

**THE DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE ON ROOT  
CAUSE ANALYSIS**

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## ABSTRACT

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**Background:** Root Cause Analysis (RCA) is a method of investigating adverse events (AEs). The purpose of RCA is to improve quality of care and patient safety through a retrospective, structured investigative process of an incident, resulting in recommendations to prevent the recurrence of medical errors.

**Aim:** The aim of the study was to develop and validate a prototype questionnaire to establish whether the RCA model and processes employed at the research setting were perceived by the users to be acceptable, thorough and credible in terms of internationally established criteria.

**Methods:** This is a validation study comprising four phases to meet the study objectives: 1) the development of a prototype questionnaire guided by a literature review; 2) assessing the validity of the content of the questionnaire by and numerical evaluation of the face validity thereof; 3) assessing the qualitative face validity cognitive interviews; and 4) reliability by test-retest.

**Results:** Content validity assessment in Phase 2 resulted in removal of 1/36 (2.77%) question items and amendment of 7/36 (19.44%), resulting in 35 for the revised questionnaire. Analysis of data from the cognitive interviews resulted in amendment of 20/35 (57.14%) question items but no removal. Reliability of the final questionnaire achieved the predetermined  $\geq 0.7$  level of agreement.

**Conclusion:** The questionnaire achieved a high content validity index and face validity was enhanced by cognitive interviews by providing qualitative data. The inter-rater coefficient indicated a high level of reliability. The tool was designed for a local private healthcare sector and this may limit its use.

**Keywords:** Adverse events, patient safety, quality of care, root cause analysis [MESH checked 12/11/19]

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## **ABBREVIATIONS**

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AE= adverse event

CVI = Content Validity Index

FMEA = Failure Modes and Effects Analysis

IRR = Interrater Reliability

OHSC = Office of Health Standards Compliance

PDSA = Plan Do Study Act

QI = Quality Improvement

QM = Quality Manager

RCA = Root Cause Analysis

RPN = Registered Professional Nurse

WHO = World Health Organisation

## OPERATIONAL DEFINITIONS

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*Adverse Event:* An event or unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof (The Joint Commission, 2017).

*Incident:* Any action or failure to act that results in compromised care quality and patient safety (Kiekkas, Aretha, Stefanopoulos, & Baltopoulos, 2012).

*Medical error:* A failure to complete a planned action as intended by commission or omission, which may or may not result in injury, harm or death of the patient (Grober & Bohnen, 2005).

*Quality of care:* the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (Mitchell, 2008).

*Registered Professional Nurse:* A professional nurse is a person who is qualified and competent to independently practise comprehensive nursing in the manner and to the level prescribed and who is capable of assuming responsibility and accountability for such practice. A Registered Professional Nurse is a Professional Nurse who is Registered to practice with the South African Nursing Council (South African Nursing Council, 2005).

*Sentinel event:* An adverse event that results in death or harm that requires immediate investigation and intervention (The Joint Commission, 2017).

*Root Cause Analysis:* RCA is a systematic and structured approach to examine and investigate the underlying causes of an adverse event (Bagian, King, Mills, & McKnight, 2011; Bowie, Skinner, & de Wet, 2013).

## CHAPTER ONE: INTRODUCTION

---

### 1.1 Background

Healthcare is a challenging and stimulating environment that is becoming increasingly complex, producing increased risks to patients and healthcare workers (Cassin & Barach, 2012; Woher, 2015). Risks include adverse events (AEs) which are unexpected occurrences involving death or serious physical or psychological injury (The Joint Commission, 2017). Healthcare workers are expected to function efficiently and without error in this constantly changing environment, often despite time and human resource constraints. Although mistakes are predominantly unintentional, humans are imperfect and flawed, thereby supporting the adage “to err is human” which is also applicable to healthcare settings (Institute of Medicine Committee on Quality of Health Care in America, 2000).

At times healthcare workers make decisions and take actions based on the information they may have at the time (Elliott, Page, & Worrall-Carter, 2012). Factors like anxiety, fatigue and inattention add to the fallibility and imperfections of humans, and patients are an already vulnerable group, susceptible to consequences of the actions of healthcare workers. Despite many years of intense analysis and efforts made to address the rate of medical error, the high number of AEs is not improving (Kellogg et al., 2017). This is regardless of measures taken to put system, process and policy defences in place to prevent AEs (Reason, 2000) and to address patient safety and quality of care issues (Schriefer & Leonard, 2012).

Root Cause Analysis (RCA) is one such measure to improve patient safety. It is a method of investigating an AE, adapted from high risk industries for use in healthcare settings in response to the increasing number of medical errors (Zastrow, 2015). The purpose of RCA is to identify the root causes and system errors that resulted in a clinical AE, in an attempt to prevent a recurrence (Mengis & Nicolini, 2010). The tenet of RCA is that it is an in depth analysis of an incident for the purpose of developing corrective actions, intentionally a proactive process provided that the RCA methodology is used rigorously and meticulously. Despite the many positive attributes of RCA described in the healthcare literature, there are also many challenges to using RCA effectively (Woher, 2015; Zastrow, 2015). When RCA was introduced into healthcare settings in 1999 by the US Department of Veterans’ Affairs Veterans’ Health Administration National Centre for Patient

Safety (Bagian et al., 2011), no guidelines were developed on how to approach and undertake the process (Latino, 2015). This has resulted in great variability in the method and quality of RCAs in healthcare both in terms of how RCA is approached and the credibility of recommendations, thus challenging its efficacy. There is a paucity of evidence on the success of RCA in the literature (Kellogg et al., 2017). This lack of evidence-based efficacy of the RCA method has resulted in the questioning of its rigour and accuracy, and thus the quality of recommended action plans and the benefits thereof (Francois et al., 2018; Peerally, Carr, Waring, & Dixon-Woods, 2017; Shaqdan, Aran, Daftari Besheli, & Abujudeh, 2014). To enhance quality assurance, the South African National Department of Health developed National Core Standards against which service delivery by health establishments is assessed.

Domain 2 of the National Core Standards for Health Establishments addresses Patient Safety, Clinical Governance and Clinical Care thereby acknowledging the importance of identifying and managing AEs promptly (National Department of Health, 2011). This domain requires staff in the private or public sector to be aware of risks and to routinely analyse AEs with the expectation that control measures will be put in place (National Department of Health, 2011). The standards are upheld by the Office of Health Standards Compliance (OHSC) (Molekoi, Msibi, & Marshall, 2013) and aligned with the eight Batho Pele [*People First*] principles. These principles, developed by the South African Government, formed part of a political initiative for improved delivery of service and goods to the public, a strategy used by all governmental departments to focus their attention on improving service delivery (Russell & Bvuma, 2001). These principles are an imperative for both public and private healthcare facilities to improve the quality of care, increasing the likelihood of desired health outcomes (Hughes, 2008) by innovation and excellent service when standards are not met. The principle of the right to health for all is embedded in the Constitution of the Republic of South Africa (Meyer et al., 2017).

The purpose of this study was to develop and validate a research instrument (survey questionnaire) on RCA. Use of such a validated instrument in further research could provide valid data about effective and appropriate methods and use of RCA to ensure the provision of quality healthcare and patient safety, but that is beyond the scope of this study.

## **1.2 Problem statement**

The purpose of RCA is to improve the quality of care and patient safety through a retrospective, structured investigative process of an incident, resulting in recommendations to prevent the recurrence of medical errors. At the time of undertaking this study it was not known whether the RCA method employed at private healthcare facilities within one healthcare organization (the research setting) was acceptable, thorough and credible in terms of established international criteria (The Joint Commission, 2017), outlined further in Chapter 3. A research instrument was not found in the available published literature to undertake such a study.

## **1.3 Aim**

The aim of the study was to develop and validate a prototype survey questionnaire to establish whether the RCA model and processes employed at the research setting were perceived by the users to be acceptable, thorough and credible in terms of internationally established criteria.

## **1.4 Research question**

What level of validity and reliability will a self-designed prototype survey questionnaire on RCA achieve using content validity index (CVI) testing, cognitive interviewing and test-retest reliability testing?

## **1.5 Objectives**

The objectives of this study were to:

- 1.5.1 develop a prototype survey questionnaire (Appendix A) guided by a review of the literature;
- 1.5.2 assess the validity of the content of the prototype survey questionnaire by CVI and numerical evaluation of the face validity thereof (Appendices B and C);
- 1.5.3 assess the qualitative face validity of the questionnaire through cognitive interviews (Appendices D and E); and
- 1.5.4 assess reliability of the questionnaire by test-retest intra-rater reliability (IRR) testing (Appendices A and F).

## **1.6 Relevance of the study**

Developing a valid and reliable survey questionnaire on the current practice of conducting RCA, measured against international criteria, is the first step in ensuring that the constructs in the questionnaire will measure what is intended and that the questionnaire is stable and consistent when used over time. Further research at a later stage has the potential for the administration of the validated questionnaire to generate valid data on current RCA practices to ensure quality care, patient safety and good patient outcomes in a selected local healthcare setting.

The literature reviewed for this study is presented in Chapter 2 and includes the search strategy employed and the main themes that emerged in relation to the aim of the study: to develop and validate a survey questionnaire on RCA.

## **CHAPTER TWO: LITERATURE REVIEW**

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### **2.1 Introduction**

The literature search was guided by the research question, aims and objectives of this study as outlined in Chapter 1. The available literature was searched for keywords and themes that could guide an understanding of Adverse Events (AEs) and the use of Root Cause Analysis (RCA). It was necessary to evaluate the history of safety improvement trends and the current situation of patient safety in healthcare. The literature assisted with identifying gaps in knowledge relating to RCA, providing motivation for the importance of this study.

In addition, to strengthen the rigour of this study, research papers on validation studies and questionnaire design were accessed and assessed for relevance to guide the methodology used for this study. There is a paucity of published literature on validation studies per se and not all research papers describe the validation processes of research instruments used in these studies (Bolarinwa, 2015).

### **2.2 Search strategy**

The available published literature from 2009 to 2019 was searched using the keywords: quality of health care, risk, safety, quality improvement, adverse events, root cause analysis. Databases searched included PUBMED, SCOPUS and EBSCOHost (including Africa-Wide Information, Health Source: Nursing/Academic Edition, CINAHL and MEDLINE) outlined in Table 2.1. A separate search was undertaken to find existing questionnaires relating to use of the RCA approach and validation studies.

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**Table 2. 1: Search Strategy for keywords**

Database	Keywords	Results	No. of relevant papers
EBSCO HOST • Africa-Wide Information • Health Source: Nursing/Academic Edition • CINAHL • MEDLINE	(Quality of Health Care) OR (Risk Management) OR (Quality Control) OR (Recur* OR repeat OR repetition) OR (prevention and control) OR prevention OR (risk* OR safety OR hazard OR readmissions OR epidemiology OR surveillance) OR (quality assurance, health care) OR	1102 (391 after removing duplicates)	39
PUBMED	(health care quality assurance quality) OR assurance OR (quality assurance) OR (quality control) OR	606	31
SCOPUS	(outcome AND assessment AND health AND care) OR (outcome AND assessment) OR reduction OR (quality improvement) OR (quality of health care) OR (quality AND healthcare) AND (Medical Errors) OR Accidents OR (Adverse events) OR (adverse occurrences) OR (adverse effects) OR (medical errors) OR (medical incidents) OR (sentinel event) OR accidents OR wounds OR injuries OR injur* OR (unintended events) OR incidents OR mistakes OR wrong OR (wrong methods) OR procedures OR omissions OR (accidental falls) OR falls OR (medication errors) OR (drug errors) AND Root Cause Analysis OR Root Cause Analys*	437	27
	Question* AND Valid* AND Reliab* AND Root Cause Analysis	0	0
OTHER SOURCE (Hand searched from References)			12
<b>TOTAL</b>			<b>99</b>

Note to table:

\*denotes truncation

“OR” denotes the Boolean operator used to find results for alternative terms

“AND” is the Boolean operator used to find results with both keywords

() denotes grouping of terms into search phrases.

The literature search strategy was limited to English peer-reviewed articles and those that were accessible without payment due to financial constraints. Papers were excluded that discussed RCAs used for specific AEs, for example, medication errors, in a specific environment, for example, an Emergency Department (El Sakr, Kenaan, Menees, Seth, & Gurm, 2017; Gertler, Coralic, Lopez, Stein, & Sarkar, 2016; Graves et al., 2017; Holdsworth, Bond, Parikh, Yacop, & Wittstrom, 2015; Jayashree, Sasidharan, Singhi, Nallasamy, & Baalaji, 2017). Editorials were excluded. References were further hand searched for further relevant books and articles. Some recurring, important references in articles and books were then accessed, as well as relevant government literature pertaining to the situation in South Africa.

Results of the search strategy are shown in a flow diagram in Figure 2.1.

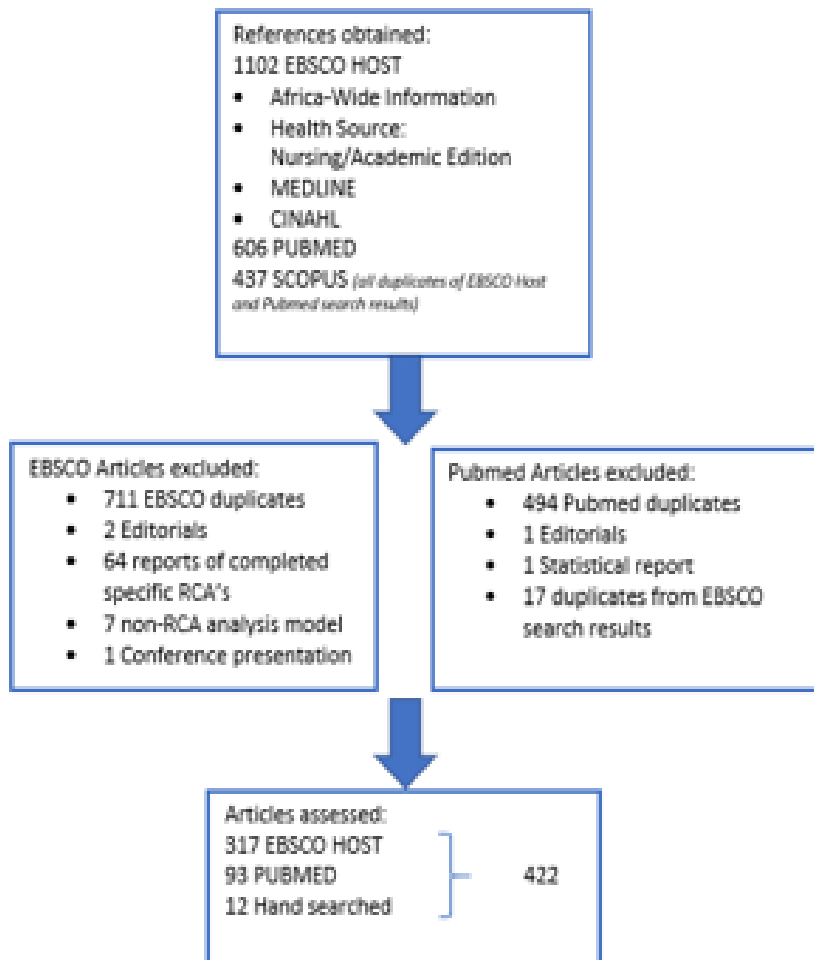


Figure 2. 1: Results of Search Strategy

## 2.3 Discussion of the reviewed literature

Six themes emerged from a review of the literature on RCA and another category of literature that was considered relevant referred to validation studies in general:

- 2.3.1 Quality Improvement
- 2.3.2 AE investigation
- 2.3.3 Root Cause Analysis
- 2.3.4 Benefits and Effectiveness of RCA
- 2.3.5 Challenges of RCA
- 2.3.6 Questionnaires related to experiences or perceptions of RCA
- 2.3.7 Content validity, face validity and reliability Studies

Each theme, and the relevant literature, is discussed in this section of the chapter. A guide for gauging the level of evidence of the reviewed studies is shown in Figure 2.2.

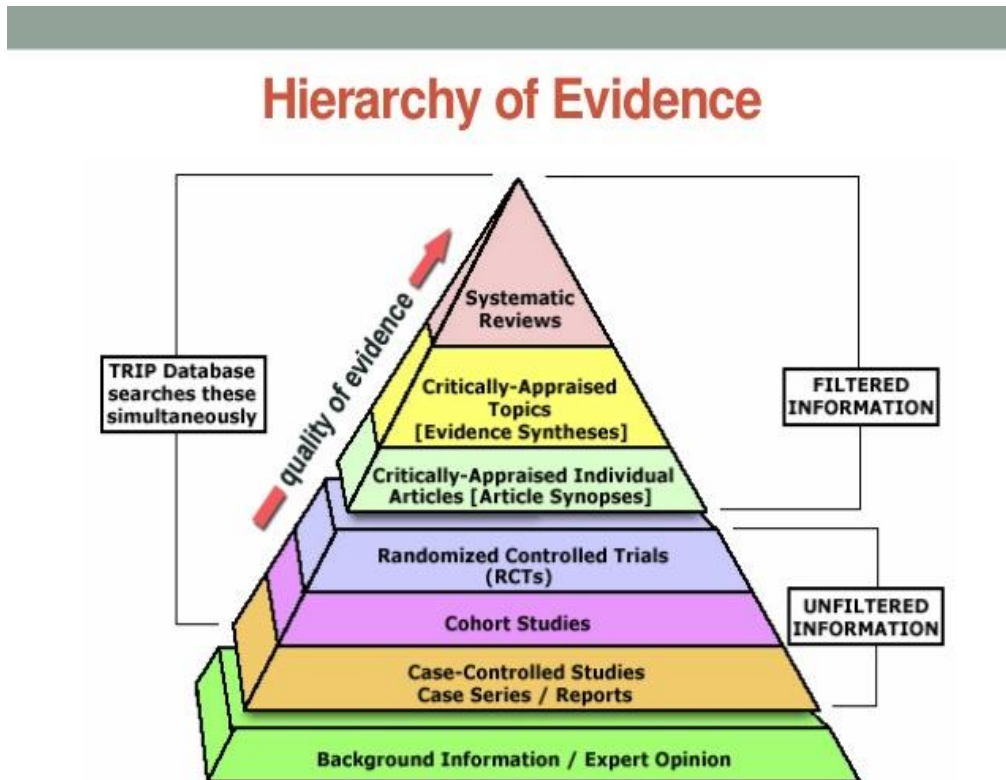


Figure 2. 2: Hierarchy of evidence (Costigliola et al., 2012)

The Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) Evidence Level and Quality Guide, explained in Table 2.2, was referred to for guidance to evaluate the studies used in the literature review (Institute for Johns Hopkins Nursing, 2017).

**Table 2. 2: JHNEBP Guideline for Level and Quality of Evidence (Institute for Johns Hopkins Nursing, 2017)**

<p><b>Level I</b></p> <ul style="list-style-type: none"> <li>• Experimental study, randomized controlled trial (RCT)</li> <li>• Explanatory mixed method design that includes only a level I quantitative study</li> <li>• Systematic review of RCTs, with or without meta- analysis</li> </ul> <p><b>Level II</b></p> <ul style="list-style-type: none"> <li>• Quasi-experimental study Explanatory mixed method design that includes only a level II quantitative study</li> <li>• Systematic review of a combination of RCTs and quasi-experimental studies, or quasiexperimental studies only, with or without metaanalysis</li> </ul> <p><b>Level III</b></p> <ul style="list-style-type: none"> <li>• Nonexperimental study Systematic review of a combination of RCTs, quasi-experimental and nonexperimental studies, or nonexperimental studies only, with or without meta-analysis</li> <li>• Exploratory, convergent, or multiphasic mixed methods studies Explanatory mixed method design that includes only a level III quantitative study</li> <li>• Qualitative study meta-synthesis</li> </ul>	<p><b>Quantitative Studies</b></p> <p><b>A High quality:</b> Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence.</p> <p><b>B Good quality:</b> Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence.</p> <p><b>C Low quality or major flaws:</b> Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn</p> <p><b>Qualitative Studies</b></p> <p>No commonly agreed-on principles exist for judging the quality of qualitative studies. It is a subjective process based on the extent to which study data contributes to synthesis and how much information is known about the researchers’ efforts to meet the appraisal criteria. For meta - synthesis, there is preliminary agreement that quality assessments of individual studies should be made before synthesis to screen out poor - quality studies</p> <p><b>A/B High/Good quality</b> is used for single studies and meta-syntheses. The report discusses efforts to enhance or evaluate the quality of the data and the overall inquiry in sufficient detail; and it describes the specific techniques used to enhance the quality of the inquiry. Evidence of some or all of the following is found in the report: • Transparency: Describes how information was documented to justify decisions, how data were reviewed by others, and how themes and categories were formulated. • Diligence: Reads and rereads data to check interpretations; seeks opportunity to find multiple sources to corroborate evidence. • Verification: The process of checking, confirming, and ensuring methodologic coherence. • Self-reflection and scrutiny: Being continuously aware of how a researcher’s experiences, background, or prejudices might shape and bias analysis and interpretations. • Participant-driven inquiry: Participants shape the scope and breadth of questions; analysis and interpretation give voice to those who participated. • Insightful interpretation: Data and knowledge are linked in meaningful ways to relevant literature.</p> <p><b>C Low quality studies</b> contribute little to the overall review of findings and have few, if any, of the features listed for high/good quality.</p>
<p><b>Level IV</b></p> <p>Opinion of respected authorities and/or nationally recognized expert committees or consensus panels based on scientific evidence Includes:</p> <ul style="list-style-type: none"> <li>• Clinical practice guidelines</li> <li>• Consensus panels/position statement</li> </ul>	<p><b>A High quality:</b> Material officially sponsored by a professional, public, or private organization or a government agency; documentation of a systematic literature search strategy; consistent results with sufficient numbers of well-designed studies; criteria-based evaluation of overall scientific strength and quality of included studies and definitive conclusions; national expertise clearly evident; developed or revised within the past five years</p>

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	<p><b>B Good quality:</b> Material officially sponsored by a professional, public, or private organization or a government agency; reasonably thorough and appropriate systematic literature search strategy; reasonably consistent results, sufficient numbers of well-designed studies; evaluation of strengths and limitations of included studies with fairly definitive conclusions; national expertise clearly evident; developed or revised within the past five years</p> <p><b>C Low quality or major flaws:</b> Material not sponsored by an official organization or agency; undefined, poorly defined, or limited literature search strategy; no evaluation of strengths and limitations of included studies, insufficient evidence with inconsistent results, conclusions cannot be drawn; not revised within the past five years</p>
<p><b>Level V</b> Based on experiential and nonresearch evidence Includes:</p> <ul style="list-style-type: none"> <li>• Integrative reviews</li> <li>• Literature reviews</li> <li>• Quality improvement, program, or financial evaluation</li> <li>• Case reports</li> <li>• Opinion of nationally recognized expert(s) based on experiential evidence</li> </ul>	<p><b>A High quality:</b> Clear aims and objectives; consistent results across multiple settings; formal quality improvement, financial, or program evaluation methods used; definitive conclusions; consistent recommendations with thorough reference to scientific evidence</p> <p><b>B Good quality:</b> Clear aims and objectives; consistent results in a single setting; formal quality improvement, financial, or program evaluation methods used; reasonably consistent recommendations with some reference to scientific evidence</p> <p><b>C Low quality or major flaws:</b> Unclear or missing aims and objectives; inconsistent results; poorly defined quality improvement, financial, or program evaluation methods; recommendations cannot be made</p> <p>Integrative Review, Literature Review, Expert Opinion, Case Report, Community Standard, Clinician Experience, Consumer Preference</p> <p>A High quality: Expertise is clearly evident; draws definitive conclusions; provides scientific rationale; thought leader(s) in the field</p> <p>B Good quality: Expertise appears to be credible; draws fairly definitive conclusions; provides logical argument for opinions</p> <p>C Low quality or major flaws: Expertise is not discernable or is dubious; conclusions cannot be drawn</p>

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Summarised results of the literature review according to study design/level of evidence (Figure 2.1) and the relevant JHNEBP level (Table 2.2) are displayed in Table 2.3.

**Table 2. 3: Literature search results with JHNEBP level and quality**

Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
<b>Randomised Controlled Trials</b>				
Ocelli et al., 2019	QI and benefits and effectiveness of RCA.	To assess the impact of vignette-based analysis of AEs on the safety climate	Vignette-based analysis was associated with improvement of the perception of participants regarding their institution's capacity for organizational learning and continuous improvement.	IB
<b>Quasi experimental</b>				
Bagian et al., 2011	Challenges for using RCA	To assess the effect of a non-monetary award on the improving the quality and timeliness of RCAs	The non-monetary award improved the timeliness and quality of RCAs	IIB
Braithwaite, Westbrook, Mallock, Travaglia, & Iedema, 2006	RCA, benefits and effectiveness of RCA, challenges for using RCA and questionnaire related to experiences of RCA.	To investigate the characteristics, attitudes and experiences of healthcare professionals after attending a safety improvement programme.	RCA participants reported improved skills and commitment to safety. There is a need for more support from the health system.	IIA
Cima et al., 2011	QI	To apply Lean and Six Sigma methodologies across a surgical suite to improve efficiency.	Use of Lean and Six Sigma methodologies across a increased OR efficiency and financial performance.	IIA
Hand & Seibert, 2016	RCA and benefits and effectiveness of RCA.	To describe an approach to engage nursing students in the RCA process using problem-based learning (PBL) within a senior leadership and management course	Students gained valuable experience participating in the RCA process through the use of actual medical error cases. In addition, this activity equipped students	IIA

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Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
			with essential knowledge and skills associated with the overall quality improvement process.	
<b>Cross-sectional studies</b>				
Wallace, Spurgeon, Adams, Earll, & Bayley, 2009	RCA, Benefits and effectiveness of RCA, challenges for using RCA and questionnaires related to experiences of attitudes of RCA users.	A survey evaluation of health professionals at immediately after RCA training and 6 months after RCA training	The RCA improved RCA knowledge but there is a need for further personal development and organizational support	IIA
Carter, Sidebotham, Creedy, Fenwick, & Gamble, 2014	Benefits and effectiveness of RCA	To examine the effectiveness of an innovative teaching strategy involving RCA to improve students' perceptions of their critical thinking abilities.	Analysing complex real-life clinical cases to determine a root cause enhances midwifery student' perceptions of their critical thinking.	IIA
Bowie, Skinner, & de Wet, 2013	RCA, Benefits and effectiveness of RCA, challenges for using RCA and questionnaires related to experiences of attitudes of RCA users.	To learn from reported experiences, benefits and attitudes of RCA-trained staff	Healthcare authorities need to look more critically at the system and cultural complexities that effect RCA	IIB
Smits et al., 2009	AE investigation	To determine the inter-rater reliability of descriptions, number and classification of root causes.	Use of the causal tree analysis is reliable.	IIB

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Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
Francois et al., 2018	QI, AE investigation, benefits and effectiveness of RCA and challenges for RCA.	To investigate the functioning of experience feedback committees that involve medical teams in patient safety management through RCA	Healthcare professionals adhered to the system-based approach to patient safety but there are difficulties practicing RCA.	IIB
Hooker, Etman, Westra, & Van der Kam, 2019	QI, AE investigation, RCA and challenges for RCA.	To examine if clustering of root causes can improve healthcare and patient safety.	Clustering helps to delineate a hospital-specific profile by providing detailed insight into risk factors, patterns and trends and determine the best strategy for improvement	IIA
Hagley, Mills, Shiner, & Hemphill, 2018	QI, AE investigation, RCA and benefits and effectiveness of RCA.	The objective of this study was to determine the types of AEs, root causes, and action plans for risk mitigation that exist within the disciplines of rehabilitation medicine	Based on this RCA review, the safety of rehabilitation services can be improved by implementing strong practices to mitigate risk to patients. Checklists should be considered to aid timely decision making when initiating an emergency response.	IIA
Percarpio & Watts, 2013	Benefits and effectiveness of RCA and challenges for RCA.	To review the link between RCA and patient safety in Veteran Affairs Medical Centres.	Large, high-spending VAMCs conduct more RCAs per year than smaller, low-spending facilities. VAMCs that do more RCAs develop more corrective actions. VAMCs that complete fewer than four RCAs per year have higher rates of postoperative complications. It is unclear if RCAs are associated with a functional patient safety program or directly improve patient safety.	IIA
<b>Cohort studies</b>				
Brennan et al., 1991	QI	To estimate the incidences of AEs	There is a substantial amount of injury to patients from medical management, and	IIIA

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Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
			many injuries are the result of substandard care	
Leape et al., 1991	QI	To report an analysis of adverse events and their relation to error, negligence, and disability.	Although the prevention of many adverse events must await improvements in medical knowledge, the high proportion that are due to management errors suggests that many others are potentially preventable now. Reducing the incidence of these events will require identifying their causes and developing methods to prevent error or reduce its effects	IIIA
Hibbert et al., 2018	AE investigation, RCA, benefits and effectiveness of RCA and challenges for RCA	To assess the strength of RCA recommendations and their perceived levels of effectiveness and sustainability	Only a small proportion of recommendations were strong.	IIIA
Wilson et al., 2012	QI	To assess the frequency and nature of adverse events to patients in selected hospitals in developing or transitional economies.	Unsafe patient care represents a serious and considerable danger to patients in the hospitals that were studied, and hence should be a high priority public health problem.	IIIA
Kellogg et al., 2017	RCA, benefits and effectiveness of RCA and challenges for RCA.	To examine the types of solutions proposed in RCAs over an 8 year period	The most commonly proposed solutions were weaker actions.	IIIA
<b>Ethnographic Studies</b>				
Nicolini, Waring, & Mengis, 2011b	QI, AE investigation, RCA, benefits and effectiveness of RCA	To examine the challenges of investigating clinical incidents through RCA and where the challenges originated.	RCA is considered not only as an improvement technique but also as a governance tool.	IIIA

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Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
	and challenges for using RCA.			
Iedema, Jorm, Long, Braithwaite, Travaglia, & Westbrook, 2006b	AE investigation, RCA, benefits and effectiveness of RCA and challenges for using RCA.	To assess the technique of RCA.	Investigators become engaged in the technical inquiry and in performance of new kinds of conducts and sensibilities.	IIIA
Iedema, Jorm, & Braithwaite, 2008	AE investigation, RCA, benefits and effectiveness of RCA and challenges for using RCA.	To understand the value of RCA recommendations for practice improvement purposes	Negative reviews of the improvement potential of RCA as there are too many constraints to be able to produce valuable recommendations	IIIA
Nicolini, Waring, & Mengis, 2011a	RCA, benefits and effectiveness of RCA and challenges for using RCA.	To identify the barriers to successful learning in healthcare and make recommendations for service developments.	Health service leaders need to endorse RCA and its participants, enhance staff participation in learning activities ad new analytic tools and develop capabilities in change management.	IIIA
Iedema, Jorm, Braithwaite, Travaglia, & Lum, 2006a	AE investigation, RCA, benefits and effectiveness of RCA and challenges for using RCA.	To assess the disjunction between formal RCA rules and the clinical situation.	RCA team members struggle to recognized the formal brief of RCA and their clinical intuition that the development of procedure protocols were not necessarily a good solution.	IIIA
<b>Position Statement</b>				
National Patient Safety Foundation, 2016	RCA	To ensure efforts undertaken in performing RCA <sup>2</sup> will result in the identification and implementation of system-based improvements that make patient care safer.		IVA
<b>Case reviews</b>				

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Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
Carroll, Rudolph, & Hatakenaka, 2002	QI, RCA, benefits and effectiveness of RCA and challenges to RCA	To show some of the promise of RCA and that changing the culture of an organisation adds to its benefit.	RCA is useful tool but it has challenges. Healthcare management teams need to embody root cause analysis learning.	VB
Kadivar et al., 2017	QI, AE Investigation and benefits and effectiveness of RCA	To present different aspects of patient safety in terms of RCA and risk management	Ethical and legal challenges should be taken into account with respect to patient safety	VA
Perotti & Sheridan, 2015	QI, AE Investigation, benefits and effectiveness of RCA and challenges to RCA	To review all RCA case reports involving Neurosurgical patients in New South Wales, Australia	RCAs have improved the patient safety profile but the RCA committees do not have the power to enforce recommendations or ensure compliance. Through aggregation and dissemination of RCA data, health care workers can learn from AEs and prevent future AEs from occurring.	VA
Ewen & Bucher, 2013	RCA and benefits and effectiveness of RCA	To describe the use of RCA in the home care setting.	The use and understanding of RCA is essential to healthcare risk management.	VA
<b>Literature Reviews</b>				
Peerally et al., 2017	RCA, benefits and effectiveness of RCA and challenges for RCA.	To summarise the problems with root cause analysis in order to make recommendations for improvement.	RCA is a promising technique for investigating AEs but it has a number of limitations. Implementation and evaluation of risk controls need to be more evident and the information needs to be shared with other organisations.	VA
Zastrow, 2015	QI, RCA and challenges for RCA.	To describe optimal RCA techniques from published literature	RCA is a powerful tool that can improve care if thoughtfully applied with measurable and sustainable improvements and institutional support	VA

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Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
Percarpio, Watts, & Weeks, 2008	Benefits and effectiveness of RCA.	To review the literature to assess the effectiveness of RCA in patient safety.	The limited literature on RCA effectiveness provides anecdotal evidence that RCA improves safety. And highlights the numerous theoretical problems with the analytical framework. Formal studies at the system level and cost-benefit analysis are needed to determine the effectiveness of RCA.	VA
Card, Ward, & Clarkson, 2012	Benefits and effectiveness of RCA	To examine how the healthcare sector translates risk analysis to risk control action plans and how to do better	The hierarchy of risk controls should inform risk control action plans and new tools should be developed to improve the risk control process	VA
<b>Reviews</b>				
Reason, 1990	QI	To explain active and latent failures and provides a framework to understand the dynamics of accident causation.	High reliability organisation should be research for the understanding the prevention of disasters.	
Hettinger et al., 2013	Benefits and effectiveness of RCA and challenges for using RCA.	To develop a model and toolkit to help guide RCA teams to develop sustainable and effective solutions to prevent AE recurrence.	Systems safety principled developed guidelines for RCA teams to promote system-level sustainable and effective solutions for AEs.	VA
Shaqdan et al., 2014	RCA, benefits and effectiveness of RCA and challenges for using RCA.	Provision of guidelines for performing RCA and HFMEA effectively.	RCA and HFMEA can assist in reducing errors. Leadership support of RCA and HMFEA is essential in the success of these programs.	VA
Latino, 2015	RCA, benefits and effectiveness of RCA and challenges for using RCA.	To focus on RCA processes, its results and how the results are communicated	Human decision making can be greatly improved by RCA through participation in RCA and the dissemination of results through a management system.	VB

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Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
Schriefer & Leonard, 2012	QI and benefits and effectiveness of RCA.	To provide information of the different QI tools	Information summary	VB
Brook, Kruskal, Eisenberg, & Larson, 2015	RCA and challenges for using RCA.	To illustrate the steps and tools used to perform an RCA	It is essential to perform an RCA after an AE in the environment of a culture of safety. It should focus on underlying system contributors and take into account confidentiality and emotional factors. Strategies should be put in place to mitigate AE recurrence.	VA
Boyer, 2001	AE investigation, RCA, benefits and effectiveness of RCA and challenges for using RCA.	To present strategies to make RCA meaningful and efficient.	RCA is a crucial process to improve the safety in the health care system.	VA
Karl & Karl, 2012	QI	To describe the process of root cause analysis and suggest some ways to make it more robust and helpful	RCAs can be used for any AE	VA
Pham et al., 2010	RCA, benefits and effectiveness of RCA and challenges for using RCA.	To propose adapting a risk prioritization and reduction process modeled after Commercial Aviation Safety Team	The framework seeks to improve the RCA process and provide further insights into advancing patient safety.	VA
Cassin & Barach, 2012	QI, AE investigation, RCA, benefits and effectiveness of RCA and challenges for using RCA.	To make sense of the situations behind factors and systems that are more important than a statistical count	RCA can be reductionistic but an RCA team can counteract that and engage in rich, social stimulation in the process.	VA
Balakrishnan, Brenner, Gosbee, & Schmalbach, 2019	QI, RCA, benefits and effectiveness of RCA	To investigate how RCA is used to prevent AEs and to provide strategies for the implementation of RCA	Active participation in RCA is an integral step toward creating a culture of safety and no harm.	VA

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Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
	and challenges for using RCA.			
Maamoun, 2009	QI, AE investigation and benefits and effectiveness of RCA.	To explain the facts relating to and the building blocks for patient safety, and to recognise the scope and appreciate the cost of error.	Many AEs are preventable and it calls for an orderly and comprehensive approach to patient safety.	VA
Jones & Despotou, 2016	RCA and benefits and effectiveness of RCA.	To reviews RCA techniques, using a Health Informatics example, and discusses barriers to their successful uptake by healthcare organisations.	A critical assessment to examine the uptake and evaluate the success of RCA, and other safety related techniques, within healthcare is long overdue.	VA
Klein, 2019	QI and benefits and effectiveness of RCA.	To review the basic principles of risk management, the role of the risk manager, and the importance of risk management in the patient safety movement as it pertains to obstetrics and gynecology.	Patient safety and risk reduction strategies are intertwined and all have the same goal—the safe delivery of the newborn and safe obstetrical care for the mother.	VA
Dattilo & Constantino, 2006	RCA and benefits and effectiveness of RCA.	This article discusses root cause analysis and nursing management responsibilities as they relate to wrong-site surgery.	Healthcare providers cannot operate in patient safe environments without the support of hospital administrators. By using root cause analysis tools and effective action plans with evaluation follow-up, sentinel events such as wrong-site surgery should be greatly reduced and eventually eliminated	VA
Trbovich & Shojania, 2017	RCA and challenges for using RCA.	To consider factors of an AE holistically as parts of a sociotechnical system (ie, interactions between people and technology embedded in an organisational structure).	There is a need for substantial investments in RCA.	VA
Senders, 2004	QI	To present information about RCA and FMEA	RCA and FMEA really do work	VB
Charles et al., 2016	RCA and challenges for using RCA.	To provide a structured approach on how to conduct a formal RCA.	The model provides guidance for the development and implementation of	VA

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Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
			quality improvement initiatives to reduce surgical errors.	
Card, 2017	Benefits and effectiveness of RCA and challenges for using RCA.	To present controversial topics related to efforts to improve healthcare quality, including widely recommended but deceptively difficult strategies for improvement and pervasive problems that seem to resist solution.	Other more systems-focused techniques, such as fishbone etc should be considered instead of the 5 Whys approach.	VA
Leape, 1994	QI	To describe the principles of error in Medicine and to explain cognitive errors and latent errors.	Healthcare institutions need a culture change to institutionalise safety and implement changes to reduce the number of errors in medicine.	VA
Reason, 2000	QI	To explain that the human error problem can be viewed in two ways: the person approach and the system approach to understanding these differences as they have important practical implications for coping with the ever-present risk of mishaps in clinical practice.	High reliability organisations are good examples of using the systems approach even though they are not immune to adverse events. They have learnt the knack of converting these occasional setbacks into enhanced resilience of the system.	VA
Welzel, 2012	QI	To explore and describe patient safety in a developing country.	South African healthcare is dealing with increased numbers of patients with the same or fewer resources. Patient safety is a necessity and patient care depends on many things, not just the clinician.	VA
Mengis & Nicolini, 2010	RCA, benefits and effectiveness of RCA and challenges for using RCA.	To examine how RCA is addressed as well as the challenges that are faced and how to address these challenges.	Recommendations were made to address various identified challenges to RCA	VA

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Reference	Literature theme identified	Aim/Objective	Conclusion	JHNEBP level and quality
Cerniglia-Lowensen, 2015	RCA and challenges for using RCA.	To provide an overview of the RCA process and discuss its importance of improving quality care.	If RCA is implemented properly it can reduce the number of AEs and promote patient safety.	VA
Boyd, 2015	RCA and challenges for using RCA.	To show that many causal factors can be identified by RCA but current approaches do not adequately distinguish between these causes resulting in many potential targets of intervention.	Possible concerns about RCA may be eliminated by using the methods explained.	VA
<b>Guides</b>				
Vorley, 2008	RCA	Guide to RCA		VB
Elliott et al., 2012	QI, AE investigation and RCA	To discuss the theoretical underpinnings of Reason's model and describe its application to adverse event analyses via clinical exemplars.	By using an accident causation framework such as Reason's model, adverse events may be analysed in a way that allows for the underlying causes to be isolated thus helping to improve care quality and patient safety, and prevent future adverse events.	VA
<b>Opinions</b>				
Woher, 2015	Benefits and effectiveness and effectiveness of RCA and challenges for using RCA.	To emphasise the importance of a rigorous RCA	RCA is one of the best tools to understand what, why and how and to make recommendations for improvement.	VA
Wu, Lipshutz, & Pronovost, 2008	Benefits and effectiveness of RCA and challenges for using RCA.	To evaluate RCA for effectiveness	More emphasis should be placed on understanding variations of RCA and on evaluating its effectiveness.	IVB

### 2.3.1 Quality Improvement

Quality Improvement (QI) has become an essential element for healthcare organizations due to increased government and public scrutiny, financial pressures and the complexity of healthcare (Hooker, Etman, Westra, & Van der Kam, 2019; Krause, 2017; Schriefer & Leonard, 2012). QI emphasises patient safety as there is a constant drive to upgrade the quality of patient care and ensure healthcare systems are safer for their users. Improvement in the safety culture should improve the quality of care and its outcomes (Occelli et al., 2019) but it remains one of the biggest challenges to healthcare systems (Francois et al., 2018).

The concept QI has been apparent throughout the history of medicine and nursing, evidenced by the adage of medical ethics first, do no harm, or non-maleficence (Balakrishnan, Brenner, Gosbee, & Schmalbach, 2019; Francois et al., 2018; Kadivar et al., 2017; Leape, 1994). This ethical maxim underpins the responsibility of healthcare establishments with respect to protecting their users and ensuring quality care. The principle is to improve care and increase accountability for quality by implementing incremental improvement changes and measuring the effects of the changes (Krause, 2017). These measures can be difficult to define as they could be process measures, such as compliance, or outcome measures, such as impact, which can be assessed in terms of clinical effectiveness, the financial impact and patient and family satisfaction (Schriefer & Leonard, 2012).

QI can incorporate one or more of several theories or models. Deming's model for improvement, described in Schriefer and Leonard (2012), identifies what the organization is trying to accomplish and then applies a Plan-Do-Study-Act (PDSA) cycle to implement and assess changes (Schriefer & Leonard, 2012). The Six Sigma methodology uses data collection and analysis to standardize processes and reduces variation in practice, limiting error and improving efficiency (Cima et al., 2011). The Lean methodology is another theory that focuses on improving efficiency by reducing waste and improving workflow (Cima et al., 2011). The Failure Modes and Effects Analysis (FMEA) model requires risk assessment and then the determination of actions for the reduction or elimination of risk (Senders, 2004). FMEA is similar to RCA which attempts to identify systems based flaws and to develop systems based solutions (Schriefer & Leonard, 2012). Evidence based practice and Best Practice Guidelines support QI in improving quality and safety by reducing variation and thus moderating risk (Schriefer & Leonard, 2012). A recent study has shown that a vignette-based approach to analyzing AEs is effective as it is proactive, in-depth and non-

threatening (Occelli et al., 2019). Enterprise risk management considers risks as interrelated and examines multiple categories of risk to estimate the repercussions for the organisation to improve quality management (Klein, 2019).

There are four building blocks to QI, also known as the 4 Cs, described in the literature as: Changing the culture of safety, Collecting data through incident reporting systems, Calculating the risk to patients and Clinical audits (Maamoun, 2009). Changing the culture of safety should improve patient safety as the management teams then advocate a culture of safety as a primary goal and learn from mistakes. Collecting data requires improved incident reporting which can be achieved in a setting of trust with no fear of retribution. Calculating risks and hazards can be achieved by analysing real or potential risks, using techniques such as RCA or FMEA. Clinical audits are part of quality improvement initiatives that allow for a proactive, data driven, preventative approach (Maamoun, 2009).

The last three decades have seen a heightened focus on quality and safety in healthcare. In the early 1990s, two pivotal articles were published that highlighted the high number of AEs and the excessive proportion of those that were preventable (Brennan et al., 1991; Leape et al., 1991). These studies emphasised the importance of identifying AEs, analysing the incidence of preventable errors and developing strategies to mitigate or prevent these errors from recurring (Brennan et al., 1991; Leape et al., 1991). Further published articles in the 1990s turned the tide of blaming individuals for errors, resulting in punitive action, to the wider factors relating to the systems and processes within the healthcare facilities (Leape, 1994; Reason, 1990).

Reason (1990) defined the factors contributing to error as being active factors or latent factors, or both. Active factors would be the individual at the front line, for example, the nurse. These are considered to be random or personal errors that are isolated and cannot be explained in terms of personal behaviour (Maamoun, 2009). Latent factors include aspects of the work setting or contributing factors that are not immediately associated with the AE (Balakrishnan et al., 2019), such as the ward floorplan, referred to as the 'resident pathogen' (Reason, 1990). Reason (1990) gives a further explanation of the latent factors as relating to five basic elements: decision makers, line management responsible for implementing the decision makers' strategies, a precondition that equipment is reliable, workers are skilled and activities between the workers and machines are productive, and lastly, that there are defences as safeguards to prevent injury

damage and loss (Elliott et al., 2012; Reason, 1990). Any of these elements can result in an AE and is best explained by the Swiss Cheese Model as shown in Figure 2.3 where each slice of cheese represents a defense mechanism and the resulting AE occurs when these defence mechanisms fail (Reason, 2000). The purpose of QI and AE investigation is to fill the holes in the cheese by identifying weaknesses in the system and putting plans in place for the defences to be more effective (Elliott et al., 2012; Perotti & Sheridan, 2015). For AE investigations to focus solely on the point of interaction between the patient and the healthcare worker will yield few lasting improvements as human failure is infinite (Zastrow, 2015).

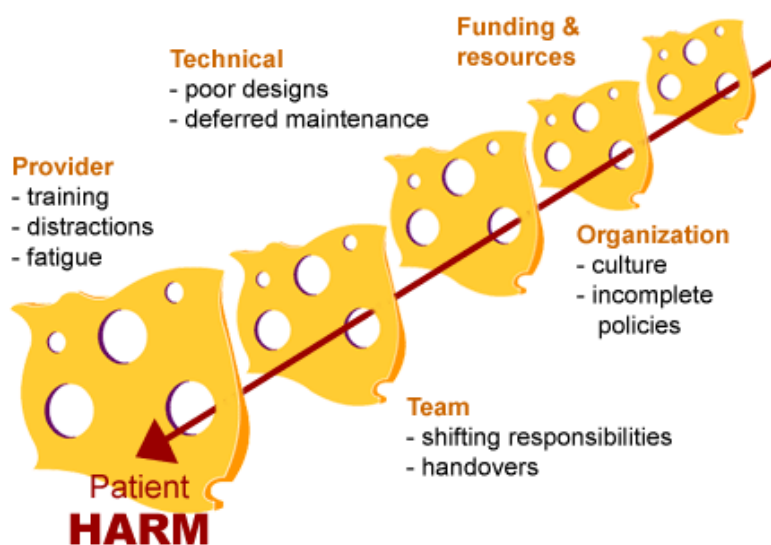


Figure 2. 3: Reason's Swiss Cheese Model (Bigam & Patterson, 2015)

Subsequent to Leape and Reason's publications (Leape, 1994; Reason, 1990), the Institute of Medicine Committee on Quality of Health Care in America published a book entitled *To Err is Human*, reporting that it is not bad people working in healthcare institutions that cause AEs, but rather good people working in a flawed system within that healthcare facility (Hagley, Mills, Shiner, & Hemphill, 2018; Institute of Medicine Committee on Quality of Health Care in America, 2000). Human beings are fallible and mistakes will occur even if unintentional and given the complex and challenging environment in which healthcare is provided, these errors still happen (Kadivar et al., 2017; Karl & Karl, 2012). It is therefore better to focus on the fact that error results from poor processes or bad systems that have not protected patients from error (Cassin & Barach, 2012). Improved systems and better processes should be put in place as defences to

protect patients from possible harm but, for this to succeed, rigorous analysis is needed to identify and mitigate the potential risk of AEs (Klein, 2019).

These changes in the approach to limiting avoidable AEs, along with a healthcare culture of valuing excellence and care for others (Carroll, Rudolph, & Hatakenaka, 2002), have led to a widespread international paradigm shift towards analysing AEs and focussing on the quality of healthcare and patient safety (Nicolini, Waring, & Mengis, 2011b). Furthermore, strategies have been adopted that necessitate complete analyses of AEs in a manner that eliminates, reduces or prevents recurrence. In South Africa the Office of Health Standards Compliance (OHSC) was instituted in terms of Section 78 of the National Health Amendment Act (No. 12 of 2013) (Republic of South Africa, 2013), to ensure that public and private healthcare establishments in South Africa comply with regulated standards (Molekoi et al., 2013). The purpose is to promote and monitor the performance of healthcare establishments against National Core Standards which define what is expected and required for health establishments to deliver safe, quality care (National Department of Health, 2011).

### **2.3.2 AE Investigation**

The World Health Organisation (WHO) reports that over 134 million AEs per year occur in Lower to Middle Income Countries, such as South Africa (National Academies of Sciences & Medicine, 2018). AEs occur in almost 10% of all health care encounters. Of this 10%, 7.4% of are lethal (Hooker et al., 2019; Perotti & Sheridan, 2015). In the United States of America (USA), AEs are the third leading cause of death (Hagley et al., 2018). There is limited data on AE rates in healthcare in South Africa specifically (Welzel, 2012). In African countries, including South Africa, the average AE rate was 8.2% in 2012, of which 83% were preventable (Wilson et al., 2012). These statistics are of concern and have led to intense efforts over the last two decades to improve patient safety in hospitals to avoid compromising patients, the risk of medico-legal action and increased healthcare costs (Francois et al., 2018; Iedema, Jorm, Braithwaite, Travaglia, & Lum, 2006a; Iedema et al., 2006b; Nicolini et al., 2011b; Perotti & Sheridan, 2015; Smits et al., 2009). Reported costs of AEs range from \$750 million in Canada to \$37.6 billion in the USA (Maamoun, 2009). There is no denying that quality improvement is vital in the current practice of medicine (Schriefer & Leonard, 2012).

Creating a safer health system is a priority for all health care professionals (Boyer, 2001). Healthcare facilities must adopt and support quality and safety initiatives to improve the awareness of AEs and to address the need for change to prevent further occurrences. The South African Department of Health acknowledged that there are significant levels of error and that this error rate can improve by identifying the causes and by redesigning health systems (National Department of Health, 2007). More recently, a South African national policy advocated for RCA use for investigating incidents to determine cause and prevent recurrence (National Department of Health, 2015).

Patient safety is grounded in medical ethics, including beneficence and non-maleficence (Kadivar et al., 2017). To uphold these principles and to protect patient safety and prevent harm, it is imperative that health care professionals should actively attempt to reduce the number of AEs. The international standard requires healthcare facilities to adopt the approach that all AE's will be identified, reported and investigated, and recommendations made to prevent recurrence (Black, 2019; Hibbert et al., 2018; Iedema et al., 2006b). Progress to improve patient safety has been slow, possibly due to the complexity of healthcare and the complexity of the sociology of healthcare organisations (Francois et al., 2018). Fortunately, there is a growing awareness that the current complex healthcare systems cannot expect people to perform perfectly all the time and that management teams must support safe practices with improved systems (Cassin & Barach, 2012; Elliott et al., 2012).

Globally, different formats of AE investigations are used, but the overarching method is that investigative teams analyse the causes and develop recommendations for change (Iedema, Jorm, & Braithwaite, 2008). Regardless of the method, AE investigation is only valuable with effective actions and sustainable system-level changes that result in avoiding hazardous situations (Balakrishnan et al., 2019; Hettinger et al., 2013). Follow through to ensure loop closure and long-term follow up is essential through dissemination of analysis conclusions following AE analyses and maintaining improvements (Balakrishnan et al., 2019).

### **2.3.3 RCA**

RCA is a structured methodology used to review AEs (Perotti & Sheridan, 2015). It was borrowed from non-medical, high risk industries, such as aviation and engineering (Carroll et al., 2002; Nicolini, Waring, & Mengis, 2011a; Zastrow, 2015), adapted by the USA Department of Veterans Affairs. It soon became a requirement for accreditation by The Joint Commission (Card, Ward, &

Clarkson, 2012; Iedema et al., 2006b; Pham et al., 2010; The Joint Commission, 2017; Zastrow, 2015). The Joint Commission is an independent, not-for-profit organization that accredits and certifies many healthcare organizations and programs in the USA. Subsequently RCA was adopted by the National Patient Safety Agency in England and Wales (Wallace, Spurgeon, Adams, Earll, & Bayley, 2009) and the National Health Service in Scotland (Bowie et al., 2013). RCA has become an extensively and internationally used process in investigate AEs (Braithwaite, Westbrook, Mallock, Travaglia, & Iedema, 2006; Card et al., 2012; Hand & Seibert, 2016; Hooker et al., 2019; Jones & Despotou, 2016; Nicolini et al., 2011a; Peerally et al., 2017; Perotti & Sheridan, 2015). It is described as a tool to improve systems, diminish harm, and prevent recurrence of AEs (Ewen & Bucher, 2013; Hooker et al., 2019; Vorley, 2008) without being punitive (Hagley et al., 2018). The premise of RCA is that systems are corrected rather than blaming individuals (Hagley et al., 2018; Hooker et al., 2019), encouraging a culture shift enabling and encouraging healthcare workers to report errors (Boyer, 2001; Perotti & Sheridan, 2015). Reporting is an essential element to map and assist with QI.

RCA offers learning opportunities in the workplace (Iedema et al., 2006a) and inculcates a culture of vigilance with an increased awareness of patient safety and an acceptance of the need to make changes. It brings discipline and predictability to the process of investigating AEs (Nicolini et al., 2011a). In the process of analysis, good process can be repeated, people involved in AEs can be supported and feedback provided to staff, patients who are involved and their family (Mengis & Nicolini, 2010).

RCA involves asking “what” and “why” to establish the causes of an AE. This process of analysis allows for the formation of effective and relevant action plans to address the cause and prevent recurrence (Boyd, 2015; Brook, Kruskal, Eisenberg, & Larson, 2015; Wallace et al., 2009). These action plans should identify the persons responsible and the timeline for its implementation, as well as how its effectiveness will be measured (Dattilo & Constantino, 2006; Hooker et al., 2019). A well thought out action plan should have specific and quantifiable outcomes and measures, providing a timeline for evaluation (Charles et al., 2016). Referring back to James Reason’s Swiss Cheese model, RCA is used as a method of filling the holes in the slices of cheese to ensure there are barriers and defences thereby avoiding the occurrence of an AE (Perotti & Sheridan, 2015). RCA aims to displace attention from individual actions and blame to fixable problems (Cerniglia-Lowensen, 2015; Elliott et al., 2012; Iedema et al., 2006a)

RCA aspires to identify the system hazards causing the AE (Kellogg et al., 2017; Trbovich & Shojania, 2017). It is a retrospective method of investigation attempting to dig to the bottom of the problem (Shaqdan et al., 2014). The process includes a sequential, step-wise approach comprising multiple steps which should include (Boyd, 2015; Cerniglia-Lowensen, 2015): (i) identifying the problem - an AE occurs which triggers the subsequent steps; (ii) searching for the causes - data should be collected from a number of sources, for example, from patient records and interviews of those involved, in order to dig down to the root causes; (iii) actions are developed to address the causes - implementations and recommendations are devised to prevent recurrence; (iv) implementations are evaluated for effectiveness (Boyd, 2015; Brook et al., 2015; Cerniglia-Lowensen, 2015; Dattilo & Constantino, 2006; Jones & Despotou, 2016; Nicolini et al., 2011b). There are variations to this approach, but however RCA is approached, it is ordered and disciplined (Nicolini et al., 2011b) and allows for a conversation space which is a meaningful way to capture the collective mindset of healthcare workers as they discuss improvement strategies (Cassin & Barach, 2012).

RCA should commence as soon as possible, ideally within 72 hours (National Patient Safety Foundation, 2016), as it will result in quicker resolution of the problem (National Patient Safety Foundation, 2016; Shaqdan et al., 2014). Timeous investigation also assists with improved recall and the availability of information (Ewen & Bucher, 2013; Iedema et al., 2008). The analysis process should be done by a team of individuals who were not involved in the AE to promote objectivity and avoid bias (Balakrishnan et al., 2019; National Patient Safety Foundation, 2016; Shaqdan et al., 2014). The team dynamic will enhance brainstorming with respect to identifying possible causes and interventions (Cerniglia-Lowensen, 2015; Vorley, 2008). The causes and interventions must be prioritised to begin with creating achievable solutions (Braithwaite et al., 2006; Mengis & Nicolini, 2010; Shaqdan et al., 2014).

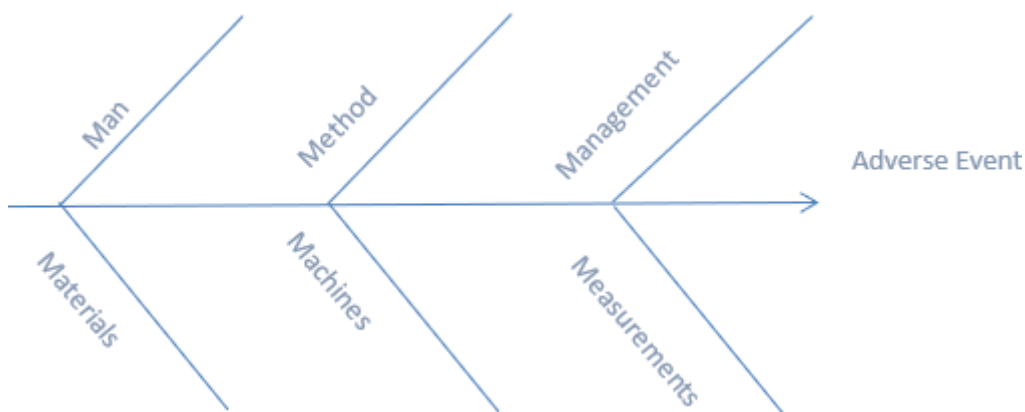
There are more than 40 (Nicolini et al., 2011a) methods and strategies for completing a RCA (Boyd, 2015; Ewen & Bucher, 2013; Shaqdan et al., 2014). Irrespective of the method employed, the five rules of causation, adapted to healthcare from the aviation industry and shown in Box

2.1, should be considered to improve AE analysis by creating standards and minimising bias (US Department of Veterans' Affairs, 2015).

1. Clearly show the cause-and-effect relationship
2. Use specific and accurate descriptors for what has occurred, rather than negative or vague words
3. Human errors must have a preceding cause
4. Violations of procedure are not root causes but must have a preceding cause
5. Failure to act is only causal when there is a preexisting duty to act

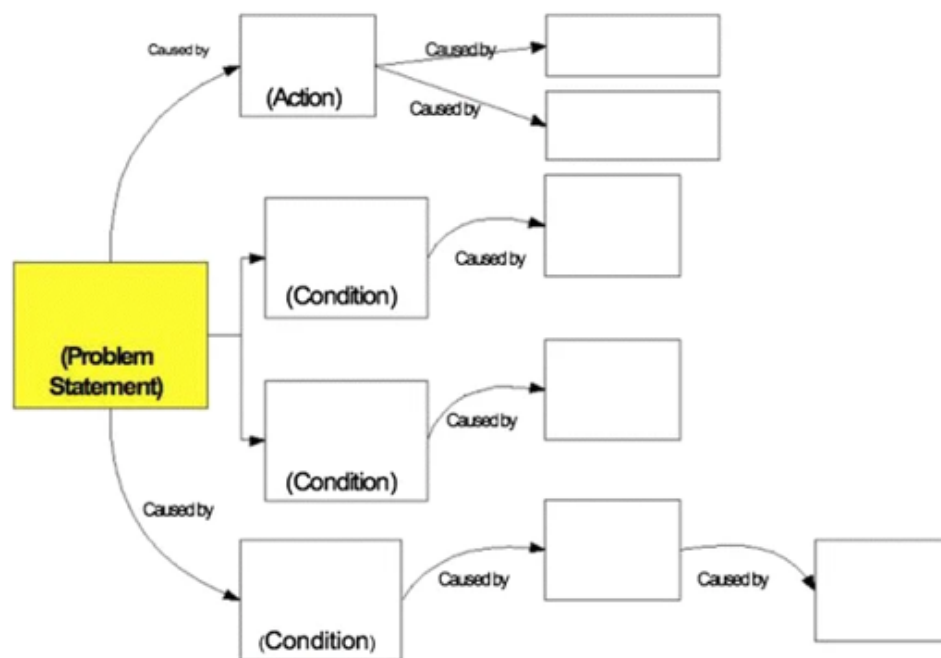
**Box 2. 1 The five rules of causation (US Department of Veterans' Affairs, 2015)**

The Joint Commission (2013) recommends that specific questions should be asked when analysing the data of an AE to identify the root causes which will then be categorised according to the framework laid out by The Joint Commission. These categories include: (i) communication factors; (ii) environmental factors; (iii) equipment, device, supply or healthcare IT factors; (iv) task or process factors; (v) staff performance factors; and (vi) team factors (The Joint Commission, 2013). Other tools have been used to analyse human and system or process errors. One such tool is the “Five Whys” approach: a consecutive series of “why” questions is asked (Brook et al., 2015; Jones & Despotou, 2016; Vorley, 2008). Another tool includes the cause-and-effect diagram, also known as the fishbone model (Figure 2.4), which is insightful and visually powerful (Balakrishnan et al., 2019). This model looks like the spine and bones of a fish, the spine reflecting the timeline leading to the AE. The bones identify the cause categories: Man, Method, Management, Materials, Machine and Measurement, for example (Jones & Despotou, 2016; Latino, 2015; Vorley, 2008).



**Figure 2. 4: Example of a Fishbone model (Balakrishnan et al., 2019)**

The “logic tree” is a cause and effect approach that poses hypotheses that need to be proved by asking “How can” (Jones & Despotou, 2016; Latino, 2015; Vorley, 2008) questions allowing for deeper analysis of causal layers (Balakrishnan et al., 2019). The cause-and-effect diagram is shown in Figure 2.5. This process should address all the communication problems, policies, rules, procedures and human error leading to the AE. The process is iterative and should continue until there is no new information or the causes identified are too remote to be valuable (Charles et al., 2016).



**Figure 2.5: Cause-and-effect diagram (Charles et al., 2016)**

Irrespective of the approach is used, the importance is that it is structured and uniform (Latino, 2015). Ultimately, the information gleaned from these methods allows the investigative team to explore contributing causes and develop an action plan in response to these (Balakrishnan et al., 2019). The Joint Commission has defined what is required to ensure that an RCA is acceptable, thorough and credible (The Joint Commission, 2017). Recommendations from RCA can be classified in terms of their strength: strong, medium and weak. Strong recommendations do not rely heavily on healthcare workers’ memories and actions and are more likely to be effective. They remove opportunities for human error by making physical changes to the work environment, improving equipment, standardizing work or removing unnecessary steps in a process (Hagley et al., 2018). Weak actions are less likely to be effective as they rely on changes in

human behaviour and require decision-making by staff in situations requiring quick thinking and when they are under pressure (Hagley et al., 2018; Hibbert et al., 2018). Recommendations that are clearly linked to the cause of the AE and that are concrete and easily understood, are more effective (Ewen & Bucher, 2013).

The National Patient Safety Foundation (2016) emphasises the actions resulting from RCA, calling their guidelines “RCA<sup>2</sup>”, Root Cause Analysis and Action (Balakrishnan et al., 2019; National Patient Safety Foundation, 2016). These guidelines consist of qualities of RCA including leadership responsibilities, RCA teams, resources, feedback and tools. They were developed in response to the lack of sustainable changes made as a result of RCA. The guideline stresses the importance of action after a RCA as system changes to the work setting will support the cognitive work of healthcare workers (Kellogg et al., 2017). Proposed actions must consider cost, resources, sustainability and barriers and it must include support from the healthcare establishment’s management team (Ewen & Bucher, 2013; National Patient Safety Foundation, 2016). The guidelines of RCA<sup>2</sup> are presented in Box 2.2.

RCA<sup>2</sup> recommendations:

1. Leadership should be actively involved in the root cause analysis and action (RCA<sup>2</sup>) process. This should be accomplished by supporting the process, approving and periodically reviewing the status of actions, understanding what a thorough RCA<sup>2</sup> report should include, and acting when reviews do not meet minimum requirements.
2. Leadership should review the RCA<sup>2</sup> process at least annually for effectiveness.
3. Blameworthy events that are not appropriate for RCA<sup>2</sup> should be defined
4. Facilities should use transparent, formal, and explicit risk-based prioritisation system to identify adverse events, close call and system vulnerabilities requiring RCA<sup>2</sup> review.
5. An RCA<sup>2</sup> review should start within 72 hours of recognising that a review is needed.
6. RCA<sup>2</sup> teams should be composed of 4 to 6 people. The team should include process experts as well as other individuals drawn from all levels of the organisation, and inclusion of a patient representative unrelated to the event should be considered. Team membership should not include individuals who were involved in the event or close call being reviewed, but those individuals should be interviewed for information.
7. Time should be provided during the normal work shift for staff to serve on the RCA<sup>2</sup> team, including attending meetings, researching and conducting interviews.
8. RCA<sup>2</sup> tools (e.g. interviewing techniques, Flow Diagramming, Cause and Effect Diagramming, Five Rules of Causations, Action Hierarchy, Process/Outcome Measures) should be used by teams to assist in the investigation of strong and intermediate strength corrective actions.
9. Feedback should be provided to staff involved in the event as well as to patients and/or their family members regarding the findings of the RCA<sup>2</sup> process.

**Box 2.2: RCA<sup>2</sup> recommendations (National Patient Safety Foundation, 2016)**

An advancement to improve the effectiveness of RCA has been the clustering or aggregation of Root Causes (Hooker et al., 2019). The sharing of this information and the planned recommendations can be disseminated to other departments or healthcare establishments, providing detailed information of risk factors and determining the best strategies for patient safety enhancement (Hooker et al., 2019) and quality improvement (Charles et al., 2016). This can be key to reducing the effort and resources required for individual RCAs, making it a more efficient process.

**2.3.4 Benefits and Effectiveness of RCA**

RCA is a vital component of QI for healthcare establishments to improve their understanding and awareness of AEs and mitigate harm to patients (Balakrishnan et al., 2019; Perotti & Sheridan, 2015). It is used to seek a truth that cannot be compromised by conflicting interpretations and challenging causes (Iedema et al., 2006b). RCA has been proven to improve the quantity and quality of causes of AEs identified as well as helping to identify many problems and solutions

(Card, Ward, & Clarkson, 2011; Card et al., 2012; Occelli et al., 2019; Wu, Lipshutz, & Pronovost, 2008). It can be applied to any identified possible or actual risk or AE (Shaqdan et al., 2014).

RCA directs analytical attention to the latent factors and errors in the system, resulting in an AE (Wu et al., 2008). This can identify the system error that could lead to an active cause, the human error aspect (Nicolini et al., 2011a). RCA can identify multiple risks that can range from work environment factors to organizational factors showing that there is rarely one causal factor, but rather a combination (Shaqdan et al., 2014). If only one cause were to be identified, the resulting action plan would be limited and unlikely to prevent recurrence of another AE (Shaqdan et al., 2014).

Healthcare workers performing RCA agree that it is a good use of staff resources (Braithwaite et al., 2006). It is an easily understood and practical tool (Balakrishnan et al., 2019) which is a comprehensive and system-based review (Klein, 2019). The positive effects of RCAs are listed as improving work practices, improving patient safety, facilitating teamwork, improving communication about patient care, improving patient outcomes and improving professional standings (Braithwaite et al., 2006). RCA practice can improve skills, knowledge and understanding of QI processes (Hand & Seibert, 2016).

Studies have shown that RCA improves both patient safety and decreases patient risk and is a critical process in quality improvement initiatives (Boyer, 2001; Dattilo & Constantino, 2006; Hibbert et al., 2018; Jones & Despotou, 2016; Klein, 2019; Maamoun, 2009; Perotti & Sheridan, 2015; Schriefer & Leonard, 2012; Wocher, 2015). It is a powerful tool for correcting the causes and not the error or mistake (Ewen & Bucher, 2013) by emphasizing the importance of unbiased investigation and the avoidance of blame (Kadivar et al., 2017; Nicolini et al., 2011b).

Retrospective studies of completed RCAs have shown RCA to have identified risks and preventative actions resulting in the correction of flaws to prevent recurrence (Hagley et al., 2018; Kadivar et al., 2017; Percarpio & Watts, 2013; Perotti & Sheridan, 2015). The ability to prevent AE recurrence proves RCA to be a proactive tool (Boyer, 2001; Ewen & Bucher, 2013; Latino, 2015). RCA may save organizations 25% to 40% of the cost resulting from morbidity and mortality of patients who have suffered an AE (Boyer, 2001; Klein, 2019).

One of the noted benefits of RCA goes beyond the realm of patient safety management. This includes the building of relationships by improved communication within the investigative team and across the multidisciplinary team (Boyer, 2001; Cassin & Barach, 2012; Iedema et al., 2006b).

It can assist with engaging health care professionals in critical analysis of their own standard of care, and that of their colleagues (Carroll et al., 2002; Cassin & Barach, 2012; Iedema et al., 2006a). This engagement can lead to organizational learning, as health care professionals learn to monitor their actions in specific situations and consciously focus and reflect on best practice (Iedema et al., 2006a; Nicolini et al., 2011a). It has been noted that using RCA as a training tool can provide a high level of critical thinking skill and can stimulate deep learning (Carter, Sidebotham, Creedy, Fenwick, & Gamble, 2014). The 5 Whys tool has been identified as a powerful didactic technique for learning about systems' safety in quality improvement by revealing hidden causes that seem remote from the event (Card, 2017). RCA can promote more trust and openness between healthcare workers and it creates a space for new discussions and reflection (Iedema et al., 2006b; Nicolini et al., 2011b). Further learning takes place when organizations share lessons, either internally or with other organizations, leading to global process and system changes (National Patient Safety Foundation, 2016; Wallace et al., 2009).

The aim of RCA is to establish the causes of an AE. The causes are focused on systems or processes within the health care facility that can be adjusted or rectified to prevent recurrence of a similar AE (Schriefer & Leonard, 2012). This focus on the system, rather than the person (Wallace et al., 2009), avoids individual punitive management, engendering a culture of trust and open disclosure (Carroll et al., 2002; Kronman, Paasche-Orlow, & Orlander, 2012; Mengis & Nicolini, 2010). The current movement is to aggregate RCAs and share the information among various health establishments (Ocelli et al., 2019; Peerally et al., 2017). This allows for a more proactive approach to AE, and reduces the individual resources required (Ocelli et al., 2019).

Evidence of effectiveness of RCA is scarce (Card et al., 2012; Latino, 2015; Mengis & Nicolini, 2010; Shaqdan et al., 2014). There is anecdotal evidence that RCAs have a positive impact on patient safety, but there is no peer-reviewed study to verify this assertion (Bowie et al., 2013; Hettinger et al., 2013; Kellogg et al., 2017; Percarpio, Watts, & Weeks, 2008; Wocher, 2015). The problem seems to be that health care facilities do not follow up on the effectiveness of the recommended interventions following a RCA and there are no tools available to assist with this (Francois et al., 2018; Hettinger et al., 2013; Jones & Despotou, 2016; Pham et al., 2010). Despite RCA asking what happened, why it happened, and what will stop it happening again, it should also ask if there has been a reduction in the associated risk (Wu et al., 2008).

### 2.3.5 Challenges of RCA

The literature reflects that using RCA is confusing, time consuming and politically risky (Boyer, 2001; Carroll et al., 2002; Wallace et al., 2009; Wocher, 2015; Zastrow, 2015). It requires people with expertise and time to complete RCA effectively, time being a significant factor evident in the literature (Bowie et al., 2013; Boyer, 2001; Braithwaite et al., 2006; Card et al., 2012; Francois et al., 2018; Iedema et al., 2008; Keating & Tocco, 2013; Pham et al., 2010; Trbovich & Shojanian, 2017). Studies have identified that it is difficult to determine the causes of an AE and developing and implementing adequate action plans are challenging (Hooker et al., 2019; Kellogg et al., 2017; Peerally et al., 2017; Percarpio et al., 2008; Pham et al., 2010). Lack of knowledge can result in poor outcome quality as the quality of a RCA is dependent on the accuracy of the input data (Carroll et al., 2002; Charles et al., 2016; Shaqdan et al., 2014). The output recommendations are often weak and unlikely to be effective and sustainable because of the lack of integration of the principles of sociology and human factors in the investigation (Hibbert et al., 2018).

RCA has been critiqued, even for its name alone, as “Root Cause” implies that there is a single causal factor of an AE (Brook et al., 2015; Peerally et al., 2017). Rather, all potential latent and active factors need to be identified. The oversimplification of RCA is compounded by the fact that some methods, for example, the five whys, are used in isolation rather than in combination with other techniques (Card, 2017). This simplification can lead to a narrative explanation rather than clinical reasoning, thus lacking interpretation of the overall system complexity (Nicolini et al., 2011a; Peerally et al., 2017). Latent factors may be overlooked or discounted due to the fact that improvement recommendations may be too complex and difficult to resolve (Nicolini et al., 2011a). On occasion, the first identified cause is where the analysis stops rather than identifying all possible causes (Trbovich & Shojanian, 2017). RCA may have aims embedded that are ambitious and ambiguous when used in healthcare practice (Iedema et al., 2006a).

Barriers to the process have been noted to include lack of resources (Trbovich & Shojanian, 2017) and data, as well as unsupportive management teams (Braithwaite et al., 2006; Francois et al., 2018; Iedema et al., 2008; Wu et al., 2008). There are limited published protocols or best practice guidelines explaining how RCA should be used, allowing it to be open to interpretation (Boyd, 2015; Card et al., 2012; Wu et al., 2008). Having introduced RCA from other industries, there is a lack of contextualising of RCA into the healthcare environment (Peerally et al., 2017). Training, re-training and a supportive management team, is required to ensure that the process achieves the

objectives intended in use of RCA (Braithwaite et al., 2006; Francois et al., 2018). Some healthcare establishments use RCA as a negative production process, where RCA outcome data are analysed to set reduced safety targets and give the impression of improving quality care (Cassin & Barach, 2012).

RCA is noted to have potential value, but it lacks customisation to healthcare, resulting in its potential remaining under-realised (Francois et al., 2018; Nicolini et al., 2011a; Peerally et al., 2017). Because RCA tools are imperfect, they can often work as a result of chance, rather than by design (Shaqdan et al., 2014).

RCA has become misused and misunderstood, impacting negatively on its effectiveness and the attitude of those involved in the process (Latino, 2015). These limitations make it challenging to conduct RCA in an effective manner (Bagian et al., 2011; Peerally et al., 2017). Investigative teams may not have the required expertise and may result in the development of a limited number of causes and superficial interventions (Pham et al., 2010). RCA teams usually comprise of healthcare workers which may limit their ability to develop effective interventions. Often solutions to problems require the expertise of a clinical engineer or a maintenance supervisor, for example (Pham et al., 2010).

Because of the complexity of RCA, reports and outcomes are delayed and may lack accuracy and rigour, thus resulting in recommendations that may vary in quality (Trbovich & Shojania, 2017) with the potential to even do harm (Card et al., 2012; Francois et al., 2018; Iedema et al., 2008; Mengis & Nicolini, 2010; Peerally et al., 2017; Shaqdan et al., 2014). Lengthy RCAs with delayed recommendations give more time for further AEs to take place (Bagian et al., 2011). Conversely, the pressure to produce quick results may focus attention on factors that are easily remedied, leading to superficial action plans to mitigate further errors (Balakrishnan et al., 2019; Nicolini et al., 2011a; Pham et al., 2010).

RCA quality depends on the expertise of the team and the information they can assimilate (Peerally et al., 2017). This information depends on the adequacy of the recording of clinical data, and the willingness and ability of the involved healthcare workers to articulate the evidence relating to the AE (Balakrishnan et al., 2019; Peerally et al., 2017). Hindsight bias (Trbovich & Shojania, 2017) and fear of retribution may compound the inability or resistance to providing accurate data to the investigators (Nicolini et al., 2011a; Peerally et al., 2017). Within the team itself, there may be cultural differences in terms of their understanding and approach to RCA

(Nicolini et al., 2011a). Further challenges may result from the influence of professional status and the resulting hierarchy where one or two clinicians dominate the process of analysis and the development of action plans (Nicolini et al., 2011a). It is even possible that RCA investigators may be vulnerable to criticism and conflict, and may lack personal control over their participation (Bowie et al., 2013). To avoid difficulties with interprofessional relationships (Braithwaite et al., 2006) and to avoid hierarchical tension, investigators may keep analyses superficial and avoid addressing socio-political and organisational issues (Francois et al., 2018). This affects the quality of the RCA recommendations as the input data is limited (Carroll et al., 2002). It is only in a nonjudgemental trusting environment that RCA is effectively conducted (Cerniglia-Lowensen, 2015).

Integral to the RCA is the need to account for clinical errors, characterised by complex social and cultural issues (Cassin & Barach, 2012). The clinical experience is dynamic, too complex to reduce it to cause and effect, thus RCA has been criticised for its reductionist nature (Cassin & Barach, 2012; Peerally et al., 2017). The impact of searching for clinical causes gives the impression that complex social and cultural problems are explained, but the particular clinical environment needs investigating itself (Cassin & Barach, 2012). Instead of identifying the latent and active factors of an AE, the results of RCA tend to be more of a simple, linear explanation (Peerally et al., 2017). Using the 5 Whys technique in RCA could lead to the identification of a single cause, which is unreliable as a tool to improve patient safety, especially within the complexity of healthcare (Card, 2017). RCA lacks the ability to identify the severity and probability of AEs, limiting the prioritisation of actions to manage potential AEs in the future (Shaqdan et al., 2014).

Politics and pressures within an organisation can hamper RCA as it has become a bureaucratic model of authentication and authority (Nicolini et al., 2011b). RCA has developed into a mechanism of monitoring, regulation and audit (Nicolini et al., 2011b). Despite the intention and philosophy of RCA requiring a systems approach, rather than improving the system, management teams often deal with problems at an individual level to manage poor performance (Kellogg et al., 2017). Healthcare organisations may not be committed to making permanent changes that are needed to reduce risk due to interdepartmental political or economic reasons (Pham et al., 2010). Often the RCA report is seen as the end-product, rather than the beginning of a learning cycle. These reports may be skewed due to the possibility of analysts attempting to protect colleagues and to avoid hierarchical tensions (Iedema et al., 2006b; Peerally et al., 2017). RCA is a delicate process which can often lead to shame, anxiety and defiance (Iedema et al., 2006b).

Organisations use RCA as a tool to appear efficient, proactive and compliant in their consensus, closure and control rather than the potential for learning (Latino, 2015; Nicolini et al., 2011b). RCA has become something that has to be done, rather than being the right thing to do, and has thus become bureaucratic (Latino, 2015; Mengis & Nicolini, 2010; Nicolini et al., 2011b). It is often used more as a reactive, rather than a proactive tool, to comply with expectations (Latino, 2015) which is contrary to the philosophy of RCA which prioritises fixing system errors to prevent harm (Kellogg et al., 2017). To recommend consequence management as part of the preventative action plan is undesirable and inadequate (Hibbert et al., 2018). Recommended actions may often not be implemented as intended as resources are limited compromising the RCA process in its attempt to mitigate risk (Pham et al., 2010).

It may be difficult to implement the recommended changes following a RCA investigation (Boyd, 2015; Perotti & Sheridan, 2015) possibly due to limited attention to the complexity of the causal factors (Cassin & Barach, 2012; Nicolini et al., 2011a) or due to focussing on easy fixes to appear compliant (Nicolini et al., 2011b; Zastrow, 2015). The RCA committee is often not in a management position, and may not feel empowered to or cannot enforce or ensure the implementation of a recommendation (Hettinger et al., 2013; Perotti & Sheridan, 2015). It is possible that the management teams themselves lack the mandate and authority to implement changes (Trbovich & Shojania, 2017).

There is also a lack of focus on the change recommendations and action plans as RCA teams tend to pay more attention to the analysis process itself (Nicolini et al., 2011a). RCA has been described as having a “tombstone” effect because it has become a procedural ritual that leaves behind a memorial to claim something has been done, and yet the recommendations may not have been implemented (Peerally et al., 2017). This is a waste of time and resources (Bagian et al., 2011; Brook et al., 2015). It is estimated that implementation rates vary between 45 to 70% (Peerally et al., 2017) due to lack of follow through and evaluation of the changes actioned (Balakrishnan et al., 2019; Nicolini et al., 2011a) as well as ineffective approaches to change (Kellogg et al., 2017).

Despite RCA being described as a tool for individual and organisational learning, poorly functioning feedback loops and mechanisms can impact on this advantage (Balakrishnan et al., 2019; Braithwaite et al., 2006; Peerally et al., 2017). There is a lack of communication about AEs within and between organisations, resulting in a siloed focus and disaggregated analyses and

limited learning opportunities from other establishments (Balakrishnan et al., 2019; Hooker et al., 2019; Nicolini et al., 2011a; Peerally et al., 2017). Furthermore, trending of AEs is often overlooked as the RCA focuses its attention on the current adverse event, rather than addressing several AEs of the same type (Nicolini et al., 2011a). A shortcoming of RCA is that it does not assess whether risks have been mitigated, possibly due to the difficulty in measuring it and that it may be costly to do so (Boyd, 2015; Pham et al., 2010). There is no experimental control to measure RCA (Cassin & Barach, 2012).

### **2.3.6 Questionnaires related to experiences or perceptions of RCA**

No studies were found in the available literature on the development and validation of a questionnaire relating to RCA. Three studies were found that investigated the experiences and attitudes of healthcare professionals after receiving safety improvement and RCA training. In the first study published in 2006 (Braithwaite et al., 2006), a questionnaire was developed to investigate the experiences of health professionals after undergoing a safety improvement programme in Australia. The questionnaire focussed on course satisfaction, skills learnt and transferred into the workplace, attitudes regarding the benefits of the safety improvement project and RCA, and the experiences when conducting RCA (Braithwaite et al., 2006). The study reported on the last two aspects. The results identified the perceived problems with RCA, variable attitudes towards RCA and the need for further training. Unfortunately, none of the authors responded to emails requesting information and a copy of the original questionnaire.

The second study in 2009, undertaken in England and Wales, included participants who had taken part in a three-day RCA training programme run by the National Patient Safety Agency (NPSA) in England and Wales (Wallace et al., 2009). The study explored the participants' knowledge of RCA, beliefs regarding RCA and reported RCA practices. This questionnaire was developed as a post-training survey and the authors reported that they had not yet proven its reliability and validity (Wallace et al., 2009). The results were very similar to the first study mentioned. The author was contacted by e-mail and the questionnaire was obtained but it was not relevant to this study as it included testing of theoretical knowledge.

In the third study, Bowie, Skinner and De Wet (2013) piloted and adapted the questionnaire from the study by Braithwaite et al. (2006). Their sample was healthcare workers who had attended RCA training by the National Health Service in Scotland (NHSIS). The results were very similar to

that of Braithwaite et al. (2006). Attempts to contact Bowie, listed as the article correspondent, via email were unsuccessful.

The studies did not address the objectives of the present study and it was therefore necessary to develop and validate a survey questionnaire to assess the attitudes, experiences and issues surrounding RCA in a local context. Patient safety studies on questionnaire development and validation are available and support the robustness aimed for in this proposed study (Reiman, Silla, & Pietikainen, 2013; Taylor, Parveen, Robins, Slater, & Lawton, 2013).

### **2.3.7 Content validity, face validity and reliability studies**

Content validity is defined as the degree to which items in a questionnaire are appropriate for and applicable to the construct being studied (Polit & Beck, 2004). It describes whether the question items are representative of the construct (Waltz, Strickland, & Lenz, 2010). This is a vital step when developing a new questionnaire (Artino, La Rochelle, Dezee, & Gehlbach, 2014).

A literature search had identified studies that validated questionnaires. Torabizadeh et al. (2017) developed a questionnaire through focus groups and literature searches (Torabizadeh, Yousefinya, Zand, Rakhshan, & Fararoei, 2017). The initial stage of their study assessed content validity using experts in the field to assess the content validity index for the individual question items (I-CVI) and the overall questionnaire in relation to the constructs (S-CVI). Face validity was assessed both quantitatively and qualitatively, but the methodology and analysis of the data is not explicit. Qualitative face validity was evaluated using face-to-face interviews but the data analysis for this stage is not articulated. Some adjustments were made before test-retest reliability was evaluated using Cronbach's Alpha.

Milliken et al. (2018) performed a study to investigate the face validity, construct validity and content validity of a scale (Milliken, Ludlow, DeSanto-Madeya, & Grace, 2018). The assessment of CVI using a panel of experts is explained. The results for face validity and reliability are well described, but the process for achieving them is not. A thorough explanation of CVI, including S-CVI and I-CVI is available in the research performed by Schilling et al. (2007) however, this study does not address face validity and reliability (Schilling et al., 2007).

## **2.4 Summary**

The literature reviewed showed conformity with respect to the background, purpose and aims of RCA. Healthcare services world-wide are making a concerted effort to address the high rate of AEs. Considerable investment has been made to show commitment to the improvement of patient safety and quality standards.

There is limited literature regarding the overall efficacy of RCA and measurement tools. Many reports reflect the complexity in completing RCA. Despite its positive effects and characteristics in recommending improvements, promoting teamwork and providing educational opportunities, it remains a process that requires management support, an advanced level of expertise and increased resources.

There is no literature on assessment of the usage of RCA in South Africa. It has been promoted by the Department of Health, but no guidelines and protocols have been disseminated. There is also limited availability of studies that investigate the practices, attitudes and experiences of those involved in RCA. This justifies the aim of the study, to develop and validate a survey questionnaire to establish current local RCA practice. This study will add knowledge to the limited available published studies on development and validation of a research instrument, and specifically related to RCA.

Chapter 3 deals with all aspects of the research process relevant to this study: study design, sampling, data collection processes, ethical considerations and data analysis for each of the four phases of the study.

## CHAPTER THREE: METHODS

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### 3.1 Introduction

This is a validation study comprising four phases each of which is described in this chapter to meet the study objectives: 1) the development of a prototype questionnaire (Appendix A) guided by a literature review; 2) assessing the validity of the content of the questionnaire by Content Validity Index (CVI) and numerical evaluation of the face validity of the questionnaire (Appendices B and C); 3) assessing the qualitative face validity of the questionnaire through cognitive interviews (Appendices D, E and F); and 4) assessing reliability of the questionnaire by test-retest reliability testing (Appendix G and H). A questionnaire was designed based on a review of the RCA literature. The questionnaire was divided into three content domains to assess how thoroughly the Root Cause Analysis (RCA) is used, perceptions relating to changes implemented as a result of RCA, and perceived barriers to RCA.

Evaluating validity and reliability is an integral part of questionnaire development (Karanicolas et al., 2009; Kazi & Khalid, 2012; Polit & Beck, 2006). A questionnaire must have been through a process of validation to show it will measure what it intends to measure (Artino et al., 2014). Reliability must be tested to show the questionnaire is consistent and stable (Karanicolas et al., 2009). Omitting these processes would result in data that cannot be trusted, which defeats the purpose and value of a study. This is particularly pertinent to a validation study.

### 3.2 Research design

A mixed methods research design was used to develop and validate the developed questionnaire to achieve the aim of the study (discussed in Chapter 1). This design draws on strengths from both quantitative and qualitative research methods and minimizes their weaknesses (Johnson & Onwuegbuzie, 2004). Following a review of the RCA literature and of questionnaire design (Phase 1), Phase 2 incorporated a quantitative process, establishing the content validity index (CVI) and face validity. As this step is insufficient in truly representing validity, a qualitative step, Phase 3, using cognitive interviewing, was employed to assess the response process validity (Willis, 2005). By assessing both quantitative and qualitative forms of face validity, the study was designed to provide rich data (Noble & Smith, 2015). Phase 4 aimed to establish the internal reliability of the questionnaire which is a necessary component of testing validity (DeVon et al., 2007). The phases of the study are represented in the diagram shown in Figure 3.1.

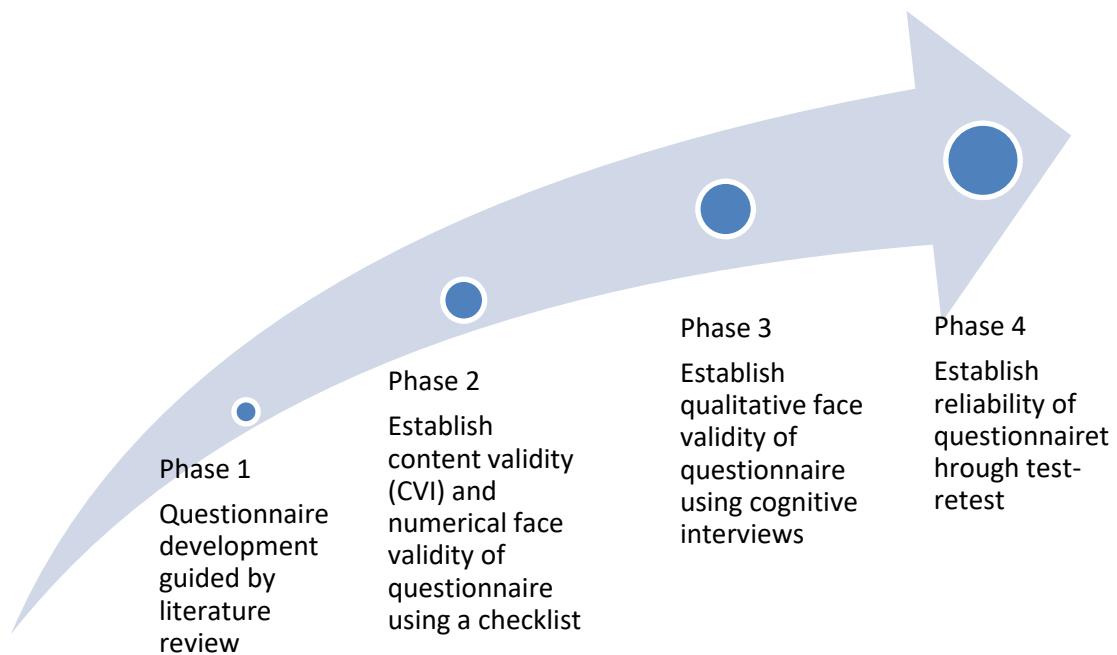


Figure 3. 1: Diagram of research design

### 3.3 Research site

Due to time and financial constraints, the five acute, private hospitals in the Western Cape were identified as study sites, located in Cape Town, Vredenburg, Knysna and Mossel Bay.

This hospital group requires each AE to be investigated using RCA. Since 2013, RCA training for Registered Professional Nurses (RPNs) has been standardised nationally within the private hospital group. The 5-hour didactic RCA training programme is also participatory, appropriate for the type of programme. It includes analysing data from anonymised case studies, applying RCA to the scenario and then developing corrective actions for that scenario. Trainees are taught to use the Fishbone method (discussed in Chapter 2) to analyse information and to determine the cause and effect of a variety of processes and situations. Learners are taught questioning and interviewing techniques to assist with collection of information.

The RCA trained RPNs are required to investigate AEs under the guidance of a Quality Manager (QM). The QM oversees safety aspects and quality standards at each respective hospital within the private hospital group. There is no evidence of RCA training programmes for RPNs in public sector hospitals nationally and specifically in the Western Cape Province and for this reason these hospitals will be excluded from this study.

The researcher works for the private hospital group and assists with training on quality initiatives and with investigating AEs. Measures were in place to ensure rigour and to avoid bias.

### **3.4 Study population**

The study population included RPNs working permanently for the private hospital group at each of the five study sites. The RPNs were required to be RCA trained. The different phases of the study utilised different sampling techniques. These techniques, and the inclusion and exclusion criteria, are described in Section 3.5 of this Chapter.

### **3.5 Data Collection Process**

#### **3.5.1 Phase 1: Questionnaire Development**

The literature review strategy described in Chapter 2 directed the construction and content of the questionnaire (Appendix A) to ensure that the constructs are clear and aligned with the evidence based RCA literature (Gehlbach & Brinkworth, 2011). The Joint Commission (2013) provides a guideline in determining whether RCA is acceptable, thorough and credible. The characteristics of RCA have been defined and have been used as a model when developing the questionnaire construct items as shown in Box 3.1.

**An RCA will be considered acceptable if it has the following characteristics:**

The analysis focuses primarily on systems and processes, not on individual performance.

The analysis progresses from special causes in clinical processes to common causes in organizational processes.

The analysis is used to repeatedly dig deeper by asking “Why?” and then, after obtaining an answer, asking “Why?” again, and so on.

The analysis is used to identify changes that could be made in systems and processes (either through redesign or development of new systems or processes) that would reduce the risk of such events occurring in the future.

The analysis is thorough and credible.

**To be thorough, the RCA must include the following:**

A determination of the human factors and other factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence.

An analysis of the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk.

An identification of risk points and their potential contributions to this type of event.

A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future or a determination, after analysis, that no such improvement opportunities exist.

**To be credible, the RCA must do the following:**

Include participation by the leadership of the hospital and by individuals most closely involved in the processes and systems being reviewed.

Be internally consistent (that is, not contradict itself or leave obvious questions unanswered).

Provide an explanation for all findings of “not applicable” or “no problem.”

Include consideration of any relevant literature.

**An action plan will be considered acceptable if it does the following:**

Helps identify changes that can be implemented to reduce risk or helps formulate a rationale for not undertaking such changes.

Helps identify, in situations where improvement actions are planned, who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.

**Box 3.1: The Characteristics of RCA (The Joint Commission, 2013)**

Next, the constructs and how they contributed to the development of the individual questionnaire sections are summarised in Table 3.1.

**Table 3. 1: Summary of constructs and literature support**

<b>Construct</b>	<b>Construct Rationale</b>	<b>References</b>	<b>Questionnaire Section</b>
RCA is approached in a manner that allows for a thorough investigation of all the root causes, both human and system causes of an AE	The literature describes RCA as being a pedantic and systematic process of investigation. There are no set guidelines or protocols as to how RCA should be done. Many RCA systems still focus on the human error rather than the system that compounded the resulting AE. It has been described as time-consuming.	(Boyer, 2001; Brook et al., 2015; Cerniglia-Lowensen, 2015; Hibbert et al., 2018; Nicolini et al., 2011a, 2011b; Peerally et al., 2017; Wu et al., 2008)	1
RCA results in recommending changes identified by the root causes of AEs. These changes are implemented to prevent recurrence of the AE.	RCA is time-consuming and difficult. The literature refers to RCA as a bureaucratic tool purely to seem compliant. These factors result in recommendations for change that are superficial and often not implemented or evaluated.	(Boyd, 2015; Francois et al., 2018; Iedema et al., 2008; Mengis & Nicolini, 2010; Peerally et al., 2017; Pham et al., 2010; Shaqdan et al., 2014; Wu et al., 2008)	2
There are significant barriers to using RCA for investigating AEs.	Investigators have reported lack of resources, particularly time, required to perform RCA. Hospital management should be supportive of this and should also represent the principles of RCA, investing into its aims and objectives, rather than using it as a punitive tool.	(Boyer, 2001; Braithwaite et al., 2006; Carroll et al., 2002; Francois et al., 2018; Hibbert et al., 2018; Iedema et al., 2008; Kellogg et al., 2017; Peerally et al., 2017; Woche, 2015; Wu et al., 2008; Zastrow, 2015)	3
Demographic data	Data used to confirm that the inclusion criteria have been met. It also assists with identifying the approach and attitude towards RCA in relation to experience and position.	(Rattray & Jones, 2007)	4

The constructs identified and supported by the literature review were combined with the Joint Commission’s (2017) definitions and characteristics of an acceptable, thorough and credible RCA. This information was used to develop the first three sections of the questionnaire. Section 4 of

the questionnaire requires the participants' demographic data (Rattray & Jones, 2007). The prototype questionnaire (Appendix A) comprised 4 sections and 36 item statements.

***Construct 1: Approaches to the use of RCA***

This construct contains 12 question items that focus on respondents' perceptions and understanding of RCA and are summarised in Table 3.2.

**Table 3. 2: Summary of the construct items in Section 1 of the Prototype Questionnaire (Appendix A)**

Question item theme	Recommendations from Literature	Item numbers
Completing the analysis as a process	<ul style="list-style-type: none"> <li>• The analysis should commence within 72 hours of identification of an AE</li> <li>• A team of people not necessarily involved in the AE should form part of the analysis</li> <li>• Feedback should be given to the relevant people involved in the AE</li> </ul>	1.8 1.10 1.11
Thorough analysis of the possible root causes	<ul style="list-style-type: none"> <li>• All possible causes of the AE should be identified</li> <li>• The investigator(s) should continue to look for all root causes by repeatedly asking "Why?"</li> </ul>	1.2 1.3 1.6 1.7
Root Causes are both human and system related	<ul style="list-style-type: none"> <li>• The principles of RCA acknowledge that AEs are not caused by human error alone, therefore systems and processes should be in place to prevent these from occurring</li> </ul>	1.1 1.4
Perceptions of RCA	<ul style="list-style-type: none"> <li>• RCA is difficult and time-consuming</li> <li>• Investigators of AEs require training and critical thinking in order to analyse and make deductions</li> </ul>	1.5 1.9

***Construct 2: Implementing changes as a result of RCA***

Construct 2 consists of 8 question items assessing the ability of investigators to develop, implement and evaluate action plans that should prevent recurrence of AEs. These items are summarised in Table 3.3.

**Table 3. 3: Summary of the construct items in Section 2 of the Prototype Questionnaire (Appendix A)**

Question item theme	Recommendations from Literature	Item numbers
Recommendation of system changes	<ul style="list-style-type: none"> <li>The value of RCA is that it is a tool that not only identifies the root causes, but also makes recommendations to prevent the recurrence of the AEs</li> </ul>	2.2
Action plans to implement changes	<ul style="list-style-type: none"> <li>Acceptable action plans should identify the changes that could reduce risk, or supports reasons why the actions should not be implemented</li> <li>These action plans identify who will be responsible, what the timeframe is and how the outcome will be measured</li> </ul>	2.1 2.3 2.5 2.7 2.8
Recommended changes are implemented	<ul style="list-style-type: none"> <li>For the prevention of recurrence of an AE the recommendations ought to be implemented</li> </ul>	2.6
Effectiveness of RCA	<ul style="list-style-type: none"> <li>RCA's effectiveness has been difficult to measure</li> <li>The action plan should identify how the effect of the changes will be measured</li> <li>Evaluation of the outcomes is an essential step in RCA</li> </ul>	2.4

***Construct 3: Barriers to RCA***

Construct 3 contains 7 question items that aim to evaluate perceptions of the potential challenges for investigators that have been placed towards the end of the questionnaire, as it might raise some level of anxiety and discomfort (Rattray & Jones, 2007). The items are summarised in Table 3.4.

**Table 3. 4: Summary of the construct items in Section 3 of the Prototype Questionnaire (Appendix A)**

Question item theme	Recommendations from the literature	Item number
Guidelines for RCA	<ul style="list-style-type: none"> <li>RCA was introduced into healthcare services without clear protocols and guidelines defining how the process should be fulfilled. This has resulted in varying levels of quality of RCA and implementation of the recommendations for change</li> </ul>	3.1
Resources available to investigators	<ul style="list-style-type: none"> <li>Studies have shown that investigators perceive a lack of resources as a challenge</li> <li>RCA is time consuming, and this is supported in the literature as being the most reported challenge</li> </ul>	3.2 3.4
Management support	<ul style="list-style-type: none"> <li>Management should be supportive of RCA, and provide the resources required to follow the process accurately and thoroughly</li> <li>Management should review its RCA performance annually to ensure correct implementation and practice</li> <li>Management should be aligned with and adhere to the principles of RCA</li> <li>Regular feedback should be provided to investigators on their performance</li> </ul>	3.3 3.5 3.7 3.8

***Construct 4: Demographic data***

This construct consists of 9 close-ended questions that explore the respondents’ level of experience and their possible exposure to RCA as a result of their position, their hours of work and whether they currently do day duty or night duty shifts. The demographic question items were placed at the end of the end of the questionnaire to prevent bias or acquiescence during the completion of the preceding sections (Rattray & Jones, 2007). The demographic data can facilitate further analysis of the responses if the validated questionnaire will be used in a further study.

Each question item in the questionnaire was worded in an as simple, clear and understandable format as possible to provide the best quality data (Kazi & Khalid, 2012). Double-barreled and double negative worded items were avoided (Artino et al., 2014). Items were worded both positively and negatively to avoid compliance bias (Rattray & Jones, 2007). The order of the

sections was considered carefully and, as stated previously, as perceptions of barriers to RCA might be the most controversial or challenging, these questions were placed later in the questionnaire (Rattray & Jones, 2007).

Validation and reliability processes are described next.

### **3.5.2 Phases 2 to 4: Validation and reliability processes**

A summary of the research activities, sampling methods, potential participants and the rationale for selection of participants prior to data collection for each of the validation processes is presented in Table 3.5. These phases of the research included the following methodologies: i) Evaluation of the content and quantitative face validity of the questionnaire, ii) evaluation of face validity through cognitive interviewing, and finally iii) the assessment of reliability using test-retest.

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**Table 3. 5: Summary of the research validation activities for Phases 2-4**

Research Activity	Sampling method	Inclusion/exclusion criteria	Respondents/ Participants	Rationale
Validation of Questionnaire (CVI and numerical face validity) (Phase 2)	Convenience sampling	<u>Inclusion criteria:</u> <ul style="list-style-type: none"> <li>• QMs (RPNs) <ul style="list-style-type: none"> <li>➤ Permanently employed</li> </ul> </li> </ul> <u>Exclusion criteria:</u> None	5 QMs (one QM is employed by each of the 5 hospitals in the Western Cape)	Expert knowledge of the RCA process: QMs train RPNs on the RCA process and oversee investigation of AEs. Purposive sampling is used because there are only 5 QMs, one at each hospital.
Cognitive interviews (for qualitative face validity) (Phase 3)	Purposive sampling	<u>Inclusion criteria:</u> <ul style="list-style-type: none"> <li>• Clinical RPNs: <ul style="list-style-type: none"> <li>➤ Trained in the RCA process</li> <li>➤ Have conducted investigations using RCA</li> <li>➤ Permanently employed</li> </ul> </li> </ul> <u>Exclusion criteria:</u> <ul style="list-style-type: none"> <li>• Unavailable to participate</li> <li>• Participated in CVI process</li> </ul>	5 Clinical RPNs per iteration	Willis (2005) recommends this number of participants per iteration for a small scale study. The selected 5 hospitals require investigation of reported AEs by RPNs trained in the RCA process. Purposive sampling will ensure rich, thick data (Morse, 2015).
Reliability (Test-retest) (Phase 4)	Random sampling	<u>Inclusion criteria:</u> <ul style="list-style-type: none"> <li>• Clinical RPNs: <ul style="list-style-type: none"> <li>➤ Trained in the RCA process</li> <li>➤ Have conducted investigations using RCA</li> <li>➤ Permanently employed</li> </ul> </li> </ul> <u>Exclusion criteria:</u> <ul style="list-style-type: none"> <li>• Unavailable to participate</li> <li>• Participated in CVI process</li> <li>• Participated in Cognitive interviews</li> </ul>	10 Clinical RPNs (n = 10/52 = 19.2%)	The selected 5 hospitals require investigation of each reported AE by RPNs trained in the RCA process.

The research activities for Phases 2 to 4 will be described in the following sections.

### ***3.5.2.1 Phase 2: Establishing the content validity index (CVI) and numerical face validity***

Measuring the content validity (CVI) required content experts to evaluate the prototype questionnaire. This process aims to assess if the question items are relevant to the construct being measured (Polit & Beck, 2004; Waltz et al., 2010). The content validity for the items (I-CVI) individually and the content validity index for scales (S-CVI), assessing the overall questionnaire, are essential for this phase (Polit & Beck, 2006). The quality of the questionnaire was improved by the inclusion of this step (Polit & Beck, 2006).

The experts were chosen based on their expertise and experience of the construct (McKenzie, Wood, Kotecki, Clark, & Brey, 1999; Schilling et al., 2007). For practical reasons, these experts had to be accessible to the researcher and willing to participate (McKenzie et al., 1999). The experts were required to rate the clarity and relevance of the question items (Milliken et al., 2018). There is limited agreement in the literature with respect to the number of experts required to ensure consensus, but a minimum of 5 is recommended to overcome possible agreement inflation (Lynn, 1986).

A Likert-type scale was used to rate the relevance of each item. This scale was selected for its usability and adaptability (McCoach, Gable, & Madura, 2013). A 4-point scale was used as recommended to avoid an indecisive middle score (Lynn, 1986). The scale rating includes 4 = highly relevant, 3 = quite relevant, 2 = somewhat relevant, and 1 = not relevant (Appendix C). A comments section was included to provide qualitative data that enriched the quantitative data obtained (McKenzie et al., 1999). The addition of free text permitted explanation of concerns relating to the question items, allowing for critical decisions regarding altering, keeping or discarding of items (McKenzie et al., 1999; Rattray & Jones, 2007).

The appearance and style of the questionnaire, as well as the terminology and structure of the question items, has a direct effect on the responses and the time needed to complete the questionnaire (Kazi & Khalid, 2012). The expert questionnaire included numerical assessment of face validity (Section 5 of Appendix C) of the questionnaire where 4 = Excellent, 3 = Good, 2 = Needs Improvement and 1 = Unsatisfactory. This included the layout, clarity, font type and size, readability, sequence, wording, terminology and appearance of the questionnaire. There was a column for comments to indicate if an aspect of the construct is not represented well or whether rewording or rephrasing is required (Artino et al., 2014).

### *3.5.2.1.1 Population and Sampling*

Non-probability convenience sampling was used in selecting the experts for this phase of the study. Convenience sampling is described as being quick and inexpensive as the experts were selected according to their availability and accessibility (Elfil & Negida, 2017).

#### **Inclusion Criteria**

The population included RPNs in the role of Quality Managers and part of the Hospital Management Committee (MANCO). They are responsible for RCA training of the staff and for overseeing the investigation of AEs that occur. Due to their experience in RCA, they were considered to be suitable experts for the study. Each of the sites identified for this study as described in Section 3.3, employs a Quality Manager. The Quality Manager at each site was requested to participate in phase 2 of the study. The Quality Managers are known to the researcher, as they are part of the same hospital group and we have been involved in mutual projects and training so contact details were easily available.

#### **Exclusion Criteria**

There were no exclusion criteria for respondents.

### *3.5.2.1.2 Procedure*

The Hospital Managers and the Nursing Managers of each hospital were contacted by email to ensure that they were aware of the study which had ethical clearance from the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (HREC Ref 794/2018). Each Quality Manager was contacted to request participation in the study. The prototype questionnaire (Appendix A), information sheet and consent form (Appendix B) and the content validity checklist (Appendix C) were emailed to them. The information sheet included the background and purpose of the developed questionnaire to adequately prepare them for participation (Waltz et al., 2010). Consent forms were completed and returned to the researcher to ensure adherence to the ethical requirements of research (World Medical Association, 2013).

There was a poor response to the initial communication and request with only one response. A follow up email was sent, providing more clarity and requesting participation. This is identified as a possible disadvantage of self-administered questionnaires (Kazi & Khalid, 2012). Two Quality Managers responded following the second request. It proved difficult to recruit further participants despite telephonic requests to ensure emails had been received and not to coerce

potential participants. The UCT ethics committee had approved recruitment in provinces beyond the Western Cape Province should this be necessary. The researcher then contacted Quality Managers within the private hospital group in Port Elizabeth and East London, both in the Eastern Cape Province. A completed questionnaire, along with consent, was received from the Quality Manager in Port Elizabeth. The researcher's supervisor recommended approaching a Master's-prepared RPN who had a Nursing Education qualification and who has investigated AEs using RCA was currently employed within the hospital group in the Nursing Education department.

### ***3.5.2.2 Phase 3: Establishing qualitative face validity of the questionnaire through cognitive interviewing***

As with content validity, cognitive interviewing is an evidence-based qualitative practice that assesses if a questionnaire measures what it intends to measure concerning the underpinning constructs (Willis & Artino, 2013). This process determines how potential participants would interpret the items and if that interpretation aligns with that of the researcher (Karabenick et al., 2007) for the purpose of identifying interpretation or response errors (Karabenick et al., 2007; Napoles-Springer, Santoyo-Olsson, O'Brien, & Stewart, 2006).

Despite cognitive interviews being logistically complicated, requiring face-to-face contact at a variety of research sites, they provide clarification of interpretation and responses (Kazi & Khalid, 2012). The interviewer does not necessarily have to be trained and skilled in interviewer techniques as a scripted, semi-scripted or improvised structure can be used (Beatty & Willis, 2007).

The paradigms of cognitive interviewing are described as Thinking-aloud and Probing (Artino et al., 2014; Beatty & Willis, 2007; Willis & Artino, 2013) and the techniques adopt the approach that a series of cognitive processes take place when responding to question items. These steps include comprehension of the question item, retrieval of information from memory, judgement dependent of comprehension and retrieval and the selection of the response (Tourangeau, Rips, & Rasinski, 2000). Any of these steps can be difficult, therefore using a scripted think-aloud and improvised prompting can elicit understanding of the problems and attempt to address these problems and difficulties (Artino et al., 2014).

Think-aloud interviewing requires the participant to verbalize their thought processes when attempting to score a question item. This avoids participant bias as they are not directed by the interviewer (Willis & Artino, 2013). Participants can be asked questions such as "tell me what you

are thinking” (Beatty & Willis, 2007). Pure think-aloud techniques do not require prompting as this is disturbing to the natural thought processes. The addition of probing though can make the interview more conversational and natural rather than arduous and uncomfortable (Artino et al., 2014; Beatty & Willis, 2007).

Verbal probing is valuable in producing more detailed information from the participant. These can be developed and structured prior to the interview (proactive probes), or during the interview process in response to the participant’s behavior (reactive probes) (Willis & Artino, 2013). Probing can take place concurrently as the participant responds to the question item or retrospectively at the end of the questionnaire. The latter lends itself to potential recall bias (Drennan, 2003). A combination of these timings for probing would be less disruptive, as the interviewer can probe the participant after each question item has been answered, before progressing to the next question item (Watt et al., 2008).

#### *3.5.2.2.1 Population and sampling*

The population included RPNs who are involved in RCA. Purposive sampling was used because the cognitive interviewing process requires verbalizing of thoughts and articulate candidates were required. An appropriate sampling included RPNs who are confident and capable of reflection and verbalisation. The sample was thus based on the researcher’s preferences and expectations (Van Hoeven, Janssen, Roes, & Koffijberg, 2015). Purposive samples are sufficiently representative of the population (Van Hoeven et al., 2015). Including participant that can participate valuably in the cognitive interviews will produce thick, rich data.

The adequate sample size for cognitive interviews is not well defined in the literature (Beatty & Willis, 2007; Morse, 2015). Five to fifteen interviews are required until no new problems have been identified, question items have been revised and problems have been eliminated (Conrad & Blair, 1996; Willis, 2005). Five candidates were selected by the researcher, supported by Willis & Artino (2013).

#### **Inclusion Criteria**

The population for selection included RPNs who are trained in RCA and are involved in AE investigations using RCA. Lists of potential participant were provided by the Quality Managers from each of the five hospitals. Quality Managers advised who would be most suitable to participate in the interviews: those who were confident and articulate. The selection of

candidates by the Quality Manager resulted in all potential participants interviewed being Unit Managers who are regularly using RCA to investigate adverse events and thus knowledgeable of the process.

#### **Exclusion Criteria**

Any candidate who was not available during the time of the interview process was excluded. This was problematic as the interviews took place over December and January and the identified candidates at the more remote sites (Mossel Bay and Knysna) were on annual leave at the time.

#### *3.5.2.2.2 Procedure*

Invitations to the participants were sent by email directly to the Unit Managers and followed up telephonically or face-to-face. The email outlined the interview process. Interviews were set up at mutually convenient times. Before commencement of the interview, the researcher provided information including the background and purpose of the study, the developed questionnaire and the interview process, as guided by the information sheet (Appendix D) (Waltz et al., 2010). Consent forms were completed to ensure adherence to the ethical requirements of research (World Medical Association, 2001).

The interviews, structured according to Appendix F, were voice recorded on the interviewer's Voice Memos application on a mobile phone, and field notes were taken, written on the interview guide (Appendix F) during the interview. The initial strategy was to ask the participants to read each question item aloud and thereafter were asked to explain in their own words what they understood, how they could rephrase the question item and how they would rate the question item on a 5-point Likert scale. They were then asked to describe what was being asked in Sections 1, 2 and 3. Between each section, after they had described it, probing questions such as "why did you say...", "tell me more" and so on to elaborate on their understanding.

At the end of the interview, the problems participants encountered with the revised questionnaire were summarized and checked to confirm correct interpretation by the researcher. The recommendations for alterations were agreed upon before concluding the interview and the revised questionnaire was amended accordingly

### ***3.5.2.3 Phase 4: Establishing reliability of the questionnaire***

The fourth phase of the study involved pilot testing the amended questionnaire following analysis of the data from Phases 2 and 3.

Establishing reliability requires a sample of the population completing the questionnaire and then repeating the same process after an interim period to evaluate variance of results (Bartlett & Frost, 2008; Karanicolas et al., 2009). The variance indicates the stability of the question items and the scale, thus identifying further changes that may be required (Artino et al., 2014).

#### ***3.5.2.3.1 Population and sampling***

Random sampling was used in this phase of the study to ensure heterogeneity (Bartlett & Frost, 2008). Ten percent of the total population is considered an adequate number for this phase of the study (Brink, Van der Walt, & Van Rensburg, 2006; Hertzog, 2008). The population (N=52) comprised RCA trained RPNs from the 5 research sites. A sample size of 5-6 is considered adequate based on this, but a random sample of n=20 respondents was selected in anticipation of expected attrition (Brink et al., 2006).

#### **Inclusion Criteria**

The population for selection included RCA trained RPNs involved in AE investigations using RCA. Lists of potential respondents were provided by the Quality Managers from each of the five hospitals. The population data was captured on Excel spreadsheets (2016 Version 1803) so that a random selection of potential respondents using the RANDBETWEEN function.

#### **Exclusion Criteria**

Any RPN that had participated in the cognitive interview phase or was unavailable at the time of the study was excluded.

#### ***3.5.2.3.2 Procedure***

All potential respondents were sent a direct email requesting their participation. This email included the information sheets with consent forms (Appendix H), along with the revised questionnaire (Appendix G). The information sheet included the background and purpose of the questionnaire to adequately prepare them for participation (Waltz et al., 2010). Consent forms were completed and returned to the researcher to ensure adherence to the ethical requirements of research (World Medical Association, 2013). The questionnaire was self-administered by

respondents via email (Time 1) and returned to the researcher within 4 days. Two weeks later (Time 2) the same questionnaire was sent to the same respondents and returned to the researcher. The Quality Managers confirmed that in the interim 2-week period, the respondents did not have any further RCA training or input.

### 3.6 Data analysis

This section describes the data analysis processes used in the different phases of the study. CVI ratings of the questionnaire by each respondent, including numerical assessment of its face validity, (Appendix C) were entered into a password protected Excel spreadsheet, cleaned and imported into a file in the Statistical Package for the Social Sciences (SPSS) version 25 (IBM Corp.) for analysis. The Likert scale of the prototype questionnaire is ordinal level data so a median was calculated for each item statement. However, a proportion, percentage, mean and standard deviation can be calculated for the number of ratings of 3 or 4 of the total number of item statements. An overview of the statistical analyses can be seen in Table 3.6.

**Table 3. 6: Summary of data analysis processes**

Study Phase	Scale of Measurement	Data	Statistical analysis
Content validity (phase 2)	Likert-type scale 4 = highly relevant, 3 = quite relevant, 2 = somewhat relevant, and 1= not relevant	Ordinal	Frequency, percentage, proportion, median (IQR), mean (SD) for number of items
Numerical face validity (phase 2)	4 point ordinal scale: 4 = Excellent, 3= Good, 2 = Needs Improvement and 1 = Unsatisfactory.	Ordinal	Frequency, percentage, proportion
Face validity (phase 3)	Qualitative	n/a	Analysis through coding
Reliability (phase 4)	Likert-type scale where 5 = Strongly Agree. 4 = Agree, 3 = Neutral, 2 = Disagree and 1 = Strongly disagree	Ordinal	Weighted Kappa

#### 3.6.1 Phase 2: Data analysis process for assessment of CVI and numerical face validity

The CVI was assessed in order to determine if each question item in the prototype questionnaire was relevant. The percentage of agreement was calculated to identify the average congruence of each item (Polit & Beck, 2006). Item-level CVI (I-CVI) was computed by the number of experts rating each item according to the Likert-type scale as 3 = Quite Relevant and 4 = Highly Relevant. As the sample size was small (n = 5), a preset I-CVI was set at  $\geq 70\%$  agreement (Guttman, Razzaq, Lindsay, Zagorski, & Anderson, 2006).

While this proportion focusses on the individual question items, the scale-level CVI (S-CVI) should also be assessed (Polit & Beck, 2006). S-CVI evaluates the proportion of items given the rating of 3 = Quite Relevant and 4 = Highly relevant, thus calculating the average item quality and the overall validity of the items with respect to the construct (Polit & Beck, 2006).

The median and mean ratings of the experts for each question item rated 3 = Quite Relevant and 4 = Highly Relevant was calculated to establish the central tendency or the most typical or average scores (Brink et al., 2006). An excerpt of the CVI evaluation checklist is shown in Table 3.7.

**Table 3. 7: Excerpt of the CVI evaluation checklist (n=5 respondents)**

Item	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Number (%) raters scoring 3 or 4	Median score
1.1	My analysis of root causes focuses primarily on systems and processes	4 80%	0	1 20%	0	4/5 (80)	4
1.2	I do not identify the risk factors leading to the adverse event	4 80%	1 20%	0	0	5/5 (100)	4
1.3	I do not repeatedly dig deeper by asking "Why?"; then, when answered, "Why?" again, and so on	4 80%	1 20%	0	0	5/5 (100)	4
Total number of items with this score amongst 180 ratings (4, 3, 2, 1)							
Median of items with this score (IQR)							
Mean of items with this score (SD)							

There is not much information in the available literature about the analysis of numerical data for face validity. The proportion of agreement was established by calculating the percentage of raters that scored face validity as 1 = unsatisfactory, 2 = needs improvement; 3 = Good and 4 = excellent. This will calculate the average item quality. An excerpt of the face validity assessment form is shown in Table 3.8.

**Table 3. 8: Excerpt of the face validity assessment form (n=5 respondents)**

	Excellent 4	Good 3	Needs improvement 2	Unsatisfactory 1
Questionnaire layout	4 (80%)	1 (20%)	0	0
Questionnaire clarity	2 (40%)	2 (40%)	1 (20%)	0
Total number of items this score amongst 5 raters	30 (67%)	12 (26.7%)	3 (6.7%)	0

### **3.6.2 Phase 3: Data analysis process for assessment of data from cognitive interviews for qualitative face validity**

The interviews were transcribed and checked before analysis. The transcriptions, along with the field notes, were analyzed to identify the common issues with question items, format, instructions and response scales (Napoles-Springer et al., 2006). Analysis of the transcribed qualitative data from the cognitive interviews allowed for classifying of the identified problems with the questionnaire items (Conrad & Blair, 1996). This was done by reviewing all items and responses to ascertain the respondents' understanding and their ability to respond. Knafl et al (2007) describe that this analysis of the qualitative data would identify limited applicability, unclear reference and perspective, and problems with wording. Thus it gave an overview of interpretation and problems.

The item-by-item analysis highlighted common issues, which were then coded to rank the frequency of the issue to decide whether to retain, rephrase or remove a question item (Napoles-Springer et al., 2006). It was important for each participant to understand each item the same way and to interpret it as the researcher intended it to be interpreted (Artino et al., 2014). Using this process, the questionnaire was amended prior to Phase 4 (Appendix G).

### **3.6.3 Phase 4: Data analysis process for assessment of intra-rater reliability of the prototype questionnaire**

The weighted kappa coefficient was used to estimate the internal reliability and stability of the questionnaire by establishing the proportion of consistency (Brown, 2002). Data for respondents' test-retest was captured electronically on an Excel spreadsheet for analysis using the weighted kappa statistic appropriate for categorical data such as Likert scale scores. Karanicolas et al. (2009) indicate that a reliability coefficient is rated from 0 to 1.0, with 0 indicating that the

variability is due to error. Rattray and Jones (2007) recommend a reliability coefficient of  $\geq 0.7$  for a developing questionnaire. A higher value indicates a greater the level of reliability, with 1.0 indicating perfect reliability (Karanicolas et al., 2009). The proportion rating ranges between 0.00 and 1.00, where 0.00 is no variance is consistent, and 1.00 is all variance is consistent. A coefficient of  $\geq 0.70$  is satisfactory for developing questionnaires (Rattray & Jones, 2007), thus a preset agreement of  $\geq 70\%$  was established for reliability. The responses from Time 1 and Time 2 were captured on a Statistical Package for the Social Sciences (SPSS) version 25 (IBM Corp.) file.

The data were interpreted using the classification of Cohen's Kappa (May, Chance-Larsen, Littlewood, Lomas, & Saad, 2010) shown below:

Cohen's Kappa	Classification of agreement
0.00-0.2	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Almost perfect agreement
1.0	Perfect agreement

(May et al., 2010)

### **3.7 Ethical considerations**

This study involved healthcare workers, specifically RPNs, and thus needed ethical approval before implementation (Polit & Beck, 2010) to ensure that the principles of the Declaration of Helsinki are upheld (World Medical Association, 2013). Ethical approval was granted by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (HREC Ref 794/2018) (section 3.7).

All persons were shown respect, thereby protecting them from harm. No harm was intended in the conduct of this study. It was overseen by an experienced researcher and supervisor of postgraduate degrees. A questionnaire is less intrusive than observation, but there was a possibility that it, along with the interviews, might cause anxiety. To reduce the likelihood thereof, the researcher adhered to the participants' right to confidentiality, privacy, voluntary participation and anonymity. Only the researcher had access to the participants' codes and corresponding names, which, along with the data, was stored on a password-protected computer. Only the researcher had knowledge of this password and the personal computer was kept in a locked office.

The study involved participants within one private hospital group, therefore the likelihood exists that some participants may have known each other and the researcher. Every attempt was made to conceal the identity of participants, but they may have chosen to reveal their decision to participate or not to each other.

There were no foreseeable risks to participating in this study. However, a potential burden may have been associated with an extra workload as participation is not part of the job requirement and will probably take place outside of working hours. This may have resulted in stress and tiredness.

There were no immediate benefits for participants. However, a valid questionnaire is essential for accurately assessing current practice of conducting RCAs as measured against international criteria. With further research, the intention is that data gathered by means of a valid questionnaire will lead to an improvement in quality of care, patient safety and health outcomes within the hospital group. Potential participants were not coerced into participating in the study but may have felt a sense of altruism in having assisted in a patient safety study.

The healthcare establishment ethics' department granted permission for the study to take place at its facilities. The healthcare establishments themselves were approached for permission to gain access to potential participants for all stages of the study. Anonymity was assured. Potential participants were given the relevant information regarding the study and the opportunity to ask questions, after which they were invited to participate voluntarily in the study. Once participants agreed they were requested to sign the attached consent form (Appendix B, E and H) respectively.

The researcher alone had access to the data gathered during the study that was stored on a password-protected personal computer. To ensure anonymity, participants had codes and only the researcher had access to the data relating to the participant linked to the code. The stored data will be destroyed 5 years after the completion of the study (2025) and deleted from storage devices.

On completing the study, the intention is to present the results as a poster and/or presentation at a conference and publish in a peer-reviewed journal. Study results have been made available to the participants and research hospitals as an executive summary. The participants may request

more detail of this study which will be made available while maintaining anonymity and confidentiality.

### **3.8 Summary**

This chapter described all aspects of the research methods employed in conducting the study: research design, site and population, data collection for all four phases of the study and how the data were analysed. In Chapter 4 the data for all four phases are presented and discussed in Chapter 5 in relation to the reviewed published literature.

## CHAPTER FOUR: RESULTS

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### 4.1 Introduction

The aim of the study was to develop a survey questionnaire to establish whether the Root Cause Analysis (RCA) model and processes employed at the research setting were perceived by the users to be acceptable, thorough and credible in terms of internationally established criteria. The prototype questionnaire (Appendix A) was developed guided by the available literature as described in Section 3.5.1. It included 36 question items in 4 sections: Section 1: Approaches to the use of RCA, Section 2: Implementing changes as a result of RCA, Section 3: Barriers to RCA and Section 4: Demographic data.

All sections of the questionnaire were then tested for content validity (CVI), face validity through cognitive interviews and reliability through test-retest methodology. The results of these tests are described in this chapter.

### 4.2 Objective 1.5.2: To assess content and numerical face validity

#### 4.2.1 Experts' opinion of content validity index (CVI)

Content validity measured how well the question items represented RCA: its process, purpose, action plans, and perceived barriers. Experts in the field who assessed the content validity comprised of four Quality Managers and one Registered Professional Nurse (RPN) with a Master's degree who is knowledgeable on RCA. They evaluated each item on the questionnaire with regard to the degree to which the variable tested was represented, as well as the questionnaire's overall suitability for use. The pretest was used to analyse the clarity of the question items and whether the questionnaire measures the essential aspects of RCA. The experts rated the relevance of the question items to assess the content validity of each item (I-CVI) and the overall questionnaire (S-CVI). Tables 4.1-4.4 present the data from this phase of the study per section of the questionnaire. The tables display the number of ratings of relevance (4 = highly relevant, 3 = quite relevant, 2 = somewhat relevant and 1 = not relevant), the proportion and percentage of ratings of 3 and 4, and the median rating and interquartile range (IQR) appropriate for ordinal level data. A mean and standard deviation was calculated for the number of ratings of each item. This data analysis informed the decision to retain, modify or delete an item from the questionnaire, which

is also represented in the tables, as the level of agreement was preset at  $\geq 0.7$  (Guttman et al., 2006).

#### 4.2.2.1 Section 1: Approaches to the use of RCA

The results from the CVI assessment by the experts for the first section of the questionnaire relating to how RPNs approach and utilise RCA, is represented in Table 4.1. An I-CVI proportion of  $\geq 70\%$  was preset to determine if items were retained or removed (Guttman et al., 2006).

**Table 4. 1: CVI assessment for Section 1 of the questionnaire (n=5 respondents)**

Question item number	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Number (%) raters scoring 3 or 4	Median	Comment
1.1	My analysis of root causes focuses primarily on systems and processes	4 80%	0	1 20%	0	4 (80)	4	Item retained
1.2	I do not identify the risk factors leading to the adverse event	4 80%	1 20%	0	0	5 (100)	4	Item retained
1.3	I do not repeatedly dig deeper by asking "Why?"; then, when answered, "Why?" again, and so on	4 80%	1 20%	0	0	5 (100)	4	Item retained
1.4	I determine the human and other factors most directly associated with the adverse event	5 100%	0	0	0	5 (100)	4	Item retained. Expert suggestion: Consider listing the "other factors" or separating the statement out to differentiate between the factors. <i>*I determine other factors, for example, processes and procedures, most directly associated with the adverse event.</i>
1.5	It is difficult to do a thorough RCA	3 60%	2 40%	0	0	5 (100)	4	Item retained
1.6	I believe an enquiry into all areas appropriate to the specific type of event is important	5 100%	0	0	0	5 (100)	4	Item retained

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Question item number	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Number (%) raters scoring 3 or 4	Median	Comment
1.7	I identify the potential contribution of the risks that led to the adverse event	5 100%	0	0	0	5 (100)	4	Item retained
1.8	RCA need not start within 72 hours of an adverse event occurring	4 80%	0	0	1 20%	4 (80)	4	Item retained
1.9	I am not confident of my use of RCA	4 80%	0	1 20%	0	4 (80)	4	Item retained
1.10	I provide feedback to the people involved in the adverse event	4 80%	1 20%	0	0	5 (100)	4	Item retained
1.11	It is not necessary to have an RCA team of people not related to the adverse event	4 80%	0	1 20%	0	4 (80)	4	Item retained
1.12	My analysis of Root Causes focuses on the individuals involved	5 100%	0	0	0	5 (100)	4	Item retained
Total number of items of this score amongst 60 ratings of 12 items		51	5	3	1			
Median (IQR) of items with this score		5 (1)	0.00 (1)	0.00 (1)	0.00 (0)			
Mean (SD) of items with this score		4.25 (0.622)	0.42 (0.669)	0.25 (0.452)	0.80 (0.289)			
Count scores (%) of 3 and 4 of 12 items		56 (93.33)						

Note to table: A total of five raters each scored 12 items; \* donotes question item edited

A summary of each rating presented in Table 4.1 is as follows:

Number of items with a median of 4	12 = 100%
Number of items with an I-CVI proportion $\geq 0.7$	12 = 100%
Average I-CVI	0.93
Number of items retained	12 = 100%
Number of items edited	1 = 8.3%
Number of 4 ratings	51 = 85%
Number of 3 ratings	5 = 8.3%
Number of 2 ratings	3 = 5%
Number of 1 ratings	1 = 1.7%
Number of item ratings of 3 or 4	56 (93.3)

The data in Table 4.1 reflects the experts' opinions of question items in Section 1. All items scored a median of 4 and I-CVI of above the predetermined level of  $\geq 0.7$ . The average I-CVI was 0.93. Thus all items (n=12) were retained in this section of the questionnaire. One question item was edited for clarification.

**4.2.2.2 Section 2: Implementing changes as a result of RCA outcomes**

The results from the CVI assessment by the experts for the second section of the questionnaire relating to the RPNs perception of the implementation of changes after a RCA, is represented in Table 4.2. An I-CVI proportion of  $\geq 70\%$  was preset to determine if items were retained or removed (Guttman et al., 2006).

**Table 4. 2: CVI Assessment for Section 2 of the questionnaire (n=5 respondents)**

Question Item Number	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Number (%) raters scoring 3 or 4	Median	Comment
2.1	The outcome of my analysis identifies changes that could be made in systems and processes	5/5 100%		0	0	5 (100)	4	Item retained
2.2	I have the ability to decide on the potential improvement in processes or systems	4/5 80%	1/5 20%	0	0	5 (100)	4	Item retained
2.3	The action plan I develop does not identify the changes that can be implemented to reduce risk	4/5 80%	1/5 20%	0	0	5 (100)	4	Item retained Expert suggestion: Clarify – link between the risk and the event for the statement to be complete. <i>*The action plan I develop does not identify the changes that can be implemented to reduce the risk of the adverse event investigated.</i>
2.4	I believe RCA is achieving an improvement in the quality of patient care	4/5 80%	1/5 20%	0	0	5 (100)	4	Item retained Expert suggestion: Maybe change the work achieving to “contributing”. Maybe explain what quality of patient care means. <i>*I believe RCA is contributing to an improvement in the quality of patient care.</i> Definition quality of patient care added to clarification of terms in questionnaire information

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Question Item Number	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Number (%) raters scoring 3 or 4	Median	Comment
2.5	In the action plans, I do not identify who is responsible for implementation	5/5 100%	0	0	0	5 (100)	4	Item retained
2.6	Actions I recommend are implemented	5/5 100%	0	0	0	5 (100)	4	Item retained
2.7	In the action plans, I identify when the action should be implemented	5/5 100%	0	0	0	5 (100)	4	Item retained
2.8	I identify how the effectiveness of the actions will be evaluated in the plan of action	5/5 100%	0	0	0	5 (100)	4	Item retained
Total number of items of this score amongst 40 ratings of 8 items		37	3	0	0			
Median (IQR) of items with this score		5 (1)	0 (1)	0 (0)	0 (0)			
Mean (SD) of items with this score		4.63 (0.518)	0.38 (0.58)	0 (0)	0 (0)			
Count scores (%) of 3 and 4 of 8 items		40 (100)						

Note to table: A total of five raters each scored 12 items. \* denotes question item edited

A summary of each rating presented in Table 4.2 is as follows:

Number of items with a median of 4	8 = 100%
Number of items with an I-CVI proportion $\geq 0.7$	8 = 100%
Average I-CVI	1.0
Number of items retained	8 = 100%
Number of items edited	0 = 0%
Number of 4 ratings	37 = 92.5%
Number of 3 ratings	3 = 7.5%
Number of 2 ratings	0 = 0%
Number of 1 ratings	0 = 0%
Number of item ratings of 3 or 4	40 = 100%

The data in Table 4.2 reflect the experts' opinions of question items in Section 2. All items scored a median of 4 and I-CVI of above the predetermined level of  $\geq 0.7$  with the average I-CVI was 1.0. Thus all items (n=8) were retained in this section of the questionnaire. Two question items were edited for clarification. An expert suggested clarification of terms which resulted in amendment in the Information Sheet and Consent Form (Appendices D and F).

#### 4.2.2.3 Barriers to RCA

The results from the CVI assessment by the experts for the third section of the questionnaire relating to the RPNs perception of the barriers to RCA, is represented in Table 4.3. An I-CVI proportion of  $\geq 70\%$  was preset to determine if items were retained or removed (Guttman et al., 2006).

**Table 4. 3: CVI assessment for Section 3 of the questionnaire (n=5 respondents)**

Question Item Number	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Number (%) raters scoring 3 or 4	Median	Comments
3.1	The process of identifying incidents needs to be more explicit	5/5 100%	0	0	0	5 (100)	4	Item retained Expert suggestion: Incidents / events – possibly be consistent in terminology used. <i>*The process of identifying adverse events needs to be more explicit</i>
3.2	I have adequate time to complete a thorough RCA	4/5 80%	1/5 20%	0	0	5 (100)	4	Item retained
3.3	Management is supportive as RCA is a priority for quality improvement	5/5 100%	0	0	0	5 (100)	4	Item retained
3.4	I do not have adequate resources to complete RCA	4/5 80%	1/5 20%	0	0	5 (100)	4	Item retained
3.5	There are no conflicting values within the institutional hierarchy that interfere with RCA	5/5 100%	0	0	0	5 (100)	4	Item retained
3.6	I do not get adequate feedback about how well I am conducting RCA	4/5 80%	1/5 20%	0	0	5 (100)	4	Item retained
3.7	I believe leadership should review the process of RCA annually	4/5 80%	0	1/5 20%	0	4 (80)	4	Item retained Expert suggestion: Leadership, management –

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Question Item Number	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Number (%) raters scoring 3 or 4	Median	Comments
								consistency in terminology <i>*I believe management should review the process of RCA annually</i>
Total number of items of this score amongst 60 ratings of 7 items		31	3	1	0			
Median (IQR) of items with this score		4 (1)	0 (1)	0 (0)	0 (0)			
Mean (SD) of items with this score		4.43 (0.353)	0.43 (0.535)	0.14 (0.378)	0 (0)			
Count scores of 3 and 4 of 7 items		34 (97.1)						

\* denotes question item edited

A summary of each rating presented in Table 4.3 is as follows:

Number of items with a median of 4	7 = 100%
Number of items with an I-CVI proportion $\geq 0.7$	7 = 100%
Average I-CVI	97.1%
Number of items retained	7 = 100%
Number of items edited	2 = 29%
Number of 4 ratings	31 = 89%
Number of 3 ratings	3 = 9%
Number of 2 ratings	1 = 28.6%
Number of 1 ratings	0 = 0%
Number of items rated 3 or 4	34 = 97.1%

The data in Table 4.3 reflects the experts' opinions of question items in Section 3. All items scored a median of 4 and I-CVI of above the predetermined level of 0.7 with the average I-CVI was 1.0. Thus all items (n=7) were retained in this section of the questionnaire. Two question items were edited for clarification.

#### 4.2.2.4 Demographic data

The results from the CVI assessment by the experts for the third section of the questionnaire relating to the RPNs perception of the barriers to RCA, is represented in Table 4.4. An I-CVI proportion of  $\geq 70\%$  was preset to determine if items were retained or removed (Guttman et al., 2006).

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**Table 4. 4: CVI assessment for Section 4 of the questionnaire (n=5 respondents)**

Question Item Number	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Number (%) raters scoring 3 or 4	Median	Comments
4.1	How many years and months of experience have you had as a Registered Professional Nurse?	4/5 80%	1/5 20%	0	0	5 (100)	4	Item retained
4.2	What is your current position? E.g. Unit Manager, Shift Leader etc.	5/5 100%	0	0	0	5 (100)	4	Item retained
4.3	How long have you been in that position?	4/5 80%	1/5 20%	0	0	5 (100)	4	Item retained. Expert suggestion: Specify months and years <i>*How many years and months have you been in that position?</i>
4.4	What was your previous position?	3/5 60%	1/5 20%	1/5 20%	0	4 (80)	4	Item retained
4.5	How long have you been involved in Incident Investigations?	4/5 80%	1/5 20%	0	0	5 (100)	4	Item retained. Expert suggestion: Specify months and years <i>*How many years and months have you been involved in Incident Investigation?</i> Expert suggestion from Section 3 relating to the consistency in terms resulted in the change <i>How long have you been involved in adverse event investigations?</i>
4.6	Did you attend training on Root Cause Analysis?	5/5 100%	0	0	0	5 (100)	4	Item retained
4.7	In what year did you attend the Root Cause Analysis training?	5/5 100%	0	0	0	5 (100)	4	Item retained
4.8	Are you on Day duty or Night duty?	2/5 40%	1/5 20%	2/5 40%	0	3 (60)	3	Item removed

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Question Item Number	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Number (%) raters scoring 3 or 4	Median	Comments
4.9	Are you full-time or part-time employment?	3/5 60%	1/5 20%	1/5 20%	0	4 (80)	4	Item retained
Total number of items of this score amongst 60 ratings of 9 items		35	6	3	0			
Median (IQR) of items with this score		5 (1)	0 (1)	0 (1)	0 (0)			
Mean (SD) of items with this score		4.25 (0.622)	0.42 (0.669)	0.25 (0.452)	0 (0)			
Count scores of 3 and 4 of 9 items		41 (74.5)						

\* denotes question item edited

A summary of each rating presented in Table 4.4 is as follows:

Number of items with a median of 4	8 = 88.8%
Number of items with an I-CVI proportion $\geq 0.7$	8 = 88.8%
Average I-CVI	91.1%
Number of items retained	8 = 88.8%
Number of items edited	3 = 33%
Number of 4 ratings	35 = 77.8%
Number of 3 ratings	6 = 13.3%
Number of 2 ratings	4 = 8.9%
Number of 1 ratings	0 = 0%
Number of items rated 3 or 4	41 = 91.1%

The data in Table 4.4 reflects the experts' opinions of question items in Section 4. One item (n=9) scored a median of 3, the other eight items scored a median of 4, 88.8%. Eight items resulted in an I-CVI of above the predetermined level of  $\geq 0.7$  with the average I-CVI was 0.91. One item scored and I-CVI of 0.6 and was thus removed from the questionnaire leaving 35 items for assessment of face validity by cognitive interview. Three question items were edited for clarification of the item intention, two from comments directly pertaining to the question item, and one from comment in Section 3. The number of remaining item statements was n=8.

#### 4.2.2 Experts' opinion of face validity (quantitative data)

The five experts rated the face validity of the prototype questionnaire (Appendix A). This was a numerical assessment including rating of various factors of the questionnaire as 4 = Excellent, 3 = Good, 2 = Needs improvement and 1 = Unsatisfactory. The factors assessed and the results are represented in Table 4.5.

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**Table 4. 5: Experts’ assessment of quantitative face validity (n=5 respondents)**

Face validity of the prototype questionnaire	Excellent 4	Good 3	Needs improvement 2	Unsatisfactory 1	Median	Comments	Changes made
Questionnaire layout	4/5 80%	1/5 20%	0	0	4	No comment	Nil
Questionnaire clarity	2/5 40%	2/5 40%	1/5 20%	0	3	“Rephrase some questions”	Unspecific comment: nil changes made
Font type	5/5 100%	0	0	0	4	No comment	Nil
Font size	5/5 100%	0	0	0	4	No comment	Nil
Question readability	3/5 60%	2/5 40%	0	0	4	No comment	Nil
Questionnaire sequence	3/5 60%	2/5 40%	0	0	4	No comment	Nil
Question wording	1/5 20%	2/5 40%	2/5 40%	0	3	“Reword negatively worded questions” “Minor editing suggestions given in the above sections 1-4”	Negatively worded questions maintained as per reasoning in Section 3.5.1: Phase 1: Questionnaire development. Editing made as per Tables 4.1-4.4.
Question terminology	3/5 60%	2/5 40%	0	0	4	“Consistency suggested as given in the above sections. Possibly consider including definitions of pertinent terminology prior to section 1. Also – possibly include that all sections should be completed.”	Definitions edited for clarification of terms as per Appendix E.
Questionnaire appearance	4/5 80%	1/5 20%	0	0	4	“Align tables right hand side”	Section 3 aligned to other sections.
Number of items with a median of 4							7 = 77.8%
Number of 4 ratings (n=45)(%)							30 (66.7)
Number of 3 ratings (n=45) (%)							12 (26.7)
Number of 2 ratings (n=45) (%)							3 (6.7)
Number of 1 ratings (n=45) (%)							0 = 0

The font size and font type of the prototype questionnaire was rated as excellent by all the experts. Questionnaire layout, question readability, questionnaire sequence, question terminology and questionnaire appearance were all rated good or excellent by all the experts. The comments related to question terminology identified the need to clarify terms and provide definitions in the questionnaire instructions. The definition of Quality of Care was added to the Information Sheet (Appendix D). Furthermore, edits were made to ensure the consistency of terminology with the term “adverse event” replacing error, and “cause” replacing risk.

Questionnaire clarity was scored excellent or good by four of the experts. The fifth expert rated it as needs improvement recommending rephrasing of some question items. There was no elaboration on this comment and thus edits could not be made.

Question wording was scored excellent by one expert. Two experts rated this and good. Two experts rated it as needing improvement with related recommendations. The first recommendation was to reword negatively worded question items. However, Rattray & Jones (2007), recommend using some negatively worded questions to prevent compliance bias, acquiescence and to ensure attention. Further edits were made as suggested to some question items as per Table 4.6.

#### 4.2.3 Summary of results for content validity and quantitative face validity assessment

The prototype questionnaire comprised 36 question items. Data shown in Table 4.6 represents a summary of the edits made to eight of the 36 question items of the Prototype Questionnaire (Appendix A) resulting in 35 remaining items in the Revised Questionnaire (Appendix D).

**Table 4. 6: Summary of question item edits for Phase 2**

Question Item	Original	Edit
1.4	I determine the human and other factors most directly associated with the adverse event	I determine <i>other factors, for example, processes and procedures</i> , most directly associated with the adverse event
2.3	The action plan I develop does not identify the changes that can be implemented to reduce risk	The action plan I develop does not identify the changes that can be implemented to reduce <i>the risk of the adverse event investigated</i>
2.4	I believe RCA is achieving an improvement in the quality of patient care	I believe RCA is <i>contributing</i> to an improvement in the quality of patient care.
3.1	The process of identifying incidents needs to be more explicit	The process of identifying <i>adverse events</i> needs to be more explicit

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Question Item	Original	Edit
3.7	I believe leadership should review the process of RCA annually	I believe <i>management</i> should review the process of RCA annually
4.3	How long have you been in that position?	<i>How many years and months</i> have you been in that position?
4.5	How long have you been involved in Incident Investigations?	How long have you been involved in <i>adverse event</i> investigations?
4.7	Are you on Day Duty or Night Duty?	Item removed

The last edit made was to align the right border of Section 3 as this was to the right of the other sections, thus impacting on the uniformity. This was corrected in Appendix D.

The content validity results are summarised in Tables 4.7 and 4.8

**Table 4. 7: Summary of content validity assessment**

Measure	Section 1: Approach to the use of RCA n=12 (%)	Section 2: Implementation of changes as a result of RCA (n=8)	Section 3: Barriers to RCA (n=7)	Section 4: Demographic Data (n=9)	Total (n=36 items)
Items remaining unchanged	11 (91.7)	6 (75)	5 (71.4)	5 (55.5)	27 (75)
Items edited	1 (8.3)	2 (25)	2 (28.6)	2 (22.2)	7 (19.4)
Items removed	0 (0)	0 (0)	0 (0)	1 (11.1)	1 (2.7)
Median of 4	12 (100)	8 (100)	7 (100)	8 (88.8)	35 (97.2)
Median of 3	0 (0)	0 (0)	0 (0)	1 (11.1)	1 (2.8)
Rating of 4 only	3 (25)	5 (62.5)	3 (42.8)	3 (33.3)	14 (38.9)
Rating of 3 or 4 only	10 (8.3)	8 (100)	7 (100)	6 (66.7)	31 (86.1)
Rating <3	2 (16)	0 (0)	0 (0)	3 (33.3)	5 (13.9)
Number of items (%) with CVI ≥70%	12 (100)	8 (100)	7 (100)	6 (85.7)	35 (97.2)

**Table 4. 8: Overall results for the Prototype Questionnaire (Confidence Interval 95%)**

Median (IQR) of items rated 4	4 (1)
Mean (SD) of items rated 4	4.28 (0.560)
Median (IQR) of items rated 3	0 (1)
Mean (SD) of items rated 3	0.47 (0.560)
Median (IQR) of items rated 2	0 (0)
Mean (SD) of items rated 2	0.22 (0.485)
Median (IQR) of items rated 1	0 (0)
Mean (SD) of items rated 1	0.03 (0.167)
Median (IQR) of items rated 3 + 4	5.00 (1)
Mean (SD) of items rated 3 + 4	4.72 (0.513)
S-CVI	86.1%

The only question item (4.3) with a median of 3 and a 60% I-CVI (below the required ≥70%) was deleted from the revised questionnaire leaving 35 question items. In total 75% of the original 36

items remained unchanged in the revised questionnaire (Appendix D) for the next phase of assessing face validity through cognitive interviews. Seven items, 19.4%, were edited as recommended by the experts' comments. Five items of the 36 (13,9%) had a rating below 3. The overall S-CVI, question items rating 3 and 4 only, was 86.1%.

As a result of the numerical face validity assessment and the experts' comments, the table formatting of the revised questionnaire (Appendix D) was addressed. This meant that the formatting of the Cognitive Interview Guide (Appendix F) had to be amended accordingly.

### **4.3 Objective 1.5.3: To assess the qualitative face validity**

The results were derived from an item by item analysis and review to assess the understanding and interpretation of the question items (Knafl et al., 2007). The difficulties in readability of the question items was similarly assessed by identifying mistakes in reading as well as hesitation and the need to reread a question item. This analysis provided feedback on which question items were ambiguous or difficult and needed changes in the wording or sentence structure. Table 4.9 summarises the data produced. Participant codes were used, for example CI01 refers to cognitive interview participant number one.

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**Table 4. 9: Summary of cognitive interview Data (n=5 participants)**

Question Item Number	Question Item	Problem	Frequency of problem identified n=5 (%)	Recommendation	Amendments
<b>Section 1: Approach to the use of Root Cause Analysis (RCA)</b>					
1.1	My analysis of root causes focuses primarily on systems and processes	Participants CI03 and CI04 both queried if this related to adverse events. Participants CI02 and CI04 did not interpret the question as intended, missing the intention of “primarily”	2 (40)  2 (40)	Question item amended	When analysing root causes of an <i>adverse event</i> , I primarily focus on the systems and processes <i>that failed to avoid it, rather than the individual’s error.</i>
1.2	I do not identify the risk factors leading to the adverse event	Participants CI02 and CI04 needed clarity on “risk factors”	2 (40)	Question item amended	I do not identify the <i>possible causes leading to the adverse event</i>
1.3	I do not repeatedly dig deeper by asking “Why?”; then, when answered, “Why?” again, and so on	Participants CI02, CI03 and CI04 all needed to read the question again and recommended changing the question item format	3 (60)	Question item amended	I do not repeatedly dig deeper by asking “Why?” and “Why?” again, and so on.
1.4	I determine the human and other factors, for example, processes and procedures, most directly associated with the adverse event	Question understood and there were no suggested amendments	Not applicable	No amendments required	
1.5	It is difficult to do a thorough RCA	CI02, CI03, CI04 and CI05 all asked what “RCA” was. Recommended not using the abbreviation	3 (60)	Question item amended	It is difficult to do a thorough <i>root cause analysis</i>

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Question Item Number	Question Item	Problem	Frequency of problem identified n=5 (%)	Recommendation	Amendments
1.6	I believe an enquiry into all areas appropriate to the specific type of event is important	CI02, CI04 and CI05 all hesitated with the reading of “enquiry”. Recommended changing the word.	3 (60)	Question item amended	I believe an <i>investigation</i> into all areas appropriate to the specific type of event is important
1.7	I identify the potential contribution of the risks that led to the adverse event	Suggested replacing the word “risk” as per 1.2	2 (40)	Question item amended	I identify the potential contribution of the <i>possible causes</i> that led to the adverse event
1.8	RCA need not start within 72 hours of an adverse event occurring	CI04 recommended continuing to spell out RCA	1 (20)	Question item amended	<i>Root Cause Analysis</i> need not start within 72 hours of an adverse event occurring
1.9	I am not confident of my use of RCA	Question understood and there were no suggested amendments	Not applicable	Question item amended as per 1.5 and 1.8	I am not confident of my use of <i>Root Cause Analysis</i>
1.10	I provide feedback to the people involved in the adverse event	Question understood and there were no suggested amendments	Not applicable	No amendments required	
1.11	It is not necessary to have an RCA team of people not related to the adverse event	No amendments were recommended but CI01 and CI05 repeatedly read the question in order to understand. CI02 misinterpreted the question. CI01 missed the negative “not necessary” in the first reading.	3 (60)	Question item amended to avoid the word “not” twice and as per 1.5 and 1.8	It is necessary to have a <i>Root Cause Analysis</i> team of people not related to the adverse event
1.12	My analysis of root causes focuses on the individuals involved	CI03 misinterpreted the intention of the question and required explanation	1 (20)	Question item amended	My analysis of root causes focuses <i>only</i> on the individuals involved in the adverse event

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Question Item Number	Question Item	Problem	Frequency of problem identified n=5 (%)	Recommendation	Amendments
<b>Section 2: Implementation of changes as a result of RCA outcomes</b>					
2.1	The outcome of my analysis identifies changes that could be made to systems and processes	Question understood and there were no suggested amendments	Not applicable	No amendments required	
2.2	I have the ability to decide on the potential improvement in processes or systems	Question understood and there were no suggested amendments	Not applicable	No amendments required	
2.3	The action plan I develop does not identify the changes that can be implemented to reduce the risk of the adverse event investigated	Question understood and there were no suggested amendments	Not applicable	No amendments required	
2.4	I believe RCA is contributing to an improvement in the quality of patient care	Question understood and there were no suggested amendments	Not applicable	Question item amended as per 1.5 and 1.8	I believe <i>Root Cause Analysis</i> is contributing to an improvement in the quality of patient care
2.5	In the action plans, I do not identify who is responsible for implementation	Question understood and there were no suggested amendments	Not applicable	No amendments required	
2.6	Actions I recommend are implemented	Question understood and there were no suggested amendments	Not applicable	No amendments required	
2.7	In the action plans, I identify when the action would be implemented	Question understood and there were no suggested amendments	Not applicable	No amendments required	

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Question Item Number	Question Item	Problem	Frequency of problem identified n=5 (%)	Recommendation	Amendments
2.8	I identify how the effectiveness of the actions will be evaluated in the plan of action	Question understood and there were no suggested amendments	Not applicable	No amendments required	
<b>Section 3: Barriers to RCA</b>					
3.1	The process of identifying adverse events needs to be more explicit	Question understood and there were no suggested amendments	Not applicable	No amendments required	
3.2	I have adequate time to complete a thorough RCA	Question understood and there were no suggested amendments	Not applicable	Question item amended as per 1.5 and 1.8	I have adequate time to complete a thorough <i>Root Cause Analysis</i>
3.3	Management is supportive as RCA is a priority for quality improvement in the company	Question understood and there were no suggested amendments	Not applicable	Question item amended as per 1.5 and 1.8	Management is supportive as <i>Root Cause Analysis</i> is a priority for quality improvement in the company
3.4	I do not have adequate resources to complete an RCA	Question understood and there were no suggested amendments	Not applicable	Question item amended as per 1.5 and 1.8	I do not have adequate resources to complete a <i>root cause analysis</i>
3.5	There are no conflicting values within the institutional hierarchy that interferes with the RCA process	Question understood and there were no suggested amendments	Not applicable	Question item amended as per 1.5 and 1.8	There are no conflicting values within the institutional hierarchy that interferes with the <i>Root Cause Analysis</i> process
3.6	I do not get adequate feedback about how well I am completing RCA	Question understood and there were no suggested amendments	Not applicable	Question item amended as per 1.5 and 1.8	I do not get adequate feedback about how well I am completing <i>root cause analysis</i>

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Question Item Number	Question Item	Problem	Frequency of problem identified n=5 (%)	Recommendation	Amendments
3.7	I believe management should review the RCA process annually	Question understood and there were no suggested amendments	Not applicable	Question item amended as per 1.5 and 1.8	I believe management should review the <i>Root Cause Analysis</i> process annually
<b>Section 4: Demographic data</b>					
4.1	How many years and months of experience have you had as a Registered Professional Nurse?	Question understood but all participants could not recall how many months. Recommended just asking years.	Not applicable	Question item amended	How many years of experience have you had as a Registered Professional Nurse?
4.2	What is your current position? E.g. Unit Manager, Shift Leader etc.	Question understood and there were no suggested amendments	Not applicable	No amendments required	
4.3	How many years and months have you been in that position?	Question understood but participants CI03, CI04 and CI05 could not recall how many months. Recommended just asking years	Not applicable	Question item amended	How many years have you been in that position?
4.4	What was your previous position?	Question understood and there were no suggested amendments	Not applicable	No amendments required	
4.5	How many years and months have you been involved in adverse event investigations?	Question understood but all participants could not recall how many months. Recommended just asking years.	Not applicable		How many years have you been involved in adverse event investigations?
4.6	Did you attend training on Root Cause Analysis?	Question understood and there were no suggested amendments	Not applicable	No amendments required	
4.7	In what year did you attend Root Cause Analysis training?	Question understood and there were no suggested amendments. Recall of the exact year was	Not applicable	Item amended	How long ago did you attend root cause analysis training?

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Question Item Number	Question Item	Problem	Frequency of problem identified n=5 (%)	Recommendation	Amendments
		difficult as participants CI03, CI04 and CI05 had been involved in adverse event investigation for a long period of time and had had the training before the start of their involvement.			
4.8	Are you full-time or part-time?	Question understood and there were no suggested amendments	Not applicable	No amendments required	

#### **4.3.1 Amendments required for Section 1: Approach to the use of Root Cause Analysis (RCA)**

The use of the abbreviation RCA raised questions and recommended amendment to the entire revised questionnaire (Appendix D). It was evident that most of the participants (n = 4, 80%) were not familiar with the abbreviation. All question items with the abbreviation “RCA” were replaced with “root cause analysis”. There were four such question items in Section 1 amended in Appendix G.

Another term that confused two of the participants (n = 5, 40%) and required clarity, was the use of “risk”. To avoid potential misinterpretation or lack of understanding, risk was replaced with “possible causes” in items 1.2 and 1.7.

Question item 1.1, “My analysis of root causes focuses primarily on systems and processes”, resulted in two of the participants querying if it related to adverse event investigation. The question item was reworded and a definition of the term “root cause analysis” in the Information Sheet (Appendix H) was added.

The intention of the question item 1.1 was to assess if investigators using the RCA approach are primarily analysing the effect of the systems and processes that lead to the adverse event, rather than focussing on the individuals involved. Two of the participants (n = 5, 40%) did not understand or respond to the question item as intended, raising the need to amend it in order to be more understandable to the larger population (See Appendix G).

Question item 1.3, “I do not repeatedly dig deeper by asking “Why?”; then, when answered, “Why?” again, and so on” caused three participants (n = 5, 60%) to stumble over the wording. The particular area of difficulty was the “when answered” and the decision was made to reword the question removing that phrase. This improved the readability of the question item.

The word “enquiry” hindered the readability of question item 1.6. Three of the participants (n = 5, 60%) paused significantly before reading the word. On probing, it was evident that this word was difficult to relate to root cause analysis and that “investigation” would be a more appropriate word. This amendment is included in Appendix G.

Question item 1.11, “It is not necessary to have an RCA team of people not related to the adverse event”, caused difficulty in both readability and interpretation for three of the participants (n = 5,

60%). There was evidence of the participants having to repeatedly read the question item in order to understand the intention of the question. This resulted in one of those three participants (n = 3, 33.3%) incorrectly interpreting the question and recommending the removal of “not” in “not necessary” in order for it not to read as a double negative. The amendment was made in Appendix G.

Similarly to the misinterpretation in question item 1.1, question item 1.12 was misinterpreted. “My analysis of root causes focuses on the individuals involved” (1.12) required further explaining to one participant (n = 5, 20%). The intention of the question item was to assess if the investigators of an adverse event tend to blame the individuals involved rather than considering the faulty systems and processes. The question item was amended to “My analysis of root causes focuses only on the individuals involved in the adverse event.”

#### **4.3.2 Amendments required for Section 2: Implementation of changes as a result of RCA outcomes**

As discussed above, all use of the abbreviation “RCA” was altered to root cause analysis. In section 2, this amendment was made to the section domain itself, as well to question item 2.4. All question items in this section were easily read and were understood as per the intention. All participants had no difficulty rating the question items.

#### **4.3.3 Amendments required for Section 3: Barriers to RCA**

As per the previous section, all question items were easily read and understood as per the intention of the question item. No participants had difficulty rating the question items. The abbreviation “RCA” was replaced with root cause analysis in the section title and question items 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7, as per Appendix G.

#### **4.3.4 Amendments required for Section: Demographic Data**

Question item problems in this section related to the requirement of the participants to recall both years and months for some of their responses. None of them (100%) could recall the number of months and years that they had been an RPN, instead they only gave the number of years. The recommendation was that the question item was removed to only request the number of years they had been qualified and registered.

Similarly, for question item 4.3, “How many years and months have you been in that position?”, three participants (n = 5, 60%) could not recall the number of months and recommended removing it. The other two participants (n = 5, 40%) found the months easier to recall as they were new to their positions having been appointed within the last two years. The words “and months” were removed from Question item 4.3. The same action was required for question item 4.5, “How many years and months have you been involved in adverse event investigations?” as three of the participants (n = 5, 60%) had been involved for more than ten years. The other two (n = 5, 40%) had been involved in their prior place of employment for a significant period of time. This made recall of the months challenging.

A further challenge was for 4.7, “In what year did you attend Root Cause Analysis training?” as three (n = 5, 60%) of the participants could not recall the exact year and had to estimate the answer. This indicated a need to amend the question item to “How long ago did you attend Root Cause Analysis training?”

#### **4.3.5 General comments on the questionnaire**

Cognitive interview participant 01 felt that each section was “cohesive” with the title of each section. The participant felt that Section 1 was exploring “how RCA is used” and “what that process of investigation entails”. Section 2 explored “the changes needed in an action plan to address the issues that can lead to an error”. Section 3 addressed the “difficulties one could face within a hospital” when doing adverse event investigation.

When asked about the overall questionnaire, CI01 said: “...you can see the difference. The questionnaire flows and you can understand the different sections...without a problem. It’s quite good. It seems fine for me. I could see there was a difference, that the questions changed ...The relevance of the questions was appropriate.” When probed about the difficulty with the negatively worded question item 1.11 “It is not necessary to have an RCA team of people not related to the adverse event”, the participant responded that the negatively worded questions did make her hesitate but it meant “...you have to pay attention that you are not saying everything in a yes direction. But it was good because it made you stop and think”.

Cognitive interview participant 02 could also identify the intention of the different section and felt that the question items matched the section domain. He gave further commentary on the necessity of the questionnaire “it could help minimise adverse event in department.”

Cognitive interview participant 03 described section 1 as “How do you get to the root cause. The procedure in other words. How do you do it.” Section 2 was described as “..to see how effective it is and how you can improve it at the end of the day”. Section 3 was “....about what makes it difficult. Do you have support?” The questions in each section were considered to be “aligned” to the section domains and the overall questionnaire was “relevant and comprehensive.”

Cognitive interview participant 04 described the questionnaire as “cohesive” and that the question items were “consistent” with the section domains. The participant understood the intention of each section, for Section 2 she responded, “it asked about analysing and implementation of the process”. This required further probing as the intention this section does not have to do with the analysing itself but rather to do with the outcomes. In response, CI04 said “by analysing I mean taking the information about the root causes and developing action plans” and “the action plans must be implemented to complete the process and sign off the adverse event.”

The last participant, CI05, agreed with the section domains, but it took some probing to reword the titles. Instead the terminology from the questionnaire was repeated, “approach”, “implementation” and “barriers”. However, CI05 verbalised that the question items related “well” to the topic and that “nothing more should be added”. In conclusion, CI05 said, “this is the perfect length for a questionnaire and easy to do.”

#### 4.3.6 Summary of results for qualitative face validity assessment

As a result of the cognitive interviews, a total of 20/35 (55.6%) of the question items were amended and these are summarised in Table 4.10.

**Table 4. 10: Summary of cognitive interview data**

Section	Number (%) of items amended
1. Approach to the use of Root Cause Analysis (RCA)	10/12 (83.3)
2. Implementation of changes as a result of RCA outcomes	1/8 (12.5)
3. Barriers to RCA	6/7 (85.7)
4. Demographic data	3/8 (37.5)

Of the 20 question items amended, 45% (n=20) of these amendments were due to the necessity to not use the abbreviation “RCA” but to replace it with “root cause analysis”. The explanation of the term root cause analysis was added to the Information Sheet prior to the test-retest reliability assessment. One question item (n = 35, 2.8%) was amended due to its poor readability. Two

question items (n = 35, 5.6%) were amended due to participants not interpreting the question item as per intention. These question items were reworded in order to make the intention more explicit.

Three question items (n = 35, 8.3%) were difficult to answer. They were all in the last section relating to Demographic Data. The participants verbalised difficulty recalling both years and months for two of the question items, and the specific year they attended RCA training.

#### **4.4 Objective 1.5.4: To assess the reliability of the questionnaire**

Analysis of the CVI, numerical face validity and cognitive interview results gave rise to question items that required editing or deletion, as summarised in Section 4.2.3, leaving 35 question items in the final questionnaire (Appendix G). The Final Questionnaire (Appendix G) was distributed to 20 potential respondents. Data in Table 4.10 represents a summary of the response rate.

**Table 4. 11: Response rate for Time 1 and Time 2 Questionnaire completion**

Time 1 Questionnaire completion			Time 2 Questionnaire completion		
Questionnaires distributed	Questionnaires returned	% Returned	Questionnaires distributed	Questionnaires returned	% Returned
20	12	60	12	10	83.3

A total of 10 respondents completed the questionnaire after a two week interval. No items were omitted from the completed questionnaire. The results of the test-retest reliability of the amended questionnaire will now be presented.

##### **4.4.1 Results of reliability assessment for Section 1: Approach to use of Root Cause Analysis (RCA)**

In this section of the final questionnaire, four negatively worded question items (1.2, 1.3, 1.8 and 1.9) were reverse coded in SPSS prior to analysis. The results of the reliability assessment through test-retest are presented in Table 4.12 and interpreted in Table 4.13 using the classification of Cohen’s Kappa (May et al., 2010) as presented in Section 3.6.3 and shown below:

Cohen’s Kappa	Classification of agreement
0.00-0.2	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Almost perfect agreement
1.0	Perfect agreement

(May et al., 2010)

As described in Section 3.6.3 the predetermined level of reliability coefficient was  $\geq 0.7$  for a developing questionnaire as higher value indicates a greater the level of reliability, with 1.0 indicating perfect reliability (Karanicolas et al., 2009).

**Table 4. 12: Results of Test-Retest Reliability assessment for Section 1 of the Final Questionnaire (Appendix G)**

Question Item Number	Weighted Kappa	Standard Error	Z Score	P value	95% Confidence Interval: Lower – Upper bound
1.1	1.00	0.000	4.628	0.000	1.000
1.2	1.00	0.000	4.445	0.000	1.000
1.3	1.00	0.000	4.111	0.000	1.000
1.4	0.865	0.139	3.869	0.000	0.592-1.138
1.5	0.875	0.110	2.996	0.003	0.660-1.090
1.6	1.00	0.000	3.162	0.002	1.00
1.7	0.857	0.138	3.750	0.000	0.588-1.127
1.8	0.800	0.186	2.582	0.010	0.436-1.164
1.9	1.00	0.000	4.128	0.000	1.000
1.10	1.00	0.000	4.128	0.002	1.000
1.11	1.00	0.000	4.527	0.002	1.000
1.12	0.884	0.117	4.088	0.000	0.655-1.113

The level of agreement is presented in Table 4.13.

**Table 4. 13: Level of agreement for Section 1 of the Final Questionnaire (Appendix G)**

Question item number	Level of agreement
1.1	Perfect Agreement
1.2	Perfect Agreement
1.3	Perfect Agreement
1.4	Almost perfect agreement
1.5	Almost perfect agreement
1.6	Perfect Agreement
1.7	Almost perfect agreement
1.8	Substantial agreement
1.9	Perfect Agreement
1.10	Perfect Agreement
1.11	Perfect Agreement
1.12	Almost perfect agreement
Total number of items (%): Perfect Agreement	7/12 (58.3)
Total number of items (%): Almost Perfect Agreement	4/12 (33.3)
Total number of items (%): Substantial Agreement	1/12 (8.3)
Total number of items (%): Moderate Agreement	0
Total number of items (%): Fair Agreement	0
Total number of items (%): Slight Agreement	0

The results of the test-retest reliability assessment reflect that 7 (n=12) ,58.3%, question items had a weighted kappa of 1.0, perfect agreement, between Time 1 and Time 2. Four of the

question items (n = 12, 33.3%) resulted in a weighted kappa of 0.81-0.99, almost perfect agreement between Time 1 and Time 2. This accounts for 11/12 (91.66%) question items at between almost perfect and perfect agreement. One (8.3%) resulted in substantial agreement due to the weighted kappa being 0.41-0.6.

#### 4.4.2 Results of reliability assessment for Section 2: Implementation of changes as a result of Root Cause Analysis outcomes

In Section 2 of the final questionnaire, two (n=8) question items were worded negatively. These items were recoded in SPSS prior to analysis. The data are presented in Table 4.14 and interpreted in Table 4.15 using the classification of Cohen’s Kappa (May et al., 2010) as presented in Section 3.6.3 and shown below:

Cohen’s Kappa	Classification of agreement
0.00-0.2	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Almost perfect agreement
1.0	Perfect agreement

(May et al., 2010)

**Table 4. 14: Results of Test-retest Reliability assessment for Section 2 of the Final Questionnaire (Appendix G)**

Question Item Number	Weighted Kappa	Standard Error	Z Score	P-Value	95% Confidence Interval: Lower – Upper bound
2.1	1.000	0.000	4.278	0.000	1.000
2.2	0.825	0.141	3.162	0.000	0.550-1.105
2.3	0.800	0.186	2.582	0.000	0.436-1.164
2.4	0.909	0.086	4.419	0.000	0.740-1.078
2.5	0.800	0.121	2.887	0.003	0.563-1.037
2.6	0.868	0.199	3.865	0.002	0.363-1.101
2.7	1.000	0.000	3.162	0.000	1.000
2.8	0.821	0.173	3.512	0.010	0.483-1.160

The level of agreement is presented in Table 4.15.

**Table 4. 15: Level of agreement for Section 2 of the Final Questionnaire (Appendix G)**

Question Item	Level of Agreement
2.1	Perfect agreement
2.2	Almost perfect agreement
2.3	Substantial agreement

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2.4	Almost perfect agreement
2.5	Substantial agreement
2.6	Almost perfect agreement
2.7	Perfect agreement
2.8	Almost perfect agreement
Total number of items (%): Perfect Agreement	2/8 (25)
Total number of items (%): Almost Perfect Agreement	4/8 (50)
Total number of items (%): Substantial Agreement	2/8 (25)
Total number of items (%): Moderate Agreement	0
Total number of items (%): Fair Agreement	0
Total number of items (%): Slight Agreement	0

The results of the test-retest reliability assessment reflect that 2 (n=8), 25%, question items had a weighted kappa of 1.0, perfect agreement, between Time 1 and Time 2. Four of the question items (50%) resulted in a weighted kappa of 0.81-0.99, almost perfect agreement between Time 1 and Time 2. Two question items (25%) resulted in moderate agreement due to the weighted kappa being 0.41-0.6.

#### 4.4.3 Results of reliability assessment for Section 3: Barriers to Root Cause Analysis

In Section 3 of the final questionnaire, two (n=7) question items were worded negatively. These items were recoded in SPSS prior to analysis. The data analysis are presented in Table 4.16 and interpreted in Table 4.17 using the classification of Cohen’s Kappa (May et al., 2010) as presented in Section 3.6.3 and shown below:

Cohen’s Kappa	Classification of agreement
0.00-0.2	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Almost perfect agreement
1.0	Perfect agreement

(May et al., 2010)

**Table 4. 16: Results of Test-retest Reliability assessment for Section 3 of the Final Questionnaire (Appendix G)**

Question Item Number	Weighted Kappa	Standard Error	Z Score	P-value	95% Confidence Interval: Lower – Upper bound
3.1	1.00	0.000	4.331	0.000	1.00
3.2	1.00	0.000	4.339	0.000	1.00
3.3	1.00	0.000	4.035	0.000	1.00
3.4	1.00	0.000	4.032	0.000	1.00

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3.5	0.925	0.071	3.565	0.000	0.786-1.065
3.6	1.00	0.000	3.565	0.000	1.00
3.7	1.00	0.000	3.976	0.000	1.00

The level of agreement in Table 4.17 uses the classification of Cohen’s Kappa (May et al., 2010).

**Table 4. 17: Level of agreement for Section 3 of the Final Questionnaire (Appendix G)**

Question item number	Level of agreement
3.1	Perfect agreement
3.2	Perfect agreement
3.3	Perfect agreement
3.4	Perfect agreement
3.5	Almost perfect agreement
3.6	Perfect agreement
3.7	Perfect agreement
Total number of items (%): Perfect Agreement	6/7 (85.7)
Total number of items (%): Almost Perfect Agreement	1/7 (14.3)
Total number of items (%): Substantial Agreement	0
Total number of items (%): Moderate Agreement	0
Total number of items (%): Fair Agreement	0
Total number of items (%): Slight Agreement	0

The results of the test-retest reliability assessment reflect that 6 (n=7), 85.7%, question items had a weighted kappa of 1.0, perfect agreement, between Time 1 and Time 2. One of the question items (14.3%) resulted in a weighted kappa of 0.81-0.99, almost perfect agreement between Time 1 and Time 2.

#### 4.4.3 Results of reliability assessment for Section 4: Demographic Data

In Section 4 of the final questionnaire, the respondents completed their demographic data for the question items. There were no negatively worded items requiring recoding. The data analysis are presented in Table 4.18 and interpreted in Table 4.19 using the classification of Cohen’s Kappa (May et al., 2010) as presented in Section 3.6.3 and shown below:

Cohen’s Kappa	Classification of agreement
0.00-0.2	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Almost perfect agreement
1.0	Perfect agreement

(May et al., 2010)

**Table 4. 18: Results of Test-retest Reliability assessment for Section 3 of the Final Questionnaire (Appendix G)**

Question item number	Weighted Kappa	Standard Error	Z Score	P-value	95% Confidence Interval: Lower – Upper bound
4.1	1.000	0.000	4.726	0.000	1.0
4.2	1.000	0.000	3.162	0.02	1.0
4.3	1.000	0.000	4.859	0.000	1.0
4.4	1.000	0.000	4.403	0.000	1.0
4.5	1.000	0.000	4.362	0.000	1.0
4.6	Unable to calculate Cohen’s Kappa: Agreement 100%				
4.7	1.000	0.000	4.776	0.000	1.0
4.8	Unable to calculate Cohen’s Kappa: Agreement 100%				

Question item 4.6, “Did you attend Root Cause Analysis training?”, resulted in all respondents answering yes. Question item 4.8, “Are you full-time or part-time?”, resulted in all respondents answering full-time. Because all ratings and raters were in agreement for these two items, Cohen’s Kappa could not be calculated. The agreement is 100%. The interpretation of the level of agreement in Table 4.19, uses the classification of Cohen’s Kappa (May et al., 2010).

**Table 4. 19: Level of agreement for Section 4 of the Final Questionnaire (Appendix G)**

Question item number	Classification of agreement
4.1	Perfect Agreement
4.2	Perfect Agreement
4.3	Perfect Agreement
4.4	Perfect Agreement
4.5	Perfect Agreement
4.6	Perfect Agreement
4.7	Perfect Agreement
4.8	Perfect Agreement
Total number of items (%): Perfect Agreement	8/8 (100)
Total number of items (%): Almost Perfect Agreement	0
Total number of items (%): Substantial Agreement	0
Total number of items (%): Moderate Agreement	0
Total number of items (%): Fair Agreement	0
Total number of items (%): Slight Agreement	0

All question items in Section 4: Demographic Data of the Final Questionnaire were in perfect agreement for Time 1 and Time 2.

#### 4.4.4 Summary of results for reliability assessment

The results for assessing the reliability using Cohen’s Kappa and the classification of agreement (May et al., 2010) are presented in Table 4.20.

**Table 4. 20: Results of agreement**

Classification of agreement	Number of items (%) n=35
Slight agreement	0 (0)
Fair agreement	0 (0)
Moderate agreement	0 (0)
Substantial agreement	3 (8.6)
Almost perfect agreement	9 (25.7)
Perfect agreement	23 (65.7)

All question items had a weighted kappa ranging from 0.800 – 1.000, thus the classification of agreement ranged from substantial agreement to perfect agreement. No question items rated as slight, fair or moderate agreement. Two question items, 4.6 and 4.8, could not be calculated for Cohen’s Kappa as all the ratings were the same for all raters at Time 1 and Time 2. These question items thus had an agreement of 100%.

## 4.5 Summary

This chapter described the results from the three phases of the study: Phase 2 to assess content and numerical face validity; Phase 3 to assess qualitative face validity; and Phase 4 to assess the reliability of the final questionnaire.

As a result of the CVI assessment in Phase 2, the experts recommendations resulted in one of n=36 question item being removed and seven question items being amended for the Revised Questionnaire (Appendix D) resulting in 35 question items for the revised questionnaire. Furthermore, the clarification of the term “Quality of Care” was added to the Information Sheet.

Analysis of data from the the Cognitive Interviews resulted in the amendment of 20 of n=35 question items but no removal. The abbreviation “RCA” was spelt out in 9 of the question items to provide clarity. The definition of the term “Root Cause Analysis” was added to the information sheet prior to the test-retest reliability assessment.

Reliability of the Final Questionnaire (Appendix G) was established using test-retest methodology. Twenty three (n=35; 65.71%) of the question items were shown to have perfect agreement (1) between Time 1 and Time 2. Nine question items showed almost perfect agreement (0.81-0.99) and two question items resulted in substantial agreement (0.61-0.80). No question items showed moderate, slight or fair agreement.

## **CHAPTER FIVE: DISCUSSION, IMPLICATIONS, RECOMMENDATIONS AND CONCLUSION**

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### **5.1 Introduction**

Root cause analysis (RCA) is a process aimed at improving patient safety through in depth analysis to develop corrective actions thus intentionally a proactive process provided that the RCA methodology is used rigorously and meticulously. The purpose of this study was to develop and validate a questionnaire to establish whether the RCA model and processes employed at the research setting were perceived by the users to be acceptable, thorough and credible in terms of internationally established criteria (The Joint Commission, 2017). The purpose was achieved by the questionnaire on the RCA constructs having a high level of validity and reliability at the conclusion of the study. Participants understood the constructs because the RCA model and processes employed at the research setting were described in the respective Information Sheets for each of the validation processes. The description informed participants that the purpose of RCA is to improve quality and patient safety through a retrospective, structured investigative process that makes recommendations to prevent the recurrence of medical errors. The high level of validity and reliability endorses participants' perception of the RCA model and processes being acceptable, thorough and credible.

Furthermore, many challenges are faced during RCA particularly as healthcare is an increasingly complex and challenging environment that is producing a growing number of risks to patients (Cassin & Barach, 2012; Woher, 2015) despite efforts made to address the rate of medical error (Kellogg et al., 2017). One such challenge is that no guidelines were developed on how to approach and undertake the process when it was introduced to healthcare (Latino, 2015). This has resulted in great variability in the method and quality of RCAs in healthcare thus challenging its efficacy.

In this chapter the wider meanings and implications of the principal findings are discussed and recommendations are made for healthcare (clinical practice and management) and nursing education institutions respectively and for further research. Strengths and limitations of the mixed methods research design are addressed.

## 5.2 Wider meanings of the principal findings in relation to the literature

This questionnaire on RCA appears to be the only one in the available literature that assesses the perceptions of RCA trained RPNs' approach to RCA, its outcomes and potential barriers. The development of the questionnaire was guided by a thorough search of the available literature on RCA and thus evidence based. The study used a mixed methods approach as the quantitative data from content validity, face validity and reliability assessments were complemented by the qualitative data gained from the cognitive interviews. The outcome of the study proved that this questionnaire is both valid and reliable.

DeVon et al. (2007) highlight the importance of confirming validity and reliability of a survey questionnaire in order for it to be sound and for the study to have integrity. Recommendations by Polit and Beck (2004) and Waltz (2005) include using experts to systematically review the questionnaire's content. The experts' feedback can improve the quality of the survey questionnaire and the representativeness of the question items (Artino et al., 2014; Polit & Beck, 2017) through CVI testing (Lynn, 1986). After removing one item, the remaining 36 question items (97.3%) were retained as they achieved a Content Validity Index (CVI)  $\geq 70\%$  agreement (Guttman et al., 2006). The S-CVI was 86.1% indicating applicability of the question items to the questionnaire subject domains.

The numerical face validity of the prototype survey questionnaire reflected an acceptable layout and font. It is important to assess the readability of the questionnaire (Polit & Beck, 2017). Some of the experts (n=5) recommended removing the negatively worded question items, but the decision to retain negatively worded items is supported by Rattray and Jones (2007). Overall, 77.8% of the items had a median of 4 (excellent), 30 (66.7%) question items had a rating of 4 and 12 (26.7%) a rating of 3 (good).

The cognitive interviews using the Revised Questionnaire resulted in valuable data relating to the wording and interpretation of the question items (Knafl et al., 2007). Participants found 1/35 (2.9%) of the question items difficult to read which was amended and they had difficulty interpreting 5.6% (2/35) of the question items which were amended. Participants had difficulty in answering 3/8 (8.3%) of the question items in the Demographic Data domain of the questionnaire as specific information could not be recalled about the number of months in employment, being involved in RCA and following training. Interestingly, although English is the official company language used, none of the five participants were English first language speakers.

The results of the four phases of the study showed that a valid and reliable questionnaire has been developed. This questionnaire will be useful to assess how nurses are approaching RCA, their perception of the outcomes of an RCA in terms of mitigating measures and their apparent barriers to completing a thorough and credible RCA. This information can provide input as to recommendations to improve RCAs in response to an AE.

### **5.3 Limitations and strengths of the study methods**

#### **5.3.1 Content validity assessment (CVI)**

##### ***5.3.1.1 Limitations of CVI assessment***

The limitations of the CVI assessment include difficulties with the sample. None of the Quality Managers that responded hold a Master's degree and have limited exposure to research. This may have affected their scoring of the relevance of the questions, possibly being biased by personal experiences and ideas (Noble & Smith, 2015). The response rate was slow and poor, with three of the five Quality Managers returning completed checklists. The decision to seek participation from a Quality Manager in the Eastern Cape Province was made to improve the response rate. With the guidance of the study supervisor, another candidate who holds a Master's degree was requested to participate. They both returned completed checklists.

Random sampling can reduce research bias for quantitative studies (Noble & Smith, 2015). Convenience sampling was used for this study as the CVI required experts in the field. The non-probability sampling methods may or may not accurately represent the population (Brink et al., 2006). The five research sites each only employ one Quality Manager thereby limiting the overall population and sample size. Lynn (1986) recommends a sample size of five to ten experts, but if a sample of five is used, 100% agreement should be required however a more reasonable level of agreement of  $\geq 0.7$  was set as described by Guttman et al., (2006).

Expert comment included concern about the consistency of the terminology used and this may be attributable to the researcher's lack of research experience. A general recommendation by one expert to reword some of the questions without being specific could not be addressed. Similarly, another expert was concerned that the use of the negatively worded question items had the potential to be confusing. The intention of these negatively worded question items was to prevent or limit risk of acquiescence bias, the tendency for survey respondents to agree with statements regardless of their content (Holbrook, 2008) therefore none of these items were

amended before cognitive interviews were conducted. A repeat round of CVI assessment might have been useful to gain more information about the relevance of the question items.

### ***5.3.1.2 Strengths of CVI assessment***

Phase 2 of the study required assessment of the CVI by having experts rate the relevance of the question items. A Likert scale was used as it is a valuable and reliable tool frequently used in medical research (Croasmun & Ostrom, 2011; Sullivan & Artino Jr, 2013). A four point scale was used to avoid a neutral or undecided score, ensuring useful data was obtained (Lynn, 1986).

The prototype questionnaire used in this phase included 36 question items over four sections. This is a relatively concise questionnaire taking 15-20 minutes to complete as a long questionnaire may discourage a response (Brink et al., 2006). This assisted with the recruitment of experts as it was not time consuming, an important consideration as the Quality Managers have a responsible, difficult job profile. The response rate, although slow, resulted in achieving the preset sample size of five experts. All sections of the questionnaire were completed.

The results showed the necessity to remove only one item in the section including demographic data. This question item achieved an I-CVI of 0.6, below the recommended  $\geq 0.7$  agreement because the experts felt that whether an RPN was on day duty or night duty was not relevant. The overall S-CVI for the prototype survey questionnaire was 86.1% for items scoring 3 (quite relevant) and 4 (highly relevant). This is well above the preset limit of agreement of  $\geq 0.7$  (Guttman et al., 2006) showing a high degree of representation of the content domain. A Likert scale is ordinal level data therefore the calculation of a median is appropriate, which in this case was 4 for 97.2% of question items. The overall mean of all scores was 3.7/4, where 4 = highly relevant.

The numerical face validity resulted in 77.8% of question items with a median of 4 (Excellent). The overall mean was 3.5 (3 = Good and 4 = Excellent). This represents good face validity as assessed numerically. The prototype questionnaire had an appearance that was legible and well laid out.

The results of the validity assessment reflect that the questionnaire and the question items were relevant to RCA. This outcome supports the fact that the questionnaire was based on evidence from international studies and applicable in the local setting.

### **5.3.2 Qualitative face validity**

#### ***5.3.2.1 Limitations of qualitative face validity***

Sampling for this phase of the study was challenging and may have affected the data obtained. Purposive sampling with the guidance of the Quality Managers at each of the five study sites was intended to provide rich data (Morse, 2015). However, participants at two of the selected study sites were not available for the cognitive interviews as they were on annual leave but eventually all five were from three study sites which may have limited the richness of the data as different sites may have different approaches and experiences of RCA.

The purpose of cognitive interviews is to gain feedback on the revised questionnaire, but one participant did not elaborate much despite prompting and probing. It would have been valuable to have completed a further round of cognitive interviews to ensure no further themes were identified. Surprisingly, four of the five participants were not familiar with the abbreviation 'RCA' so 9/35 question items (25.71%) were amended, comprising 45% of all amendments made.

Qualitative data is subjective and there may have been a subconscious desire to confirm the researcher's own hypothesis or personal experience (Noble & Smith, 2015). Analysis of cognitive interviews is also a subjective process, and as there was only one researcher, there may have been some analysis bias (Noble & Smith, 2015).

#### ***5.3.2.2 Strengths of qualitative face validity***

Cognitive interviews were conducted for Phase 3 of the study. The interviews were short, taking about 30 minutes, reducing the anxiety of taking healthcare workers away from their work or imposing on their personal time. Face-to-face interviews provided an opportunity to identify non-verbal cues which were documented in the field notes. These notes provided valuable information about the subtle difficulties participants experienced with the amended questionnaire. As there was only one interviewer, this ensured consistency in the method of phrasing questions phrasing and verbal probing. The transcripts were checked several times for errors and the field notes contributed to a thorough analysis.

The participants for this round of validation were all very willing to take part in the interviews and assist with the research process. All interviews took place at a mutually convenient time which assisted with the participation rate. Despite there being limited guidance in the available literature with respect to sample size for cognitive interviews, five RPNs was considered adequate (Beatty & Willis, 2007; Willis & Artino, 2013). By the fifth interview, no new data emerged.

The cognitive interviews provided useful feedback of the applicability of the content and the readability of the question items. Although there was some hesitation or rereading of the question items, the process affirmed that the negatively worded items could be identified and that these were acceptable, whereas the CVI experts had suggested that these should be removed.

The interviews resulted in useful discussion around the topic of RCA. This affirmed the need for the study as the themes identified were similar to those identified in the relevant literature. Three of the five respondents commented that a study using the questionnaire would provide valuable feedback.

### **5.3.3 Reliability assessment**

#### ***5.3.3.1 Limitations of the reliability assessment***

Although there was a 50% return rate of the final questionnaire by the RPNs which is considered acceptable (Burns & Grove, 2010) it was time consuming as regular reminders were sent by email which did not improve the response rate. The test-retest for reliability was entirely electronic requiring no personal contact so uncertainty about a particular rating by one respondent could not be clarified.

#### ***5.3.3.2 Strengths of reliability assessment***

The response rate was adequate at 50% (10/20) (Burns & Grove, 2010) and the respondents all rated every question item of the Final Questionnaire (Appendix G). This resulted in useful data to assess the reliability of the questionnaire. The majority of question items (65.7%) resulted in a perfect level of agreement (1.0) (May et al., 2010), and no items scored moderate (0.41-0.6) to slight (0-0.2) agreement. Cohen's kappa was used to assess this level of agreement which accounts for chance agreement (Karanicolas et al., 2009). These results reflect a stable and reliable questionnaire.

To strengthen the study and limit attrition the recommended sample size of  $n=10$  (Brink et al., 2006; Hertzog, 2008) was inflated to  $n=20$  (Polit, 2014). Achieving a sample size of  $n=10$  was therefore acceptable. The ten respondents who were contacted by email completed the questionnaires for Time 1 and Time 2 and comprised 19.2% of the estimated target population ( $N=52$ ). The respondents were randomly selected to provide a representative sample (Brink et al., 2006) and all study sites were included in this phase of the study. This process was inexpensive,

not time consuming and the respondents returned the questionnaires within approximately four days for the second round.

## **5.4 Implications of the study**

### **5.4.1 Implications for health care institutions**

RCA is an analysis method with the potential to prevent recurrence of similar AEs. A universal theme in patient safety is that the number of AEs is not improving, challenging the efficacy of RCA. If healthcare establishments can explore the perceptions of the RPNs doing RCA, there may be an indication if RCA is reliable, thorough and credible in their establishment. The identified gaps potentially can be addressed by this assessment and, with intervention, could improve the effectiveness of RCA. Interventions could include retraining RCA, closer monitoring of the AE investigation and analysis process, following up on the recommended action plans and evaluation of their efficacy of those action plans.

The responses from the cognitive interviews and test-retest reflected that the participating RPNs felt that they were approaching RCA according to requirements. They were mostly confident in their ability and felt that they developed thorough action plans identifying responsible people to implement the recommendations and the timeline for doing so. Most of the respondents felt that RCA is improving the quality of patient care, however a couple were neutral. The responses to question items relating the barriers to RCA identified that there is a need for the RPNs to get more feedback on how well they are doing RCA and that the hospital management team should review the process annually. The majority of respondents felt they did not have adequate time to complete a thorough RCA, but the availability of resources led to mixed responses. There were also very mixed responses relating to the support of the management team and that there was conflict amongst the management team in terms of their values of RCA. This requires more exploration.

### **5.4.2 Implications for Nursing Education Institutions**

The literature review showed that RCA can provide learning opportunities and develop critical thinking skills. The nursing training at the college affiliated to the study site requires that all students are involved in AE investigations. This should be part of all nursing programmes to ensure that the process of identifying AEs is explicit. Participating in RCA can expose students to how medical errors occur and teach them skills to be alert to their own practice. This awareness

can enhance their practice of safety through reflecting on the processes to which they are subjected and closely reflecting on their actions and those of their colleagues.

A validated questionnaire that assesses RCA can provide students with the information relating to the RCA process and the possible barriers in their clinical placements. Knowing this should prepare them in advance by giving them the tools to approach RCA correctly and to overcome the challenges.

The research methodology in this study can be a valuable resource for students. Research is an essential element of their curriculum and they require valuable examples of completed studies to guide them in their own research. The researcher has learnt a significant amount relating to the process of reviewing literature, research methodology and data analysis and thus can be a useful resource in teaching the students.

#### **5.4.3 Unanswered questions and future research**

The high rate of AEs could be interpreted as RCA being ineffective, but it is important to consider where the fault lies. Is it with RCA itself or with the manner in how it is done and how the outcomes are implemented?

The data obtained has provided some insight into the local situation relating to RCA. The perceptions and challenges described in international literature are very similar but there is a paucity of South African data and literature, indicating a dire need to do further research here. Despite the impetus to improve patient safety by the National Department of Health, statistics and measures are not in place to measure the AE rate, how these are analysed, mitigating measures and if the mitigating measures are effective.

The available literature has shown that RCA has not been adequately contextualised to healthcare settings. There are no set guidelines to assist with this. Studies are required to investigate how this can be done in order to standardise the RCA process.

A tool like the validated questionnaire resulting from this study can assist in investigating the process of analysing AEs and identify corrective actions needed. The questionnaire needs to be validated in further healthcare contexts to be more generalised but then valuable data can be obtained.

Further research should include systematic reviews of literature, both in South Africa and internationally, to objectively identify common trends and improvement methods. Likewise, studies on RCA should include control trials to identify the effectiveness of RCA and provide essential comparative data.

## **5.5 Recommendations**

Adverse event analysis such as RCA should be included in the curricula of all healthcare training. It is important that all students are exposed to how to identify and report AEs, along with how they are managed. This exposure of students to the types and consequences of AEs means their awareness of patient safety and the quality of care will improve. The importance of AE identification being incorporated into their training in a non-punitive manner should develop a culture of transparency.

Teaching RCA and incorporating RCA examples into training curricula will give the students opportunity to develop confidence in the analysing process. Practicing RCA can highlight the common causes and the importance of aggregation of similar root causes and the resulting preventative actions. This way, students can reflect on and share best practice. The process of analysis should inculcate vigilance with respect to medical error and create a habit of looking beyond the superficial, obvious factors.

Likewise, healthcare workers should have in-service and formal training on RCA. If all staff have the same training, there should be standardisation of expectations and practice. These learning opportunities can expose them to how to prevent errors and to be more critical of existing policies and procedures.

Recommendations to healthcare establishments include referral to the RCA<sup>2</sup> guidelines developed by the National Patient Safety Foundation (2016). These include having an RCA team to brainstorm and analyse root causes. By exposing staff and students to brainstorming within RCA teams, they can gain confidence and improve on their communication skills. This is valuable for their professional development.

An explicit process of identifying AEs and analysing them thoroughly must be clearly defined. This should include the methodology, for example, the 5 Whys and the Fishbone, to ensure that in depth and meticulous analyses are completed. The process cannot be a checklist or option selection, but each analysis should be unique and specific to the AE being investigated.

Management teams in hospitals have an obligation to adopt the principles of RCA. Representatives must review RCAs and give feedback in order to affirm or better practice. Identified personnel should be responsible for monitoring the implementation of action plans to ensure they are completed, and then to assess their effectiveness. Successful action plans should be shared between departments and hospitals to assist them with altering practice and processes.

RCA focusses on processes that failed, rather than the human error. Management teams should recognise that being punitive and changing behaviour is challenging, causing anxiety and fear. These emotions may hamper the transparency and the willingness to identify or recognise AEs. The emphasis should move away from this and rather encourage reporting without the fear of retribution. This should lead to accurate and representative statistics of AEs and patient safety, a benchmark for improvement.

The results were derived from study sites within one private healthcare organisation. Different data may have been reported if the study had been done across hospital groups and in both private and public healthcare settings to ensure external validity (generalisability) of the study results (Brink et al., 2006) The study sites limited the data to the experiences of RPNs in a small sample of the national South African nursing population. The final questionnaire requires validation in public healthcare settings and among a variety of private hospital groups. Thereafter, a larger RCA study should be undertaken to provide data essential for improving quality care and patient safety.

## **5.6 Conclusion**

This study resulted in a validated and reliable questionnaire on root cause analysis that established that the RCA model and processes employed at the research setting were perceived by the users to be acceptable, thorough and credible in terms of internationally established criteria. Further validation of the questionnaire in both public and private healthcare settings across South Africa is required to ensure generalisability of the study findings.

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## APPENDICES

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### Appendix A: Prototype Questionnaire

**Respondent code (Researcher to complete):**

**Title: THE DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE ON ROOT CAUSE ANALYSIS**

The questionnaire on Root Cause Analysis has four sections.

Please answer the questions by indicating your response with a v in the most appropriate column.

#### Section 1: Approach to use of Root Cause Analysis (RCA)

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1.1	My analysis of root causes focuses primarily on systems and processes					
1.2	I do not identify the risk factors leading to the adverse event					
1.3	I do not repeatedly dig deeper by asking "Why?"; then, when answered, "Why?" again, and so on					
1.4	I determine the human and other factors most directly associated with the adverse event					
1.5	It is difficult to do a thorough RCA					
1.6	I believe an enquiry into all areas appropriate to the specific type of event is important					
1.7	I identify the potential contribution of the risks that led to the adverse event					
1.8	RCA need not start within 72 hours of an adverse event occurring					
1.9	I am not confident of my use of RCA					
1.10	I provide feedback to the people involved in the adverse event					
1.11	It is not necessary to have an RCA team of people not related to the adverse event					
1.12	My analysis of Root Causes focuses on the individuals involved					

**Section 2: Implementation of changes as a result of RCA outcomes**

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2.1	The outcome of my analysis identifies changes that could be made to systems and processes					
2.2	I have the ability to decide on the potential improvement in processes or systems					
2.3	The action plan I develop does not identify the changes that can be implemented to reduce risk					
2.4	I believe RCA is achieving an improvement in the quality of patient care					
2.5	In the action plans, I do not identify who is responsible for implementation					
2.6	Actions I recommend are implemented					
2.7	In the action plans, I identify when the action would be implemented					
2.8	I identify how the effectiveness of the actions will be evaluated in the plan of action					

**Section 3: Barriers to RCA**

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
3.1	The process of identifying incidents needs to be more explicit					
3.2	I have adequate time to complete a thorough RCA					
3.3	Management is supportive as RCA is a priority for quality improvement in the company					
3.4	I do not have adequate resources to complete an RCA					
3.5	There are no conflicting values within the institutional hierarchy that interferes with the RCA process					
3.6	I do not get adequate feedback about how well I am completing an RCA					
3.7	I believe leadership should review the RCA process annually					

#### Section 4: Demographic Data

**Instructions: Please complete the information as required below**

4.1	How many years of experience have you had as a Registered Professional Nurse?	
4.2	What is your current position? E.g. Unit Manager, Shift Leader etc.	
4.3	How long have you been in that position?	
4.4	What was your previous position?	
4.5	How long have you been involved in incident Investigations?	
4.6	Did you attend training on Root Cause Analysis?	
4.7	In what year did you attend Root Cause Analysis Training?	
4.8	Are you on Day duty or Night duty?	
4.9	Are you full-time or part-time?	

For any questions related to this questionnaire and the study, please contact:

<b>Researcher:</b> Clare Wepener (MSc Candidate, Division of Nursing & Midwifery, University of Cape Town) SACS High School Newlands Avenue Newlands 7700 Telephone number: 0828404017 Email: <a href="mailto:dbscla001@myuct.ac.za">dbscla001@myuct.ac.za</a>	<b>Supervisor:</b> Associate Professor Una Kyriacos Division of Nursing & Midwifery Department of Health & Rehabilitation Sciences Faculty of Health Sciences University of Cape Town Anzio Rd Observatory 7925 Telephone number: (021) 4066410 Email: <a href="mailto:una.kyriacos@uct.ac.za">una.kyriacos@uct.ac.za</a>
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## **Appendix B: Information Sheet and Consent Form for assessment of the index of content validity of the prototype questionnaire on the use of the Root Cause Analysis**

**Title: The development and validation of a questionnaire on Root Cause Analysis**

### **Information Sheet**

I am a currently a Master's degree student at the University of Cape Town in the Division of Nursing and Midwifery. The aim of this proposed study is to develop and validate a questionnaire that can establish whether Root Cause Analysis in the private healthcare setting is as acceptable, thorough and credible as required by the Joint Commission (The Joint Commission, 2013)<sup>1</sup>. This questionnaire will also assess the practice of those completing the investigations of adverse events that require establishing root causes. It will identify if the organisation is supporting Root Cause Analysis as recommended by the National Patient Safety Foundation (2016)<sup>2</sup>.

The purpose of Root Cause Analysis is to improve quality and patient safety through a retrospective, structured investigative process that makes recommendations to prevent the recurrence of medical errors. The published literature that was reviewed showed that many challenges are faced during Root Cause Analysis. It is important to establish if the purpose of the Root Cause Analysis model is understood by those conducting the adverse event investigations and whether the process of getting to the root cause(s) is being thoroughly completed. Likewise, it is important to assess if there is adequate support within the organisation, not limited to completion of the investigation, but including execution of the recommendations that are made.

A valid and reliable questionnaire for assessing the experiences and attitudes of Registered Professional Nurses responsible for employing Root Cause Analysis can provide vital data on patient safety practices. For purposes of this invitation to you to consider participating in the study, the

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<sup>1</sup> The Joint Commission (2013). Sentinel Events. Retrieved from [https://www.jointcommission.org/assets/1/6/CAMH\\_2012\\_Update2\\_24\\_SE.pdf](https://www.jointcommission.org/assets/1/6/CAMH_2012_Update2_24_SE.pdf)

<sup>2</sup> National Patient Safety Foundation. (2016). RCA<sup>2</sup> improving root cause analyses and actions to prevent harm. Retrieved from [www.npsf.org](http://www.npsf.org)

process of validity will be assessed by calculating the content validity index (CVI) of the questionnaire.

### **Clarification of Terminology**

**Validity** is defined as the extent to which a questionnaire adequately represents the phenomenon being researched or, in other words, the questionnaire is measuring what it intends to measure (Polit & Beck, 2006; Wynd, Schmidt & Schaefer, 2003).

**The Content Validity Index** is a quantitative approach used to analyse and estimate the content validity of a questionnaire (Wynd, Schmidt & Schaefer, 2003). It uses the ratings of question items in terms of relevance to the research construct (Polit & Beck, 2006).

### **Purpose of the Content Validation Evaluation**

To ensure validity of the questionnaire, the content validity index (CVI) needs to be established. The CVI is established for each question item statement. It is evaluated by experts, such as yourself, assessing the relevance of each statement by rating the individual item statements using a Likert Scale of four points, namely: not relevant = 1, somewhat relevant = 2, quite relevant = 3 and highly relevant = 4 (Appendix C). There is a column alongside each statement for any comments or if there is anything requiring clarity or to expand on your selection. This will assist the researcher with identifying if there is a need to keep an item, remove an item, or reword or expand on an item.

There is a concluding section that requires you to comment on the layout and readability of the questionnaire for a numerical evaluation of its face validity.

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### ***Has ethics approval been granted for the study?***

The study has been approved by the University of Cape Town's Faculty of Health Science Human Research Ethics Committee (HREC Ref 794/2018).

### ***Why has the researcher selected you to participate in the study?***

You have been invited to participate in this study as you hold the position of Quality Manager and you are therefore regarded as the guardian of the adverse event investigation process. You are

considered an expert who has knowledge of both on the investigative process and the use of the Root Cause Analysis process.

***How will you participate in this study?***

All aspects of the survey will be explained to you either telephonically or face to face, as you wish, by the researcher. All communication will be in English as it is the language of the healthcare provider by whom you are employed. You will receive this document with an attached consent form (Appendix B), the tool for assessing the content validity (Appendix C), as well as the prototype questionnaire (Appendix A). If you are willing to participate in the study, you will complete the content validity tool and return it to the researcher along with the signed consent form within two weeks of receiving it. If editing of the questionnaire is required with significant changes, another round of validation assessment may be required as done for the first round.

***What is the anticipated time commitment for participation in the study?***

The initial consultation should take 20 minutes. The content validation assessment should take about 30 minutes to complete.

***Are there any risks associated with participation in this study?***

There are no identified risks to the participants and all feedback will remain anonymous by providing you with a code number and your responses will be confidential. The researcher alone will have access to your completed evaluation form and your name with the associated code number. All data will be stored on a password protected computer to which only the research has access.

***Are there any benefits associated with participation in this study?***

Participation in the study will have no gain financially, it is purely based on you being willing to assist in this validation process.

***What will happen if you decide not to participate in this study?***

Any expert participant has the freedom to choose not to participate in the study, or to withdraw at any time.

***What will happen to the information gathered and the results of the study?***

All data collected will be anonymous and will remain confidential. The documents will be stored securely by the researcher for three years after the completion of the study.

***Who can be contacted if there are any questions related to the study?***

<p><b>Researcher:</b> Clare Wepener (MSc Candidate, Division of Nursing &amp; Midwifery, University of Cape Town) SACS High School Newlands Avenue Newlands 7700 Telephone number: 0828404017 Email: <a href="mailto:dbscla001@myuct.ac.za">dbscla001@myuct.ac.za</a></p>	<p><b>Supervisor:</b> Dr Una Kyriacos Division of Nursing &amp; Midwifery Department of Health &amp; Rehabilitation Sciences Faculty of Health Sciences University of Cape Town Anzio Rd Observatory 7925 Telephone number: (021) 4066410 Email: <a href="mailto:una.kyriacos@uct.ac.za">una.kyriacos@uct.ac.za</a></p>
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**Appendix B (continued)**

**Consent to participation into the study**

Please read the consent statements below and then sign acknowledgment. If you agree with the statement, please initial in the column alongside each statement. On completion of this, please complete your full name, signature and date as indicated below, and return to the researcher by scanning and by email or by hand.

	Consent Statement	Initials
1	I, _____ (full name), have read the participant information for the study.	
2	I have had the opportunity to raise questions relating to the study, and these have been answered adequately.	
3	I acknowledge that there will be no benefit to me for my participation in the study.	
4	I understand that I can decline or withdraw from the study at any time.	
5	I am aware that my participation and all my responses will remain anonymous to all except the researcher and confidential.	
6	I will not receive any financial award for participating in this study	
7	I know that my participation in this study will happen in my own time as it is not related to my employment.	

\_\_\_\_\_  
Participant's Name

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

Acknowledged by researcher:

\_\_\_\_\_  
Researcher name

\_\_\_\_\_  
Researcher Signature

\_\_\_\_\_  
Date

## Appendix C: Content Validity Assessment

Scale: 4 = Highly Relevant, 3 = Quite Relevant, 2 = Somewhat Relevant, 1 = Not relevant

### Section 1: Approach to use of Root Cause Analysis (RCA)

Item	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Comments
1.1	My analysis of root causes focuses primarily on systems and processes					
1.2	I do not identify the risk factors leading to the adverse event					
1.3	I do not repeatedly dig deeper by asking "Why?"; then, when answered, "Why?" again, and so on					
1.4	I determine the human and other factors most directly associated with the adverse event					
1.5	It is difficult to do a thorough RCA					
1.6	I believe an enquiry into all areas appropriate to the specific type of event is important					
1.7	I identify the potential contribution of the risks that led to the adverse event					
1.8	RCA need not start within 72 hours of an adverse event occurring					
1.9	I am not confident of my use of RCA					
1.10	I provide feedback to the people involved in the adverse event					

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Item	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Comments
1.11	It is not necessary to have an RCA team of people not related to the adverse event					
1.12	My analysis of Root Causes focuses on the individuals involved					

**Section 2: Implementation of changes as a result of RCA process outcomes**

Item	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Comments
2.1	The outcome of my analysis identifies changes that could be made in systems and processes					
2.2	I have the ability to decide on the potential improvement in processes or systems					
2.3	The action plan I develop does not identify the changes that can be implemented to reduce risk					
2.4	I believe RCA is achieving an improvement in the quality of patient care					
2.5	In the action plans, I do not identify who is responsible for implementation					
2.6	Actions I recommend are implemented					
2.7	In the action plans, I identify when the action should be implemented					

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Item	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Comments
2.8	I identify how the effectiveness of the actions will be evaluated in the plan of action					

**Section 3: Barriers to the RCA process**

Item	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Comments
3.1	The process of identifying incident needs to be more explicit					
3.2	I have adequate time to complete a thorough RCA					
3.3	Management is supportive as RCA is a priority for quality improvement in the company					
3.4	I do not have adequate resources to complete an RCA					
3.5	There are no conflicting values within the institutional hierarchy that interferes with the RCA process					
3.6	I do not get adequate feedback about how well I complete the RCA					
3.7	I believe leadership should review the RCA process annually					

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The development and validation of a questionnaire on root cause analysis

**Section 4: Demographic Data**

Item	Item statement	Highly Relevant 4	Quite Relevant 3	Somewhat Relevant 2	Not Relevant 1	Comments
4.1	How many years of experience have you had as a Registered Professional Nurse?					
4.2	What is your current position? E.g. Unit Manager, Shift Leader etc.					
4.3	How long have you been in that position?					
4.4	What was your previous position?					
4.5	How long have you been involved in Incident Investigations?					
4.6	Did you attend training on Root Cause Analysis?					
4.7	In what year did you attend Root Cause Analysis training?					
4.8	Are you on Day duty or Night duty?					
4.9	Are you full-time or part-time?					

**Evaluation of face validity**

<b>Please comment on the questionnaire with respect to the following:</b>	Excellent	Good	Needs improvement	Unsatisfactory	Comments
Questionnaire layout					
Questionnaire clarity					
Font type					
Font size					
Question readability					
Questionnaire sequence					
Question wording					
Question terminology					
Questionnaire appearance					

Thank you for completing this assessment

## Appendix D: Revised Questionnaire

### Section 1: Approach to use of Root Cause Analysis (RCA)

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1.1	My analysis of root causes focuses primarily on systems and processes					
1.2	I do not identify the risk factors leading to the adverse event					
1.3	I do not repeatedly dig deeper by asking “Why?”; then, when answered, “Why?” again, and so on					
1.4	I determine the human and other factors, for example, processes and procedures, most directly associated with the adverse event					
1.5	It is difficult to do a thorough RCA					
1.6	I believe an enquiry into all areas appropriate to the specific type of event is important					
1.7	I identify the potential contribution of the risks that led to the adverse event					
1.8	RCA need not start within 72 hours of an adverse event occurring					
1.9	I am not confident of my use of RCA					
1.10	I provide feedback to the people involved in the adverse event					
1.11	It is not necessary to have an RCA team of people not related to the adverse event					
1.12	My analysis of root causes focuses on the individuals involved					

### Section 2: Implementation of changes as a result of RCA outcomes

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2.1	The outcome of my analysis identifies changes that could be made to systems and processes					
2.2	I have the ability to decide on the potential improvement in processes or systems					
2.3	The action plan I develop does not identify the changes that can be implemented to reduce the risk of the adverse event investigated					

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Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2.4	I believe RCA is contributing to an improvement in the quality of patient care					
2.5	In the action plans, I do not identify who is responsible for implementation					
2.6	Actions I recommend are implemented					
2.7	In the action plans, I identify when the action would be implemented					
2.8	I identify how the effectiveness of the actions will be evaluated in the plan of action					

**Section 3: Barriers to RCA**

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
3.1	The process of identifying adverse events needs to be more explicit					
3.2	I have adequate time to complete a thorough RCA					
3.3	Management is supportive as RCA is a priority for quality improvement in the company					
3.4	I do not have adequate resources to complete an RCA					
3.5	There are no conflicting values within the institutional hierarchy that interferes with the RCA process					
3.6	I do not get adequate feedback about how well I am completing RCA					
3.7	I believe management should review the RCA process annually					

**Section 4: Demographic Data**

**Instructions: Please complete the information as required below**

4.1	How many years and months of experience have you had as a Registered Professional Nurse?	
4.2	What is your current position? E.g. Unit Manager, Shift Leader etc.	
4.3	How many years and months have you been in that position?	
4.4	What was your previous position?	

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4.5	How many years and months have you been involved in adverse event investigations?	
4.6	Did you attend training on Root Cause Analysis?	
4.7	In what year did you attend Root Cause Analysis training?	
4.8	Are you full-time or part-time?	

For any questions related to this questionnaire and the study, please contact:

<b>Researcher:</b> Clare Wepener (MSc Candidate, Division of Nursing & Midwifery, University of Cape Town) SACS High School Newlands Avenue Newlands 7700 Telephone number: 0828404017 Email: <a href="mailto:dbsla001@myuct.ac.za">dbsla001@myuct.ac.za</a>	<b>Supervisor:</b> Associate Professor Una Kyriacos Division of Nursing & Midwifery Department of Health & Rehabilitation Sciences Faculty of Health Sciences University of Cape Town Anzio Rd Observatory 7925 Telephone number: (021) 4066410 Email: <a href="mailto:una.kyriacos@uct.ac.za">una.kyriacos@uct.ac.za</a>
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## **Appendix E: Information Sheet and Consent Form for assessment of face validity of the prototype questionnaire on the use of the Root Cause Analysis model using cognitive interviews**

**Title: The development and validation of a questionnaire on Root Cause Analysis**

### **Information Sheet**

I am currently a Master's degree student at the University of Cape Town in the Division of Nursing and Midwifery. The aim of this proposed study is to develop and validate a questionnaire that can establish whether Root Cause Analysis in the private healthcare setting is as acceptable, thorough and credible as required by the Joint Commission (The Joint Commission, 2013)<sup>3</sup>. This questionnaire will also assess the practice of those completing the investigations of adverse events that require establishing root causes. It will identify if the organisation is supporting Root Cause Analysis as recommended by the National Patient Safety Foundation (2016)<sup>4</sup>.

The purpose of Root Cause Analysis is to improve quality and patient safety through a retrospective, structured investigative process that makes recommendations to prevent the recurrence of medical errors. The published literature that was reviewed showed that many challenges are faced during Root Cause Analysis. It is important to establish if the purpose of Root Cause Analysis is understood by those conducting the adverse event investigations and whether the process of getting to the root cause(s) is being thoroughly completed. Likewise, it is important to assess if there is adequate support within the organisation, not limited to completion of the investigation, but including execution of the recommendations that are made.

A valid and reliable questionnaire for assessing the experiences and attitudes of Registered Professional Nurses responsible for employing the Root Cause Analysis model can provide vital data on patient safety practices. The process of validity will be assessed by completing cognitive interviews.

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<sup>3</sup> The Joint Commission (2013). Sentinel Events. Retrieved from [https://www.jointcommission.org/assets/1/6/CAMH\\_2012\\_Update2\\_24\\_SE.pdf](https://www.jointcommission.org/assets/1/6/CAMH_2012_Update2_24_SE.pdf)

<sup>4</sup> National Patient Safety Foundation. (2016). RCA<sup>2</sup> improving root cause analyses and actions to prevent harm. Retrieved from [www.npsf.org](http://www.npsf.org)

### **Clarification of Terminology**

**Validity** is defined as the extent to which a questionnaire adequately represents the phenomenon being researched or, in other words, the questionnaire is measuring what it intends to measure (Polit & Beck, 2006; Wynd, Schmidt & Schaefer, 2003).

**Cognitive Interviewing** is used to determine questionnaire validity by assessing how participants interpret the question items employing interview techniques requiring the participant to think-aloud and the researcher to use verbal probing (Artino, La Rochelle, Dezee & Gehlbach, 2014).

**Adverse Event:** is an event or unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof (The Joint Commission, 2017).

**Quality of care:** the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (Mitchell, 2008).

### **Purpose of the Interview**

To assess the quality of the questionnaire, a sample of participants have been identified for the process of cognitive interviews. These interviews assist with the assessment of face validity, ensuring the questionnaire is measuring what it intends to measure. The process of interviews will help make changes to the wording and clarity of the questions as needed. The interviews will be recorded, and notes will be written, for analysis by the researcher.

Each question item will be read out loud in a face to face interview. The participant will then be asked to rephrase the question in their own words. As the participant answers the question, he/she will be asked to verbalise all thoughts out loud.

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### ***Has ethics approval been granted for the study?***

The study has been approved by the University of Cape Town's Faculty of Health Science Human Research Ethics Committee (HREC Ref 794/2018).

***Why has the researcher selected you to participate in the study?***

You have been invited to participate in this study as you are a Registered Professional Nurse conducting investigations of adverse events occurring in your healthcare setting. The Root Cause Analysis (RCA) process, forms part of this investigative process. You thus have experience of this process.

***How will you participate in this study?***

All aspects of the interview will be explained to you either telephonically or face to face, as you wish, by the researcher. Once the purpose of the study has been explained, you will be asked to consent to participation (Appendix D). All communication will be in English as it is the language of the healthcare provider by whom you are employed. Subsequently, an interview venue, time and date, which is mutually convenient, will be established. During the interview (Appendix E), each question item will be read out loud in the face to face interview. You will be asked to rephrase the question in their own words. As you answer the question, you will be asked to verbalise all thoughts out loud. Please be encouraged to speak freely and openly during the interview. The interview will be recorded, and the researcher will take notes for later analysis that will assist with identifying if there are necessary alterations to be made to the questionnaire.

***What is the anticipated time commitment for participation in the study?***

The initial consultation should take 20 minutes. The interview is expected to take about 45-60 minutes to complete.

***Are there any risks associated with participation in this study?***

There are no identified risks to the participants and all feedback will remain anonymous by providing you with a code number and your responses will be confidential. The researcher alone will have access to your completed evaluation form and your name with the associated code number. All data will be stored on a password protected computer to which only the research has access.

***Are there any benefits associated with participation in this study?***

Participation in the study will have no gain financially, it is purely based on you being willing to assist in this validation process.

***What will happen if you decide not to participate in this study?***

Any participant has the freedom to choose not to participate in the study, or to withdraw at any time.

***What will happen to the information gathered and the results of the study?***

All data collected will be anonymous and will remain confidential. The documents will be stored securely by the researcher for three years after the completion of the study.

***Who can be contacted if there are any questions related to the study?***

<p><b>Researcher:</b> Clare Wepener (MSc Candidate, Division of Nursing &amp; Midwifery, University of Cape Town) SACS High School Newlands Avenue Newlands 7700 Telephone number: 0828404017 Email: <a href="mailto:dbscla001@myuct.ac.za">dbscla001@myuct.ac.za</a></p>	<p><b>Supervisor:</b> Dr Una Kyriacos Division of Nursing &amp; Midwifery Department of Health &amp; Rehabilitation Sciences Faculty of Health Sciences University of Cape Town Anzio Rd Observatory 7925 Telephone number: (021) 4066410 Email: <a href="mailto:una.kyriacos@uct.ac.za">una.kyriacos@uct.ac.za</a></p>
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**Appendix D (continued)**

**Consent to participation into the study**

Please read the consent statements below and then sign acknowledgment. If you agree with the statement, please initial in the column alongside each statement. On completion of this, please complete your full name, signature and date as indicated below, and return to the researcher by scanning and by email or by hand.

	Consent Statement	Initials
1	I, _____ (full name), have read the participant information for the study.	
2	I have had the opportunity to raise questions relating to the study, and these have been answered adequately.	
3	I acknowledge that there will be no benefit to me for my participation in the study.	
4	I understand that I can decline or withdraw from the study at any time.	
5	I am aware that my participation and all my responses will remain anonymous to all except the researcher and confidential.	
6	I will not receive any financial award for participating in this study	
7	I know that my participation in this study will happen in my own time as it is not related to my employment.	

\_\_\_\_\_

Participant's Name

\_\_\_\_\_

Participant's Signature

\_\_\_\_\_

Date

Acknowledged by researcher:

\_\_\_\_\_

Researcher name

\_\_\_\_\_

Researcher Signature

\_\_\_\_\_

Date

## Appendix F: Cognitive Interview Guide

### The Interview Process

Before commencement of the interview, consent for participation in the study was confirmed.

Audiotaping commenced, and field notes were taken by the researcher during the interview.

The participant was asked to read each item out loud and then requested to do the following per item:

1. What they understood about the question or statement in their own words
2. To put the question or statement in their own words
3. How they would you rate the question or statement according to the Likert scale explaining their thought out loud as they did so

### Section 1: Approach to use of Root Cause Analysis (RCA)

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1.1	My analysis of root causes focuses primarily on systems and processes					
1.2	I do not identify the risk factors leading to the adverse event					
1.3	I do not repeatedly dig deeper by asking “Why?”; then, when answered, “Why?” again, and so on					
1.4	I determine the human and other factors, for example, processes and procedures, most directly associated with the adverse event					
1.5	It is difficult to do a thorough RCA					
1.6	I believe an enquiry into all areas appropriate to the specific type of event is important					
1.7	I identify the potential contribution of the risks that led to the adverse event					
1.8	RCA need not start within 72 hours of an adverse event occurring					
1.9	I am not confident of my use of RCA					
1.10	I provide feedback to the people involved in the adverse event					
1.11	It is not necessary to have an RCA team of people not related to the adverse event					

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Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1.12	My analysis of Root Causes focuses on the individuals involved					

**Section 2: Implementation of changes as a result of RCA outcomes**

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2.1	The outcome of my analysis identifies changes that could be made to systems and processes					
2.2	I have the ability to decide on the potential improvement in processes or systems					
2.3	The action plan I develop does not identify the changes that can be implemented to reduce the risk of the adverse event investigated					
2.4	I believe RCA is contributing to an improvement in the quality of patient care					
2.5	In the action plans, I do not identify who is responsible for implementation					
2.6	Actions I recommend are implemented					
2.7	In the action plans, I identify when the action would be implemented					
2.8	I identify how the effectiveness of the actions will be evaluated in the plan of action					

**Section 3: Barriers to RCA**

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
3.1	The process of identifying adverse events needs to be more explicit					
3.2	I have adequate time to complete a thorough RCA					
3.3	Management is supportive as RCA is a priority for quality improvement in the company					
3.4	I do not have adequate resources to complete an RCA					
3.5	There are no conflicting values within the institutional hierarchy that interferes with the RCA process					

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Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
3.1	The process of identifying adverse events needs to be more explicit					
3.6	I do not get adequate feedback about how well I am completing RCA					
3.7	I believe management should review the RCA process annually					

#### Section 4: Demographic Data

**Instructions: Please complete the information as required below**

4.1	How many years and months of experience have you had as a Registered Professional Nurse?	
4.2	What is your current position? E.g. Unit Manager, Shift Leader etc.	
4.3	How many years and months have you been in that position?	
4.4	What was your previous position?	
4.5	How many years and months have you been involved in adverse event investigations?	
4.6	Did you attend training on Root Cause Analysis?	
4.7	In what year did you attend Root Cause Analysis training?	
4.8	Are you full-time or part-time?	

The participant would then be asked:

1. How would you describe what is being asked in Section 1: Approach to the use Root Cause Analysis (RCA)?

*Probing questions will be asked if necessary: "why did you say...", "tell me more...", and so on if necessary*

2. How would you describe what is being asked in Section 2: The implementation of change as a result of an RCA?

*Probing questions will be asked if necessary: "why did you say...", "tell me more...", and so on if necessary*

3. How would you describe what is being asked Section 3: Barriers to completing RCA?

*Probing questions will be asked if necessary: "why did you say...", "tell me more...", and so on if necessary*

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Summarising the interview:

The participant will be asked the following:

In summary, the problems you have identified during the interview are (.....). Do you agree with this summary?

Do you agree that (.....) are your recommendations regarding the questionnaire?

Are there any further comments or suggestions you would like to make before concluding this interview?

Concluding the interview:

Are there any questions you would like to ask before concluding this interview?

Thank you for your time. The contents of this interview will be confidential.

For any questions related to this questionnaire and the study, please contact:

<p><b>Researcher:</b> Clare Wepener (MSc Candidate, Division of Nursing &amp; Midwifery, University of Cape Town) SACS High School Newlands Avenue Newlands 7700 Telephone number: 0828404017 Email: <a href="mailto:dbsccla001@myuct.ac.za">dbsccla001@myuct.ac.za</a></p>	<p><b>Supervisor:</b> Associate Professor Una Kyriacos Division of Nursing &amp; Midwifery Department of Health &amp; Rehabilitation Sciences Faculty of Health Sciences University of Cape Town Anzio Rd Observatory 7925 Telephone number: (021) 4066410 Email: <a href="mailto:una.kyriacos@uct.ac.za">una.kyriacos@uct.ac.za</a></p>
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## Appendix G: Final Questionnaire

### Section 1: Approach to use of Root Cause Analysis (RCA)

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1.1	When analysing root causes of an adverse event, I primarily focus on the systems and processes that failed to avoid it, rather than the individual's error.					
1.2	I do not identify the possible causes leading to the adverse event					
1.3	I do not repeatedly dig deeper by asking "Why?" and "Why?" again, and so on.					
1.4	I determine the human and other factors, for example, processes and procedures, most directly associated with the adverse event					
1.5	It is difficult to do a thorough Root Cause Analysis					
1.6	I believe an investigation into all areas appropriate to the specific type of event is important					
1.7	I identify the potential contribution of the possible causes that led to the adverse event					
1.8	Root cause analysis need not start within 72 hours of an adverse event occurring					
1.9	I am not confident of my use of Root Cause Analysis					
1.10	I provide feedback to the people involved in the adverse event					
1.11	It is necessary to have a Root Cause Analysis team of people not related to the adverse event					
1.12	My analysis of root causes focuses only on the individuals involved in the adverse event					

### Section 2: Implementation of changes as a result of Root Cause Analysis outcomes

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2.1	The outcome of my analysis identifies changes that could be made to systems and processes					

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Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2.2	I have the ability to decide on the potential improvement in processes or systems					
2.3	The action plan I develop does not identify the changes that can be implemented to reduce the risk of the adverse event investigated					
2.4	I believe Root Cause Analysis is contributing to an improvement in the quality of patient care					
2.5	In the action plans, I do not identify who is responsible for implementation					
2.6	Actions I recommend are implemented					
2.7	In the action plans, I identify when the action would be implemented					
2.8	I identify how the effectiveness of the actions will be evaluated in the plan of action					

**Section 3: Barriers to Root Cause Analysis**

Item	Item statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
3.1	The process of identifying adverse events needs to be more explicit					
3.2	I have adequate time to complete a thorough root cause analysis					
3.3	Management is supportive as Root Cause Analysis is a priority for quality improvement in the company					
3.4	I do not have adequate resources to complete an root cause analysis					
3.5	There are no conflicting values within the institutional hierarchy that interferes with the Root Cause Analysis process					
3.6	I do not get adequate feedback about how well I am completing root cause analysis					
3.7	I believe management should review the Root Cause Analysis process annually					

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**Section 4: Demographic Data**

**Instructions: Please complete the information as required below**

4.1	How many years of experience have you had as a Registered Professional Nurse?	
4.2	What is your current position? E.g. Unit Manager, Shift Leader etc.	
4.3	How many years have you been in that position?	
4.4	What was your previous position?	
4.5	How many years have you been involved in adverse event investigations?	
4.6	Did you attend training on Root Cause Analysis?	
4.7	How long ago did you attend Root Cause Analysis training?	
4.8	Are you full-time or part-time?	

For any questions related to this questionnaire and the study, please contact:

<p><b>Researcher:</b> Clare Wepener (MSc Candidate, Division of Nursing &amp; Midwifery, University of Cape Town) SACS High School Newlands Avenue Newlands 7700 Telephone number: 0828404017 Email: <a href="mailto:dbsccla001@myuct.ac.za">dbsccla001@myuct.ac.za</a></p>	<p><b>Supervisor:</b> Associate Professor Una Kyriacos Division of Nursing &amp; Midwifery Department of Health &amp; Rehabilitation Sciences Faculty of Health Sciences University of Cape Town Anzio Rd Observatory 7925 Telephone number: (021) 4066410 Email: <a href="mailto:una.kyriacos@uct.ac.za">una.kyriacos@uct.ac.za</a></p>
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## **Appendix H: Information Sheet for the assessment of reliability**

**Title: The Development and Validation of a Questionnaire: A mixed methods study**

### **Information Sheet**

I am currently a Master's degree student at the University of Cape Town in the Division of Nursing and Midwifery. The aim of this proposed study is to develop and validate a questionnaire that can establish whether the RCA process in the private healthcare setting is as acceptable, thorough and credible as required by the Joint Commission (The Joint Commission, 2013)<sup>5</sup>. This questionnaire will also assess the practice of those completing the investigations of incidents that require establishing root causes. It will also identify if the organisation is supporting the RCA process as recommended by the National Patient Safety Foundation (2016)<sup>6</sup>.

The purpose of Root Cause Analysis is to improve quality and patient safety through a retrospective, structured investigative process that makes recommendations to prevent the recurrence of medical errors. The published literature that was reviewed showed that many challenges are faced during the RCA process. It is important to establish if the purpose of the RCA model is understood by those conducting the incident investigations and whether the process of getting to the root cause(s) is being thoroughly completed. Likewise, it is important to assess if there is adequate support within the organisation, not limited to completion of the investigation, but including execution of the recommendations that are made.

A valid and reliable questionnaire for assessing the experiences and attitudes of Registered Professional Nurses responsible for employing the Root Cause Analysis model can provide vital data on patient safety practices. The process of reliability will be assessed by Test-retest reliability.

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<sup>5</sup> The Joint Commission (2013). Sentinel Events. Retrieved from [https://www.jointcommission.org/assets/1/6/CAMH\\_2012\\_Update2\\_24\\_SE.pdf](https://www.jointcommission.org/assets/1/6/CAMH_2012_Update2_24_SE.pdf)

<sup>6</sup> National Patient Safety Foundation. (2016). RCA<sup>2</sup> improving root cause analyses and actions to prevent harm. Retrieved from [www.npsf.org](http://www.npsf.org)

### **Clarification of Terminology**

**Reliability** refers to the quality of a questionnaire in terms of its consistency over time and across respondents and situations (Karanicolas *et al.*, 2009).

**Test-retest reliability** is a method of establishing the consistency of a questionnaire by having the same participant complete the questionnaire more than once under the same conditions (Rattray & Jones, 2007).

**Adverse Event:** is an event or unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof (The Joint Commission, 2017).

**Quality of care:** the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (Mitchell, 2008).

**Root Cause Analysis:** RCA is a systematic and structured approach to examine and investigate the underlying causes of an adverse event (Bagian *et al.*, 2011; Bowie *et al.*, 2013)

### **Purpose of Test-Retest reliability assessment**

A reliability analysis needs to be done to ensure that the questionnaire will achieve consistency. The Test-retest approach includes giving the same set of subjects the same questionnaire at two different points in time to establish the stability of the questionnaire. This means the same results should be noted in the repeated trial with the same group in the same circumstances.

### ***Has ethics approval been granted for the study?***

The study has been approved by the University of Cape Town's Faculty of Health Science Human Research Ethics Committee (HREC Ref 794/2018).

### ***Why has the researcher selected you to participate in the study?***

You have been invited to participate in this study as you are a Registered Professional Nurse conducting investigations of Incidents occurring in your healthcare setting. The Root Cause Analysis (RCA) process, forms part of this investigative process. You thus have experience of this process.

***How will you participate in this study?***

As a potential participant, you will be contacted, and all aspects of the survey will be explained to you either telephonically or face to face, as you wish, by the researcher. You will receive this document with an attached consent form as well as the prototype questionnaire. If you are willing to participate in the study, you will complete the questionnaire. The completed questionnaire will be returned to the researcher. After an interval of at least two weeks (but within a month), the questionnaire will then be sent to you again. The results from the same participants will be analysed to ensure there are comparable results on different occasions, confirming reliability. All communication will be in English as it is the language of the healthcare provider by whom you are employed.

***What is the anticipated time commitment for participation in the study?***

The initial consultation should take 20 minutes. The content questionnaire should take about 30 minutes to complete.

***Are there any risks associated with participation in this study?***

There are no identified risks to the participants and all feedback will remain anonymous by providing you with a code number and your responses will be confidential. The researcher alone will have access to your completed evaluation form and your name with the associated code number. All data will be stored on a password protected computer to which only the research has access.

***Are there any benefits associated with participation in this study?***

Participation in the study will have no gain financially, it is purely based on you being willing to assist in this validation process.

***What will happen if you decide not to participate in this study?***

Any expert participant has the freedom to choose not to participate in the study, or to withdraw at any time.

***What will happen to the information gathered and the results of the study?***

All data collected will be anonymous and will remain confidential. The documents will be stored securely by the researcher for three years after the completion of the study.

***Who can be contacted if there are any questions related to the study?***

<p><b>Researcher:</b> Clare Wepener (MSc Candidate, Division of Nursing &amp; Midwifery, University of Cape Town) SACS High School Newlands Avenue Newlands 7700 Telephone number: 0828404017 Email: <a href="mailto:dbscla001@myuct.ac.za">dbscla001@myuct.ac.za</a></p>	<p><b>Supervisor:</b> Dr Una Kyriacos Division of Nursing &amp; Midwifery Department of Health &amp; Rehabilitation Sciences Faculty of Health Sciences University of Cape Town Anzio Rd Observatory 7925 Telephone number: (021) 4066410 Email: <a href="mailto:una.kyriacos@uct.ac.za">una.kyriacos@uct.ac.za</a></p>
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