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2

### Morbidity in anaesthesia: Today and tomorrow

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Based on results recorded of perioperative mortality, anaesthetic care is often cited as a model for its improvements with regard to patient safety. However, anaesthesia-related morbidity represents a major burden for patients as yet in spite of major progresses in this field since the early 1980s. More than 1 out of 10 patients will have an intraoperative incident and 1 out of 1000 will have an injury such as a dental damage, an accidental dural perforation, a peripheral nerve damage or major pain. Poor preoperative patient evaluation and postoperative care often contribute to complications. Human error and inadequate teamwork are frequently identified as major causes of failures. To further improve anaesthetic care, high-risk technical procedures should be performed after systematic training, and further attention should be focussed on preoperative assessment and post-anaesthetic care. To minimise the impact of human errors, guidelines and standardised procedures should be widely implemented. Deficient teamwork and communication should be addressed through specific programmes that have been demonstrated to be effective in the aviation industry: crew resource management (CRM) and simulation. The impact of the overall safety culture of health-care organisations on anaesthesia should not be minimised, and organisational issues should be systematically addressed.

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The risks associated with anaesthesia have long been recognized and anaesthesia is often cited as a model for its achievements in the field of patient-safety improvements.<sup>1,2</sup> One of these improvements is the continuous monitoring of adverse outcomes following anaesthesia and the systematic development of strategies to minimise the adverse outcomes.<sup>3</sup> This review article summarises the major findings of current epidemiological studies reporting on anaesthesia-related mortality and morbidity and identifies certain strategies that are frequently recommended to minimise the occurrence of adverse outcomes.

## **Epidemiology of anaesthesia-related mortality and morbidity**

### *Anaesthesia-related mortality*

The measurement of anaesthesia-related mortality has been employed since the middle of the 19th century. Anaesthesia-related mortality is defined as patients dying under, or following, the care of an anaesthetist. Studies have been published on a regular basis and used as a proxy to measure patient safety in anaesthesia. Some of the largest and most well-known studies include the review of anaesthesia-related mortality between 1997 and 1999 in Australia,<sup>4</sup> the National Confidential Enquiry into Peri-Operative Death (NCEPOD) in the United Kingdom,<sup>5</sup> the anaesthesia-related mortality and morbidity over a 5-year period in 2 363 038 patients in Japan,<sup>6</sup> the Canadian four-centre study of anaesthetic outcomes,<sup>7,8</sup> the prospective survey of complications associated with anaesthesia in France,<sup>9</sup> the mortality associated with anaesthesia in a study conducted in South Africa,<sup>10</sup> the study of deaths associated with anaesthesia in Finland,<sup>11</sup> the anaesthesia-related-mortality assessment performed in a study in New Zealand<sup>12</sup> and the study on the prevention of intraoperative anaesthetic accidents and related severe injury through safety monitoring in the United States.<sup>13</sup> These studies complete the observations reported by several others from the 19th century onwards, and contribute to provide a remarkable picture of the reduction in anaesthesia-related mortality throughout the 20th century. For example, at the end of the 19th century, 1/900 patients died as a result of their anaesthesia.<sup>14</sup> In the late 1950s, anaesthesia-related mortality was much lower and ranged from 3.1/10 000 to 6.4/10 000 following the administration of anaesthetics.<sup>15,16</sup> During the last three decades, mortality figures associated with anaesthesia dropped to 0.04–7 per 10 000 patients administered anaesthetics<sup>17</sup>; this represents a 10-fold decrease in the anaesthesia-related mortality rate since the 1980s. As a result, anaesthesia is often cited as the only speciality in health care to have reached the six sigma defect rate. A six sigma process is defined as one in which 99.99966% of the 'end-products' are statistically free of defects (3.4 defects per million).<sup>18</sup> Is this really true?

There are significant limitations in using anaesthesia-related mortality rates to measure and determine the level of safety in anaesthesia. Thus, the above-mentioned figures should be interpreted with caution. The first problem is the lack of a standardised definition of anaesthesia-related mortality. For some authors, this term includes mainly perioperative death to which human error on the part of the anaesthesia provider has contributed.<sup>19–22</sup> For others, anaesthesia-related mortality refers to all potential causes of deaths occurring during or following anaesthesia, including those associated with both anaesthetic and surgical factors.<sup>23–25</sup> In addition, there is a lack of consensus with regard to the overall period of time following anaesthesia that when anaesthesia-related mortality can be defined. Depending on studies, this period can vary between 24 h and 30 days following an anaesthetic procedure.<sup>23–26</sup> This variation has a significant impact on prevalence estimates of anaesthesia-related mortality. There have been some attempts to identify a consensus definition such as, for example, in 1985, when several experts in an International Symposium in Vancouver defined anaesthetic mortality as "death which occurred before recovery from the effects of a drug or drugs given to relieve the pain of a condition or arising from an incident which occurred while the drug was effective."<sup>27</sup> However, this definition and others that followed have never been widely accepted or promulgated sufficiently to become standards in reports and studies of anaesthesia-related mortality. Another limitation relates to the peer-review process itself. To determine whether death is associated with anaesthesia, individual cases are often reviewed by a committee of experts. There is a significant level of variability amongst reviewers with regard to causes of adverse outcomes. Certain studies found that the level of agreement between reviewers regarding the standard of care was, at times, only marginally better than

coincidental.<sup>28</sup> As a consequence, there exists some uncertainty with regard to the actual figures of anaesthesia-related mortality. The fourth limitation relates to the measurement of the denominator of the equation. Most studies use coroners' registries, voluntary reports, surveys and malpractice claims as their main data source for perioperative death. As a consequence, the denominator of the mortality equation – the overall number of patients anaesthetised – is unknown. Most often, approximations of the overall number of patients undergoing a surgical procedure where anaesthesia is likely to have been used, or estimates of discharges from public and private hospitals, are used. As a result, prevalence data available for anaesthesia-related mortality are approximate estimates. This has led to several controversies emerging in the anaesthetic literature.<sup>26–29</sup> Finally, anaesthesia-related mortality does not exactly reflect patient safety during anaesthesia, which is to “ensure that no patient should be harmed by anaesthesia,” as established by the Anaesthesia Patient Safety Foundation.<sup>30</sup> Furthermore, harm includes anaesthesia-related morbidity, which should be explored together with anaesthesia-related mortality in order to assess the true level of patient safety during anaesthesia.

### *Anaesthesia-related morbidity*

Anaesthetic morbidity (*indicative of disease* – The Oxford Dictionary of Science and Medicine)<sup>31</sup> incorporates any complication, excluding death, occurring during the perioperative period.<sup>32</sup> It can be classified into three groups:

- 1) *Minor morbidity*: Moderate distress without prolongation of hospital stay or permanent sequelae (e.g., postoperative nausea and vomiting (PONV)).
- 2) *Intermediate morbidity*: Serious distress or prolongation of hospital stay, or both, without permanent sequelae (e.g., dental injury).
- 3) *Major morbidity*: Permanent disability and sequelae (e.g., spinal cord injury).

Cardiac arrests and coma are the most widely applied morbidity-related adverse outcomes employed to measure patient safety. Because major morbidity such as cardiac arrests or coma can often lead to death, these adverse outcomes have often been analysed within studies looking at anaesthesia-related mortality. The current prevalence of anaesthesia-related cardiac arrests is between 0.8 and 3.3/10 000 anaesthetics administered, and the prevalence of anaesthesia-related brain injuries is between 0.15 and 0.9/10,000.<sup>6–9</sup> These are closely followed by other neurological complications that occur subsequent to anaesthesia. Paraplegia secondary to spinal or epidural anaesthesia occurs at the rate of 0.6–0.9 per 100 000 patients; however, neuropathy following peripheral nerve blockade is present in approximately 3% of patients, with most of these recovering after some weeks or months.<sup>33</sup> Ulnar neuropathy after anaesthesia and surgery, consisting mostly of unilateral paraesthesias of the ring and little finger, can be present in 0.5% of patients, with residual symptoms persisting up to 2 years later in 0.2% of patients.<sup>34</sup> After anaesthesia and surgery in lithotomy positions, lower extremity neuropathies are identified in 1.5% of patients; however, symptoms resolve in most patients within 6 months.<sup>34</sup>

The incidence of adverse outcomes with intermediate or low morbidity is quite high. Bothner et al., as well as Fasting and Gisvold, found an overall incidence of minor anaesthesia-related, perioperative incidents between 18% and 22%.<sup>35,36</sup> Minor events such as hoarseness of voice following tracheal intubation, occurring within 24 h postoperatively, have been reported in 14–50% of patients. These may accompany a traumatic lesion of the larynx or hypopharynx in 6.3% of patients.<sup>37</sup> The same holds true for dental injury requiring further dental interventions that occur in one patient per 1000–2073.<sup>38,39</sup>

Furthermore, errors associated with drug administration are frequent and occur in 0.1% of anaesthetic administrations.<sup>40</sup> In addition, problematic performance of anaesthetic equipment have been shown to occur in 0.23% of patients during general anaesthesia and in 0.05% during regional anaesthesia; one-third of these problems was related to the anaesthetic machine, and one-quarter to human error.<sup>41</sup> Accidental dural perforation during epidural anaesthesia occurs in 0.5–0.6% of obstetrical anaesthetics.<sup>42,43</sup> PONV is the most frequent adverse outcome. Depending on the presence of risk factors for PONV, it can occur in 10–79% of anaesthetic procedures.<sup>44,45</sup>

As a result, if morbidity is included in the definition of harm caused by anaesthesia, adverse outcomes are much more frequent and anaesthesia appears to be far from 99.99966% free of defects (Fig. 1).

However, when looking at the evolution of morbidity over the last decades, the same level of improvement as the one observed for anaesthesia-related morbidity can be identified. For instance, cardiac arrests following neuraxial anaesthesia have been halved between 1970 and 1990.<sup>46</sup> The same is true for awareness during obstetric anaesthesia, which decreased from 1.3% to 0.4% between 1982 and 1989.<sup>47</sup> Claims for nerve injuries have been reported to decrease from 37% to 17% between 1980 and 1990.<sup>46</sup> Once again, these figures should be interpreted with caution. They suffer from similar limitations as figures provided by anaesthesia-related mortality studies: lack of clear definition of the adverse outcome measured and lack of consensus as to what defines the perioperative period. Furthermore, as these outcomes are not, by themselves, measures of patient safety, they need to be further analysed and interpreted by observers or reviewers in order to determine whether the adverse outcome described is related to health-care management rather than patients' conditions and whether an error or a deviation from standard of care has occurred. Only then can the adverse outcome be considered as a true measure of patient safety and the prevalence of safety issues in anaesthesia be reliably determined. The reliability of the peer-review process has been questioned several times, and the main limitation of this method is selection, information, recall and insight bias from unblinded reviewers.<sup>48</sup> Nevertheless, they indicate that iatrogenic complications following anaesthesia are not rare and, although the situation may have improved since the 1970s, there is still a long way to go to reach the six sigma defect rate.

### Causes of mortality and morbidity: proposals for future improvements in anaesthesia

Anaesthesia remains risky, particularly in a specific number of procedures such as airway control during general anaesthesia, intra- and post-operative management of haemorrhage and circulatory disturbances associated with regional anaesthesia.<sup>49</sup> These can result in severe complications or even death. A number of additional activities such as central venous catheter (CVC) placement, the use of infusion pumps and the administration of medication<sup>50</sup> contribute to increasing morbidity.<sup>36</sup>

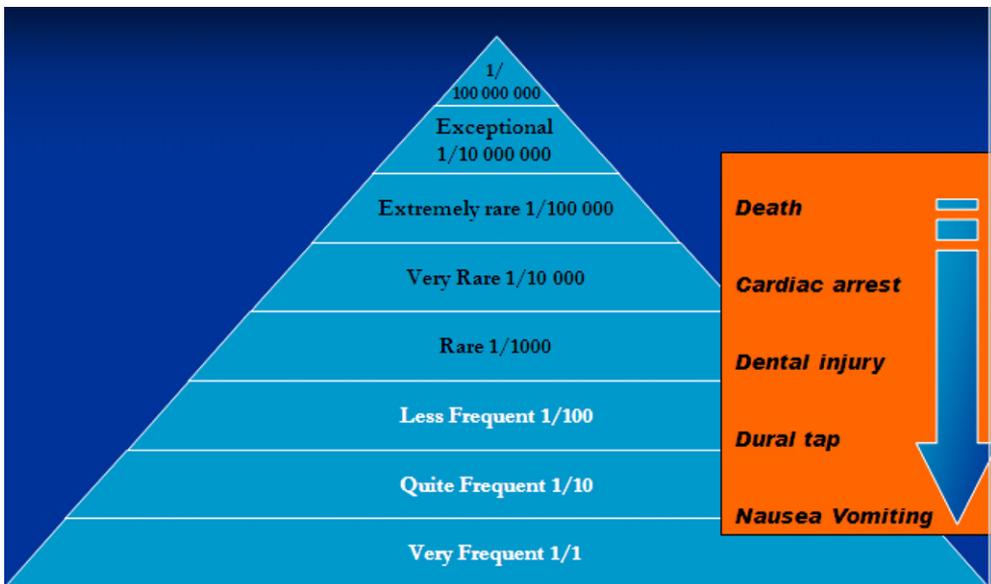


Fig. 1. Anaesthesia morbidity.

Adverse outcomes occur not only during the intraoperative period but also as a result of activities performed by anaesthetists during the pre- and post-operative periods. Preoperatively, suboptimal care related to inadequate patient evaluation or incorrect preoperative management, has been found to be a major contributing factor in 38–42% of deaths.<sup>49–51</sup> Whereas respiratory depression has become extremely rare during the postoperative period with the development of post-anaesthesia care units (PACUs), other factors such as suboptimal management of postoperative blood loss, insufficient supervision of care-team members or inadequate resuscitation procedures still contribute to 43% of anaesthesia-related deaths.<sup>49</sup>

Therefore, the first message is that future efforts should aim at improving anaesthesia safety not only during the intraoperative period, but also during the pre- and postoperative periods.

Another cause of adverse outcomes relates to human error. Human failures have been identified in 51–77% of anaesthesia-related deaths.<sup>49</sup> Most cases are related to lack of experience or competence, which have been observed in 89% of human-failures-related deaths, and, less frequently, errors of judgement or analysis, detected in 11% of these deaths. As a result, good practices clinical guidelines may significantly improve practice. Clinical guidelines can be defined as systematically developed statements that assist clinician decisions about appropriate health care for specific clinical circumstances. There are three different types of guidelines: 1) protocols – strict rules to be followed in detail with little space for variability; 2) consensus guidelines – a set of best practices recommendations developed on an expert-based support; and 3) evidence-based guidelines – a set of recommendations based on a systematic retrieval and appraisal of information from the scientific literature including the rating of the strength of the evidence.<sup>52,53</sup> Protocols are the most formalised method of procedure-based strategies and are close to the approach seen in the industry. They are usually used in high-risk areas such as emergency resuscitation or cardiac anaesthesia. Guidelines represent a weaker type of procedure-based strategy and appear more as systematically developed statements to assist clinicians rather than formal steps to guide a diagnostic or treatment process. Guidelines are available from professional organisations and health-care governmental agencies or can be found in the scientific medical literature.

Although guidelines have shown some effectiveness in improving patient safety in anaesthesia,<sup>54</sup> the low level of compliance with guidelines is disturbing, although this is not a phenomenon specific to anaesthesia. There are several reasons for this.

First, procedures and guidelines inherently challenge professional autonomy. Medical knowledge is complex and takes a long time to acquire. This inevitably results in professional control of the nature of clinical work and the relationship with patients.<sup>55</sup> The use of predefined procedures challenges this autonomy and is often viewed as ‘cook-book medicine’ by many anaesthetists. This may be attributed to their industrial roots based on a formal, orderly, organisational framework for clinical work. In reality, clinical work in anaesthesia, particularly during emergency situations, is far from being linear and rational. This contributes to the poor reputation of guidelines and protocols among anaesthetists. Second, when assessing guidelines more specifically, it appears that there is a large number of guidelines available from a wide range of sources which may be incomplete, out of date or have conflicting recommendations. Finally, their distribution relies largely on passive diffusion while studies show that this is often a very poor way to encourage changes in professional practice.<sup>56</sup>

Therefore, the second message is that human error is a key factor leading to adverse outcomes and guidelines have a great potential to minimise errors, particularly those associated with a lack of experience or competence. However, there are significant barriers to their wide implementation and future efforts should aim at better understanding of these obstacles to develop strategies that can overcome them.

Another cause of adverse outcomes relates to poor teamwork and communication. These factors have been shown to contribute to 43–65% of sentinel events occurring in operating theatres (e.g., operation on the wrong side, transfusion error, incorrect administration of potassium chloride).<sup>57</sup> Teamwork has been identified as being inadequate in 62% of deaths, mainly communication breakdown (oral communication in 36% and written communication in 20%), or poor supervision and absence of help when needed (in 44% of failures).<sup>58,59</sup> These difficulties in communication were confirmed in a study by Arbous et al., showing that the risk of anaesthesia-related mortality was

reduced when a senior anaesthetist was available and could be reached (odds ratio (OR): 0.45), when there was no intraoperative change of anaesthetist, reducing the need for transfer of information (OR: 0.44) and when two individuals were present during the initiation and termination of anaesthesia (OR: 0.69).<sup>17–19</sup> These findings confirm other reports that identified the importance of operating-room teamwork, which should not be seen as restricted to anaesthesia caregivers, but must also include the surgical and operating-room nursing personnel. In a large survey, Davenport and colleagues found that with better communication and collaboration of the operating-room care team, the incidence of postoperative complications was lower.<sup>60</sup>

There are several methods through which teamwork and communication can be improved. The most well known are CRM and Simulation. Both methods have been developed in the aviation industry and have increasingly been used in health care since the end of the 20th century. The concept of team management of crisis situations (CRM) was first presented in 1979 at a NASA workshop on aviation safety. The first CRM formal programme was implemented in commercial aviation in 1981, and has increasingly become a key element of aviation crew training. In addition, it is used in other high-risk areas such as the nuclear industry.<sup>61</sup> This concept has gradually been integrated into the medical field following the pioneering work done in the late 1980s at the Stanford University by Gaba and colleagues.<sup>62</sup> They were the first to introduce the concept of crisis management into anaesthetic practice.

CRM is designed to improve the way health-care professionals think and act during crisis or routine management of patients by improving communication and teamwork. The key concept of CRM is “Training crews to reduce ‘pilot errors’ by making better use of the human resources on the flight deck.”<sup>63</sup> The CRM technique aims at developing shared behaviours to improve patient safety (team resources rather than individual resource). There is no ‘unique’ format for CRM programmes, and these can vary depending on individual organisational needs.

However, all programmes address issues in the following areas: communication, coordination, leadership and human factors leading to errors.<sup>64</sup>

They are designed to:

- Improve leadership (everyone must be able to propose solutions, improvement of capacity management, etc.);
- Awareness of the risk situation (collect and sort information, identify priorities, etc.);
- Stress management (identifying stressors, propose collective solutions, prioritise options based on risk, evaluate available choices, etc.);
- Management of ‘core skills’ (maintain standards, identify and use available resources, etc.);
- Teamwork (create a vision and team dynamics, distribute and coordinate activities, etc.);
- Communication (exchange of information, adopt effective communication strategies, etc.).

This safety-improvement method is at an early stage in the health-care context as yet. It has been used, mainly, in limited settings and virtual environments to train anaesthetists and neonatologists to deal with crisis scenarios,<sup>64–67</sup> emergency physicians to build effective teams<sup>55,67–71</sup> and medical and nursing students to improve their communication and cooperation skills.<sup>72</sup>

Simulation is a widely used teaching method in high-risk industries, such as aviation or the nuclear industry. In the health-care industry, and more particularly in anaesthesia, this is an underused method as yet, due, in particular, to high costs. Conventionally, clinical training is based on a mix of theoretical and practical teaching in a clinical setting with real patients. This traditional teaching method raises several ethical issues and, in particular, the fact that invasive techniques are performed by beginners for the first time on real patients. Simulation offers an answer to this problem. However, in addition to improvement of technical and procedural skills (i.e., catheter insertion, resuscitation procedures, etc.), simulation can be used to train individuals in non-technical skills such as teamwork, coordination and communication.

A number of clinical ‘scenarios’ can be reproduced in a simulated environment with predefined teaching objectives in accordance with ‘real life’ situations. Scenarios can replicate routine or unusual critical situations. Learning by participants occurs both during and after the simulated scenario – such as during a feedback session enriched with videotapes from the simulated scenario. This method

is particularly well adapted for the acquisition of non-technical skills. It allows each participant to question his/her own behaviour and communication skills while realising that everyone is prone to making mistakes. Used in various environments such as obstetrical units and neonatology units, simulation has been clearly demonstrated to be able to improve participants' non-technical skills. More specifically, improvements have been observed in team-coordination abilities. A recent study has shown that improving non-technical skills could reduce, by as much as 50%, adverse events following difficult deliveries.<sup>65</sup>

Therefore, the third message is that poor teamwork and communication can lead to serious adverse outcomes following anaesthesia. Serious improvements in patient safety during anaesthesia can be expected from the wide implementation of CRM programmes and simulation to improve teamwork and communication in operating theatres and other hospital settings.

Finally, organisational and management factors have been identified as having contributed to 26% of deaths and severe morbidity. They consisted of: inadequate matching between the required resources and the patients' condition seen in 38% of deaths, inadequate surgical scheduling in 31%, production pressure in 20% and inappropriate night-call organisation in 11%.<sup>49–51</sup> This suggests that efforts to improve patient safety during anaesthesia should not be exclusively directed to improving individual competence but also should address optimisation of organisations themselves. Again, aviation has led the way with a new approach called 'safety management'. First mentioned in the early 1990s, safety management has evolved from the idea that safety needs to be managed<sup>73</sup> to the concept of 'safety-management systems'.<sup>74,75</sup> It implies an analysis of critical tasks which impact on overall flight safety and the development of detailed procedures and instructions for those tasks.<sup>76</sup> Integrated into the management of an organisation, it can be understood as a quality management of safety-related operational and support processes to achieve safety goals. In other words, a quality assurance process to manage safety itself. This can be considered as the ultimate stage of organisational safety.

Therefore, the fourth message is that poor organisational management-related factors can seriously impact on patient safety, and that overall improvements in anaesthesia safety also rely on the development of a safety culture at all levels, including at the management level. The aviation industry has addressed this problem with the development of 'safety-management systems', a concept which could be transferred into hospitals for the benefit of patients and safety overall.<sup>77</sup>

## Conclusion

Insurance premiums for anaesthetists have remained stable or have even decreased in European or North American countries in recent years.<sup>78</sup> This is clearly due to a decrease in the number of major accidents associated with anaesthetic care. However, although anaesthesia can claim successes in reducing the number of major adverse outcomes including death, anaesthesia-related morbidity still remains significant. Human errors, poor teamwork and organisational failures play an important role in contributing to adverse outcomes. At this stage, conventional improvement methods such as the development of new and safe anaesthetic agents or advanced monitoring have limited impact. In addition to minimal standards for anaesthetic practice and strict regulation of staff qualifications, the next improvements in anaesthesia safety should consider the following interventions.

- 1) Reduce complications of procedures that remain high risk (such as airway control, intra- and post-operative management of haemorrhage, preoperative evaluation, etc.) through simulation.
- 2) Minimise human errors (in particular, those associated with a lack of experience or competence leading to deviations from recommended practice in patient care) by the systematic use of good practice clinical guidelines and standardisation of work practices.
- 3) Improve communication and teamwork among the different caregivers within the anaesthetic team and among anaesthetists, surgeons and operating-room nurses through CRM programmes.
- 4) Reduce organisational failures by implementing safety-management systems developed within the aviation industry.

## Practice points

- Avoiding death during anaesthesia is not enough; significant efforts should be put into minimising anaesthesia-related morbidity.
- Poor preoperative patient evaluation and postoperative care often contribute to complications. These are often associated with human error and poor teamwork.
- High-risk technical procedures should be systematically trained and further attention focussed on preoperative assessment and post-anaesthetic care.
- Deficient teamwork and communication should be addressed through special training programmes such as Crew Resource Management and simulation.
- The structure and working processes of hospitals can significantly impact on anaesthetic care. Their influence on anaesthesia should not be minimised, and organisational issues should be systematically addressed.

## Research agenda

- Further research is warranted into the development of training and management processes that minimise complications during high-risk procedures.
- The best method to overcome barriers to the wide implementation of guidelines and protocols into anaesthetic practice should be investigated.
- The benefits of using aviation-industry-related training programmes in anaesthesia should be further assessed.
- The best methods to develop safety culture at the organisational level should be explored.

## Conflict of interest

None declared.

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