives.

Examples of initiatives leading to patient safety education frameworks

The UEMS recognised in its 2001 Basel Declaration on continuing professional development that education is a safety mechanism.[226] In 2006, the Council of Europe passed a patient safety recommendation underscoring the importance of developing patient safety education programmes for all healthcare personnel. These programmes should be developed and implemented by educational institutions as well as accrediting, certifying, licensing, diploma appraisal and revalidation bodies.[227,228]

The Australian Council for Safety and Quality in Healthcare endorsed a National Patient Safety Education Framework in 2005.[229,230] This framework, also called 'APSEF' (Australian Patient Safety Education Framework), is an evidence-based description of the knowledge, skills and behaviours required by healthcare professionals to ensure safe patient care, and for developing educational curricula and training programmes for all healthcare workers, across all levels of responsibility.[229–231]

In 2008, the Canadian Patient Safety Institute developed Safety Competencies, a framework of interprofessional patient safety competencies (defined as 'important observable knowledge, skills and attitudes') for education and continuing professional development.[232,233] Based on the internationally acknowledged CanMEDS framework of physician competencies, and following principles of outcome-based education, the Safety Competencies framework is designed to help develop locally adapted teaching curricula.[232–234]

WHO: patient safety curriculum guides

The WHO World Alliance for Patient Safety sponsored the development of a universal patient safety curriculum guide for medical schools worldwide.[231] A team from the University of Sydney and Monash University, assisted by an Expert Consensus Working Group representing the six WHO regions, developed the curriculum guide based on the Australian APSEF as an evidence-based foundation.[231] From 22 topics in the APSEF, 16 were included in the curriculum guide topics. After regrouping, the guide finally contained 11 topics.[231] APSEF topics not included in the curriculum guide were those that would already be covered in medical school curricula, for example, consent, evidence-based practice, learning and teaching, and information technology (because of disparity in the access to technology).[231] As teaching formats, the curriculum guides suggest lectures, clinical placements, online activities, on the ward activities, small group tutorial teaching, problem-based learning, simulation/skills laboratories and traditional tutorials. Subsequently, after revision of the 2009 curriculum guide by experts from dentistry, midwifery, nursing and pharmacy, a multiprofessional edition of the WHO Patient Safety Curriculum Guide maintaining the basic 11 topics (Table 12) was finally published in 2011. Importantly, the WHO curriculum guides offer freely available and comprehensive programmes for teaching patient safety as well as resources and practical hints for implementation (https://www.who.int/patientsafety/education/mp_curriculum_guide/en/). However, these guides need to be tailored to existing local professional curricula, and to the local requirements.

After grouping the 11 topics into three major areas, the guides provide an overview of general topics like the extent of patient harm in health care, human factors, complexity of systems, teamwork and error (topics 1 to 6); methodical approaches like quality improvement or communication with patients and families (topics 7 to 8); and topics of specific clinical interest, namely infection control, safety of invasive procedures and medication safety (topics 9 to 11). The multiprofessional edition of the curriculum guide also covers all topics. Except for some of the topics of specific clinical interest, these topics are also covered (but to varying extent) by the APSEF, and by the Canadian Safety Competencies.[229,230,233]

Table 12 WHO patient safety curriculum guide for medical schools – curriculum guide topics

Topics of the WHO patient safety curriculum guide for medical schools
Topic 1: What is patient safety
Topic 2: What is human factors and why is it important to patient safety?
Topic 3: Understanding systems and the impact of complexity on patient care
Topic 4: Being an effective team player
Topic 5: Understanding and learning from errors
Topic 6: Understanding and managing clinical risk
Topic 7: Introduction to quality improvement methods
Topic 8: Engaging with patients and carers
Topic 9: Minimising infection through improved infection control
Topic 10: Patient safety and invasive procedures
Topic 11: Improving medication safety

Teaching patient safety to medical students

Implementation of patient safety curricula

Apparently, implementation of formal patient safety teaching into medical school curricula has been sporadic rather than straightforward. While the WHO curriculum guide for Medical Schools was designed to provide a universally applicable comprehensive educational approach, some local medical school curricula already contain patient safety topics, and most are filled beyond capacity.[231] Lack of time in the curricula schedules and limited availability of adequately trained faculty may pose problems.[235] In view of limited evidence of the beneficial impact of defined patient safety education interventions on patient outcomes, it may also be helpful for patient safety educators to learn from successfully established patient safety courses or curricula.

Medical student's view

How do students see undergraduate medical patient safety education? Medical students themselves have indicated a need for more attention to patient safety and quality of care.[231] A survey conducted among medical students in Hong Kong found that students knew about the risk of medical errors, but were less aware of the importance of a multidisciplinary approach to the management of incidents.[236] These students also supported an initiative for a formal curriculum on patient safety.[236] In North Carolina, more than 70% of students thought patient safety and quality improvement were equally or more important than basic science or clinical skills.[235] Regarding teaching and learning styles, this survey of medical students in North Carolina found that respondents clearly preferred 'hands-on' teaching in clinical settings about patient safety and quality improvement rather than lectures and independent studies.[235] Medical students surveyed in Singapore regarding their preferred learning style favoured discussions of real-life near misses (75.3%) and internet-based learning (69.9%).[237] Potentially, due to cultural reasons, the latter finding contrasts with the survey results from North Carolina, where computer modules were not rated being helpful.[235]

Practical experience: the Patient Safety Module for medical students at the University of Zurich

National background in Switzerland

The following account describes a course that has been successfully run for 7 years in Switzerland, and with which the authors of this chapter are involved as faculty. In 2007, a report by the Swiss Academy of Medical Sciences pointed out that the University of Geneva was the only one among the five universities in Switzerland to offer a structured module about medical errors within their medical curriculum.[238] The report called for considerable efforts in Switzerland to promote patient safety education for healthcare professionals, and stated the particular need of integrating these learning targets into the relevant curriculum: the "Swiss Catalogue of Learning Objectives for Undergraduate Medical Training" (hereafter "Swiss Catalogue").[238,239] The second edition of this "Swiss catalogue" (2008) was enhanced by a revised chapter about 'General Objectives' based on the CanMEDS 2005 Framework and on the British Curriculum for the Foundation years in Postgraduate Education and Training.[232,239] This revised chapter of the "Swiss Catalogue" chapter lists many particular learning objectives related to patient safety and quality improvement.[239]

Conception and development of the module

Against this national background in Switzerland, preparation of a dedicated educational unit for medical students on patient safety was started at the University of Zurich in 2010.[240] Concepts and contents were adapted from the WHO curriculum and the APSEF.[229,231] The course concept is also based on the idea that developing and fostering safety culture should start early during medical education.[227,238] Run without interruption since 2012, this course is performed semi-annually and continually as an elective curricular module for approximately 20 second to fourth-year medical and dentistry students.[240] The 28 hours of lessons are taught in 4-h morning sessions distributed over several weeks.[240] A high value was set on interprofessional and interdisciplinary approaches, and the course faculty includes representatives from surgery, anaesthesiology, nursing, internal medicine, infection control, clinical pharmacy, psychology, risk management and aviation.[240]

The course covers all topics of the WHO patient safety curriculum guide, and conveys basic knowledge such as patient safety concepts, epidemiology of patient harm, complexity of health systems, human factors, communication; clinical patient safety issues including medication errors, surgical errors, nosocomial infections and hygiene, diagnostic errors, handover-related patient harm and communication failures; and approaches like critical incident reporting and root-cause analysis, open disclosure, dealing with the so called second victim, clinical risk management and principles of interdisciplinary teamwork, and the 'art' of 'speak-up', among others.[240] Hands-on and simulation-based experiences are important teaching methods, for example, one morning session is performed in collaboration with Swiss International Airline (SWISS) at the Lufthansa Aviation Training Centre Switzerland (https://www.swiss.com/corporate/de/unternehmen/ueber-uns/lufthansa-aviation-training-switzerland#), and benefits from their long lasting team training experience.[240] This scenario is designed to provide a team learning experience of communicating under stress, multitasking and reaching limits of human performance.[240]

Evaluation and practice experience

The implementation and educational effectiveness of the course were monitored systematically throughout the initial semesters.[240] Pre–post surveys of the students before and after the course documented explicit learning

success regarding systems thinking, self-efficacy of applying learned knowledge, knowledge about latent errors and attitudes about patient safety. As a longitudinal assessment, students were also briefly interviewed after each session. Notably, individual student feedbacks were suggestive of fears or concerns that might have been triggered by the course topics. Although not formally evaluated for this course, providing encouraging feedback and nurturing competencies that help students with their autonomous management of such concerns may be an important educational objective for undergraduate patient safety curricula.

Beyond learning success, task sharing among faculty was also evaluated. Review of the session contents revealed multiple overlaps that were adapted to reduce redundancies. Future advancement of the course could include enhanced integration into the undergraduate medical curriculum to reach more students. Meanwhile, the current concept has attracted interest in the patient safety community: in 2014, the course was awarded the third prize of the German patient safety award offered by the German Coalition for Patient Safety (https://www.aps-ev.de/archiv-dpfps). The justification for the award stated that the novel patient safety teaching module for medical students had resulted in measurable improvements in participants' safety consciousness. In addition, the experience gained at the University of Zurich with this course concept was incorporated into a proposal for a corresponding curriculum at German Universities.[241]

Perspective beyond medical school: teaching patient safety to residents and to specialist physicians

Interdisciplinary and multiprofessional patient safety education in professional practice

The core contents of the WHO curriculum guides are also very useful for the diverse and less formalised ways of teaching patient safety to residents during specialist training, and to specialist physicians during continuous medical education. However, most important patient safety challenges have an interdisciplinary and multiprofessional nature, and some patient safety education frameworks specifically address multiprofessional audiences.[229] For example, the APSEF addresses everyone working in the Australian healthcare system, irrespective of their position or role within an organisation.[229] Practically, the comprehensive synopsis provided by patient safety education frameworks needs to be adapted and tailored to the circumstances of the local education structures, and to the priorities of individual healthcare professions. Intrinsically, the *interprofessional* dimensions of patient safety challenges call for *interprofessional* patient safety education interventions, faculty, and multiprofession course audiences, respectively.[240,242,243] Locally established traditional education structures and differing curricula and certification requirements of different professions may make such approaches more difficult.

Examples of patient safety education interventions addressing interdisciplinary challenges

Many patient safety interventions or courses address patient safety issues that have an interdisciplinary and/or multiprofessional nature. As outlined above, this does not always imply that courses are given for multiprofessional audiences. The first example is teaching communication algorithms, for example, to anaesthesia providers, to enable them to speak up.[244] According to a recent review, educational interventions are essential to improve speak up behaviour, but the interventions as such are not enough, and other institutional changes need to occur as well.[245] As a second example, educational interventions have been used to improve event reporting by residents and medical students in anaesthesia.[244] Although such interventions have been found to improve reporting, the duration of this effect remained unclear.[244] As a third example, team training interventions are widely used. For instance, the TeamSTEPPS intervention has been related to significant decreases in medication and transfusion errors,[244] and the Veteran's Affairs Medical Team-Training to a reduction in mortality.[244,246] As a fourth example, evaluations of teaching clinical handovers have yielded inconsistent results: such interventions have resulted in improved quality of handovers, improved information transfer, and in reductions of selected complications in the ICU.[247–250] However, a systematic review concluded that more methodologically robust studies were needed to establish the effectiveness of handover interventions for improving patient outcomes.[248]

Patient safety education provided by professional societies: European Society of Anaesthesiology

Professional societies are particularly important for realising patient safety education activities.[223] Their activities complement courses and curricula organised by teaching institutions (e.g. fellowship programmes), hospitals and many other organisations.[251] As a supranational society, and in line with the Helsinki Declaration on Patient Safety in Anaesthesiology, the ESA has a long-standing commitment to organising respective teaching activities through its PSQC (https://www.esahq.org/about/committees/patient-safety-and-quality-committee/). Among these activities, the European Patient Safety Course has been run for many years; a new version is in preparation.[214] As an online learning resource, ESA offers the Patient Safety Starter Kit (http://html.esahq.org/patientsafetykit/resources/index.html). In addition to an extensive scientific patient safety education programme during 'Euroanaesthesia' (the annual congress of ESA), the fifth edition of the ESA Patient Safety and Quality Masterclass has been held in 2019 (https://www.esahq.org/patient-safety/patient-safety/european-

patient-safety-and-quality-masterclass). In collaboration with the ASA, ESA organises the semi-annual International Forum on Perioperative Safety & Quality (ISQ: https://www.asahq.org/ifpsq).

Outside Europe, the Anesthesia Patient Safety Foundation (APSF) Stoelting Conference in Phoenix, Arizona, is an important, focussed meeting on anaesthesia-related patient safety issues (https://www.apsf.org/event/apsf-stoelting-conference-2019/). Other patient safety education events have been summarised before.[225]

Examples of innovative teaching concepts in undergraduate and postgraduate patient safety education

In view of changing the learning habits of new generations of medical students, the use of serious games has been proposed as being helpful for identification of gaps in patient safety training, and to raise patient safety awareness.[252]

Furthermore, a patient safety teaching tool for medical students during paediatric clerkships called 'Patient Safety Morning Reports' was developed: students were asked to write up patient encounters that included a patient safety concern or an adverse event. These observations were discussed in a safe environment with faculty experienced in patient safety and quality improvement, and led to improved knowledge and ability to identify lapses, and to propose potential solutions.[253]

As an example for 'teach the teachers' approaches, residents have been successfully integrated as teachers in a patient safety curriculum for medical students.[254] The preclinical students in this setting valued the interaction with residents as teachers as a 'near-peer involvement', while simultaneously the residents gained experience in teaching and leadership.[254] Senior doctors have been successfully recruited to engage in teaching patient safety to trainees during 'lessons learnt' sessions using incident analysis. Their preparation consisted of a half day course in patient safety theory, RCA and small group facilitation.[255]

Evaluations of patient safety education interventions and curricula

Assessing learning outcomes

Patient safety education interventions ultimately aim at improving patient outcomes, but not all studies investigating the effectiveness of such interventions can be funded and designed to finally measure patient outcomes in clinical practice. Learning outcomes can be evaluated using Kirkpatrick's levels of evaluation in the modified version adopted by the Best Evidence Medical Education collaboration (Table 13).[215,256]

Formal evaluations of patient safety teaching curricula

An evaluation study followed the implementation of the WHO curriculum guide for medical schools after its publication.[257] Investigating ten medical schools in all WHO regions, the study found that parts of the WHO curriculum guide had been implemented in medical school curricula across the world within 18 months, that the WHO guide was an important resource for faculty, and had led to improved knowledge and attitudes among students.[257] However, it also pointed to the importance of time requirements, and found that in many cases the teaching was delivered by the lead tutor alone or with few additional faculty.[257] Another study assessed the learning effect of teaching interventions among nurses.[258] Despite significant increases in subscales, no impact of the educational intervention on participants' knowledge and attitudes was observed.[258] A 'strengths, weaknesses, opportunities and threats' analysis of integrating the WHO curriculum guide into undergraduate medical education in Pakistan identified a lack of a patient safety culture as the primary obstacle, and called for regulatory support.[259] A Chinese study investigating the effects of a patient safety course compiled from the WHO curriculum guide for medical schools and elements related to frequent adverse events in Chinese clinical practice found no significant effect on safety attitudes, but remarkable influence on knowledge.[260] A survey-based evaluation in 2016 found that implementation of the WHO curriculum guide for medical schools and of the multiprofessional edition in low-income and middle-income countries were at consideration or planning stages, rather than actually implemented.[261] As common barriers, the study identified obstacles at the faculty level, for example, lack of collaboration and of sufficient training to address implementation challenges, lack of governmental and institutional support which resulted in lack of on-going financial support, among others.[261] Furthermore, it would be important to know more about the cost-effectiveness of patient safety education interventions to justify their costs. Cost-effectiveness has been analysed for Crew Resource Management training.[262] However, with the current literature search, no comparable studies of patient safety education interventions for medical schools could be found.

Table 13 Kirkpatrick's levels of evaluation adopted by the Best Evidence Medical Education collaboration

Evaluation of learning outcomes[256]
Level 1: Participation in educational experiences
Level 2A: Change of attitudes
Level 2B: Change of knowledge and/or skills
Level 3: Behavioural change
Level 4A: Changes in professional practice
Level 4B: Benefits to patients

Systematic reviews

Nie *et al.*[263] included seven studies investigating patient safety education for undergraduate medical students. They reported mostly positive effects on knowledge, skills, and attitudes, but pointed to the limited design

of most studies.[263] Wong *et al.*[264] investigated effects of 41 quality improvement and patient safety curricula for medical students, residents or both. They reported that most curricula were well accepted and improved knowledge, 32% of curricula implemented local change in care delivery, and 17% even improved processes of care.[264] The review also identified sufficient faculty as a 'facilitator' for implementation.[264] Kirkman *et al.*[215] reviewed 26 studies of patient safety education interventions for trainee physicians and medical students. Most of the training courses were well accepted and improved knowledge, skills and attitudes, and some courses also resulted in positive behaviours. However, no patient benefits were reported.[215] Implementation was affected by availability of faculty, competing curricula or service demands, as well as by institutional culture. The authors concluded that more evidence of the impact of patient safety education interventions on actual patient outcomes is needed.[215]

Current challenges, ideas for improving patient safety education, and research agenda

As long as an evidence-based gold standard for teaching patient safety is missing, debates about the optimal course contents and formats will likely continue. Current controversies include new developments in health care which may create new risks, and so the inclusion of new topics into patient safety curricula must be constantly considered. For example, while digital health care may open new opportunities, new sources of error may also lead to new risk potentials.[265] There are manifold ideas about priorities regarding the conceptual contents and practical realisation of patient safety education: On the one hand, there are voices calling for better evidence of a beneficial impact of patient safety education interventions on actual patient outcomes,[215] and for emphasising preventable harm as an educational topic.[219] On the other hand, integration of the Safety-II approach into patient safety education is promoted: in a recent publication, Sujan *et al.*[266] suggested revising the WHO curriculum using resilient healthcare principles and Safety-II thinking either by adding a dedicated module to the curriculum, or by integrating these principles systematically into a revised version. Concerns have been raised regarding gaps between course contents and the realities of every day clinical practice that may interfere with optimal learning.[264,267] Such gaps may be caused by the unclear roles of learners, rotational models of training and a shortage of expert faculty: an expert conference called for better integration of patient safety and quality education with clinical care delivery.[267] Many questions of course accreditation and certification are subject to local or national regulations. To our knowledge, and despite the existence of well established patient safety education frameworks and local or national courses, there is no generally accepted or multinational modular course system related to patient safety education for medical students, for example, like the Advanced Cardiac Life Support certificate course.[268] Methodologically sound research is needed to establish additional evidence of impact on patient outcomes, and of the sustainability of such interventions.[215]

Conclusion

Teaching patient safety is one strategy to reduce preventable patient harm. It remains an exciting area where improvements can be pioneered, and where close collaboration between teachers and learners is necessary. Several curricula for medical schools have improved *learning* outcomes, but evidence supporting beneficial impact on *patient* outcomes is still largely missing. In view of this limited evidence, developing patient safety curricula adapted to the *local* medical requirements as well as measuring learning effects *locally* remains important. The on-going quest for improving patient safety education should prioritise evidence-based contents as much as possible.

Chapter 7: Multidisciplinary simulation for patient safety training: putting human factors theory into action (Neuhaus)

Simulation to educate practitioners

Around 30 years ago, medicine started to explore the use of simulation to educate practitioners about human factors.[269,270] Modelled after experiences from the aviation industry, training programmes were created to address various cognitive and social competencies that were identified as, or presumed to be, relevant and essential for the safe provision of peri-operative care. These oftentimes called 'nontechnical skills' (NTS) were meant to complement traditional skill-based medical education, and their training concepts resemble evolutions of the initial 'Cockpit Resource Management' programmes in the aviation industry.[271–273] Subsequently, more differentiated frameworks such as 'Anaesthesia Crisis Resource Management (CRM)' or 'Emergency Medicine CRM' have emerged over the years.[269,274] Initially, simulation-based training programmes were established for emergency teams (e.g. trauma teams or cardiac arrest teams). Later the benefit of training healthcare professionals in recognising and treating the critically ill patient on the internal medicine or surgical ward has been recognised.

Terminology

It is important to note what almost amounts to an amalgamation in terminology in regard to human factors interventions. Significantly, the terms 'CRM' or 'CRM training' have become often-used synonyms for a multitude of training concepts. While not automatically tied to simulation, most human factors training programmes in health care today employ both high-fidelity and low-fidelity simulation to teach and train CRM principles.[275,276] Moreover, a certain overlap exists between the terms NTS and CRM, to the point where the original authors talk about 'NTS/CRM training' (for further

Table 14 Comparison of elements in the anaesthesia nontechnical skills system and the crisis resource management system[282]

ANTS	CRM
Cognitive and mental skills	
Planning and preparing	Anticipate and plan know your environment
Prioritising	Exercise leadership Set priorities dynamically
Provide and maintain standards	Use cognitive aids
Identify and use resources	Distribute workload mobilise all available resources
Gathering information	Use all available resources
Recognising and understanding	Allocate attention
Anticipating	Anticipate and plan
Identifying options	
Balancing risks and selecting options	Prevent and manage fixation errors
Re-evaluating	Re-evaluate repeatedly
Social and interpersonal skills	
Coordinating activities with team	Communicate effectively, teamwork
Exchanging information	Communicate effectively
Using authority and assertiveness	Exercise leadership and followership
Assessing capabilities	
Supporting others	Exercise followership

ANTS, anaesthesia nontechnical skills; CRM, crisis resource management.

information, refer to Table 14).[277] One explanation lies in the fact that both terms can describe general areas of interest for human factors research. NTS has been defined as 'the cognitive, social and personal resource skills that complement technical skills, and contribute to safe and efficient task performance'.[277] The NTS encompass the cognitive skill areas 'situation awareness' and 'decision-making' as well as the social skills 'communication', 'cooperation' and 'leadership'. Behavioural marker systems have been developed for a wide variety of healthcare specialties like Anaesthetists' Non-Technical Skills (ANTS) or Non-Technical Skills for Surgeons, but have also been adapted for certified anaesthesia nurses (N-ANTS) and operating room nurses (SPLINTS).[278–281]

Application and effect

Over the last 25 years, simulation-based CRM training in health care has raised awareness about the influence of human factors in medicine, and generally contributed to positive attitudes towards patient safety and CRM training.[282,283] As a speciality, anaesthesiology has been at the forefront of developing and promoting simulation-based education for the development of clinical skills and improved teamwork, as well as disseminating human factors and quality improvement science.[284]

The basic didactic concept of simulation-based medical education is that participants engage in a pre-scripted scenario that is managed up to a predetermined endpoint. This is followed up with a debriefing session facilitated by trained faculty, often supplemented with audio/video recordings, to promote reflection and feedback among the participants.[285] If managed well by the instructing staff, the ensuing interaction between participants, as well as emotions spurred by the simulation, can be harnessed to enhance learning and increase training effectiveness. While different debriefing techniques exist, one cannot overemphasise the importance of high-quality standards and professional development of the debriefing faculty: instead of mere teaching, their role is to promote learning by stimulating critical self-reflection among participants and steer their discussion while striking the fine balance between the delivery of constructive critique and the maintenance of psychological safety.[282,286]

While simulation as a training modality can take on many different forms (e.g. full-scale simulation of clinical environments, role play, standardised patients), it has been shown to be incorporated in roughly 2/3 of team training programmes.[275] The basic assumption is that simulation can offer a sufficiently realistic yet safe learning environment in which stress, ambiguities, time-pressures and goal conflicts of daily practice are mirrored, and where new skills, behaviours and strategies can be experienced and trained without endangering the patient.[271] In addition, critical situations that cannot be trained in the clinical setting, such as anaphylactic shock or the unexpected difficult airway, can be trained in the simulated setting. While not exclusively tied to positive training effects or a measurable reduction in mortality and morbidity, results indicate that simulation can greatly supplement and enhance the effect of training programmes.[287] The most sensible approach seems to be one where simulation training is incorporated into a broader curriculum for residents in training and for healthcare teams to achieve sustainable results. Effect of simulation-based training on learning is easier to show at the individual level than on the team level, even though behavioural marker systems have been developed for specific teams (e.g. Observational Teamwork Assessment for Surgery).[282] Ideally, simulation training is coupled with further peer support and learning opportunities during daily practice to build a comprehensive bundle design supporting a systems-based approach to patient safety.[287] As a sufficiently large amount of proof-of-concept studies (as in 'does simulation work?') has been published, researchers are advocating for a shift towards more granularity as to how and why simulation has certain effects.[276]

More recently discussed issues concern the specific design principles regarding multidisciplinary simulation in an effort to maximise its utility and effectiveness. Heavily intertwined are questions about the influence of the setting, which can be either in situ in the actual work environment or off-site in a simulation centre. Moreover, training concepts have started to incorporate unannounced in situ 'drills' to complement traditional, scheduled training interventions.[288,289] In a comprehensive review, Sørensen *et al.*[290] recently compiled and discussed various advantages and disadvantages of different training designs (Table 15). From a learning

Table 15 Influence of various aspects of simulation-based medical education on the physical simulation setting (from 288)

	Off-site simulation in simulation centre	Off-site simulation in-house in department	In situ simulation announced	In situ simulation unannounced
Less risk of cancellation due to heavy patient load	++	++	+	o
Reported to promote better involvement of all postgraduate healthcare professionals	o	+	+	+
No risk of staff being called away for clinical work	++	+	o	o
Does not require travel time; accessibility for staff easier	o	++	++	++
Popular and promotes recruitment of postgraduate healthcare professionals	o	o	+	+
Not described as anxiety provoking	+	+	+	o
May potentially give a greater feeling of safety psychologically	+	o	o	o
Enhances individual learning	+	+	+	+
Enhances team learning	+	++	++	++
More time potentially set aside, especially for debriefing	++	+	+	+
Ideas for organisational changes brought back to the organisation (latent patient safety issues)	o	+	++	++
No potential risk of safety hazards due to mixing up medical equipment and utensils	++	+	o	o
No potential risk of unintentional involvement of patients and relatives	++	++	+	o
More efficient use of simulation equipment, which can be shared by many departments, and better facilities to ensure efficient use of high-tech simulation equipment	++	o	o	o
Potentially more efficient simulations due to development of simulation curriculum	++	+	+	+
Easier access for technicians if simulation equipment has technical problems	++	o	o	o
Team-based and low-tech simulation can be cheaper due to use of local facilities and equipment	o	+	++	++
Potentially more efficient simulations due to better training of simulation instructors	++	+	+	+

o Indicates that the item has little or no effect; + that the item can have an effect; ++ that the item can have a strong effect[288].

perspective, announced in situ simulation is more favourable than unannounced. However, one key characteristic of any type of simulation-based education remains the clear definition of learning objectives at the individual, team, and organisational level.[291] This is of utmost importance in a multiprofessional setting, where a multitude of curricula have to be aligned, and different participants from various specialties need to be included in a simulation scenario.[292]

Limitations and criticism

While favourably received in general, several issues have been critically appraised in the literature with regard to multidisciplinary simulation training. One issue concerns technical limitations and their possible effects on participants and their learning experience. Another addresses the reality of limited resources in medical education: it has been questioned if profound weaknesses that are discovered in training can be adequately reviewed, given their ensuing potential professional and psychological consequences, or are likely to be glossed over.[293] There is clearly a need for preparing the participants as thoroughly as possible for the simulation-based training using e-learning, video or written material as well as developing initiatives that can facilitate the implementation of learning in daily tasks. From a financial perspective, it remains to be determined which educational activities can be stopped if simulation-based training is finally implemented.

In a critical review, Salas *et al.*[294] point out a lack of standardisation of human factors content across various domains, which is potentially confusing for practitioners if not carefully adapted to the respective setting and speciality. A review on the impact of CRM training by the same researchers could only find partial support for its effectiveness: there seems to be a limited influence on teamwork attitudes as well as demonstrated behaviours, as well as a certain 'ceiling effect' related to trainees' experience.[269,283] Moreover, we currently have little to no standard for faculty qualification in regard to human factors in health care. In a review of 48 studies on team training in health care, Weaver *et al.*[275] report that '[n]one of the studies provided meaningful details regarding how trainers themselves were prepared to train teamwork skills or explicated the skills sets important for trainer effectiveness'. In addition, the evidence for so-called train the trainer activities is very limited. Especially due to the growing commercial availability of a variety of training concepts, the literature suggests that individual needs are only rarely established for training development and implementation, thereby supporting a 'one-size-fits-all' approach to team training.[275] It has been reinforced that careful adaptation to local culture and context have to be considered as prerequisites for successful teaching and learning practices.[295] In an attempt to improve these limitations, the development of the Debriefing Assessment for Simulation in Healthcare tool is intended to address the need for a debriefing assessment based on a behaviourally anchored rating scale.

On a more conceptual level, it has been suggested that research contributions from social sciences are partially being excluded from the current discourse on patient safety and human factors training.[296,297] With much focus on individual skills and behaviours that are subsequently extrapolated to the team level as a unit of analysis, it has been cautioned that complex, systemic issues are

effectively obfuscated while much of the responsibility for undesired outcomes is pushed towards the 'sharp end' in an act of responsibilisation.[298] Instead, it has been suggested to position team training in a wider, more comprehensive context of resource allocation and systems redesign.

Conclusion

Medical simulation training has come a long way since its first inception several decades ago, especially with the development and integration of multiprofessional curricula into comprehensive training concepts. As an indispensable tool for the education of practitioners in human factors principles, simulation can provide the canvas for modern concepts of patient safety training in anaesthesiology. Current limitations can be overcome by careful training conception that incorporates contemporary advances in safety science in combination with increased efforts of faculty development and standardisation.

Chapter 8: Care transitions, handovers and continuity of peri-operative medical care: recent developments and how to train residents and staff (Østergaard)

Patient handovers are 'situations where the professional responsibility for some or all aspects of a patient's diagnosis, treatment or care is transferred (hand over, hand off) from one healthcare professional to another on a temporary or permanent basis'.[299,300] Peri-operative anaesthesia care transitions (Fig. 5) involve changes in the level of monitoring or staff attendance, and changes in environment. According to the WHO, care transition is a high-priority patient safety issue because it can, for example, result in delayed treatment and increased morbidity if done improperly.[301,302] Several countries have implemented WHO recommendations and incorporated them in national care transitions strategies. They also are part of the Helsinki Declaration on Patient Safety in Anaesthesiology.[303]

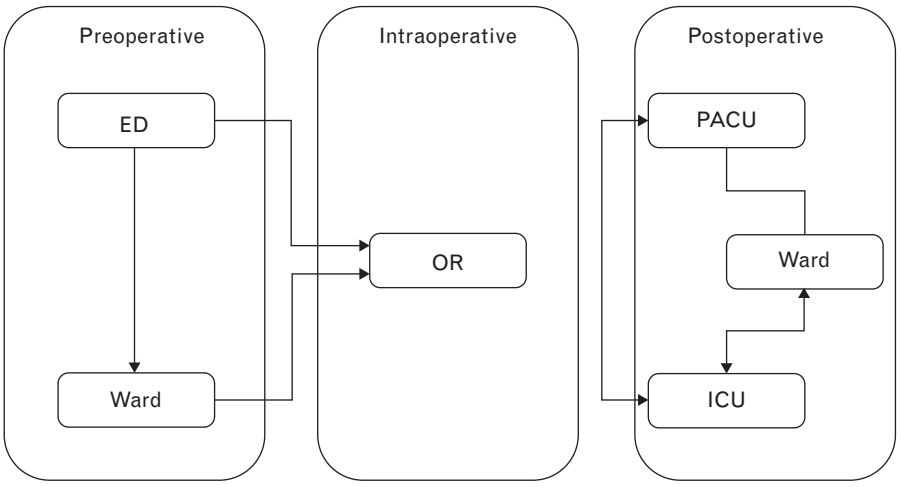
Handover used to be seen as a simple information and communication issue. Numerous detailed communication tools have been studied and developed, but many remained difficult to implement because they went into too much detail.[304] User-friendlier tools have been developed, such as the SBAR tool (situation, background, assessment and recommendation) used by nurses when calling a doctor.[305] But even though intended to support written and verbal communication, they failed to sufficiently mitigate the risk of misinterpretation and fixation errors. Actually, even an 'ideal' handover tool might not be able to improve handover quality and prevent incidents because they are context and culture dependent.[306] Care transitions are complex activities that involve multiple professionals, each of which has their own way of working (culture). Co-ordination of individual processes and activities therefore is important.[307]

The current chapter reviews the factors that affect peri-operative handover; highlights the anaesthesiologists' role in patients' peri-operative transition and shifts; provides an example of a context-specific design process to analyse handover processes and implement changes; describes how to train anaesthesiologists; and provides recommendations for future studies.

Factors of importance for a safe handover

Poor handover has been related to problems with communication, information, organisation, infrastructure,

Fig. 5



An overview of the most prominent peri-operative care transitions, where the anaesthesiologist is involved. Arrows mark respective handovers. ED, emergency department; PACU, post operative care unit; OR, operation room.

professionalism, responsibility, team awareness and culture,[299] for which the following solutions have been offered: information transfer, shared understanding, working atmosphere and teamwork.[299,308,309] These are reviewed in more detail.

Information transfer

A handover protocol in-and-by-itself does not solve the challenges of a handover, but it could be one element in a bundle of measures to improve patient safety.[310,311] Poor design, inadequate training, poor integration and cultural barriers may cause 'checklist fatigue', which may be avoided by tailoring checklists to the specific needs of the users and the environment in which they will be used.[312] Even though information transfer may have been deemed sufficient during the initial transfer, it may later turn out to have been incomplete if the missing information only becomes clinically relevant later. This limits the significance of studies that only evaluate the quality of the handover immediately after the handover process.[309,313] Because electronic patient records already provide up to date patient information, only that information relevant to the patients' actual care has to be verbalised during handover. Still, it is important to understand handovers are a combination of written and verbal communication.

Shared understanding

A shared perception of the handover situation (shared mental model) by the different health professionals that are involved is important for patient safety.[314] Nurses have a specific interest in vital parameters, laboratory data and treatment, whereas doctors focus on patients' disease trajectories and try to anticipate problems.[314,315]

These differences between different professions' interests and behaviour need to be taken into account during handover. In addition, the receiving team has more information-seeking behaviours, for example, requesting explanations and asking for predictions or anticipated problems, especially if the assessments were not volunteered by the transferring team.[316] The time of the handover is the time to pause, to ask questions, to detect errors, and to confirm critical information. A handover has an educational function for the team members – a possibility to share information about concerns and possible patient trajectories. Studies in other domains have addressed the importance of such a 'question and answer period' to detect errors in assessments and plans.[317]

Working atmosphere and teamwork

Care transition involves health professionals from different professions and specialties, which brings individual knowledge, skills and attitude into the team. The organisational culture will be a mix of the individual culture of these professions and specialties. A mature patient safety culture entails participation of all parties in decision-making and giving all involved a chance to speak up. Such culture has been associated with a wide range of positive patient outcomes such as reduced mortality, falls and hospital-acquired infections, as well as improved patient satisfaction.[318]

The question 'what makes a good handover' overlaps with the question 'what makes teamwork effective'.[302] Communication, collaboration and leadership are important aspects of teamwork. The team members must be able to adapt to changes in the situation – from a routine noncritical to a critical situation. A shared understanding of team tasks and roles as well as mutual respect and trust is essential for good teamwork.[307] Task-related, situational and organisational factors can influence safe performance of teams in high-risk domains such as health care.[307,308] Resources, like space and staffing level and competence, as well as patient volume and flow can differ, and time pressure, interruptions and distractions have a significant influence on task management within teams.

The anaesthesiologists' role in peri-operative patient handovers

Anaesthesiologists are part of different care transitions during the patient's journey (Fig. 5): transitions take place in various institutions involving different procedures, context (acute vs. elective) and organisation of work (number of team members, direct or phone contact).

Handover in the emergency department

The risk of miscommunication when transferring care for the acutely ill patient from the ambulance crew to the receiving emergency department (ED) team is high. Both teams do not necessarily have a shared mental model or understanding of different tasks. Cultural and organisational aspects might contribute to gaps. Ambulance crew and the ED nurses work in different contexts and might have different perspectives on how and what information needs to be transferred. Some information might not be useful for the immediate treatment but may become valuable for other professions later.[319] The anaesthesiologist can be part of the emergency medical services (EMS) that bring the patient to the ED or may be taking over the patient as a member of the trauma and medical emergency team in the ED. The anaesthesiologist will often be involved in the immediate care of the patient, while simultaneously providing or receiving important information. This might result in a conflict and it is recommended that essential information is delivered immediately, and supplementary information later, after the initial treatment.[320] Distraction and lack of training in handover and non-technical skills (NTS) can contribute to poor handovers. Organisational factors may also affect the quality of handover in the emergency care pathway.[321] The health professionals' experience, competing organisational demands and priorities such as patient flows and time-related performance targets might

also affect the quality of the handover. For example, the EMS anaesthesiologist might have to trade off delaying patient departure from the ED against providing patient important information to another health professional.

Handover from the surgical ward or ICU to the operation room

In the operating room, the WHO surgical checklist is widely used. Handover from the ward to the operating room is less structured.[19] Challenges have been identified in several of the steps prior to entering the operating room.[322] Most communication failures (62%) occur in the pre-operative phase.[323] Three types of failures are described: source, transmission and receiver-failures, all of which had an impact on patients, healthcare team or organisation.[324] A generic checklist developed to facilitate this care transition resulted in only minor improvements 12 months after its introduction, maybe because it was too comprehensive.[325] Handover from the ICU to the operating room remains poorly studied.

Handover during surgery

It is safe to have an anaesthesiologist give a short break to a colleague during surgery.[326] In some cases, the relieving anaesthesiologist detected an error, resulting in better care. In contrast, complete handover of anaesthesia care during major surgery was associated with a higher risk for adverse postoperative outcomes compared with no handover.[327]

From the operating room to the postoperative care unit (PACU)

Postoperative handover in the PACU is a complex and dynamic process because it involves multitasking: simultaneously providing information to the PACU nurse, moving equipment and taking care of the patient. It also represents a 'step down' from an anaesthetist taking care for only one patient to a ward with a nurse taking care of several patients.[328] The pressure to maintain short turnover times in the operating room may be one of the main reasons for this difference: the anaesthesiologist is making a trade-off between taking the time to handover a patient and going back to the operating room to prepare the next patient. A systematic review recommended analysing the challenges in the local setting and customising solutions to fit the specific context. NTS of all staff members play a significant role.[322]

From the operating room to the ICU

During operating room to ICU handovers, the patient may be critically ill or may have just undergone major surgery and may be receiving circulatory or ventilatory support while being extensively monitored.[313] The risk of technical problems is increased. The handover team may consist of different professions and specialities. A structured handover has been shown to decrease communication and task errors, specifically information omission.[313,329,330]

From the PACU or the ICU to the ward

When the patient is transferred from the PACU to the ward, the sender (anaesthesiologist) and receiver (ward nurse, ward physician) my not meet in person – it may be done by phone before the patient is transferred. Expectations about the content of this communication have been frequently reported to be inconsistent. The sender primarily provides information about vital signs, eager to demonstrate that the patient is in a stable condition. The receiving nurse is more interested in pain control and whether the patient is allowed to get out of bed.[331] The most vital information should be presented first, and the remaining information should be brief and relevant.

The transfer of a patient from a highly staffed, technology-intensive ICU to a general ward that does not have the same observational level poses several patient risks. Whether a handover tool improves patient safety remains poorly documented because of study heterogeneity.[332] Providing the patient and the relatives with a written summary before transfer might improve safety.[332] A liaison nurse may improve communication between and participation of all members of the care team of the two departments. An electronic 'attend-to' follow-up list rather than a 'check' list has been proposed to mitigate the risk patient transfer from the ICU to the ward.[333]

A context-specific handover design process

Healthcare professionals may not understand their individual roles and responsibilities and often blame others for problems experienced during handover (Table 16).[331] This suggests a shared understanding of the role and the needs of each professional is critical. The sender needs to understand what information the receiver needs before taking responsibility for the patient, and the receiver needs to understand the context in which the sender works. It is important that one views oneself as part of a larger team while working in different settings.[334]

How to train residents and staff

Residents

There is no consensus among anaesthesia residents on how to conduct a handover. They found the impact of lectures and written material to be limited and preferred directions by their supervisors.[335] They felt most comfortable doing a handover in a one-to-one situation (e.g. to a nurse in the PACU) rather than to a group of health professionals.

The Accreditation Council for Graduate Medical Education requires that residents be competent in handover communication,[336] and guidelines have been published.[337] To evaluate and entrust residents to perform handover, in-training assessment of a handover situation might be useful.[338] Such training reduced medical errors by paediatric residents from 33.8 to 18.3%.[339] A tailored e-learning programme to improve handover is available, but the programme did not improve the adherence to a guideline.[340] Simulation-based training (locally in the

Table 16 Brief overview of steps in a context-specific handover design process[331]

Context-specific handover design process
Engagement of leaders before – during and after the pilot phase.
Choose a facilitator whose main task is to lead the team members and make them understand the steps in the process, be curious of all perspectives, and keep the good tone, helping team members understand each others' frames and actions instead of blaming
Establish an interdisciplinary team of staff members from all involved departments to work with the given handover throughout the process supporting the implementation in collaboration with the facilitators – anchoring
Involve other staff members in the development and iterative process of the context-specific handover, bringing all involved perspectives in the given handover situation together
Acquiring knowledge about the handover situation using a broad range of methods; that is observations, interviews and/or tabletop simulations to identify strengths, weaknesses and variables of 'work-as-done'
Suggest a context-specific handover structure in accordance with 'work-as-done'
Conduct training activities to support the change/implementation in the context-specific handover. The learning objectives should involve communication and team awareness and can be trained using simulation and debriefing

department or in simulation centres) is increasingly used to train both the sender and the receiver.

Team training of staff

Training of staff is needed to get a shared understanding of the handover situation, of the different needs of the sender and receiver, and of the challenges in care transitions, where a team member often is distracted or interrupted. Training has to address the vulnerability of the handover situation and involve learning objectives related to a specific handover.[341] The debriefing after the simulation-based session is particularly useful.

The essence of the existing literature and the way forward

Because most research on handovers has been limited to one speciality,[342] there is a need for a broader view: we need to distil common problems and separate them from speciality specific ones. There is a need for a patient-centred approach.[342] We have to listen to valuable information from patients and relatives and involve them in our research.

An analytical framework for investigating the contextual, organisational and sociocultural aspects of care transition is needed. At the conceptual level, many studies have focused on protocols and guidelines, both of which are characteristic of what is known as Safety-I thinking: if we all follow the rules, the system will be safe-behaviour also referred as 'work-as-imagined'.[181] But peri-operative care is characterised by changing demands and finite resources, which implies that healthcare professionals have to prioritise tasks,[343] and make many trade-offs that involve risk assessments based on their experience and their understanding of the situation. In other words, 'work-as-done' is often different from 'work-as-imagined'.[181] It is, therefore, important to understand how everyday work functions and why there is variability. Changes in procedures should not be based on how we 'imagine' the work is or should be done, but on understanding of 'work-as-done'.

To improve our understanding of the different handover situations, we need to look at the individual, team and organisational level. Study methods have to evolve: besides handover observations and interviews, video recordings, in situ simulations in the clinical setting, and scripted scenarios in a simulation centre might be useful to better analyse the causes of poor and good handovers. Finally, we need to study how changes can be successfully implemented in an organisation.

Conclusion

While a structured peri-operative handover is useful and can improve communication, its content alone does not suffice to ensure a safe handover. A proper understanding of context and organisational factors is equally important. Care transitions are complex activities and it is crucial to understand how everyday work functions ('work-as-done' vs. 'work-as-imagined'). Organisational factors may force healthcare professionals to make trade-offs when handing over a patient. For safe peri-operative handover, the individual and the team must be able to adjust when work conditions change. We must recognise that team members have different roles and have different information needs and goals, and therefore will have different perspectives during a handover situation.

For a safe handover, the transfer of accountability and responsibility, teamwork is essential. Therefore, any training has to involve the whole healthcare team with the goal of obtaining a shared mental model of peri-operative handover. This includes gaining an understanding of the social and cultural aspects of teamwork. Simulation-based training followed by debriefings can be particularly useful. But one should not forget that every clinical handover situation is a training opportunity in and of itself. Future research should be based on theoretical frameworks from the social and cognitive sciences, should focus on the patient journey and involve the patient in the team.

Chapter 9: Incident reporting in complexity (Staender)

Stimulated by direct contact with National Aeronautics and Space Administration (NASA) safety experts and based on work in Australia, the first widely accessible anonymous critical incident reporting system (CIRS) in Europe was established at the Department of Anaesthesiology at the University of Basel in 1995.[344,345] The focus was primarily on discovering weak points in the anaesthesia system, learning from them and thus becoming safer. As a result, CIRS has developed far beyond Basel,

beyond Switzerland and far beyond the field of anaesthesia. Experience with CIRS in Europe has been the inspiration for a whole range of national incident reporting systems, such as in England and Spain. Incident analyses today complement the classical accident investigations in morbidity and mortality conferences and can thus uncover multiple factors that have potentially contributed to an event; providing insights that can be used to prevent an identical event in the future (so-called *find and fix* approach). With this impact, incident reporting systems have also found their way into the recommendations of the Helsinki Declaration on Patient Safety in Anaesthesiology and are now operated both locally and nationally in a number of countries (including Denmark, Finland, England, Spain, Germany, Switzerland etc.).[346]

This 'find and fix' approach is based on the consideration of avoiding errors and thus generating safety. This includes the traditional definition of safety, where a state is described as safe when no errors occur. This definition is not unproblematic because it considers safety to be a 'dynamic nonevent'.[347] In view of the more or less constant rates of avoidable harm over time, the question must be asked whether this traditional definition of safety, and thus the 'find and fix' approach is still entirely fit for purpose in ever increasingly complex healthcare systems.[348]

Complexity as a challenge

In previous decades, health care was far less complex than today, and many processes were linear, many processes could be defined in cause–effect relationships. Today, not only has the knowledge base become far more complex (e.g. with an unmanageable number of clinical guidelines), but also our organisational structures and their interfaces, our patients (multimorbidity) and our therapies (polypharmacotherapy) have become more complex too.

In error causality, we have traditionally assumed a majority of linear relationships. This thinking was established in Heinrich's so-called *Domino Model* (or also *Accident Causation Model*) from 1931 and was based on simple cause–effect relationships.[349] These concepts were propagated in the *Swiss Cheese Model* and later in the *Threat and Error Model*, both by Reason.[350]

Complex systems, however, are characterised by a multitude of components and in particular by a high number of interrelationships; that is complex systems are no longer linear. This means that they also elude a linear approach to analysis and are therefore on the one hand very difficult to control, and on the other hand also carry a great risk if they get *out of control*. With regard to medicine and safety thinking in our discipline, this means that we succumb to an illusion when we believe that we can make a complex system safer with simple, linear process descriptions, rules and regulations and a 'find and fix' approach (classical incident reporting concept).

Complex systems, such as modern health care, are today largely dependent on well trained experts being able to interpret a new and previously unknown constellation of factors on the basis of their knowledge and to adapt previous behaviour on the basis of their expertise. This behaviour has been known in industry since the introduction of the concept of *resilience* (resistance to interference).[347] It is based on the findings that there is a clear difference between *work-as-imagined* and *work-as-done*. The term *textbook performance* can also be found in resilience literature, which today is no longer sufficient to deal with imponderables, because the *textbook* may be incomplete, overly limited or simply outdated because we face change constantly in our working conditions with new requirements, pressures or even threats. *Textbook performance* only works if the environmental factors are completely known and stable; but this condition can no longer be assumed in today's sociotechnical systems state of flux.[351]

The resilience of a system is now characterised by the understanding that changing environmental conditions are managed while the system nevertheless still continues to function to a greater or lesser degree. This is achieved by the following:

(1) Buffer capacity: the size or extent of disturbances a system can tolerate without collapsing.
(2) Flexibility: the ability of a system to restructure itself in response to external pressure.
(3) Tolerance: the knowledge of how a system behaves at its performance limits, that is, whether it degrades slowly under pressure or collapses rapidly as soon as the pressure exceeds its adaptive capacities.[351]

In addition, individual behaviour can also show characteristics of resilience. Johnson and Lane[352] defined the so-called C terms for resilient behaviour (Table 17).

Incident reporting systems under *Safety-I* and *Safety-II*

When thinking about safety, this means that we must not rely solely on process descriptions, we must not only learn from incidents, mistakes and accidents in the past, and we must not ignore the daily fluctuations in *performance*.

Table 17 Individual behaviour showing characteristics of resilience[352]

'C' terms for resilient behaviour
Cohesion (mutual respect)
Communication and challenge (speak-up)
Competence (knowledge transfer)
Capture (situational awareness)
Cognition (fast and slow thinking)
Constraints (resource management)

This new safety thinking is today referred to as *Safety II*, in contrast to *Safety I*.[353]

So, in the future we should use a new definition of safety that moves away from *avoiding things going wrong* to *making sure everything goes right*.[353] We can no longer rely on our systems to work well only because we prevent errors. We also need to know why our systems work well every day. Accordingly, in the future we will have to spend much more time understanding how professionals cope with ever-changing daily challenges and still deliver excellent results; what adaptations are being made and what they have achieved.[354]

That is, we should not only look at what 'went wrong', but also at what goes well. Everyday life is often successful because people do their best job in the workplace and make sensitive decisions, make adjustments according to the requirements of the moment, to cope with the situation. Understanding these adjustments and learning from them is at least as important as uncovering the causes of adverse events.

With regard to incident reporting systems, we can continue to use these proven instruments of patient safety in the future; but we should expand these incident reporting systems with instruments that help us to learn from everyday practice. Incident reporting systems should therefore be systematically extended by the factor *learning from success* by encouraging employees to also report successful solutions to difficult, unexpected situations.

In addition to incident reporting, regular *de-briefings* and so-called *safety walk around* could be introduced. These *Safety* or *Leadership-Walk-Around* are used to collect suggestions for improvement from employees at the grassroots level and are an integral part of *Lean-Management Systems*.[355,356] A recent review article summarises the advantages and disadvantages of these methods and gives useful recommendations for the concrete implementation of the *Safety Walk Around*.[357] Adequate resources are needed, and if these resources are not granted because of efficiency reasons, improvements in our hospital systems may not materialise. In aviation it is said: *If you think safety is expensive, try an accident*. *Faster, better and cheaper* was a NASA quote leading to several major accidents and disasters (e.g. *Columbia Accident Report* or the *Mars Climate Orbiter Mishap Investigation Report*).[358]

Safety-II is also important in the context of the ever-increasing production pressure in the healthcare sector: this production pressure is increasingly straining the resilience of our systems and thus potentially endangers patient safety. The pressure to achieve given annual targets (e.g. case numbers etc.) to obtain sufficient revenues despite insufficient financing leads to the situation that the word 'safety' is too often omitted when communicating such target agreements to the chief physicians – *hospital managers and even medical staff appear more preoccupied with survival in the marketplace than with survival of their patients*.[359]

Chapter 10: Supporting healthcare individuals and teams after an adverse event: the care for the second victim (Staender)

Work in anaesthesia and the peri-operative setting takes place in a complex and dynamic environment. Decisions often have to be made under time pressure and not all the information necessary for the decision-making process is always available. Accordingly, it is important for patient safety that the necessary technology is available, that sufficient resources exist, that processes are clarified and that well trained personnel work in these areas, with as little stress as possible.

Nevertheless, despite the best conditions, there will, unfortunately always be avoidable errors in patient treatment because the healthcare system is highly complex, conditions are rarely optimal and even the best specialists can never work without errors. The rate of avoidable errors and corresponding harm in medicine is substantial and continues to be high.[219] This primarily affects the patients and their relatives, who are accordingly referred to as 'first victims'. But also, the employees involved in the incorrect treatment suffer to an often not inconsiderable extent from the event and are referred to as 'second victims'.[360] The effects on these 'second victims' can be considerable. Taking into account that physicians are bound by the edict 'Primum non nocere' (first, do no harm), any harm to patients due to actions of the healthcare provider shakes the fundamentals on which physicians practice. Fear, feelings of guilt or self-doubt can be the consequences of treatment errors for the persons involved. In the extreme, experiencing somatic symptoms, medication or drug abuse, thoughts of giving up one's job, thoughts of suicide or even committing suicide have been described.[361–367] Williams *et al.*[368] showed that stressed and burned-out physicians reported a greater likelihood of making errors and mentioned more often suboptimal patient care. A study involving internal medicine residents showed that higher levels of fatigue and distress were independently associated with self-perceived medical errors.[369] An increased error-rate in depressed residents in paediatrics and a comparable phenomenon in nurses has been shown before.[370,371] This means that the 'second victim' is not only an individual problem for the healthcare provider involved, but also for safety in general. The question to address must be first of all how to avoid medical error, and second how to support those that suffer after having been involved in a medical error. The overall extent of that problem is not that well documented. A study in anaesthesiology from 2012 found that, in their career, 85% of the respondents reported having been involved in at least one unanticipated death or serious harm to a peri-operative patient.[362]

Considering the significance of the 'second victim' problem, the question arises how to deal best with this phenomenon to minimise the consequences for the employees involved. Healthcare professionals can be affected by a treatment error in different ways; first, by the experience of the treatment error itself; and second, by the way in which they were treated themselves after such an event happened.[365] It is important to address these aspects not only at the individual level, but also institutionally. Burlison *et al.*[367] showed that an adequate response by the organisation to the needs of 'second victims' has a positive effect on the retention of the 'second victim' in current employment.

What are the needs of 'second victims'? Numerous studies demonstrated that after a treatment error happened the member of staff involved needs coping strategies and an opportunity to discuss the unwanted event with peers.[372] An excellent publication on this topic made recommendations to support affected persons, including, for example, the prompt debriefing and crisis intervention for the individual and/or team involved, an opportunity to discuss any ethical concerns, as well as a safe opportunity to contribute any insights into how similar events could be prevented in the future.[372] The initial debriefing should be done as quick as possible, through the most senior peer available, assuring complete confidentiality. The conversation should focus on 'why' and not 'who', and should show empathy and avoid the questions of 'guilt'.

The most important aspect from the perspective of the 'second victim' was the confirmation of professional competence by a peer,[372] because those persons affected may have considerable self-doubt about their competence and the feedback of a peer, being able to comprehend the decision in the present case, can be extremely helpful. Conversely, there are behaviours or remarks from colleagues after a treatment error that are inappropriate or even harmful, for example, *Didn't you realise what would happen?*, or *What were you thinking?*, or *I wouldn't have done that!*.[372]

There is a general recommendation that organisations have a support programme in place as part of a comprehensive process for responding on an adverse event. Today, a variety of supporting programmes are described, especially in large hospitals, for example, the programme of the University of Missouri (ForYou Program) or at Johns Hopkins (RISE) in the United States.[373,374] The support programme Medically Induced Trauma Support Services Toolkit is available on the Internet (www.mitss.org). It offers not only individual support but also training programmes for nursing staff and doctors as well as assistance in the creation of organisational programmes.

There is only little research on the effects of existing support programmes: even one of the first programmes to support 'second victims' at Johns Hopkins Hospital (RISE) did not report a systematic follow-up of outcomes of the people involved in their programme. Nevertheless, they demonstrated a success based on the self-reports of the peers involved. Especially, the training programme as part of that initiative to support peers dealing with 'second victims' was reported to be successful.[373]

Conclusion

Healthcare professionals confronted to having made an error leading to patient harm suffer from that error, being a 'second victim'. This effect has different degrees of expression but can lead to severe impairment of the healthcare professional, which again could promote further errors happening in future treatment by the respective professionals. When dealing with these 'second victims', one of the most important aspects is an early debriefing, emotional support and the opportunity to discuss the events that happened with peers. There is a general recommendation to have programmes in place at the organisational level to support these professionals and to make it easier to break the wall of silence, but further research is needed to demonstrate the effect of such programmes.

Chapter 11: The role of checklists in peri-operative care (Haugen)

Quality and safety have been a central focus in peri-operative anaesthesia care, and checklists have been used to get close to zero complications during anaesthesia and surgery. This chapter focuses on the role of surgical safety checklists in peri-operative care (pre-operative, intra-operative and postoperative phases).

Modern history of patient safety started in late 1970s when the cost of malpractice insurance for anaesthesiologists brought patient safety issues to the fore.[375] The malpractice crisis forced the American Society of Anesthesiologists (ASA) to address the causes of anaesthesia accidents and to focus on patient safety.[376,377] In 1985, the ASA initiated the Anesthesia Patient Safety Foundation, a collaboration between anaesthesia-related professions including anaesthesiologists, nurse anaesthetists, nurses, drug and equipment manufacturers, regulators, insurers and others. The common goal was a zero tolerance for injury of patients with the vision that 'no patient shall be harmed by anaesthesia'.[376,378]

Anaesthesia professional organisations have developed international standards for the safe practice of anaesthesia, outlining minimum requirements for performing safe anaesthesia care at a global level,[40,379] in the United States[377,380] and in Europe[12,381–383] (http://www.eba-uems.eu/resources/PDFS/safety-guidelines/EBA-UEMS-recommendation-for-use-of-Capnography.pdf). The EBA and the ESA have produced a European Declaration known as 'Helsinki Declaration on Patient Safety in Anaesthesiology'.[1] This Declaration recommends safety standards including checklists are implemented in peri-operative care.

What is a checklist?

A checklist identifies single items or a group of elements to be verified and checked consecutively and is intended to compensate for memory flaws.[384–386] There are two main types of checklists and thus two methods to develop a checklist. The first type is the Do-List, a checklist is used for a step-by-step procedure or task. The second type is the Challenge–Verification–Response, where one person reads aloud the item and challenges someone else to verify and confirm that the task corresponding to the item on the list has been accomplished.[385] The Challenge–Verification–Response method is used in the WHO Safe Surgery Saves Lives campaign on how to perform the multidisciplinary team Checklist, the WHO SSC.[387]

Types and effectiveness of checklists in peri-operative care

Different types of checklists have been developed such as pre-operative briefings and debriefings after surgery,[388] ''time out'' protocols,[389] equipment checklists[390] and surgical safety checklists.[391–393] Pre-operative checks of anaesthetic equipment are embedded in anaesthesia guidelines from Great Britain and Ireland.[394,395] In Norway, anaesthesia equipment and machines are now checked electronically prior to induction with a pre-anaesthetic checklist which became possible after the machines evolved from being mechanical to electronically driven.[396]

In 1998, prior to the introduction of the surgical safety checklists, the US Joint Commission focused on surgical safety issues: operating on the wrong site or the wrong patient, and performing the wrong surgical procedure. In a sentinel event alert they recommended surgical teams to use a 'time out' protocol that verifies the identity of the patient, the surgical procedure and the site of surgery by use of active communication techniques (www.jointcommission.org/assets/1/18/SEA_24.pdf). In 2007, the Royal College of Surgeons of England obligated surgeons to use briefings as a part of their responsibility to safe team behaviour.[397]

The WHO Surgical Safety Checklist (SSC) was globally introduced in 2008.[398] Between October 2007 and September 2008, the checklist was successfully piloted in eight hospitals in eight countries comprising high and low-income status.[387] Its effectiveness was examined by comparing errors in patients undergoing noncardiac surgery before (n=3733) and after (n=3955) the introduction of the SSC.[393] Complications dropped from 11 to 7% ($P < 0.001$) and mortality from 1.5 to 0.8% ($P = 0.003$).[393] This publication was the first to evaluate the impact of the WHO SSC in a global population.

Another effective contemporary checklist was the comprehensive surgical patient safety checklist system (SURPASS) developed in the Netherlands,[399] based on a literature review of surgical errors and adverse events. The multidisciplinary SURPASS checklist is conducted by different professions along patients' entire surgical pathway in the hospital. When it was tested in 171 high-risk procedures, 593 process deviations were observed, 96% of which corresponded to a checklist item.[399] When comparing the outcome of 3760 patients before and 3820 patients after introducing the SURPASS checklist in Dutch hospitals, the proportion of patients with one or more complications decreased from 15.4 to 10.6% ($P < 0.001$) and mortality from 1.5 [95% confidence interval (CI) 1.2 to 2.0] to 0.8% (95% CI 0.2 to 1.2), respectively.[392] No changes were observed in control hospitals. The SURPASS checklist is currently used in the Netherlands, Canada, India, Sweden and Norway.[400,401]

The WHO SSC and SURPASS address different aspects of patient safety issues in surgery. Some surgical specialties have developed more procedure-specific checklists. One example is a neurosurgical checklist used in the Mayo Clinic in Arizona. The checklist contains elements of both the time out protocol and the SSC. Over an 8-year period there was a 99.5% compliance rate; no incidents of wrong patient, wrong site or wrong procedure were documented.[402]

Other checklists have been published, for example, one piloted to detect and remediate procedural errors in movement disorder (deep brain) surgery,[403] or the peri-operative team communication checklist is used before patient arrival in the operating theatre for vascular surgery. The team check was developed to promote interprofessional communication and was piloted in 18 surgical procedures. It included team discussions of case-related information, confirmation of details, articulation of concerns, team building and decision-making. This pre-operative team briefing resulted in improved clinical practice, for example, physician compliance with antibiotic administration guidelines.[404]

To summarise, a variety of peri-operative anaesthesia and surgical checklists have been developed and introduced during the last decades.

How much evidence is needed for using checklists?

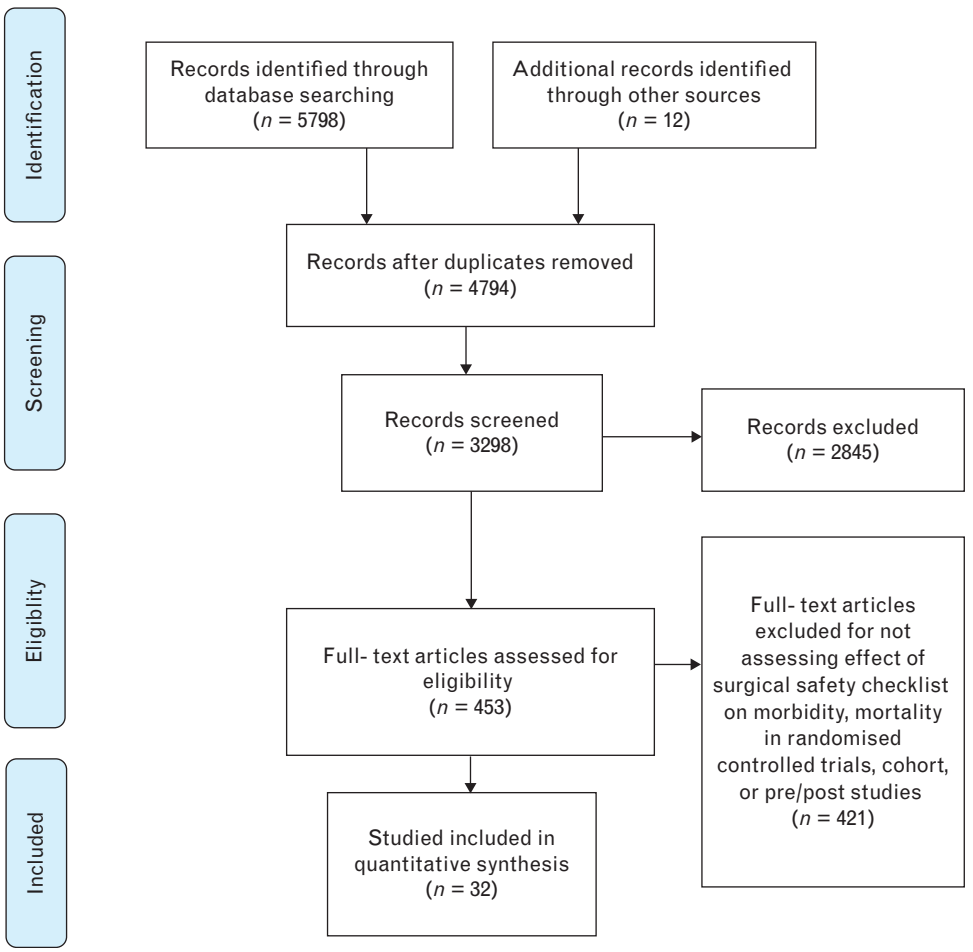
Evidence-based medicine seeks to optimise clinicians' decision-making processes for the individual patient and seeks to set standards. The most stringent evidence for these standards is derived from systematic reviews, meta-analysis and randomised controlled trials, with case series and case reports providing only low level evidence.[405] Some of the accepted standards and proposed safety changes in anaesthesia lack high level evidence. Some standards are based on common sense and consensus guidelines, and basically summarise current knowledge and clinical routine (i.e. better equipment and monitoring standards, or electronic information systems).[378] Safety advances and a perceived decrease in anaesthesia morbidity and mortality over past decades

are attributed to a bundle of changes such as better training, equipment, organisation, supervision, process optimisation and teamwork.[378] While not all types of quality improvement can be 'proven' by randomised controlled trials,[405,406] interventions aimed to improve patient safety ought to be based as much as possible on clinical and theoretical frameworks and robust scientific methodologies with the ultimate goal of determining whether they do more good than harm.[405] The available external clinical evidence of the effectiveness of peri-operative checklists has been systematically reviewed.[407] The literature search is illustrated in Fig. 6 with a Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram. The identified studies are narratively reported.

The literature search identified 5810 publications of which 453 were found relevant. Of these, 395 were published in 2013, and 58 in 2019. A total of 32 articles were finally included. The studies are listed alphabetically according to the first author's names in Table 18.

The identified original studies investigating the effects of surgical safety checklists on patient outcomes, were published between 2009 and 2019. Of the 32 included studies, effects of the WHO SSC were evaluated in 29 studies,[174,409–413,415–437] and the SURPASS checklist in two studies.[392,400] One study investigated a surgical safety briefing checklist.[414] There are large variations in study sample sizes, ranging from less than 200 patients per group, to millions of patients included in larger population-based studies with pooled analyses over several years (Table 18). In 15 studies investigating morbidity, positive effects of the WHO SSC were reported.[174,410–412,414–416,419,422,424–426,430–434,437] A smaller proportion of studies (n=6) did not find a significant impact of the WHO SSC on morbidity.[409,420,423,427,432,435] In studies evaluating mortality rates, several studies reported that the WHO SSC reduced mortality (n=12).[174,395,409,413,414,416–418,421,428,436,437] A stepped wedge cluster randomised controlled trial reported reduced mortality in a subgroup of patients.[419] In contrast,

Fig. 6



Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of the systematic literature review on surgical safety checklists effects on patient outcome in peri-operative care.[408]

Table 18 Literature review about effects of surgical safety checklists on morbidity and mortality in peri-operative care

Reference	Study design	Aim	Population/Setting	Outcomes
Abbot *et al.*[409]	7 day prevalence cohort	To evaluate effectiveness of the WHO SSC on in-hospital mortality and postoperative complications	44 814 patients from 497 hospitals in 27 countries were included (40 245 was exposed to checklist, and 7508 were not)	Associated with reduced mortality, odds ratio 0.49 (95% CI 0.32 to 0.77), $P < 0.01$. Postoperative complications did not change, odds ratio 1.02 (95% CI 0.88 to 1.19), $P = 0.75$
Anwer *et al.*[410]	Pre and post	To assess the WHO SSC effectiveness in reducing complications	Over 4 years, in a postgraduate medical centre, Karachi, Pakistan, 3638 laparoscopic cholecystectomy patients were included	Surgical site infection was 7.50, 6.47, 4.70%, and 2.12% per year, respectively, $P < 0.0001$
Askarian *et al.*[411]	Pre and post	To encourage use of the WHO SSC and measure effect on surgical outcomes	374 bed referral educational hospital in Shiraz, Iran	Incidence of any complications was 22.9% before and 10% after, $P = 0.03$
Bliss *et al.*[414]	Cohort with historical controls	To increase safety environment by adopting aviation industry teamwork principles with a checklist in the OR	2079 historical patient cases, 246 cases without checklist, 73 cases with checklist 600 beds tertiary hospital in the United States	WHO checklist compliance was 97.3% 30-Day morbidity decreased from 23.6% for historic cases and 15.9% in cases with only team training, to 8.2% in cases with checklist use, $P < 0.001$
Boaz *et al.*[412]	Pre and post	Estimate effect of the WHO SSC in orthopaedic surgery over 12 months	380 patients in baseline vs. 380 patients in intervention	Postoperative fever 5.3% before and 10.6% after, $P = 0.008$, odds ratio 0.53 (95% CI 0.29 to 0.96). Surgical site infection 3.2 vs. 2.1%, $P = 0.368$. Composite postoperative complications 25.9 vs. 18.9%, $P = 0.02$
Bock *et al.* 2016[413]	Retrospective pre and post	To evaluate 90-day mortality, 30-day mortality, length of stay, and 30-day readmission rate after WHO SSC introduction	5444 patients, pre and 5297 postintervention, from a public, regional hospital, Italy	90-Day mortality was 2.4 vs. 2.2%, adjusted odds ratio 0.73 (95% CI 0.56 to 0.96), $P = 0.02$. 30-day mortality was NS. 30-day readmission was NS. Length of stay decreased 10.4 (95% CI 10.2 to 10.6) to 9.6 (95% CI 0.94 to 0.97), $P < 0.001$
Chaudhary *et al.*[416]	Randomised controlled trial, parallel group design	To evaluate the WHO SSC effect on postoperative complications	Tertiary care hospital in India, 350 patients in checklist arm compared with 350 patients in no checklist group, over 14 months	Postoperative wound complications decreased from 8.5 to 4.5%, $P = 0.01$. Abdominal complications decreased from 28 to 19.7%, $P = 0.01$. Bleeding decreased from 2.8 to 0.5%, $P = 0.03$ Mortality was 10 vs. 5.7% in checklist arm, $P = 0.04$
Chhabra *et al.*[415]	Pre and post	To evaluate WHO SSC impact on adverse events	500 patients were enrolled into pre and postintervention groups, in a Nigerian hospital	Postoperative wound disruption decreased from 10.8 to 5.2%, $P < 0.05$. Surgical site infection decreased from 29.2 to 13.6%, $P < 0.05$. Sepsis decreased from 2% to zero, $P < 0.05$
de Jager *et al.*[417]	Retrospective review	To examine the WHO SSC effect on postoperative outcomes.	Data from 21 306 procedures, over 5-year time period, in a tertiary care centre in Australia	Postoperative mortality decreased from 1.2 to 0.9%, $P = 0.038$, odds ratio 0.74 (95% CI 0.56 to 0.98) Length of stay decreased from 5.2 to 4.7 days, $P = 0.014$
de Vries *et al.*[392]	Pre and post with control hospitals	Evaluate effect of using the Surgical Patient Safety Systems (SURPASS) checklist on morbidity and mortality	3760 patients before and 3820 after implementation; 2592 vs. 2664 in control hospitals Six intervention and five control hospitals in Holland	Morbidity decreased from 15.4 to 10.4%, $P < 0.001$. Adjusted for covariables rate ratio decrease was 9.7 (95% CI 7.8 to 11.5) Mortality decreased from 1.5 (95% CI, 1.2 to 2.0) to 0.8% (95% CI 0.6 to 1.1), $P = 0.003$. Adjusted for covariables corrected rate ratio decrease was 0.54 (95% CI, 0.33 to 0.88) Length of stay decreased from 9.1 to 8.5 days, $P = 0.15$. No change in control hospitals
GlobalSurg Collaborative. *et al.*[418]	Pooled analysis	To evaluate the WHO SSC effects in global emergency laparotomy settings on 30-day peri-operative mortality	12 296 patients included from 76 countries, 4843 underwent emergency laparotomy and were compared with elective procedures	Adjusted analysis associated the WHO SSC with decreased 30-day mortality rates in emergency laparotomy, odds ratio 0.60 (95% CI 0.50 to 0.73), $P < 0.001$

Table 18 (*continued*)

Reference	Study design	Aim	Population/Setting	Outcomes
Haugen *et al.*[419]	Stepped wedge cluster randomised controlled trial	Evaluate the WHO SSC effect on in-hospital morbidity and mortality up to 30 days after surgery	2212 control procedures vs. 2263 procedures (full SSC compliance) and 3083 procedures (ITT)	Complications decreased from 19.9% in controls to 11.5% in SSC procedures, and 12.4% in all intervention procedures (ITT), $P < 0.001$. Mortality from 1.6 to 1.0%, $P = 0.151$ Length of stay decreased from 7.8 to 7.0 days, $P = 0.022$
Haynes *et al.*[393]	Pre and post	To reduce complications and deaths associated with surgery after implementing the WHO SSC	3733 patients before and 3955 after implementation of the WHO SSC 8 hospitals from 8 countries in various economic circumstances	Complications were reduced from 11 to 7%, $P < 0.001$ Rate of death during hospitalisation (30 days after surgery) was reduced from 1.5 to 0.8%, $P = 0.003$ Improved safety process measures $P < 0.001$, objective airway evaluation, pulse oximeter, iv catheters, prophylactic antibiotics, patient/site checked and retaining of instruments checked
Haynes *et al.*[174]	Pre and post	To determine the WHO SSC South Carolina statewide programme effect on mortality rates	14 hospitals completed the programme by December 2013 (40 626 patients) and were compared with 44 other hospitals (69 094 patients)	Risk adjusted 30-day mortality was 3.38% in 2010 and 2.84% in 2013, $P < 0.00001$
Igaga *et al.*[420]	Prevalence cohort	To determine compliance and associations of the WHO SSC with surgical outcomes	5 referral hospitals in Uganda, 859 patients	Low levels of SSC compliance. Adverse events, length of hospital stay, mortality, no significant changes
Jammer *et al.*[421]	7 Day point prevalence study	To evaluate WHO SSCs impact on mortality in European hospitals	45 591 patients from 426 European hospitals	SSC exposure was associated with lower crude hospital mortality, odds ratio 0.84 (95% CI 0.75 to 0.94), $P = 0.002$
Kwok *et al.*[422]	Pre and post	To reduce complications in a severely resource-limited hospital by introducing the WHO SSC and pulse oximetry	2145 before and 2212 after WHO SSC and pulse oximetry implementation Governmental, university affiliated, general and trauma hospital in Moldova	Overall complications decreased from 21.5 to 8.8%, $P < 0.001$ Safety processes increased from 0.0 to 66.9% Hypoxic episodes lasting 2 min or longer per 100 h of oximetry was reduced from 11.5 to 6.4, $P < 0.001$
Lepanluoma *et al.*[424]	Pre and post	To assess impact of the WHO SSC on safety-related issues and postoperative adverse events	Neurosurgical procedures, 89 operations in baseline and 73 postintervention, a tertiary teaching hospital in Finland	Unplanned readmission decreased from 25 to 10%, $P = 0.02$. Wound complications decreased from 19 to 8%, $P = 0.04$
Lübbeke *et al.*[423]	Pre and post	To evaluate effectiveness of the WHO SSC in a high standard care environment on unplanned re-operations or admission to ICUs, and in-hospital death within 30 days	609 patients at baseline and 1818 after (552, 558 and 708 in three periods) University hospital in Switzerland	Unplanned return to operating room in 45/609 (7.4%) vs. 109/1818 (6.0%), re-operation for SSI in 18/609 (3.0%) vs. 109/1818 (1.7%), in-hospital death in 26 (4.3%) vs. 108/1818 (5.9%) Checklist prevented one re-operation for SSI in 77 procedures No significant changes were found
Mayer *et al.*[425]	Pre and post	To evaluate impact of the WHO SSC on risk adjusted clinical outcome	In 5 UK academic and community-based hospitals over 14 months, including 6714 patients	Postoperative complications were lowered from 16.9 to 11.2%, odds ratio 0.57 (95% CI 0.37 to 0.87). Mortality nonsignificant change
Metha *et al.*[400]	Pre and post	Evaluate effect of Surgical Patient Safety System (SURPASS) checklist on postoperative complications and mortality up to 30 days	In a tertiary care hospital, India, over 13 months, 200 elective/emergency patients were compared with 172 postintervention patients	Postoperative complications decreased from 66.7 to 51.9% in elective patients, $P = 0.008$. In emergency patients complications decreased from 77.2 to 67.5%, $P = 0.024$ Mortality nonsignificant change
Morgan *et al.*[426]	Pre and post	To evaluate if postoperative pain, nausea/vomiting, length of stay and SAQ improved after WHO SSC Implementation	180 patients before and 195 after implementation Ambulatory surgical setting in Canada	Compliance with briefings 99.49%, Timeout 97.95% and Debrief 96.92% Median difference in pain scores was 0.5 (97.5% CI 0 to 1, $P = 0.13$). Median difference in post discharge nausea/vomiting was −8.4% (97.5% CI, −17.9 to 1.1, $P = 0.06$) Length of stay: hours median 3.1 [2.4 to 3.9] to 3.2 [2.6 to 3.9], $P = 0.38$ Safety attitudes were not significantly changed

Table 18 (*continued*)

Reference	Study design	Aim	Population/Setting	Outcomes
O'Leary *et al.*[427]	Pre and post	To determine WHO SSC associations with peri-operative complications in paediatric patients	116 ontario hospitals, comparing 14 458 procedures with 14 314 procedures in postintervention group, from 2008/2009 to 2010/2011	Peri-operative complications were 4.05% (95% CI 3.76 to 4.40) at baseline, and 4.12% (95% CI 3.80 to 4.45) in checklist group. No significant change ($P = 0.9$)
Ramsay *et al.*[428]	Longitudinal	To investigate the WHO SSC impact on mortality rates over 16 years	23488 312 procedures in baseline (1998 to 2006), to 7667 142 procedures (2012 to 2014) in Scotland	From baseline and over pre-SSC implementation (2006 to 2008), SSC implementation (2008 to 2010), post SSC implementation (2010 to 2012), and end line (2012 to 2014), mortality decreased by 39% (relative reduction), with postoperative mortality rates from 1.16, 1.02, 0.90, 0.84, 0.79, respectively
Rodella *et al.*[429]	Retrospective longitudinal	To explore WHO SSC impact on mortality, readmissions and length of stay	48 public hospitals in Italy between 2006 and 2014, including 1166 424 patients	30-day readmission rate odds ratio 0.96 (95% CI 0.94 to 0.98), Length of stay >8 days rate odds ratio 0.88 (95% CI 0.87 to 0.89). No significant change in mortality
Rodrigo-Rincon *et al.*[430]	Retrospective pre and post	To determine effect of WHO SSC on adverse events	A cohort of 1602 patients from a tertiary teaching hospital in Spain (baseline 801 vs. 801 postintervention)	Rate of adverse events per 100 patients decreased 31.5 to 26.5%, $P < 0.39$, infections decreased from 13.9 to 9.6%, $P = 0.037$. Mortality was 1.5% pre and 0.9% postintervention, $P = 0.35$
Rosenberg *et al.*[431]	Pre and post	To evaluate effect of an office-based surgical safety checklist on patient outcome	In a single-centre US hospital, from February 2010 to March 2012 (25 months), 219 procedures pre and 184 procedures postintervention	Per 100 patients, complications decreased from 15.1 to 2.72, $P = 0.0001$, with absolute risk reduction 12.4 Patients with one or more complication decreased from 11.9 to 2.74%, $P = 0.0006$
Sewell *et al.*[432]	Pre and post	To assess compliance, early complications, death and staff perceptions after implementing the WHO SSC	480 patients before and 485 patients after SSC implementation. 100 OR staff in trauma and orthopaedic hospital in the United Kingdom	Compliance changed from 7.9 to 96.9% (RR 12.2, 95% CI 9.0 to 16.6). Early complications and mortality was not significantly changed, RR 0.89 (95% CI 0.58 to 1.37), and 0.88 (95% CI 0.34 to 2.26), respectively. 77% of staff believed that the SSC improved team communication
Tillman *et al.*[433]	Pre and post	To determine if the WHO SSC would improve patient outcomes for surgical site infections and care improvement	10 126 patients before SSC and 9676 patients after SSC 636 bed tertiary hospital in Texas, USA	Antibiotic timing improved 92.7 to 95.4%, $P < 0.05$. Temperature management 93.8 vs. 97.7%, $P < 0.001$. Patients with postoperative temperature <98.6 °F dropped from 9.7 to 6.9%, $P < 0.001$ Overall no significant change for SSI rates, except for subgroup: colorectal surgery 24.1 to 11.5%, $P < 0.05$
Toor *et al.*[434]	Pre and post	Evaluate effect of the WHO SSC on postoperative infections, With 3 months baseline and 6 months intervention	303 patients at baseline vs. 310 patients in the postintervention phase, in a Mayo Hospital, Lahore, Pakistan	Postoperative infections decreased from 33.7 to 15.2%, $P < 0.001$. Mean hospital stay was reduced from 7.8 ± 5.7 to 6.5+/5.6 days, $P < 0.001$
Urbach *et al.*[435]	Pre and post	Evaluate WHO SSC's effect of on complications, mortality and readmissions up to 30 days after discharge, 3 months before and after implementation	109 341 procedures at baseline, 106 370 procedures after SSC implementation in 101 Canadian hospitals	Adjusted risk of complications 3.86% (95% CI 3.76 to 3.96) before vs. 3.82% (95% CI 3.71 to 3.92) after, $P = 0.26$). Adjusted risk of mortality 0.71 (95% CI 0.66 to 0.76) before vs. 0.65% (05% CI 0.60 to 0.70) after, $P = 0.13$ Readmissions were nonsignificant
van Klei *et al.*[436]	Cohort study with historical baseline cases	Evaluate the WHO SSC effect of implementation on mortality and compliance	25 513 adult patients in baseline, 11 151 after SSC A tertiary university hospital in Holland	After SSC implementation mortality was reduced from 3.13 to 2.85%, $P = 0.19$. Adjusted for baseline differences mortality was significantly decreased with odds ratio 0.85 (95% CI 0.73 to 0.98). Strongly related to SSI compliance (all parts used) with odds ratio 0.44 (95% CI 0.28 to 0.70)
Weiser *et al.*[386]	Pre and post	Assess if the WHO SSC reduces deaths and complications and improves compliance with basic standards of care in urgent surgical cases	842 patients before and 908 patients after SSI implementation (8 hospitals in 8 countries of various economic circumstances of the WHO trial to Haynes *et al.* 2009)	Complications decreased from 18.4 to 11.7%, $P = 0.0001$. Mortality was 3.7% at baseline and 1.4% after SSI, $P = 0.0067$ Safety process steps improved from 18.6 to 50.7%, $P < 0.0001$

ICU, Intensive Care Unit; ITT, intention to treat analysis; SSI, surgical site infection; SSC, surgical safety checklist.

other studies (n=5) did not report a significantly decreased mortality with using the checklist.[423,425,429,430,435] Studies on the effects of the comprehensive SURPASS checklists used in the entire surgical pathway report a decrease in surgical complications,[392,400] and a decreased mortality.[392] Two of four studies reporting on WHO SSC effects on readmissions showed decreased readmission rates with using the checklist.[424,429] WHO SSC and SURPASS checklists' impact on length of hospital stay was reported in six studies, with five of these studies reporting a significant reduction in the length of hospital stay.[392,413,417,419,429]

Discussion

The current updated review of the literature suggests morbidity and mortality in surgical patients decreases when healthcare personnel use checklists, both intra-operatively (e.g. the WHO SSC) and during peri-postoperative care (e.g. the SURPASS). The cited studies consisted mainly of 'before and after' studies (n=24), prevalence cohort design studies (n=4), longitudinal studies (n=2) and randomised controlled trials (n=2). Evidence-based medicine refers to using the best available evidence to address clinically relevant questions.[405] The review identified only one stepped wedge cluster randomised controlled trial,[419] which has been judged to be the most robust checklist study to-date.[438] However, use of the WHO SSC has become mandatory in most hospitals, which makes it challenging to design new randomised controlled trials, especially as the checklists have already been implemented and most likely do more good than harm for patients.

Implementation, compliance and proper use

Implementation of surgical safety checklists requires persistency and long-term perspectives. Conley *et al.*[439] investigated features of effective implementation strategies and found that leaders need to explain to their staff members the 'why and how' of the checklist. Staff had to be adequately prepared, otherwise they became frustrated, disinterested and stopped using the checklist despite a hospital-wide mandate.[439]

Some of the identified studies reported better outcomes when there was higher compliance with the WHO SSC.[419,420,426,432,436] This suggests quality improvement reports on compliance rates are very valuable in helping us understand which parts of the checklist work well, and which parts could be omitted. Such reports provide possibilities for more targeted quality improvement interventions. However, compliance rates do not tell us anything about the quality of checklists performance. Production demands and time pressure are elements that may contribute to substandard use of a checklist[385,419] as reflected in checklists being used as 'tick-box' exercises, the omission of items, or poor team members' attention.[440–443] However, wider implementation and spread of standards like the Helsinki Declaration on Patient Safety in Anaesthesiology,[1] and professional associations' endorsement of safety standards may enhance a culture of safety and promote surgical safety checklists as clinical best practice.[379,380,444]

Need to change the order of operating room workflow?

When implementing a checklist, we always face the question whether to change our workflow or to adapt the checklist to an established order of work processes. For a successful implementation, the WHO encourages adapting the checklist to local routines and to balance inclusion of important items against brevity of the list.[387] Systematic use of checklists may still require the workflow and the order of performing our tasks to be adjusted. The exact timing of when to do the checklist should be agreed upon by all team members. To avoid being perceived as an obstacle, performing the checklist needs to fit into the workflow of the operating room.[384] Checklist briefings allow important information to be shared between team members, and provide an opportunity to speak up about any foreseen problem (see also Chapter 3 of this collection).[384] When tailoring a surgical checklist, we always face the challenge of inadvertently changing or removing an item or creating a more laborious workflow. To keep attention on critical items (analogous to 'killer' items in aviation), the WHO favours not removing items from the original list nor making the list too exhaustive.[445] If the WHO SSC is modified it is recommended the WHO adaptation guide be followed.[445]

Checklist sustainability

Are the effects of the WHO SSC sustainable over time? An investigation based on a large population from Scotland (1998 to 2014) attributed decreased mortality in most of the surgical specialties to checklists.[428] Similar findings have been reported in a 5-year retrospective study in Australian hospitals.[417] For more procedure-specific pooled analysis of emergency laparotomy procedures in 76 countries, mortality rates were significantly reduced when checklists were used.[418] In a large prevalence study from 426 European hospitals, checklist procedures were associated with lower crude mortality.[421] Even though other reasons could also explain some of the progress, for example, procedure-specific improvements and focus on patient safety in general, these results suggest that surgical safety checklists have a role in reduction of morbidity and mortality across continents.

Conclusion

Checklists like the WHO SSC and SURPASS represent a number of safety items that jointly can reduce pre-operative, intra-operative and postoperative errors. This updated literature review suggests that use of surgical safety checklists in peri-operative care can reduce morbidity and mortality after surgery.

Chapter 12: Emergency manuals as cognitive aids: from simulations to clinical implementations and uses (Goldhaber-Fiebert)

There is a mountain of published literature on optimal management for many operating room crises, such as local anaesthetic systemic toxicity or cardiac arrhythmias. But despite this, even expert clinicians frequently omit or delay key actions, with detrimental impacts on patient morbidity and mortality.[446,447] In the decade since the 2010 Helsinki Declaration on Patient Safety in Anaesthesiology, great strides have been made in the arena of cognitive aids to enable healthcare teams to deliver better care to our patients, during and peri-crisis. One of the first actions of the EBA/ESA Helsinki Declaration Implementation Task Force was to produce and promote a series of Crisis Checklists. Building upon the WHO Surgical Safety Checklist for normal workflow, which was highlighted in Helsinki,[392,393] multiple groups globally have worked on emergency manuals, including development, simulation testing, clinical implementation studies and training resources. Examples include 'The Anaesthetic Crisis Manual' by David Borshoff, the ESA Quick Reference Handbook (http://html.esahq.org/patientsafetykit/resources/checklists.html), and Guidelines for crises in anaesthesia https://anaesthetists.org/Portals/0/PDFs/QRH/QRH_complete_August_2019.pdf?ver=2019-08-23-113330-550. Others are Ariadne Labs Crisis Checklists (https://www.ariadnelabs.org/areas-of-work/surgery-or-crisis-checklists/), Society for Pediatric Anesthesia Critical Events Checklists (https://www.pedsanesthesia.org/critical-events-checklist/) and the Stanford Emergency Manual (https://emergencymanual.stanford.edu/).

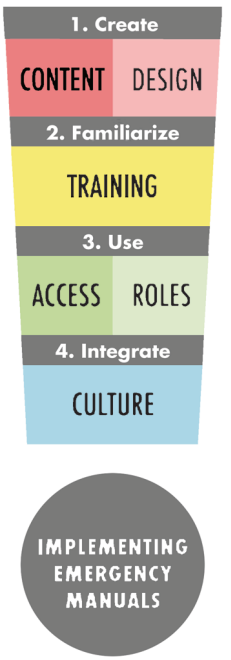
Other articles provide a history of the development of emergency manuals as patient safety tools and a conceptual framework for going from simulation-based evidence to clinical implementation and use (Fig. 7).[448,449] This work is a continuation of a previous publication in Anesthesiology Clinics (the author retained copyright of that text and gave permission to EJA to use those parts). The Emergency Manuals Implementation Collaborative (EMIC) provides a central repository, including links to many cost-free downloadable tools and an adaptable implementation toolkit at www.emergencymanuals.org.

Terminology

Emergency manuals are context-relevant sets of cognitive aids that are intended to provide professionals with key information for managing rare crises.

Synonyms and related terms are 'Crisis Checklists', 'Emergency Checklists' and 'Cognitive Aids'. The latter is a much broader term for any resource that enhances cognition, decision-making, or delivery of current best practices. This term is also often used to describe tools for crises specifically. To differentiate from normal workflow cognitive aids, throughout this article the term 'Emergency Manual' is used, except when referring generically to any of these as 'tools' or when describing a specific study with its own terminology. The synonyms above are also commonly used in the literature.

Fig. 7



Four vital elements for implementing emergency manuals ©S. Goldhaber-Fiebert and S. Howard, 2012; reprinted with permission.

Simulation: proof of concept, stress, teamwork, design testing and immersive training

In multiple simulation-based studies, correct performance of key actions during crises dramatically increased when emergency manuals were used.[450–452] One of the most impactful and widely cited simulation studies examined interprofessional operating room teams managing eight different operating room crises.[450] Each team served as its own control, randomly assigned to half of the events with, and half without crisis checklists. Participants were familiarised with the crisis checklist concept and format, though not the specific study events. A comparison between the simulated operating rooms with and without check lists, showed that fewer key management steps were omitted when check lists were used: 6 vs. 23%, respectively, signifying considerable improvement in crisis event management when using a checklist. Similar results have recently been shown in a large simulation-based study of surgical ward teams managing deteriorating postoperative patients (10 vs. 33%).[453]

Why are these tools so helpful, even for experienced clinicians? Stress reduction and enabling teamwork are both relevant mechanisms, as well as the broad benefits of

cognitive aids detailed previously that include directly helping to prevent omissions in medical management.[271,446,454] Across diverse safety-critical industries including health care, there is mounting evidence that even when they 'know' what to do, stress causes well trained professionals to omit key actions, to narrow their thinking, and to diverge from optimal management: emergency manuals serve as a powerful antidote.[455,456]

Simulation provides a powerful technique for training with emergency manuals: it is a laboratory in which to study their effectiveness, and a safe setting to test the usability of their design features.[312] One of the most impactful ways of enabling effective clinical use of emergency manuals is engaging clinicians immersively, demonstrating both the rationale of why to use emergency manuals and the practical details of when and how to use them, and, conversely, when clinicians are not familiar with emergency manuals they rarely use them, even if available.[448,457] A simulation-based study showed the power of a 'reader' reading out the steps aloud, and, dynamically interacting with the leader: this has led to read aloud steps, leading to exploratory work regarding a clinical reader role.[458–461]

Enabling tools

Emergency manuals are intended as both educational and clinical tools. They represent highly condensed repositories of practical knowledge that must be carefully and iteratively designed and that require training to enable effective use under conditions of significantpressure.[312,448,462–464]

Emergency manuals are intended to be symbiotic adjuncts, rather than replacements, for good preparation, teamwork and clinical judgment. Emergency manual use should never precede necessary immediate actions such as chest compressions for a pulseless patient. Their intended use begins only once resources allow – either sufficient help is available for synchronous use from the beginning of a crisis, or initial clinical actions are already underway.

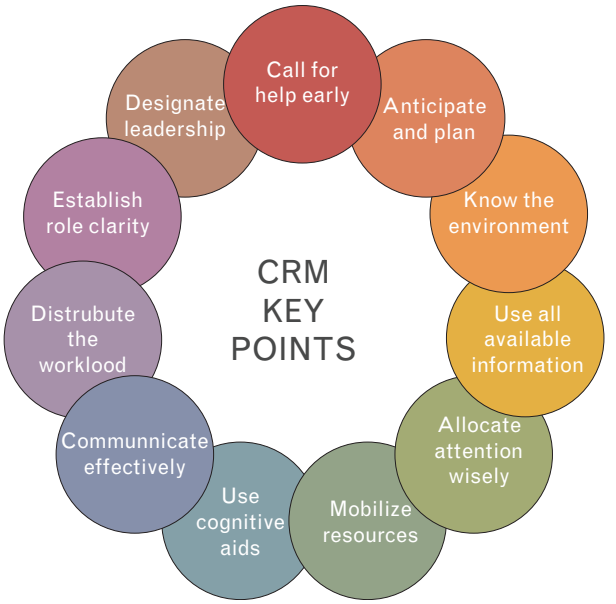
Effective team co-ordination and NTS are crucial to providing effective patient care and decreasing failure of rescue events.[448,465] Increasingly, studies in both simulation and clinical settings are finding that emergency manual use improves team co-ordination and decision making.[461,466,467] Within CRM, cognitive aids, including emergency manuals are one of multiple constructs which interact synergistically, all helping healthcare teams to provide better patient care (Fig. 8).[446,448,468] In addition to helping surgical teams and their patients, the concept of emergency manuals has spread to other settings, such as Labour and Delivery wards.[469]

Dissemination, clinical implementations and uses

Since the EMIC began in 2012, there has been broad dissemination of multiple tools globally. Conservative estimates are that more than half a million clinicians have downloaded various English-language tools or their translations (data from EMIC members), including robust data from Chinese translations.[470] Many clinicians stated they shared the tools widely with colleagues at their local institutions, implying even broader dissemination. These tools seem to be filling a need, with active interest in the concept from clinicians, though downloading is only one initial step towards clinical use. Building on simulation-based evidence of positive impacts, early implementations of emergency manuals spread the concept in clinical contexts and sought to understand questions including awareness (that the tool was available), range of clinical uses and usefulness.

In survey studies, clinicians reported significant numbers of emergency manual clinical uses (though none yet with denominators of applicable crises), and stated that emergency manual use during crises helped teams deliver better care to their patients and, when asked, none expressed distraction from patient care nor negative impacts.[470–472] Given that crises occur infrequently, the patterns of use necessarily differ from normal workflow tools such as the Surgical Safety Checklist: there is the added challenge that not only do clinicians need to familiarise themselves ahead of time with the why, the when and the how to effectively use emergency manuals, but also the clinicians must remember to trigger the emergency manual use during a stressful crisis. Of note, across the studies above, the vast majority of clinicians who used an emergency manual during a crisis had prior exposure and familiarity with the tool, as well as an increased intent

Fig. 8



Crisis resource management skills, including 'Use cognitive aids'. ©2008 S. Goldhaber-Fiebert, K. McCowan, K. Harrelson, R. Fanning, S. Howard, D. Gaba; reprinted with permission.

to use emergency manuals when applicable in future. This demonstrated a 'use begets use' feedback loop, with a positive reinforcement value of experiential use.

Changing clinical culture from 'you should know and remember everything', towards 'it's smart to use cognitive aids to help you provide better patient care', ensuring accessibility and familiarity with the manuals, empowering multiple team members to suggest emergency manual use, and incorporating immersive training, were among significant themes of successful emergency manual implementations.[459,471,473–475]

As more institutions are pursuing emergency manual implementation, a common question is how to implement this effectively. A study of 368 clinicians across the United States found multiple controllable factors to support success.[474] Success was correlated with the number of implementation steps they took, with a dose–response relationship, and leadership support was key. Training mattered, with interprofessional and immersive drills particularly impactful. Local customisation also helped, at a minimum for phone numbers and conformity with local policies. Simply hanging copies in the operating room rarely has much impact during stressful crises. This national survey work led also to develop an implementation toolkit, including a roadmap, training resources and common challenges. The toolkit is available cost-free from the AHRQ and the EMIC (www.emergencymanuals.org).

There are multiple case reports describing early emergency manual use during clinical crises, with both geographic and event diversity, and a case study including interviews with all team members.[461,476–478] While many biases exist for single cases, the combination of case reports and large surveys reinforces the fact that these tools are being used clinically, with clinicians perceiving helpful impacts in at least some circumstances. This underscores the need for more formal mixed-methods research on clinical implementation and use of emergency manuals.

As discussed further elsewhere, implementing emergency manuals shares with other complex, socially adaptive, processes the need to influence frontline clinicians' knowledge, attitudes and behaviours, and requires local adaptation and multiple coordinated approaches.[479,480] The vital prework is to agree locally on the problem as well as the need and potential for improvement. In this case, the problem and a potential solution are well represented in the simulation literature described above. There was a large gap between evidence-based literature and the management of stressful crises, and increasing clinical emergency manual use is helping to decrease that gap.

Conclusion

In the past decade since publication of the Helsinki Declaration on Patient Safety in Anaesthesiology, emergency manuals have been shown to enable healthcare teams to deliver better care to our patients, during and peri-crisis. Building upon initial simulation-based evidence of emergency manual efficacy, there has been widespread interest and with global dissemination, increasing clinical implementations. In early studies of peri-operative clinical implementations, emergency manual use showed positive engagement from clinicians and also a promise of improving care in clinical settings, with further work needed to fully assess their effectiveness across diverse clinical contexts. There is active spread of the concept and content development within other contexts, such as surgical wards and labour and delivery units.

Chapter 13: Anaesthetic monitoring recommendations during general anaesthesia: how consistent are they across the globe? (Hendrickx, Feldman, Schüler)

Since patient safety is a universal concern for all anaesthesia professionals, one might expect monitoring recommendations to be consistent across the world. To evaluate this assertion, we reviewed the recommendations from several professional societies (AAGBI, ANZCA, ASA, EBA, HKCA, IFNA, WFSA, WHO) selected for varied geographic representation. Monitoring recommendations for parameters describing cardiac and pulmonary function were mostly consistent. Recommendations are less consistent for monitoring other physiological systems or the anaesthetic state, for example, unconsciousness and immobility.

Professional organisations provide practice recommendations, but there are also manufacturing standards from the International Organization for Standardization (ISO) and International Electrotechnical Commission governing how devices are designed and built for clinical use. In some cases, manufacturing standards exceed practice recommendations and therefore become de facto clinical standards. For example, ISO requires end-expired agent monitoring when inhalation anaesthetics are used which is not true for all practice recommendations.

Reconciling the inconsistencies between monitoring recommendations uncovered in this comparison is a challenge for the various professional organisations. Recommendations from professional societies can provide guidance to the practitioner about whether or not it is acceptable to proceed with an elective procedure if one or more monitoring modalities are not available. Standards provide a consistent approach to practice for clinicians and offer patients a guarantee that they will receive the safest possible care. We should seek to ensure that these standards are clear and provide *common* protections for all patients no matter where they live.

Background

Monitoring recommendations for patients during anaesthesia care are intended to increase patient safety. Professional organisations develop these recommendations

to provide guidance for safe anaesthesia practice. Since patient safety is a universal concern for all anaesthesia professionals, one might expect recommendations across the world to be consistent. But are they? In this nonsystematic review, the monitoring recommendations of seven different professional organisations and the relevant ISO anaesthesia workstation standards are compared. This work is a continuation of a project initiated by the Anesthesia Patient Safety Foundation (APSF) Committee on Technology (of which two authors are members) and published initially in the APSF Newsletter.[481] At the invitation of the ESA PSQC, we have updated the original data with the recommendations of the Australian and New Zealand College of Anaesthetists and ISO anaesthesia workstation standards. The APSF kindly gave written permission to publish an update of the original article. The review is limited in scope to intra-operative monitoring recommendations during general anaesthesia.

Selection of standards: design and data sources

The monitoring recommendations of professional organisations were compared (Table 19). These organisations were selected as a cohort representative of standards in different parts of the world and varied practice settings. The list was not meant to be exhaustive – other professional organisations throughout the world such as the American Association of Nurse Anesthetists and those of many other countries offer important patient safety guidance to their constituents (https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/standards-for-nurse-anesthesia-practice.pdf?sfvrsn=e00049b1_18). ISO standards for anaesthesia workstations were added to examine the congruency between manufacturing and practice standards. Anaesthesia workstation manufacturers have to comply with the mandatory ISO standards to achieve regulatory approval.

Table 19 Monitoring recommendations of professional organisations

Monitoring recommendations of professional organisations
ASA: Standards for Basic Anesthetic Monitoring[482]
AAGBI: Recommendations for Standards of Monitoring during Anaesthesia and Recovery[383]
EBA: Recommendations for Minimal Monitoring during Anaesthesia and Recovery[382]
HKCA: Guidelines on Monitoring in Anaesthesia[483]
ANZCA Recommendations on Monitoring during Anesthesia http://www.anzca.edu.au/documents/ps18-2013-recommendations-on-monitoring-during-ana
IFNA: Monitoring Standards https://ifna.site/ifna-standards-of-education-practice-and-monitoring/
WHO–WFSA: International Standards for a Safe Practice of Anesthesia[484]
ISO, Geneva, Switzerland: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation (ISO80601-2-13:2011)

AAGBI, Association of Anaesthesists of Great Britain and Ireland; ANZCA, Australia and New Zealand College of Anaesthetists; ASA, American Society of Anesthesiologists; EBA, European Board of Anaesthesiology; HKCA, Hong Kong College of Anaesthesiologists; IFNA, International Federation of Nurse Anesthetists; ISO, International Organization for Standardization; WHO–WFSA, WHO and World Federation of Societies of Anaesthesiologists.

Findings

'Standards': what's in a name?

The ASA, IFNA, WHO–WFSA, AAGBI and ISO include the word 'Standards' in their title, whereas the EBA uses 'Recommendations' and the HKCA and ANZCA uses 'Guidelines'. Further evaluation of these documents reveals nuances of language that are important to the practitioner. In particular, it is important to understand what is considered an absolute monitoring requirement for every anaesthetic vs. monitoring modalities that are useful but not essential. Reconciling the various approaches will require agreement on the implications of the terms used.

The EBA document defines 'core standards' for monitoring as to 'be used whenever a patient is anaesthetised'.[382] The WHO–WFSA uses a tiered approach.[484] A 'highly recommended' standard is considered mandatory, that is, if not met, provision of anaesthesia for elective surgical procedures is unsafe and unacceptable. 'Recommended' and 'suggested' standards should be practiced 'when resources allow and if appropriate for the healthcare being provided'.

The ASA Policy Statement on Practice Parameters provides detailed definitions of standards, guidelines and advisories (which can be either evidence or practice based) (https://www.asahq.org/standards-and-guidelines/policy-statement-on-practice-parameters). Evidence-based *standards* provide rules or minimum requirements and are regarded as generally accepted principles of patient management, may be modified only under unusual circumstances, are supported by meta-analyses of findings from multiple clinical trials and are agreed upon by all or nearly all expert consultants and surveyed ASA members. A standard is the most stringent recommendation. Failing to comply with a standard would constitute a practice breech and not only put the patient at risk but expose the provider to liability that would be difficult to defend if an adverse event occurred. Evidence-based practice *guidelines* provide recommendations that describe a basic management strategy supported by meta-analyses of multiple clinical trials and are agreed upon by a majority of expert consultants and surveyed ASA members. Finally, evidence-based practice *advisories* provide statements to assist decision-making in areas of patient care where there is not a sufficient number of adequately controlled studies to permit meta-analysis. Evidence-based practice guidelines and practice advisories are not intended to be standards or minimum requirements. The ASA Committee on Standards and Practice Parameters is one such committee that supervises the creation of new and revision of older practice parameters.

Inconsistent monitoring requirements

Keeping in mind the 'semantic modifiers' alluded to in the previous paragraph, we provide a brief review of the recommendations contained in the 'standards' from these different organisations. All societies require that every anaesthetised patient be continuously attended by a qualified anaesthesia professional and have requirements for clinical monitoring. All require alarms to be activated and audible, with limits properly applied. There are, however, differences in recommendations for individual parameters. For purposes of this discussion, the term 'standard' will be used to indicate an absolute requirement. Because ISO standards pertain to manufacturers of anaesthesia workstations but not clinicians, they are considered in a separate paragraph.

Oxygenation

Blood oxygenation monitoring by pulse oximetry is a universal standard among all organisations. Monitoring of the inspired O_2 concentration accompanied by a low threshold alarm is a standard for all except the WHO–WFSA document where it is 'recommended'. Monitoring skin colour is a standard for all except the AAGBI and EBA who state it 'may be included as an appropriate clinical observation'.[383,482]

Ventilation

All organisations surveyed require end-expired carbon dioxide (CO_2) to be detected after intubation or supraglottic airway placement, and all but the WHO–WFSA require end-expired CO_2 to be monitored thereafter. WHO–WFSA cites cost and lack of robustness as the reasons for only 'recommending' continuous CO_2 monitoring. Qualitative assessment of ventilation (movement of chest and breathing bag, auscultation) is considered standard by WHO–WFSA, IFNA and EBA, but not by ASA, AAGBI, HKCA. According to ANZCA, ventilation 'must be monitored continually'. Monitoring cuff pressure of airway devices is considered a standard by the AAGBI and HKCA, and so is *inspired* CO_2 concentration monitoring (HKCA only). Standards for monitoring during mechanical ventilation differ: ASA 'strongly encourages' and WHO–WFSA 'suggests' expired volume be measured; all but ASA, ANZCA, IFNA and WHO–WFSA explicitly require airway pressure monitoring as standard; and a disconnection detector with alarm is a standard for all except the WHO–WFSA which 'recommends' it.

Circulation

ECG, intermittent BP measurements and heart rate (HR) monitoring are consistent standards, except for the WHO–WFSA who only 'recommends' ECG for rhythm monitoring; ANZCA requires ECG monitoring 'as clinically indicated'. In the AAGBI and EBA guidelines, HR monitoring is present implicitly in the ECG and pulse oximetry is a monitoring requirement. All guidelines require confirmation of a pulse [i.e. mechanical activity resulting in cardiac output (*CO*)] in the form of at least one of these: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry (Table 20). The AAGBI and HLCA standards require a stethoscope 'be available'. The IFNA standards also refer to end-expired CO_2 as a means to monitor *CO*.

Temperature

Recommendations are inconsistent and range from 'a means to measure temperature has to be available' to 'recommended' to 'essential for procedures more than 30 min', to 'when clinically significant changes in body temperature are intended, anticipated or suspected'. Temperature is not advocated as a standard to be adhered to throughout the entire procedure by any of the organisations except by the IFNA in paediatric patients and ANZCA 'whenever warming devices are being used'.

Kidney function

Monitoring urine output is either not mentioned, or 'suggested in appropriate cases' (WHO–WFSA, AAGBI).

Neuromuscular transmission after administration of muscle relaxants

Recommendations range from being a standard (AAGBI) to not being mentioned (ASA) to variations in between. For example, the WHO–WFSA 'recommends' it, the EBA states that a nerve stimulator has to be available, and the HKCA states that 'it should be used whenever the anaesthetist is considering extubation following the use of nondepolarising neuromuscular blockade'. The IFNA states that professionals should 'measure, assess, and score neuromuscular function by a neuromuscular monitor (if available) when neuromuscular blocking agents are being used'.

Concentration of inhaled anaesthetics

Monitoring the end-expired concentration of inhaled anaesthetic agents is a standard for the AAGBI, EBA, ANZCA and the HKCA (the latter, in addition, requires automated agent detection). The WHO-WFSO 'suggests' both inhaled and exhaled concentrations to be measured. The ASA standards do not mention inhaled anaesthetic agent concentration monitoring. The IFNA recommends that both inspiratory and expiratory anaesthetic concentrations of volatile agents be measured continuously 'if possible'.

Measure of drug effect on the central nervous system/ unconsciousness

According to the HKCA, 'When clinically indicated, equipment to monitor the anaesthetic effect on the brain should be applied, especially for patients at high risk of awareness, for example, those receiving total intravenous

Table 20 Monitoring standards

Name of organisation			ASA	AAGBI	EBA	HKCA	ANZCA	IFNA	WHO–WFSA	ISO
Geography			USA	UK, Ireland	European	Hong Kong	Australia, New Zealand	Global	Global	Global
Professional group			Anesthesiologists	Anaesthetist	Anaesthesiologist	Anaesthesiologists	Anaesthetists	Nurse Anesthetists	'All anesthesia providers throughout the world'	'Machine standards
Reference			482	383	382	483	See Table 19	See Table 19	484	See Table 19
Semantics in title of referenced document		Standards	Standards	Recommendations	Guidelines	Guidelines	Standards	Standards	Standards	
Physiologic system	Parameter	Device					Monitor required per standards?			
Oxygenation	Inspired gas	O_2 analyzer + low threshold alarm	Yes	Yes	Yes	Yes	Yes	Yes	Recommended	Yes
	Blood	Pulse oximeter	Yes	Yes	Yes	Yes	Yes	Yes	Highly recommended	No
	Skin colour	Exposed + well lit	Yes	'May include'	'May include'	Yes	Yes	Whenever feasible	Highly recommended	No
Ventilation	Qualitative	Chest & bag moving, breath sounds	'Are useful'	'May undertake auscultation'	'Must auscultate'		'Must be monitored continually'	'At least observe and auscultate'	Highly recommended	No
	Quantification	Expired tidal volume	Strongly encouraged					Respiratory volume	Suggested	Yes
	ETT or LMA present	Confirm $FACO_2$ after insertion	Yes	Yes	Yes	Yes		Yes	Highly recommended	No
		Airway device cuff pressure		Yes		Yes				
		Capnography during case[a]	Yes	Yes	Yes	Yes (+ $FICO_2$)	Yes	Yes	Recommended[b]	Yes
	With mechanical ventilation	Disconnection detector with audible alarm	Yes	Yes	Yes	Yes	Yes	Yes; if possible in- and expired volumes and inhaled agent concentration	Recommended	Yes
		Paw		Yes	Yes	Yes				Yes
Circulation	ECG	ECG	Yes	Yes	Yes	Yes	'As clinically indicated'	Yes	Recommended (for rhythm)	No
	NIBP intermittent	BP q5'	Yes	Yes	Yes	Yes	Yes q10 min	Yes	Highly recommended	No
	HR	HR q 5'	Yes	Implicit in ECG	Implicit in ECG	Yes	Yes q10 min	Yes	Highly recommended (by SpO_2)	No
	Pulse	Palpation, IAP trace, ultrasound, Pleth, SpO_2	yes (≥1 of these)	[c]	Yes (palpation)	[c]		Yes (at least 3 of 7 parameters)[d]	Highly recommended (pulse, heart sounds)	No
Heat balance	Temperature	Thermometer	If significant changes expected	Yes if >30 min	Must be available	yes if >30 min	Yes if warming device used	Yes in paediatrics; in adults 'if indicated'	Recommended	No
Kidney		Urine output		Where appropriate					Suggested (elective)	No
NMT if MRX used	Muscle strength	NMT monitor		Yes	Must be available	Must be used prior to extubation	Must be used prior to extubation	If available	Recommended	No
CNS (unconsciousness)	Exhaled agent %	Multi gas analyser		Yes	Yes	Yes (+ automated agent detection)	Yes (if inhaled agent used)	If available	Suggested (+ inspired %)	Yes
CNS (unconsciousness)	EEG/EEG-derived index	BIS or analogue		Recommended with TIVA + MRX	'Yet to be fully considered'	High risk of awareness (TIVA + MRX)	When clinically indicated (esp. high awareness risk)	Consider, esp. if high awareness risk	Suggested (elective: high risk of awareness)	No

AAGBI, Association of Anaesthesists of Great Britain and Ireland; ANZCA, Australia and New Zealand College of Anaesthetists; ASA, American Society of Anesthesiologists; BIS, bispectral index; BP, blood pressure; CNS, central nervous system; EBA, European Board of Anaesthesiology; EEG, electroencephalogram; ETT, endotracheal tube; F_ACO_2, end-expired CO_2 concentration; F_ICO_2, inspired CO_2 concentration; HKCA, Hong Kong College of Anaesthesiologists; HR, heart rate; IAP, intra-arterial pressure; IFNA, International Federation of Nurse Anesthetists; ISO, International Organization for Standardization; LMA, laryngeal mask airway; MRX, neuromuscular blocking agents; NMT, neuromuscular transmission; Paw, airway pressure; Pleth, plethysmography; S_pO_2, pulse oximetry; TIVA, total intravenous anaesthesia; WFSA, World Federation of Societies of Anaesthesiologists. [a] Or capnometry/mass spectrometry + audible alarm. [b] Only 'recommended' for now due to costs and lack of robustness. [c] Stethoscope must be available. [d] Also refer to F_ACO_2 to assess circulation.

anaesthesia with a muscle relaxant'. The IFNA states that the application of an electronic device intended to measure cerebral function should be 'considered', particularly in cases with high risk of awareness under general anaesthesia. According to ANZCA, 'When clinically indicated, equipment to monitor the anaesthetic effect on the brain should be available for use on patients, especially those at high risk of awareness, during general anaesthesia'. The WHO–WFSA states that its 'use ... while not universally recommended or used, is suggested, particularly in cases at risk of awareness under general anaesthesia or postoperative delirium'. The AAGBI recommends the 'use of depth of anaesthesia monitors, for example processed EEG monitoring ... when patients are anaesthetised with total intravenous techniques and neuromuscular blocking drugs, to reduce the risk of accidental awareness during general anaesthesia. However, there is no compelling evidence that routine use of depth of anaesthesia monitoring for volatile agent-based general anaesthetics reduces the incidence of accidental awareness when end-tidal agent monitoring is vigilantly monitored, and appropriate low agent alarms are set'. According to the EBA, '... their routine use has yet to be fully considered as part of our recommended minimum monitoring standards'. ASA does not consider EEG or EEG-derived indices in its Standards for Basic Anaesthetic monitoring.

International Organization for Standardization workstation standards

ISO workstation standards use the terms 'shall, should and may' to designate the degree of required compliance. 'Shall' indicates that compliance is mandatory, 'should' implies it is recommended but not mandatory and 'may' is used to describe a permissible way to achieve compliance. Mandatory monitoring recommendations for anaesthesia workstations include inspired O_2 fraction monitoring with a low threshold alarm, quantification of respiratory volumes, capnography, and, during mechanical ventilation, airway pressure monitoring and a disconnection detector with an audible alarm. Anaesthetic agent monitoring is considered mandatory when inhalation agents are used. Since the ISO workstation standard applies to all devices used together to provide anaesthesia care, agent monitoring is not a required hardware component of the anaesthesia machine since separate free-standing devices for agent monitoring can be employed to be compliant.

To obtain regulatory approval (CE marking or Food and Drug Administration approval), manufacturers would be expected to comply with all essential requirements in the ISO standards, that is, those designated as 'Shall'. For the recommendations designated as 'should' or 'may', regulatory approval will be influenced by the risk analysis required of the manufacturer as part of the regulatory submission.

Discussion

The current brief review has identified a number of inconsistencies between the anaesthesia monitoring recommendations promoted by professional organisations in different parts of the world, and with manufacturing standards stipulated by ISO. In general, monitoring standards for parameters that describe the cardiopulmonary system are mostly consistent. This is less true for other physiological systems or for other aspects of the anaesthetic state like immobility or unconsciousness. In addition, ISO standards exceed certain monitoring requirements for which professional societies differ in opinion, for example, for tidal volume measurements and airway pressure monitoring during mechanical ventilation. As a result, ISO standards become de facto practice standards when using an ISO compliant anaesthesia workstation.

If safety is universal, why are recommendations not?

Published recommendations are developed by consensus within each organisation, so it is not surprising that the results are different around the world. For the developing world, professional organisations are sensitive to resource limitations and are reluctant to impose requirements that are difficult to comply with. Nevertheless, the importance of patient safety does not change by geography. The WHO–WFSA has made a major effort to reconcile guidelines by different societies and develop practical recommendations that can be followed anywhere in the world. In the developed world, the differences in recommendations are more difficult to understand as the resource constraints are not as significant.

Which important recommendations might merit reconciliation?

The recommendations for end-expired agent monitoring, anaesthetic depth monitoring and neuromuscular transmission monitoring are different from each organisation yet can be important tools for assessing anaesthetic effect and should be considered when thinking of aligning the various recommendations.

During surgery under general anaesthesia, the patient expects to be unconscious and to not experience pain. Both inhaled and intravenous agents are commonly employed to achieve that goal. When inhaled agents are used, end-expired anaesthetic agent monitoring can ensure that the inhaled anaesthetic agent is being delivered, and, in a dose that at least ensures unconsciousness.[485] As noted above however, only four organisations consider end-expired agent monitoring a standard. WHO–WFSA 'suggests' that it be used whereas the ASA monitoring standard does not even mention inhaled agent monitoring. IFNA only recommend its use 'if available'. In the authors' opinion, sufficient rigorous scientific data exist to elevate end-expired anaesthetic agent monitoring to the status of standard. Three

properties of inhaled agents provide the rationale for end-expired agent monitoring: the steep dose response curve of volatile anaesthetics; the small effect opioids have on this relationship [only a 10 to 15% reduction in minimal alveolar concentration (MAC) awake, the median anaesthetic level for patients to respond to verbal command][486]; and the ease of continuous measurement of their concentration. The end-expired agent concentration is a good indicator of how likely it is the patient is unconscious after taking into account the short delay for the brain partial pressure to equilibrate with that in the blood and alveoli. With an expired concentration of 0.7 MAC, awareness is extremely unlikely.[487,488] Fortunately, ISO workstation standards impose anaesthetic agent monitoring so all ISO compliant workstation configurations will offer anaesthetic agent monitoring either built into the anaesthesia machine or part of a bedside monitoring device. Practice recommendations from professional societies can provide guidance on the safety of proceeding with an inhaled anaesthetic if the agent-monitoring device is not functional.

When intravenous agents are used, we cannot assess the serum concentration quantitatively, so we are left with measures of drug effect such as processed EEG. Despite the technology limitations of processed EEG monitoring, more than one organisation (but not all) advocates that it be used, especially for patients at high risk for awareness. Whether or not the current technology for brain monitoring to assess anaesthetic depth is sufficiently robust to be a required monitor remains a matter of debate.[489] Similarly, while there is inconsistency about requiring neuromuscular transmission monitoring when using neuromuscular blocking agents, it is notable that the Anesthesia Patient Safety Foundation clearly advocates for this requirement.[490]

Conclusion

The primary responsibility of the anaesthesia professional is to keep the patient safe. Resources, liability concerns, patient needs and clinical scenarios all play a role in determining the monitoring needs for any given patient. Standards provide a reference for practitioners and a guarantee to patients of a certain level of safety. We should seek to ensure that standards are as consistent as possible and provide common protections for all patients no matter where they live.

Chapter 14: Avoiding failure-to-rescue: rapid response systems (Subbe, Welch)

Failure to rescue of patients with quantifiable signs of deterioration is a preventable complication of hospital treatment. Rapid response systems represent a comprehensive approach to reduce failure to rescue and consist of an afferent limb and an efferent limb. The afferent limb aims to monitor for relevant signs of deterioration and usually includes a standardised method of evaluation of vital signs to identify changes from a stable status. Escalation of deteriorating patients can be through any member of staff. In a patient centred service patients and relatives should be able to raise concerns too. The team that responds to the deterioration is labelled a rapid response team, medical emergency team or critical care outreach team. Systematic reviews and meta-analyses of published studies show a reduction in cardiac arrests and mortality in hospitals deploying rapid response systems.

Background

The configuration and funding of health care at local, regional and national levels vary across the world, but the epidemiological challenges of ageing populations, an increasing burden of chronic disease and rising costs are common themes.

Modern hospitals manage larger numbers of increasingly complex cases. For example, 'Finished Admission Episodes' have grown by 21% in 10 years in England, with patients aged 70 to 74 making up the single largest group when broken down into 5-year age bands (with the exception of patients aged zero to 4, including babies born in hospital).[491] Such patients commonly have several medical conditions. At the same time, treatment regimens are ever more complicated, and many patients take a variety of often-interacting and sometimes immunosuppressive medications. Surgical procedures are becoming more sophisticated and are performed on patients with significant comorbidities. Beyond the burden of disease, ageing is related to increasing frailty with a decreasing ability to adapt to physiological and psychological insults such as acute respiratory or heart failure, acute kidney injury, sepsis, clotting disorders and delirium.

Not surprisingly, ward staff in hospitals worldwide struggle to manage the acuity and dependency of patients either at-risk or actually experiencing deterioration. Insufficient staff numbers, an inadequate skill-mix and a higher proportion of temporary staff are associated with gaps in care and increased mortality.[492] Moreover, acute deterioration in one patient increases the risk of a critical illness event in neighbouring patients, illustrating that wards tend to lack the resilience to ensure patient safety when unexpected additional demands are brought to bear.[493]

Typically, 5 to 10% of hospital patients have periods of significant instability. Deterioration is usually revealed by abnormal vital signs and/or laboratory/diagnostic results. Altered physiology may be transient and resolve with little or no treatment, but deterioration to the level of critical illness, organ failure and death can occur precipitously; one multinational study found that one in 10 ward patients referred for a rapid response died within 24 h.[494] The absence of a reliable response to warning signs of impending harm was initially described

in the surgical literature as 'failure to rescue' but the term is now used in a broader sense including missed opportunities to recognise or act on signs of deterioration in the general hospital population.

There is considerable evidence that deteriorating ward patients often receive suboptimal care. Inadequate monitoring is a major problem, with signs of abnormal mental and respiratory function frequently overlooked. This can result in cardiopulmonary arrest and (often belated) transfer to an ICU. Delayed treatment of deterioration is associated with worse outcomes even when ICU admission does occur, and patients and families are left with physical and psychological complications including increased dependency and posttraumatic stress disorder. Furthermore, missed deterioration is a growing cause of complaints and litigation as patients are better informed and less tolerant of suboptimal care.

Based on the observation that deterioration is common, often predictable and sometimes preventable, hospitals in Australia, the United Kingdom, the United States of America, Scandinavia and the Netherlands developed systems of surveillance and escalation to reduce the number of avoidable deterioration events in the 1990s and 2000s. In Australia, Ken Hillman established a medical emergency team triggered by abnormalities in any one vital sign, in the UK critical care outreach teams alerted by a whole range of indicators were formed, while in the USA Michael DeVita's rapid response team was activated by predefined abnormalities.[495–497] The commonalities were that personnel with experience in ICU and training in the management of critical illness responded to altered physiology and ward staff concern about patients outside ICU. The insight that a whole system is needed for timely identification and management of potential or actual deterioration has led to the term ''rapid response system'' being used to describe the essential components required.

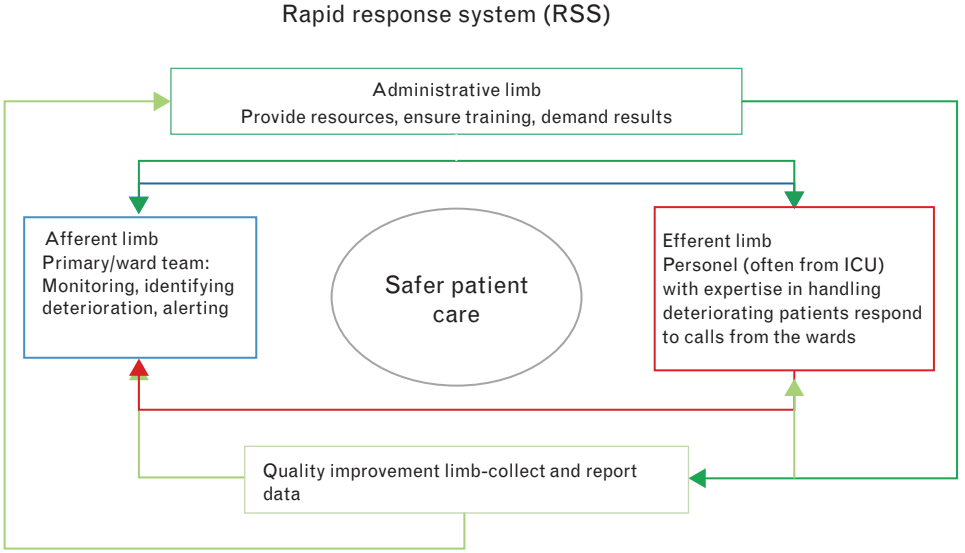
The current chapter describes the structure and processes of a rapid response system and the current understanding of its potential impact on clinical outcomes, particularly with regard to peri-operative patients.

Structure

The first international consensus conference on rapid response systems in 2010 summarised the key elements of a functioning system (Fig. 9) that detects early deterioration and provides timely escalation and treatment using the terms 'afferent limb' for a mechanism of deterioration detection and 'efferent limb' for the mechanism of response.[498]

Afferent limb: Patients at risk of significant deterioration are generally identified by physiological 'Track and Trigger' systems. Vital signs including respiratory rate, oxygen saturation, pulse rate, BP, level of consciousness, temperature and other indicators such as urine output and reported pain are 'tracked', with 'trigger' of an escalation if threshold values are reached. track and trigger systems may use threshold values of single physiological parameters, summary scores (generally known as 'Early Warning Scores', Fig. 10), or complex composites including laboratory data and other markers of acute and chronic

Fig. 9



The structure of a rapid response system, adapted from the findings of the first Consensus Conference of medical emergency teams.[499]

Fig. 10

	Physiological Parameters	3	2	1	0	1	2	3
A	Respiratory rate (bpm)	≤8		9-11	12-20		21-24	≥25
B	O2 Saturations (%)	≤91	92-93	94-95	≥96			
	Any supplemental Oxygen		Yes		None			
C	Systolic BP (mmHg)	≤90	91-100	101-110	111-219			≥220
	Pulse (bpm)	≤40		41-50	51-90	91-110	111-130	≥131
D	AVPU score				Alert			VPU
E	Temperature (°C)	≤35.0		35.1-36.0	36.1-38.0	38.1-39.0	≥39.1	
	Concern about a patient should lead to escalation, regardless of the score.							

National Early Warning Score, AVPU, alert, voice, pain, unresponsive; BP, blood pressure; bpm, beats per minute; O_2, oxygen.[502]

illness. Escalation to the efferent limb might include activation by patients or family members.[500–502]

Efferent limb: Triggers can lead to escalation to a patient's own medical teams or to specialist personnel with critical care skills. The latter can be critical care nurses or doctors or mixed teams including medical residents and respiratory therapists. In the United Kingdom, dedicated critical care outreach nurses usually provide the response. In Australia and the United States, it is more typically a medical emergency team or rapid response team that leaves the ICU to review patients on general wards. Rapid response teams can expedite transfers into higher care areas as well as facilitating invasive and noninvasive ventilation, insertion of central venous catheters and administration of inotropic and vasoactive drugs on general wards. The quality of the co-ordination between the patient's primary, ward-based team and the response team is important;[503] the location and characteristics of the patient, the nature of the episode of deterioration and the skill mix of the clinical teams are all factors. At an organisational level, the underlying concept of care is 'right time, right people, right place'.

The afferent and efferent limbs of the rapid response system are supported by administrative functions and data collection for audit, quality assurance and improvement. A recent systematic review found that 'clear leadership and continuous quality improvement provide the foundation for the continuing collaboration to manage deteriorating patients'.[499] At an organisational level, regular evaluation of the safety culture should underpin other metrics.[504] Governance of a hospital-wide system to provide safe care requires interprofessional training tailored to the needs of the different areas to assure whole system performance as well as structures to ensure widespread learning from both best practices and serious adverse events.

Process: The risk of deterioration is usually derived from considerations of physiological instability and pre-existing morbidity such as conditions that might suppress the immune response to infection. In addition, staff concern (nurse worry) and patients' self-reports are increasingly understood to enable a more complete understanding of the patient's condition and trajectory.[505]

At microlevel, management of the individual patient at-risk of deterioration can be structured with a 'record, recognise, report, respond and repeat' framework (Fig. 11).[506] The regular, reliable recording of vital signs is essential in detecting patients in impending or actual crisis;[507] noting that recognition of deterioration is a complex problem and many patients deteriorate 'in plain sight'. This has led to the development of rule-based systems to encourage awareness of the need for escalation once threshold values have been reached. The UK National Early Warning Score (NEWS) is an example of a widely validated scoring system with an associated escalation protocol (Fig. 10).[502] The ambition is to have a 'common language of deterioration' with an expected response that is understood across both primary and secondary care.

Healthcare technicians or nurses usually undertake recording of vital signs. The translation of the underlying pathology that leads to deterioration into the ordering of confirmatory tests and prompt treatments generally requires the involvement of other healthcare

Fig. 11

Process of activation and response of a rapid response system. Chain of survival.[506]

professionals such as advanced nurse practitioners or doctors. The process of reporting to more senior staff is one of the weak points in the translation of data about deterioration into active management. Automated electronic systems for vital sign capture might support more reliable escalation.[508] Structured communication tools such as 'Situation–Background–Assessment–Recommendation' are recommended to increase the amount of actionable information relayed to the responding team.[509]

Rapid response to deterioration requires the immediate availability of suitably skilled staff. Cognitive aids can help these personnel deliver the required actions in intrinsically stressful situations in a more timely and complete manner.[510] Nonetheless, acute illness is by definition unstable and variable. Many patients will improve for a period only to deteriorate again, meaning that surveillance of those at-risk does not end with the initial escalation event. In addition, many deteriorating patients may not have a reversible condition but may instead be suffering from terminal illness. De-escalation and referral to more palliative orientated services is not infrequently the most appropriate action.[494,511] Equally, unstable patients who do have potentially reversible conditions are likely to need safe transfer to a higher level of care such as ICU or the operating theatre.

The expert consensus is that patients who require organ support or other critical care type interventions should receive such treatments in a timely fashion,[512] certainly within 6 h of documented deterioration; and that all patients who trigger on whichever criteria is locally agreed should have a documented plan of the goals of care within 24 h of triggering.[504] The plan should specify if, how and when a patient's treatment should be escalated or de-escalated.

Outcomes: The impact of a functioning rapid response system can be described along the dimensions of the quadruple aim: around clinical outcomes, patient and staff satisfaction and health-economic metrics. In 2018, the International Society for rapid response systems convened a consensus conference to agree on a set of metrics that can be applied to hospitals worldwide.[504] Given that the majority of cardiac arrests are known to be preceded by documented deterioration, the number of cardiac arrests is consistently found to be one of the outcomes that decreases in hospitals with a functioning rapid response system.[513] It would be expected that a reduction in the number of cardiac arrests occurring 30 min or more after abnormal vital signs are recorded would be seen.

Meta-analyses and systematic reviews of the peer reviewed literature on rapid response systems suggest a measurable impact on mortality at a hospital level.[514,515] Nonetheless, the only two randomised controlled trials of rapid response systems – from the UK and Australia – showed mixed results with reduced mortality in the step wedge design UK trial but no improvement in the cluster randomised controlled trial from Australia.[497,516] The reasons for the difference in results are unclear, but may be linked to a difference in day-to-day engagement with ward teams. While there is a clear link between delayed initiation of life-saving treatment and mortality, this is difficult to monitor outside a research setting. Many patients who die in hospital are expected to die and the attributable mortality of acute complications is often difficult to quantify.[517]

Transfer to ICU is sometimes used as a surrogate indicator of timely escalation but the relationship between early detection of deterioration and ICU admission is somewhat tenuous; with early detection leading appropriately to avoidance of admission in some cases and to more admissions in other patient groups or healthcare systems. It is also often difficult to define where rapid response systems incur or save costs; prompt intervention might lead to shorter courses of acute illness in and outside ICU, but the set-up and maintenance of a system with monitoring equipment, acquisition of vital signs and the staff required to respond to escalation in a timely manner will incur costs too. Other effects of rapid response systems are documented in qualitative studies; for example, in the suggestion that the support of a rapid response system improves ward staff satisfaction and retention – as well as patient satisfaction – but this requires further investigation.[518]

Rapid response and peri-operative care

In the context of peri-operative care, rapid response systems have additional safety functions, especially in the critical care outreach format where a follow-up service for patients discharged from the operating theatre recovery area or ICU after major surgery is available. Critical care outreach systems allow potentially more flexible use of bed-capacity with the ability to support the 'flex-up' beds on general wards so as to provide care for relatively unstable patients for a limited period after surgery. This model also incorporates pro-active rounds with the ward staff with regards to patients who are causing concern but can be effectively managed with pre-emptive measures.

After major surgery or a prolonged stay in ICU, many patients struggle with complications such as critical illness neuromyopathy, anxiety, depression and posttraumatic stress disorder. The rapid response critical care outreach team can assist with the surveillance of patients' physical and mental health after recovery from critical illness, guide goal setting and aid continuity between critical and general care, even if the most effective interventions to reduce the burden of disease after critical care are less clear.[519]

Discussion and conclusion

At the third international consensus conference on rapid response systems, we reviewed metrics for evaluating the function of an individual hospital's rapid response system with the intention to provide a universally applicable model of quality assurance, independent of any particular healthcare system or size of hospital. It is arguable whether or not some of the metrics should be made public and how this would affect the engagement of clinical teams and hospital administrators. Due to the complexity of hospitals that within much larger systems that support patients, it may not be possible to compare metrics directly between hospitals – especially those from different regions or countries – but this should not preclude an open debate about outcomes informed by transparent data. Regardless of the goals of care for individual patients, timely delivery of the right care for deteriorating ward patients will reduce the impact of acute illness on patient morbidity and, importantly, suffering.

Rapid response systems do not operate in an organisational vacuum but can be used as the safety-thermometer of an organisation or indeed as the engine of patient safety across all general wards. Metrics of organisational culture including the ability of staff to correct care decisions of senior colleagues and to speak out and escalate care outside a primary care team might be the measures that give managerial teams the confidence that patients are safe. In a similar vein, standards of staff training and assurance of competence to detect and care for vulnerable patients are key to overall hospital safety and can be delivered and monitored by a good quality rapid response system. The financial impact of a deficit in the safety of a hospital could include many other indicators such as poor staff retention, costs of litigation and the broader allocation of a value to patient and staff satisfaction.

Hence, catastrophic deterioration of patients in hospital might be predictable and preventable with the whole-system approach to safety of a rapid response system.

Chapter 15: Diagnosing the deteriorating patient: remote monitoring on the ward and beyond (Preckel, Kalkman)

Current monitoring on the surgical ward

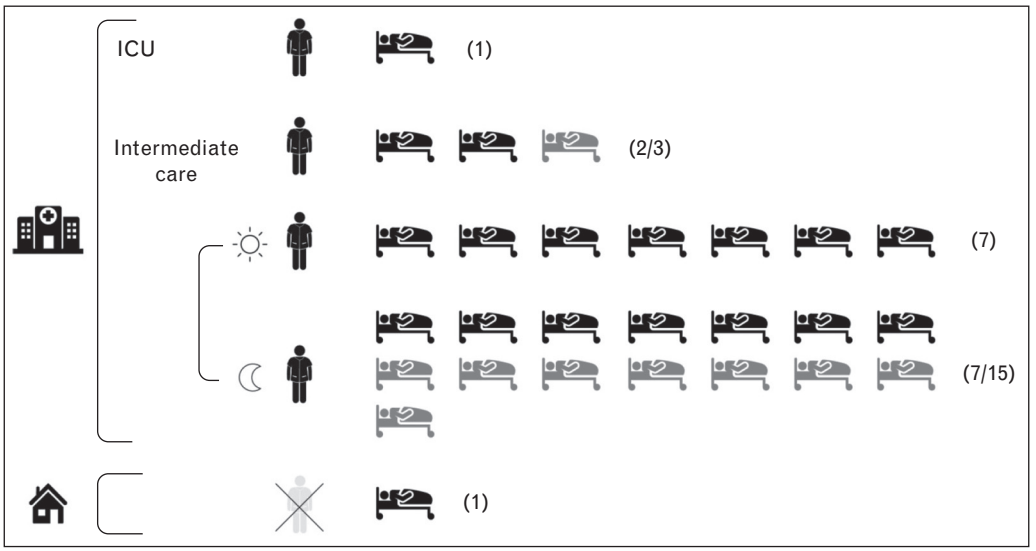
Measuring vital signs such as HR, respiratory rate, non-invasive BP, body temperature, urine output and peripheral oxygen saturation at regular intervals is the cornerstone of patient surveillance, not only in the operating room and ICU, but also on hospital wards. Measuring these physiologic variables and possible deviations from what is defined as 'normal' should alert healthcare professionals to check whether additional treatment is necessary to prevent patient deterioration.

Although the hospital ward is a perfect location for surveillance of postoperative patients, about 50% of the in-hospital cardiac arrests occur on these wards. The EUSOS study taught us that most patients who died in the hospital never received care in a high-dependency monitoring unit, for example, a medium care unit or ICU.[520] Comparing hospitals with high and low peri-operative mortality rates, Ghaferi *et al.*[521] observed similar postoperative complication rates, but the lower mortality in top-performing hospitals could be attributed to timely detection and adequate treatment of complications. In most cases of intrahospital cardiac arrest, deteriorations of physiologic parameters minutes to hours before the emergency event have been observed.[522] Thus, optimising the 'afferent arm' of a rapid-response system by timely detection of vital signs abnormalities, summarising and interpreting deviations with the help of scores such as the NEWS,[510] notifying relevant medical staff (e.g. the rapid response team),[523] and adequate and timely treatment decisions to prevent further deterioration should significantly decrease the incidence of fatal events on the ward as well as transfers to the ICU. This should not only improve patients' outcomes, but should also reduce care costs. A recent expert opinion-based Consensus Statement by the International Rapid Response Society states that cardiac arrest rates on general wards with a well performing rapid response system should be close to zero.[504]

So much for the theory: in practice not all elements of this theory are supported by robust evidence. But what then is the reality? For this chapter, we will focus on the monitoring part of the rescue chain, also known as the 'afferent arm' of the rapid response system.[524]

We can easily recognise that we have a significant monitoring gap on our wards, as well as in patients discharged home from hospitals (Fig. 12). In the operating room and

Fig. 12



The monitoring gap on the ward and after discharge of patients.

on the ICU, we continuously measure HR, respiratory rate and peripheral oxygen saturation, and blood pressure at least intermittently every 3 to 5 min. Results are manually written down in the patient chart or registered electronically in the patient data management system. In addition, more invasive measurements such as intra-arterial or central venous pressures are performed in high-risk patients undergoing major surgery.

In the operating room, an anaesthesiologist – in Europe often together with an anaesthesia nurse – is caring for the patient. This staff-patient ratio of 2 : 1 reverses on the postoperative care unit, but then dramatically decreases further when the patient is discharged to the ward, especially during the late evening and night hours when nurse–patient ratios of 1 : 15 are common (Fig. 12). When the patient is finally discharged from hospital to home, monitoring of vital parameters at home most likely completely stops. A large European study demonstrated that both nurse staffing numbers and nurse qualifications are associated with patient outcome.[525] However, with the shortage of nurses in most care systems in the world it is unlikely that we can easily improve nurse–patient ratios on most wards in the future. This urges us to find other possibilities for improving monitoring of vital parameters.

On the ward, manual measurement of physiologic variables by the nurse takes place every 8 to 12 h; this interval can be adapted according to the patient needs and monitoring will be more frequent in wards with critical patients.[526] Measuring vital signs is time consuming, and adds a huge burden to nurses' workload. Even if we could afford increasing nurse staffing to allow measuring vital parameters every 2 h, and assuming that the taking and recording of such a set of vital parameters lasts about 10 min, the patient will only be monitored for 120 min during a 24-h period. Thus, even in these optimised conditions patients on the ward are still not monitored for 22 of 24 h. Most complications occur on postoperative days 2 to 4.[527] We therefore urgently need to optimise our surveillance protocols on the postsurgical wards to detect postoperative deterioration early, thereby further improving patient outcome.

Future monitoring on the ward

Conclusions on the afferent limb of the rapid response system from a consensus conference of safety experts addressed the following topics. First, to what extent do physiologic abnormalities predict risk for patient deterioration? Second, do workload changes and their potential stresses on the healthcare environment increase patient risk in a predictable manner? Third, what are the characteristics of an "ideal" monitoring system, and to what extent does currently available technology meet this need? And fourth, how can monitoring be categorised to facilitate the comparison of systems?'[507] The authors reviewed the literature up to 2008, and concluded their publication as follows: 'first, vital sign aberrations predict risk; second, monitoring patients more effectively may improve outcome, although some risk is random; third, the workload implications of monitoring on the clinical workforce have not been explored, but are amenable to study and should be investigated; and fourth, the characteristics of an ideal monitoring system are identifiable'.[507]

It has been shown that patients and nurses do not accept continuous monitoring with 'wired' systems on general

wards, as these systems hamper mobilisation and are prone to false alarms from (movement) artefacts. Only 16% of patients were continuously monitored up to 72 h postoperatively; monitoring was stopped early for mobilisation reasons by nurses (37%) or by patients themselves (30%).[528] Some monitoring systems that previously only used wired sensors can now be upgraded to allow complete wireless surveillance.[529] In addition, fully wireless monitoring systems have recently become available.[530] Several of the newer systems use an adhesive wireless 'patch' sensor to detect multiple vital signs such as HR from ECG, respiratory rate, and axillary or skin temperature. Some systems have an accelerometer to detect motion and patient position.[531] Regarding the characteristics of an ideal monitoring system, DeVita *et al.*[507] proposed a long 'wish list' of desired features, including such characteristics as evidence-based, multimodal, accurate, sensitive and specific, continuous, having the ability to trend in real time, not hindering patient mobility and being comfortable, allowing automated alerts/alarms directed to specific caregivers, and being cost-effective and upgradable at low cost with low maintenance costs.

Of course, these systems should effortlessly interface with the electronic health record, and have failure mode recognition as well as default modes to allow for speciality specific displays.[507] Expecting to see such fully mature system in our hospitals very soon is wishful thinking, but might become a reality in the near future.

Wireless monitoring systems will, of course, obviate the need to tie patients with wires and tubes to a (bedside) monitor, thereby allowing for early mobilisation and yet allow staff to be able to locate the patient in a given emergency. But whether these systems are also accurate, specific and sensitive still has to be investigated thoroughly. Surprisingly little validation data has been published on currently available wireless sensors, and a CE mark can be obtained easily by showing that the sensor correctly measures vital signs in healthy volunteers at rest. Nonetheless, current data are promising, showing reasonable accuracy in measuring different vital parameters with different systems.[532–534] While detection of HR seems to be no real problem for most systems, respiratory rate is more prone to be influenced by talking and moving. A recent study noted that respiratory rate data determined by a wireless monitoring system showed less variability than simultaneously recorded respiratory rate data from the reference bedside monitor (thoracic bio-impedance via the ECG electrodes).[532] Thus, for some vital signs these wireless systems might even be more accurate than our current standard measurement methods. These are open questions that have to be solved for individual systems in the future. However, final data on accuracy, sensitivity and specificity are still lacking for most new wireless monitoring systems.

In the future, 'smart' wireless monitoring systems will incorporate a clinical decision support engine to improve the specificity of the generated alerts to caregivers. Such systems may not only use vital signs as inputs, but could also receive inputs from the patient (via smartphone), informal carers, nurses and also use data available in the electronic medical record (e.g. new lab values). In theory, this approach could help us to save lives lost to unrecognised deteriorations. Some wireless monitoring systems can automatically calculate modified early warming scores (EWSs), albeit without the important 'nurse only' inputs such as 'nurse worry', allowing earlier detection of deteriorating patients on the ward.[508]

However, a recent analysis showed only minimal impact after implementing early warning scores and best practice alerts for patient deterioration, most likely because the manual EWS were not calculated correctly and consistently.[535] Determination of EWS is user-dependent and prone to inaccurate determination of vital signs. For example, while it has been shown that changes in respiratory rate are the most important predictor of clinical deterioration, nurses relied more on oxygen saturation and regarded respiratory rate as the least important vital sign.[536] Therefore, it is not surprising that respiratory rate is infrequently measured and often inaccurate (or even simply 'guessed' by medical staff).[537,538] Another limitation of manually determined EWS is its intermittent character,[539] which could at least partially be overcome by automation.[526] A speciality-specific EWS might be advantageous, for example, in patients with chronically compromised pulmonary function or in patients with neurologic disorders. We should also keep in mind that the EWS was originally developed from recordings of vital signs in ICU patients, and has never been optimised for postsurgical patients. Specific treatments in this population, for example, changes in ventilatory patterns due to abdominal incision, residual muscle relaxation and the use of opioids for pain management, as well as occurrence of complications such as infections and sepsis, make it most likely that postoperative respiratory rate is different from the rate in patients not undergoing surgery.[540,541] A recent analysis of respiratory rate measured by a wireless monitoring system in a postsurgical population showed lower rates than expected, and indicate that respiratory rate numbers in different EWSs probably need to be adapted.[542]

To further improve the value of EWS, not only data from vital signs, but integration of additional information is probably necessary. A score including nurse assessments and nurse judgements, as well as laboratory data recorded in the electronic patient file and updated as soon as new entries were available, showed improved sensitivity to detect deteriorating patients.[543] The European Union Horizon 2020-funded Nightingale project () tries to develop this Holy Grail: inventing a system suitaly detection of patient deterioration on general wards AND sfety

monitoring at home. The goal is to develop a wireless, multiparameter vital sign sensor combined with clinical decision support, and analysis of laboratory data, with patient and nurse inputs in order to prevent death and disability in general ward patients and in the early days after discharge home from hospital.

Future monitoring after hospital discharge

Up to the current time, there are no data available investigating (continuous) monitoring of vital parameters in patients being discharged home after surgery. But we can learn from lessons in other specialties, for example, cardiology and pulmonology. Patients with chronic diseases (e.g. patients with severe heart failure) frequently seek medical care. Studies using e-health systems have shown that patients' self-determination of vital parameters and subsequently sending data via e-health support to the treating physician significantly reduced the need for healthcare support and hospitalisation.[544] All hospitals today struggle with limited resources – both in terms of finance and nurse staffing – which increases the pressure to discharge postoperative patients from the hospital earlier. Enhanced Recovery after Surgery programmes have shown that early hospital discharge can have benefits in terms of patient outcomes. Wireless monitoring in the first 24 to 72 h – combined with caregiver contact via phone or video – might prove to be advantageous for patients sent home early who are at risk for late postoperative complications. Future technologies that may be useful in this setting are bed-based ('under the mattress' or infrared camera) systems and sensing systems built into comfortable 'smart textiles', which all might play a role for specific patients in the postoperative period at home.[545]

Wireless monitoring on the ward: risks to be considered

The experience with alarm fatigue from frequent false alarms in the operating room and ICU teaches us that the dense data streams from multiparameter sensors in multiple patients might generate unacceptably high rates of false alarms, leading probably to alarm fatigue.[546] A monitoring system, which is improperly used, will not achieve the intended goals of improving patient outcome. New systems therefore need suitable algorithms to reduce the number of notifications and nonactionable alarms, while at the same time actionable alarms are forwarded to the respective ward staff, either nurses, or in case of emergency alarms also directly to physicians and rapid response teams.[526] Hospital management, physicians, nurses, but also patients, insurance companies and medico-legal experts should realise that we are not simply transferring ICU-style monitoring – in wireless form – to the ward. There will likely be notifications or alarms that are not noticed or acted upon by the ward staff, for example when other patients are in more need of urgent attention. While this would be unacceptable on an ICU with a one-to-one nurse–patient ratio, the situation on a ward is significantly different and needs other interpretations, in particular a much higher focus on vital signs trends.

Smart monitoring systems should be able to 'learn' the vital parameters of a given patient: while a HR of 45 bpm might be perfectly normal in a patient on betablockers, it might represent a dangerous progressive bradycardia in another patient. Self-learning systems should be able to adapt to the individual patient, allowing recognition of deviations from individualised measurements.[547] In the future, machine learning and artificial intelligence should be able to integrate other physiological parameters and laboratory values with the vital sign measurements from a patch sensor,[548] and adequate filtering of artefacts would be able to reduce false alarms and associated alarm fatigue. While nurses are already able to adjust alarm limits of most wireless systems, only an intelligent self-learning system will help to decrease the nurses' workloads, thereby increasing acceptance to use the new system.[549] Direct transfer of electronically determined patient data into the electronic patient data file also supports this, without forcing nurses to make annotations themselves. As with other innovations, nurses' acceptance will likely be higher if they are integral participants in the design and implementation of the systems.[550,551] Nurses are convinced that the availability of continuously measured vital parameters will support them in taking clinical decisions.[552] However, there might be a risk that patients are seen less frequently by nurses and physicians in those cases where every vital parameter is normal, thus all 'lights are on green'.

Cost-effectiveness and patients' experience

Implementation of new monitoring systems is expensive. Although most people support the idea that improved patient monitoring on the ward using continuous, wireless monitoring devices will improve patient outcomes, to date there is hardly any evidence to support this claim. One study investigated the cost-effectiveness of continuous monitoring implementation on a general medical–surgical/trauma ward. Assuming a 5-year Return-of-Investment model, for a single hospital the authors calculated a cost reduction of 0.6 to 2.1 million US dollar per year, with a break even point as early as 0.5 to 0.75 years.[553] This calculation seems to be extremely optimistic, and we urgently need trustable data on the cost-effectiveness of implementing of wireless ward monitoring to support physicians during negotiations with the hospital management. However, the only way to achieve such data are to implement and study remote monitoring systems in a controlled fashion in several hospitals simultaneously. The on-going Shepherd trial, a two-centre controlled implementation study of a wireless patch sensor with a stepped-wedge design and a patient-centred outcome recently started in Amsterdam UMC

and UMC Utrecht, the Netherlands (ClinicalTrials.gov NCT02957825).

Our patients are quite optimistic and positive regarding these new monitoring modalities: very few patients declined wearing a pulse-oximetry sensor, and patients wearing an adhesive patch for vital signs determination were positive regarding patient comfort.[552,554] They appreciated not being woken up during the night for vital signs checks, but also they appreciate contact with nurses and thus advised the use of the continuous wireless monitoring in addition to normal nurse–patient contacts.[552]

Future clinical studies will need to address the question whether continuous monitoring on general wards, most likely by wireless monitoring systems, indeed reduces the rate of cardiorespiratory events and mortality, and also to what extent this technology can improve patient physical and mental outcomes after surgery. It is unlikely that all patients will benefit equally from additional monitoring, and the potential benefit of an individualised risk-tailored monitoring approach needs to be evaluated. Improvements in biomedical signal detection using ever smaller wearable wireless sensors, along with advances in data science and appropriate use of machine learning should lead to further improvement, in particular with respect to 'smart' artefact rejection and reduced rates of false alarms. Finally, all medical staff will need to familiarise themselves with a new culture of ward monitoring, including its advantages and potential drawbacks.

Chapter 16: Standardisation of the 'Cardiac Arrest Call' telephone number 2222 (Whitaker)

When a patient has an in-hospital cardiac arrest the response time of the resuscitation team is critical to their survival. Commonly a member of staff will dial an internal telephone number to start the process of summoning the resuscitation team. Although in many countries, outside the hospital the general public have a standard number to call (e.g.112), inside hospitals a wide variety of different numbers is used. If all hospitals were to use the same standard number, for example, *2222*, this would reduce the possibility of delays and provide other advantages as well. Some countries have already implemented *2222* as a standard national number and many organisations now recommend this simple low-cost patient safety initiative.

Background

Many of the population in Europe and worldwide are aware of the single standard emergency number 112 which can be dialled as a free call from any telephone in Europe (https://ec.europa.eu/digital-single-market/en/eu-rules-112). If there is a cardiac arrest in the street, a call to this number will put them through to the local ambulance service who will attend as soon as possible to help with resuscitation of the patient (https://www.sos112.be/en/).

Inside hospitals in Europe however there are no similar standard emergency number. It is estimated there are about 300 000 cariac arrests in European hospitals every year and when one happens, in many hospitals a nurse or other member of staff will dial a telephone number to contact the operator at the hospital telephone switchboard.[555] The answering of of calls to this 'cardiac arrest number' is given priority by the operator who then invokes the appropriate emergency callouts of the medical and nursing members of hospital's, cardiac arrest team. About 80% of European hospitals that have a cardiac arrest team use the telephone system in this way. Some other hospitals use red call buttons on the wall of the ward or the patient's room but not all hospitals have cardiac arrest teams (ESA Newsletter, Issue 65, 2016 http://newsletter.esahq.org/a-standard-cardiac-arrest-call-2222/).

Patient survival depends on the effectiveness of the emergency team response and any delays in the team's arrival, defibrillation or initiation of cardiopulmonary resuscitation (CPR) all seriously reduce survival, decreasing by 10% per minute.[556] A recent study from the United States, 'Get With The Guidelines-Resuscitation Database' has confirmed that time to initiation of CPR and subsequent time to administration of defibrillation (for shockable arrhythmias) and epinephrine injection were both associated with reduced patient survival.[557] Another study showed that survival was significantly higher when the resuscitation team arrived within 3 min: there were no survivors when the team arrived after 6 min.[558]

Evidence to support a standardised cardiac arrest call number

In 2016, a European wide survey conducted by the ESA showed that 105 different telephone numbers were used in about 200 hospitals for example, 4361, 19, 623, 80932 but the commonest was *2222*: (Fig. 13). Additionally, respondents were asked if they thought this cardiac arrest number should be standardised in all hospitals: 81% thought that it should (ESA Newsletter, Issue 65, 2016 http://newsletter.esahq.org/a-standard-cardiac-arrest-call-2222/).

Previous national surveys revealed that in Denmark where there were 41 different numbers, Ireland 18, England and Wales 27 and Australia 51 (Table 21). Recently the Netherlands reported 46 different numbers from 121 hospitals, with 12% already using *2222*, and Spain had 51 different numbers from 288 different hospitals. A survey in Japan showed 370 different numbers from 756 hospitals having a cardiac arrest system.

One reason for delay in the arrival of the cardiac arrest team is ward or other staff not knowing the correct

Fig. 13

1	333	1112	2222	3218	5000	18007
19	412	1212	2222	3274	5555	30100
86	417	1222	2222	3333	5555	50000
105	418	1333	2222	3333	5714	52001
111	444	1333	2222	3333	7070	55525
112	500	1333	2222	3333	7090	55600
113	623	1453	2222	3333	7165	80001
121	624	1464	2222	3720	7530	80932
123	777	1555	2234	3777	7777	254445
123	800	1777	2323	4000	7900	999111
144	864	1999	2407	4361	8852	
144	888	2153	2451	4444	8888	
148	911	2222	2222	4444	9000	
173	999	2222	2580	4444	9386	
222	1010	2222	2633	4475	9999	
222	1111	2222	2769	4475	15555	

Some cardiac arrest numbers used in European hospitals.

number to call. A survey in Denmark showed that only 50% of medical staff and 58% of nursing staff knew the correct number to call in their own hospital.[559] Another study noted that 12% of staff only found out the number during a cardiac arrest incident when they had to call it.[560] Standardising the number improves staff knowledge and makes it easier for them to remember it. In a survey from Denmark more of the physicians from a region that used a standard cardiac arrest number could remember that number compared with physicians from other regions with nonstandardised numbers (78 vs. 33%, $P < 0.001$).[561] In the United Kingdom where there has been a national standardised number *2222* since 2004, 96% of the staff knew the *2222* resuscitation number.[562] From consideration of human factors it can be expected that in stressful situations it is likely that memory will be even poorer.

Nurses make most of these telephone calls and increasingly they move posts between different hospitals and also between different countries. In 2017 in Spain, one in five nurses entering the workforce was foreign trained or a foreign national and in 2018 in Italy this reached one in three.[563]

Table 21 National 'Cardiac Arrest Call' surveys

Location of survey	Year	How many different numbers used	What number now used?
Europe	2016	105	Some use 2222
Denmark	2010	41	Now use 2222
Ireland	2016	18	Now use 2222
England	2002	27	Now use 2222
Australia	2018	51	Now use 2222

Standardisation is a fundamental principle of safety

The airline industry is well aware that standardisation is a fundamental principle of safety. Pilots trained to fly an Airbus A320 can fly an Airbus A320 belonging to any airline company in any country in the world. Leotsakos said that standardisation of hospital processes should enable trained healthcare workers to perform effectively in any facility in the world.[564] Logically it should be possible to arrange for every healthcare worker to learn one standardised telephone number (*2222*) to call the cardiac arrest team in any hospital in any country in the world. Martin Bromiley, Chair of the Clinical Human Factors Group CHFG says 'standardisation has been shown to be an effective mechanism for reducing human error in complex processes or situations. The CHFG fully supports this patient safety initiative and encourages all European hospitals to standardise their cardiac arrest telephone number to *2222*'. European Standardisation of the in-hospital 'Cardiac Arrest Call' number *2222*. Joint press release by the European Resuscitation Council, the EBA and the ESA *22* September 2016 (https://www.esahq.org/uploads/media/ESA/Files/Resources/Cardiac%20Arrest/Joint%20Press%20release%202222%2020-9-2016%20v6.pdf).

Calls for national standardisation of the in-hospital cardiac arrest telephone number have been made since the 1990s and some countries have successfully standardised.[565,566] In 2015, the EBA recommended that all European hospitals use *2222* for in-hospital cardiac arrest calls and in 2016 they were joined by the European Resucitation Council and the ESA who issued a joint statement recommending that all European hospitals use the same internal telephone number *2222* to summon help when a patient has a cardiac arrest.[567] This was

supported by the WFSA and the International Liaison Committee on Resuscitation.

Additional benefits of standardisation to 2222

Having a common standard number will facilitate and standardise teaching, and *2222* is particularly memorable. A standardised number helps overcome some human factor issues such as memory being less reliant during stressful situations, and will enable standardisation of documents. Standardisation will make staff more confident that they will remember the number and reduce the potential for staff to become second victims if their lack of knowledge of the number results in a delay which causes patient harm. Organisations demonstrating attention to standardisation helps raise the safety culture, and this helps to create multidisciplinary safety interactions between nurses, doctors and other hospital staff. Implementing standardisation for such a simple and logical thing sets a precedent for more difficult standardisation issues in the future and emphasises appreciation of standardisation.

Why was the number 2222 chosen?

Having the same number is much more important than the actual number itself and discussions about the actual digits could continue for a long time and delay implementation: *2222* was chosen because it was the commonest number in surveys (ESA Newsletter, Issue 65, 2016 http://newsletter.esahq.org/a-standard-cardiac-arrest-call-2222/).[568] It is also easy to remember and find on the telephone. From surveys, most hospital switchboards now use four digits and *2222* was already a standard national number for some time in England, Wales, Scotland, Turkey, Ireland and regions of Denmark and Slovakia.[569] If hospitals only have a three-digit switchboard they could standardise to *222* and then if a member of staff dialled four 2s by mistake the call will still go through.

Costs for hospitals to change to 2222

As patient safety interventions go, this standardisation would be described as a very low-cost intervention. When England and Wales standardised, 30 hospitals changed for no cost at all and 43 for less than £1000. The average cost for 105 hospitals was £4500.[568] Recently the Chief Executive from Ramsay Healthcare in Australia reported a cost of only AU$250.

How to implement 2222

There appear to be three possible ways to implement this standardisation: international, national and local. *International* regulation or legislation would be a robust way of achieving standardisation, but it is usually a long process to achieve this. The EU directorate to standardise the public emergency telephone number to 112 in Europe took 17 years. *National* professional bodies can recommend *2222* to their members and Health Ministers can recommend *2222* nationally to hospitals. In 2017, the German Society for Anaesthesia and Intensive Care (DGAI) contacted the German Health Minister who supported this initiative and wrote to the Federation of German hospitals to recommend *2222* be adopted. Similarly, in April 2018 the Irish Health Service Executive wrote to all the acute hospitals in Ireland and asked them to establish *2222* as a standard cardiac arrest number by January 2019. In December 2018, the health minister of New South Wales Australia standardised the internal hospital emergency number as *2222* and Ramsay Healthcare with 70 private hospitals nationally are also adopting *2222*. In October 2018, the Ministry of Health in Portugal issued a legal order requiring hospitals with cardiac arrest teams to use the standardised number *2222* from 31 March 2019. Similarly the Czech Republic and Israel standardised to *2222* in November and December 2019, respectively.

Examining the numbers from surveys it appears that many of the original numbers used were often chosen locally at random and there was no structured process involved. Therefore, logically by the same *local* process *2222* could be implemented in hospitals that choose to do so as a local patient safety improvement project. In 2016, in Slovakia a group of doctors and managers agreed to change to *2222* and quickly and safely achieved all this in 2 weeks with very little cost and with no problems.[570] Changing the cardiac arrest number can be perfectly safe if the switchboard operates the old number in parallel with *2222* for say a year until all staff had stopped using the old number. Local implementation may also be helped by the European Resuscitation Council (ERC) recommendation of the number *2222* in the ERC Quality standards for cardiopulmonary resuscitation practice and training 2019 (https://www.erc.edu/sites/5714e77d5e615861f00f7d18/assets/5dedf6664c84860818e4d3c0/CPR_quality_standards_In_hosp_accute_ERC_V3_Final_1_.pdf).

Why would hospitals not want to change?

As discussed, the cost is very low, particularly when compared with most other safety interventions. Standardisation simplifies training with only one memorable number to be learnt whichever hospital one is working in. It has been demonstrated that the change can take place quickly. One region in Slovakia chose a changeover date and then implemented it in only 2 weeks, although it took a year for all of England and Wales to standardise the number. There should be no concern about the risk of changing because it is very safe if the hospital continues to use the old number along with *2222* until no one calls the old number. The easiest response is not to change at all, but this will send a negative signal about a lack of safety culture within that particular hospital and suggest that there is not an understanding of the value of standardisation for patient safety. The number *2222* may already be used for some other function within the hospital but in this case this number should be changed anyway because once widespread cardiac arrest call standardisation takes place this extension

may be called by mistake when someone is trying to activate the cardiac arrest team. Many modern switchboards are now computerised and even five-digit or six-digit switchboards can still accept a four-digit 2222. Most technical switchboard problems that have been encountered have had solutions but if there are currently insurmountable technical problems with the particular switchboard then the change to 2222 can be delayed and specified for when the next switchboard upgrade or replacement takes place.

Conclusion

Standardisation of cardiac arrest call numbers in hospitals to 2222 is common sense and 14 countries have already demonstrated the change to 2222 can be a safe, easy, smooth and low-cost patient safety improvement. An action list is shown in Table 22. In low-income countries where cardiac arrest teams are not yet established, designating 2222 in advance as the number to be reserved and used in the future will imbed this patient safety initiative into their system from the outset.

If all healthcare staff use the same global number 2222 this will promote the message of global standardisation and the development of a global safety culture for the future. Once the benefit of this relatively simple global standardisation becomes apparent, it will make the implementation of others easier.

Practical advice on how to change is available from several links:

(1) Local Implementation Pack for establishing a standard 'Cardiac Arrest Call' telephone number for all hospitals in Europe – 2222 (http://www.esahq.org/resources/resources/cardiac-arrest-call/).

Table 22 Action list for changing cardiac arrest telephone numbers

Action list
Most hospitals can easily make this change locally https://www.resuscitationjournal.com/article/S0300-9572(16)30583-4/fulltext
Meet and discuss with colleagues, nurses and resuscitation trainers. Nurses are most important as they are the staff who make the most of these calls
Use the 2222 presentation at meetings: downloadable from https://bit.ly/2CnQQa5
Discuss with patients groups/representatives if available
Discuss with/send letter to Hospital medical director/management
Discuss with switchboard colleagues the technical issues
If possible, continue to run the old number and 2222 in parallel for a period. If you can monitor the use of both numbers, continue to use two numbers until old number is no longer used. If a new switchboard is being planned in the future it could be part of that programme
Choose a suitable date to change and tell everyone
Raise awareness, train staff, organise publicity, notices and posters
Put 2222 stickers on every phone
Make the change on the appropriate date
Remind staff about change
Thank staff and management for taking part in the process
Please pass on details and any advice about your successful change to encourage hospitals to implement the change

(2) Establishing a standard crash call number in hospitals. (https://www.resus.org.uk/archive/archived-cpr-information/standardisation-of-the-crash-call-number-2222/).
(3) European Society of Anaesthesiologists (https://www.esahq.org/patient-safety/2222-cardiac-arrest-call/).

A website includes a world map (https://ishen.ushahidi.io/views/map) where hospitals can enter the particular cardiac arrest number they use and this can demonstrate the implementation of this patient safety initiative as it rolls out throughout the globe.

Chapter 17: Safe medication administration in anaesthesia practice: new developments (Whitaker)

Intravenous medication administration is an essential part of anaesthesia practice and a large amount of an anaesthetist's clinical work. Very significant developments and improvements have been made in patient monitoring and airway management that have transformed the safety of patient care several folds. However, advances in the safety of medication administration have largely been lacking. The Helsinki Declaration on Patient Safety in Anaesthesiology highlighted several relevant issues, which led to the development of more specific and practical advice in the EBA recommendation for Safe Medication Practice. Recently the wider appreciation of the importance of medication safety has led to the WHO launching its third WHO Global Patient Safety Challenge 'Medication without Harm'. EBA Recommendations for Safe Medication Practice have now been updated and these and some more recent developments will be discussed in this chapter.

Background

Safe medication administration in anaesthesia practice has not received the attention it deserves over the years and the last major improvement was the introduction of single use plastic syringes and disposable needles in the 1950s.[571] In 2010, the Helsinki Declaration on Patient Safety in Anaesthesiology referred to the importance of a supply of safe drugs, the checking of drugs and the labelling of syringes.[1,572] It also made reference to the large part played by human factors in delivery of safe care to our patients. Around 70% of errors are due to human factors and this is particularly applicable to medication safety. The aim should always be to promote best practice in human factors, a science that has successfully helped make other safety critical industries safer by 'making it easy to do the right things' (https://chfg.org). The same year the Anesthesia Patient Safety Foundation (APSF) hosted its landmark medication safety conference (https://www.apsf.org/article/apsf-hosts-medication-safety-conference/) and in 2011 the EBA published the first European Recommendations for Safe Medication Practice.[573]

The incidence of medication errors varies from one in 450 through one in 133 to one in 20 and over 600 medication incidents are voluntarily reported by anaesthetists every month in the United Kingdom (https://www.salg.ac.uk/sites/default/files/PSU-September-2019.pdf) and they represent 28% of all peri-operative incident reports in the Spanish Anaesthesia Incident Reporting System.[574–577] In 2017, the GMC report on Preventable patient harm across healthcare services (understanding harmful care) said that 13% of patients experienced total harm but only 6% of patients experience preventable harm. The most common type of this preventable patient harm was medication-related incidents which represented 25% of the identified harm.[219,348] A further acknowledgement of this issue was the instigation of the third WHO Global Patient Safety Challenge 'Medication without Harm' (https://www.who.int/patientsafety/medication-safety/en/). This intends to reduce the incidence of iatrogenic medication-related harm by 50% in 5 years. It is hoped to mirror the success of the first Global Patient Safety Challenge 'Clean Care is Safer Care' in 2005 (https://www.who.int/patientsafety/information_centre/ICHE_Nov_05_CleanCare_1.pdf) which promoted handwashing, and the second Global Patient Safety Challenge 'Safe Surgery Saves Lives' 2008 which changed practice with the Surgical Checklist (https://www.who.int/patientsafety/safesurgery/knowledge_base/SSSL_Brochure_finalJun08.pdf).

In the first instance, the WHO wish to prioritise harm associated with high-risk medicines, polypharmacy and transitions of care. All these three areas are particularly relevant to anaesthetic practice. The WHO do not feel it is necessary to reinvent the wheel as guidance on these is already available, but this just needs to be widely and consistently implemented. For European anaesthesia, it would seem appropriate to try and implement the EBA Recommendations for Safe Medication Practice second edition 2015. To help and encourage their implementation these recommendations also included a 13-point checklist so that departments can monitor their progress.[573]

Organisational improvements

To raise the profile of safe medication administration at a local level and focus departments thinking about it, it is suggested that all departments of anaesthesiology should develop a peri-operative medication policy and implement it. The Royal College of Anaesthetists now have this as one of the departmental accreditation standards in their Anaesthesia Clinical Services Accreditation scheme (https://www.rcoa.ac.uk/safety-standards-quality). They expect this policy to incorporate relevant items from the Royal Pharmaceutical Society Professional guidance on the safe and secure handling of medicines (https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines). At least one medication safety item could be included in the Annual Safety Report recommended by the Helsinki Declaration on Patient Safety in Anaesthesiology (https://bit.ly/2Zf7INa). Suitable items for inclusion in this peri-operative medication policy could also include some others discussed later in this chapter. The logical way to develop this might be considered a 'chain of safe medication administration' and follow the pathway from purchasing and acquisition of injectable medicines through their storage, preparation, administration to patients and recording and finally analysis of the outcomes.

Because of the complexity of the process of selecting, preparing and administering injectable medicines, human factor considerations must be taken into consideration throughout. It is remarkable to note that in a recent Health Service Investigation Branch report on a medication incident they commented that the NHS Specialist Pharmacy Service has no reference to human factors considerations anywhere in their procurement overview (https://www.hsib.org.uk/investigations-cases/inadvertent-administration-oral-liquid-medicine-vein/). Without this, nurses and medical staff in certain circumstances are being set up to fail when they become an end user of some of the particular medicines that they have been purchased and that they are required to use. Look-alike and sound-alike medicines and poor labelling are well known examples of these, as are frequent changes of supplier without notification. Implementing a 'purchasing for safety' policy to promote procurement of injectable medicines with inherent safety features should be a priority.

Drug shortages

Although in low and middle-income countries drug shortages are a daily occurrence, a recent development has been their appearance in high-income countries. The reasons for this can be complex. However, reductions in the number of suppliers, manufacturer and commercial considerations require that departments are aware of this possibility and are prepared with contingency plans for drug shortages. Adequate supplies of essential medicines should be kept and maybe buffer stocks of say 6 months of some particularly important ones. The WFSA has produced an essentials medicine list (https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1) and national ones are available as well (https://anaesthetists.org/Portals/0/PDFs/Safety/NEADL_2015_FINAL.pdf?ver=2018-09-25-154824-287).

Storage of medicines

It has long been recognised that local anaesthetic drugs should be stored separately from general anaesthetic drugs to avoid their inadvertent intravenous administration. Similarly it has been recommended that potassium should be kept separately in a locked cupboard.[578]

Errors with the administration of medicines of a different pharmacological class group from the intended one, for

example, a muscle relaxant instead of a sedative drug are likely to cause more harm than errors within the same pharmacological class. To reduce the possibility of not selecting the intended drug, medicines should be stored in their pharmacological class groupings rather than say alphabetical order (see WHO Essential Medicines and Health Products Information Portal and recommendation on drug storage: http://helid.digicollection.org/en/d/Js4885e/4.4.html).[579] It is not uncommon for alphabetical storage to cause administration incidents and recently there was a report of a patient mistakenly being given Vecuronium instead of the intended Vancomycin (http://www.salg.ac.uk/sites/default/files/PSU-September-2019.pdf) and this has been commented upon.[579]

Preparation of injectable medicines

This should take place on a clean uncluttered, adequately sized surface and not on a spare corner of an anaesthetic machine. Recently standardised surface arrangements for this have been recommended and demonstrated to reduce the incidence of medication errors.[580] At this time departments should probably try and use a logical local arrangement in all possible locations. Not only will this ensure clarity and safety for individual practitioners but also when working in teams and with assistance (https://www.sps.nhs.uk/wp-content/uploads/2018/02/2007-NRLS-0434-Injectable-medicines-PSA-2007-v1.pdf). Anaesthesia drug storage trays incorporating ISO coloured compartments have also been developed.[581] Each injectable medicine should be prepared in one syringe, one medicine, one at a time and standard operating procedures are available for this purpose (https://www.sps.nhs.uk/wp-content/uploads/2018/02/2007-NRLS-0434F-Promoting-safeSOP-template-2007-v1.pdf). All syringes should be clearly labelled. The purpose of the label is to identify the syringe before it is picked up and so the label should be fully visible when the syringe is resting on the work surface. Existing standardised arrangements suggest that at least one label or the writing should be longitudinal along the barrel of the syringe (https://www.safetyandquality.gov.au/our-work/medication-safety/safer-naming-labelling-and-packaging-medicines/national-standard-user-applied-labelling-injectable-medicines-fluids-and-lines) and they should then be placed horizontally (rather than vertically) on the work surface so the labels are clearly readable.

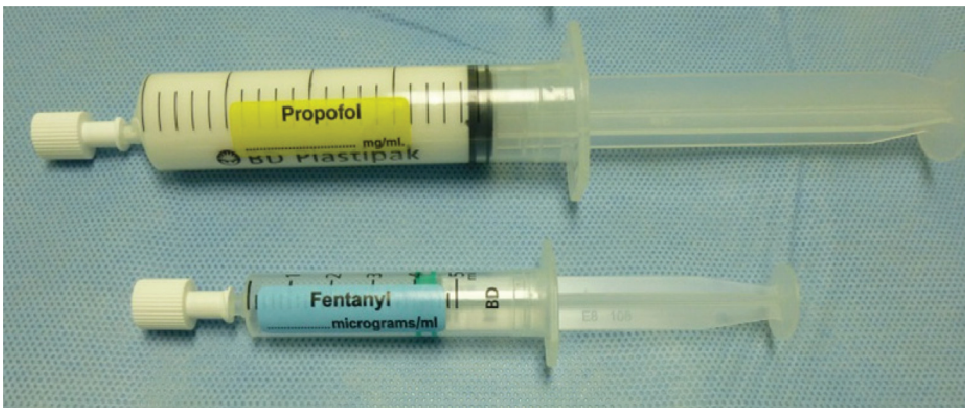
Ideally, syringe labelling should be further standardised and all labels applied while the syringe is pointing from right to left ('right-handed' syringe orientation). This is essential anyway for all syringes being used in syringe drivers, which all drive from right to left, if the label is to be readable and checkable while in use (Fig. 14).

Every syringe should be labelled immediately after drawing the medicine into the syringe and before the syringe leaves the operator's hand (https://www.usp.org/compounding/general-chapter-797). In emergency situations where the filled syringe never leaves the operator's hand before the drug is administered to the patient this may be omitted but it is still good practice to label the syringe if possible. Errors are more likely to occur in stressful emergency situations.

Empty syringes should never be labelled, as the purpose of a label is to indicate what is in the syringe; therefore, any label is always wrong if the syringe is empty. Another reason why syringes should always be labelled after the injectable medicine is drawn up into them is the many errors from prelabelling syringes and other containers that have been reported elsewhere in health care, for example, 'wrong blood in tube' incidents from blood transfusion practice (https://b-s-h.org.uk/media/16505/shot-report-summary-2017.pdf).

All syringes labels should meet the ISO 26825 standards for coloured user-applied labels for syringes containing drugs used during anaesthesia – colours, design and

Fig. 14



Syringes labelled in 'right-handed' orientation.

performance (https://www.iso.org/standard/43811.html; https://anaesthetists.org/Portals/0/PDFs/Guidelines%20PDFs/Guideline_syringe_labelling_critical_care_review_2014_updated_2016_final.pdf?ver=2018-07-11-163757-317&ver=2018-07-11-163757-317). Using the different ISO colours for different pharmacological classes of drugs has been shown to reduce the potentially very dangerous syringe swap errors between drug classes by 66%.[582] If the use of ISO labels is not possible then handwritten labels using paper or tape with a strong adhesive can be used or a marker pen that will not rub off the syringe. No standard abbreviations for drug names currently exist so they should be avoided.

During the preparation of injectable medicines it is important to avoid any distractions. Explain this to team members in advance and if it happens the operator should stop what they are doing, attend to the distraction and then carefully restart the process. If in any doubt about at what stage they were up to then, discard any unlabelled drugs and start that part of the process again. At any stage of the process particularly during medicine verification, consider asking a colleague to help double check. It is advisable to not use a leading question, but for example say 'What is the drug and the dose in this ampoule please?' When administering an injectable medicine always be certain of the identity of the patient. This should have taken place as part of the WHO checklist but if in doubt always recheck. Also be aware of any drug allergies and clearly record them in the patient records.

Microbial contamination of syringes during preparation must be avoided and to minimise the risk of cross infection between patients the contents of any one ampoule should only be administered to one patient (https://www.cdc.gov/injectionsafety/one-and-only.html).[583,584] The use of multidose ampoules is not recommended.[585,586] Storing the empty ampoules that have been drawn up and administered to a patient in a safe container until the end of the anaesthetic enables any further checks that may be necessary during or at the end of the case if it appears there has been an error during the anaesthetic. This can also help medication practice learning to occur; finally they can be disposed into a sharps bin.

Administration of medicines

From reports of peri-operative critical incidents the administration phase is the most prevalent and harmful.[577,587] Ensure you have a correctly prepared syringe and before commencing the injection always consider the expected dose of the drug you intend to give. When titrating an injectable medicine always consider the most suitable injection rates, increments and time intervals to use. After administration of an injectable medicine promptly record this on the anaesthetic record with the drug name, dose and time of injection. It is important particularly at the end of a procedure to flush any residual anaesthetic or sedative drugs from all intravenous lines and cannulae. If this is not done the residual drug can be later inadvertently introduced into the patient's circulation in the recovery unit or on the ward causing muscle paralysis, unconsciousness and respiratory and cardiac arrest. It is even more important in paediatric practice where fatal incidents have been reported (https://improvement.nhs.uk/documents/1922/Patient_Safety_Alert_-_Confirming_removal_or_flushing_of_lines_and_cannulae_af_EVC1Yb2.pdf).

Wrong route medication errors due to tubing misconnections are potentially life threatening complications that have been made possible by the universal use of the luer connector. With an initial target of implementation in 2011, the non-luer initial prototypes resulted in technical and non-technical problems. Following a delay of the widespread use of the non-luer connectors, the new ISO standards for small bore connectors, ISO 80369 series, have been developed to reduce the risk of these types of erroneous connections. The nonluer ISO 80369-6 standard has now been tested and seems to be acceptable in terms of its ease of use, reliability, lack of leakage and versatility.[588]

Unsafe injection practices are still putting patients and healthcare personnel at risk of disease transmission, including bacterial infections like MRSA or blood borne pathogens like hepatitis C virus.[589] The Safe Injection Practices Coalition One & Only Campaign is a public health effort to eliminate unsafe medical injections that promotes the rule to remember is 'One Needle, One Syringe, Only One Time' (https://www.cdc.gov/injectionsafety/one-and-only.html).

Prefilled syringes

Although 28% of the 10 billion units of injectable medicines sold annually are supplied in ready to administer/prefilled preparations, only 4% of those used in the acute sector are, and prefilled syringes have not been commonly used in anaesthesiology at all (https://www.grandviewresearch.com/industry-analysis/pre-filled-syringes-market). Recent developments, however, have led to a number of anaesthesia drugs being available in prefilled syringes and this is to be welcomed. A significant number of the potential human factor error steps in preparation of injectable medicines can be completely eliminated when using prefilled prelabelled syringes. There are very few areas of medicine where such a major step change in safety can be so easily achieved.

The latest Royal Pharmaceutical Society Safe and Secure Handling of Medicines (https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines) now includes a section on operating theatres including interventional areas, for example, radiology and cardiac catheterisation labs. This says that, as outlined in its core guidance, manipulation of medicines in clinical areas should be minimised and medicines be presented as prefilled

Fig. 15

'In Safe Hands' The Medical Emergency Response Team aboard a CH47 Chinook above Southern Afghanistan, battles to save the life of an injured soldier by Stuart Brown. With permission, Skipper Press LTD, www.skipperpress.com.

syringes or other 'ready-to-administer' preparations wherever possible. Many other specialities have stopped preparing their treatments and equipment at the bedside or operating table and anaesthesiology should regard this phase as inevitable and follow other specialties' good practice as soon as possible. Patient transfers are also a complex process and prefilled syringes are recommended as part of the essential equipment to go with the patient in the ambulance.[590] The manual preparation of intravenous syringes in moving vehicles is fraught with hazard particularly when the circumstances are not ideal (Fig. 15).

Prefilled syringes usually have a higher purchase cost than ampoules, but they can be economical in circumstances where they reduce wastage and expensive medication errors.[591] They simplify work processes and reduce cognitive complexity during medication delivery.[592] Prefilled syringes have zero contamination as against 6% for manually prepared syringes.[583,584] The advantages of prefilled syringes may actually be of even greater benefit if they were made available in many of the difficult circumstances in low-income and middle-income countries. By eliminating packaging, ampoules, drawing up needles, and transportation, prefilled syringes also have environmental advantages.[593] About 59% of anaesthesia departments in Japan use prefilled syringes a practices stimulated by the breaking of glass ampoules during the Great Hanshin earthquake in 1995.[594]

There are two main types of prefilled syringes and both are now usually plastic. The first type are compounded prefilled syringes where the medicine is added to the syringe in a clean room and because of this these usually only have a shelf life of around 8 weeks. Although this appears short for high-usage medicines such as insulin in 50 ml prefilled syringes, or intensive care infusions of inotropes, sedatives, and analgesics, insulin in 50 ml prefilled syringes (Fig. 16) this does not materially affect clinical practice.

Infusion syringes prepared by nurses on ICU show wide variations in concentrations which do not occur with prefilled syringes.[595] One-third of all inpatient medical errors leading to death within 48 h of the error involve insulin administration and 50 ml prefilled syringes for insulin infusions are a robust systemic barrier to such concentration errors.[596,597] Compounded prefilled syringes are now used in theatres by over 1000 departments in the United States where a wide range of anaesthetic drugs are now available.

The second type are manufactured prefilled syringes where the syringe is filled and prepared and then the whole combination of the syringe and its contents are sterilised at the end of the process providing a shelf life of around 3 years (https://www.aguettant.fr/nos-medicaments/nos-produits-en-details/). Having a long shelf life makes pharmacy stock management easier and more economical and the sterilisation at the end of the process

Fig. 16

Prefilled 50-ml syringes in 'right handed' orientation for use in syringe drivers.

adds the new possibility of using these pre labelled syringes directly on the sterile field.

Other technological advances

Technological advances to improve the safety and accuracy of administering intravenous medicines have been around for some time, initially using barcodes (https://safersleep.com/about-safersleep/company-history/).[598] The electronic aspects of these arrangements can work satisfactorily but the whole system can still rely on the operator self-filling the syringes and applying the barcode themselves.[599] Until departments are using almost a complete range of their anaesthetic drugs in appropriately labelled prefilled syringes it seems hard to justify the investment and training in this technology as one of the major benefits of giving the right drug will not be guaranteed. Perhaps the money should be spent providing prefilled syringes first. Barcodes also may not be the ultimate technology as embedded radio frequency identification tagging is available and other technologies will surely be developed. Such systems also have the benefit of linkage to electronic anaesthetic record systems both for recording doses and timing and also for identifying potential drug interactions, alerting the operator when about to give a drug to which the patient is allergic (http://www.bd.com/intelliport/).

Incident reporting and learning

Local and national incident reporting systems have existed for some time (https://www.rcoa.ac.uk/salg) and many of the recommendations above have been developed from consideration and analysis of previous critical incidents.[345] Local Incident Reporting Systems provide the additional opportunity for the implementation of corrective measures and system improvements particularly adapted to the local circumstances.[577] This process has reduced the amount of patient harm produced, but it is a continuous and never-ending process. With learning, its dissemination and reliable implementation it is hoped that lessons will not need to be relearnt, but as new medicines and administration techniques are introduced it is only natural for unintended incidents to occur and so critical incident reporting should be a routine part of clinical practice. Without a linked system to analyse these incidents and then recommend and promote ways to reduce them it is not coherent. Also, for an effective and sustainable reporting system the staff needs to be given regular feedback and their must be demonstrable learning from their reporting efforts: without this they will naturally see no good purpose in spending their time continuing to submit reports and stop, to the detriment of all.

Conclusion

Anaesthetists are becoming increasingly aware of the potential pitfalls of administering intravenous medicines and medication safety has been recognised as a global problem by the WHO with their third WHO Global Patient Safety Challenge 'Medication without Harm'. Following on from the Helsinki Declaration the EBA produced Recommendations for Safe Medication

Practice. This chapter has discussed many of these and other recent developments in this complex area. Guidelines without implementation are of limited value and the latest edition of these recommendations also included a 13-point checklist to help and encourage departments to implement them and monitor their progress.[573] Every individual anaesthetist should be mindful of medication safety issues in their own daily practice as they prepare and administer the necessary medicines to the patients in their care.

Chapter 18: Safe sedation: where are we today? (Fuchs-Buder, Struys)

Introduction

Over the last decades there has been a remarkable increase in demand for procedural sedation and analgesia (PSA), driven by an increasing number of minimally invasive diagnostic and therapeutic procedures. All this has been facilitated by the availability of potent short-acting analgesic and sedative drugs, leading to the perception that PSA can also be managed easily by nonanaesthesiologists. In addition, improved medical devices and instruments combined with new imaging and ultrasound equipment now allow major surgical procedures to be performed by minimally invasive techniques, for example, endovascular or perendoscopic procedures. This has resulted in an ever-increasing number of patients presenting for PSA with more and more of them being managed by nonanaesthesiologists. The ESA and the EBA have published guidelines for PSA in adult patients.

Sedation is also a topic of the Helsinki Declaration on Patient Safety in Anaesthesiology, signed in 2010 by the ESA, EBA and NASC (National Anaesthesia Societies Committee) and by numerous countries and anaesthesia societies all over the world thereafter. This chapter will briefly highlight the key messages of the 2017 ESA/EBA guidelines on PSA and it will make a few recommendations about how patient safety during PSA could be further improved.[600]

Key messages of the European Society of Anaesthesiology/European Board of Anaesthesiology guidelines for procedural sedation and analgesia in adults

The main objectives of these guidelines are to provide evidence-based recommendations on the preprocedure evaluation of patients undergoing PSA; the role and competence required from clinicians to safely administer PSA; the minimum monitoring requirements; prevention and management of adverse events; the commonly used drugs for PSA; and postprocedure discharge criteria.

During their initial development, the joint ESA/EBA guidelines successfully followed the ESA rules for guideline development. If there was insufficient evidence about a specific safety recommendation, the Rand Appropriateness Method with three rounds of Delphi voting was used. These guidelines were then reviewed externally and posted on the ESA website for 30 days to allow ESA members to comment. NASC members of the EBA and of the ESA NASC were also consulted; all resulting in detailed and valuable suggestions to improve the original document, and the guidelines were amended accordingly.

Strong recommendations could be made for all of the following items [the respective level of evidence (LoE) is also indicated – more detailed information is available in the original document[600]].

What type of comorbidities and patients require preprocedural evaluation and procedural sedation and analgesia by an anaesthesiologist?

(1) Patients with cardiovascular diseases should be carefully evaluated and optimised, which involves full evaluation of the physical status and cardiac reserve prior to PSA. However, for emergency procedures (e.g. gastroscopy for bleeding) this evaluation may have to be limited (LoE: A).
(2) Patients with a documented or suspected risk of obstructive sleep apnoea syndrome (OSAS) are more vulnerable to drug-induced cardiopulmonary depression during deep sedation. There are different validated questionnaires to identify patients at risk for OSAS like the Berlin or STOP BANG score. Patients with OSAS therefore should also be assessed and managed by an anaesthesiologist (LoE: B).
(3) Morbidly obese patients are at higher risk of respiratory complications during PSA. It is proposed that the severity of OSAS (Berlin or STOP BANG questionnaire) be assessed in these patients. Endotracheal intubation is proposed as the default choice of airway management (LoE: A).
(4) Patients with chronic hepatic disease often need PSA for diagnostic purposes (e.g. oesophageal varices; portal hypertensive gastropathy). Hepatic dysfunction, however, can significantly change the metabolism and pharmacokinetic properties of hypnotic drugs. Preprocedural assessment and PSA should therefore be performed by an anaesthesiologist (LoE: A).
(5) There are many age-related physiological changes in the cardiac, pulmonary, renal, hepatic, endocrine and nervous systems of the elderly that need to be assessed to judge PSA-related risk such as hypotension, hypoxaemia, cardiac arrhythmias and aspiration (LoE: A).
(6) ASA physical status III and IV should also be assessed and managed by an anaesthesiologist (LoE: A) prior to PSA.

What are the requirements to provide well tolerated procedural sedation and analgesia?

(1) Because the majority of severe complications of PSA are upper airway obstruction and/or respiratory

depression, examination of the upper airway before PSA is essential (LoE: B).
(2) All personnel *in charge* of PSA should be certified for CPR (LoE: B). Staff *directly involved* in PSA need specific certified training (LoE: B).
(3) PSA should be carried out only in locations where an anaesthesiologist is immediately available (LoE: C).
(4) The risks, benefits and techniques to deliver PSA have to be explained to the patient by the clinician prior to the procedure (LoE: B).
(5) There should be a dedicated room for PSA (LoE: B) and an algorithm for difficult airway management. A difficult airway cart or specific prepacked material should be immediately available (LoE: B).
(6) Continuous visual bedside observation represents the basic level of clinical monitoring during and after any PSA (LoE: B). Intermittent noninvasive measurement of BP, continuous ECG monitoring and pulse oximetry are considered mandatory in all patients undergoing PSA (LoE: B). Capnography should be used for continuous evaluation of ventilation in all patients receiving deep sedation for PSA (LoE: A).
(7) PSA can be the cause of a wide range of complications that can happen during and after the procedure, for example, respiratory depression, airway obstruction, hypertension, hypotension, chest pain, cardiac arrest or an allergic reaction. The clinician involved in the administration of PSA should be able to recognise these complications early and manage them appropriately (LoE: B). Supplemental oxygen should be available whenever PSA is started, and it can be administered to prevent hypoxia (LoE: B).
(8) Patients must be monitored in a recovery room for at least 30 min after PSA (LoE: B).

How to further improve patient safety

To further improve the safety of patients undergoing PSA, the authors of this chapter suggest the following be considered.

Improve guideline implementation: The ESA/EBA guidelines for PSA in adults, embedded in the Helsinki Declaration on Patient Safety in Anaesthesiology, are conceived as an evidence/consensus-based document on which different National Societies of Anaesthesiology may build their own recommendations about to how professionals should deliver PSA and how PSA can be provided in the safest possible way. By limiting the heterogeneity in the manner in which PSA is administered across Europe, patient safety should improve, but this can only happen if the guidelines are implemented in routine clinical practice. Surveys, continuing medical education, training courses and quality insurance programmes may serve that goal, and thus contribute to increasing the acceptance and implementation of the guidelines.

Better training: All national and international guidelines advocate healthcare professionals be trained in providing sedation with the help of theoretical courses, workshops, bed side teaching and continuing medical education. This would include topics such as patient selection, improved understanding of pharmacokinetics and pharmacodynamics of drugs, airway management, infrastructural requirements to provide safe sedation including monitoring and treatment of complications. These workshops, supervised bed-side training and certification should be mandatory: examples of these can be found in the United Kingdom, the Netherlands and various other countries.[453] On the contrary, a diverse offer of training programmes that all lead to a 'sedationist' certificate exists. Because the quality of these programmes is inconsistent, uniform and well described course requirements should be developed that are audited by an authorised accrediting body.

Better define what constitutes 'sedation': Guidelines differ in their definition of the various levels of sedation. The ESA and EBA guidelines on PSA in adults use the five-level Ramsay scale to define the various levels of sedation, with level five defining general anaesthesia (unconsciousness and no response to a strong physical stimulus).[600] In contrast, the 2018 ASA Practice Guidelines for Moderate Procedural Sedation and Analgesia and the 2018 American Society of Gastrointestinal Endoscopy (ASGE) Guidelines for sedation and anaesthesia in gastro-intestinal endoscopy uses a four-level scale to define the various levels of sedation.[601,602] The American guidelines apply to moderate sedation only. On top of this, various national societies have defined their own standards. As a result, 'sedation' might be interpreted differently among healthcare professionals involved in clinical care across the globe, which complicates the interpretation of study results on quality, safety, adverse events and outcome, and making benchmarking difficult.[603,604] Certainly, for deep sedation levels, uniform guidelines and interpretation of what is considered to be 'sedation' should be promoted: small margins exist between deep sedation and general anaesthesia with a (hopefully) still spontaneously breathing patient but with an unprotected airway and requiring support for the cardiovascular system.

Better drugs/improved drug delivery: For mild sedation, various hypnotic drugs are still considered state-of-the art, ranging from a low dose of midazolam, propofol and ketamine to dexmedetomidine.[605,606] For moderate-to-deep sedation, continuous administration of propofol is still considered the most appropriate drug due to its favourable pharmacokinetic and dynamic properties.[607] However, propofol has well known side effects such as pain on injection, dose-dependent cardiovascular and respiratory depression, and hyperlipidaemia secondary to the infusion of the required lipid formulation.[607] Because propofol has no clinically relevant antinociceptive effect, remifentanil administration in particular may be considered because of its potency combined

with short-acting onset and offset. It can be used in combination with propofol or as a standalone sedative.[605] Target-controlled infusion (TCI) based on pharmacokinetic-dynamic models can be used to fine-tune the administration of both, propofol and remifentanil.[608] TCI is considered a mature technology and being as safe as manual administration of intravenous drugs.[608] Recently, new general purpose pharmacokinetic-dynamic models for both propofol and remifentanil have been developed allowing general application of this technology for sedation in a broad patient group.[609–611]

Targeting a lower concentration of remifentanil in combination with higher targets for propofol results in the highest probability of tolerating oesophageal instrumentation without unacceptable ventilatory problems. Nevertheless, caution is always warranted because no guaranteed 'safe zone' without respiratory depression exists.[612] In an attempt to lower respiratory and cardiovascular side effects, the combination of propofol and ketamine or lidocaine has been studied in an attempt to lower respiratory and cardiovascular side effects.[613,614] Another useful drug may be dexmedetomidine, an alpha-2 agonist known for its combined sedative, anxiolytic and analgesic properties. It has been recently approved for procedural sedation by the European Medicines Agency.[605,615] The ASA presents dexmedetomidine as an alternative to propofol in their 2018 Practice Guidelines for Moderate Procedural Sedation and Analgesia. It has a slower onset and offset than propofol, with sustained arousability during sedation, even when combined with remifentanil.[616–619] It causes less respiratory depression than propofol,[620] but has a profound and complex effect on haemodynamic stability (certainly during rapid infusion): initial hypertension is followed by hypotension and HR changes.[616–618]

Because the existing drugs are still less than perfect, various new compounds have been developed, none of which is clinically available yet. These drugs are soft-analogues from existing drugs and alternative formulations.[621] Remimazolam is a short-acting benzodiazepine currently undergoing phase III trials in ASA III and IV patients undergoing general anaesthesia (ClinicalTrials.gov, NCT02296892) and in phases IIa and IIb trials in patients undergoing sedation. During upper gastrointestinal endoscopy, a single administration of remimazolam (0.10 to 0.20 mg kg^{-1}) rapidly induced sedation, followed by a quick recovery. The safety profile was favourable and appeared to be similar to that of midazolam.[622] A single dose of remimazolam or midazolam, followed by top-up doses to maintain suitable sedation, provided adequate sedation during colonoscopy in a phase III study, with 92 and 75% success rate in the remimazolam and midazolam group, respectively. There was no requirement for mechanical ventilation in any group; procedure failures in both groups were all related to administration of rescue sedatives.[623] Remimazolam is likely to be introduced into the market for sedation in the near future.

Better monitoring: It should be stressed that sedation should be provided and patients should be monitored by a trained and certified healthcare professional other than the person involved in the procedure. Continuous observation of the level of sedation according to well defined clinical endpoints is mandatory. Vital signs that have to be monitored include NIBP, electrocardiography and pulse oximetry. The use of capnography remains controversial. ESA–EBA and ASA support the use of capnography.[600,601] A meta-analysis concluded that capnography reduced the incidence of respiratory compromise (ranging from respiratory insufficiency to failure). There is less mild and severe oxygen desaturation, which may reduce the need for assisted ventilation. In contrast, the ASGE guidelines only recommend capnography during procedures under deep but not moderate sedation.[602] These guideline discrepancies should be avoided for medico-legal reasons and because they cause confusion when translating these guidelines into institutional standard operating procedures.[624]

Conclusion

The common set of guidelines for PSA published by ESA and EBA is a first important step towards more homogeneity in the way PSA is provided across Europe. These guidelines must be implemented in routine clinical practice and certified training programmes must be proposed to further improve patient safety. The ESA should be a strong stakeholder in this process.

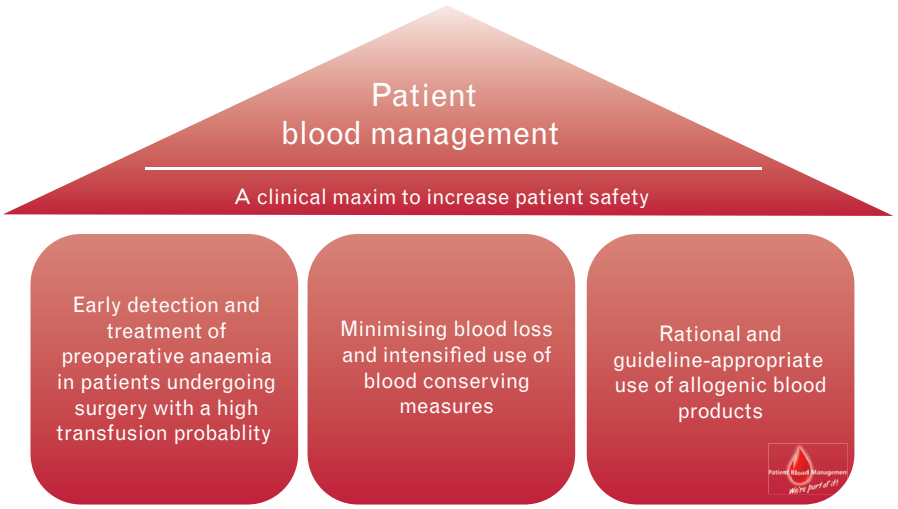
Chapter 19: Patient blood management: an update of its effects on patient safety (Meybohm, Zacharowski)

Patient blood management (PBM) is an interdisciplinary diagnostic, behavioural and therapeutic concept, which reduces and avoids unnecessary blood loss and focuses on the rational handling of blood components. Based on the possibility of increasing and maintaining a patients' own blood resources and to enable safe handling of donor blood, the World Health Assembly endorsed PBM in 2010 (WHA63.12).[625] The use of PBM in clinical practice follows the three main pillars: first, comprehensive pre-operative anaemia management; second, minimisation of iatrogenic (unnecessary) blood loss; third, harness and optimise the patient-specific physiological tolerance of anaemia (Fig. 17).[626]

Comprehensive pre-operative anaemia management

In 18 large observational studies encompassing more than 650 000 surgical patients, the prevalence of pre-operative anaemia varied between 10 and 48%.[627] Pre-operative screening should include evaluation and management of anaemia. From a practical point of view, patients

Fig. 17



The three main pillars of patient blood management: first, comprehensive pre-operative anaemia management; second, minimisation of iatrogenic (unnecessary) blood loss; third, rationale use of allogenic blood p

scheduled for surgical procedures with expected blood loss (>500 ml) or a at least 10% probability of red blood cell (RBC) transfusion should be identified and assessed at the earliest opportunity, and be screened for iron-deficiency and other likely causes of anaemia.[628–630] The availability of an easy-to-follow, diagnostic algorithm is desirable.[631] Intravenous iron is efficacious, safe and should be used in patients in whom oral iron is not tolerated, or if surgery is planned in less than 4 to 6 weeks after the diagnosis of iron deficiency.[632–634] It is notable that most effective increments of haemoglobin (Hb) levels could be reached when intravenous iron was administered between 2 and 4 weeks before surgery.[633,635] If possible, elective surgery should be postponed until pre-operative anaemia has been appropriately classified and treated. Treatment of anaemia a few days before surgery has also been shown to effectively increase Hb level postoperatively, and to reduce transfusion rate.[636] Spahn *et al.*[637] recently demonstrated the clinical benefits of an ultra-short-term combination treatment consisting of a slow infusion of 20 mg kg^{-1} ferric carboxymaltose, 40 000 U subcutaneous erythropoietin alpha, 1 mg subcutaneous vitamin B12, and 5 mg oral folic acid in patients undergoing elective cardiac surgery with anaemia or isolated iron deficiency. The combination treatment increased Hb levels and reduced RBC transfusions from a median of one unit in the placebo group to a median of zero units in the treatment group.[637]

Minimisation of iatrogenic (unnecessary) blood loss

Surgical procedures may be associated with a higher risk of bleeding and transfusion. For example, total knee or hip arthroplasty are associated with extensive blood loss up to 1500 ml.[638] The average cardiac surgery patient loses between 500 and 1200 ml of blood peri-operatively, and about 5% of all cardiac surgery patients are re-explored due to excessive bleeding.[639] In this respect, intra-operative RBC recovery and autologous transfusion is highly effective to minimise allogeneic RBC transfusion. A recent meta-analysis showed that the use of cell salvage reduced the number of patients exposed to allogeneic RBCs by 39%.[640]

Blood loss associated with invasive laboratory testing can either cause or aggravate hospital-acquired anaemia. Reduction of blood drawn for laboratory analyses can be achieved by avoiding unnecessary laboratory tests and a lower frequency of sampling and using the smallest collection tube size that is feasible for the required analysis.[641] Further reduction of phlebotomy associated blood loss can be achieved by using closed in-line flush blood sampling devices for arterial (and central) lines.[642] Advanced peri-operative coagulation monitoring and management are crucial for avoiding unnecessary blood loss and should be a precondition before RBC transfusion is considered. In this respect, the use of a coagulation algorithm is recommended, encompassing pre-operative assessment, ensuring basic conditions for haemostasis (e.g. temperature, calcium, pH), reversal of anticoagulants, point-of-care diagnostics in bleeding (e.g. coagulopathic) patients and optimised coagulation management with the use of clotting factor concentrates.[643–645] To reduce surgical blood loss, tranexamic acid should be used unless contraindicated (e.g. history of venous thromboembolic events).[646]

Harness and optimise the patient-specific physiological tolerance of anaemia

Several trials have been conducted to compare outcomes in patients undergoing either a restrictive or a liberal transfusion strategy. Significantly, outcome measures (e.g. mortality, length of hospital stay, acute kidney failure) were similar in critical care patients, patients undergoing cardiac surgery, patients with hip fracture or acute upper gastro-intestinal haemorrhage either assigned to a pretransfusion Hb trigger of below 7 to 8 g dl^{-1} or 9 to 10 g dl^{-1}, respectively.[647–650] At this point, it remains unclear whether cardiovascular risk patients, geriatric or oncological patients will benefit more from a higher transfusion trigger than from the one currently recommended.[630] A clinical corridor for making medical discretionary decisions is still needed in this context. To optimise utilisation of allogeneic blood products, a physician order entry with a clinical decision support based on electronic medical records has been suggested.[651] Thereby, indication for transfusion considering patient-specific factors (e.g. age, diagnosis, comorbidities, surgical or nonsurgical setting), signs/symptoms of acute anaemia, laboratory values (e.g. Hb) and presence or absence of bleeding can be confirmed with required checkboxes.[652] If a RBC transfusion is indicated in case of patients not actively bleeding, only a single RBC should be administered (Single-Unit Policy).

Multimodal patient blood management programme

Significantly, a multidisciplinary, multimodal PBM programme might have the highest potential in reducing RBC utilisation and improving postoperative outcomes. The overall clinical efficacy of PBM has been confirmed by many recent large studies encompassing several hundred thousands of patients.[653–660] Overall, implementation of PBM is associated with a reduced transfusion rate of allogeneic blood products by about 40%, improved clinical outcomes, a reduced complication rate, reduced length of hospital stay and reduced costs. Meybohm *et al.* conducted a prospective, multicentre study with a total of 129 719 patients discharged between July 2012 and June 2015 from four German University Hospitals and analysed patients before (pre-PBM) and after the implementation of PBM. The PBM programme included multiple measures, for example, pre-operative optimisation of Hb levels, blood-sparing techniques, and standardisation of transfusion practice. While the mean number of RBCs transfused per patient was reduced by 17%, the primary safety composite endpoint was comparable between both cohorts.[661] Based on a retrospective analysis of 836 patients undergoing visceral surgery for cancer treatment, Keding *et al.*[662] demonstrated PBM as a quality improvement tool with a significant improved 2-year overall survival (80.1 vs. 67.0% of patients). Leahy *et al.* published a retrospective study of 605 046 patients admitted to four major adult tertiary-care hospitals between July 2008 and June 2014 in Western Australia. Comparing final year with baseline measurements, units of RBC, fresh frozen plasma and platelets transfused per admission decreased by 41%, representing a direct saving of AU$18 507 092, and between AU$80 million and AU$100 million estimated activity-based savings. This PBM programme was even associated with risk-adjusted reductions in hospital mortality, length of stay and hospital-acquired infections.[653] A PBM monitoring and feedback programme at the University Hospital of Zurich/Switzerland resulted in a reduction of allogeneic blood transfusions of 27% with savings of direct transfusion costs of 84 USD per inpatient which yielded more than 2000 000 USD per year.[657] The beneficial effects of PBM were also demonstrated in a recent systematic meta-analysis including seventeen studies addressing each of the three PBM pillars with at least one measure per pillar, comprising 235 779 surgical patients.[663] Implementation of PBM significantly reduced transfusion rates (−39%), hospital length of stay (−0.5 day), total number of complications (−20%) and mortality rate (−11%). Significantly, PBM had the highest impact on patients undergoing orthopaedic and cardiac surgical procedures: the relative risk for RBC transfusion decreased by 55% and 50% in these patients, respectively.

Implementation strategies

Different characteristics of published studies may contribute to clinical heterogeneity and persistent lack of clinical PBM implementation. Only a minority of hospitals have yet adopted measures for all three pillars. Therefore, implementation strategies should target complementary measures for all three PBM pillars to specifically minimise risk factors associated with anaemia and transfusion. So far, more than 100 individual PBM measures addressing the three main pillars have been defined based on the broad interdisciplinary fields (e.g. anaesthesia, surgery and central laboratory) and temporal application (pre-operative, intra-operative to postoperative).[664] The great advantage of this PBM bundle concept is that the selection can be dynamically adapted to the individual local, financial and personal resources as well as the respective focus of each hospital. Many important factors, such as infrastructure, staff, equipment and economic resources differ between hospitals. Individualisation is vitally important for the social acceptance of any new standard. For this reason, PBM programmes need to be specifically designed for each site using the bigger frame of the recommended concept.

Moreover, implementation of PBM needs to include practical and strategic components aimed at increasing knowledge. This can be achieved by stressing the clinical implications of anaemia and the need for alternatives to allogeneic transfusion. The focus should be placed upon clinical outcomes and the inappropriateness of transfusion practice variability. The learning materials can be provided by a website (www.patientbloodmanagement.eu), a

comprehensive e-learning programme (www.patient-bloodmanager.com), a central virtual room for documents/guidelines/posters/education materials, and numerous media reports. In addition, quantification and validation of successful training should be measured by a local online certification course for anaemia management, PBM and general transfusion practice.

The huge evidence base should motivate all executives and healthcare providers to support further PBM activities. Up to the present, only a few regulatory authorities support the implementation of PBM. For example, the European Commission previously released an EU PBM implementation and dissemination guide; however, PBM measures are not an obligatory part of clinical routine yet.[665,666] The National Blood Authority supported the first worldwide implementation of PBM in Western Australia in 2008 and the National Institute for Health and Care Excellence guidelines in the United Kingdom postulate treatment with iron in iron-deficiency anaemic patients 2 weeks prior to surgery.[667,668]

Acknowledgements relating to this article

Assistance with the study: Marlene Dyrløv Madsen, Copenhagen Academy for Medical Education and Simulation participated in structuring and finalising Chapter 8. Expert librarian Regina Küfner Lein, University of Bergen, performed literature searches and made substantial contributions to Chapter 11.

Financial support and sponsorship: the study described in Chapter 1 (three-phase investigation to assess the uptake and use of the Declaration) was funded by the European Society of Anaesthesiology, supported by the following industry partners: Philips Healthcare, Masimo International, Fresenius Kabi and Nihon Kohden Europe. These companies played no role in data collection, analysis or writing the article.

Conflicts of interest: BP participated in advisory boards for Laboratoire Aguettant, France; and Sensium Healthcare, UK, and received research grants from NovoNordisk, the Netherlands. SS received lecture fees from ASPEN Global which were donated to the European Patient Safety Foundation (EuPSF). GB is the founder and unpaid chair of the board of The BEST: Better & Systematic Team Training, a not-for-profit foundation. JMF consults for Micropore Inc, a manufacturer of CO_2 absorbent. TF-B received lecture fees from MSD. ASH is funded by a postdoctoral grant (grant number: HV1172) from the Western Norway Regional Health Authority's Patient Safety Program and received travel reimbursement from the International Federation of Nurse Anaesthetists. CJK received funding from the European Commission, Horizon 2020: Nightingale Project Precommercial Procurement, grant #728534. PM received grants from B. Braun Melsungen, CSL Behring, Fresenius Kabi and Vifor Pharma for the implementation of Frankfurt's Patient Blood Management programme and honoraria for scientific lectures from B. Braun Melsungen, Vifor Pharma, Fearing, CSL Behring and Pharmacosmos. AP received a grant from the Health Foundation to support Learning from Excellence training. HUS is an employee of Draegerwerk AG & Co KGaA, Luebeck, Germany. AFS has acted as an expert advisor on patient safety to the WHO and the 2nd Global Ministerial Patient Safety Summit in 2017. MMRFS research group/department received grants, funding and/or honoraria from The Medicines Company (Parsippany, New Jersey, USA), Masimo (Irvine, California, USA), Fresenius (Bad Homburg, Germany), Becton Dickinson (Eysins, Switzerland), Dräger (Lübeck, Germany), Pion (Aachen, Germany) and Demed Medical (Temse, Belgium). CPS did consultancy work for Philips Healthcare and is Principal Investigator of the VITAL II study. JWe received funding from the European Commission, Horizon 2020: Nightingale Project Precommercial Procurement, grant #728534. DKW is a Past President of the Association of Anaesthetists and Chair of the Patient Safety Committee of the European Board of Anaesthesiology. He has received lecture fees from Aguettant Ltd. and Medtronic, all of which were donated to Lifebox. KZ received grants from B. Braun Melsungen, CSL Behring, Fresenius Kabi and Vifor Pharma for the implementation of Frankfurt's Patient Blood Management programme and honoraria for scientific lectures from B. Braun Melsungen, Vifor Pharma, Fearing, CSL Behring and Pharmacosmos.

AFS, DKW, JM-O and SS were the authors of the published version of the Helsinki Declaration for Patient Safety in Anaesthesiology.

Comment from the Editor: this Special Article was checked and accepted by the editors but was not sent for external peer review.

Presentation: none.

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