Development of the ‘People–Processes–Paradigm’ critical analysis tool for mortality and morbidity reviews: improving understanding of systems factors

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Abstract
Background: The impact of systems problems and human factors on delivering safe, high-quality patient care is well recognized. In the surgical setting, mortality and morbidity reviews (MMRs) are the key forum for reviewing and analysing adverse events in patient care yet there is a paucity of simple tools for undertaking such analyses. The aim of this study was to develop and pilot a new tool for analysing mortality and morbidity cases incorporating human factors and systems analysis.

Methods: The published literature, professional standards, guidelines and existing audit tools for MMRs were reviewed. The ‘People–Processes–Paradigm’ tool was developed and pilot testing was undertaken and stakeholder feedback was obtained.

Results: Models found for undertaking systems-based analysis of adverse surgical events included the 3D model, SEIPS and the Queensland Health human error and patient safety (HEAPS) Incident Management Tool. Guidelines for standards in MMRs are provided by the Royal Australasian College of Surgeons, New South Wales Clinical Excellence Commission and Australia and New Zealand audit of surgical mortality (ANZASM). The People–Processes–Paradigm model incorporates these standards and evidence-based systems analysis tools into a single effective tool. The pilot study evaluating the use of this tool demonstrated it to be practical and easily applicable to regular use by clinicians, with the ability to be tailored to individual health service use. Improvements such as electronic format and clarification of case selection processes were recommended by users.

Conclusion: The People–Processes–Paradigm tool has been developed for surgeons by surgeons incorporating current professional, legal and regulatory requirements in Australasia, easily transferrable to electronic platforms. This model requires further testing for validation.

Introduction
The quest for quality and safety improvements in health care has gained significant momentum in recent times not only because error and inefficiency are expensive, but also because the community demands accountability in health care.1,2 A key aspect of surgical work is reviewing and learning from incidents of mortality and morbidity with the goal to improve patient care and facilitate learning.3,4 However, there is often a disconnect between such meetings and broader hospital governance structures responsible for creating actual systems change.5 Although recommendations exist regarding best practice for how mortality and morbidity reviews (MMRs) should be conducted, there is significant variability in practice and often poor participation.1,6,7 There are many complex reasons for this but in part there is fear of a culture of blame being associated with such discussions with participant surgeons not understanding that errors and critical incidents usually occur due to systems errors.5,8 Due to this, there is little in the Australian Healthcare framework about how to critically analyse surgical MMR cases and identify systems errors despite there being extensive evidence surrounding human factors and ergonomics (HFE) theory and methodology (which aims to examine human factors to reduce error and enhance safety).9,10

The aims of this study were to review the literature and current best practice guidelines for conducting MMRs and performing HFE
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analysis on surgical practice, and to develop and pilot a simple tool combining both functions that surgeons across a broad range of experience, specialities and geographical settings can use with minimal training.

Methods

Papers for inclusion in the literature review were identified by searching PubMed using the following search terms: surgical morbidity and mortality review; human factors in surgery; systems analysis human factors in health care. Best practice guidelines were identified by searching government and professional websites including the Royal Australasian College of Surgeons (RACS), the New South Wales (NSW) Clinical Excellence Commission (CEC) and individual state Department of Health websites. Eligibility criteria included published papers in international journals or guidelines published in Australasia describing tools or methods to aid MMR in surgery. General medical articles were also reviewed as well as non-medical models. Exclusion criterion included articles using non-validated models.

Key findings from the published papers were synthesized to identify factors that should be included in an ideal MMR tool. Using information from the papers and the list of ideal qualities, the new ‘People–Processes–Paradigm’ tool was developed by amalgamating these with aspects of already validated healthcare systems-based analysis tools such as the SEIPS model11 and NSW CHASM registry.

A pilot study was undertaken in June 2018 to evaluate the utility of the new tool in a medium-sized regional/district hospital with 12 surgeons (seven general surgeons, one vascular, one urology, one plastics and two ENT) and four accredited surgical trainees. Clinicians were asked to use the tool to present at least one case each at two consecutive MMRs. They evaluated it by rating its ease of use, time to complete, adequacy for capturing safety issues and ability of the tool to prompt them to consider improvements, and they made general suggestions for improvement. The tool was updated according to the evaluation of the tool and further feedback was gained from presentations to state-wide stakeholder groups over a further 12-month period until June 2019. This study was deemed ‘low risk’ from an ethics viewpoint.

Results

The literature search identified 918 papers. Of these, 30 met the inclusion criteria and were included in the review. They discussed issues related to MMR in the following categories: role and format, problems and models (Table 1).

The role and format of MMR

Traditionally, surgical MMR has been considered a cornerstone of surgical practice because as a peer review process for examining individual surgical practice and complications but less so as a quality improvement process.1,7,19 This is an important distinction in the nature of meetings and how culture has changed and is a standard set by both the RACS and the NSW CEC as well as being discussed in the global literature.2–6,8–12

The 2017 RACS review of MMRs included key recommendations about best practice principles including format, conduct and outcomes (Appendix S1), reaffirmed by Vreugdenburg et al.1 in a systematic review.1 The CEC is also a proponent of a basic standard for MMRs including multidisciplinary input18 and similar recommendations are made by Higginson et al.,12 Bal et al.3 and Davies et al.,6 focusing on frequent meetings to better delineate complex issues. A review of the same topic commissioned by the Australian Healthcare Commission by Joseph et al.20 arrives at a similar conclusion with a focus on these attributes of the meeting rather than tools for analysis. A consistent concept is the educational benefit for participants of MMRs, in particular, the opportunity to improve surgical techniques or learn from peers.1,12 Indeed, RACS awards both continuing professional development points for fellows and includes participation in MMRs for assessing trainee performance and the quality of the training site.7

Problems with MMR

Key problems in the MMR process identified by CEC and RACS, as well as by other authors such as Vreugdenburg et al.1 include case selection processes, making recommendation and follow-up, as well as legal privilege associated with the meeting. This underpins the problem of blame culture being associated with MMRs in practice although not their intention.

The source of cases or types of cases discussed based on indicators for concern such as unplanned return to theatre or admission to intensive care unit or readmission within 30 days can identify incidents of poor care;18,21 however, they do not always capture cases well or include those that clinicians are concerned about.22 This is evidence by the mismatch between cases identified by programmes such as National Safety and Quality Improvement Program (NSQIP) versus surgeon-reported cases.23 As such, more research is needed to better understand which method of case identification more frequently identifies cases with HFE problems to improve the quality of MMRs.20

Adverse outcomes discussed at MMRs have traditionally been attributed to individual incompetence in treating patients rather than system failures, so doctors are disproportionately hesitant to participate in incident reporting.8

There are many complex reasons for this, but it is important that MMRs are conducted in a non-judgemental and non-punitive manner to allay fears of retaliation, blame or legal action.24 However, in Australia, MMRs have ‘no special legal privilege…It is the skill of the meeting secretariat to document meetings on the assumption that they could potentially become public documents’.18 Although application for Qualified Privilege (legal protection) under section 6B of the Medical Administration Act can be made, this is seldom undertaken.1 Therefore, it is understandable why there may be a fear or blame culture associated with MMRs and this is an important aspect the quality improvement process that should be revised.
Table 1 Summary of Australian and international literature on human factors ergonomics and MMR models

| Study                        | Year | Model                                                                 | Strengths                                                                                           | Weaknesses                                                                                         |
|------------------------------|------|-----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| International literature     |      | Analyses factors of ‘staff, bed availability, infection, delay in diagnosis, drug error’ | Systems approach                                                                                   | Too few factors considered for modern complex health systems                                      |
| Higginson et al.12           | 2012 | 3D model using domains of ‘technology’, ‘system’ and ‘culture’         | Made by surgeons for surgeons                                                                     | Does not include patient factors, literature review or benchmarking to standards                   |
| McCulloch and Catchpole5     | 2011 | '3D model' using domains of 'technology', 'system' and 'culture'       | Recognizes that no single 'root cause' is the source of error and that in complex systems many spontaneous events may be occurring influencing even apparently unrelated departments |
| Holden et al.11              | 2013 | SEIPS 2.0: factors: tools: technology, persons, tasks, organization, internal + external environmental factors | Robust systems factors analysis with healthcare focus                                              | Involves detailed process with outputs such as complex diagrams which are beyond MMRs              |
| Waterston and Catchpole10    | 2016 | 'Onion Model': people, technology, artefacts, tasks and goals with focus on changing work culture, design and performance | Detailed systems analysis with focus on ways to create improvement                                 | No literature review aspect or benchmarking                                                       |
| Australian models            |      |                                                                       |                                                                                                      | Difficult to use without training and experience                                                   |
| QLD HEAPS Incident Management Tool13 | 2018 | 'Swiss Cheese Model' based on multiple errors or holes in the cheese aligning causing error | One of the only models in use locally that uses a systems-based approach in a structured manner13   | Largely focuses on individual error and a reductionist model of thought14                            |
| IIMS NSW                     |      | Incident reporting system collating 140 000 incidents annually and producing 600 root cause analysis18 | Graded assessment of severity of incidents and impact                                               | Reporting and documentation focused with little clinician engagement                               |
| CHASM/ANZASM                  |      | Surgical mortality reporting registries/audits for all surgical deaths by defied criteria for each state | Bi-national                                                                                         | Does not connect MMRs or quality improvement projects16,17                                        |
| CEC NSW 'Cognitive Autopsy'  | 2016 | Individuals reflect on their performance and events18                 | Bi-national                                                                                         | Lacks literature review                                                                            |
| RACS                         | 2017 | College-based guidelines for MMRs                                      | Bi-national                                                                                         | No detailed systems analysis                                                                       |
|                              |      | Recommend systems-based approach under ‘conduct’ section              | Bi-national                                                                                         | No connection to quality improvement process within hospital                                       |
|                              |      |                                                                       | Bi-national                                                                                         | No systems analysis                                                                                 |
|                              |      |                                                                       | Bi-national                                                                                         | Internal process not connecting to quality improvement beyond the individual’s actions          |
|                              |      |                                                                       | Bi-national                                                                                         | No actual tools for doing systems-based analysis                                                   |
|                              |      |                                                                       | Bi-national                                                                                         | No benchmarking/literature review                                                                  |

ANZASM, Australia and New Zealand Audit of Surgical Mortality; CEC, Clinical Excellence Commission; CHASM, Collaborating Hospitals’ Audit of Surgical Mortality; HEAPS, human error and patient safety; IIMS, incident information management system; MMR, mortality and morbidity review; NSW, New South Wales; QLD, Queensland; RACS, Royal Australasian College of Surgeons; SEIPS, systems engineering initiative for patient safety.

The Vreugdenburg et al.'s review,1 RACS and CEC all identify that making recommendations and having processes in place to follow these up are essential to enabling the effectiveness of the MMR process. A further practical issue for departments who lack funding for data collection officers or clerical staff is documenting the discussions of the meeting and creating the necessary action items.

Models of MMR/HFE

There were a limited number of studies that used a validated HFE model to structure MMRs5,10,12 but this does not mean such tools do not exist or are not in use. Table 1 summarizes the current literature and local guidelines and standards. Table 1 demonstrates that there is an apparent paucity of HFE models or theory being incorporated into everyday practice beyond a sentiment expressed in a guideline somewhere in the Australian Healthcare system is exposed by the recent Safety Culture review by the Australian Commission on Quality and Safety in Healthcare.9 An extensive review of multiple safety culture tools was assessed (yielding only a 26% participation rate of 39 hospitals contacted) uncovering a dismal and chaotic understanding of safety culture in Australian hospitals with no consistent models, processes or validated tools in place.9 This leaves significant room for improvement when considering how MMRs could be utilized to identify systems problems within health care and improve the quality of patient care as well as the incorporation of evidence-based medicine practices.

Development of the new People–Processes–Paradigm MMR tool

The above-mentioned analysis demonstrates that even in this era of robust HFE models and a strong political and professional drive towards improving patient safety and the quality of health care,2,9 there are few tools suited for simple critical analysis of surgical cases that incorporate both surgical and systems factors. The ideal model or tool would address the issues discussed above from
Fig. 1. Critical analysis tool for mortality and morbidity review: ‘People–Processes–Paradigm’. Part one: patient and case identification. ISBAR, identify-situation-background-assessment-recommendation. Part two: analysis based on People–Process–Paradigm model with traffic light system to rate the importance of each factor. Green, consideration – care COULD have been better. Yellow–concern – care SHOULD have been better. Red, adverse event – direct harm. Part three: literature, learnings and recommendations.
technical and standardization aspects of the meeting to a detailed validated process for systems analysis and literature review. The key features would be a tool that would:

- Be simple and efficient to use without requiring training.
- Have the ability to incorporate multiple cases.
- Critically evaluate both surgical and systems factors.
- Facilitate learning for the whole team.
- Distil recommendations and action items within a prescribed time frame.
- Facilitate documentation and connect to relevant incident reporting system internally or externally (e.g. incident information management system (IIMS), collaborating hospitals audit of surgical mortality (CHASM) or root cause analysis).

To address these aspects, the People–Processes–Paradigm tool was developed, which includes the above-mentioned key issues and incorporates structural and theoretical elements of models such as SEIPS and 3D model as well as the CHASM triage system for the severity of adverse events or errors into a proforma tool for critical analysis of MMR cases (Fig. 1). The tool consists of three key sections: basic patient data, systems analysis and action items. The basic patient data section includes classification of how and why the case was selected based on set selection criteria as well as standardized ISBAR (identify-situation-background-assessment-recommendation) communication tool to give the details of the events and operations performed. The analysis section is divided into People–Process–Paradigm systems review with a traffic light system to rate the severity of each factor. The action items section prompts the user to undertake a literature review to benchmark their results, suggests ways to improve and then directs them to complete an incident management form and delegate a responsible person and timeline for reporting.

A new structural theory is proposed based on People–Processes–Paradigm to adapt known validated models into the Australian context, where Paradigm is the socio-cultural-economic and political construct within which surgical care is undertaken. This intentionally incorporates the organizational and environmental (internal and external) aspects of SEIPS model and recognizes the ‘system’ and ‘culture’ domains from 3D model. This is central to the application of HFE analysis in surgery because surgery is a highly technical and task-oriented field and surgeons are interested in improving performance and learning whilst recognizing that this occurs within the reality of a socio-cultural-economic and political system. Similarly, the ‘People’ domain is akin to the same domain in the SEIPS model recognizing the agents completing the work, including surgical team and patient factors. This is important because as discussed in the SEIPS model the agents within any case may change from being the surgeon to the ward staff to the patient’s family and of course the patient themselves. In the proposed new model, the ‘Processes’ domain incorporates ‘technology and tools’ as well as ‘Task’ from SEIPS and the 3D model because in surgical care the two are connected closely; thus, grouping these closer together in the model assists untrained users to understand the interactions in the surgical context.

The proposed new model not only incorporates key concepts of validated HFE tools such as SEIPS and 3D model, but also adopts key performance indicators important to Australian authorities and links into existing national audit structures. For example, case sources are identified based on the safety I and safety II principles and standards set by the CEC as well as including NSW health quality metrics such as length of stay, dates and times of surgery and elective versus emergency case type. Links to known surgical audit tools such as CHASM, IIMS and NSQIP are included to facilitate recommendations and development of action items. Detailed patient factors such as comorbidities like obesity and diabetes, and risk factors known to result in surgical mortality based on the research of CHASM are included (e.g. presence of malignancy, infection and delays to diagnosis). Furthermore, users are prompted to analyse the surgical decision-making process and consider evidenced-based medicine guidelines such as the use of clinical risk scores such as Portsmouth Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity (P-POSSUM) and American Society of Anaesthesiologists Physical Status score (ASA) as well as to conduct a literature search or at least review NSQIP reviews to benchmark their units’ performance.

**Pilot test**
Initial user testing was performed at the author’s hospital at the July 2018 MMR. Registrars and consultants used the tool for discussing the cases as well as presenting them in their usual PowerPoint style for comparison. Feedback included suggestions for:

- Clarifying which sections need to be completed and if some sections not relevant to every case.
- Time taken to complete was 1–2 h instead of the usual 30–45 min which is potentially impractical for use for every case in busy units but possible for select cases.
- Case selection and whether detailed assessment is needed for all suggested safety I cases or only a few select complex cases.
- Addition of imaging assessment – now included (Fig. 1).

It is the intention to imbed this proforma into existing online surgical tools and to link into the electronic reporting systems developed to aid action of items, follow-up and documentation. The further stakeholder feedback sessions identified keen interest to use the tool in surgery but also other sectors such as paediatric intensive care and anaesthetics. Stakeholders appreciated that whilst the tool was specific and covered all the key aspects of safety it was sufficiently versatile to be tailored to suit individual health services’ needs.

**Discussion**
The widespread use and understanding of HFE concepts already exist in many industries from aviation and automotive to nuclear power. Many of these high-risk industries have evolved beyond assuming they operate in stable systems with intrinsic components that either functioned correctly or not. Instead they now operate in complex, unstable systems where even correctly functioning components can still result in adverse events. Hence, modern HFE concepts now more closely align with the healthcare sector, particularly surgery because of its application to complex, high pressure systems. Therefore, HFE type analysis is essential to improving patient care and can be incorporated into surgical thinking and practice by the development and use of HFE tools into existing professional activities such as MMRs.

The current disconnects between best practice guidelines and clinical practice in MMRs and patient safety culture in Australia
has been identified by multiple sources. Recommendations for improvement disproportionately centre around the characteristics of MMRs rather than how to practically undertake systems-based reviews and lack implementation attributes despite the independent existence of some highly robust tools such as the CHASM audit.

The literature review identified only a very small number of papers presenting tools for use in MMR. The review found discussion about MMR in the areas of role and format, problems and models. Challenges exist in convincing surgeons that the purposes of MMR are safety and education rather than attributing blame. Criteria for identifying cases for discussion are often inconsistent and poorly defined. Lack of legal privilege may be a barrier to analysis of cases. The literature review identified a number of characteristics that an ideal tool would have, but no tool containing all of these was identified.

The People–Processes–Paradigm tool, which incorporates important systems factors, safety issues and surgical factors into a graded severity tool, benchmarks unit performance to national standards and incorporates evidence-based medicine concepts. The model synthesizes validated tools such as the SEIPS and 3D models in the literature and adapts these to the Australian setting. Limitations of the proposal include complexity and time to complete the assessment. This model requires wider user testing and would ideally be suited to an electronic format which is simplest for surgeons to use.

One of the limitations of this study is that the literature review was targeted rather than systematic. However, as many articles were clinical guidelines and government or college documents, this approach was considered appropriate. The pilot study was very small and more widespread evaluation is required across a number of different settings to confirm its utility.

Conclusion

The future of patient safety and the ability of the healthcare sector to deliver high standards of care depend on our ability to learn from adverse events and develop a culture of continuing quality improvement. To achieve this, clinicians must be able to easily engage with safety and quality improvement tools to best analyse how care is delivered and could be delivered in the future to improve patient outcomes. Adapting validated HFE tools to the Australian surgical context by developing the People–Processes–Paradigm tool is a way in which this academic practice can be enhanced to deliver more tangible user-centred quality improvement and patient safety outcomes.

Conflicts of interest

None declared.

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**Supporting information**

Additional Supporting Information may be found in the online version of this article at the publisher’s web-site:

**Appendix S1.** Royal Australasian College of Surgeons standards for mortality and morbidity meetings.