Patient safety: latent risk factors

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Key points
- The system approach focuses on working conditions rather than on errors of individuals.
- This approach assumes that systems must be designed to prevent humans from making errors.
- The factors that promote errors are described as LRFS.
- Understanding how LRFS affect safety can enable us to design more effective control measures.

Summary. The person-centred analysis and prevention approach has long dominated proposals to improve patient safety in healthcare. In this approach, the focus is on the individual responsible for making an error. An alternative is the systems-centred approach, in which attention is paid to external factors that create precursors for individual errors. This approach assumes that since humans are fallible, systems must be designed to prevent humans from making errors or to be tolerant to those errors. The questions raised by this approach might, for example, include asking why an individual had specific gaps in their knowledge, experience, or ability. The systems approach focuses on working conditions rather than on errors of individuals, as the likelihood of specific errors increases with unfavourable conditions. Since the factors that promote errors are not directly visible in the working environment, they are described as latent risk factors (LRFS). Safety failures in anaesthesia, in particular, and medicine, in general, result from multiple unfavourable LRFS, so we propose that effective interventions require that attention is paid to interactions between multiple factors and actors. Understanding how LRFS affect safety can enable us to design more effective control measures that will impact significantly on both individual performance and patient outcomes.

Keywords: medical errors; quality assurance, health care; risk management; safety

Patient safety has become a major concern in the healthcare system. Two questions therefore arise. How can systematic action be taken to avert preventable errors? In particular, how can we identify and prioritize remedial actions?

For a long time, a person-centred analysis and prevention approach has dominated proposals to improve patient safety in healthcare. In this approach, the focus is on the ever-present ‘human factor’, concentrated on the individual responsible for making an error. Such human errors can be classified as knowledge-based, rule-based, or skill-based and imply specific deficits in an individual's knowledge, ability to apply procedures, or specific technical skills, respectively. As a result of this vision, solutions typically involve (re-)training, extra supervision, and even disciplinary actions applied to individual doctors and nurses. An alternative is the systems-centred approach, in which attention is paid to external factors that create precursors for individual errors. The questions raised by this approach might include asking why an individual had such specific gaps in their knowledge, experience, or ability. Anaesthetists have made significant advances in patient safety through systematic incident monitoring and analysis, paying attention to the design and ergonomic aspects of equipment, implementing safety devices, and considering fatigue and cognitive overload. Despite this growing recognition of the role of human error in anaesthesia, it still remains unclear what should best be done to mitigate its effects and how its occurrence can best be prevented or mitigated in the first place. The problem is that solutions are often proposed as a result of the most recent analyses or the introduction of new technologies, neither of which may tackle the problems that are the most pressing in a wider context.

The systems-centred approach assumes that humans are fallible and that systems must be designed so that humans are prevented from making errors. An example is the pin index for connections of gas cylinders that prevents erroneous connections, removing the possibility of error. Human performance involves a complex interaction of factors, including the inseparable tie between individuals, their equipment, and their general working environment. Where the environment is one that makes errors by individuals more likely, we can identify the underlying problems that will have been present in the system, often recognized but long tolerated. The factors that make errors more likely, or more dangerous, can be characterized as latent risk factors (LRFS). Generally, a single underlying failure will be compensated for. It is when multiple factors come together that an incident becomes increasingly likely, as expressed in Reason’s Swiss cheese model. It is important to understand why a highly trained individual can commit
an error and how events and conditions coincided to permit it. Understanding how and which LRFs affect safety should enable us to design more effective control measures that will impact significantly on both individual performance and patient outcomes.7

Accident theories

High-risk systems, which are typical of our technologically complex era, include not only nuclear power plants and commercial aviation, but also hospitals and anaesthesia systems, and the practice of medicine. An analysis of many different technological systems shows how certain general characteristics can make systems either inherently safer or inherently more dangerous.5 In high-risk systems, no matter how effective safety devices are, some types of accidents are often seen as inevitable because the system’s complexity leads to multiple and unexpected interactions.9 Perrow’s Normal Accident Theory10 proposes that certain types of accident will happen regardless of the number of safety devices. Perrow characterized systems according to two important dimensions: interaction and tight or loose coupling. A task or process is said to have complex interaction if there are many alternative and interrelated subtasks at any point in its completion. Complex interaction reflects high levels of specialization and interdependency among their various components and creates opacity to those within the system. The coupling dimension describes the extent to which an action in the task or process is related to its consequences. A system is tightly coupled if serious and unrecoverable consequences are likely to occur immediately after a mistake is made—hence, tightly coupled systems are unforgiving, and at high risk for accidents, and must therefore be made more reliable. The pace of recent development suggests that the practice of hospital medicine, and especially the operating theatre (OT), is becoming both more complex and more tightly coupled, thus both more opaque and less forgiving when things go wrong.

Reason’s Swiss cheese model11 was originally developed for domains such as oil and gas, aviation, railways, and nuclear power generation. It revolutionized accident investigation worldwide and has since gained widespread acceptance and use in healthcare.11 This model has the advantage of explaining why accidents are so rare, even in high-risk activities. High technology systems have many defensive layers: some are engineered (alarms, physical barriers, automatic shut downs, etc.), others rely on skilled individuals (anaesthetists, surgeons, pilots, control room operators, etc.), and yet others depend on procedures and administrative controls. The model assumes that if errors occur, several simultaneous failures must have occurred within the organization. Although adverse events occur where the work is done, where practitioners interact directly with the system in their roles as anaesthesiologists, surgeons, and nurses, those events emerge from a chain of failures elsewhere in the organization, from conditions that are not directly visible. According to the model, serious adverse events and complications are often preceded by a chain of individually unimportant errors and problems, in turn influenced by a wide variety of contributory factors.2 To investigate errors proactively, using the concepts of the Swiss cheese model, various groups have developed a variety of tools and approaches. The Tripod-Delta (Diagnostic Evaluation Tool for Accident prevention) tool is a checklist-based approach to carrying out ‘safety health’ checks.12 The four levels of the Human Factors Analysis and Classification System (HFACS) have been applied to aviation13 and to cardiovascular surgery.14 HFACS can also be applied to help understand the interplay of human factors in the OT environment and the organizational context.15 Others have argued for ‘a systems approach to surgical safety’,16 suggesting that it is necessary to study all aspects of the system that comprises a surgical operation, including such issues as equipment design and use, communication, team coordination, factors affecting individual performance, and the working environment.

Both Normal Accident Theory and the Swiss cheese model direct attention to systemic issues but do not, of themselves, provide a structure of underlying factors that can serve as a taxonomy of causes. Such a taxonomy is required to diagnose why accidents are occurring and to support prioritization of remedial actions in ways that go beyond the purely symptomatic. The next section describes such a list, specifically developed for the OT and anaesthetic practice, based upon the Tripod-Delta methodology developed for the Swiss cheese model.

Latent risk factors

Analyses of major disasters, ship accidents, accidents in the exploration and production of oil and gas, railway operations, and aviation have shown that the contributing causes that occur in all these accidents can be captured with a limited classification system. These underlying latent causes can be categorized into a limited number of classes: LRFs.17 18 The choice of a particular taxonomic structure is driven by the need to capture all types of potential causes together with the need to identify where in the organization remedial actions can be put in place. These LRFs describe the total working environment, the setting in which accidents and incidents occur. The LRFs identified in the OT environment19 are listed in Table 1 and described in further detail below. They have been identified through a combination of factor analysis of questionnaire data and logical analysis adapted from the original structure developed for oil and gas.2 12 16 17 Each of the 10 factors is prefaced with a short description relevant to anaesthetic practice, although most are equally applicable in the wider hospital setting.

Equipment, design, and maintenance

By the late 1980s, a number of articles featuring human factor concepts and applications could be found in the literature, many of which dealt with anaesthesia equipment.4 20 This factor covers the broad design of equipment, including
Staffing

Adequate staffing is fundamental to quality care. The staff are often the last layer of defence for error occurrence, and understaffing and inadequate skill mix are threats to patient safety in the OT. There is little published work examining the relationship between workload and either quality or safety of anaesthetic care, but a survey by Singer and colleagues found that 49% of respondents had witnessed production pressure resulting in what they believed to be unsafe actions by an anaesthesiologist. High rates of staff turnover degrade the collective experience in the OT to the point that educators of new staff are themselves relatively inexperienced. Understaffing is one of the greatest threats to patient safety, but rapid turnover can be another.

Communication

Failures of communication between OT personnel are common. This may involve communicating too little or even too much, too early or too late, and may involve a failure of either the person initiating the communication or the receiver, who may fail to understand or even hear the message. Most surgical errors are not attributable to an individual but involve multiple personnel and steps; 43% of such errors are thought to be due to poor communication. There is evidence from a variety of sources that communications between members of health-care teams emerge as a key factor in poor care and are especially apparent where medical errors occur. Lingard and colleagues took this as their starting point for an observational study of communication failures in OTs. They found that 31% of all communications could be categorized as a failure in some way: the information was missing, the timing was poor, there were unresolved issues, or key people were absent.

Training

Lack of training and experience is often mentioned as sources of medical errors. In a study of surgical errors leading to malpractice claims, Rogers and colleagues found that the leading causes (41%) were lack of experience and lack of technical competence. This study should be interpreted with some caution as it concerned accepted closed claims that were therefore possibly selected on the basis of liable causes. Training has been shown to decrease error and increase the ability to solve problems, particularly for inexperienced professionals. The concept of simulation as an educational tool in healthcare is not a new idea, but its use has blossomed over the last few years. It has been most widely studied in anaesthesia. In 1992, Chopra and colleagues reported that the performance of anaesthesiologists who trained on the simulator was superior to those subjects who did not receive such training. The recent enthusiasm for simulator-based training is partly driven by an attempt to increase patient safety and also because the technology is becoming more affordable and advanced. Concerns about patient safety are leading to changes in educational methods. Simulation now plays a major role in training efforts designed to foster the acquisition of new skills and knowledge outside the clinical environment.

Failure of training is often attributed as a major cause of incidents, implying a lack of competence in the person. This LRF is intended to catch the system-based failures, such as lack of needs analysis, failure to train at all, use of appropriate vs inappropriate training methods for the skill required, failure to assess the results of training, and lack of consideration for alternatives to person-based approaches. For instance, good design reduces the need for extensive training in the use of equipment, whereas poor design may be only partially compensated for by extensive training.

Table 1 Latent risk factors

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<thead>
<tr>
<th>Latent risk factors</th>
<th>Issues</th>
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<tbody>
<tr>
<td>Equipment, design, and maintenance</td>
<td>Availability, functioning, standardization design, and maintenance of machines</td>
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<tr>
<td>Staffing</td>
<td>Adequate staffing, skills</td>
</tr>
<tr>
<td>Communication</td>
<td>Work-directed communication, openness, interrelation, atmosphere</td>
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<tr>
<td>Training</td>
<td>Training for machines, procedures, team training</td>
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<td>Teamwork and team training</td>
<td>Team performance</td>
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<td>Procedures</td>
<td>Presence of protocols, adherence to protocols</td>
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<td>Situational awareness</td>
<td>Awareness of present situation, own tasks, and future developments</td>
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<td>Incompatible goals</td>
<td>Balance between goals and safety</td>
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<td>Planning and organization</td>
<td>Process of care</td>
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<td>Housekeeping</td>
<td>Hygiene</td>
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Teamwork and team training

The unintended consequences of clumsy automation, task complexity, and excessive workloads on human performance in high-risk patient environment have received much attention. During the 1980s and 1990s, publications on teams in aviation appeared, documenting the belief that pilot performance is directly influenced by the nature and quality of the interactions among group members. The same is true for doctors who operate in complex environments where teams interact with technology. Much work pioneering work on the impact of team behaviour, attitudes towards safety, and professional culture on human performance in medicine has come from the department of anaesthesia of the University of Basel, Switzerland, starting in the mid-1990s.

Individual team members may be highly skilled in their individual roles, but they are not necessarily trained in working together as a team. Substantial discrepancies in perceptions of teamwork exist in the OT with physicians rating the teamwork of others as good, whereas at the same time, nurses perceived the teamwork as poor. These findings mirror similar results of discrepant attitudes about collaboration between physicians and nurses in intensive care units (ICUs). A growing awareness of the importance of team interactions of aviation crews lead to the concept of Crew Resource Management (CRM) in the 1980s. Analogous training was developed by Gaba’s group at Stanford (initially in anaesthesiology) and has since enjoyed global spread in healthcare.

Procedures: protocols

The presence of protocols is generally considered as helpful to improve safety. Doctors and nurses often have opposing views on protocol violation and hold different attitudes to clinical work. In particular, nurses appear to hold more systematized and less individualistic conceptions of clinical work than doctors. The results indicate that when best practice is defined in the form of a written protocol, deviations from these are more likely to be reported, at least by nurses. This also suggests that healthcare professionals are, in general, reluctant to report behaviour that has negative consequences for the patient when that behaviour reflects either compliance with a protocol or improvisation where no protocol is in place. Reluctance to report non-compliances, even when the outcome for the patient is bad, may be a function of the widespread and well-documented resistance among doctors to clinical protocols, perceived by many in the medical community as a threat to their professional competence. Alternatively, reporting on colleagues may simply reflect the professional culture. Part of the issue with protocols in the clinical setting is due to cultural factors that will be considered below, but there are also systemic issues with protocols even when they are fully accepted. These issues include the relevance, design, and accuracy of protocols and whether the system is capable of continuously amending protocols and ensuring that they are kept up to date and whether they are accepted by those supposed to use them.

Situational awareness

Situational awareness (SA) can be defined by three questions ‘Where have we come from? Where are we now? Where are we going?’ At best, in the OT, SA requires active involvement in the progress of the operation by the anaesthesiologist, nursing, and surgical crews that make up the operating team. Shared situation awareness refers to the degree to which the team members have the same interpretation of ongoing events. Surgical teams with the best outcomes were not those who were error-free, but those who successfully compensated for the errors that had occurred. Good SA can provide essential corrections to problems that may arise as a result of complexity and tight coupling. SA allows proactive intervention and can drive changes in priorities as a result of changes in the patient, the OT environment, or outside the OT. Although SA may be seen as a result rather than a factor, it appears reliably as a distinct underlying factor and is a skill that can be trained for.

Incompatible goals

All organizations must find a balance between their goals and safety. To some extent, there will always be a trade-off between safety and finance, because achieving the highest feasible levels of safety will cost increasing amounts of money that no organization can eventually afford to pay. Incompatible goals may involve more than finance, as any choice made under pressure may create situations that are inappropriate. Incompatible goals can be regarded as one of the most fundamental LRFS, as all behaviour can be seen as an adaptation to conflict situations, with errors arising when the ‘incorrect’ choice is made. It is not just the incompatibility of safety and finance. Safety goals can even conflict with other safety goals, such as when a requirement for a rapid unplanned surgical intervention conflicts with the need to ensure that necessary checks are carried out before proceeding. One of the problems associated with complexity is an increasing locality of priorities. Anaesthetists, surgeons, nursing staff, and administrators can all have different priorities that can easily conflict.

Planning and organization

Donabedian observed in 1966 that the best outcomes depend on good processes of care, which in turn depend on the correct structures and organization being in place. Hospitals cannot control for the severity of underlying
illness in patients, but they can ensure that their services are effectively staffed and organized to manage those for whom they care. For instance, changing the OT schedule overnight often leads to confusion, resulting in late starts, the wrong patient in the OT, and equipment and materials being unavailable. Since the operation programme is a coordinating mechanism and changes are often not well communicated, the lack of effective coordination results in errors and risks. Hospitals try to decrease their risks by applying rules for programme changes or better (electronic) communication about changed programmes. This LRF captures the systemic issues around having an organization that needs to be optimized to support its clinical tasks rather than, for instance, having clinical tasks altered to fit the demands of the organization. One particular issue that arises in hospitals is the disparity in structures required for different specialities.

Housekeeping

Housekeeping refers generally to tidiness, but from experience means ‘a place for everything and everything in its place’. Superficially, clean and tidy environments may in fact cover a situation where everything is impossible to find, again resulting in unsafe practices seen as necessary to work around the shortcomings. In medical settings, housekeeping naturally extends to hygiene and the support and discipline required achieving levels compatible with patient and staff safety. As the use of electronic devices (i.e. mobile phones and personal digital assistants) has become commonplace in the OT and ICU in recent years, these devices are being increasingly used in close proximity to the patients. A rate of 7% bacterial contamination with potentially pathogenic bacteria was found on telephones and intercoms in patient care areas.60 Housekeeping is a critical test of the organization, and the NHS experience in the UK suggests that this has been at least a part of many important clinical problems such as Methicillin-resistant Staphylococcus aureus (MRSA). Management may know that there is a problem and does not act or they may not even know that there is a problem.

Each one of these LRFs is the responsibility of the organization rather than of individuals, which is why they form an appropriate level of description for the system-based approach, as opposed to the person approach that refers to individual performance factors such as skill or vigilance. Individual clinicians, no matter how capable, do not usually define and test their own training, decide on staffing levels or scheduling, set up and ensure that protocols are up to date, fund equipment, or make sure that communication issues are discovered and attended to. It is at this organizational systemic level that the preconditions for error, such as haste, ignorance, and fatigue, are created and it as the level of the LRF that the ‘disease’ can be best treated, rather than relying upon a purely symptomatic and often palliative approach directed at individuals found to have failed when being hasty, ignorant, or fatigued. The question that remains however is: how can these LRFs be identified, measured, and managed in the hospital setting? Without an adequate approach to providing answers to these questions, the system-based approach remains an unachievable vision.

The list of LRFs details the organizational, management, and work environment factors in ways that make the identification of effective interventions easier. Systematic approaches to improvement, taking small concrete interventions rather than large sweeping initiatives, often impact more effectively on the culture as successes are observed in the working environment. Although effects on outcomes may not always appear immediately, the development of a virtuous circle may be expected to show gains relatively rapidly.

Measuring the state of latent risk factors

Most incident analyses only describe ‘who’ was involved and ‘what’ occurred, with limited attention paid to the underlying causes that can be captured systematically by LRFs. Although the state of the individual LRFs could be assessed objectively, their effect on workplace safety and patient safety is unknown. Therefore, other techniques have been developed in which the immediate effects on workers and accidents have been studied, notably in the oil industry and aviation.

The most significant development in this area was the development of the TRIPOD instruments. TRIPOD is the name used originally by Shell International for what elsewhere is known as the Swiss cheese model.12 61 TRIPOD is based on deficiencies in the working situation labelled as General Failure Types (GFTs),12 the equivalent to the LRFs discussed above. It provides an accident analysis method to identify and classify problem areas into underlying causes, scored as GFTs that led to the accident. The reactive understanding of how accidents happen described by TRIPOD led to the development of a specific proactive instrument, TRIPOD-Delta.62 The questionnaire is applied to workers and is based on their experience in the workplace. Where TRIPOD is retrospective, the TRIPOD-Delta instrument is prospective. Prospective methods offer significant theoretical advantages over retrospective methods. They do not rely on an adverse event having occurred. They allow the identification of latent factors in the system that may lead to hazards but that have yet to become manifested in incidents. TRIPOD-Delta measures the ‘safety health’ of an organization rather than waiting for accidents to happen or even observing what actual unsafe acts people were performing. The approach taken is analogous to a health check, assessing a limited number of well-chosen diagnostic vital signs.62 In the prospective survey, items can be either indicators of either potential problems or good practice. Possessing the former or lacking the latter can both be treated as indications that there are latent failures present in a particular LRF and generate a negative score. Failure to find indications of problems and possession of the factors that are evidence of good practice both contribute to a positive
score. The sum total of poor and good indicators can then be represented as a standard score indicating whether there is a serious problem or cause for relief. TRIPOD-Delta was developed by Leiden and Manchester Universities for the oil and gas industry and concentrated on workplace safety and lost hours due to incidents. An early version of this approach was applied to a comparison of two intensive care wards. In such cases, it is possible to show that different units (wards, theatres, and hospitals) differ in their relative scores on LRFs, supporting the understanding that effective solutions should reflect the pattern of scores rather than having a ‘one size fits all’ approach.

The SWIFT technique is also a prospective approach. It is a systematic team-oriented technique for hazard identification adapted for healthcare and particularly suitable for environments where human and organizational factors predominate, such as the OT.

We developed the Leiden Operating Theatre Intensive Care Scale (LOTICS) as an instrument to detect the underlying causes of medical errors proactively by measuring LRFs (Table 1). It shows the strengths and weakness of an organization, allowing the possibility of data-driven interventions. Changes in patient safety performance can then be monitored and the effects of interventions to improve the level of patient safety can be evaluated. Similarly, LOTICS can be used for comparison of different organizations and disciplines within the medical system.

The LRFs described here are broadly equivalent to the original set of GFTs. The original set of GFTs was developed to provide coverage of all the areas that might create problems, not just technical or human, and to facilitate identification of where remedial actions might best be applied. The LRF taxonomy used has been configured to provide a better mapping onto the medical setting, and the OT in particular, rather than a set originally designed for oil and gas operations.

Culture

The system-based approach concentrates upon characteristics and behaviours of the organization, just as the person-based approach concentrates upon the characteristics and behaviours of individuals. A number of recent major accidents have highlighted the importance of the organizational culture within which both of these are played out. British Petroleum’s own analysis of the Texas City refinery disaster in 2005 and NASA’s analysis of the Columbia disaster both stressed the importance of organizational culture. The culture of an organization determines how the systemic components are treated. A poor safety culture pays little attention to what is seen as unnecessary and bureaucratic, whereas a good safety culture takes the best out of what is on offer. Poor cultures deny problems until they cannot be ignored, attribute failure to personal shortcomings in individuals, and are afraid to report, both on themselves and on others. Good safety cultures, in contrast, accept accountability, treat problems once identified as opportunities to learn, understand that incidents have multiple causes, and search actively for ways to improve.

The advanced safety culture has been characterized in a number of domains under the label of High Reliability Organizations (HROs). HROs theory is based on the belief that accidents can be prevented through good organizational design and management. It describes core principles of organizations that have few accidents despite operating in highly dynamic, technologically rich, and hazardous industries. These were identified in diverse settings such as aircraft carrier flight operations, air traffic control, and nuclear power plant operation. They are characterized by a high level of mindfulness, deference to specific expertise, regardless of an individual’s position in the hierarchy and a just and fair culture in which people feel able to report errors by themselves and others. The problem in many areas is that the organizational culture is nowhere near as advanced as an HRO, even if people think they are close to attaining that level of responsiveness to safety issues. There is a clear interaction between the organizational factors, defined in terms of the LRFs, and the culture, in that less advanced safety cultures will have more identified issues and fewer implementations of good practices.

Discussion

Although the best measure of safety performance is not clear other than in terms of patient outcomes, it is certainly too multidimensional to put a single figure as a safety score. It is also clear from studies elsewhere that single changes, especially when performed without due regard for the total context, are often ineffective and may even be detrimental. One person’s improvement may be another’s LRF. Ideally, safety should be embodied throughout the institution, part of the culture, and minimizing possible latent causes that might accidentally combine to produce injury. This continuing search, improving with small incremental measures, is very similar to the quality concept of continuing quality improvements.

Individual errors are personally attributable and it is tempting to address these errors only, as there is a clear connection between error and single agents who can be blamed. Yet, this approach still does not solve the problem of recurrent erroneous behaviour. Such errors do not occur of themselves, but arise within the context of the work environment, described by LRFs. There is a clear need to develop approaches that allow organizations to measure in an ongoing and prospective way the injuries that healthcare causes.

Tackling the LRFs will improve the overall safety condition of the organization by reducing safety problems before they arise, in particular if combined with explicit improvements in the safety culture. We have argued here that systematic analyses and step-by-step improvements are feasible and can impact directly on the culture. The traditional fields of practice, such as risk analysis, have so far been unable to provide many effective or long-lasting solutions. There are
several reasons for this, the most important probably being that they are based on oversimplified accident models. Simple repair work will not mend the problem, because if one part of the system is changed that may affect another part of the system with unanticipated results.

Conflict of interest

None declared.

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