Are root cause analyses recommendations effective and sustainable? An observational study

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Abstract

Objective: To assess the strength of root cause analysis (RCA) recommendations and their perceived levels of effectiveness and sustainability.

Design: All RCAs related to sentinel events (SEs) undertaken between the years 2010 and 2015 in the public health system in Victoria, Australia were analysed. The type and strength of each recommendation in the RCA reports were coded by an expert patient safety classifier using the US Department of Veteran Affairs type and strength criteria.

Participants and setting: Thirty-six public health services.

Main outcome measure(s): The proportion of RCA recommendations which were classified as ‘strong’ (more likely to be effective and sustainable), ‘medium’ (possibly effective and sustainable) or ‘weak’ (less likely to be effective and sustainable).

Results: There were 227 RCAs in the period of study. In these RCAs, 1137 recommendations were made. Of these 8% were ‘strong’, 44% ‘medium’ and 48% were ‘weak’. In 31 RCAs, or nearly 15%, only weak recommendations were made. In 24 (11%) RCAs five or more weak recommendations were made. In 165 (72%) RCAs no strong recommendations were made. The most frequent recommendation types were reviewing or enhancing a policy/guideline/documentation, and training and education.

Conclusions: Only a small proportion of recommendations arising from RCAs in Victoria are ‘strong’. This suggests that insights from the majority of RCAs are not likely to inform practice or process improvements. Suggested improvements include more human factors expertise and independence in investigations, more extensive application of existing tools that assist teams to prioritize recommendations that are likely to be effective, and greater use of observational and simulation techniques to understand the underlying systems factors. Time spent in repeatedly
investigating similar incidents may be better spent aggregating and thematically analysing existing sources of information about patient safety.

**Key words:** patient safety, root cause analysis, patient harm, sentinel event

### Introduction

Adverse events (AEs), which are incidents that cause harm to patients, occur in the Australian healthcare system and across the world at an unacceptable rate [1–3] with ~5–10% resulting in serious harm or death [1, 4, 5]. They continue to occur despite two decades of concerted effort to reduce their frequency by policy makers, health service managers and clinicians [6]. One common approach to try to prevent the recurrence of AEs is to undertake a review of care, such as a root cause analysis (RCA), to find out what went wrong and why [7]. In the Australian public health system, sentinel events (SEs) are serious AEs that are generally followed up by a RCA.

RCA is a systematic process that originated in industry and was introduced to healthcare by the US Department of Veteran Affairs in the mid-1990s and into Australia shortly thereafter [7]. RCA represents a ‘toolbox’ of approaches rather than a single method—more than 40 RCA techniques have been described for healthcare [8–10]. However, all versions use a structured process of creating chronological maps that track the time and sequence of events, undertaking interviews and analysis of other data sources, and developing cause and effect diagrams and recommendations.

RCAs are time and resource-intensive. They typically require teams of 3–6 people to attend several meetings, to undertake interviews, and to collect and analyse other data. The key output of RCAs is a set of recommendations for health services to implement in order to reduce the likelihood of a similar AE occurring again. These are usually presented in a structured format comprising of one or more recommendations, and identification of the person responsible for implementing them, the date when this should be completed, and performance and evaluation measures.

Recommendations can be characterized according to their type, effectiveness, and sustainability, collectively often referred to as ‘strength’, and presented in an ordinal manner as ‘strong’, ‘medium’, or ‘weak’ [11, 12]. Strong recommendations are those that, once implemented, rely less on people’s actions, and memories, and are more likely to be effective and sustainable. Conversely, weak recommendations, such as training and policy changes, are less likely to be effective and sustainable. Weak recommendations are often necessary to establish proficiency, but rely on a change in human behaviour, and when used alone are unlikely to be sufficient to provide sustained improvements in patient safety [12]. They are less likely than strong recommendations to prevent future events.

‘Sentinel Events’ (SEs) are infrequent incidents that occur in health services and ‘commonly reflect hospital (or agency) system and process deficiencies’ [13]. They usually result in serious harm to patients. There are eight nationally agreed ‘core’ SEs in Australia (Table 1) [13]. The Victorian Department of Health and Human Services (DHHS) has added a further category (Category 9 – ‘Other, catastrophic’) [13]. Victorian health services must report all SEs to the DHHS’ SE Program and then conduct an RCA, and then report their findings and recommendations [13].

The number of RCAs performed and the time they take means that they represent significant investments by health services [7]. Both the efficacy and value of RCAs have been questioned because, despite the effort and investment in RCA for over 15 years, similar serious AEs continue to occur [6, 8, 14–16]. As one of the stated aims of the RCA process is to reduce the rate of further similar incidents, the proportion of recommendations considered strong or weak is of critical interest. In this study we aimed to assess the proportion of RCA recommendations in terms of their strength, and therefore, their likely effectiveness and sustainability.

### Methods

#### Participants and setting

**Victorian public health services**

**Data source.** The health services had provided the Victorian DHHS with RCA reports as part of the DHHS’ SE policy [13]. The demographic data and reports from these RCAs related to SEs and reported to the Victorian DHHS between 2010 and 2015 were retrieved. All RCAs related to SEs were included in the analysis.

**Analysis.** The incidents associated with the RCAs were coded according to the primary type of incident using the SE classification [13]. A descriptive analysis of these types, together with patient’s age and gender, location of the health service in which the incident occurred, and specialties or disciplines involved, was then undertaken.

The type and strength of each recommendation in the RCA reports was coded by an expert patient safety classifier (AD), using the US Department of Veteran Affairs’ criteria (see Table 2 for examples) [11, 12]. Prior to the coding process, the consensus group (PH, MT, WR) and classifier discussed and jointly coded 10 RCA reports [17]. Another four sets of five RCAs were discussed and jointly coded during the course of the process to ensure coding quality. If a recommendation was unclear or could not be classified using the ‘Strength of Recommendations’ classification, advice was sought from the consensus group. The consensus group and classifier iteratively added new recommendation types to the classification and agreed on their strength [17]. A descriptive analysis was then undertaken with respect to recommendation type and strength.

**Ethics.** Ethics approval was granted by the Victorian DHHS’ Human Research Ethics Committee (no. 03/16).

### Results

Table 1 summarizes the types of SEs reported between 2010 and 2015. Of these 129 (57%) were Category 9—(SE9 ‘Other, catastrophic’), of which 57 ‘Clinical process/procedure’ events made up 44%. Together with falls (27/129, 21%), and behaviours (27/129, 21%), these accounted for 86% of the SE9 incidents. Of the 57 clinical process/procedure SE9s, 27 (47%) were associated with problems with diagnosis and 22 (39%) with problems with procedures or interventions. Just over half of the diagnostic incidents occurred
in emergency departments. Of the 27 SE9 ‘behaviour’ incidents, 26 were suicides and one was an ‘other significant self-harm’.

Across the 5 years, 21 of 36 health services reported only one SE each, whilst 10 reported between six and eight SEs. Only five health services reported more than 10 SEs. Of these, four reported between 11 and 18 and one reported 37. The most commonly involved specialties (or area) represented were psychiatry, emergency medicine, surgery and obstetrics/maternity, comprising 54% of the SEs. Although only small numbers (\(n = 8\)) were reported, 57% of Category 7 (maternal deaths) occurred outside of metropolitan regions, whilst only 26% of births occurred there.

The 227 RCAs resulted in 1137 recommendations, averaging 5.0 (SD 3.1) per RCA. Table 2 summarizes recommendation types including their frequency and the total number of RCAs using the type. Only 8% of recommendations were ‘strong’ whilst 48% and 44% were ‘weak’ and ‘medium’, respectively (Table 2). In 31 RCAs, or nearly 15%, only weak recommendations were made. In 24 RCAs (11%), there were five or more weak recommendations. In 165 RCAs (72%) no strong recommendations were made. There was no association between the proportion of RCAs with strong recommendations with the health service in which the SE occurred, ‘experience’ of the health service measured by number of RCAs performed in the relevant period, health service location (metropolitan, regional or rural) or SE category.

The most frequent recommendation types were ‘reviewing or enhancing a policy/guideline/documentation’, followed by ‘training and education’, followed by ‘development of a new procedure/memorandum/policy’ (Table 2). Together these three types comprise nearly two-thirds (65%), 744/1137 of all recommendations. The latter two types are ‘weak’ in the strength classification, whilst the former type, which we designated as medium strength, was added.

### Discussion

#### Principal findings

With a view to assessing the utility of a statewide SE program, we analysed recommendations in RCA reports over 6 years. The relative proportion of the eight nationally agreed SEs in Victoria (Table 1) [13] leading to the RCAs were broadly similar to the 5-year national average, although rates of SEs reported varied considerably between states [18]. In Victoria, with the addition of the SE9 ‘Other, catastrophic’ category, and with 21% of these associated with behaviour, psychiatry was the most frequent specialty involved. Variation in incident reporting rates and the perception of their severity between jurisdictions or hospitals, and provider types is well known [19].

Nearly half of the recommendations arising from the RCAs were designated as weak. Only about 1 in 12 were classified as strong. About two-thirds of the recommendations involved developing new or modifying existing policies or training and education. Such weak recommendations are less likely to result in effective and sustainable changes to reduce the probability of a similar incident recurring. Given the time and investment in RCAs, their potential for effecting change remains under-realized [15].

#### Meaning of the findings

The relatively high proportion of weak RCA recommendations has been noted previously [6, 20–24]. In 2010, another Australian state-based public health system (New South Wales) reported that 86% of RCA recommendations were considered weak, 7% medium and 5% strong [24]. More recently, a tertiary care academic medical centre in New York reported that about half of their recommendations were weak [6].

Our results are likely to be generalizable to other health systems. This is because, although the Victorian healthcare system has its own RCA policy framework and education program, it uses RCA tools and techniques that are commonly used in many health systems such as chronological flow charting, cause and effect diagrams, five rules of causation, hierarchy of recommendations and a stepped and orderly approach [8, 9, 25, 26].

Formulating recommendations is usually more difficult than finding problems [7, 27] and numerous issues relating to the conduct of RCAs have been cited [8, 20, 21, 27–29] (Box 1). Many of these issues fit under the umbrella of failing to consider human factors and other underlying system issues that are inherent in the development of an incident [30]. The investigation of an incident sometimes ends when an error or violation is identified as the cause. However,
<table>
<thead>
<tr>
<th>Strength of the recommendation</th>
<th>Recommendation type</th>
<th>Example</th>
<th>Number of recommendation types</th>
<th>Number of RCAs using the recommendation type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>Architectural/physical plant changes (including checking for hanging points)</td>
<td>As the current layout of Central Sterilizing does not allow for the redesign of workflow, review the design and size of the new CS to ensure that the issues with workflow and separation of unsterile and sterile stock will be addressed</td>
<td>28</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>Standardize on equipment or process including benchmarking against other organizations</td>
<td>Equipment trays, instrument trolleys, language and instrument names to be standardized</td>
<td>26</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>New devices with usability testing</td>
<td>Consider implementation of non-slip socks if this is considered a useful strategy following trial and evaluation on an acute ward</td>
<td>21</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Engineering control (forcing function)</td>
<td>Remove short cycle option from sterilizers to ensure correct sterilization cycle for wrapped loads</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Tangible involvement by leadership (including establishing clinical governance)</td>
<td>Continue work of cross campus Falls Working Party to continuously evaluate and improve falls reduction strategies, including consideration of efficacy and use of a range of aids such as: low beds, zipper quilts, falls action plans</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Simplify process</td>
<td>Revise admission criteria for the Short Stay Unit (SSU). These criteria will align with ED Physician scope of practice and minimize variation generated by individual decision making. These admission criteria will give strong consideration to Clinical Risk. Pregnant women beyond 20 weeks gestation will be excluded from SSU admission</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total Strong</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>Policy/guideline/documentation, etc. review/enhancement</td>
<td>Review the model of care in the Antenatal Clinic for women who present with history of multiple caesarean sections in line with current/emerging evidence</td>
<td>248</td>
<td>141</td>
</tr>
<tr>
<td></td>
<td>Audit undertaken</td>
<td>Annual audit of ligature points to be incorporated into audit schedule. Ligature point audit to be conducted and risk rated by appropriately skilled multidisciplinary staff and managed as per the assessed risk</td>
<td>88</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>Enhanced documentation, communication</td>
<td>Enhance wandering check chart to include behaviours of concern which will serve as a trigger for implementation of/documentation on the behaviour chart</td>
<td>40</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>Review rostering/appropriateness of staff mix</td>
<td>Add O&amp;G Consultant to Code Blue (neonatal) notification team</td>
<td>32</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>Re-Evaluate use/appropriateness of equipment</td>
<td>Review the use of laryngeal masks when diathermy is being used for tonsillectomy. Laryngeal masks not to be used when diathermy is also to be used— interim measure until review is completed</td>
<td>26</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>Checklist/cognitive aids</td>
<td>A handover checklist to be developed to ensure consistent approach</td>
<td>23</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Standardized communication tools</td>
<td>The handover processes in the unit are reviewed with a view to utilizing a standardized tool to assist in consistency and coverage of all required information each time a handover occurs</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Software enhancements, modifications</td>
<td>Develop a non-person dependant notification system that informs the treating consultant(s) in the event that a patient is transferred to the Intensive Care Unit Simulated code blue sessions as part of training</td>
<td>7</td>
<td>7</td>
</tr>
</tbody>
</table>

*Table continued*
identifying pre-existing performance-shaping factors (e.g. task complexity, workflow, time availability or urgency, process design, experience, training, fatigue, stress) or other environmental conditions, system weaknesses or equipment design flaws that contribute to the error or violation to occur, is often not undertaken [20]. This means that the recommendation is focussed on the active error, i.e. ‘not following the protocol’, thus leading directly to a recommendation for more education (for example) which is weak, rather than latent factors such as the organization not having in place a process for reviewing, storing and maintaining protocols that are based on evidence, and are accessible, workable and embedded in clinical workflow. As well as the factors in Box 1 that may predispose recommendations to be weak, stronger recommendations tend to come at a greater cost and effort, which tends to discourage their use. This cost and effort premium occurs in their implementation and also in monitoring for hazards which may occur with new technologies [2, 31].

Healthcare system and research implications
The findings of our study have healthcare system and research implications in relation to the role of human factors expertise and tools to support RCAs, methods of gathering information in RCAs, the personnel and organizations conducting RCAs, use of classifications to determine whether an AE should be subjected to an RCA, alternatives to undertaking RCAs, and methods of making safety changes to medications and equipment as a societal level. These are each discussed in turn below.

Better integration of the principles of human factors in RCAs is needed. Indeed, it has been suggested that formally trained human

<table>
<thead>
<tr>
<th>Strength of the recommendation</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Education using simulation based training, with periodic refresher sessions and observations</td>
<td>Develop a system that is responsive to relocating staff where the acuity and clinical demands exceed the resources available within ED</td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Increase in staffing/decrease in workload</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implement a new team eg MET team initiated (excludes high level teams such as formed clinical governance)</td>
<td>Implement a (paediatric) Medical Emergency Response at Hospital 1 that activates prior to catastrophic deterioration</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Eliminate/reduce distractions</td>
<td>Undertake audit of cytology specimen laboratory environment with a view to reducing clutter, improving work efficiency and minimizing the potential for process error</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Redundancy</td>
<td>The Health Service terminated the contract with AHMHT (After Hours Mental Health Triage) and the triage service</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Eliminate look- and sound-alikes</td>
<td>(none coded as such)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total Medium</strong></td>
<td><strong>495 (44%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Weak</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training and education (including counselling)</td>
<td>Education must be provided to nursing staff on the guidelines &amp; importance of informing the HMO promptly after incidents involving patient harm and following up within 30 min if HMO is delayed to optimize treatment outcomes</td>
<td>251</td>
<td>134</td>
<td></td>
</tr>
<tr>
<td>New procedure/memorandum/policy</td>
<td>Develop massive blood transfusion policies and procedures in line with the National Blood Authority Australia 2010 guidelines</td>
<td>245</td>
<td>134</td>
<td></td>
</tr>
<tr>
<td>Formal discussion/taken to meeting</td>
<td>Implement an audit schedule monitoring staff training. Present at the Critical care and Emergency Review Committee. The Safety and Quality committee will oversee this schedule</td>
<td>26</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Informing/Notifying/Warning</td>
<td>The Surgical Consultative Council and Victorian Consultative Council on Anaesthetic Mortality and Morbidity are notified of this event</td>
<td>22</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Double checks</td>
<td>Increase checkpoints in the slide processing process with a view to ensuring any errors in slide labelling are prevented or detected early</td>
<td>6</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Warnings</td>
<td>(none coded as such)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total Weak</strong></td>
<td><strong>550 (48%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total number of recommendations</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>1137</strong></td>
</tr>
</tbody>
</table>
Box 1. Potential problems when developing RCA recommendations

- Analyses may end when the most convenient root cause is found, or one that fits the investigator’s biases [27].
- The accuracy of the cause is dependent on the quality of the information gathered, which is often flawed [28].
- RCA teams are not obliged to use evidence to justify their recommendations [28].
- Recommendations are not clearly linked to one or more causative factors [20].
- Systematic methods for generating risk control recommendations are not widely used [21].
- Reports are often circulated to the participants for repeated comment and feedback, with the aim of ‘getting everybody on board’ and maintaining consensus, resulting in few containing highly consequential findings or recommendations [8].
- Producing a ‘nice’ report at times becomes the main goal of the investigation and displaces the original objective of influencing learning and promoting change [8].
- The RCA process supports changes that hospital departments had tried to previously promote without success. Instead of a process of ‘evidence-based change’, this is ‘change-based evidence’, whereby ‘evidence’ about ‘root causes’ is used to support existing agendas [8, 29].

Factors experts should be included in the membership of all RCA teams [6–8, 32]. Increased access to training for members of RCA teams is also necessary [23, 27, 33]. This should include human factors principles and the methodology of undertaking RCAs, including the pitfalls of biases and personal agendas, and balancing the requirements of professional autonomy and external accountability.

Related to this is the increased access to and use of tools to support investigations to promote strong recommendations [20, 26]. There are some tools that categorize interventions by their reliability or strength that are quite useful for teams to discuss and consider [23, 26]. Card et al. used a two-dimensional framework to assess interventions against effectiveness and sustainability [21]. Pham et al. applied a risk prioritization and reduction process similar to the model used by the Commercial Aviation Safety Team (CAST) [32]. This method divides the tasks of risk identification and risk mitigation into distinct but related expert teams. Two new steps are added to the process: (a) prioritizing the factors that contributed to harm in the incident and (b) evaluating the probability that these factors will cause harm in the future [32].

Gathering information during the investigation is often confined to interviewing the staff involved and reviewing documentation, whilst observational techniques and patient or carer interviews are used less often [20, 23]. This may weaken RCA outcomes because interviews are more susceptible to recall bias compared to direct observations of workflow and processes [23]. During interviews, staff members may recite what they thought was the right answer or what they think ‘must have happened’ rather than what actually happened [23]. Teams relying too much on the written content of policies and procedures to illustrate what normally happens when care is provided are assuming that what is in the policies is reflective of what really happens day-to-day. That is, work ‘as imagined’ rather than ‘work as done’ [20, 34]. This means the team may find no systems issues because the policies may be well written and broadly applicable. Techniques such as in-situ observations and low-fidelity simulation may help identify ‘work-arounds’ and organizational structures or processes that influence or constrain behaviours or actions by individuals [16].

The actions that we have suggested thus far to improve the efficiency and sustainability of RCA recommendations relate mainly to the conduct of, and personnel involved in, the investigation. However, broader systems-based solutions are also necessary, with considerable implications for cost and organizational structure. The concept of separating safety and operational processes, especially performance management of individuals, is well established in other high risk industries [35]. The rationale is to minimize the impact of personal agendas and overt or covert influences on the teams to modify recommendations according to, for example, cost concerns or political palatability. This can act to reduce pressure to wind up the investigation to free up expensive clinical staff within the organization. There are currently models where independent agencies undertake RCAs, such as in England (Healthcare Safety Investigation Branch) and Ireland (Health Service Executive National Incident Management and Learning Team). Whilst these types of models have merit they may be viewed as ‘invasive’ by the affected health service. A less confrontational approach would be to ensure that each investigative team contain at least one member who is independent of the health service, preferably with human factors expertise. In this way, balance may be struck so RCA teams can include both frontline staff who have intimate knowledge of the clinical area where the incident occurred [36] and personnel with knowledge of systems factors and who, due to their independence, may be less likely to make assumptions on causal factors.

Trosvich and Shojainia point out that, unlike biomedical science problems which are tackled via independent research institutions with highly trained scientists, patient safety problems, which are arguably just as complex, are expected to be solved with fewer resources, using part-time staff with little task-specific experience, at a local healthcare organization level [16]. These complex problems require appropriate investments in expertise and effort analogous to the requirements for research into biomedical problems [16].

The use of an arbitrary list of ‘Sentinel Event’ classifications to drive policy and practice on whether RCAs should be undertaken is questionable. There is no evidence that the list of sentinel events, compared to other incidents which result in serious outcomes, usefully signpost a failing healthcare system. The rationale for their adoption, development and continued use is unclear and, we suggest, not evidence based. Risk management matrices that classify incidents according to two axes—outcome severity and probability—provide a more logical and equitable method of allocating scarce patient safety resources.

‘Waste’ in clinical practice has recently been the subject of much attention in research and policy circles [37]. Futile medical tests and investigations are discouraged, as they consume expensive resources unnecessarily that may be deployed more productively. Undertaking RCAs that investigate recurring patient safety problems, whilst learning no new lessons, may be seen in a similar light. An
alternative is to aggregate existing information from RCAs, incidents and other data sources (such as confidential enquiries [38]), then undertake thematic analysis of their contextual and contributory factors, and research on viable solutions [39, 40]. This may be more efficient than repeatedly developing the recommendations from individual local investigations, particularly for incidents such as falls that are widespread [40]. This process also may use incidents that resulted in a near miss. These incidents are often reported, but no local action is taken, meaning significant wasted effort by clinical staff. However, they can be as valuable for learning and characterizing contextual and contributory factors as incidents that result in serious harm, and are more likely to be recorded faithfully [40].

Making changes to the way equipment or medication is designed or labelled are considered strong recommendations. In most cases, these require gaining agreements and support from external manufacturers or suppliers. As individual health services have small market shares, they may consider that requesting changes from manufacturers or suppliers have little chance of success and they may instead propose weaker recommendations. One approach may be to use a high level forum to convene representatives of manufacturers, professional societies, healthcare organizations (especially hospitals), and end users to agree on appropriate redesign priorities [41]. This group would need sufficient purchasing power to entice manufacturers, as well as technical and clinical expertise, to redesign wisely [7, 41]. National and international leadership might be needed to organize this effort [7].

Conclusion
Few recommendations arising from RCAs are 'strong', meaning that most recommendations are unlikely to be effective or sustainable. Actions that can be taken include more human factors expertise and independence in investigations, more extensive application of existing tools that assist teams to prioritize recommendations that are likely to be effective, and greater use of observational and simulation techniques to understand the underlying systems factors. Time spent in repeatedly investigating similar incidents may be better spent aggregating and thematically analysing the full range of existing sources of information about patient safety. At a national level, convening structured and meaningful dialogue with equipment manufacturers and key drug 'industry' representatives regarding safety, and discontinuing the use of arbitrary lists of sentinel events, provide ways forward.

The changes in healthcare safety management systems that we and others have proposed are profound in terms of cost and organization of the health system. However, they are unlikely to exceed the resources and the opportunity costs currently dedicated to RCAs with questionable outcomes.

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Conflict of interest statement
Co-authors SL, JP, GC, AS, TS and CF are current employees of the Victorian Department of Health & Human services.

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