High reliability organisations and collective mindfulness for improving healthcare safety management: a scoping review protocol of factors, measures and instruments

Manikam Pillay\textsuperscript{a}, Andrew Enya\textsuperscript{b}, Emmanuel Boateng\textsuperscript{c}

\textsuperscript{a}School of Health Sciences, University of Newcastle, AU (Manikam.Pillay@newcastle.edu.au) ORCID: 0000-0002-7010-277X, \textsuperscript{b}School of Health Sciences, University of Newcastle, AU (Andrew.enya@newcastle.edu.au) ORCID: 0000-0002-2355-4239, \textsuperscript{c}School of Health Sciences, University of Newcastle, AU (Emmanuel.bannorboateng@newcastle.edu.au) ORCID: 0000-0002-6434-0085

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Abstract
A growing body of peer-reviewed studies demonstrate the importance of high-reliability organisations and collective mindfulness in improving healthcare safety. However, limited attention has been devoted to developing a common set of characteristics, dimensions, indicators and instruments for measuring collective mindfulness. This can limit its operationalisation and ability to benchmark. This protocol outlines the key procedures that will be used to conduct a scoping literature review, in order to summarise key definitions; identify theoretical underpinnings, dimensions, measures and instruments; and develop a theoretical model to advance research and practice. Specifically, a five-step process and the Preferred Reporting Instruments for Systematic and Meta-Analyses will be used to search, screen and select literature published in five electronic databases. Keywords will include a combination of 'high-reliability organisations', high-reliability theory' with 'health care', 'patient safety', 'medical errors', 'medical mistakes', 'medication error'. A double-blind process will be used for searching, screening and selection of abstracts and full-articles, and inter-observer agreement assessed using Cohen’s kappa.

1. INTRODUCTION
Safety management is an important issue in the healthcare industry. The Australian government has identified this as one of the priorities industries for action under the Australian work health and safety strategy (Safe Work Australia, 2012). Currently the industry is the largest employer, accounting for thirteen percent of total employment, but sixteen percent of serious workers’ compensation claims (Safe Work Australia, 2018). The Australian Institute of Health and Welfare (2016) has also identified safety as a key performance area of attention, with a focus on reducing human error and harm, which was one of the main areas identified by the Institute of Medicine (IOM) (2000). The report also highlighted that harm to patients was often the result of both system and individual level errors, and addressing these required more than the efforts of doctors and nurses (Affare, Tolk, & Cantu, 2015). The IOM referred to High reliability organisations (HROs) as a model the health care sector needed to emulate.

HROs are able to manage and sustain a nearly-error free operation despite operating in highly complex and uncertain environments where the consequences of errors can be catastrophic (Enya, Dempsey, & Pillay, 2018; Hopkins, 2009; Lekka, 2011). The term was first introduced in the 1980s by a group of the University of California, Berkeley researchers as an alternative to Normal Accident Theory (NAT) suggested to be the case of the nuclear disaster at Three Mile Island (Perrow, 1981).
The basic tenet of NAT was that accidents were inevitable in tightly-coupled complex technological systems because complexity yielded unexpected interactions leading to rapid escalation of multiple failures in ways that could not be foreseen by the designers nor comprehended and intervened in by operators. Perrow posited that accidents in these types of systems were normal and inevitable because they had become so complex and tightly-coupled such that a small event could trigger a series of cascading failures in many parts of the system, leading to an eventual disaster (Perrow, 1999). However, a group of Berkeley researcher’s contended there were some organisations that could be deemed complex and tightly-coupled, but had achieved excellent safety and production goals (Hopkins, 2009). These authors argued that organisational accidents in such organisations were able to be prevented, controlled or managed effectively by implementing a number of organisational practices. These practices have since been associated with ‘collective mindfulness’: a cognitive mindset that is characterised by pre-occupation with failure, reluctance to simplify, sensitivity to operations, commitment to resilience, and deference to expertise (Enya, Pillay, & Dempsey, 2018; Hopkins, 2009; Weick & Sutcliffe, 2011). Conceptually, HROs have been associated with the fourth age of safety, and collective mindfulness an advanced strategy for safety management (Pillay, 2014, 2015).

Early research on HROs concentrated on a few selected industries ranging from commercial airlines, air traffic control operations, nuclear power plants, amusement parks and wildfire management (Bourier, 2011; Hopkins, 2009). Over the last four decades HRO studies have escalated, with recent reviews examining its utility in construction (Enya, Dempsey, et al., 2018; Enya, Pillay, et al., 2018), major hazard facilities (Lekka, 2011) and healthcare (Tolk, Cantu, & Beruvides, 2013, 2015). These reviews suggests that most research in this area has been published from a qualitative perspective, generating a rich body of knowledge about HROs and the principles of collective mindfulness. However, limited attention has been devoted to developing a common set of characteristics, dimensions, indicators and instruments that can be used to measure collective mindfulness. This can limit its operationalisation and ability to benchmark health care safety management. The proposed review seeks to address this gap. Specific objectives will include:

a. Identifying and reviewing quantitative research studies on HROs and collective mindfulness published from healthcare settings using a structured, scoping method

b. Summarising definitions of HROs and collective mindfulness

c. Identifying any theoretical underpinnings, dimensions, measures and instruments, and

d. Developing a theoretical model to benchmark and advance research and practice.

2. METHODS

This research involves a scoping review, an approach which has been suggested to be useful for examining “emerging evidence when it was unclear what other, more specific questions can be posed and valuably addressed by more a more precise systematic review” (Munn et al., 2018, p. 2). Some authors have commented that scoping reviews do not assess the quality of studies included (Levac, Colquhoun, & O’Brien, 2010), so this review will include this additional step. The specific approach includes five main stages adapted from Khan, Kunz, Kleijnen, and Antes (2003), Tranfield, Denyer, and Smart (2003) and Hempel, Xenakis, and Danz (2016). These stages include:

i. Framing the research question(s),

ii. Searching and selecting relevant literature,

iii. Quality assessment of included studies,

iv. Data extraction, and

v. Data synthesis.

Each of these steps is discussed below.
2.1. Framing the research question

A set of four, interrelated research questions were formulated to achieve the research objectives. These include:

1. How are HROs and Collective mindfulness conceptualised, defined and measured in the healthcare literature?
2. What attributes / factors have been used in quantitative studies of collective mindfulness?
3. What research instruments have been used to measure HRO and collective mindfulness quantitatively?
4. Which statistical tests have informed the quality (in terms of reliability and/or validity) of these studies?

In framing these questions, it was noted that previous authors such as Enya, Dempsey, et al. (2018); Enya, Pillay, et al. (2018) sought to address some of these, their research focussed on the construction industry. This review will focus on the healthcare sector, largely because it is one of the sectors that has been actively engaged in implementing HRO and collective mindfulness.

2.2. Searching and selecting relevant literature

Preferred Reporting Instruments for Systematic and Meta-analysis (PRISMA) guidelines (Liberati et al., 2009; Moher, Liberati, Tetzlaff, Altman, & The PRISMA Group, 2009) will be used for searching and selecting the relevant literature. Five electronic databases (CINAHL, EMBASE, MEDLINE, PsycINFO, and SCOPUS) will be searched, using the keywords / combinations shown in Table 1.

<table>
<thead>
<tr>
<th>Table 1. Keywords to be researched</th>
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<tbody>
<tr>
<td>“High reliability organisations” “High reliability theory” “Collective mindfulness”</td>
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<tr>
<td>“High reliability organisations” AND “health care” OR patient safety* OR medical errors* OR medical mistakes* OR medication error*</td>
</tr>
<tr>
<td>“High reliability theory” AND “health care” OR patient safety* OR medical errors* OR medical mistakes* OR medication error*</td>
</tr>
<tr>
<td>“Collective mindfulness” AND “health care” OR patient safety* OR medical errors* OR medical mistakes* OR medication error*</td>
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</tbody>
</table>

The selected articles will be collated in citation files using an EndNote referencing software, and any duplicates removed.

Next, the titles and abstracts will be screened by two reviewers, using a double blind process, based on an agreed inclusion and exclusion criteria.

2.2.1 Inclusion criteria

- All quantitative and mixed method studies.
- Studies published in English.
- Studies which used and/or described an instrument to assess HRO / collective mindfulness.
- Studies which covered and/or focussed on the psychometric properties of the research instrument as part of the development, testing.
- Published from 1 January 2000 to 30 April 2019.

2.2.2 Exclusion criteria

- Studies which used qualitative methods only will be excluded.
- Studies which focussed on non-health care settings will be excluded.
- Studies which focussed on other aspects of reliability will be excluded.
- Opinion papers, editorials, letters to the editor and short communications will be excluded.
- Studies published prior to 2000 will be excluded.
Two reviewers will complete the title and abstract screening. Results will be compared and any disagreements will be resolved through discussions until consensus is reached, or in discussion with the senior reviewer. Interobserver agreement will be assessed using Cohen’s kappa (Viera & Garrett, 2005).

A similar process will be applied to the full-text searching and selection of articles.

### 2.3. Quality assessment of included studies

Quality assessment of the selected articles will be assessed by two reviewers using an adapted version of a critical appraisal framework from Critical Appraisal Skills Program previously used by Gillman and Pillay (2017). The questions informing this assessment are presented in Table 2. The results of the assessment will be reported, but no articles will be excluded from the synthesis and reporting based on the assessment.

<table>
<thead>
<tr>
<th>Table 2. Modified Critical Appraisal Skills Program Questions</th>
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<tbody>
<tr>
<td>1. Aim/s: Was the aim of the research clear?</td>
</tr>
<tr>
<td>2. Method: Was the research methodology used appropriate?</td>
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<tr>
<td>3. Design: Did the study design address the aims of the research?</td>
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<tr>
<td>4. Data: Did the data collected address the research aim?</td>
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<td>5. Data analysis: Was the data analysis sufficiently rigorous?</td>
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<td>6. Bias: Was any bias considered adequately?</td>
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<tr>
<td>7. Findings: Are the findings clearly stated?</td>
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<tr>
<td>8. Gap/s: Have gaps in the literature been clearly identified?</td>
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<tr>
<td>9. Acceptance: Can I accept these findings as true?</td>
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<tr>
<td>10. Value: Can I apply these findings to my own work?</td>
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</tbody>
</table>

In adapting these tools it was observed that previous systematic reviews (Tolk et al., 2013, 2015) did not report on any risk of bias assessment completed, while Enya, Pillay, et al. (2018) used a similar approach as above. A coding scheme of ‘yes’, ‘no’ or ‘limited’ will be used.

### 2.4. Data extraction

Data extraction from all selected articles will be carried out by one researcher using a specifically designed Excel spreadsheet adapted from Newaz, Jefferies, Davis, and Pillay (2018). These will be cross-checked by two researchers. The following data will be extracted from each study:

- i. Full citation of the original article
- ii. Conceptualisation of HRO
- iii. Study design and sample size
- iv. Research instrument used
- v. Analytical approaches used
- vi. Key findings

### 2.5. Data Synthesis

A structured, narrative synthesis will be utilised, with the results presented with a summary of findings and assembled tables. Discussions will include the studies’ characteristics and findings. Quantitative synthesis, including meta-analysis, will be undertaken if the final list of included studies is sufficiently homogeneous. The overall outcome will be used to provide a synthesised definition and linkages between HROs and collective mindfulness, psychometric variables and measures of collective mindfulness, the instrument used, analytical approaches used. The synthesis will include a theoretical model that can be used to advance quantitative research on collective mindfulness for benchmarking healthcare safety management.
2.6. Meta-biases
This parameter does not apply to the review to be carried out.

2.7. Confidence in cumulative evidence
This parameter does not apply to the review to be carried out.

2.8. Registration
The protocol has not been submitted for registration, consistent with previous reviews of research instruments published on safety culture (Halligan & Zecevic, 2011).

AUTHORS’ CONTRIBUTIONS
MP conceptualized, drafted and finalized this protocol. All authors reviewed and provided comments, and approved on the first and revised submissions.

REFERENCES


