DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE ON NURSES' KNOWLEDGE AND RECOGNITION OF EARLY SIGNS OF CLINICAL DETERIORATION

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ABSTRACT

Introduction: There is evidence-based concern that nurses on general wards do not recognise signs of physiological and clinical deterioration and delay calling for more skilled assistance for review of a patient showing signs of deterioration.

Aim: The development and validation of a questionnaire to assess factors influencing general ward nurses' ability to recognise and respond to patient deterioration; nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and nurses' self-reported clinical reasoning ability.

Methodology: A mixed methods sequential 4-phase study design was employed: 1) an in-depth literature review to identify and develop content domains and item statements for a prototype questionnaire; 2) determining the content validity index (CVI) (n=5 expert registered professional nurses) of all item statements; 3) conducting cognitive interviews (n=3 expert registered professional nurses) to explore face validity and the quality of the revised prototype questionnaire; and 4) assessing stability of the final validated questionnaire through test-retest reliability testing (n=30 qualified nurses: Registered Professional Nurses with four years of training, Enrolled Nurses with two years of training, Enrolled Nursing Auxiliaries with one year of training) two weeks apart.

Results: The CVI exceeded the pre-set proportion of ≥70% agreement for 56/65 (86.2%) item statements scoring 3 (relevant only needing minor editing) or 4 (extremely relevant); removal of 3/65 (4.6%) items from the prototype questionnaire. Cognitive interviews then resulted in amendment of 30/78 (38.5%) item statements; removal of 2/78 (2.6%) from the revised prototype questionnaire. The weighted kappa statistic for level of agreement beyond chance for nurse respondents' test-retest data was fair (0.21-0.4) for 18/47 (38.3%) items, moderate (0.41-0.6) for 12/47 (25.5%) items and substantial (0.61-0.8) for 13/47 (27.7%) items. Registered Professional Nurses' responses between time 1 and time 2 were more consistent than for Enrolled Nurses and Nursing Auxiliaries.

Conclusion and recommendations: The researcher-developed questionnaire was validated by registered professional nurses, but there is concern about its stability, tested on three categories of nurses. The questionnaire should be reassessed for content and face validity using a sample inclusive of all categories for nurses who take and interpret patients' vital signs in an attempt to improve the reliability of the questionnaire.

Key words: Nurse; Knowledge; Clinical reasoning; Clinical deterioration; Questionnaire; Validation

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OPERATIONAL DEFINITIONS

Adverse event (AE) refers to an event in a healthcare general ward setting where there is evidence of failure to recognise clinical and physiological signs of deterioration, failure to take action in response to signs of deterioration, failure to initiate a call for a more qualified healthcare professional to review a patient, or failure of a more qualified healthcare professional to respond to the call for review timeously (Chua, Mackey, Ng, & Liaw, 2013; Kyriacos, Jelsma, & Jordan, 2014; NHS National Patient Safety Agency, 2007).

Clinical observations refer to the subjective and objective findings gathered during a patient assessment. For example, pain, bleeding, sweating, skin colour (De Meester, Van Bogaert, Clarke, & Bossaert, 2013; Kyriacos, 2011).

Cognitive interviewing (CI) is a process where a researcher asks each participant face to face, open-ended questions to explore whether participants have sufficient understanding to answer each item in an instrument in an attempt to improve the user's rate of completion of a questionnaire (Beatty & Willis, 2007).

Content validity index (CVI) is a measure for assessing the relevance (validity) of the content of an instrument compared to the instrument's content domains using a 4-point Likert scale. The CVI for each item (I-CVI) is calculated as the percentage of expert respondents assessing each item as 3 (relevant needing minor correction) or 4 (extremely relevant). The CVI for scales (S-CVI) for the instrument as a whole is calculated as the proportion of items scored at 3 (relevant needing minor correction) or 4 (extremely relevant) (Lynn, 1986).

Early warning score (EWS) / Modified early warning score (MEWS) refers to a patient monitoring tool for vital sign data serving as a "track and trigger system" for healthcare professionals. A score of 0 (normal range) or upper or lower 1-3 is assigned to each vital sign parameter dependent on its deviation from the determined normal value. Scores (0-3) for all of the recorded vital signs are added together to calculate a total (aggregate) score. The total scores are grouped to indicate level of risk (1-4 is low risk; 5-6 is medium risk; a single score of 3 is medium risk; 7 or more is high risk) in an algorithm to trigger an appropriate action by the healthcare professional in response to the degree of deterioration in a patient's condition (Christofidis, Hill, Horswill, & Watson, 2016; Kyriacos, Jelsma, James, & Jordan, 2014).

Enrolled Nurse (EN) is a qualified nurse who has successfully completed the education and training programme in terms of the South African Nursing Council's Regulation 2175 of 19 November 1993 (South African Nursing Council, 1993a).

Enrolled Nursing Auxiliary (ENA) is a qualified nurse who has successfully completed the education and training programme in terms of the South African Nursing Council's Regulation 2176 of 19 November 1993 (South African Nursing Council, 1993b).

Face validity by definition is an expert evaluation of a measurement instrument's items relevance to the instrument's content domains (Lynn, 1986).

Physiological parameters refer to the vital signs measured and recorded by nurses as part of their scope of practice. For the purposes of this study, the parameters include a patient's heart rate, blood pressure, respiratory rate, temperature, oxygen saturation level and level of consciousness (Ludikhuize, Smorenburg, de Rooij, & de Jonge, 2012; Royal College of Physicians, 2012).

Registered Professional Nurse (RPN) is a qualified nurse who has successfully completed the education and training programme in terms of the South African Nursing Council's Regulation 425 of 22 February 1985 or Regulation 683 of 14 April 1989 (South African Nursing Council, 1985, 1989).

Test-retest reliability testing is a methodology used to assess the stability or consistency of a measuring instrument such as a questionnaire over a determined duration when used repeatedly (Polit & Beck, 2017; Rattray & Jones, 2007).

Validity refers to the ability of a tool or test such as a questionnaire to measure what it is intended to measure (Polit & Beck, 2017).

ABBREVIATIONS

CCOT	Critical care outreach team
CI	Cognitive interview
CPR	Cardiopulmonary resuscitation
CVI	Content validity index
EN	Enrolled nurse
ENA	Enrolled nursing auxiliary
I-CVI	Item content validity index
MCQ	Multiple choice question
MET	Medical emergency team
MEWS	Modified Early Warning Score
NCRS	Nurses' Clinical Reasoning Scale
NEWS	National Early Warning Score
RPN	Registered professional nurse
RCT	Randomised controlled study
RRT	Rapid response team
SA	South Africa
SANC	South African Nursing Council
SBAR	Situation, background, assessment and recommendation
S-CVI	Scale content validity index
UK	United Kingdom

CHAPTER 1: INTRODUCTION

The occurrence of adverse events (AEs) in the healthcare environment has triggered national and international concern. A classic confidential inquiry by McQuillan et al. (1998) in the United Kingdom (UK) into suboptimal care rendered to patients before admission to intensive care units reported that suboptimal care contributed to morbidity or mortality in most instances. Contributing factors to suboptimal care were failures at various levels: organisational, knowledge, recognising clinical urgency, supervision and calling for assistance (McQuillan et al., 1998; Quirke, Coombs, & McEldowney, 2011). There has since been an increase in research to explore the occurrence of AEs, the contributing factors to deterioration in a patient's condition and practices to improve patient safety in healthcare facilities.

Validation studies need to achieve validity and reliability standards (Paiva et al., 2014). The present study has focused narrowly on the robust development and validation of a questionnaire as a measurement tool to assess the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and nurses' self-reported clinical reasoning ability.

1.1 Background

A nurse has a fundamental responsibility to monitor patients' health status for indications of improvement or deterioration (South African Nursing Council, 1984). Nurses are able to fulfil this expectation by acquiring knowledge, psychomotor skills and clinical reasoning competencies during their formal nursing education programmes in line with their scope of practice. This includes the ability to monitor a patient's physiological parameters (vital signs) and clinical observations. Thereafter a nurse needs to assimilate the information, recognise changes in a patient's condition, make decisions based on the identified patient need and respond appropriately (Levett-Jones et al., 2010). A literature search for a validated questionnaire to measure nurses' competence in early recognition and response to clinical deterioration provided disappointing results but relevant item statements were identified for the construction of a questionnaire. The literature was simultaneously searched for methods for validating a questionnaire which is the focus of this study.

Retrospective patient document reviews have shown that gaps are evident in the number and frequency of monitoring physiological parameters and clinical observations recorded by nurses (Kyriacos, Jelsma, & Jordan, 2014). It is assumed that recorded evidence in

patient documentation reflects the nursing care carried out. Therefore the failure to record vital signs and clinical observations could reflect suboptimal care delivery by nurses to patients (Cardona-Morrell et al., 2016).

Suboptimal care is thought to contribute to the occurrence of AEs (Ludikhuize, Smorenburg, et al., 2012; Quirke et al., 2011). AEs are described as evidence of failure to recognise clinical and physiological signs of deterioration, failure to take action in response to signs of deterioration, failure to take action to initiate a call for a more qualified healthcare professional to review a patient, or failure of a more qualified healthcare professional to act timeously in response to the call for review (NHS National Patient Safety Agency, 2007). Since evidence of a change in vital signs has been shown to be evident during the 24 hours prior to escalation of calls to a more qualified healthcare professional to review a patient, it is important to explore the antecedents to AEs (Ludikhuize, Smorenburg, et al., 2012). The ability to identify and understand these contributing factors could allow healthcare organisations to develop patient safety strategies to improve patient care with the intention of reducing the incidence of AEs.

1.1.1 A patient safety culture

In the UK, reviews of AEs have led experts to believe that cardiac arrests can be predicted and are possibly preventable (National Confidential Enquiry into Patient Outcome and Death, 2012). Findings reveal an inconsistency in identifying warning cues in patients at risk of deterioration. Poor recognition of these warning cues and delayed action to escalate calls for patients at risk of deterioration are also evident in patient records (National Confidential Enquiry into Patient Outcome and Death, 2012). Coupled with these findings, the UK Patient Safety 2030 report highlighted four trends that will challenge existing patient safety practices placing patients at risk for AEs and harm. The trends include: “increasingly complex care, increasingly complex cases, antimicrobial resistance and budget constraints” (Yu, Flott, & Chainani, 2016).

Results from a study by Aiken et al. (2011) showed that a positive clinical work environment and improved staff to patient ratios lead to a positive reduction in the risk of patient mortality and AEs related to clinical and physiological deterioration. Aiken et al. (2011) also confirmed the positive impact of reducing patient mortality by 4% and improving patient outcomes, when increasing the ratio of bachelor-prepared nurses to other categories of nurses by 10%. This study has made an important contribution to research into patient safety.

As a result of the known challenges, it is recommended that healthcare organisations should prioritise the implementation of patient safety practices. Regular reviews of practice compared to set target outcomes is required to monitor the antecedents impacting the occurrence of AEs to progress towards a sustainable patient safety culture (Australian Commission on Safety and Quality in Healthcare, 2011).

Locally a patient safety culture has been prioritised in the Department of Health (2011) gazetted publication, the National Core Standards for Health Establishments in South Africa. Domain 2 of the Core Standards document outlines the expected minimum standard of care in terms of "patient safety, clinical governance and clinical care" that promotes patient safety and a reduction in potential harm to the patient. South African healthcare organisations are mandated to ensure that governance structures, guidelines and processes are in place and regularly audited to achieve target patient health outcomes and to identify and manage healthcare risks and AEs (Department of Health, 2011). Studies exploring the antecedents to suboptimal healthcare and patient AEs have resulted in a number of recommendations for healthcare organisations to consider implementing to promote and sustain a patient safety culture (Allen, Elliott, & Jackson, 2017; Quirke et al., 2011).

1.1.2 Recommendations to reduce adverse events

The National Confidential Enquiry into Patient Outcome and Death (2012) report in the UK suggests that healthcare organisations should regularly conduct audit reviews of AEs to accurately identify causative factors and the possible impact thereof on patient outcomes. Recommended strategies to reduce the incidence of AEs have been implemented in Australia (Australian Commission on Safety and Quality in Healthcare, 2011). These recommendations are classified into afferent and efferent limb interventions (McNeill & Bryden, 2013).

Afferent limb recommendations include interventions that influence the early recognition of patients at risk of clinical deterioration and the timeous response relevant to the identified patient risk. Efferent limb interventions refer to the prompt, accurate reaction by more skilled healthcare professionals in response to an escalation call for assistance most commonly made by a nurse or junior doctor. It is suggested that a holistic approach inclusive of the afferent and efferent limbs should be introduced into a healthcare organisation (McNeill & Bryden, 2013).

Prompt reactions by healthcare professionals firstly require accurate monitoring of patients' vital signs and clinical observations (Kyriacos, Jelsma, & Jordan, 2011). Record

reviews have however highlighted gaps in nurses' documentation of vital signs and clinical observation as a phenomenon that gives cause for concern (Kyriacos, Jelsma, & Jordan, 2014; Ludikhuize, Smorenburg, et al., 2012). To optimise the impact of the afferent limb, it is recommended that clear guidelines of assessment and instructions for monitoring a patient's health status need to be in place (National Confidential Enquiry into Patient Outcome and Death, 2012). Early Warning Scoring (EWS) systems, also referred to as Track and Trigger systems, have been implemented in healthcare organisations as standards of practice to track identified early signs of deterioration and to trigger relevant and timeous actions required. Such responses might include repeat measurement of vital signs in response to the trigger cue (for example a systolic blood pressure of 94 mmHg). A well-known example of an EWS is the National Early Warning Score (NEWS) validated and implemented in the UK to standardise the monitoring and recognition of signs of early patient deterioration (Royal College of Physicians, 2012).

In South Africa (SA), the Cape Town Modified Early Warning Score (MEWS) was developed, validated and tested in a government sector public hospital in the Western Cape (Kyriacos, 2011) and will soon be implemented (personal communication L Strauss, 2018). In addition, a modified MEWS-linked Cape Town Situation-Background-Assessment-Recommendation (SBAR) communication tool for reporting patient deterioration information has been validated to support the transfer of information to a more skilled healthcare professional (Burger, Jordan, & Kyriacos, 2017). The SBAR tool is recommended to ensure a standard format for nurses to use when communicating clinical deterioration to a medical doctor. The tool encourages clear, efficient transfer of patient information, teamwork and timeous activation of the efferent limb, thus contributing to a patient safety culture (Quirke et al., 2011).

Responders fulfilling the efferent limb component are referred to as rapid response teams (RRTs), medical emergency teams (METs) or critical care outreach teams (CCOTs), each varying in their composition depending on the healthcare organisation. Nevertheless, unsatisfactory patient outcomes continue to occur despite the implementation of these specialist response teams (Maharaj, Raffaele, & Wendon, 2015). Further investigation is suggested to explore the underutilisation of specialist response teams following the recognition of clinical deterioration (Massey, Aitken, & Chaboyer, 2010).

1.1.3 The current reality

There is concern about nurses' inability to recognize and respond to deterioration in a patient's condition as a contributing factor in the occurrence in patient AEs in general

ward settings (Kyriacos et al., 2011; Liaw, Scherpbier, Klainin-Yobas, & Rethans, 2011a). Nurses are considered to be in an optimal position to improve the recognition and responsiveness when a patient's condition deteriorates (Liaw et al., 2011a). Monitoring and reacting to a change in a patient's vital signs and clinical condition and response to treatment is an essential part of SA nurses' Scope of Practice relative to their level of qualification (South African Nursing Council, 1984).

Statistics from the South African Nursing Council (2016) indicate that in 2016, 43.6% of all categories of nurses (including student nurses) were Registered Professional Nurses (RPNs) and that 27% of new RPN registrations completed their training at a university, inferring a bachelor's degree qualification. The low percentage of degree-prepared RPNs in SA challenges the recommendation to increase the ratio of bachelor-prepared RPNs to effect an anticipated reduction in patient mortality and improved patient outcomes (Aiken et al., 2011; Institute of Medicine, 2010).

Coetzee, Klopper, Ellis, and Aiken (2013) conducted a study of RPNs in SA public and private hospitals and found that 20% of RPNs rated the quality of care rendered to patients as fair or poor. In the same study, 6% of the RPN's considered patient safety in their hospitals to be of a poor or failing standard. It is therefore important for healthcare organisations to explore the factors that influence registered and non-registered nurses' ability to competently recognise early cues of deterioration and factors that influence actions to report or not report these findings to more skilled healthcare professionals.

All categories of nurses play an important role in the early recognition of and response to clinical deterioration (James, Butler-Williams, Hunt, & Cox, 2010). Therefore all nurses in healthcare organisations therefore have to be adequately educated to reduce the incidence of patient AEs and to contribute to a sustainable patient safety culture. Education programmes for healthcare professionals, particularly nurses, should aim to develop their knowledge, psychomotor skills as well as communication skills, clinical reasoning ability and interdisciplinary teamwork. These competencies are needed for early identification of a patient's deteriorating condition and triggering of a timeous response to the change in condition (Liaw et al., 2011a; Purling & King, 2012; Quirke et al., 2011). Knowing what to include in such an educational programme can be ascertained by surveying nurses' opinions using a valid, reliable questionnaire. A survey by questionnaire is a useful method to elicit feedback from respondents about a particular topic of interest (Polit & Beck, 2017). Published questionnaires have been reviewed to determine their suitability to meet the intended aim of the present study and to contribute broadly to a patient safety culture.

1.2 Scope of the study

The scope of the present study has been limited to the robust development and validation of a questionnaire that will serve as a measurement tool to understand the factors influencing nurses' ability to timeously recognise and respond to patient deterioration and to assess nurses' knowledge and clinical reasoning skills. This is in response to published evidence highlighting the need for nurses to improve their ability to recognise and to take action in response timeously and appropriately to deterioration in a patient's condition (Bogossian et al., 2014; Kyriacos et al., 2011; Liaw et al., 2011a).

1.3 Problem statement

There is an evidence-based concern about nurses' ability to recognise deterioration in a patient's condition and to respond timeously and accurately when presented with a patient showing signs of deterioration (Brier et al., 2015; Considine, Trotter, & Currey, 2016; Kyriacos et al., 2011; Liaw, Scherpbier, Klainin-Yobas, & Rethans, 2011b; Purling & King, 2012; Quirke et al., 2011). A questionnaire was not identified that addressed all three areas of interest for this study: assessment of nurses' knowledge of physiological and of clinical parameters associated with patient deterioration; the factors influencing a nurse's ability to recognise and respond to patient deterioration; or their self-reported clinical reasoning ability. Liaw et al. (2011b) recommend that healthcare institutions should investigate the educational and experiential needs of nurses working in general wards prior to implementing any quality improvement plans. The current reality at the research setting in the Western Cape represents an opportunity to develop and validate a questionnaire to assess nurses' knowledge, clinical reasoning skills and factors influencing these before an early warning system is implemented in general wards.

1.4 Research question

What are the validity and reliability outcomes for a self-designed questionnaire on nurses' knowledge and recognition of early clinical deterioration using the processes of calculating the content validity index, cognitive interviewing and test-retest reliability testing?

1.5 Aim

The aim of this study was the robust development and validation of a questionnaire to assess: 1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; 2) nurses' knowledge of physiological and clinical

parameters associated with patient deterioration; and 3) nurses' self-reported clinical reasoning ability.

1.6 Objectives

The objectives of this study were to:

1.6.1 conduct an in-depth literature review to find the best available evidence on: 1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; 2) nurses' knowledge of clinical and physiological parameters linked to patient deterioration; and 3) nurses' self-reported clinical reasoning ability;

1.6.2 design a prototype questionnaire based on the literature review (Appendix A);

1.6.3 assess the content validity index and face validity of the prototype questionnaire by experts (Appendices B, C) and further assessment of face validity by cognitive interviewing of experts (Appendices D, E, F) and then amending the revised prototype questionnaire (Appendix G);

1.6.4 assess the reliability (stability) of the validated questionnaire by test-retest reliability testing using three categories of nurses (Appendices G, H).

1.7 Significance of the study

The research site in the Western Cape had not yet explored the factors influencing nurses' ability to recognise, interpret and act in response to patients' clinical and physiological deterioration. Clarke, Kelleher, and Fairbrother (2010) recommend that organisations need to understand the complexities and barriers to early recognition of and response to signs of patient deterioration in general wards for planning patient safety improvement initiatives to contribute to a reduction in AEs.

The task of measuring and monitoring vital signs and clinical observations in the general wards is routinely delegated by RPNs to Enrolled Nursing Auxiliaries (ENAs) who are the least qualified nurses and to student nurses. Studies have reported that deficits in knowledge and decision making skills of healthcare assistants, the equivalent to ENAs in SA (Quirke et al., 2011) and nursing students (Bucknall, Jones, Bellomo, & Staples, 2013) in general wards can contribute to suboptimal care and failure to recognise patient's clinical deterioration.

A valid questionnaire for self-administration by all categories of nurses in a SA healthcare setting should provide valid and reliable results for planning patient safety improvements

in recognising and responding to deterioration in a patient's vital signs and clinical observations.

1.8 Summary

Factors contributing to suboptimal care resulting in the occurrence of AEs in the healthcare environment have triggered national and international concern. Healthcare organisations should prioritise the implementation of patient safety practices. The nurse has the fundamental responsibility to monitor patients' health status for indications of improvement or deterioration. Retrospective patient document reviews have shown gaps in the number, frequency and interpretation of vital signs and clinical observations recorded by nurses. The factors impacting nurses' recognition of and actions in response to patient deterioration are complex and diverse. The scope of the present study has been limited to the robust development and validation of a questionnaire that will serve as a measurement tool to assess the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of physiological and clinical parameters associated with patient deterioration and their clinical reasoning skills. Validation of the developed questionnaire will be assessed using content validity index, face validity assessment, cognitive interviewing and test-retest reliability to assess the stability of the questionnaire.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This narrative review of the literature was guided by the research question, aim and objectives described in Chapter 1. A search was conducted of the available literature firstly to establish what is already known about adult patient AEs linked to clinical deterioration in a ward setting and nurse competence. In addition the literature search served to identify gaps in existing knowledge and suggested opportunities for research as many studies suggest further research ideas and replication. An additional search was made of published literature on validation studies particularly relating to early identification of and response to clinical deterioration.

An in-depth review of the literature was conducted to find the best evidence for construction of the prototype questionnaire guided by the study objectives: 1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; 2) nurses' knowledge of clinical and physiological parameters linked to patient deterioration; and 3) nurses' self-reported clinical reasoning ability. The literature review search strategy is outlined next.

2.2 Literature review search strategy

The literature review search engines included EBSCOHost (including CINAHL), PUBMED and SCOPUS. Articles published in English in peer reviewed journals between 2010 and 2017 were included in the review process to ensure relevance of the literature to current clinical reality. Exclusion criteria included articles where the full text was unobtainable, articles related to paediatric patients, obstetric patients and patients in acute care, critical care, intensive care, or emergency unit settings.

The search terms and truncations utilised included: Nurs* AND competenc* AND ward AND adult AND deteriorat* OR failure to rescue OR failure event* OR adverse event* OR escalat* care OR suboptimal care OR patient safety OR education OR train* OR communicat* OR question* design OR early warning* OR vital sign* OR document* OR monitor* OR record* OR physiolog* OR knowledge OR clinical reason*.

A further search was conducted to explore the availability of studies validating questionnaires that assessed factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward, nurses' knowledge of clinical and physiological

parameters associated with patient deterioration and nurses' self-reported clinical reasoning ability.

The literature search strategy is reported in Table 2.1 showing a total of 54 articles that were found to be relevant to this study.

Table 2.1: The literature search strategy and useful references

Search engine	Keywords	Total no. of articles found	No. of relevant articles
EBSCOHost (CINAHL)	Nurs* AND competenc* AND ward AND adult AND deteriorat* OR failure to rescue OR failure event* OR adverse event* OR escalat* care OR suboptimal care OR patient safety OR education OR train* OR communicat* OR question* design OR early warning* OR vital sign* OR document* OR monitor* OR record* OR physiolog* OR knowledge OR clinical reason*	286	39
PUBMED		251	9 (plus 21 duplicate articles)
SCOPUS		227	4 (plus 8 duplicate articles)
EBSCOHost (CINAHL)	Validat* stud* AND question* AND nurse* knowledge AND clinical deteriorate*	7	0
PUBMED		2	0
SCOPUS		75	0
Literature identified from the reference list of another literature source		2	2
	Total	**849**	**54**

The types of research designs found during this literature search included systematic and integrative reviews, randomised controlled trials, qualitative designs using semi-structured interviews, quantitative research designs, retrospective document reviews and doctoral study theses. In addition, expert opinions were also considered.

2.3 Literature review results

The predominant theme identified during the literature search was evidence of the multitude of complex factors influencing a nurse's ability to recognise and respond to deterioration in a patient's condition. Some factors enhance while others act as barriers to a nurse's ability to contribute to patient safety by accurately and timeously identifying and managing deterioration in a patient's condition in a general ward setting. These factors have been consolidated into three main themes.

The three main themes discussed in this literature review include:

1. Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward;
2. Nurses' knowledge of clinical and physiological parameters linked to patient deterioration;

3. Nurses' clinical reasoning ability.

Miller's (amended) pyramid (Figure 2.1) is a framework for assessing overall individual competency provides (Cruess, Cruess, & Steinert, 2016; Miller, 1990). The graphic representation provides the rationale for emphasising the importance of the last two themes: nurses' knowledge and their clinical reasoning.

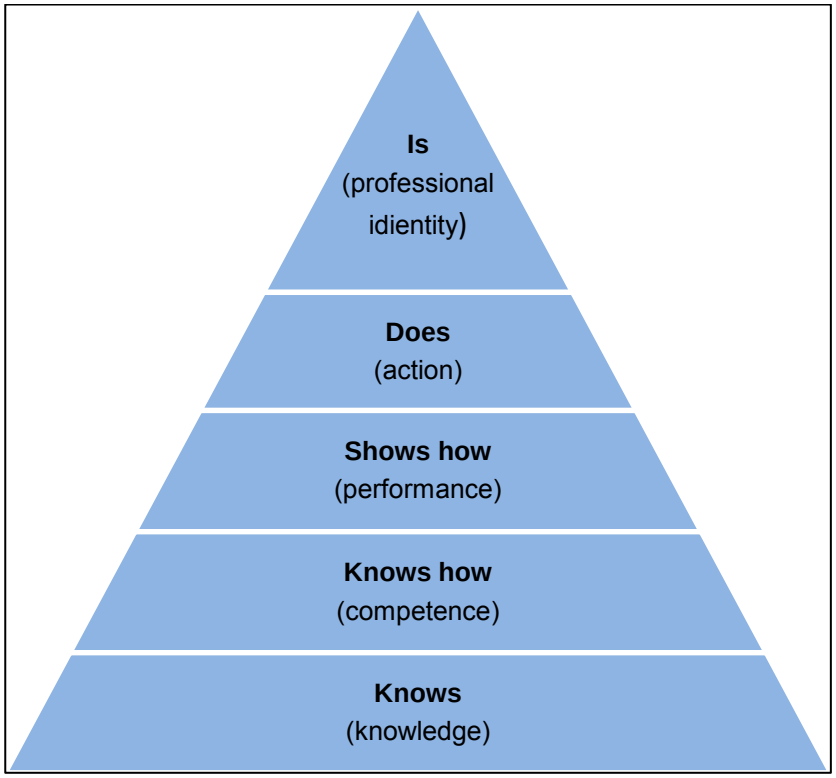

Figure 2.1: Miller's (amended) pyramid (Cruess et al., 2016)

The base of the amended pyramid establishes the competency of "knowing" (Cruess et al., 2016; Miller, 1990) which means having the knowledge required to act to achieve desired clinical outcomes. The clinical outcome relevant to this study is the nurse's ability to recognise and respond to deterioration in a patient's condition. Once knowledge is established, the pyramid suggests that it is then essential to be able to "know how" to achieve a clinical outcome. This second tier of knowing how in the pyramid relates to the healthcare professional's ability to gather information (physiological parameters and clinical observations), to analyse the information to find connections between facts and to interpret the information to create meaning using cognitive reasoning processes (Cruess et al., 2016).

Successful gathering, analysis and interpretation is required to achieve the desired patient safety clinical outcome, namely prioritised patient recognition and timely action relevant to

a patient's deteriorating condition (Cruess et al., 2016; Miller, 1990). Therefore the last two themes, nurses' knowledge and their clinical reasoning ability, have been presented separately from the generic factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward. Nurses' knowledge and their ability to gather and analyse information is critical to their ability to recognise any changes in a patient's condition and thereafter to respond appropriately (Purling & King, 2012).

There are a number of evidence hierarchies for research (Ingham-Broomfield, 2016). One example of an evidence hierarchy is shown in Figure 2.2 (Glover, Izzo, Odato, & Wang, 2006).

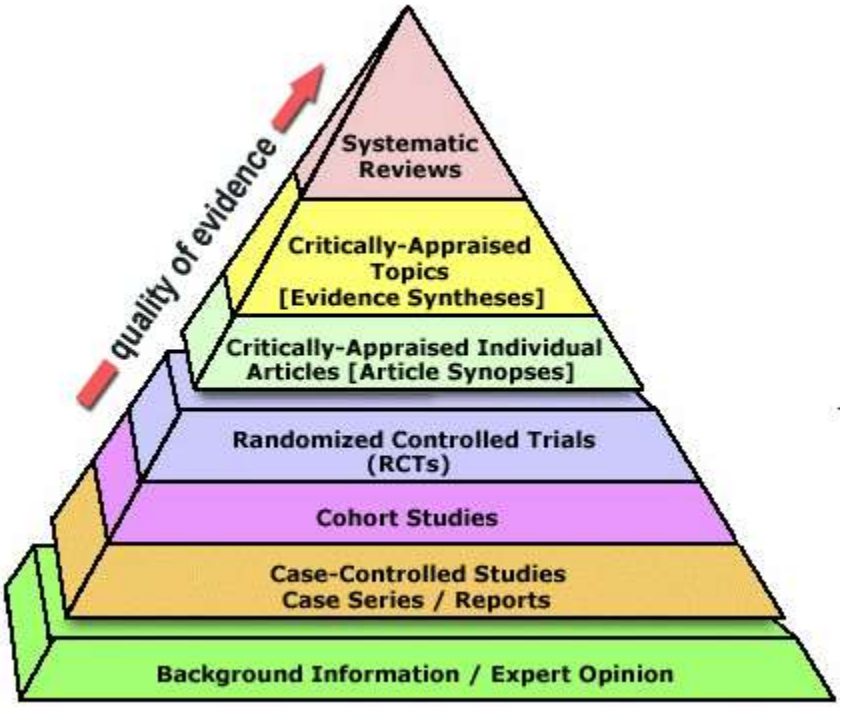

Figure 2.2: Evidence hierarchy for research: Levels of evidence (Glover et al., 2006)

An evidence hierarchy provides a scholarly approach to categorising research based on the methodology used (Grimes & Schulz, 2002; Ingham-Broomfield, 2016). Systematic reviews are suggested as being the highest ranked research evidence and in contrast expert opinion is ranked the lowest (Polit & Beck, 2017).

In addition to an evidence hierarchy for research, the quality of published studies has been evaluated using the Johns Hopkins Nursing Evidence-Based Practice Appraisal Tool (Johns Hopkins Medicine, 2017) shown in Table 2.2.

Table 2.2: Johns Hopkins Nursing Evidence-Based Practice Appraisal Tool (Johns Hopkins Medicine, 2017)

A High quality:	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
B Good quality:	reasonably consistent results; sufficient sample size for the study design; some control, and fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
C Low quality or major flaws:	little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn

The 54 studies pertaining to the three identified themes as well as identified validation studies have been summarised and are presented in Table 2.3. Only one relevant systematic review was identified. Most of the evidence was categorised as case controlled or case series studies. The quality of all of the studies that were reviewed was rated as high or good.

Table 2.3: Level of evidence of the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward

Author/s	Study objective/s	Methodology	Sample size	Findings	Level of evidence	Literature theme
Systematic reviews						
Connell et al. (2016)	To review evidence supporting the effectiveness of educational interventions in the recognition and management of the deteriorating patient; and the outcome measures used to evaluate educational effectiveness.	A mixed methods systematic review of literature using a four phase decision process.	A total of 23 peer reviewed studies published in English with abstracts between 2002 and 2014 relevant to the effectiveness of education to healthcare professionals in the recognition and management of deteriorating patients.	Studies reviewed used self-assessed perception of knowledge and skill; objective outcomes with pre and post intervention studies; patient outcomes (mortality, admission to ICU rates); and the frequency of activation of more skilled healthcare professionals to measure the effectiveness of education programmes. Complexity of systems and processes associated with the recognition and management of deteriorating patients, make it challenging to isolate education strategies as sole influence. The methods of education delivery varied often using a blended approach. Utilising simulation; particularly medium to high fidelity simulation and more recently in situ simulation, has showed encouraging improvement results following education in the ability to recognise and manage the deteriorating patient.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Paiva et al. (2014)	To evaluate the validation (test-retest reliability) methods of multi-symptom and health-related qualities of life based on patient-reported outcomes in oncological settings.	A systematic review: COSMIN checklist was used to rate the quality of the studies.	Thirty-one articles were included from systematic search of: PubMed (1966 to June 2013), EMBASE (1980 to June 2013), PsychInfo (1806 to June 2013), CINAHL (1980 to June 2013), and SCIELO (1998 to June 2013), and specific PRO databases.	The proportion of articles analysed for the total quality of the criteria used to determine the test-retest reliability rated as good, fair, or poor: 6 (19.4%), 17 (54.8%), and 8 (25.8%). None of the articles were rated as excellent.	A	Validation studies.

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Critically-appraised topics						
Allen et al. (2017)	To review current literature for inter-professional practice matters within organisations considered to be barriers or facilitators of recognition and response to clinical deterioration.	An integrative review of literature.	29 studies were reviewed using he Critical Assessment Skills Programme checklist.	Four themes emerged as barriers and facilitators of recognition and response to clinical deterioration: "organisational culture; role perceptions and professional accountability; communication of clinical needs; team-based practices". In addition, the interlinking concept "inter-professional learning opportunities" also emerged.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Massey, Chaboyer, and Anderson (2017)	The aim was to conduct a review and appraisal of the literature relating to ward nurses' recognition of and response to patient deterioration with the intention to report on opportunities for future research.	An integrative review using the Mixed Method Appraisal Tool.	Seventeen articles were selected from the search from CINAHL, Ovid Medline, Informit and Google Scholar databases between. 1990–2014.	Four themes relating to recognition of patient deterioration were identified, including: "assessing the patient; knowing the patient; education and environmental factors". Three themes relating to responding to patient deterioration were identified in the literature as "non-technical skills; access to support and negative emotional responses".	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Purling and King (2012)	To review research literature about the factors that influence new graduate nurse's preparedness for recognition and response to patient deterioration in the acute care setting.	Integrative review using the Critical Appraisal Skills Programme evaluation tool.	Seventeen qualitative studies were included relating to novice and experienced registered nurse experiences.	Themes that emerged: clinical staff support, lack of nurse experience, overwhelming workload, holistic patient assessment, past experiences and lack of available resources.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' clinical reasoning ability.
Kyriacos et al. (2011)	To review the available literature to study the evidence for the need for a MEWS system, the rigor of the MEWS systems developed for adult inpatients in general wards.	Literature review.	English, full text journal articles published from 1998 related to the study's purpose were included in the review.	Main issues identified included: occurrence of deterioration in patient's conditions in general wards requires monitoring of vital signs; the ability to deduce meaning from the vital signs measured and observed to identify signs of clinical deterioration; and initiating requests for skilled clinical assistance. Solutions identified relate to	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological

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				prioritising patient safety in healthcare nationally and at an organisational level. The inclusion of a validated, reliable MEWS system should be considered as part of the patient safety strategy.		parameters linked to patient deterioration; nurses' clinical reasoning ability.
McGaughey, O'Halloran, Porter, and Blackwood (2017)	To critique studies related to the clinical context and the implementation of Rapid Response Systems as either facilitating or constraining the impact of Rapid Response Systems on the deteriorating patient in hospital.	A realist review of literature.	Two hundred and seventy-five articles were reviewed from 1997 to 2017 using the Critical Appraisal Skills Programme tools.	Early warning systems and rapid response systems supported nurses' clinical decision making and quantification of severity of clinical deterioration. Factors influencing the operational utilisation of the rapid response systems included: sufficiency in staffing; staff workload allocations; availably of experienced nurses; continuous education programmes to support competency; hierarchical referral systems; communication; organisational and ward cultures.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Quirke et al. (2011)	To define the concept of suboptimal care.	Literature review using the Walker and Avant approach.	Cumulative Index Nursing and Allied Health (CINAHL), Cochrane and Medline databases were searched, finding 40 literature items.	Attributes of suboptimal care: delays in diagnosis, treatment or referral, poor assessment and inadequate or inappropriate patient management. Antecedents to suboptimal care: patient complexity, healthcare workforce, organization and education factors.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Randomised controlled trials						
Kyriacos, Jelsma, James, and Jordan (2015)	To evaluate the impact of a MEWS system and a linked training program in an intervention versus a standard care group by testing for improvements in nurses' knowledge, recording of vital signs, and their responses to	A quantitative study using a prospective, pragmatic, cluster randomized trial methodology.	The hospital's 6 surgical wards were randomised into intervention and control wards. All the nurses working in the randomised intervention arm wards were invited to participate voluntarily in the training program.	Overall, significant improvements were noted in the nurses' knowledge (p=0.001) and recording of respiratory rates (p<0.001*)*. Improvements noted in recording of all seven physiological parameters during the first eight postoperative hours in the intervention group. There was a lack in evidence of improvement in the intervention unit nurses' responses to patients with abnormal vital signs that triggered a MEWS requiring intervention was	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.

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	predetermined physiological thresholds.			concerning.		
Liaw et al. (2017)	Firstly to assess the effectiveness of the Web-based educational program on enrolled nurses' knowledge and simulated performances in assessing, managing and reporting of clinical deterioration. Secondly to explore the enrolled nurses' perception of the Web-based education programme as an educational tool.	A randomised controlled trial with a pre-test–post-test design.	Sixty-seven ENs randomised into the experimental group (n=34) and the control group (n=33).	Significant increase (p<0.001) in the knowledge post test results (compared to pre-test) in the experimental group. Significant increase (p<0.001) in the experimental group test for assessing, managing and reporting of clinical deterioration. The experimental group were significantly (p<0.001) more likely to monitor the respiratory rate compared to the control group post intervention.The respondents perceived the web based education programme, learning material and net value positively.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Quasi-experimental studies						
Liaw, Wong, Ang, et al. (2016)	The aim of the study was to evaluate the impact of an interactive internet driven education programme on a ward nurse's ability to assess, recognise and manage the patient whose condition is deteriorating.	A quantitative study, with pre and post intervention assessments.	Seventy general ward nurses randomly assigned to either the intervention or the control groups.	Significant improvement (p<0.001) by the intervention group of nurses in the post test knowledge assessment and a significant difference between the groups for the post test knowledge assessment. Significant improvement in recording heart rate (p<0.001) and respiratory rate (p<0.05), the interpretation and managing the deterioration scenario (p<0.001) and the ability to report (p<0.001) the deterioration to a more skilled healthcare professional in comparison with the control group of nurses.	A	Nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Cohort studies						
Cahill et al. (2011)	To assess the impact of the newly introduced revised	A prospective, before-and-after intervention study.	Included all discharged patient records over a 14	Vital signs recording at pre intervention, 2 weeks post intervention and 3 months post intervention: Respiratory rate had	B	Factors influencing nurses' ability to recognise and

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	observation chart and an education intervention for nurses on the recording of vital signs in a general ward setting.		day period pre-intervention, 2 weeks post intervention and 3 months post intervention in three wards in one hospital (excluding patients transferred from another unit in the hospital).	a significant increase (p<0.001) from 47.7% to 97.8% and 98.5% respectively; small significant increase in blood pressure (p<0.001); significant increase in the complete set of vital sign data (p<0.001) recorded per observation set (47.6%; 96.3%; 96.4% respectively).		respond to patient deterioration in a general ward
De Meester, Verspuy, Monsieurs, and Van Bogaert (2013)	To evaluate the SBAR communication tool's impact on the nurses perceived collaboration and communication with physicians and the occurrence of severe AEs (SAE's) in adult patients in a hospital's general ward.	Quantitative study, using a pre and post intervention design.	A questionnaire was completed by 425 and 180 nurses pre and post intervention respectively; a total of 207 patient SAE's were assessed (81 pre intervention and 126 post intervention).	The SBAR communication tool improved the nurses' perception of the communication and collaboration with the physicians; prepared the nurses more effectively and recorded an increase in the number of unexpected transfers into the intensive care unit during the post intervention period from the wards while decreasing the number of recorded patient deaths.	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Liaw, Wong, Lim, et al. (2016)	To evaluate the impact of Web-based simulation on nurses' recognition of and response to deteriorating patients in clinical settings.	A quantitative study, measuring the pre and post intervention incidence and type of triggers that initiated a request for assistance for deterioration in patient conditions. Self-assessments of motivation, knowledge and behavioural change were completed by the participating nurses in relation to the web based education programme completed.	Sixty four registered nurses and thirty five enrolled nurses from the general wards of a large hospital completed the web based education programme as well as the self-assessments of motivation to the programme, knowledge and behavioural change. 2155 patient records and 1841 patient records in the pre and post intervention periods (6 months	The results showed a significant increase (p<0.001) in the frequency of triggered incidence only in the medical ward (not the surgical ward). Both categories of nurses showed a significant improvement (p<0.001) in the knowledge gained in the post intervention assessment, the improvement by the registered nurses was more significant (p<0.001) than the enrolled nurses. Both the registered nurses and enrolled nurses scored the assessment of knowledge transfer to clinical practice positively.	A	Nurses' knowledge of clinical and physiological parameters linked to patient deterioration.

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			each) were analysed for the frequency and type of triggers for escalation of care due to deterioration.			
Case series studies						
Burger et al. (2017)	To develop and validate a structured SBAR communication tool to assist nurses to systematically give essential information about a deteriorating patient to a more skilled healthcare professional.	Mixed methods instrument development and validation including: cognitive interviews, content validation and inter-rater reliability testing.	Purposive sampling: three RPNs and two medical doctors (CI); five medical doctors, 5 medical-surgical RPNs and eight surgical doctors (CVI); two RPNs (inter-rater reliability).	Cognitive interviews resulted in amendments to: 15/42 (35.71%) items. Content validation of the revised tool was higher than the pre-set ≥70% and 4/49 (8.2%) items were amended. Inter-rater reliability testing resulted in substantial to full agreement (Cohen's kappa .61–1) on 37/45 (82%) items. Overall percentage agreement 82% and 45 items remained in the tool after validation.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Brier et al. (2015)	Development of a systematic algorithm as a guide to the early detection of patient deterioration and the successful communication of findings.	Mixed methods study included retrospective nursing documentation review, semi structured interviews, and the development of a "Surveillance Algorithm for Post-Surgical Patients".	Ten expert nurses: 5 at each of the two sites.	Themes from the interviews related to early patient deterioration identification included the expert nurses' reliance on visual patient triggers, prior experience to guide their expectations and interpretation of observations, the verification of concerns with colleagues; the ability to coherently communicate the patient's condition change influencing the medical practitioner's timely response to the nurse's perceived change in patient condition.	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Considine et al. (2016)	To explore the type and frequency of vital signs measured and documented in three clinical units in one healthcare facility.	Explorative descriptive study using record review.	Review of 178 patient records across three clinical units in one facility.	Parameters: most frequent evidence of respiratory rate, oxygen saturation level, heart rate and systolic blood pressure documented. Least evidence in temperature and Glasgow coma scale documented. Evidence in 79.8% of records of abnormal parameters with of reporting in 19.7% of these cases.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Cardona-Morrell et al. (2016)	To explore the nurses' current vital sign and	Qualitative, observational, cross-	Forty-two registered nurses took part	From 229 vital sign related interactions, only 21% resulted in the full vital signs	A	Factors influencing nurses' ability to

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	observation monitoring activities and the interactions between the nurse and the patient in two wards at a single facility.	sectional design.	providing 441 nurse to patient observed engagements.	data being measured and recorded possibly based on clinical reasoning and work pressures. Blood pressure, heart rate, oxygen saturation were monitored in ≥ 94% of interactions; while respiratory rate in only 22% of interactions. Nurse-patient discussions varied with 49% initiated based on the need to measure and record vital sign data from the patient.		recognise and respond to patient deterioration in a general ward
Cioffi, Conway, Everist, Scott, and Senior (2010)	The study's aim was to determine the content validity of 'changes of concern' used by nurses to call emergency response teams.	Bausell's criteria of necessity and sufficiency were used to evaluate the content validity of the "changes of concern" used by nurses when calling emergency response teams using criterion, "patient of concern".	Ten expert nurses, each with five or more years of experience with emergency response teams.	Validated ten clinical observations as "changes in concern" including: noisy breathing, inability to speak in sentences, increasing need for supplemental oxygen to maintain desired oxygenation levels, agitated and restless behaviour, impaired cognition, impaired peripheral perfusion, lack of predicted clinical progress in health status, new or unresolved pain, new symptoms and observations.	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Clarke et al. (2010)	To evaluate and improve patient assessment practices, care practices, recognition of patient deterioration and communication in the acute ward environment.	Phase 1 of a multi method developmental study: conducting clinical audits to examine practice and documentation of patient assessment parameters and care planning, specifically identifying whether changes in clinical parameters were identified and acted on.	Eight evaluators performed 96 patient case record reviews randomly selected from 11 units at a single site.	Record review findings: poor documentation of vital signs; 33% of actions taken responding to patent deterioration documented. Identified areas of concern: patient assessment; care planning; verbal and written communication; recognising and responding to patient deterioration. Domains for practice development identified: personal care, documentation and communication, promoting self-care, medication administration, privacy and dignity, clinical interventions, clinical monitoring and management and preventing risk and promoting safety.	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Cooper et al. (2010)	To study the extent to which final-year	Mixed methods study including a	The sample included 51 nursing students	Overall 37.3% has experienced some form of participation in patient	A	Factors influencing nurses' ability to

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	student nurses' are able to assess, identify and respond to deterioration or risk thereof in patient condition.	questionnaire to assess knowledge and participation in simulation scenarios that were recorded to assess skill and situational awareness incorporating post scenario reflection.	in their final year, final semester of studies.	deterioration management. The average total score for the knowledge questionnaire was 74.2% (range 45.5–100 %). Hypovolaemia scenario: results of the skills assessment: 55%, SD 12.1; 95% CI: 52.3–59.1. Septic Shock scenario: results of the skills assessment: 63.2%; SD 12.5; 95% CI: 59.7–66.7). Situational awareness scores for both scenarios (total of 34 items) average of 58.9% (range 38.2–82.3%; SD 10.7; 95% CI: 55.9–61.9). Least assessed: respiratory rate and level of consciousness. Study adds that assessing situational awareness in action using simulation could be a useful educational strategy.		recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Cooper et al. (2011)	Using a simulated environment to assess the knowledge, skill and situational awareness of registered nurses working in a general ward of a rural hospital.	Quantitative methodology using an exploratory design to review the registered nurses' performance.	Thirty five registered nurses working in a general ward of a rural hospital.	The average total score for the knowledge questionnaire was 66.5%. Cardiac scenario: results of the skills assessment: 52.1% (n=35, range 36-72%, SD=9.3). Respiratory scenario: results of the skills assessment: 48.6% (n=34, range 26.1-73.9%, SD=11.7). The respiratory rate and the capillary refill time were poorly assessed despite cues in the scenarios. The nurses' skill performance declined over time in the scenarios. Situational awareness scores for both scenarios that included a total of 24 items, respondents scored an average of 50%, struggling with perception, however performing well in comprehending the situation and anticipating the health status progression.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
De Meester, Van Bogaert, et al. (2013)	To investigate nursing care eight hours prior to serious AEs (in-hospital mortality) on	Mixed methods study: retrospective patient record review where outcome was death;	Sixty-three records reviewed. Three clinical experts: 1 emergency physician	Respiratory failure in 24 (38.1%) cases. Deteriorating in 49.2% of 63 cases from medical and surgical units considered available by experts. Respiratory rates	B	Factors influencing nurses' ability to recognise and respond to patient

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	medical and surgical units; to evaluate if serious AEs were potentially preventable.	independent expert record review of same patient records; pilot survey of nurses: experience of patient deterioration; knowledge of vital signs and escalation call cues.	and two directors of nursing. Forty-four nurses surveyed.	not recorded (0.0%). Nurses delayed calling for assistance: escalated call for assistance when vital signs higher and lower than practice guidelines.		deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Endacott et al. (2010)	To study the processes implemented by final year nursing students in simulation to identify and respond to cues of deterioration in patient condition.	Mixed methods study included conducting, analysing and comparing the findings of 51 questionnaires to assess knowledge, 102 simulation scenarios that were recorded to assess respondent skill and situational awareness and post scenario respondent reflection.	The sample included 51 final year nursing students	The final year students did not identify all cues of patient clinical deterioration; comprehensive patient assessments were not conducted when faced with clinical deterioration; they also struggled to explain physiological and clinical observations and justify action in response. Recommended education that includes assessment for identifying deterioration and clinical reasoning skills for decision making.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' clinical reasoning.
Hart et al. (2014)	To describe the medical-surgical nurses' perceptions of their self-confidence and leadership abilities when in the position as the first to recognise and respond to patients condition deterioration.	A prospective, cross-sectional, descriptive quantitative design using a survey method was used.	One hundred and forty-eight medical-surgical nurses from five hospitals (part of a healthcare system) completed the survey questionnaire.	The analysed data reflected a significant positive relationship (p<0.001) between the perceived self-confidence and the perceived leadership abilities as the first to recognise and respond to patients' deterioration in condition. Secondly, the regression model used indicated that the nurses' age and certification status were shown to be effective variables in predicting their perceived self-confidence and leadership abilities.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
James et al. (2010)	To study healthcare assistant's involvement in recognition and responding to general	A postal survey of Healthcare Assistants was piloted and conducted within two district general	One hundred and thirty-one healthcare assistants from a population of 367 working in general	Health care assistants play an important role in recognising and responding to patient acute illness. While able to monitor vital signs, they have limited abilities to conduct	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a

Author/s	Study objective/s	Methodology	Sample size	Findings	Level of evidence	Literature theme
	ward patients displaying signs of acute illness.	hospitals. Open and closed questions were used.	wards at two district hospitals were invited to participate.	comprehensive patient assessments. Suggested education needs to address competency gaps included patient scenario led teaching.		general ward
Jonsson, Jonsdottir, Moller, and Baldursdottir (2011)	To describe the documentation of parameters according to the MEWS prior to emergency unplanned admission from the medical and surgical wards to the intensive care unit.	A quantitative, descriptive study using a retrospective record review of the parameters according to the MEWS of patients prior to emergency admission to the intensive care unit.	Sixty-five records from patients 18 years and older who required emergency unplanned admission from the medical and surgical wards to the intensive care unit from 1 October and 31 December 2006.	The respiratory rate was the most infrequently recorded vital sign while the most frequently occurring reason for unplanned ICU admission was for respiratory distress. On average the highest frequency of vital data recorded per data set was three out of the total six vital signs that could be recorded based on the MEWS chart used in this study. The total MEWS was therefore not calculated during the record review data analysis.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward
Fasolino and Verdin (2015)	The aim was to interrogate the frequency of documenting vital data (blood pressure, heart rate and respiratory rate and oxygen saturation) and clinical observations (mental status and urine output) during the 24 hour period prior to activation of the rapid response team to identify trends.	A retrospective chart review was conducted of patients with documented RRT calls during 2009.	All 79 of the patients in the medical-surgical wards at a large hospital who had a documented activation of the rapid response team in 2009.	The heart rate and oxygen saturation level were the vital data documented most frequently. While the respiratory rate was only documented in only 19.84% to 22.12% of data sets per time interval. The assessment of the mental status and the urine output was too infrequent to consider in terms of the results of the study.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Kyriacos, Jelsma, and Jordan (2014)	To analyse and understand the completion of immediate post-operative vital sign documentation and the nurses' responses to the vital signs in one SA public	Retrospective record review.	A total of 55 adult (over the age of 14 years) patient records from 6 general wards during the period 1 May to 31 July 2009 randomly selected, excluding obstetric	None of the patient records had all seven MEWS vital signs recorded per data set. The respiratory rate was poorly recorded in both groups of patient records reviewed (0% and 2.3% respectively). A lack of action taken in response to a MEWS that should have elicited a response was found in 22/36 (61.1%) instances of abnormal	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward

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	hospital.		cases: 11 case notes of patients who had died and four controls for each case.	recordings for the 11 deceased patients, and 81/87 (93.1%) instances of abnormal recordings for the control group.		
Odell (2015)	To review documented evidence of nurses compliance to an EWS protocol in the recognising and responding to deterioration in ward patient's condition and to investigate factors impacting nurses' practice.	Record review of patient documentation 12 hours prior to cardiac arrest.	One hundred and twenty-three patient cases where cardiac arrest occurred were included in the study.	Ward nurses' documented monitoring of patients' vital signs had improved compared with earlier research at the same site. Errors in EWS rating and non-compliance to escalate of care standards still evident.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Lavoie, Cossette, and Pepin (2016)	To develop and test an instrument to measure bachelor-level nursing students' situation awareness in a patient deterioration simulation scenario, using the Situation Awareness Global Assessment Technique,	Development and validation study.	Fifteen expert critical care nurses and 234 bachelor-level nursing students registered in a critical care programme.	Tool containing 31 queries to trigger the assessment of nurses' situational awareness in clinical deterioration simulation scenario. High content validity index: 0.97. Satisfactory determination of the difficulty, discrimination and reliability of the tool queries.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Leonard and Kyriacos (2015)	To assess respondents' ability to identify abnormal recordings for respiratory and heart rate, oxygen saturation level, systolic blood pressure, level of consciousness, urinary output and normal temperature.	A cross sectional survey.	Seventy-seven of the 212 (36.3%) fourth year nursing students at a public nursing education institution in the Western Cape.	Using the MEWS as the measure for responding to physiological parameters; there would have been delays in activating the call for assistance in 288/416 (69.2%) instances with a high-score MEWS of 3; there would have been delays in activating the call for assistance in 226/639 (35.4%) instances with a medium-score MEWS of 2.	B	Nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Ludikhuize,	To describe the	A retrospective	All the patient	The results displayed a lack of	A	Factors influencing

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Smorenburg, et al. (2012)	current frequency of documenting the measured vital signs by nurses in a university hospital in the Netherlands, and to assess the value of the MEWS in supporting the early recognition of medical and surgical patients who experienced serious adverse event.	observational study of medical and surgical patients from 2007 with a severe adverse event including cardiopulmonary arrest, unplanned intensive care unit admission, emergency surgery, or unexpected death was performed. We studied all vital parameters that were collected and documented in the 48 hours before these events, and the MEWS was retrospectively calculated.	records from the medical and surgical wards in a large general hospital during 2007 where the patient had experienced an adverse event for example: cardiopulmonary arrest, unplanned intensive care unit admission, emergency surgery, or unexpected death.	consistency in the accurate recording of measured vital signs during the 48 hour period prior to the adverse event. The blood pressure and heart rate were most frequently documented. The level of consciousness and urine output were scarcely documented. The respiratory rate was documented in 23% of data sets. Signs of a MEWS of >3 indicating the need for intervention was evident in half of the patient records reviewed 25 hours prior to the adverse event.		nurses' ability to recognise and respond to patient deterioration in a general ward
Ludikhuize, Dongelmans, et al. (2012)	To describe how nurses and medical practitioners perceived the quality of their care that they rendered to deteriorating patients in medical wards compared with the expert judgment from independent healthcare professionals.	Cross-sectional study using interviews of care providers regarding their perceived quality of care for clinically deteriorating patients compared with retrospective judgment by independent experts.	Forty-seven events and 198 nurses and medical practitioners involved in the direct care of the patients who experienced the AEs.	The results reflect the opinion from the nurses and medical practitioners involved in the cases that they generally rate their care provided to patients in the hours preceding the adverse event as good. In comparison, the expert judgment from independent healthcare professionals who critically assessed the cases indicated that the nurses and medical practitioners involved displayed a delay in recognising and responding to the patient deterioration.	A	Nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
McDonnell et al. (2013)	To assess the influence of an acute hospital's new strategy for the identification and management of	A single centre, mixed methods before-and-after study utilising a survey questionnaire to collect quantitative	Both registered and unregistered nurses were included in the population and sample. Two hundred and thirteen	Post implementation, the nurses' knowledge, and confidence to identify and respond to patient deterioration and confidence to communicate their findings increased with the greater improvement being for the unregistered	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward;

Author/s	Study objective/s	Methodology	Sample size	Findings	Level of evidence	Literature theme
	deteriorating patients on nurses' knowledge and confidence. The implemented strategy included "training, new observation charts and a new track and trigger system".	data and interviews to collect qualitative data pre and post implementation of the hospital's strategy.	nurses completed the survey questionnaire and 15 nurses were interviewed.	nurses compared with the registered nurses. The interviews conducted validated the survey results.		nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Liou et al. (2016)	The study's objective was to develop and psychometrically test the Nurses Clinical Reasoning Scale (NCRS).	Cross-sectional design; the instrument was developed based on Clinical Reasoning Model; pilot study conducted to assess the readability and reliability; then underwent psychometric assessment testing for internal consistency and test-retest reliability. Validity was tested with content, construct and known-groups validity.	Two hundred and fifty-one respondents comprising clinical nurses and nursing pre-graduates completed and returned the questionnaires in the psychometric testing phase.	Instrument consisted of 15 items, with a Likert five-point scale. I-CVI and S-CVI were both 1.0. One factor revealed during the factor analysis. The known-groups validity was significantly differentiated (p<0.001). Cronbach's alpha for the instrument was 0.9.	A	Nurses' clinical reasoning ability; validation studies.
Mok, Wang, Cooper, Ang, and Liaw (2015)	Attitudes towards vital signs monitoring in the detection of clinical deterioration: scale development and survey of ward nurses.	Development study with psychometric testing and a descriptive quantitative survey.	Six hundred and fourteen general ward nurses working in a tertiary acute care hospital	16-item instrument: Cronbach's alpha of 0.71; strong item subscale correlations (0.56–0.89). Intra-class Correlation Coefficient (ICC) of 0.85. Significantly higher knowledge subtheme score (P < 0.01) for RPNs compared to ENs. Qualitative section illustrated: incorrect perception of first indicators of decline in condition, namely blood pressure d oxygen saturation; vital signs considered time wasting and increased workload; attitudes towards vital signs influenced	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of patient deterioration; nurses' clinical reasoning ability; validation studies.

Author/s	Study objective/s	Methodology	Sample size	Findings	Level of evidence	Literature theme
				by qualification, experience, working in speciality ward.		
Pantazopoulos et al. (2012)	To evaluate the relationship between nurse demographics and accurate recognition of clinical situations requiring a response to signs of deterioration in a patient's condition.	A descriptive quantitative survey design with 13 multiple choice questions.	Ninety-four nurses (62% response rate) working in medical and surgical wards of a large tertiary hospital in Greece.	Forty-three per cent of participants assessed vital signs every six hours. Thirty per cent of nurses recorded the respiratory rate and three 3 per cent of nurses recorded the level of consciousness. Nurses with a four year qualification recognised clinical deterioration in a patient's condition as a higher rate and scored significantly higher (p=0.002) in theoretical knowledge questions that nurses with a two year qualification.	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Perkins and Kisiel (2013)	To establish how students at a higher education institution performed recognition and response to acute deterioration in a patient's condition at the end of their education programme.	Three phase study: firstly a self-evaluation questionnaire perceptions of their recognition and response skills to acute patient deterioration; secondly student interviews were conducted in clinical practice to explore students' recognition and response skills based on the physiological observations they had taken for a patient; and lastly theoretical assessment of their recognition and response knowledge.	One hundred and thirty-eight nursing students (48% response rate) took part in the survey; forty student interviews were conducted and unclear how many students took part in the theory assessment.	Student nurses perceived themselves to possess the knowledge and skills to rrecognise and respond to acute deterioration in a patient's condition The theory assessment revealed that participating students appeared to have limited recognition and response skills to deterioration in a patient's condition at the end of their education. Nursing students need to have clinical environments that assist them to develop and apply their recognition and response skills to acute deterioration in a patient's condition.	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward .
Shearer et al. (2012)	To explore the causes of failure to activate the rapid response	A multi-method study measuring the frequency of	Took place in a healthcare network across for clinical	Incidence of physiological instability found in 40.4% cases; 42% did not receive an appropriate clinical response	B	Factors influencing nurses' ability to recognise and

Author/s	Study objective/s	Methodology	Sample size	Findings	Level of evidence	Literature theme
	system (RRS).	physiological instability and activation of response team, record review of all patients experiencing a cardiac arrest, unplanned intensive care unit admission or death over an 8-week period; structured interviews of staff to explore cognitive and sociocultural barriers to activating the response team.	sites; data collected from ward patients; 91 staff interviewed.	from the staff; 69.2% recognising their patient met physiological criteria for activating the RRS. Structured interviews revealed sociocultural reasons for failure to activate the response system. The most common reason being staff perception that the patient's condition was under control in the ward.		respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Smith and Aitken (2016)	To investigate nurses' use of a single parameter track and trigger chart to inform implementation of the NEWS tool; to report the characteristics of patients with triggers, the frequency of different triggers, and the time taken to repeat observations; to explore the barriers and facilitators perceived by nursing staff relating to patient monitoring.	A mixed method study using descriptive statistics to reflect the physiological triggers and characteristics of triggering patients and questionnaires analysed sing content analysis.	Quantitative data collected from 4 wards: physiological triggers and characteristics of triggering patients. Self-administered questionnaire to all categories of nurses (n=105): student nurses, health care assistants and registered nurses.	Hypotension was found to be the most frequent abnormality. Variability evident in the time to repeat observations following a trigger. Nurses reported barriers and facilitators to monitoring patients including: 'workload', 'equipment', 'interactions between staff' and 'interactions with patients'.	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Qualitative studies						
Astroth, Woith, Stapleton, Degitz, and Jenkins (2013)	To explore the factors that influence nurses' decision making to activate rapid response teams (RRTs)	Qualitative, exploratory study.	Fifteen nurses from medical and surgical units in a single healthcare facility recruited using purposive sampling.	Rapid response team characteristics and unit culture were identified as being facilitators and barriers to RRT activation. Supportive communication facilitated activation of the RRT. Perceived workload of the RRT, poor	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.

Author/s	Study objective/s	Methodology	Sample size	Findings	Level of evidence	Literature theme
				communication styles, ward nurse overconfidence and primary doctor notification were noted as barriers to activation of the RRTs. Education was found to be an essential requirement for nurses utilising RRTs.		
Bucknall et al. (2016)	Using team based simulation to describe the approach used in the decision making process from the perceived incoming information triggers to the actions carried out and the factors influencing the decisions made.	Qualitative descriptive exploratory study	Ninety seven third-year nursing students from three universities conveniently sampled.	The types of decisions included: information seeking; patient assessment; diagnostic; intervention/ treatment; evaluation; escalation; prediction; planning; collaboration; communication and reflective; Factors influencing decisions included their lack of experience in assimilating patient incoming cues; their lack of knowledge for processing the cues and translating into actions; and the lack of experienced support.	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Chua et al. (2013)	To explore the ENs experience of the deterioration in patient condition in the ward setting; to identify the development required to support the Enrolled Nurse in their function in recognising and responding to patient deterioration.	Qualitative exploratory descriptive study; using critical incident technique	Purposive sampling. 15 enrolled nurses; more than one year of general ward experience; experience of patient deterioration in ward	Three themes associated with the ENs experience emerged: "recognition of deterioration"; "responding to deterioration"; and "taking responsibility". Two themes emerged as strategies for improving the EN's ability to recognise and respond to patient deterioration: "educational development"; and "modification of clinical processes".	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Donohue and Endacott (2010)	To study the perceptions of ward nurses and critical care outreach nurses towards the deteriorating patients' management in the ward.	Semi-structured interviews were conducted using the critical incident technique	Eleven ward nurses and 3 critical care outreach nurses involved in critical incidents between November 2006 and April 2007.	The themes that emerged included: -dependence on varying visual cues to identify deterioration possibly due to limited clinical experience; -limited utilization of the MEWS to monitor changes in a patient's condition; as a guide to initiate the required referral when a patient deteriorates or as a tool to accurately communicate the patient's condition; -despite having a process of calling for	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.

Author/s	Study objective/s	Methodology	Sample size	Findings	Level of evidence	Literature theme
				assistance, there was evidence of calling the outreach team straight away irrespective of whether the process should have included calling the junior doctor first.		
Douglas et al. (2016)	To achieve consensus about the core assessment skills required by nurses in general wards.	A modified Delphi study using focus group interviews.	One hundred and fifty acute care registered nurses were recruited to generate the framework of core skills competencies; then a further 35 acute care registered nurses participated in the consensus focus groups.	Sixteen core skills classified under headings: airway, breathing, circulation, disability, and exposure expand the primary survey approach. Eighty per cent agreement of the skills from the 2nd Delphi round. "Airway: assess airway patency. Breathing: measure respiratory rate; evaluate work of breathing; measure oxygen saturation. Circulation: palpate pulse rate and rhythm; measure blood pressure by auscultation; assess urine output. Disability: assess level of consciousness; evaluate speech; assess for pain. Exposure: measure body temperature; inspect skin integrity; inspect and palpate skin for signs of pressure injury; observe any wounds, dressings or drains, invasive lines; observe ability to transfer and mobilise; assess bowel movements.	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Gazarian, Henneman, and Chandler (2010)	To describe the triggers and influencing factors for nurses' decision making to intervene in patient condition deterioration in the pre arrest period in the medical ward setting.	Qualitative descriptive study using interviews to understand the triggers and influencing factors for decision making in the pre arrest period.	Purposive sampling was used to recruit 13 registered nurses across four medical units involved in the provision of care during patient's pre-arrest period that resulted in either cardiac arrest, transfer to an intensive care unit or referral to the rapid response team.	The triggers identified by the nurses that prompted intervention for a patient identified as risk of deterioration included: utilising the early warning system and being alerted to heightened risk; changes in the mental status, oxygenation saturation, and systolic blood pressure; insight from the patient's history and baseline data, handover report. The factors identified influencing a nurse to intervene during a patient's deterioration included: the "equipment, personnel (experience, teamwork, flexibility, and temporal	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.

Author/s	Study objective/s	Methodology	Sample size	Findings	Level of evidence	Literature theme
				concerns), and knowledge (knowing the patient, knowing the condition, knowledge from experience, knowledge about the organization)".		
Jeddian et al. (2016)	To explore the quality of care rendered to patients based on the experience of staff in general wards at Tehran University of Medical Sciences and two related general teaching hospitals.	A qualitative study using an exploratory methodology. The data was collected using interviews.	Four medical practitioners and six nurses fulfilling various positions in the Tehran University of Medical Sciences and two related general teaching hospitals. Purposive sampling technique was used.	The thematic analysis resulting in the following themes emerging from the interviews: "problems in identifying acutely ill patients in the general wards"; "problems in clinical management of acutely ill patients"; "inappropriate use of ICU beds" and "poor structure for mortality control".	B	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of clinical and physiological parameters linked to patient deterioration.
Massey, Chaboyer, and Aitken (2014)	To explore nurse's perceived access to the hospital's medical emergency team (MET) based on their experience and the factors that facilitate or act as a barrier to accessing the medical emergency team.	An interpretive qualitative approach was adopted to explore nurses' experiences and perceptions of using a MET.	Patients who had been admitted unplanned to ICU from March 2011 to August 2011 were identified daily by the researchers. The nurses caring for these patients during the 12hours prior to their admission were interviewed within 48 hours of the admission to ensure good recall of the experience.	The four themes that emerged from the data analysed included: "sensing clinical deterioration; resisting and hesitating; pushing the button; and leadership and support".	A	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.
Expert opinions						
Cruess et al. (2016) *(literature identified from in the bibliography list of another literature source)*	This article describes fives levels of assessment towards achieving professional identity used in medical education: knowledge,					Nurses' knowledge of clinical and physiological parameters linked to patient deterioration

Author/s	Study objective/s	Methodology	Sample size	Findings	Level of evidence	Literature theme
	competence, performance, action and identity.					
Levett-Jones et al. (2010)	Article describing the Clinical Reasoning Model as an approach for developing clinical reasoning skills in nursing students.					Nurses' clinical reasoning ability.
Liaw et al. (2011b)	The aim was to identify the educational needs of ward nurses to improve their ability to recognise and manage the deteriorating patient and to review the available training programmes for ward staff to develop their ability to recognise and manage the deteriorating patient.	Literature review.	Applicable literature from 2000–2010 from CINAHL, PubMed, Science Direct, Scopus and Web of Science databases was reviewed to find 26 papers that were included in this study.	The summary findings included the need for ward nurses to have sufficient knowledge and experience to recognize cues of a patient's deterioration; the need for nurses to be able to assess more than just the vital signs and to be able to interpret the data cues; the need for education programmes for pre-registration nurses, all categories of qualified nurses as well as inter-professional training programmes; and the need to improve the communication ability related to patient deterioration between nurses and medical professionals.		Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' clinical reasoning ability.
Yu et al. (2016) *(literature identified from in the bibliography list of another literature source)*	This report utilises evidence available to institute patient safety priorities by informing healthcare and political stakeholders about current and emerging threats to safe patient care delivery and providing recommendations to overcome the threats to patient safety.					Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward.

2.3.1 Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward

The literature reviewed reflects a range of factors that influence nurses' ability to recognise and respond to the deterioration in a patient's vital data and clinical observations. These factors can either inhibit or encourage nurses to recognise and respond to patient deterioration. Internationally, nurses' clinical competency, clinical patient care experience and situational awareness, knowledge of their patients, educational level, and interpersonal competencies (including communication, leadership and self-confidence) have been found to influence their ability to timeously identify and react to patient deterioration in general wards.

Additional influencing factors include collaboration with the multidisciplinary healthcare team and organisational factors. Examples of organisational factors include the organisation's culture supporting the process of quality improvement, the analysis of AEs for learning, the presence of policies and procedures to guide patient monitoring and the system for accessing assistance from more skilled healthcare providers.

Many studies have shown positive outcomes after educational interventions. However, it is increasingly evident that a healthcare institution's ability to reduce the incidence of AEs is a more complex process. The complexity for healthcare institutions relates to ensuring sustained healthcare provider behaviour modification and improved patient outcomes over time (Connell et al., 2016).

2.3.1.1 Nurses' clinical competency in the recognition and response to deterioration in a patient's condition

Measuring vital signs to identify changes in a patient's condition is a fundamental competency expected of nurses. However the level of the required competency varies and to a great extent depends on the curriculum for a particular qualification. The SA Nursing Council Regulation 2598 (1984) states that each category of nurse has a role to play in recognising and responding to changes in a patient's condition.

The enrolled nursing auxiliary (ENA), (internationally commonly referred to as healthcare assistant) is expected to provide "the care of a patient and the execution of a nursing care plan for a patient"; "taking of the blood pressure, temperature, pulse and respiration of a patient" and "the promotion and maintenance of the body regulatory functions of a patient" all under the supervisory role of the registered nurse overseeing their patient care delivery (South African Nursing Council, 1984). The enrolled nurse's (EN) scope of practice is

more extended, while also under the supervisory guidance of the registered nurse, to "carrying out of nursing care to fulfil the health needs of a patient or a group of patients"; and "caring for a patient, and executing a nursing care plan for a patient, including the monitoring of vital signs and the observation of reactions to medication and treatment" (South African Nursing Council, 1984). As the supervisor of the nursing care rendered to patients in a clinical unit, the RPN is expected to be competent in applying the scientific nursing process. This process includes comprehensive, integrated assessment, diagnosing patient healthcare related needs, planning and implementation of the required nursing care and the prescribed medical treatment (South African Nursing Council, 1984). A RPN carries out her duties either directly or by delegation to an EN or ENA under her supervision.

In busy clinical units, the RPN generally delegates the duty of measuring and recording patient vital signs and clinical observations to ENA and student nurses. They are also expected to identify and report abnormal findings to the RPN. However in a study undertaken in the UK both categories of nurse were found to have a very basic understanding of the biosciences that is often insufficient for the analysis and interpretation of clinical patient data (James et al., 2010).

A study by Perkins and Kisiel (2013) in the UK reported using a questionnaire to determine final year nursing student's (imminent RPNs) self-perception of their recognition and response skills to acute patient deterioration. The group of students also completed a theoretical assessment to evaluate their knowledge and skills about recognition and response to deterioration in a patient's condition. Forty-five per cent of the students achieved assessment scores of between 20% and 30% in the recognition part and the responding part of the theory assessment. These results contrasted the questionnaire results where students had a high self-perception of their recognition and response skills to acute patient deterioration (Perkins & Kisiel, 2013) highlighting the difference in self-perceived and actual competence of.

Data from qualitative interviews with ENs by Chua et al. (2013) in Singapore suggests that despite the limited knowledge of unregistered nurses, they relied on their clinical observation competency to identify a change in their patient's health status. In contrast, James et al. (2010) found that only 69/128 (54%) of healthcare assistants valued the importance of inspection through touch and visual observation when carrying out vital sign duties and only 45/128 (35%) of these nurses assessed the neurological status of patients. There is a common assumption that this limitation in practice is due to the

increased utilisation of mechanical electronic devices to measure vital signs such as a patient's blood pressure, heart rate and oxygen saturation levels.

Cardona-Morrell et al. (2016) and Jonsson et al. (2011) reported that more than 80% of documented recordings in patient records were gathered using automated mechanical devices. James et al. (2010) suggests that nurses using these mechanical electronic devices have reduced direct patient contact through touch. Nurses then risk missing vital clinical observations acquired through patient inspection and contact such as cold clammy skin or pain. The absence or partial completion of holistic patient assessments is acknowledged as a limiting factor in recognising patient deterioration as monitoring vital signs becomes viewed as merely a task to be completed (Massey et al., 2017; Purling & King, 2012).

Nurses' competency to accurately recognise a change in a patient's' condition and to respond appropriately is therefore a serious concern for patient safety in healthcare institutions. Cioffi et al. (2010) and Douglas et al. (2016) used expert opinion to validate clinical observation criteria for triggering concern about a patient's condition over and above the physiological vital sign data. These studies justify the inclusion of the "changes of concern" into training about patient assessment to ensure that nurses assess their patients' comprehensively to recognise clinical deterioration timeously. These clinical observations include noisy breathing, speech impairment, increasing need for supplemental oxygen to maintain desired oxygenation levels, agitated and restless behaviour, impaired cognition, impaired peripheral perfusion, lack of predicted clinical progress in response to treatment, new or unresolved pain, new symptoms and observations (Cioffi et al., 2010; Douglas et al., 2016).

Patient safety is also affected by the admission of patients into general wards not aligned to patients' diagnoses, for example admission of a patient with a vascular problem into an orthopaedic ward where standards of care are different and unfamiliar to nurses. Patients admitted to general wards are also older in age and often more acutely ill (Quirke et al., 2011). General ward nurses now render nursing care to patients with more complex healthcare needs. Complex patient healthcare needs require more nursing surveillance and more advanced nurse clinical competency to integrate the multitude of patient data to timeously recognise and respond to patient deterioration. These factors are considered contributing factors to suboptimal nursing care delivery in general wards (Quirke et al., 2011).

Nurses' clinical competency and situational awareness can be assessed in simulation settings. Actual clinical scenarios of patient deterioration can be replicated to observe and assess nurses' performance. Situational awareness is a person's ability to gather data, interpret and find meaning in the data and thereafter to predict probable patient outcomes (Cooper et al., 2010; Cooper et al., 2011).

Interestingly, in two studies conducted in Australia, one involving RPNs and a second study with final year nursing students, knowledge scores were higher than the situation awareness scores in two simulation scenarios. Deterioration in patient data in the simulation scenarios were not recognised, reasoned through, nor understood by the respondents (Cooper et al., 2010; Cooper et al., 2011). This possibly indicates a competency gap in the application of theoretical knowledge in a clinical environment where "perception, understanding and prediction" are critical nursing competencies (Cooper et al., 2010; Cooper et al., 2011).

Chua et al. (2013) suggested that a benefit of nurses' improved competency in conducting vital sign measurements could be more accurate recognition and reporting of patient deterioration in their clinical setting. Their study explored ENs experiences in recognition of and response to deterioration in a patient's condition. The respondents acknowledged their knowledge deficit related to the ability to relate basic disease pathophysiology to changes in patient's vital signs being measured. They reported reliance on a few individual vital signs such as blood pressure and oxygen saturation level instead of the full complement of vital signs. Respiratory rate were often omitted or estimated (Chua et al., 2013). During simulation scenarios that assessed situational awareness Lavoie et al. (2016) found that their sample of bachelor-prepared nurses incorrectly assessed the respiratory rate and subsequently shared the incorrect finding with their colleagues.

ENs who participated in a qualitative study by Chua et al. (2013) reported having more frequent contact with patients at the bedside and therefore more opportunities for assessment than RPNs. As a result, this study recommends the development of programmes for ENs utilising patient deterioration situations for simulation and reflective experiential learning. The purpose of such programmes would be to facilitate improvement in ENs competency in recognising and reporting deterioration in a patient's condition (Chua et al., 2013).

The success of patient safety strategies to reduce the occurrence of patient deterioration and AEs is complex; but it requires nurses to be clinically competent, having the ability to apply their theoretical knowledge to clinical practice while delivering nursing care. All

categories of nurses should have the ability to identify, interpret and timeously report patient deterioration to enhance improved patient outcomes while still working safely within the boundaries of their scope of practice.

2.3.1.2 Documentation of vital signs and clinical observations by nurses

Studies assessing nurses' documentation of vital signs and clinical observations are reliant on record reviews to collect data for comparison against accepted nursing practice standards. Although record review is useful for gaining insight into nurses' documentation of their practice with regard to recognising and responding to patients' clinical deterioration, there are limitations worth considering when interpreting study findings. Two studies in Australia and one UK study, reported that nursing care standards were not consistently evident in patient records despite existing clinical guidelines for monitoring and recording vital signs and for responding to patient condition deterioration (Cardona-Morrell et al., 2016; Clarke et al., 2010; Odell, 2015).

In developed countries, record reviews of documented patient vital signs, clinical observations and escalation actions in response to identified patient deterioration suggest variance in monitoring vital signs: a greater prevalence of compliance in measurement and documentation of blood pressure, heart rate and oxygen saturation level. Respiratory rate and level of consciousness are reported less frequently (Chua et al., 2013; De Meester, Van Bogaert, et al., 2013; Fasolino & Verdin, 2015; James et al., 2010; Jonsson et al., 2011; Ludikhuize, Smorenburg, et al., 2012; Mok, Wang, Cooper, Ang, & Liaw, 2015; Pantazopoulos et al., 2012; Smith & Aitken, 2016). Chua et al. (2013) reported that non-registered nurses admitted to not accurately measuring and recording the respiratory rate of patients not displaying signs of respiratory abnormalities. Nurses facing increasing workload and increasing complexity of patient care considered monitoring the respiratory rate of patients with no respiratory problems as inefficient use of time.

Locally in SA, two studies highlighted similar concerns regarding the lack of consistency in documented recordings of vital signs in patient records. Gaps were identified in nurses' recordings of respiratory rate and in evidence of nurses' responses to patients with abnormal vital signs (Kyriacos et al., 2015; Kyriacos, Jelsma, & Jordan, 2014).

The challenge of interpreting these results is often the retrospective nature of record reviews and nurses' perceptions of the importance of patient data. If information is not written in patient records, it is assumed that nursing care has not been given. A limitation of record review of nursing care activities such as measuring vital signs and clinical observations and then reporting changes in a patient's condition is that it could actually

have taken place but not documented (Ludikhuize, Smorenburg, et al., 2012) and warrants further investigation (Considine et al., 2016).

One randomised controlled trial (RCT) in SA (Kyriacos et al., 2015) and one Australian cohort study (Cahill et al., 2011) used educational interventions to test the impact on documentation of vital signs and clinical observations and recognition of signs of clinical deterioration. Both studies showed improved recording of respiratory rate and recording of complete sets of vital sign data recorded per observation set. However, there were no improvements in nurses' responsiveness to patients' abnormal vital signs triggering an elevated MEWS requiring intervention (Kyriacos et al., 2015).

Inconsistent documentation of complete sets of vital signs and clinical observations is evident in the published literature. Therefore it is necessary to include nurses' opinions on documentation of these parameters in a questionnaire designed for this study.

2.3.1.3 Education related to a nurse's ability to recognise and respond to deterioration in a patient's condition

Studies exploring the factors impacting the recognition and response to deterioration in a patient's condition in general wards recommend the introduction of sustainable education programmes for nurses (Chua et al., 2013; Quirke et al., 2011). Such education programmes should provide the opportunity for not only acquiring knowledge but also developing clinical skills (Liaw et al., 2017). The ability to prioritise patient data and develop clinical reasoning skills for accurate decision making should be practised during training (Liaw et al., 2011b; Purling & King, 2012). Opportunities for interdisciplinary teamwork between healthcare professionals can be included to promote timeous recognition of patient deterioration and activation of response systems (Liaw et al., 2011b; Purling & King, 2012; Quirke et al., 2011).

Traditional and technology driven educational strategy initiatives have been implemented to improve nurses' knowledge and skill in recognising and responding to deterioration in a patient's condition. Studies in Australia and Singapore using questionnaires, web-based interventions and simulation have shown both improvements and gaps in nurses' skills, knowledge, understanding and responsiveness when faced with scenarios replicating clinical deterioration (Cooper et al., 2010; Cooper et al., 2011; Liaw et al., 2017; Liaw, Wong, Ang, et al., 2016).

The average total score for a knowledge questionnaire, skills assessment performance and situation awareness was 66.5%, 50% and 50% respectively for RPNs (Cooper et al.,

2011) compared with final year nursing students' scores of 74.2%, 59.1% and 58.9% respectively (Cooper et al., 2010). Liaw, Wong, Ang, et al. (2016) assessed the impact of an internet driven programme on respondent's patient assessment knowledge in addition to their ability to recognise a patient's clinical deterioration and to initiate an appropriate intervention. In the intervention group of nurses there was significant improvement in knowledge (p<0.001), overall assessment and management (p<0.001) of patient deterioration, and the ability to report this to a more skilled clinician (p<0.001) compared to the control group (Liaw et al., 2017; Liaw, Wong, Ang, et al., 2016). RPNs were more motivated and stimulated by the content of the education programme than the EN participants. Both the RPNs and ENs scored the assessment of knowledge transfer to clinical practice positively (Liaw, Wong, Lim, et al., 2016).

The Patient Safety 2030 report supports the development and consistent implementation of quality education initiatives across healthcare systems (Yu et al., 2016). Scientifically relevant and clinically appropriate programmes are required for all healthcare professionals. Such programmes should incorporate educational methodologies that promote healthcare professional's behaviour change to support safe patient care, for example consistently measuring and recording complete sets of vital signs and clinical observations at the prescribed frequency. All healthcare professionals should have "the time and capacity to access and internalise training" (Yu et al., 2016).

The studies reviewed have illustrated that questionnaires can be useful for gathering information to evaluate the impact of interventions that include education programmes intended to reduce the occurrence of patient deterioration, AEs and improve patient safety. This supports the need for a validated questionnaire to address the objectives of this study.

2.3.1.4 Nurses' clinical practice experience and their knowledge of their patients

Both registered and non-registered nurses recognise that their clinical experience assists them in successfully recognising and responding to patient deterioration (Chua et al., 2013; McDonnell et al., 2013; Purling & King, 2012). Recognising patterns in vital signs and clinical observations from prior clinical experiences helps nurses to interpret vital signs and clinical observations to identify when to make escalation calls (Chua et al., 2013). Limited clinical experience and patient engagement can negatively influence nurses' ability to safely and proactively recognise and respond to deterioration in a patient's condition (Kyriacos et al., 2011; Levett-Jones et al., 2010; Ludikhuize, Dongelmans, et al., 2012).

Newly qualified RPNs have limited clinical experience and require role models. However hospital management and experienced nurses expect inexperienced nurses to have acquired the knowledge, skill and situational awareness to accurately identify, assimilate the data received and respond to patient deterioration. New nurses struggle with this expectation and rely on more experienced nurses in clinical practice to assist them to recognise abnormal vital signs and clinical observations and thereafter to take timeous, appropriate action (Bucknall et al., 2016; Endacott et al., 2010; Purling & King, 2012). However experienced nurses may deviate from following rapid response protocols when faced with patient deterioration and therefore do not role model the desired behaviour for inexperienced nursing colleagues (Astroth et al., 2013).

Nurses acquire knowledge about their patients during repetitive patient interactions also termed “knowing the patient”. A nurse’s clinical experience and “knowing the patient” in their care assists them in collecting a wide range of patient data and enables them to recognise the cues of early patient deterioration (Gazarian et al., 2010; Levett-Jones et al., 2010; Massey et al., 2017; McDonnell et al., 2013).

2.3.1.5 Nurses’ interpersonal competencies

Interpersonal skills such as self-confidence and communication reportedly influence nurses’ recognition and response to patients’ clinical deterioration. Hart et al. (2014) investigated nurses’ self-confidence and leadership abilities in relation to identifying and responding to physiological changes in patient conditions. Even though it was a small study in the United States of America (USA) with limitations in terms of transferability of the outcome to the general population of nurses, the study highlighted a significant positive relationship (p<0.001) between nurses’ self-confidence and their leadership abilities. A nurse’s number of years of experience and certification were also found to positively influence their self-confidence and leadership ability in the recognition of and response to deterioration in a patient’s condition (Hart et al., 2014). McDonnell et al. (2013) used a questionnaire and semi-structured interviews in the UK to differentiate the levels of confidence between registered and unregistered nurses in a single site study. The findings showed that unregistered nurses scored their confidence in their ability to recognise patient deterioration the lowest.

Communication with colleagues and interdisciplinary healthcare professionals influences a nurse’s recognition of changes in a patient’s condition as well as access to assistance when initiating a response (Massey et al., 2017; Purling & King, 2012; Quirke et al., 2011; Smith & Aitken, 2016). Medical practitioners tend to be more responsive and timely in

reviewing a patient's condition if nurses communicate tangible, measurable patient assessment findings coherently and comprehensively (Brier et al., 2015; Donohue & Endacott, 2010; Liaw et al., 2011b). Purling and King (2012) recommend a structured communication tool that provides nurses (particularly student nurses, non-registered and inexperienced registered nurses) with clear guidance for initiating assistance when escalating patient deterioration to a more skilled healthcare professional.

The Situation, Background, Assessment and Recommendation (SBAR) communication tool is recommended (Purling & King, 2012) and can improve a nurse's perception of the effectiveness of their communication with members of multidisciplinary healthcare team (De Meester, Verspuy, et al., 2013). The SBAR communication tool has been validated locally in SA to improve communication between healthcare professionals to timeously intervene in situations of patient deterioration (Burger et al., 2017).

The studies reviewed support the consideration of communication and self-confidence as factors influencing nurses' ability to fulfil the role of identifying and responding to situations of patient deterioration. A validated questionnaire could gather valuable data from SA nurses for comparison with international studies and to possibly evaluate the influence of communication and self-confidence locally.

2.3.1.6 Multidisciplinary team collaboration

Nurses are members of a multidisciplinary team of healthcare professionals responsible for providing care to patients. Collaboration and teamwork between nurses and more skilled healthcare professionals in the multidisciplinary team can enhance a nurse's ability to respond to recognised clinical deterioration but this requires further exploration (Connell et al., 2016; Jeddian et al., 2016; Massey et al., 2017; Quirke et al., 2011). Ward nurses rely on their nursing colleagues (Brier et al., 2015) and clinical experts in rapid response teams (Allen et al., 2017) to confirm their concerns about a patient's condition.

Critical to team collaboration is effective communication between members of the multidisciplinary team. Communication tools (Section 2.3.1.5) are useful to convey clear, unambiguous information between nurses and more skilled multidisciplinary response teams. Existing hierarchical healthcare structures on the other hand have been found to act as barriers to efficient communication of patient deterioration (Allen et al., 2017).

Nurses report being hesitant and fearful of being criticised for alerting more skilled healthcare professionals to a situation of patient deterioration (Astroth et al., 2013). Skilled clinicians may not consider that a patient's condition is as serious as estimated or

that nurses have rendered inadequate patient care. This results in hesitancy to escalate clinical deterioration in a patient's condition (Astroth et al., 2013).

Reportedly skilled healthcare professionals do not take action timeously when nurses communicate information about a patient's condition (Chua et al., 2013; Massey et al., 2014; Purling & King, 2012). Delays in taking action can be a result of dedicated response team members' existing direct patient care responsibilities preventing them from responding timeously to reports of patient deterioration (Allen et al., 2017). Nurses report a lack of collaboration and feeling unsupported in clinical practice when faced with a patient displaying signs of clinical deterioration (Massey et al., 2017). In contrast, nurses who received positive supportive feedback from more skilled healthcare professionals and from their own nursing colleagues reported an increase in confidence and decision making in recognising and responding timeously to patient deterioration (Astroth et al., 2013; Purling & King, 2012).

2.3.1.7 The organisational culture

National patient safety directives have influenced healthcare organisations to adopt patient safety practices (Department of Health, 2011). Organisational implementation of policies and standards of practice are essential to guide individual healthcare professionals' (including nurses) decision making when faced with patient deterioration (Jeddian et al., 2016). Patient safety systems such as early warning systems and dedicated specialist response teams have been implemented in an attempt to mitigate the factors impacting the incidence of AEs in healthcare organisations (Jeddian et al., 2016; Kyriacos et al., 2011).

Studies suggest that the organisational culture in an institution should include the promotion of clinical supervision for less experienced nurses undertaking patient monitoring and for decision making (Chua et al., 2013). Feedback to nursing assistants on the quality of their vital sign and clinical observation monitoring is recommended (James et al., 2010). Healthcare organisations should have sustainable continuing education programmes to improve healthcare professionals' clinical competency in recognising and responding to deterioration (McGaughey et al., 2017). Nurses and their team members should be encouraged to share what they have learnt from managing acute patient deterioration (Allen et al., 2017). Organisations should identify practices that influence nurses' ability to provide safe patient care in an attempt to reduce the incidence of AEs by early recognition and response to patient deterioration.

Gazarian et al. (2010) reported that nurses who had previous experience of clinical deterioration in a patient's clinical condition had identified EWS systems and rapid response systems as being beneficial and supportive. These systems empowered nurses with knowledge of whom to contact, when to seek assistance from more skilled healthcare professionals and the process to follow when intervening (Gazarian et al., 2010).

Health care organisations should consider the availability of sufficient clinical equipment to support patient safety systems that have been implemented. A lack of equipment has been identified as a limitation to timeous identification of deterioration in a patient's condition (Massey et al., 2017; Quirke et al., 2011). High acuity patients usually require more frequent monitoring. More frequent monitoring places pressure on the existing equipment available to give adequate patient care.

At a national and organisational level, in addition to implementing and sustaining a quality improvement strategy for patient safety patient, AEs should be critically analysed for improvement in patient care delivery (Kyriacos et al., 2011). Nurses are dependent on the organisation's processes and structures to perform their role competently to recognise and respond to patient deterioration (Kyriacos et al., 2011). All members of the healthcare team need to understand the value of the organisations' patient safety strategy. They need to understand each other's roles in recognition and response to the clinical deterioration in a patient's condition (Donohue & Endacott, 2010; Massey et al., 2014).

2.3.2 Nurses' knowledge relating to the recognition and responding to the deterioration in a patient's condition

The extent of a nurse's clinical experience (Chua et al., 2013; Gazarian et al., 2010) and prior exposure to managing a deteriorating patient in a general ward setting (Donohue & Endacott, 2010; Jeddian et al., 2016; Liaw et al., 2011b) influences a nurse's concern for a patient when their condition changes. In addition, their knowledge of the biosciences is critical to identifying the patient at risk of deterioration to initiate timeous intervention (Liaw et al., 2011b).

The more knowledge and experience stored in a nurse's their long term memory, the more able they are to recognise, interpret and respond to a trigger of concern (Liaw et al., 2011b). However, many healthcare organisations employ newly graduated RPNs and non-registered categories of nurses with limited knowledge and clinical experience in recognising the deteriorating patient. The respondent demographic data included in the results from studies by Liou et al. (2016) and Mok et al. (2015) illustrate that varying

categories of nurses with varying years of experience are employed by healthcare organisations.

Mok et al. (2015) reported that ENs in Singapore have limited knowledge to support their ability to interpret vital signs. They recommended developmental opportunities to promote clinical reasoning and knowledge of the biosciences to improve their competency in recognising and responding to changes in a patient's condition. A small scale cross-sectional survey was conducted at one nursing education institution in SA. The study reported that nursing students in the final year of their nursing education programme would have delayed activating assistance from more skilled healthcare providers in response to the presented physiological vital signs (Leonard & Kyriacos, 2015).

Liaw et al. (2011b) reviewed 26 international studies relating to educational strategies to improve nurses' knowledge and skill in recognizing and responding to deterioration in a patient's conditions. The study highlighted the focus on non-registered nurses' increasing responsibility and allocation to measure, record and report patients' vital signs and clinical observations. RPNs equipped with knowledge of biosciences, clinical competency and clinical decision making skills spend reduced time periods at a patient's bedside. This is due to their leadership responsibilities in coordinating care in the clinical unit (Astroth et al., 2013; Kyriacos et al., 2011; Liaw et al., 2011b).

An integrative review of the literature reported nurses' knowledge, for example of the biosciences, and their ability to relate it to a patient's reason for hospitalisation assisted them to understand what was happening to the patient physiologically and to anticipate future risks or possible complications (Massey et al., 2017). De Meester, Van Bogaert, et al. (2013) in Belgium used an unpublished survey to test the knowledge of a sample of 44 nurses while conducting documentation review of patients where the patient outcome was death following either an unplanned transfer to an intensive care unit or a request for review by a more skilled healthcare professional. The survey results found that nurses reported seeking assistance from a more skilled healthcare professional when the vital data was assessed as *higher* and *lower than* the recommended threshold limits. The researchers surmised that this finding could suggest delayed responses to possibly preventable deterioration in a patient's condition (De Meester, Van Bogaert, et al., 2013).

The frequency of vital signs recordings of blood pressure, oxygen saturation level and respiratory rate could reflect nurses' lack of bioscience knowledge (Mok et al., 2015). Miller's amended pyramid refers to "knowing" first, and then "knowing how" (Cruess et al., 2016). Therefore a fundamental gap in nurses' knowledge could exist. Knowing that

respiratory rate and heart rate are sensitive early signs of deterioration in a patient's condition rather than blood pressure and oxygen saturation level could influence a nurse's behaviour in measuring and recording a complete set of vital signs. Failing to record these sensitive markers of deterioration can lead to delayed recognition of deterioration in a patient's condition (Mok et al., 2015; Shearer et al., 2012).

Smith and Aitken (2016) conducted a record review and found that blood pressure was recorded and reported more frequently than other vital signs. In the same study, nurses then completed a knowledge questionnaire. Results for RPNs, student nurses and healthcare assistants were 76%, 80% and 66% respectively. This study reflected a concern that the category of nurse with the least knowledge not only measured patients' vital signs and clinical observations at the bedside but was expected to fulfil the critical role of interpreting the assessment findings for escalating a call to a RPN (Smith & Aitken, 2016).

Self-reporting questionnaires have been utilised in studies to collect quantitative data on nurses' knowledge about recognising and responding to deterioration in a patient's condition (Cooper et al., 2011; Kyriacos et al., 2015; Mok et al., 2015; Smith & Aitken, 2016). Connell et al. (2016) conducted a systematic review and highlighted an assumption worth considering with self-administered questionnaires. There is an assumption that nurses' self-perception of their knowledge is congruent with their behaviour in patient deterioration situations contributing to a culture of patient safety. Due to the multiple factors influencing nurses' ability to recognise and respond to deterioration in a patient's condition, improvements in knowledge may or may not result in improved recognition and response to patient deterioration in clinical practice (Connell et al., 2016).

Nurses need to have appropriate knowledge in order to provide safe patient care. A scientifically valid questionnaire able to gather relevant data could also contribute to development of an appropriate curriculum to ensure the preparation of knowledgeable nurses. Designing such a curriculum is beyond the scope of the present study.

2.3.3 Nurses clinical reasoning

Nurses require clinical reasoning and decision making competencies to recognise and respond to deterioration in patients' vital signs and clinical observations (Astroth et al., 2013; Liaw et al., 2011b; Mok et al., 2015; Purling & King, 2012). Liou et al. (2016) advocate that clinical reasoning is a vital systematic problem solving skill that nurses need to develop to enable them to render safe patient care. Clinical reasoning has been described as "a logical process by which nurses collect cues, process the information,

come to an understanding of a patient problem or situation, plan and implement interventions, evaluate outcomes and reflect on and learn from the process" (Levett-Jones et al., 2010). A study by Endacott et al. (2010) in Australia identified and recommended the need for final year nursing students to development of clinical reasoning skills following simulated patient deterioration scenarios and reflective debriefing.

This process, known as the Clinical Reasoning Cycle is shown in Figure 2.3. The cycle illustrates the continuous process of acquiring patient data, analysing the data to create meaning and identifying the patient's needs, taking action, evaluating the action and then reflecting on the learning from the experience. Nurses' experiences of situations where a patient's condition has deteriorated, assists them to recognise and respond to new changes in a patient's condition (Purling & King, 2012).

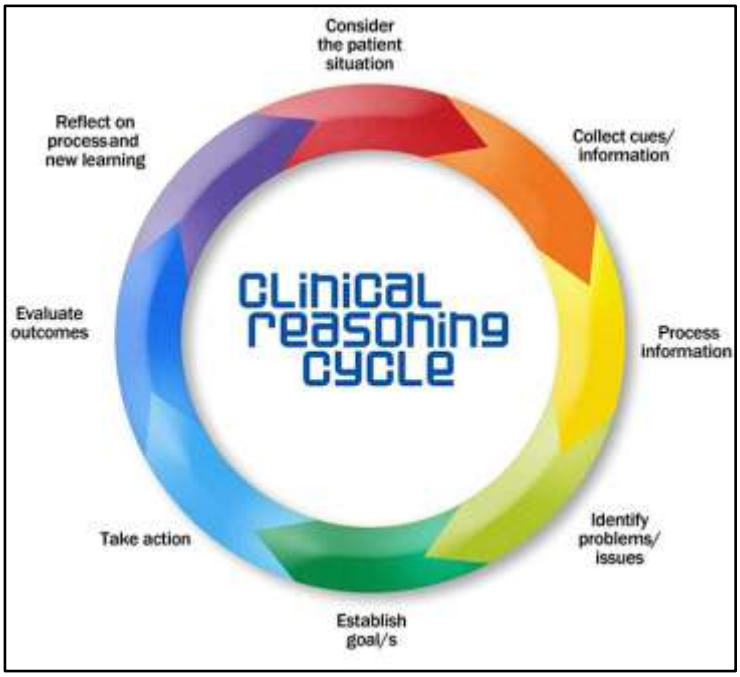

Figure 2.3: The clinical reasoning cycle (Levett-Jones et al., 2010)

The term "decision making" is described as the ability to gather and identify cues, to link the cues and then to take action (Liaw et al., 2011b). These activities are included in the definition of clinical reasoning of Levett-Jones et al. (2010). Decision making is considered to be a phase of a broader more complex cyclical process. Therefore, the term "clinical reasoning" will be used in this study to encompass reports of decision making. Clinical reasoning is a complex cognitive process that could be applied as an educational model to teach this essential skill to assist nurses to "collect the right cues and take the right action for the right patient at the right time and for the right reason" (Levett-Jones et al., 2010).

The Nurses' Clinical Reasoning Scale (NCRS) is based on the model of clinical reasoning by Levett-Jones et al (2010) in a study conducted with undergraduate student nurses in Taiwan (Liou et al., 2016). One clinical expert and two nursing faculty assessed the content validity of the question statements reflecting the Clinical Reasoning Cycle's cognitive steps. The item and scale content validity index was 1.0 indicating that the experts rated the question statements as valid. The factor loading was higher than the pre-set standard, so all statements were retained. The Cronbach's alpha was 0.93 reflecting internal consistency. The pilot study results yielded a significant difference (p<0.001) in the clinical reasoning scores of final year compared with second year nursing students. This illustrated known group validity and the scales ability to differentiate between two current groups of student nurses in different years of training. There was also a significant difference (p<0.001) between the clinical reasoning scores of clinical nurses (who had completed their training) and final year nursing students. As expected, the clinical nurses scored higher in the NCRS than the nursing students (Liou et al., 2016).

For validating the questionnaire developed for the present study, the NCRS could be used to generate understanding of respondent nurses' clinical reasoning (Liou et al., 2016) and has therefore been identified for inclusion in this study's questionnaire development and validation.

2.3.4 Validation studies

A search for literature references on validation studies on questionnaire construction on nurses' competence in early recognition and response to clinical deterioration in adult patients yielded no results. One study in Singapore described the development and psychometric assessment of a measurement tool designed to explore nurses' "attitudes towards vital signs monitoring in the detection of clinical deterioration in general wards" (Mok et al., 2015). The tool was developed from a literature view and interviews with 15 ward nurses.

Six themes emerged as the basis of the tool's subscales: "(i) knowledge, perceived ability to interpret vital signs; (i) key indicators, key vital signs indicating deterioration; (iii) communication, reporting deteriorating vital signs; (iv) workload, time and effort to record vital signs; (v) technology, impact of electronic vital signs monitoring on respiratory rates counting; and (vi) role and responsibility, staff responsibility in detecting and reporting vital sign abnormalities" (Mok et al., 2015, p. 208). Exploratory factor analysis established the construct validity of the tool. Content validity was established (CVI> 0.8). Cronbach's

alpha of 0.71 indicated adequate internal consistency. The Intra-class Correlation Coefficient of 0.85 revealed the tool's test-retest stability when completed at different times (Mok et al., 2015).

The psychometric evaluation of the NCRS was reported in Section 2.3.3. The content validity index, internal consistency, and known group validity displayed positive results for the 15 question statements in the NCRS that was developed based on the Clinical Reasoning Cycle (Liou et al., 2016).

Questionnaires assessing nurse respondents' knowledge have been included in pre and post-test intervention studies in Australia and Singapore (Cooper et al., 2010; Liaw et al., 2017; Liaw, Wong, Ang, et al., 2016; Liaw, Wong, Lim, et al., 2016). The validation of these questionnaires has been limited to expert panel review for content validity.

Perkins and Kisiel (2013) published their 9-question self-administered questionnaire used in the UK to evaluate final year, final clinical placement nursing students' self-perception of their ability to recognise and respond to patients' clinical deterioration. Assessment of the validity and reliability of the questionnaire was not published in the study.

In addition to the assessment of a questionnaire's content validity, its reliability should also be determined. In the context of cancer patients receiving palliative care a systematic review showed that test-retest reliability had been infrequently and poorly evaluated to assess the stability of questionnaires (Paiva et al., 2014).

2.3.5 Summary of the literature review

A literature review of the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and nurses' self-reported clinical reasoning ability illustrates the complexity of the identified themes. The themes are inter-related in their capacity to influence nurses' ability to deliver safe patient care and reduce the occurrence of AEs.

The paucity of published literature on validated research instruments to address the aims of the present study justifies the development and validation of a questionnaire for this study. Validating such a questionnaire in a local healthcare context could contribute to patient safety research in a local private healthcare organisation by providing useful data for future education programmes and the introduction of an EWS system. The validation methodology is outlined in the following chapter.

CHAPTER 3: METHODS

3.1 Introduction

Developing and validating a questionnaire ensures that it measures the constructs that it is intended to measure and that it is a reliable instrument. Guided by a review of the literature, the following content domains for a questionnaire were explored and validated: factors influencing nurses' ability to recognise and respond to patient deterioration on a general ward; nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and nurses' self-reported clinical reasoning ability. This chapter explains the development of a prototype questionnaire (Appendix A) and the validation process.

Failure to ensure validity and reliability negatively influences interpretation of the eventual results. The validation process consisted of the following phases: determining a numerical content validity index (CVI) and face validity of all items in the prototype questionnaire; conducting cognitive interviews to further explore face validity and the quality of the questionnaire; and lastly assessing test-retest reliability for stability. For each validation phase, data management and analysis is described.

3.2 Research design

A mixed methods sequential study design consisting of four phases was used to develop and systematically validate a researcher-developed questionnaire to meet the study objectives. The study required both quantitative and qualitative methods for data collection and analysis. Quantitative data collection and data analysis was required prior to qualitative data collection and analysis (Creswell, Klassen, Plano Clark, & Smith, 2011). "Today's research world is becoming increasingly inter-disciplinary, complex, and dynamic; therefore, many researchers need to complement one method with another, and all researchers need a solid understanding of multiple methods used by other scholars to facilitate communication, to promote collaboration, and to provide superior research" (Johnson & Onwuegbuzie, 2004, p. 15). Figure 3.1 graphically illustrates each sequential phase of the 4-phase study design.

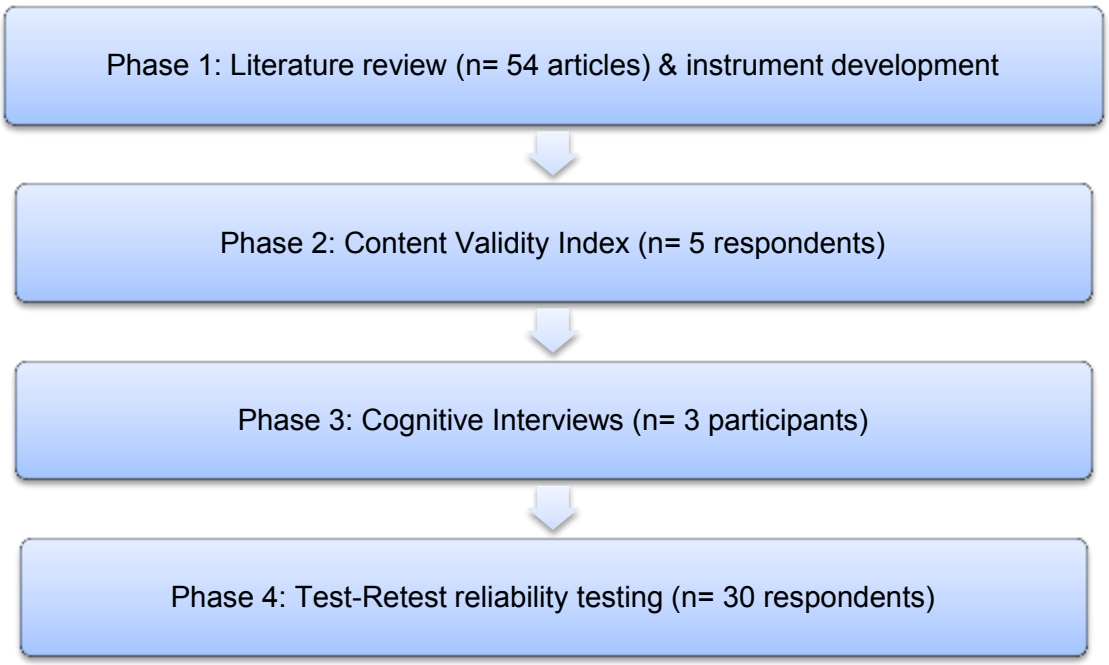

Figure 3.1: Diagrammatic representation of the mixed method sequential study design

3.3 Research setting

Data collection for the four phases of the sequential study was from January to July 2017. Respondents for phase 2 of the study were sourced from three provinces: Western Cape, Gauteng and KwaZulu Natal because their assessment of the content and face validity did not require face to face interaction between the researcher and respondent. The face to face cognitive interviews conducted in phase 3 limited the respondents to the Western Cape. The sample of respondents for the test-retest for stability was limited to permanently employed nurses at a private hospital in the Western Cape.

3.4 Data collection for development and validation of the prototype questionnaire

For the development and validation of the prototype questionnaire English was used in all documentation and communication with study respondents as it is the language of instruction at the research sites where the validation of the questionnaire was conducted.

3.4.1 Phase 1: Construction of the prototype questionnaire guided by a literature review (Objective 1.6.1)

For the construction of the prototype questionnaire (Appendix A) an in-depth literature review (Chapter 2) was conducted to identify relevant content domains. The identified content

domains (Table 3.1) were used to conceptualise the item statements and assessment scales to meet the purpose of the questionnaire (Brancato et al., 2006; Lynn, 1986).

Table 3.1: Content domains for a prototype questionnaire identified from a literature review

Content domains	Components of content domains	References from literature supporting inclusion	Section of prototype questionnaire (Appendix A)
Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward	Interpersonal competencies: nurses' ability to communicate concerns regarding patients' condition acknowledged	Massey et al. (2017); Purling and King (2012); Quirke et al. (2011)	1
	Multidisciplinary healthcare team collaboration	Allen et al. (2017); Astroth et al. (2013); Massey et al. (2017); Quirke et al. (2011)	1
	Clinical competency of nurses: qualifications of nurses measuring physiological vital signs and clinical observations	Chua et al. (2013); James et al. (2010); Kyriacos, Jelsma, and Jordan (2014); Massey et al. (2017); Purling and King (2012); Perkins and Kisiel (2013); Quirke et al. (2011)	1
	Organisational culture: clear policies, processes and tools supporting frequency of measuring vital data, recognition, interpretation, and decision making about vital signs measured and patient deterioration	Chua et al. (2013); Jeddian et al. (2016); Kyriacos et al. (2011); Kyriacos, Jelsma, and Jordan (2014), Mok et al. (2015)	1
	Documentation of vital signs and clinical observation data	Cahill et al. (2011); Cardona-Morrell et al. (2016); Chua et al. (2013); Clarke et al. (2010); Considine et al. (2016); De Meester, Van Bogaert, et al. (2013); Fasolino and Verdin (2015); James et al. (2010); Jonsson et al. (2011); Kyriacos et al. (2015); Kyriacos, Jelsma, and Jordan (2014); Ludikhuize, Smorenburg, et al. (2012); Mok et al. (2015); Odell (2015); Pantazopoulos et al. (2012); Smith and Aitken (2016)	1
	Nurses' clinical experience and knowledge of their patients	Astroth et al. (2013); Bucknall et al. (2016); Chua et al. (2013); Endacott et al. (2010); Gazarian et al. (2010); Kyriacos et al. (2011); Levett-Jones et al. (2010); Ludikhuize, Dongelmans, et al. (2012); Massey et al. (2017); McDonnell et al. (2013); Purling and King (2012)	
Nurses' knowledge of physiological and clinical parameters associated with	Knowledge of physiological and clinical parameters	De Meester, Van Bogaert, et al. (2013); Massey et al. (2017); Mok et al. (2015);	2

Content domains	Components of content domains	References from literature supporting inclusion	Section of prototype questionnaire (Appendix A)
patient deterioration		Perkins and Kisiel (2013); Cooper et al. (2010); Endacott et al. (2010); Kyriacos et al. (2011); Liaw et al. (2011b)	
Nurses' self-reported clinical reasoning ability	Nurses' clinical reasoning ability to recognise and respond to deterioration in a patient's condition	Astroth et al. (2013); Levett-Jones et al. (2010); Liou et al. (2016)	3
Respondent demographic data	Demographic data	Rattray and Jones (2007)	4

Data in Table 3.1 give a summary of the identified content domains that were used to conceptualise the questionnaire item statements: to assess the factors influencing nurses' ability to recognise and respond to patient deterioration on a general ward; nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and nurses' self-reported clinical reasoning ability. Demographic data might be useful to interpret respondents' response choices (Rattray & Jones, 2007), for example comparing differences between ENA and RPNs.

Item statements included in the prototype questionnaire were derived from studies identified in the literature review. Questionnaire item representation in the content domains contributed to the quality of the questionnaire, its content validity and the results generated (Brancato et al., 2006; Polit & Beck, 2017). Questionnaire item statements were carefully worded to support clarity, ease of understanding and to reduce ambiguity (Brancato et al., 2006). Item statements were grouped, aligned to the content domains and to the overall purpose of the prototype questionnaire to support clarity in understanding the four sections of the questionnaire (Brancato et al., 2006).

Data in Table 3.2 show the components of the prototype questionnaire (Appendix A) that consisted of 65 item statements structured as closed-ended questions in Sections 1 and 3 with a 5-point Likert scale response option. The 5-point Likert scale range of 5-1, left to right, from 5 = Strongly agree to 1 = Strongly disagree with 3 = neutral was adopted from the validation study by Liou et al. (2016). The Likert scale was applied to the Section 1 questionnaire items for consistency in response options across Section 1 and Section 3. Section 2 consisted of a multiple choice option, open-ended single answer questions and a multiple option checklist question. Section 4 consisted of limited choice closed-ended questions and open-ended single answer questions.

Table 3.2: Components of the prototype questionnaire

Part of questionnaire (Number of item statements / questions)	Content domains	Reference source of item statements	Type of data	Scale of measurement
Section 1 (25)	Factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward	Astroth et al. (2013); De Meester, Van Bogaert, et al. (2013); Kyriacos et al. (2011); Perkins and Kisiel (2013); Mok et al. (2015)	Ordinal	5-point Likert scale: 5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, 1 = strongly disagree (Polit & Beck, 2017)
Section 2 (13)	Nurses' knowledge of physiological and clinical parameters associated with patient deterioration	De Meester, Van Bogaert, et al. (2013);Kyriacos (2011);Cooper et al. (2010); Kyriacos, Jelsma, James, et al. (2014); Smelterz, Bare, Hinkle, and Cheever (2011)	Nominal	Multiple choice option questions; open-ended single answer questions and a multiple option checklist question (Brancato et al., 2006)
Section 3 (15)	Nurses' self-reported clinical reasoning ability	Liou et al. (2016)	Ordinal	5-point Likert scale: 5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, 1 = strongly disagree (Polit & Beck, 2017)
Section 4 (12)	Respondent demographic data	Rattray and Jones (2007); Liaw, Chan, Chen, Shing Chuan Hooi, and Siau (2014)	Nominal; Interval	Limited choice closed-ended questions and open-ended single answer questions (Brancato et al., 2006)

Section 1 of the prototype questionnaire (Appendix A) dealt with factors influencing the ability to recognise and respond to patient deterioration consisting of 25 item statements with a 5-point Likert scale (5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, 1 = strongly disagree). Item statements were adapted with permission from the published questionnaire items reported in the study by Perkins and Kisiel (2013). Additional item statements were formulated from the published literature to assess the factors influencing a nurse's ability to recognise and respond to patient deterioration (Astroth et al., 2013; De Meester, Van Bogaert, et al., 2013; Kyriacos et al., 2011; Mok et al., 2015).

Section 2 of the prototype questionnaire (Appendix A) dealt with nurses' knowledge of physiological (Cooper et al., 2010) and of clinical and physiological parameters (De Meester, Van Bogaert, et al., 2013; Kyriacos, 2011) associated with deterioration in a patient's condition. This section consisted of 11 multiple choice options questions, one question with nine open-ended single answer items and one checklist question with nine options. Permission was granted for the adaptation of questions for the purposes of this study (Cooper et al., 2010; Kyriacos, 2011). Cooper et al. (2010) used a multiple choice questionnaire consisting of 11 closed-ended questions. Sections of the questionnaire from Kyriacos (2011) were adapted for the purpose of this study for development of the prototype

questionnaire to assess nurses' knowledge of clinical and physiological parameters associated with recognition of and response to deterioration in a patient's condition. Item statements relating to relevant clinical observations were also drawn from the study by De Meester, Van Bogaert, et al. (2013) for inclusion in the prototype questionnaire.

Section 3 of the prototype questionnaire (Appendix A) dealt with self-reported clinical reasoning ability in 15 item statements with a 5-point Likert scale (5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, 1 = strongly disagree). The published item statements were included in the prototype questionnaire with permission from Liou et al. (2016). None of the item statements published were negatively worded in their original format (Liou et al., 2016).

Section 4 of the prototype questionnaire (Appendix A) included nine multiple choice questions and three open-ended single answer questions on respondent's demographic characteristics: current highest qualification, age, years' of experience, home language and current studies. Demographic data might inform interpretation of the respondents' answers if the validated questionnaire is implemented at the healthcare institution at the conclusion of the study. Rattray and Jones (2007) recommended that the demographic data section be included at the end of the questionnaire to reduce the possibility of the demographic data influencing the respondent's boredom or attention or bias during completion of the questionnaire.

Questionnaire items about access to electronic devices and internet services have relevance for clinical education programmes. Liaw et al (2014) conducted a randomised controlled trial to compare the ability of third year nursing students to critically evaluate and initiate interventions when faced with the clinical deterioration of a patient. The students were allocated to either undertake a web-based simulation training programme or a manikin based simulation training programme. Although the long-term benefits for the students were linked to the manikin based simulation training programme, web-based training programmes might be a more favourable choice for large student groups as a more time efficient method of reaching learning outcomes (Liaw et al., 2014).

The questionnaire item about attending a Cardiopulmonary Resuscitation (CPR) (commonly called Basic Life Support) course was included for two reasons. Firstly, Quirke et al. (2011) recommend education and training in identifying and managing the unwell patient. Secondly, it is the only formal training programme currently available at the research site for all nurses that includes education on physiological and clinical signs of deterioration and the immediate response required in such situations (Neumar et al., 2015). Inclusion was considered relevant to track nurses' attendance of the training programme.

3.4.2 Phases 2 to 4: Validation processes (Objectives 1.6.2 to 1.6.4)

Research activities for the validation process consisted of determining: 1) the content validity index (CVI) and face validity assessment by definition (Lynn, 1986) of all items (I-CVI) and of the scale of the overall prototype questionnaire (S-CVI); 2) conducting cognitive interviews (CI) for establishing the face validity quality of the questionnaire in more depth; and lastly 3) assessing the test-retest reliability of the instrument for stability when completed by the same respondents at two time points. These research activities undertaken for the study and the respondents for each activity are outlined in Table 3.3.

Table 3.3: Summary of the research activities and respondents

Research Activity	Method of sampling	Respondent inclusion criteria	Respondent exclusion criteria	Rationale for inclusion
Assessing the I-CVI and the S-CVI of the prototype questionnaire and face validity by definition (Appendix B)	Purposive sampling	Five Registered Professional Nurses with: a minimum qualification of a Master's Degree, postgraduate diploma in nursing education, and self-declared knowledge of the biosciences and basic health sciences research.	Respondents not available during the months of January to March 2017.	Academically prepared and knowledgeable experts.
Qualitative assessment of the face validity of the revised prototype questionnaire using cognitive interviews (Appendix D)	Purposive sampling	Three Registered Professional Nurses with: a minimum qualification of a Master's Degree, postgraduate diploma in nursing education, and self-declared knowledge of the biosciences and basic health sciences research.	Sample participants who participated in the assessment of the content validity of the prototype questionnaire.	Academically prepared and knowledgeable experts.
Assessing the reliability (stability) of the final validated questionnaire (Appendix G)	Stratified random sampling	Thirty nurses working on general wards in the private hospital of the Western Cape.	Nurses unavailable for participation due to being on some form of leave of absence for the duration of the test-retest period.	All three categories nurses were included as measuring and recording clinical observations and vital signs is included in their respective statutory Scope of Practice.

Each of the validation processes are presented in detail in the following sections of this chapter.

3.4.3 Phase 2: Assessing the content validity index (CVI) (Objective 1.6.2)

Determining the CVI (Lynn, 1986) was the next phase of the study and the first of the validation processes. The purpose of determining the CVI was to enable the experts to assess whether the individual items (I-CVI) and the measurement instrument as a whole (S-

CVI) were relevant and representative of the intended construct being measured (Lynn, 1986; Polit & Beck, 2017). Assessing the CVI prior to conducting the cognitive interviews establishes questionnaire item to construct alignment prior to establishing respondent's questionnaire item interpretation (Brancato et al., 2006).

3.4.3.1 Construction of the CVI assessment form

The assessment form for the CVI evaluation (Appendix B) was constructed, consisting of a tabulated version of the prototype questionnaire with each question item listed individually. Lynn (1986) recommended using a 4-point Likert scale ranging from 1 (not relevant) to 4 (extremely relevant) respectively. A column for "comments" enabled the expert respondents to qualify their recommended changes and/or their ratings to improve the relevance of the content of the instrument during the developmental phase (Lynn, 1986; Polit & Beck, 2017).

In addition, the CVI assessment form (Appendix B) included a section with instructions for the expert RPN respondents to comment on the face validity of the prototype questionnaire by definition (Lynn, 1986): readability, layout and clarity of the instructions. These factors can influence the completion of the questionnaire during data collection (Kyriacos, 2011; Polit & Beck, 2017). Numerical data for the face validity by definition (Lynn, 1986) were generated also using a 4-point ordinal scale with descriptive terms ranging from 1 (unsatisfactory) to 4 (excellent) to analyse the data (Kyriacos, 2011). The objectives guiding the development of the prototype questionnaire as well as a list of relevant definitions of terms were included in the CVI respondent information sheet (Appendix C) to ensure that the expert respondents interpreted the terminology accurately (Waltz, Strickland, & Lenz, 2005). The prototype questionnaire (Appendix A) was included with the documentation so that the expert RPN respondents could view the questionnaire in its entirety and to assist them to evaluate the face validity thereof.

3.4.3.2 Population sampling for the assessment of the CVI

Inclusion criteria: The respondent population of experts for the content validity process was defined as Registered Professional Nurses (RPNs) with a minimum qualification of a Master's Degree, a postgraduate diploma in nursing education and self-declared knowledge of the biosciences and basic health sciences research (Table 3.3). Lynn (1986) suggested using five to ten experts who are easily reachable by the researcher for this process. After careful consideration of suitable possible respondents, five RPNs who met the inclusion criteria were selected by purposive sampling by the researcher (Waltz et al., 2005).

Exclusion criteria: Respondents who met the inclusion criteria but were unavailable between January and March 2017 were excluded from assessment of the content and face validity of the prototype questionnaire.

3.4.3.3 Procedure for the CVI process

The researcher is an experienced nurse educator at a local and national level and sourced potential respondents for this phase of the study based on this experience and self-declared knowledge of the biosciences and basic health sciences research. Potential respondents who met the inclusion criteria were recruited by sending each RPN an individual invitation (Appendix C) by electronic mail to participate in this phase of the study.

Waltz et al. (2005) recommend that respondents should be adequately prepared to participate in a study. Therefore, explicit instructions in the Respondent Information Sheet (Appendix C) included background information about the purpose of the study, instructions for completing the CVI assessment form, the timeline for completion and the procedure for returning the completed documentation to the researcher. The documentation included an informed consent form for each respondent to review and complete in writing. Each participating respondent returned the informed consent form to the researcher consenting voluntarily to participation (Appendix C) in this study.

The CVI assessment form (Appendix B) was sent electronically to each individual expert RPN who returned the completed consent form declaring their consent to participate voluntarily in the assessment of the CVI and face validity of the prototype questionnaire. Two RPNs who did not respond to the initial email invitation, a follow-up email invitation, and a telephonic message did not participate. An additional two RPNs meeting the criteria were invited to participate to ensure that the sample size for the CVI assessment was achieved. Time was made available and offered to the expert RPNs to clarify participation requirements. Two expert RPNs asked questions via electronic mail while the other three RPNs replied that they understood the instructions for participation and had no further questions. Completion of the CVI assessment tool did not require face to face engagement between the researcher and consenting respondent so this took place in their own time and at their preferred venue.

Results are reported in the next chapter, nevertheless importantly, the expert RPNs did recommend amendments to item statements on the CVI assessment form. The suggested amendments were clear, understandable and applied to the items. Neither in-depth discussions nor a second round of CVI assessments were conducted (Lynn, 1986; Polit & Beck, 2017).

3.4.4 Phase 3: Assessing face validity using cognitive interviews (Objective 1.6.3)

Cognitive verbal interviewing offers a researcher the opportunity to establish face validity of a questionnaire. Problems with interpretation of questionnaire statement items were identified during the interview process with participants thereby contributing to validity of the questionnaire (Knafl et al., 2007; Willis, 2015). Interpretation errors can influence the formulation of responses given to the questionnaire items and so cognitive interviewing attempts to reduce these errors (Beatty & Willis, 2007).

Following data analysis for the CVI and face validity assessment by definition (Lynn, 1986), changes were made to the prototype questionnaire resulting in the revised prototype questionnaire (Appendix D) used for the cognitive interviews to further assess the face validity of the questionnaire.

3.4.4.1 Population and sampling for the cognitive interviews

Inclusion criteria: The population for the cognitive interviews for the purpose of assessing the questionnaire for in-depth face validity and quality of the revised prototype questionnaire (Appendix D) was defined as RPNs with a minimum qualification of a Master's Degree, a postgraduate diploma in nursing education and self-declared knowledge of the biosciences and basic health sciences research (Table 3.3). Recommendations for a specific sample size for the process of cognitive interviewing have not been clearly articulated (Beatty & Willis, 2007; Brancato et al., 2006). Suggestions have been made ranging from small numbers to possibly a maximum of 15 participants (Brancato et al., 2006) but was limited to four with success in a study by Gabe and Jordan (2014). However, adequacy in the number of interviews can be considered when no new feedback is given for the instrument items under review (Conrad & Blair, 1996). Three RPNs were selected by purposive sampling by the researcher (Polit & Beck, 2017) for the convenience of conducting face-to-face interviews to gather data (Beatty & Willis, 2007). The researcher was able to source potential participants for this phase of the study again through her knowledge of the field of nursing practice and nursing education both locally and nationally.

Exclusion criteria: The RPNs who participated in the assessment of the CVI were excluded so that the feedback from the cognitive interviewing process was not contaminated by prior interaction with the prototype questionnaire (Brancato et al., 2006).

3.4.4.2 Cognitive interviewing procedure

Establishing face validity was intended to improve the quality and the intended user's rate of completion of the questionnaire as the language utilised, phrasing of questions or

questionnaire layout could lead to participant bias and non-completion (Drennan, 2003; Rattray & Jones, 2007; Waltz et al., 2005). Using the revised prototype questionnaire (Appendix D), the three expert RPNs were contacted individually via electronic mail and invited to participate in the cognitive interviews.

The Participant Information Sheet (Appendix E) included an invitation to participate in the cognitive interviews for the study, information about the study, clarifying terminology, the cognitive interview process and the informed consent form. When the completed informed consent document was received from each participant, logistical arrangements for the cognitive interviews were finalised with each participant individually via electronic mail. Each expert's participation then took place at a time and site of their preference (Brancato et al., 2006).

Cognitive interviews were conducted with the three participants individually using the "think aloud" technique recommended for novice researchers rather than the alternative "verbal probing" technique (Beatty & Willis, 2007). On commencement of each interview, the researcher explained the purpose of the interview, verified the participant's written consent to participate voluntarily and explained the "think aloud" technique to prepare participants for the interview (Waltz et al., 2005). During each interview, each expert RPN participant was asked to verbalise the meaning of each item and to give their response to each questionnaire item across the four sections of the revised prototype questionnaire (Appendix D). This technique helped the researcher to understand whether the participant had sufficient understanding to answer each item statement (Beatty & Willis, 2007).

Probing questions or statements (Appendix F) were asked during the interviews following successful utilisation in a study conducted by Burger (2015). Permission was granted for utilisation of the probing questions. The probing questions were used when the verbal responses from the participants required further exploration and to probe their thoughts as they processed each question (Knafl et al., 2007; Presser et al., 2004).

Each interview was recorded using audio tapes and transcribed verbatim on completion of each interview by a competent individual who signed a confidentiality agreement. The researcher then read the transcripts while simultaneously listening to the audiotapes to ensure accuracy in the transcriptions for data analysis and prior to a subsequent interview should this have been necessary for clarification of data but was not needed. The researcher also wrote field notes during the interview to note any non-verbal cues or factors influencing the interview to assist with interpretation of the data (Waltz et al., 2005).

3.4.5 Phase 4: Assessing stability of the validated questionnaire using intra-rater reliability testing (Objective 1.6.4)

Data collected from assessment of the CVI and from cognitive interviews were systematically analysed. Changes were made resulting in the final validated prototype questionnaire (Appendix G). The fourth phase of the study, intra-rater reliability testing, intended to assess stability of the validated questionnaire to consistently measure the same domain under investigation on repeated occasions (Polit & Beck, 2017; Sim & Wright, 2005).

3.4.5.1 Population and sampling for reliability testing

Inclusion criteria: The final validated prototype questionnaire (Appendix G) was given to a sample of 30 nurses: 10 RPNs, 10 ENs and 10 ENAs from the total population of nurses (N=62) permanently employed and working on the general wards of a private hospital in the Western Cape to establish test-retest reliability for stability of the questionnaire (Sim & Wright, 2005). Including nurses from each of the three categories allowed for equal representation of the population in the sample of nurses (Karanicolas et al., 2009).

A sample size of 30 respondents was selected for the present study. In a published study, a sample of 30 respondents was used to successfully validate an Information Transfer Tool revealing a high intra-class correlation coefficient to establish reliability of the tool (Johnston et al., 2016). In Singapore, Mok et al. (2015) used a sample of 30 nurses to complete their instrument at two time points (test-retest) to evaluate the stability of an instrument as a measure of reliability. The Intra-class Correlation Coefficient (ICC) was 0.85 and the instrument was deemed stable.

Stratified random sampling was used to select nurses from each qualification category to ensure representation from each of the different categories of permanently employed nurses working on the general wards in a selected private hospital (Polit & Beck, 2017). Sampling was from the private hospital's alphabetised data-base, sorted by qualification.

The RANDBETWEEN function in Microsoft Excel (Version 2010) was used for the random selection of potential respondents. Names listed on the private hospital's alphabetised permanent staff database of nurses working on general wards were numerically numbered per category starting with the first name on the list being allocated the number "1" to "62". Access to the database of only the potential respondents' names and clinical units was requested from the hospital's custodian of this information after approval was granted by the hospital group's ethics committee (Appendix K). No other personal information regarding the

potential respondents was requested from the delegated custodian. Following stratified random sampling, respondents were invited to participate in the study.

Exclusion criteria: Permanently employed nurses who were unavailable for participation due to being on some form of leave of absence for the entire duration of the test-retest period.

3.4.5.2 Procedure for the test-retest assessment for reliability

After the morning handovers, the researcher verbally informed the identified nurses about the study and handed potential respondents the Respondent Information Sheet that included the consent form for voluntary participation (Appendix H). In addition, the Respondent Information Sheet included the purpose of the study, relevant terminology and the process of participation in the study. It was anticipated that this would take one week but it took two weeks due to the busyness of the unit after shift handover and the time required to explain the purpose of the test-retest process. The explanation gave nurses the opportunity to consent or not to consent to voluntary participation. Four potential respondents declined to participate, so the researcher returned to the alphabetised staff database and repeated the process of randomly selecting a further four respondents.

Thirty respondents were successfully recruited (n=10 RPNs, n=10 ENs, n=10 ENAs) and agreed to voluntary participation by consenting in writing. Respondents did not verbalise any coercion to participate as a result of being acquainted with the researcher and the consent form (Appendix H) clearly informed respondents of their freedom to participate and to withdraw at any stage of the process. Furthermore respondents saw the relevance of the item statements to their work and were pleased to participate.

The final validated prototype questionnaire (Appendix G) was then given to the respondents individually and self-administered by the sample of RPNs, ENs and ENAs for time 1 completion of the questionnaire. When determining the return date of the completed questionnaire and the timing of the retest, due consideration was given to respondents' patient care responsibilities during their work shift and their days off. A period of two weeks (fourteen days) was considered feasible between the test and retest to determine the stability of the questionnaire (DeVon et al., 2007; Marx, Menezes, Horovitz, Jones, & Warren, 2003; Polit & Beck, 2017; Rattray & Jones, 2007; Sim & Wright, 2005). The period between the test and retest was discussed and agreed to with the respondents prior to completion of the questionnaire when they were recruited. The researcher documented the date that the questionnaire was handed out to the respondent to ensure that there was a two week period between the respondent's time 1 test and time 2 retest. Two weeks after the

time 1 completion, the researcher handed the final validated prototype questionnaire (Appendix G) to the respondents again individually, so that the same sample of RPNs, ENs and ENAs could self-administer the questionnaire for the second time.

The self-administered questionnaires had been coded for each respondent as the only identifiers so that the researcher could analyse the scores accurately for each respondent (Polit & Beck, 2017). Only the researcher had access to the list of respondents' names and corresponding codes on a password protected computer.

Respondents were asked to complete and return the validated questionnaire within 48 hours in a self-addressed envelope with the researcher's details and placed in the hospital's internal mail. One round of verbal reminders had to be sent to the respondents.

During the two week test-retest period the respondents were not exposed to new programmes or training initiatives relating to the patient safety domains and constructs addressed in this study as these could have influenced the respondents' results (Marx et al., 2003; Paiva et al., 2014). There was agreement that the results of the validated questionnaire would be made available to the respondents on an individual, confidential basis but would not be reported to respondents' line managers and will not influence their employment status or performance ratings.

Recall of questionnaire items from time 1 completion of the test could have influenced respondents' answers for the retest. Recall is thought to increase the intra-rater agreement and the kappa statistic (Marx et al., 2003; Sim & Wright, 2005). The influence or dependence of the time 2 retest result on the initial time 1 test completion is considered a limitation of test-retest methodology. The time interval between the time 1 test and the time 2 retest is critical to establish so that the dependence of the time 2 retest on the time 1 test can be minimised (Sim & Wright, 2005).

3.5 Data analysis and management

Numerical data were entered directly into an IBM Statistical Package for the Social Sciences (SPSS) for Windows (version 24) data file for analysis. The strategy for data analysis for the validation process is presented in Table 3.4.

Table 3.4: Analysis for validation processes of the prototype questionnaire (Appendix A, 4 sections, 65 item statements/questions)

Data	Scale of measurement	Statistical analysis	Rationale for agreement or acceptance of items
Content validity index (CVI)			
Ordinal	4-point Likert scale: 1 = irrelevant, 2 = unable to assess relevance without item revision, 3 = relevant but needs minor correction; 4 = extremely relevant (Lynn, 1986; Polit & Beck, 2006)	Frequency, proportion, percentage, median, mean.	A pre-set proportion of ≥70% agreement (Guttmann, Razzaq, Lindsay, Zagorski & Anderson, 2006, p. 116) among raters of items rated 3 or 4 determined whether the item was valid (I-CVI) and remained in the questionnaire; and determined the overall proportion of agreement for the questionnaire (S-CVI).
Face validity (numerical data, part of CVI instrument)			
Ordinal	4-point ordinal scale: 1=unsatisfactory; 2=requires improvement; 3=satisfactory; 4 = excellent (Kyriacos, 2011)	Frequency, proportion, percentage	No evidence for management of data for face validity was found in the available literature. Therefore the same pre-set proportion of ≥70% agreement among the raters of items rated 3 or 4 (as for CVI assessment) for analysis of the data and determined whether the item was retained or amended.
Cognitive interviews			
Qualitative	Not applicable	Not applicable	Experts' interpretation of problems with item statements, applicability of the items, terms/phrases and clarity of items (Knafl et al., 2007).
Test-retest for reliability			
Ordinal	Section 1 items 1.1-1.25: 5-point Likert scale	Weighted kappa statistic	• <0=poor agreement • 0.01-0.20 = slight agreement • 0.21-0.40 = fair agreement • 0.41-0.60 = moderate agreement • 0.61-0.80 = substantial agreement • 0.81-l = almost perfect agreement (Sim & Wright, 2005)
Nominal	Section 2 items 2.1.1-2.1.8: 4-point multiple choice scale	Weighted kappa statistic	As above for section 1 (Sim & Wright, 2005).
Nominal	Section 2 items 2.2.1-2.2.8: open-ended single answer questions	Frequency and percentages because a weighted kappa statistic could not be computed	Illustrates consistency for the entire sample and between categories of nurses (Karanicolas et al., 2009)
Nominal	Section 2 items 2.3.1-2.3.9: multiple option checklist	Frequency and percentages because a weighted kappa statistic could not be computed	Illustrates consistency for the entire sample and between categories of nurses (Karanicolas et al., 2009)
Ordinal	Section 3 items 3.1-3.15: 5-point Likert scale	Weighted kappa statistic	As above for section 1 (Sim & Wright, 2005).
Nominal; Interval	Section 4 items: Limited choice closed questions and open-ended single answer questions	Frequency and percentages because a weighted kappa statistic could not be computed	Illustrates consistency for the entire sample and between categories of nurses (Karanicolas et al., 2009)

3.5.1 Measurement of content validity

Central to the analysis of the CVI, is the agreement on the validity of the content among the expert respondents. Lynn recommended applying "the standard error of proportion" (1986,

p.383) to determine how many experts of the total expert group need to agree for the questionnaire items and the total questionnaire to be declared content valid. In the present study the CVI of each question/item statement (I-CVI) was calculated separately for each of the four sections of the prototype questionnaire (Appendix A) because each section represented a distinct content domain. I-CVI was accepted as agreement by raters at a pre-set level of ≥70% (Guttmann, Razzaq, Lindsay, Zagorski, & Anderson, 2006) and S-CVI was calculated for all 65 items with a score of either 3 (relevant but needs minor alteration) or 4 (extremely relevant) (Lynn, 1986).

The median rating of the ordinal level scale of each item statement was calculated in addition to the proportion of raters giving a score of 3 or 4 for that item to illustrate the central rating for each item statement (Polit & Beck, 2017). The mean for the number of raters scoring each item 3 (relevant but needs minor alteration) or 4 (extremely relevant) was calculated for each section and for the overall prototype questionnaire (Polit & Beck, 2017).

Although Lynn (1986) recommended 100% agreement for content validity, in the present study a pre-set proportion of ≥70% agreement of raters giving a score of 3 or 4 (Guttmann et al., 2006, p. 116) determined whether the items remained in the questionnaire. Items in the prototype questionnaire with less than 70% agreement among the expert respondents were removed. The S-CVI for the instrument was calculated as the proportion of total instrument items rated as 3 (relevant needing minor correction) or 4 (extremely relevant) by the respondents (Lynn, 1986). The pre-set proportion for the overall CVI was ≥70% agreement (Guttmann et al., 2006).

No evidence directing the management of the face validity data was found in the available literature other than Lynn's (1986) acknowledgement of assessment of face validity by assumption (non-statistical) as opposed to validity by definition (experts determine relevance of items) (citing Mosier, 1947). For this purpose the criteria used by Kyriacos (2011) to assess face validity of a questionnaire, comprising a 4-point ordinal scale ranging from 1 (unsatisfactory) to 4 (excellent) was used to generate numerical data for analysis of frequencies, proportions and percentages . Due to the lack of evidence available to guide the analysis, the same pre-set proportion of ≥70% agreement among raters that applied to the CVI assessment (Guttmann et al., 2006) was used to guide the utilisation of the face validity data.

Changes were made to the prototype questionnaire (Appendix A) as a result of the CVI assessment. The revised prototype questionnaire (Appendix D) with the amendments was used to generate qualitative data during the cognitive interviews.

3.5.2 Cognitive interviews for further measurement of face validity

Once the cognitive interviews had been transcribed and checked for transcription accuracy, the qualitative data from the expert RPNs' interviews were analysed for problems with: interpretation of questionnaire items, applicability of the items to the content domain, terms or phrases used in the questionnaire and clarity of items (Knafl et al., 2007).

Whereas participants for the I-CVI interestingly did not comment on the relevance of each subsection (for example response options a, b, c and d of a multiple choice question item) when rating an item, the researcher probed participant's understanding of each subsection for questions 2.2 and 2.3 during the CI resulting in assessment of a total of 78 items.

The researcher then made the decision to amend, omit or retain items in the revised prototype questionnaire (Appendix D). After the recommended changes had been made to the revised prototype questionnaire (Appendix D),the test-retest for reliability was conducted to assess the stability of the final validated prototype questionnaire (Appendix G) on the selected group of the identified population (Knafl et al., 2007; Polit & Beck, 2017).

3.5.3 Measurement of reliability: Test-retest

Reliability measured by the stability of the self-administered final validated questionnaire completed by the selected respondent nurses on two separate occasions two weeks apart was assessed by calculating the weighted kappa statistic (Sim & Wright, 2005). Prior to inputting the data into the IBM Statistical Package for the Social Sciences (SPSS) for Windows (version 24) to calculate the weighted kappa statistic, the completed questionnaires were assessed for missing data. The weighted kappa statistic was used to assess the degree of reproducibility or stability reflecting reliability beyond chance agreement when single respondent nurses rated each questionnaire item on two separate occasions. This statistic can be applied to categorical data such as nominal or ordinal data (Mandrekar, 2011; Sim & Wright, 2005). Karanicolas et al. (2009) recommends the weighted kappa statistic to estimate the level of agreement for categorical data where there are more than two response options for questionnaire items. The kappa statistical could be used to calculate the level of agreement for categorical data with dichotomous response options. The intraclass correlation coefficient is commonly used to determine the agreement for continuous data (Karanicolas et al., 2009)

The weighted kappa statistic usually ranges between -1.00 to +1.00. The higher the statistic (or closer the value to +1.00) the greater the stability or agreement between ratings on two separate occasions beyond agreement by chance. This means greater reliability of the

questionnaire when used on multiple occasions. In contrast, the lower the statistical value (or closer to the value 0.00), the more likely that the agreement could be assigned to chance agreement. Negative values mean agreement between variables that is worse than chance (Karanicolas et al., 2009; Sim & Wright, 2005).

Initially a coefficient of 0.80 or greater was intended to be the pre-set value of agreement reflecting stability of the final validated questionnaire (Polit & Beck, 2017). However the level of agreement for the final validated questionnaire items was found to be variable. Sim and Wright (2005) offered more categories to differentiate between weighted kappa statistic values. Therefore the statistical degree of agreement (weighted kappa statistic) for each item in the final validated questionnaire when completed on two occasions by the same respondent has been assessed using the following categories:

- <0 = poor agreement,
- 0.01-0.20 = slight agreement,
- 0.21-0.40 = fair agreement,
- 0.41-0.60 = moderate agreement,
- 0.61-0.80 = substantial agreement and
- 0.81-l = almost perfect agreement (Sim & Wright, 2005).

The weighted kappa statistic could not be computed for 29 items. As a result the level of agreement beyond chance could not be calculated for the 29 items. The 29 items included items 2.2.1 to 2.2.9; 2.3.1 to 2.3.8 and 12 items in Section 4 of the final validated prototype questionnaire (Appendix G). The nurse respondents' time 1 answers were allocated the value "1" for these 29 items. The value of "1" was assigned in the time 1 test irrespective of whether the answer was correct or incorrect. If the respective nurse respondent's time 2 (retest) answer for an item was consistent with the time 1 item answer, a score of "1" was recorded for the time 2 retest answer for the respective item.

Analysis of responses for time 1 and time 2 was based on binary data: 1 was allocated if responses were the same on both occasions and 2 if the time 2 response differed from that for time 1. Consistency in respondent's time 1 and time 2 answers for each of the 29 questionnaire items was assessed and recorded for the total nurse respondent sample as well as for each category of nurse for questionnaire items. The proportion of consistency in the nurse respondents' answers was therefore evaluated for the 29 questionnaire items where the weighted kappa statistic could not be computed.

The answers to the knowledge questions in Section 2 have been included in Appendix I of this study. However the purpose of this study is not to assess whether the respondents' answers are correct or incorrect, but to assess the stability in the answer given between time 1 and time 2 of the test-retest.

3.6 Ethical considerations

The ethical principles of the World Medical Association's Declaration of Helsinki (2013) were upheld to prevent undue harm to any respondents. The study proposal was submitted to the University of Cape Town's Faculty of Health Sciences' Human Research Ethics Committee for ethics approval prior to implementation. Approval was granted (HREC REF: 881/2016).

Thereafter the study proposal was also submitted to the private healthcare establishment's Ethics Committee for approval and permission to access potential respondents for the reliability test-retest phase. Potential respondents for the test-retest phase of the study were in the employ of the private hospital group where this phase of the study was conducted and permission was required from the establishment prior to accessing the database and inviting participation from the nurses. Approval was granted (REC 251015-048).

3.6.1 General principles

This study did not include any healthcare establishment patients. The respondents were all healthcare professionals either registered or enrolled with the SA Nursing Council as RPNs, ENs or ENAs. Throughout the duration of the study, the researcher considered the well-being of the respondents, respecting their rights ensuring that the planning for their participation did not infringe on their work time or their safety when taking part outside of working hours.

The respondents for the assessment of the content validity and the cognitive interviews invited to participate in the study were only sent a follow up invitation if they did not respond voluntarily within one week of the primary invitation being sent by electronic mail. The two respondents who voluntarily chose not to participate in the study were not contacted after the second invitation therefore avoiding any form of coercion towards participation. Sending the invitation to participate via electronic mail was purposefully done to allow the potential respondents freedom and time to consider their participation free of coercion.

The likelihood of familiarity between the respondents for the assessment of the stability of the prototype questionnaire selected from the list of nurses employed at the private hospital and the researcher was due to the close geographical proximity of the private hospital

employing the respondents and the nursing education institution where the researcher is employed. Even though the researcher handed out the questionnaires to the potential respondents, the follow up of the questionnaires was carried out by a third party unknown to the respondents.

There was no harm to the environment. The study has been overseen by a PhD prepared Associate Professor in the Division of Nursing and Midwifery at the University of Cape Town.

3.6.2 Risks, burdens and benefits

The burden of participating in the study outside of work hours could lead to fatigue on the part of the respondents. This was minimised through dialogue to establish the most favourable time for the validation processes to take place; specifically the cognitive interviews.

The benefits to the respondents included the altruistic internal gratification of contributing to the validation of the questionnaire for the purposes as outlined in the study that will contribute to the anticipated use of the questionnaire to understand the education requirements required by the nurses and the factors supporting and impeding their ability to recognise and respond to patient deterioration in the general wards of the private hospital at a later stage beyond the scope of this study.

There were no intended risks associated with participating in this study to validate the questionnaire. There was no remuneration for the participation in the study.

3.6.3 Vulnerable groups and individuals

Vulnerable groups or individuals were not included in this study.

3.6.4 Privacy and confidentiality

The respondents were allocated codes as identifiers (respondent codes) on the data collection instruments utilised during the study to ensure anonymity and confidentiality. Only the researcher has a list linking the respondent and corresponding respondent code. This list has been password protected on the researcher's computer.

The transcriber for the cognitive interviews signed a confidentiality agreement to keep all information confidential during the transcription process although only the respondent code numbers were recorded on the interview sheets to ensure confidentiality.

3.6.5 Informed consent

All respondents were invited to participate voluntarily in this study without coercion or retribution. They had the right to and the opportunity to withdraw at any stage but did not. The informed consent sheet was included in the Respondent Information Sheets (Appendices C and H) and Participant Information Sheet (Appendix E) for each phase of the study which contained an explanation of the purpose of the study and instructions for each aspect of the study.

3.6.6 Dissemination of results

After successful completion of the study by external examination, the results of the study will be disseminated via conference presentation and publication of a journal article/s in a peer reviewed journal. The respondents of the study will then be offered an executive summary of the study.

CHAPTER 4: RESULTS

4.1 Introduction

The aim of this study was the robust development and validation of a questionnaire as a measuring tool to assess: 1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; 2) nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and 3) nurses' self-reported clinical reasoning ability. The development of the prototype questionnaire was described in Chapter 3. The validity and reliability of the developed questionnaire were assessed using the processes of calculating the content validity index (CVI), cognitive interviewing (CI) and test-retest reliability testing. The results of the validity and reliability testing are presented in this chapter.

4.2 Experts' opinion on the content validity index (CVI) (Objective 1.6.2)

Five expert RPNs fulfilling the selection criteria consented to individually evaluate the 65 item prototype questionnaire (Appendix A). Tables 4.1 to 4.4 outline the experts' CVI ratings for the questionnaire items in each respective section as well as the recommended changes to the prototype questionnaire items for each section. A summary of the findings, for example, the number of items retained with a pre-set proportion of agreement of ≥70% for each section are listed at the end of the respective tables 4.1 to 4.4. The experts' opinion on the face validity by definition of the prototype questionnaire is included in Table 4.5. The CVI for each section of the prototype questionnaire is discussed separately. Table 4.6 presents a summary of the results for the CVI analysis for the total prototype questionnaire.

4.2.1 CVI for Section 1: Factors influencing a nurse's ability to recognise and respond to patient deterioration

The results of the CVI ratings for Section 1 and the experts' recommended changes and opinions for the item statements are shown in Table 4.1 The pre-set proportion of ≥70% agreement (Guttmann et al., 2006) determined whether the items remained in the questionnaire. The changes that were suggested and implemented in the revised prototype questionnaire (Appendix D) were intended to improve the clarity of the respective item statement. A summary at the end of Table 4.1 lists the number of questionnaire items retained, amended and removed.

Table 4.1: Experts' opinion on the content validity (CVI) for Section 1 of the prototype questionnaire

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median score for item	Action taken
Section 1: Factors influencing your ability to recognise and respond to patient deterioration								
1.1	My nursing qualification adequately prepared me to take / measure clinical observations and vital signs.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.2	I am unsure how to respond to changes in patients' clinical observations and vital signs.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.3	Interpreting patient observations and vital signs is an essential part of my role.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.4	I feel confident recording patients' clinical observations and vital signs.				(5/5) 100%	(5/5) 100%	4	No change to the item statement. Retained. Define the terms "observations and vital signs" at the beginning of the questionnaire.
1.5	I feel knowledgeable when interpreting patients' clinical observations and vital signs which show altered physiology.			(2/5) 40%	(3/5) 60%	(5/5) 100%	4	Item amended. Experts recommended "altered" be replaced by "a change in" as questionnaire for all categories of nurses. ***I have the knowledge to interpret patients' clinical observations and vital signs which show a change in physiology.*
1.6	My nursing qualification adequately prepared me to interpret patients' clinical observations and vital signs.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.7	It is important to respond to any changes in patients' clinical observations and vital signs.			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	No change. Retained.
1.8	I believe that there is a deficit in my			(2/5) 40%	(3/5) 60%	(5/5) 100%	4	No change. Retained.

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median score for item	Action taken
	understanding of altered physiology associated with patients' clinical observations and vital signs.							
1.9	I am expected to take / measure patients' clinical observations and vital signs.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.10	I know how often I should take /measure patients' clinical observations and vital signs for the patients that I am allocated to provide care for in the clinical unit.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.11	The clinical unit in which I am employed has a policy or work procedure that prescribes the frequency of taking/measuring clinical observations and vital signs.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.12	The clinical unit in which I am employed has a policy or work procedure that prescribes the action that I should take if I recognise deterioration in a patient's clinical observations and vital signs.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.13	The registered nurse in the clinical unit checks the documented vital signs and clinical observations of every patient.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.14	I am adequately prepared to communicate with a more skilled				(5/5) 100%	(5/5) 100%	4	No change. Retained.

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median score for item	Action taken
	healthcare professional about deterioration in a patient's condition.							
1.15	I am able to use the accepted nursing terminology to communicate with a more skilled healthcare professional about deterioration in a patient's condition.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.16	I use a communication tool as a guide to communicate the relevant information about deterioration in a patient's condition to a more skilled healthcare professional.			(2/5) 40%	(3/5) 60%	(5/5) 100%	4	Item amended. Experts recommended that the tool be named to avoid any uncertainty in answering the question. ***I use a communication tool (for example the Situation, Background, Assessment and Recommendation / SBAR tool) as a guide to communicate the relevant information about deterioration in a patient's condition to a more skilled healthcare professional.*
1.17	I always document the information communicated to a more skilled healthcare professional about deterioration in a patient's condition in the patient's nursing records.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.18	I am confident that the more skilled healthcare professional will act timeously on the information that I communicate to them regarding the patient's deteriorating condition.		(1/5) 20%		(4/5) 80%	(4/5) 80%	4	No change. Retained
1.19	Information about		(1/5)	(1/5)	(3/5)	(4/5)	4	No change. Retained.

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median score for item	Action taken
	the patient's deteriorating condition that I communicate to a more skilled healthcare professional is taken into consideration.		20%	20%	60%	80%		
1.20	When reporting my concern regarding a patient's condition to a more skilled healthcare professional, I fear being criticised for reporting on a patient who is not that sick.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.21	I have the necessary equipment to take / measure clinical observations and vital signs.				(5/5) 100%	(5/5) 100%	4	No change to the item. Retained. Define the terms "observations and vital signs" at the beginning of the questionnaire.
1.22	In the clinical unit where I work I feel that I am an essential member of the multidisciplinary team responsible for the recognition of and response to deterioration in a patient's condition.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.23	I understand the consequences of failing to identify and report deterioration in a patient's condition.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.24	I measure and record every clinical observation and vital sign every time I am required to measure and record patients' clinical observations and vital signs.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
1.25	I have experienced a situation where the deterioration in a patient's condition			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	No change to the item. Retained. Define "deterioration in a patient condition" at

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median score for item	Action taken
	was not recognised leading to Cardiopulmonary resuscitation (CPR); transfer of the patient to the High Care or Intensive Care unit; or death of the patient.							the beginning of the questionnaire.

Summary of changes to Section 1	Mean, Proportion of items	Percent
Items that remained unchanged and retained	23/25	92.0
Items amended	2/25	8.0
Items removed	0/25	0.0
Items with a median score of 4	25/25	100
Items with a rating of 4	18/25	72.0
Items with a rating of 3	0/25	0.0
Items with a rating of 3 and 4	5/25	20.0
Items with a rating of 3 or 4 (CVI ≥70% agreement)	23/25	92.0
Items with a rating <3	2/25	8.0
Mean, proportion and percent: total raters for all items scoring 3 or 4 for Section 1	Mean: 4.92, (123/125)	98.4

Note: ** denotes the amended item statement

Data in Table 4.1 illustrate a high CVI for all the items rated 3 (relevant only needing minor editing) or 4 (extremely relevant): mean of 4.92, (123/125; 98.4%) and the median score for each of the 25 items was 4. Twenty-three (92%) of the items in this section were rated as 3 or 4 achieving an S-CVI for this section of ≥70% agreement (Guttmann et al., 2006): 18/25 items (72.0%) were rated as extremely relevant (score of 4) by the five expert RPN's; and 5/25 items (20.0%) were rated as 3 and 4. Two items (8.0%) each had one rating of 2 (unable to assess relevance without item revision) but this did not alter the median score of 4 for these items which were therefore retained in the questionnaire. A total of 23/25 (92.0%) items required no changes. The expert respondents recommended minor changes to 2/25 (8.0%) of the items (1.5 and 1.16).

4.2.2 CVI for Section 2: Knowledge of physiological and clinical parameters associated with deterioration

The CVI ratings for Section 2 relating to the nurse's knowledge of physiological and clinical parameters associated with deterioration are shown in Table 4.2. The recommended

changes suggested by the expert RPNs to improve the content validity and are listed in the "action taken" column. The changes were included in the revised prototype questionnaire (Appendix D). A summary at the end of the table lists the number of questionnaire items retained, amended and removed as well as the proportion of items rated 3 (relevant only needing minor editing) or 4 (extremely relevant).

Table 4.2: Experts' opinion of the content validity (CVI) for Section 2 of the prototype questionnaire

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median Score for item	Action taken
Section 2: Nurses' knowledge of physiological and clinical parameters associated with deterioration in a patient's condition								
2.1.1	A patient who is in hypovolaemic shock (and has low blood pressure) will have: a. Normal capillary refill b. Cold clammy skin c. Facial flushing d. Warm dry hands				(5/5) 100%	(5/5) 100%	4	No change. Retained.
2.1.2	A patient with hypoxia (lack of oxygen) is likely to be a. Confused b. Pink c. Happy d. Hot			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	Item amended to create homogeneity in response options. ***A patient with hypoxia (lack of oxygen) is likely to be* *a. Confused* *b. Pink* *c. Orientated to their surroundings* *d. Sweating*
2.1.3	Slow capillary refill is a sign of: a. Vasoconstriction and poor peripheral perfusion b. Malnutrition and dehydration c. Warm hands and feet d. Reduced concentrations of oxyhaemoglobin				(5/5) 100%	(5/5) 100%	4	No change. Retained.
2.1.4	The pulse can be palpated a. Every time the atria contracts b. When a vein is				(5/5) 100%	(5/5) 100%	4	No change. Retained.

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median Score for item	Action taken
	close to the surface of the skin c. Every time the left ventricle contracts d. When an artery is close to the surface of the skin							
2.1.5	A normal heart rate for an adult at rest is a. 60-80 beats per minute (bpm) b. 60-100 bpm c. 60-90 bpm d. 60-110 bpm			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	Item amended only by re-ordering the response options. ***A normal heart rate for an adult at rest is* *a. 60-80 beats per minute (bpm)* *b. 60-90 bpm* *c. 60-100 bpm* *d. 60-110 bpm*
2.1.6	Select the three appropriate statements to complete the sentence: Pulse oximeters (oxygen saturation probe) may be unreliable when…… 1. tissue perfusion is poor; 2. the patient is wearing nail varnish; 3. haemoglobin is 100% saturated; 4. measured on the ear lobe; 5. the patient has a cold; 6. haemoglobin levels are low; 7. digits are cold; 8. the patient is elderly. a. 1, 2 & 7 b. 2, 3 & 6 c. 1, 4 & 8 d. 2, 5 & 7			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	Item amended. ***Pulse oximeters (oxygen saturation probe) may be unreliable when……* *a. extremities are cold;* *b. the patient is wearing nail varnish;* *c. tissue perfusion is poor;* *d. all of the above.*
2.1.7	Select the three appropriate statements to complete the sentence: When assessing a patient's breathing:. 1. assess for 30 seconds; 2. look for chest			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	Item amended. Recommended that the 3-choice option is complicated and needs to be simplified. ***When assessing a patient's breathing…..* *a. assess the patient's breathing for 15*

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median Score for item	Action taken
	movements; 3. use a mirror to check for exhaled air; 4. listen for breath sounds; 5. feel for exhaled air on your cheek; 6. always remove dentures. a. 1, 2 & 4 b. 2, 3 & 5 c. 2, 4 & 5 d. 1, 4 & 6							*seconds;* *b. assess for 30-60 seconds looking for chest movement;* *c. use a mirror to check for exhaled air;* d. *the oxygen saturation is more important than the respiratory rate.*
2.1.8	A 14-16 gauge needle is most likely to be used for a. Elderly patients b. Paediatric patients c. Inserting in the back of the hand d. Trauma or burns patients		(2/5) 40%	(1/5) 20%	(2/5) 40%	(3/5) 60%	3	Remove item as <70% rated the question 3 or 4.
2.1.9	Which of the following is NEVER compatible with a cardiac output (adequate blood circulation): a. Supraventricular tachycardia b. Ventricular tachycardia c. Atrial fibrillation d. Ventricular fibrillation		(2/5) 40%	(2/5) 20%	(1/5) 20%	(3/5) 60%	3	Remove item as <70% rated the question 3 or 4.
2.1.10	A.V.P.U. stands for……. a. Alert, Visual, Peripheral, Unconscious b. Altered, Verbal, Pain, Unresponsive c. Anxious, Violent, Paranoid Unsettled d. Alert, Voice, Pain, Unresponsive		(1/5) 20%		(4/5) 80%	(4/5) 80%	4	No change. Item retained.
2.1.11	When using a non-rebreathe mask a. 40% O_2 is delivered to the		(2/5) 40%	(2/5) 20%	(1/5) 20%	(3/5) 60%	3	Remove item as <70% rated the question 3 or 4.

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median Score for item	Action taken
	patient b. 100% O_2 is delivered to the patient c. The reservoir bag should not be inflated prior to placing on the patient's face d. O_2 flow rates of approximately 15 litres a minute are required in adults							
2.2	Write down the <u>values</u> (numbers) for each of the physiological parameters (vital signs) below that you consider an EARLY sign of deterioration (worsening) in a patient's condition that would cause you to seek assistance (help) from a more skilled healthcare professional. 2.2.1 Increased systolic blood pressure (hypertension) 2.2.2 Decreased systolic blood pressure (hypotension) 2.2.3 Increased heart rate (tachycardia) 2.2.4 Decreased heart rate (bradycardia) 2.2.5 Increased respiratory rate (tachypnea) 2.2.6 Decreased respiratory rate (bradypnea) 2.2.7 Increased temperature (pyrexia) 2.2.8 Oxygen saturation 2.2.9 Level of consciousness			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	No change. Retained.

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median Score for item	Action taken
2.3	Select the clinical parameters below that you consider an indication of deterioration (worsening) in a patient's condition that would cause you to seek the assistance (help) from a more skilled healthcare professional for review of the patient. More than one option can be selected from the list below. Indicate your selection with a (X). 2.3.1 Decreased urine output 2.3.2 Signs of bleeding 2.3.3 Pain 2.3.4 Sweating 2.3.5 Decreased haemoglobin 2.3.6 Hypoglycaemia (decreased blood glucose level) 2.3.7 Increase in the capillary refill time 2.3.8 Change in skin colour 2.3.9 Change in appearance			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	No change. Retained.

Summary of changes to Section 2	**Proportion of items**	**Percent**
Items that remained unchanged and retained	6/13	46.1
Items amended	4/13	30.8
Items removed	3/13	23.1
Items with a median score of 4	10/13	76.9
Items with a rating of 4	3/13	23.1
Items with a rating of 3	0/13	0.0
Items with a rating of 3 and 4	6/13	46.2
Items with a rating of 3 or 4 (CVI ≥70% agreement)	9/13	69.2
Items with a rating <3	4/13	30.8
Mean, proportion and percent: total raters for all items scoring 3 or 4 for Section 2	Mean: 4.46 (58/65)	89.2

Note: ** denotes the amended item statement

Data in Table 4.2 illustrate a high CVI for all the items rated 3 (relevant only needing minor editing) or 4 (extremely relevant): mean of 4.46 and proportion of 58/65 (89.3%). Data in Table 4.2 showed that 10/13 (76.9%) items had a median score of 4, therefore a proportion

of agreement ≥70%. Four (30.8%) of the items had ratings of less than 3 by the expert RN's. Three (23.1%) item statements (2.1.8, 2.1.9 and 2.1.11) had a median score of 3 and were removed from the prototype questionnaire because the CVI for each item fell below the pre-set proportion of agreement of ≥70% by raters for items rated 3 or 4. The RPNs commented that the content being assessed in these three items was generally beyond the expected knowledge of any category of nurse working in a general ward. Three (23.1%) item statements were rated 4 by all five expert RPNs. Six (46.2%) item statements were rated 3 and 4 by all five expert RPNs. Nine (69.2%) of the items in this section were rated as 3 or 4 achieving an S-CVI for this section of <70% agreement.

After considering the expert RPNs recommendations, 4/13 (30.8%) items were amended. One respondent gave an insightful critique of the options and distractors for the items in this section. It was recommended that the options and distractors for a single item should be homogenous in origin. The order of the response options for 2.1.5 was amended to improve clarity following a respondent recommendation. Two items (2.1.6 and 2.1.7) were rated as 3 or 4 however the respondents recommended that the items should be simplified for all categories if nurses to understand. The recommendations contributed to the amendments reflected in Table 4.2 and in the revised prototype questionnaire (Appendix D).

4.2.3 CVI for section 3: Self-reported clinical reasoning ability

The results for the CVI assessment for Section 3 are illustrated in Table 4.3. Rephrasing items statements was suggested and implemented with the intention of improving clarity of the respective item statements. The changes are listed in the "action taken" column and were included in the revised prototype questionnaire (Appendix D). The number of questionnaire items retained; amended and removed is summarised at the end of Table 4.3.

Table 4.3: Experts' opinion on the content validity (CVI) for Section 3 of the prototype questionnaire

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median Score for item	Action taken
Section 3: Self-reported clinical reasoning ability								
3.1	I know how to collect an admitted patient's health information quickly.				(5/5) 100%	(5/5) 100%	4	No change. Retained.
3.2	I can apply proper assessment skills to collect a patient's current health information.			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	No change. Retained.
3.3	I can identify abnormalities from the collected patient information.				(5/5) 100%	(5/5) 100%	4	Numbering changed to 3.3 due to error in numbering. No change to the questionnaire statement.
3.4	I can identify a patient's health problems from the abnormal information collected.				(5/5) 100%	(5/5) 100%	4	Numbering changed to 3.4 No change to the questionnaire statement.
3.5	I can recognize possible early signs or symptoms when a patient's health deteriorates.				(5/5) 100%	(5/5) 100%	4	Numbering changed to 3.5 No change to the questionnaire statement.
3.6	I can explain the mechanism and development associated with the early signs or symptoms when a patient's health deteriorates.			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	Numbering changed to 3.6 Amended item. Change "mechanism and development" to "pathophysiology" as a term frequently used in nursing education and clinical practice. ***I can explain the pathophysiology associated with the early signs or symptoms when a patient's health deteriorates.*
3.7	I can accurately prioritize and manage any identifiable patient problems.				(5/5) 100%	(5/5) 100%	4	Numbering changed to 3.7 No change to the questionnaire statement.
3.8	I can correctly explain the mechanism behind a patient's problems.			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	Numbering changed to 3.8 Amended item. Change "mechanism" to "pathophysiology" as a term frequently used in nursing education and clinical practice. ***I can correctly explain*

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median Score for item	Action taken
								the pathophysiology" behind a patient's problems.
3.9	I can set nursing goals properly for the identified patient problems.			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	Numbering changed to 3.9 No change to item statement
3.10	I can provide appropriate nursing interventions for identified patient problems.				(5/5) 100%	(5/5) 100%	4	Numbering changed to 3.10 No change to the questionnaire statement.
3.11	I am knowledgeable of each nursing intervention provided.				(5/5) 100%	(5/5) 100%	4	Numbering changed to 3.11 No change to the questionnaire statement.
3.12	I can identify and communicate vital information clearly to the doctors based on the patient's current condition.				(5/5) 100%	(5/5) 100%	4	Numbering changed to 3.12 No change to the questionnaire statement.
3.13	I can anticipate the intervention requested by the doctor according to the patient information provided.				(5/5) 100%	(5/5) 100%	4	Numbering changed to 3.13 No change to the questionnaire statement.
3.14	I can accurately evaluate and identify whether a patient's condition is improved.				(5/5) 100%	(5/5) 100%	4	Numbering changed to 3.14 No change to the questionnaire statement.
3.15	I know the follow-up steps to take if a patient's condition does not improve.				(5/5) 100%	(5/5) 100%	4	Numbering changed to 3.15 No change to the questionnaire statement.

Summary of changes to Section 3	**Proportion of items**	**Percent**
Items that remained unchanged and retained	13/15	86.7
Items amended	2/15	13.3
Items removed	0/15	0.0
Items with a median score of 4	15/15	100
Items with a rating of 4	11/15	73.3
Items with a rating of 3 and 4	4/15	26.7
Items with a rating of 3 or 4 (CVI ≥70% agreement)	15/15	100
Number of items with a rating <3	0/15	0.0
Mean, proportion and percent: total raters for all items scoring 3 or 4 for Section 3	Mean: 5 (75/75)	100%

Note: ** denotes the amended item statement

Data in Table 4.3 illustrate a high S-CVI by the proportion of agreement ≥70% for all the items rated 3 (relevant only needing minor editing) or 4 (extremely relevant): mean of 5; (75/75; 100%). All of the item statements had a median score of 4. The expert RPNs rated

15/15 (100%) items in Section 3 as either 3 (relevant needing minor editing) or 4 (extremely relevant); 11/15 (73.3%) items were rated as 4 by all five expert RPNs and 4/15 (26.7%) item statements were rated as 3 and 4 by all five expert RPN's.

Changes were made to 2/15 (13.3%) items as a result of the comments from expert RPNs to improve the clarity of each of the items (3.6 and 3.8). The prototype questionnaire had an error in the item numbering in this section. The number 3.3 had been omitted; however all the item statements had been included. This error was identified by the expert RPNs and rectified in the revised prototype questionnaire (Appendix D). Expert respondents did not recommend the removal of any items resulting in 15/15 (100%) items being retained in the revised prototype questionnaire (Appendix D) for Section 3.

4.2.4 CVI for Section 4: Demographic data

Data for the expert RPNs' CVI scoring of all 12 item statements relating to demographic data in Section 4 of the prototype questionnaire are shown in Table 4.4. Actions taken to amend items following expert recommendations to improve the clarity of item statements are recorded in the "action taken" column. The summary at the end of the table lists the proportion of questionnaire items retained, amended and removed.

Table 4.4: Experts' opinion on the content validity (CVI) for Section 4 of the prototype questionnaire

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median Score for item	Action taken
Section 4: Demographic data								
4.1	Highest Nursing Related Qualification (select one option relevant to you): Doctoral Degree in Nursing; Master's Degree in Nursing; Postgraduate/post basic diploma in Nursing related field; Bachelor's degree in Nursing; Diploma in Nursing (Bridging Course); Diploma in Nursing: 4 year diploma; Diploma in Nursing: 3 year diploma; Certificate leading to enrolment as a nurse; Certificate leading to enrolment as a nurse auxiliary				(5/5) 100%	(5/5) 100%	4	Item amended. Retained. Ordering of the selection items were changed as the Diploma in Nursing (4 year diploma) is a higher level qualification than the Diploma in Nursing (Bridging Course) on the National Qualifications Sub Framework.
4.2	Are you currently studying? Yes No				(5/5) 100%	(5/5) 100%	4	Item amended. Retained. ***Are you currently registered at an education institution for nursing studies?* *Yes* *No*
4.3	If you answered "yes" to question 4.2, please indicate what you are currently studying: Doctoral Degree in Nursing; Master's Degree in Nursing; Post graduate/post basic diploma in Nursing related field; Bachelor's degree in Nursing; Diploma in Nursing (Bridging Course); Diploma in Nursing: 4 year diploma; Diploma in Nursing: 3 year diploma; Certificate leading to				(5/5) 100%	(5/5) 100%	4	Item amended. Retained. ***If you answered "yes" to question 4.2, please indicate the programme that you are registered for currently:* *Doctoral Degree in Nursing;* *Master's Degree in Nursing;* *Post graduate/post basic diploma in Nursing related field;* *Bachelor's degree in Nursing;* *Diploma in Nursing: 4 year diploma;* *Diploma in Nursing (Bridging Course);* *Diploma in Nursing: 3*

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median Score for item	Action taken
	enrolment as a nurse; Certificate leading to enrolment as a nurse auxiliary Other (please specify)_____ Not applicable as not studying							*year diploma;* *Certificate leading to enrolment as a nurse;* *Certificate leading to enrolment as a nurse auxiliary;* *Other (please specify)_____* *Not applicable as not studying.*
4.4	Your age (in years)			(1/5) 20%	(4/5) 80%	(5/5) 100%	4	No change. Item retained.
4.5	Your gender: Male Female Non-binary				(5/5) 100%	(5/5) 100%	4	No change. Item retained.
4.6	Your home language				(5/5) 100%	(5/5) 100%	4	No change. Item retained.
4.7	The number of years of clinical experience as a nurse				(5/5) 100%	(5/5) 100%	4	No change. Item retained.
4.8	Have you attended a Cardiopulmonary Resuscitation (CPR) / Basic Life Support (BLS) Course? Yes No				(5/5) 100%	(5/5) 100%	4	No change. Item retained.
4.9	If you answered "yes" to the question in 4.8 above, when did you attend the CPR/BLS Course? (Indicate the year in which you attended the training): Year _____; Not applicable as I have not attended such a course				(5/5) 100%	(5/5) 100%	4	No change. Item retained.
4.10	Do you currently have access to the following electronic devices? (Indicate with an "x". More than one device may be selected): Computer / Laptop Tablet device Smart Phone Other device (please specify)_____ No access to any electronic device		(1/5) 20%	(1/5) 20%	(3/5) 60%	(4/5) 80%	4	Amended. Item retained. Last option changed to match 4.11 and 4.12: "Not applicable as I do not have an electronic device"
4.11	If you selected one of		(1/5)		(4/5)	(4/5)	4	Amended. Item retained.

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Proportion (%) of raters scoring items 3 or 4	Median Score for item	Action taken
	the electronic devices in question 4.10, do you have internet access from the electronic device? Yes No Sometimes Not applicable as I do not have an electronic device		20%		80%	80%		***If you selected one of the electronic devices in question 4.10, do you have internet access from the electronic device? (Indicate with an "x")* *Yes* *No* *Sometimes* *Not applicable as I do not have an electronic device*
4.12	Where do you have the internet access? At home At work From 3G Sim Card in the electronic device Other:_____(Please specify) Not applicable as I do not have an electronic device		(1/5) 20%		(4/5) 80%	(4/5) 80%	4	Amended. Item retained ***Where do you have the internet access? (Indicate with an "x". More than one option may be selected):* *At home* *At work* *From 3G Sim Card in the electronic device* *Other:_____(Please specify)* *Not applicable as I do not have an electronic device*

Summary of changes to Section 4	Proportion of items	Percent
Items that remained unchanged and retained	6/12	50.0
Items amended	6/12	50.0
Items removed	0/12	0.0
Items with a median sore of 4	12/12	100
Items with rating of 4	8/12	66.7
Items with a rating of 3 and 4	1/12	8.3
Items with a rating of 3 or 4 (CVI ≥70% agreement)	9/12	75.0
Number of items with a rating <3	3/12	25.0
Mean, proportion and percent: total raters for all items scoring 3 or 4 for Section 4	Mean: 4.75, (57/60)	95.0

Note: ** denotes the amended item statement

The expert RPNs rated the CVI for all 12 item statements in Section 4 of the prototype questionnaire above the pre-set inclusion rule of ≥70% agreement (Guttmann et al., 2006) (Table 4.4) as they had done for Sections 1 and 3. The median for 12/12 (100%) item statements was 4. The mean number of raters scoring 3 (relevant needing minor editing) or 4 (extremely relevant) for all items in Section 4 was 4.75 (57/60, 65%). Eight (66.6%) items

were rated as 4 by all five expert RPNs, while 1/12 (8.3%) items was rated as 3 and 4. Three (25.0%) items (4.10, 4.11, 4.12) each had a rating of 2 (unable to assess relevance without item revision) but the median remained 4. The CVI for each of the three items was 80% and therefore retained. The expert RPN questioned the relevance of including the questions related to access to technological devices and to internet services.

The experts recommended amendments to 6/12 (50.0%) items to clarify the demographic response options. For example, it was recommended that the item statement relating to highest qualification (option items 4.1 and 4.2) be ranked from highest to lowest qualification to ensure that respondents for the test-retest would correctly select their highest qualification. The amendments were included in the revised prototype questionnaire (Appendix D).

4.2.5 Evaluation of the face validity

The face validity of the prototype questionnaire (Appendix A) was assessed by the five expert RPN respondents after rating the content validity to contribute to the readability and clarity of the questionnaire. The results and recommendations have been included in Table 4.5.

Table 4.5: Experts' opinion on the face validity of the prototype questionnaire

Evaluation of the face validity of the prototype questionnaire						
Readability and clarity (face validity) of the prototype questionnaire	**Excellent**	**Satisfactory**	**Requires improvement**	**Unsatisfactory**	**Comments**	**Changes made**
The layout of the questionnaire	(4/5) 80%	(1/5) 20%			No comment	No changes.
The format of the questionnaire	(4/5) 80%	(1/5) 20%			No comment	No changes.
The quality of the printing	(4/5) 80%	(1/5) 20%			No comment	No changes.
The length of the questionnaire	(1/5) 20%	(3/5) 60%	(1/5) 20%		"Pilot will show how long it might take respondent to complete." "People might lose interest towards the end."	Only items with CVI <70% were removed.
The response scales used in the questionnaire	(4/5) 80%	(1/5) 20%			Suggestion relating to the stated options / distractors needing to be homogenous in a questionnaire item.	Items amended in Section 2 so that item options are homogenous. (Appendix D)
Visually easy to read	(4/5) 80%	(1/5) 20%			No comment	No changes.
Visually easy to comprehend	(4/5) 80%		(1/5) 20%		Dependant on the target audience. ENA whose first language is not English might struggle to comprehend.	The terms "observations and vital signs" and "deterioration in a patient condition" were added as definitions at the beginning of the questionnaire (Appendix D).
The clarity of the instructions at the beginning of the questionnaire	(5/5) 100%				No comment	No change
The clarity of the instructions included in the questionnaire	(4/5) 80%	(1/5) 20%			No comment	No change
Additional comments: *"You will just need to acknowledge in your study that a large section of the data is subjective perceptions of the respondents – they think/assume that they know how to react or how to communicate."* *"Comprehensive questionnaire that meets the objectives."*						

Four (80.0%) respondent expert RPNs rated the prototype questionnaire's layout, format, print quality and being visually easy to read as excellent. Recommended homogeneity of item response options in Section 2 corresponded with the expert RPNs feedback when rating each item in Section 2 (section 4.2.2). The amendments to these item statements were made in the Revision 1 prototype questionnaire (Appendix D).

The length of the prototype questionnaire was rated as being long by 1/5 (20.0%) expert RPN; satisfactory by 3/5 (60.0%) and excellent by 1/5 (20.0%) respondent. Three of the total of 65 items (4.6%) with an item CVI <70% were removed. Respondents commented that the test-retest assessment could possibly give an indication of questionnaire fatigue.

All five (100%) expert RPNs rated the instructions at the beginning of the prototype questionnaire as excellent and 4/5 (80.0%) considered the instructions to be visually easy to comprehend. However one expert commented that some respondents in the intended target population might struggle to understand certain terms and recommended that the following terms or phrases be defined in the questionnaire: “observations”; “vital signs”; and “deterioration in a patient’s condition”. This comment corresponded with the suggestion given in the CVI assessment and was therefore included in the revised prototype questionnaire (Appendix D).

None of the respondents made any suggestions regarding missing items in the prototype questionnaire. One expert RPN commented that the results of the questionnaire when used for its intended purpose could be influenced by the respondent’s own perception of what they think that they know and possibly not their actual knowledge of the factors influencing their ability to recognise and respond to patient deterioration in a general ward; their knowledge of physiology and clinical parameters associated with patient deterioration; and their self-reported clinical reasoning ability. The comment, “comprehensive questionnaire” was given in the final comments section (included in table 4.5) indicating no further content needed to be included in the questionnaire.

4.2.6 Summary of the Results for the content validity index for the prototype questionnaire

A summary of the results of the CVI assessment of the 65 item statements in the prototype questionnaire (Appendix A) is shown in Table 4.6. The results show the proportion of agreement among the raters per section and for the overall questionnaire.

Table 4.6: Summary of the results for the CVI analysis for the prototype questionnaire

Proportion of items (percent)					
Summary of changes to the 4 sections	**Section 1** Proportion (%)	**Section 2** Proportion (%)	**Section 3** Proportion (%)	**Section 4** Proportion (%)	**Total prototype questionnaire** Proportion (%)
Items that remained unchanged and retained	23/25 (92.0)	6/13 (46.1)	13/15 (86.7)	6/12 (50.0)	48/65 (73.8)
Items amended	2/25 (8.0)	4/13 (30.8)	2/15 (13.3)	6/12 (50.0)	14/65 (21.5)
Items removed	0/25 (0.0)	3/13 (23.1)	0/15 (0.0)	0/12 (0.0)	3/65 (4.6)
Items with a median score of 4	25/25 (100)	10/13 (76.9)	15/15 (100)	12/12 (100)	62/65 (95.4)
Items with rating of 4	18/25(72.0)	3/13 (23.0)	11/15 (73.3)	8/12 (66.7)	40/65 (61.5)
Items with a rating of only 3 and 4	5/25 (20.0)	6/13 (46.2)	4/15 (26.7)	1/12 (8.3)	16/65 (24.6)
Items with a rating <3	2/25 (8.0)	4/13 (30.8)	0/15 (0.0)	3/12 (25.0)	9/65 (13.9)
Items with a rating of 3 or 4 (CVI ≥70% agreement)	23/25 (92.0)	9/13 (69.2)	15/15 (100)	9/12 (75.0)	56/65 (86.2)
Mean, proportion (percent): total raters for all items scoring 3 or 4 for each section and overall for the entire prototype questionnaire	Mean: 4.92 123/125 (98.4)	Mean: 4.46 58/65 (89.2)	Mean: 5 75/75 (100)	Mean: 4.75 57/60 (95.0)	Mean: 4.8 313/325 (96.3)

Overall, the S-CVI of agreement for the prototype questionnaire was: 56/65 (86.2%). Sixty-two (95.4%) items had a median of 4 (extremely relevant) and the mean number of raters scoring all the items 3 (relevant only needing minor editing) or 4 was 4.8 (313/325, 96.3%). In total, 3/65 (4.6%) items were removed because expert agreement was <70%. The items were removed from Section 2. Fourteen (21.5%) items were amended following experts' recommendations. Forty-eight (73.8%) items on the prototype questionnaire remained unchanged. Forty (61.5%) items were rated 4 and 16 (24.6%) received a rating of 3 and 4.

Item statements amended subsequent to the CVI analysis are in italics in the revised prototype questionnaire (Appendix D) for easy identification. The italic font was changed to normal font prior to handing the revised prototype questionnaire to respondents for the cognitive interviews.

4.2.7 Summary

Evaluation of the CVI and face validity of the prototype questionnaire by the expert RPN respondents provided valuable feedback and recommendations. In total, the prototype questionnaire comprised four sections and 65 items. The expert respondents recommended the removal of 3/65 (4.6%) items in Section 2 to align with the purpose of the prototype questionnaire. The items that were removed had ratings below the pre-set proportion of

≥70% agreement of items rated 3 or 4. Based on the expert recommendations changes were made to 14/65 (21.5%) items. The S-CVI for the questionnaire items rated 3 (relevant only needing minor editing) or 4 (extremely relevant) for the prototype questionnaire was 86.2% (56/65) exceeding the pre-set proportion of ≥70% agreement. The revised prototype questionnaire (Appendix D) was used for the next phase of the validation process, the cognitive interviewing process.

4.3 Findings from the cognitive interviews (Objective 1.6.3)

On completion of the transcription of the cognitive interviews and checking for transcription accuracy, the three expert RPN participants' interview comments were analysed for problems with: interpretation of questionnaire items, applicability of the items, terms or phrases used in the questionnaire and the clarity of questionnaire items (Knafl et al., 2007). Table 4.7 reports the expert RPNs recommendations for the questionnaire from the cognitive interviews and the amendments made thereafter resulting in the final validated prototype questionnaire (Appendix G) for test-retest reliability testing.

Table 4.7: Cognitive interview recommendations and amendments to the revised prototype questionnaire

Item number	**Revised prototype questionnaire items assessed during the cognitive interviews**	**Recommendations from the cognitive interviews per questionnaire item**	**Amendments**
	Section: Introduction		
No numbering in this section	The purpose of the questionnaire	No suggestion for amendment.	Remain unchanged.
	Definitions of terms or phrases used in the questionnaire "observations" refers to refer to the subjective and objective findings gathered during a patient assessment. For example, pain, bleeding, sweating, skin colour.	CI001 suggestion from evaluation of item 1.8: "clinical observations. Simple word. I don't know if you want to add it up there *(top of the questionnaire)."* CI001 suggestion "just highlight the definition". CI003 comment from item 1.14: "Who is the more skilled healthcare professional? Clarify maybe."	***"Clinical observations**" refers to the subjective and objective findings gathered during a patient assessment. For example, pain, bleeding, sweating, skin colour.* *"More skilled healthcare professional" refers to a registered nurse or a medical practitioner / doctor.*
	This questionnaire consists of four (4) sections. The fourth section relates to your demographic data. Please complete the questionnaire by answering all the questions directly onto this document as per each sections instruction.	CI002: it's just mentioned the forth section relates to your demographic data. I think you must just put in section 1 relates to data for the factors etc for all sections because questionnaire consists of 4 sections."	*This questionnaire consists of four (4) sections.* *Please complete the questionnaire by answering all the sections and questions directly onto this document as per each section's instructions.*
	Section 1: Factors influencing your ability to recognise and respond to patient deterioration (subjective data)	Section instructions. No suggestion for amendment.	Instruction remains unchanged.
1.1	My nursing qualification adequately prepared me to take / measure clinical observations and vital signs.	No suggestion for amendment.	Item remains unchanged.
1.2	I am unsure how to respond to changes in patients' clinical observations and vital signs.	No suggestion for amendment.	Item remains unchanged.
1.3	Interpreting patient observations and vital signs is an essential part of my role.	CI001 comment:" add clinical before observations"	Interpreting patient clinical observations and vital signs is an essential part of my role.
1.4	I feel confident recording patients' clinical observations and vital signs.	No suggestion for amendment.	Item remains unchanged.
1.5	I have the knowledge to interpret patients' clinical observations and vital signs which show a change in physiology.	CI003 comment "I think with the word "*that*" before show.	I have the knowledge to interpret patients' clinical observations and vital signs *that* show a change in physiology.
1.6	My nursing qualification adequately prepared me to interpret	No suggestion for	Item remains unchanged.

Item number	**Revised prototype questionnaire items assessed during the cognitive interviews**	**Recommendations from the cognitive interviews per questionnaire item**	**Amendments**
	patients' clinical observations and vital signs.	amendment	
1.7	It is important to respond to any changes in patients' clinical observations and vital signs.	No suggestion for amendment.	Item remains unchanged.
1.8	I believe that there is a deficit in my understanding of altered physiology associated with patients' clinical observations and vital signs.	CI001 suggestion: "clinical observations...simple word. I don't know if you want to add it up there *(top of the questionnaire)."*	Item remains unchanged.
1.9	I am expected to take / measure patients' clinical observations and vital signs.	No suggestion for amendment.	Item remains unchanged.
1.10	I know how often I should take /measure patients' clinical observations and vital signs for the patients that I am allocated to provide care for in the clinical unit.	No suggestion for amendment.	Item remains unchanged.
1.11	The clinical unit in which I am employed has a policy or work procedure that prescribes the frequency of taking / measuring clinical observations and vital signs.	CI001 suggestion "when there's a difference maybe let them just either put it in a different font. Italics. So the person can at least say it's not the same question *(as 1.12 for example)"*	The clinical unit in which I am employed has a policy or work procedure that prescribes the *frequency* of taking / measuring clinical observations and vital signs.
1.12	The clinical unit in which I am employed has a policy or work procedure that prescribes the action that I should take if I recognise deterioration in a patient's clinical observations and vital signs.	CI001 suggestion "Action. Maybe there italics so now I know up there it prescribes the frequency and down here 1.12 the action"	The clinical unit in which I am employed has a policy or work procedure that prescribes the *action* that I should take if I recognise deterioration in a patient's clinical observations and vital signs.
1.13	The registered nurse in the clinical unit checks the documented vital signs and clinical observations of every patient.	CI001 comment "I wonder how the nurse or the respondent would be able to answer this for you. How would the nurse know?" CI002 comment "how would the nurse know? Not sure about question. Maybe leave out." CI003 reported "*I know what you are asking, but it a good question. Maybe omit*	ITEM REMOVED.

Item number	**Revised prototype questionnaire items assessed during the cognitive interviews**	**Recommendations from the cognitive interviews per questionnaire item**	**Amendments**
1.14	I am adequately prepared to communicate with a more skilled healthcare professional about deterioration in a patient's condition.	CI003 comment: "Who is the more skilled healthcare professional? Clarify maybe."	This item remains unchanged Comment refers to the Introduction part of the prototype questionnaire.
1.15	I am able to use the accepted nursing terminology to communicate with a more skilled healthcare professional about deterioration in a patient's condition.	No suggestion for amendment.	Item remains unchanged.
1.16	I use a communication tool (for example the Situation, Background, Assessment and Recommendation / SBAR tool) as a guide to communicate the relevant information about deterioration in a patient's condition to a more skilled healthcare professional.	No suggestion for amendment.	Item remains unchanged.
1.17	I always document the information communicated to a more skilled healthcare professional about deterioration in a patient's condition in the patient's nursing records.	CI001 suggestion: "italics to highlight word 'document'".	I always document the information communicated to a more skilled healthcare professional about deterioration in a patient's condition in the patient's nursing records.
1.18	I am confident that the more skilled healthcare professional will act timeously on the information that I communicate to them regarding the patient's deteriorating condition.	No suggestion for amendment. CI002 comment: "do I actually get a response from the more skilled health care professional on what I have communicated to them. Highlights trust"	Item remains unchanged.
1.19	Information about the patient's deteriorating condition that I communicate to a more skilled healthcare professional is taken into consideration.	No amendment made. CI001 commented "Useful. I'm just wondering how will they prove or have proof that the information that they have shared is actually taken into consideration. Quite subjective. Emphasises interpersonal communication"	Item remains unchanged.
1.20	When reporting my concern regarding a patient's condition to a more skilled healthcare professional, I fear being criticised for reporting on a patient who is not that sick.	No suggestion for amendment.	Item remains unchanged.
1.21	I have the necessary equipment to take / measure clinical observations and vital signs.	No suggestion for amendment. Consideration of the recommendations made	I have the necessary equipment to take / measure clinical observations and vital signs.

Item number	**Revised prototype questionnaire items assessed during the cognitive interviews**	**Recommendations from the cognitive interviews per questionnaire item**	**Amendments**
		in item 1.11 and 1.17 to underline the emphasised verb.	
1.22	In the clinical unit where I work I feel that I am an essential member of the multidisciplinary team responsible for the recognition of and response to deterioration in a patients' condition.	No suggestion for amendment.	Item remains unchanged.
1.23	I understand the consequences of failing to identify and report deterioration in a patient's condition.	CI001 referred to consequences to the nurse; CI002 referred to consequences to the patient. Expert CI003 reported "changes made the question clearer"	I understand the consequences to the patient if I fail to identify and report the deterioration in the patient's condition.
1.24	I measure and record every clinical observation and vital sign every time I am required to measure and record patients' clinical observations and vital signs.	CI002 suggestion: "to measure and record every clinical observation and vital sign at the prescribed times and if the patient's condition changes and emphasise every	I measure and record <u>every</u> clinical observation and vital sign at the prescribed time and if the patient's condition changes.
1.25	I have experienced a situation where the deterioration in a patient's condition was not recognised leading to Cardiopulmonary resuscitation (CPR); transfer of the patient to the High Care or Intensive Care unit; or death of the patient.	No suggested amendment.	Item remains unchanged.
	section 2: Nurses' knowledge of physiological and clinical parameters associated with deterioration in a patient's condition	CI001 suggestion: "for the following questions please circle a make an example there for them...like 2.1.1 give them an H there...there is no H but just a circle with an H inside…I've learnt you have to be so clear".	For the following questions (2.1.1-2.1.11), please circle the most appropriate answer from the selection options: a - d. eg : 2.4.5 ®
2.1.1	A patient who is in hypovolaemic shock (and has low blood pressure) will have a. Normal capillary refill b. Cold clammy skin d. Facial flushing d. Warm dry hands	No suggestion for amendment.	Item remains unchanged.

Item number	**Revised prototype questionnaire items assessed during the cognitive interviews**	**Recommendations from the cognitive interviews per questionnaire item**	**Amendments**
2.1.2	A patient with hypoxia (lack of oxygen) is likely to be a. Confused b. Pink c. Orientated to their surroundings d. Hot	No suggestion for amendment.	Item remains unchanged.
2.1.3	Slow capillary refill is a sign of: a. Vasoconstriction and poor peripheral perfusion b. Malnutrition and dehydration c. Warm hands and feet d. Reduced concentrations of oxyhaemoglobin	No suggestion for amendment.	Item remains unchanged.
2.1.4	The pulse can be palpated a. Every time the atria contracts b. When a vein is close to the surface of the skin c. Every time the left ventricle contracts d. When an artery is close to the surface of the skin	No suggestion for amendment.	Item remains unchanged.
2.1.5	A normal heart rate for an adult at rest is a. 60-80 beats per minute (bpm) b. 60-90 bpm c. 60-100 bpm d. 60-110 bpm	No suggestion for amendment.	Item remains unchanged.
2.1.6	Pulse oximeters (oxygen saturation probe) may be unreliable when…… a. Extremities are cold b. The patient is wearing nail varnish c. Tissue perfusion is poor d. All of the above	No suggestion for amendment.	Item remains unchanged.
2.1.7	When assessing a patient's breathing…… a. Assess the patient's breathing for 15 seconds b. Assess for 30 -60 seconds looking for chest movement c. Use a mirror to check for exhaled air; d. The oxygen saturation is more important than the respiratory rate.	No suggestion for amendment.	Item remains unchanged.
2.1.8	A.V.P.U. stands for……. a. Alert, Visual, Peripheral, Unconscious b. Altered, Verbal, Pain, Unresponsive c. Anxious, Violent, Paranoid Unsettled d. Alert, Voice, Pain, Unresponsive	No suggestion for amendment.	Item remains unchanged.
2.2.1	**Write down** the values (numbers) for each of the physiological parameters (vital signs) below that you consider to be an	CI001 Suggested: "what you can do maybe on this side	

<table>
<tr><th>Item number</th><th>Revised prototype questionnaire items assessed during the cognitive interviews</th><th>Recommendations from the cognitive interviews per questionnaire item</th><th>Amendments</th></tr>
<tr>
<td></td>
<td>EARLY sign of deterioration (worsening) in a patient's condition that would cause you to seek assistance (help) from a more skilled healthcare professional.
<table>
<tr><th>Physiological parameters (vital signs)</th><th>I will call for a review of the patient for the following values indicating EARLY signs of deterioration (worsening) in a patient's condition:</th></tr>
<tr><td>Increased systolic blood pressure (hypertension)</td><td></td></tr>
<tr><td>Decreased systolic blood pressure (hypotension)</td><td></td></tr>
<tr><td>Increased heart rate (tachycardia)</td><td></td></tr>
<tr><td>Decreased heart rate (bradycardia)</td><td></td></tr>
<tr><td>Increased respiratory rate (tachypnea)</td><td></td></tr>
<tr><td>Decreased respiratory rate (bradypnea)</td><td></td></tr>
<tr><td>Increased temperature (pyrexia)</td><td></td></tr>
<tr><td>Oxygen saturation</td><td></td></tr>
<tr><td>Level of consciousness</td><td></td></tr>
</table>
</td>
<td>(right hand column) is put the conventions behind here. Let them just write it (value).”

Ci002 comment: “level of consciousness. Are they going to measure it with a Glasgow coma scale? That is for me the only thing I didn't know clearly what you want because you want values.”</td>
<td>
<table>
<tr><th>No.</th><th>Physiological parameters (vital signs)</th><th>I will call for a review of the patient for the following values indicating EARLY signs of deterioration (worsening) in a patient's condition:</th></tr>
<tr><td>2.2.1</td><td>Increased systolic blood pressure (hypertension)</td><td>mmHg</td></tr>
<tr><td>2.2.2</td><td>Decreased systolic blood pressure (hypotension)</td><td>mmHg</td></tr>
<tr><td>2.2.3</td><td>Increased heart rate (tachycardia)</td><td>bpm</td></tr>
<tr><td>2.2.4</td><td>Decreased heart rate (bradycardia)</td><td>Bpm</td></tr>
<tr><td>2.2.5</td><td>Increased respiratory rate (tachypnea)</td><td>Breaths/min</td></tr>
<tr><td>2.2.6</td><td>Decreased respiratory rate (bradypnea)</td><td>Breaths/min</td></tr>
<tr><td>2.2.7</td><td>Increased temperature (pyrexia)</td><td>°C</td></tr>
<tr><td>2.2.8</td><td>Oxygen saturation</td><td>%</td></tr>
<tr><td>2.2.9</td><td>Level of consciousness</td><td>Remains unchanged</td></tr>
</table>
</td>
</tr>
<tr>
<td></td>
<td>Select the clinical observations below that you consider an indication of deterioration (worsening) in a patient's condition that would cause you to seek the assistance (help) from a more skilled healthcare professional for review of the patient. More than one option can be selected from the list below. Indicate your selection with a (X).
<table>
<tr><th>No.</th><th>Clinical observations</th><th>Selection</th></tr>
<tr><td>2.3.1</td><td>Decreased urine output</td><td></td></tr>
</table>
</td>
<td>CI001 comment: “2.3.9 the other one the last one again, change in appearance that is vague.”
CI002 comment: “phrase ‘change in appearance’ ambiguous”.</td>
<td>Select the clinical observations below that you consider an indication of deterioration (worsening) in a patient's condition that would cause you to seek the assistance (help) from a more skilled healthcare professional for review of the patient. More than one option can be selected from the list below. Indicate your selection with a (X).
<table>
<tr><th>No.</th><th>Clinical observations</th><th>Selection</th></tr>
<tr><td>2.3.1</td><td>Remains unchanged</td><td></td></tr>
</table>
</td>
</tr>
</table>

Item number	Revised prototype questionnaire items assessed during the cognitive interviews	Recommendations from the cognitive interviews per questionnaire item	Amendments
2.3.2	Signs of bleeding	CI003 comment: "changing in appearance what about appearance is going to change?"	2.3.2 Remains unchanged
2.3.3	Pain		2.3.3 Remains unchanged
2.3.4	Sweating		2.3.4 Remains unchanged
2.3.5	Decreased haemoglobin		2.3.5 Remains unchanged
2.3.6	Hypoglycaemia (decreased blood glucose level)		2.3.6 Remains unchanged
2.3.7	Increase in the capillary refill time		2.3.7 Remains unchanged
2.3.8	Change in skin colour		2.3.8 Remains unchanged
2.3.9	Change in appearance		2.3.9 ITEM DELECTED
	Section 3: Self-reported clinical reasoning ability	No suggested amendments to the section instructions	
3.1	I know how to collect an admitted patient's health information quickly.	No suggestion for amendment.	Item remains unchanged.
3.2	I can apply proper assessment skills to collect a patient's current health information.	No suggestion for amendment.	Item remains unchanged.
3.3	I can identify abnormalities from the collected patient information.	No suggestion for amendment.	Item remains unchanged.
3.4	I can identify a patient's health problems from the abnormal information collected.	CI001 comment: "maybe add 'nursing diagnosis' for health problems. More common"	I can identify a patient's health problems (nursing diagnoses) from the abnormal information collected.
3.5	I can recognize possible early signs or symptoms when a patient's health deteriorates.	No suggestion for amendment.	Item remains unchanged.
3.6	I can explain the pathophysiology associated with the early signs or symptoms when a patient's health deteriorates.	See comments for item 3.8	I can explain the pathophysiology associated with the <u>early signs or symptoms</u> when a patient's health deteriorates.
3.7	I can accurately prioritize and manage any identifiable patient problems.	No suggestion for amendment.	Moved to Q3.8
3.8	I can correctly explain the pathophysiology behind a patient's problems.	CI001 suggestion: "3.6 and 3.8 very similar. I think you should put them straight behind in sequence. Are they both needed? " CI002 comment: "3.6 and 3.8 are from what I'm understanding very similar. Underline differentiator."	I can correctly explain the pathophysiology behind a patient's problems. Moved to Q3.7
3.9	I can set appropriate nursing goals for the identified patient problems.	No suggestion for amendment.	Item remains unchanged.

Item number	**Revised prototype questionnaire items assessed during the cognitive interviews**	**Recommendations from the cognitive interviews per questionnaire item**	**Amendments**
3.10	I can provide appropriate nursing interventions for identified patient problems.	No suggestion for amendment.	Item remains unchanged.
3.11	I am knowledgeable of each nursing intervention provided.	No suggestion for amendment.	Item remains unchanged.
3.12	I can identify and communicate vital information clearly to the doctors based on the patient's current condition.	CI002 comment: "doctor is the more skilled healthcare professional. Keep the same terms."	I can identify and communicate vital information clearly to the more skilled healthcare professional based on the patient's current condition.
3.13	I can anticipate the interventions requested by the doctor according to the patient information provided.	Ci001 commented: ""Provided" is the word concerning. Is it the right word? Maybe that I communicate?" CI002 comment: "doctor is the more skilled healthcare professional."	I can anticipate the interventions requested by the more skilled healthcare professional according to the patient information that I communicate to them.
3.14	I can accurately evaluate and identify whether a patient's condition is improved.	CI001 suggestion: "either you put it in two questions or you put it as identify. Evaluate is different. Shouldn't have both concepts." CI003 interpreted the questionnaire item as "identify, not evaluate. Confusing"	I can accurately identify whether a patient's condition is improved.
3.15	I know the follow-up steps to take if a patient's condition does not improve.	No suggestion for amendment.	Item remains unchanged.
	Section 4: Demographic data	CI002 comment: "I think you must also add there in to indicate the response with an x." (*refers to l questionnaire items in Section 4)*	
4.1	Highest nursing related qualification (select one option relevant to you) Doctoral Degree in Nursing Master's Degree in Nursing Postgraduate/post basic diploma in Nursing related field Bachelor's degree in Nursing	CI002 comment: "I think you must also add in there is to indicate the response with an x." (*refers to all questionnaire items in Section 4)*	Highest nursing related qualification (Select one option relevant to you. *Indicate your response with an "X")* Doctoral Degree in Nursing Master's Degree in Nursing Postgraduate/post basic diploma in Nursing related field Bachelor's degree in Nursing

Item number	**Revised prototype questionnaire items assessed during the cognitive interviews**	**Recommendations from the cognitive interviews per questionnaire item**	**Amendments**
	Diploma in Nursing: 4 year diploma ☐ Diploma in Nursing (Bridging Course) ☐ Diploma in Nursing: 3 year diploma ☐ Certificate leading to enrolment as a nurse ☐ Certificate leading to enrolment as a nurse auxiliary ☐		Diploma in Nursing: 4 year diploma ☐ Diploma in Nursing (Bridging Course) ☐ Diploma in Nursing: 3 year diploma ☐ Certificate leading to enrolment as a nurse ☐ Certificate leading to enrolment as a nurse auxiliary ☐
4.2	Are you currently registered at an education institution for nursing studies? Yes ☐ No ☐	CI002 comment: "I think you must also add in there is to indicate the response with an x." (*refers to all questionnaire items in Section 4)*	Are you currently registered at an education institution for nursing studies? (*Select one option relevant to you. Indicate your response with an "X")* Yes ☐ No ☐
4.3	If you answered "yes" to question 4.2, please indicate the programme that you are registered for currently. Doctoral Degree in Nursing ☐ Master's Degree in Nursing ☐ Post graduate/post basic diploma in Nursing related field ☐ Bachelor's degree in Nursing ☐ Diploma in Nursing: 4 year diploma ☐ Diploma in Nursing (Bridging Course) ☐ Diploma in Nursing: 3 year diploma ☐ Certificate leading to enrolment as a nurse ☐ Certificate leading to enrolment as a nurse auxiliary ☐ Other (please specify)_____ ☐ Not applicable as not studying ☐	CI002 comment: "I think you must also add in there is to indicate the response with an x." (*refers to all questionnaire items in Section 4)*	If you answered "yes" to question 4.2, please indicate the programme that you are registered for currently. (*Select one option relevant to you. Indicate your response with an "X")* Doctoral Degree in Nursing ☐ Master's Degree in Nursing ☐ Post graduate/post basic diploma in Nursing related field ☐ Bachelor's degree in Nursing ☐ Diploma in Nursing: 4 year diploma ☐ Diploma in Nursing (Bridging Course) ☐ Diploma in Nursing: 3 year diploma ☐ Certificate leading to enrolment as a nurse ☐ Certificate leading to enrolment as a nurse auxiliary ☐ Other (please specify)_____ ☐ Not applicable as not studying ☐
4.4	Your age (in years) ☐	No suggestion for amendment.	Item remains unchanged.
4.5	Your gender Male ☐ Female ☐ Non-binary ☐	CI002 comment: "I think you must also add in there is to indicate the response with an x." (*refers to all questionnaire items in Section 4)*	Your gender *(Select one option relevant to you. Indicate your response with an "X")* Male ☐ Female ☐ Non-binary ☐

Item number	**Revised prototype questionnaire items assessed during the cognitive interviews**	**Recommendations from the cognitive interviews per questionnaire item**	**Amendments**
4.6	Your home language [ ]	No suggestion for amendment.	Item remains unchanged.
4.7	The number of years of clinical experience as a nurse [ ]	No suggestion for amendment.	Item remains unchanged.
4.8	Have you attended a Cardiopulmonary Resuscitation (CPR) / Basic Life Support (BLS) Course? Yes [ ] No [ ]	CI002 comment: "I think you must also add in there is to indicate the response with an x." (*refers to all questionnaire items in Section 4)*	Have you attended a Cardiopulmonary Resuscitation (CPR) / Basic Life Support (BLS) Course? *(Select one option relevant to you. Indicate your response with an "X").* Yes [ ] No [ ]
4.9	If you answered "yes" to the question in 4.8 above, when did you attend the CPR/BLS Course? (Indicate the year in which you attended the training) Year [ ] Not applicable as I have not attended such a course [ ]	No suggestion for amendment.	Item remains unchanged.
4.10	Do you currently have access to the following electronic devices? (Indicate your response with an "X". More than one device may be selected) Computer / Laptop [ ] Tablet device [ ] Smart Phone [ ] Other device (please specify)_____ [ ] Not applicable as I do not have an electronic device [ ]	No suggestion for amendment.	Item remains unchanged.
4.11	If you selected one of the electronic devices in question 4.10, do you have internet access from the electronic device? (Indicate with an "X".) Yes [ ] No [ ] Sometimes [ ] Not applicable as I do not have an electronic device [ ]	Amendment to question phrasing to align with above questions in Section 4.	If you selected at least one of the electronic devices in question 4.10, do you have internet access from the electronic device? (*Indicate your response with an "X*".) Yes [ ] No [ ] Sometimes [ ] Not applicable as I do not have an electronic device [ ]
4.12	Where do you have the internet access? (Indicate with an "X". More than one device may be selected) At home [ ] At work [ ]	Amendment to question phrasing to align with above questions in Section 4.	Where do you have the internet access? (*Indicate your response with an "X*". More than one access point may be selected) At home [ ]

Item number	**Revised prototype questionnaire items assessed during the cognitive interviews**	**Recommendations from the cognitive interviews per questionnaire item**	**Amendments**
	From 3G Sim Card in the electronic device Other:_____(Please specify) Not applicable as I do not have an electronic device		At work From 3G Sim Card in the electronic device Other:_____(Please specify) Not applicable as I do not have an electronic device

Abbreviations:
CI001 = Cognitive Interview participant number 1; CI002 = Cognitive Interview participant number 2; CI003 = Cognitive Interview participant number 3.

4.3.1 Results for the introduction section of the revised prototype questionnaire

The three expert RPNs did not suggest any amendment to the stated purpose of the revised prototype questionnaire (Appendix D), however recommendations were made mainly for perceived difficulty with interpretation of terms and phrases to improve the clarity of the instructions. Expert CI001 made the following suggestion for item 1.8: "*clinical observations...simple word. I don't know if you want to add it up there and explain it* [pointed to the top of the questionnaire]." The same participant also suggested "*highlight the definition terms*". Expert CI003 asked the question "*Who is the more skilled healthcare professional?"* and suggested "*Clarify the term maybe*." This comment was made during the review of item 1.14.

Expert CI002 also identified a problem with the description of the revised prototype questionnaire that could impact on the intended respondents' interpretation of the questionnaire items "*it's just mentioned the forth section relates to your demographic data. I think you must just put in section 1 relates to data for the factors etc for all sections because questionnaire consists of 4 sections."*

4.3.2 Results of the cognitive interviews for Section 1: Factors influencing a nurse's ability to recognise and respond to patient deterioration

Sixteen out of 25 (64%) prototype questionnaire items in Section 1 as well as the instructions to the nurse for completing this section were declared to be clear and applicable by the three expert participants. No amendments were made to these items. "*No suggestion for amendment*" is indicted in the column for recommendations from the cognitive interviews per questionnaire item in Table 4.7.

The expert RPNs recommended amendments to the remaining nine items in Section 1 have been categorised under the themes of problems with the interpretation of questionnaire items and problems with the clarity of items. There appeared to be uncertainty in interpreting Item 1.23. Expert participant CI001 referred to "*consequences to the nurse*"; while participant CI002 referred to "*consequences to the patien*t". This item was rephrased for clarity as the intended interpretation of the item was to evaluate nurses' understanding of the consequences to the patient if the nurse fails to identify and report deterioration in a patient's condition. Probing questions were used to explore participant CI003's understanding of the amended phrasing of item 1.23. Expert CI003 reported "*changes made the question clearer".*

Item 1.13 was classified as not applicable and hence removed from the revised prototype questionnaire because 2/3 (66.7%) expert RPNs verbalised being uncertain about how a

nurse could be certain that the senior RPN on duty had checked every patient's physiological and clinical observations during a shift. Expert participant CI001 commented "*I wonder how the nurse would be able to answer this for you? How would the nurse know? I don't think a ENA or EN knows*". Expert participant CI002 commented "*How would the nurse know? Not sure about question so maybe leave out*." CI003 reported "*I know what you are asking, but it a good question. Maybe omit*."

To improve the clarity of items in section 1, expert CI001 recommended: "*add the term 'clinical' before 'observations'*" in item1.3. After reading item 1.8, expert CI001 then recommended "*clinical observations is a simple word. I don't know if you want to add it up there* [pointing to top of the questionnaire]*"* as one of the listed definitions to improve the questionnaire item interpretation.

Expert participant CI003 commented on item 1.5 "*I think with the word "that" before show added there [*pointing to after the word "change"] *to make it clearer"* to improve the clarity of the question.

Similarity in items1.11 and 1.12 caused expert CI001 to suggest that "*when there's a difference maybe let them just either put it in a different font. Italics. So the person can at least see it's not the same question" (as 1.12 for example).* The differentiating words used were "frequency" in item 1.11 and "action" in item 1.12. For item 1.17 expert CI002 recommended "*italics to highlight word 'document'*" for the nurse completing the questionnaire.

Clarification of the skilled healthcare professional was recommended for item 1.14 by expert CI003: "*Who is the more skilled healthcare professional? Clarify maybe."* This prompted the inclusion of the term "the more skilled healthcare professional" and its definition for this study at the beginning of the revised prototype questionnaire with the other listed definitions.

A suggestion to improve the clarity of item 1.24 was made by expert CI002: "*to measure and record every clinical observation and vital sign at the prescribed times and if the patient's condition changes*" and "*to emphasise the word 'every'".*

Expert CI001 commented that item 1.19 was "*useful. I'm just wondering how will they prove? Have proof that the information that they have shared is actually taken into consideration. Quite subjective. Emphasises interpersonal communication*". The comments illustrated that the expert RPN understood the question and did not have a problem with the interpretation or clarity.

4.3.3 Results of the cognitive interviews for Section 2: Knowledge of physiological and clinical parameters associated with deterioration

Seventeen out of 26 (65.4%) prototype questionnaire items in Section 2 were declared to be clear and applicable by the three expert participants. No amendments were made to these items. "*No suggestion for amendment*" is indicated in the column for recommendations from the CI in Table 4.7. The expert RPNs recommended the removal of one item in Section 2 as a result of lack of clarity and uncertainty in interpreting item 2.3.9.

Expert CI001 suggested that the instructions to the nurse for completing Section 2 be amended so that "*for the following questions please circle. Make an example there for them like 2.1.1 give them an H there. There is no H but just a circle with an H inside. I've learnt you have to be so clear*". This participant recommended that an example for selecting the correct choice from the options be given to ensure instructional clarity and the correct interpretation of how the researcher intends a respondent to select their choice of answer.

After reading item 2.2, expert participant CI001 recommended that "*what you can do maybe on this side* [pointing to the right hand column] *is add the conventions like beats per minute behind here. Then let them just write it* [the value]." This recommendation could provide clarity for the nurse completing the questionnaire simply indicating that the question requires them to only write the value for the physiological parameter that is considered an early sign of deterioration in a patient's condition.

In item 2.2, the physiological parameter level of consciousness raised a comment from expert participant CI002 in terms of clarity. "*The level of consciousness. Are they going to measure it with a Glasgow Coma Scale? That is for me the only thing for me. I didn't know clearly what you want. Because you want values*." Because the level of consciousness is commonly communicated using the Glasgow Coma Scale as a value out of 15, this specific physiological parameter remained unchanged without a unit of measure.

Uncertainty and lack of clarity in interpreting item 2.3.9 was highlighted by all three experts. Expert CI001 indicated "*2.3.9 Change in appearance that is vague*." Participant CI002 commented that the "*phrase 'change in appearance' ambiguous*". Participant CI003 verbalised "*changing in appearance what about appearance is going to change?*" Therefore due to the ambiguity and lack of specificity in item statement 2.3.9 "change in appearance" was removed from the revised prototype questionnaire.

4.3.4 Results of the cognitive interviews for Section 3: Self-reported clinical reasoning ability

Eight out of 15 (53.3%) prototype questionnaire items in Section 3 as well as the section instructions for completing Section 3 were evaluated as being clear and applicable by the three expert participants. No amendments were made to these items. "N*o suggestion for amendment*" is indicated in the column for recommendations from the cognitive interviews in Table 4.7. There was no recommendation for removal of any of the items in Section 3.

Only expert participant CI001 commented that for item 3.4 "***maybe add*** *'nursing diagnosis' for health problems. More common*". The phrase "nursing diagnoses" was therefore included in brackets after the phrase "patient's health problems" to clarify and support the correct intended interpretation of the item.

Both expert participants CI001 and CI002 considered items 3.6 and 3.8 to be very similar. Expert CI001 suggested "*I think you should put them straight behind in sequence. Are they both needed? Maybe combine*?" Participant CI002 commented "*Underline the differentiator*." Both recommendations were considered. The differentiator was underlined and item 3.8 was moved to item 3.7 in an attempt to improve interpretation of the items.

Inconsistency in the terminology used in items 3.12 and 3.13 was highlighted by expert participant CI002: "the *doctor is the more skilled healthcare professional. Keep the same terms.*" Both items were therefore amended to align with the terminology used throughout the revised prototype questionnaire to avoid misinterpretation.

In item 3.13, expert CI001 suggested changes to the statement to improve the interpretation and clarity of the item. The identified problem was reported as follows "*'Provided' is the word concerning. Is it the right word? Maybe that I communicate?"* Taking the feedback into consideration, the term "provided" was amended to "that I communicate to them".

Both experts CI001 and CI003 queried the interpretation of item 3.14 relating specifically to the phrase "evaluate and identify". Expert CI001 suggested "*either you put it in two questions or you put it as identify. Evaluate is different. Shouldn't have both concepts."* Expert RPN CI003 interpreted the questionnaire item with reference to "*identify. Not evaluate. Confusing*". The term "identify" was therefore selected and "evaluate" omitted for this item.

4.3.5 Results of the cognitive interviews for Section 4: Demographic data

Five out of 12 (41.7%) revised prototype questionnaire items in the demographic data of Section 4 were declared to be clear and applicable by the three expert RPNs. No

amendments were made to these items. Where amendment were recommended in this section, clarification of item instructions was required. The item instructions needed to clearly describe the method to mark their chosen responses. Clearly indicating where one or more responses can be selected per item in the section was also suggested. Expert CI002 identified the above need in their comment *"Also to add in there, is to indicate the response with an x. Also select one or more options."* No further problems with: interpretation of questionnaire items, applicability of the items, terms or phrases used in the questionnaire or the clarity of items were raised by the expert RPNs for Section 4 of the revised prototype questionnaire.

4.3.6 General comments from the expert participants during the cognitive interviews

Three expert participants understood the purpose of each of the four sections of the prototype questionnaire and were able to differentiate between them. Expert CI001 confirmed that Section 1 was assessing the "*internal and external influences that helped or prevented a nurse from managing the patient properly*". Expert CI002 replied that Section 2 was asking about "*what do you know about the topic*" while Section 3 "*has got a lot do to with your knowledge, your experience. But how to apply it. And then the problem solving definitely and the critical thinking."*

The cognitive interviews also raised a few possible challenges with the prototype questionnaire. Firstly, the length of the questionnaire could influence the accurate completion by the nurse. Participant CI003 thought that "*It could be a bit lengthy I think. Hopefully it shouldn't take that long".*

A second concern was related to the subjectivity of the revised prototype questionnaire. Participant CI001 thought that "*they might tell you on this form that they can correctly explain. But I just hope in essence that they put it down here truthfully*". Participant CI003 commented that "*the challenge is if you are not honest with yourself giving answers".*

The expert participants acknowledged that the same questionnaire would be given to all categories of nurses to participate even though their knowledge and skills vary relative to their qualifications. Expert participant CI003 commented "*obviously the level of education also plays a role. For example if you have a certificate leading to enrolment as a nursing auxiliary compared to somebody that has a diploma in nursing or the degree in nursing the problem solving skills or critical thinking might be lacking with this particular respondent influencing their questions as well as they won't have necessarily the capabilities to understand the pathophysiology but identifying where development is needed."* With the reliance on non-registered nurses to recognise the early signs of deterioration in a patient's

condition, the purpose of eventually using the same questionnaire for all categories of nurses would therefore be to measure the questionnaire outcome amongst nurses of the same category and the outcomes between categories of nurses.

When concluding the cognitive interviews with each of the RPNs, the participants did not give any further recommendations for inclusion, amendments or omission in the prototype questionnaire.

4.3.7 Summary of the cognitive interview findings

The cognitive interview process has established the face validity of the revised prototype questionnaire for users (RPNs, ENs and ENAs). Forty-six of 78 (59.0%) items did not require amendment. Expert participants recommended removal of 2/78 (2.6%) items from the revised prototype questionnaire: items 1.13 and 2.3.9. The expert participants gave suggestions for amendments to 30/78 (38.5%) items, the definition terms and the instructions for the sections of the questionnaire improve the understanding, interpretation and clarity of the remaining items in the revised prototype questionnaire (Appendix D). The final validated questionnaire (Appendix G) contained 76 items and was utilised in the following chapter: test-retest for assessing the reliability of the questionnaire for stability.

4.4 Findings from the test-retest for reliability (Objective 1.6.4)

On completion of the cognitive interviews, the final validated questionnaire (Appendix G) was self-administered by 30 permanently employed nurses working on general wards of a private hospital in the Western Cape. The 30 nurse respondents (10 RPNs, 10 ENs and 10 ENAs) self-administered the questionnaire at two time points (time 1 and time 2) with an interval of two weeks between test (time 1) and the retest (time 2). Table 4.8 summarises the number of final validated questionnaires handed out and returned by the nurse respondents.

Table 4.8: Summary of the final validated questionnaires handed out and returned by three categories of nurse respondents at two points with an interval of two weeks

	Time 1 completion of the questionnaire			**Time 2 completion of the questionnaire**		
Category	Number handed out	Number returned	% returned	Number handed out	Number returned	% returned
RPN*	10	10	100	10	10	100
EN**	10	10	100	10	10	100
ENA***	10	10	100	10	10	100
Total	30	30	100	30	30	100

RPN refers to Registered Professional Nurses; EN refers to Enrolled Nurses; ENA refers to Enrolled Nursing Auxiliaries

The validated final questionnaires were returned by 100% of all categories of nurse respondents within two weeks of first completion. The completed questionnaires revealed items that had not been answered. The omitted items were calculated per section of the questionnaire and per category of nurse (Table 4.9).

Table 4.9: Summary of items not answered per section of the validated questionnaire

Section	**Items not answered Time 1**					**Items not answered Time 2 retest**				
	Total	**RPN**	**EN**	**ENA**	**%**	**Total**	**RPN**	**EN**	**ENA**	**%**
Section 1	4	3	1	0	4/24 (16.7)	2	2	0	0	2/24 (8.3)
Section 2	5	2	1	2	5/25 (20.0)	5	3	2	0	5/25 (20.0)
Section 3	3	3	0	0	3/15 (20.0)	1	1	0	0	1/15 (6.7)
Section 4	0	0	0	0	0/12 (0.0)	0	0	0	0	0/12 (0.0)
Total	12	8	2	2	12/76 (15.8)	8	6	2	0	8/76 (10.5)
% omitted items per category		10.5	2.6	2.6			7.9	2.6	0.0	

RPN refers to Registered Professional Nurses; EN refers to Enrolled Nurses;
ENA refers to Enrolled Nursing Auxiliaries

Data in Table 4.9 show that there were more omitted responses for items for time 1 (12/76, 15.8%) versus time 2 (8/76, 10.5%) returned questionnaires. The RPN respondents omitted the most responses for items for time 1 (10.5%) and time 2 (7.9%) completion of the questionnaire compared to the EN and ENA respondents. The ENA respondents provided a response for 100% of the items during the time 2 self-administration of the final validated questionnaire; however the content of their answers were no assessed. Section 2, assessing nurses' knowledge of clinical and physiological parameters linked to patient deterioration, had the highest number of total items omitted across the three categories of nurse respondents for time 1 (5/25, 20.0%) and time 2 (5/25, 20.0%). Omissions were found in

respondent answers for 7/8 (87.5%) multiple choice questions in Section 2. Item 2.1.5 was the only MCQ in Section 2 answered by 30 (100%) nurse respondents at two time points. There were no omissions in respondent answers for question items 2.2.1 to 2.2.9 and items 2.3.1 to 2.3.8. Twelve (100%) items in Section 4 (demographic detail) were completed by all nurse respondents at both time 1 and time 2.

The statistical degree of agreement for each item in the validated questionnaire when completed on two occasions (time 1 test and time 2 retest) by the same nurse respondents was calculated to determine the questionnaire's measure of stability. The degree of stability was assessed by calculating the weighted kappa (degree of agreement) for the ordinal and nominal questionnaire item data using the following categories to classify the results: <0=poor agreement, 0.01-0.20 = slight agreement, 0.21-0.40 = fair agreement, 0.41-0.60 = moderate agreement, 0.61-0.80 = substantial agreement and 0.81-l = almost perfect agreement (Sim & Wright, 2005).

4.4.1 Results of the test-retest for section 1: Factors influencing a nurse's ability to recognise and respond to patient deterioration

Twenty-four items in Section 1 displayed variation in intra-rater agreement among the 30 nurse respondents. The weighted kappa coefficient and level of intra-rater agreement between the respondents' answers for the item statements at two time points are shown in Table 4.10. In addition, the table includes a summary of the proportion and number of items for each level of intra-rater agreement for Section 1 of the final validated questionnaire

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Table 4.10: Test-retest weighted kappa coefficient and level of intra-rater agreement for items in Section 1 of the final validated questionnaire

Questionnaire item number	Weighted kappa	Level of intra-rater agreement
1.1	0.517	Moderate
1.2	0.356	Fair
1.3	0.545	Moderate
1.4	0.714	Substantial
1.5	0.379	Fair
1.6	0.373	Fair
1.7	0.348	Fair
1.8	0.386	Fair
1.9	0.366	Fair
1.10	0.568	Moderate
1.11	0.604	Substantial
1.12	0.538	Moderate
1.13	0.324	Fair
1.14	0.301	Fair
1.15	0.371	Fair
1.16	0.267	Fair
1.17	0.063	Slight
1.18	0.569	Moderate
1.19	0.512	Moderate
1.20	0.423	Moderate
1.21	0.408	Fair
1.22	0.441	Moderate
1.23	0.320	Fair
1.24	0.399	Fair
Total number of items: level of agreement: almost perfect	0/24	0.0%
Total number of items: level of agreement: substantial	2/24	8.3%
Total number of items: level of agreement: moderate	8/24	33.3%
Total number of items: level of agreement: fair	13/24	54.2%
Total number of items: level of agreement: slight	1/24	4.2%
Total number of items: level of agreement: poor	0/24	0.0%

Twenty-one out of 24 (87.5%) items in Section 1 had a weighted kappa of 0.21-0.40 (fair agreement) to 0.41-0.60 (moderate agreement) between time 1 and time 2 completion of the final validated questionnaires with a two week interval by the nurse respondents. Eight of these items displayed moderate intra-rater agreement while 13 items had fair agreement. Items 1.4 and 1.11 displayed a substantial level of agreement by the nurse respondents between time 1 and time 2 completion of the final validated questionnaire. One item (4.2%) showed slight agreement when comparing the time 2 retest answers with time 1 questionnaire answers recorded by the nurse respondents.

4.4.2 Results of the test-retest for Section 2: Knowledge of physiological and clinical parameters associated with deterioration

Data obtained from the time 1 and retest time 2 completion of the final validated questionnaire for Section 2 focusing on nurses' knowledge of physiology and the clinical

parameters associated with deterioration, were classified as nominal level data as categories of answers were not ranked. The weighted kappa coefficient and intra-rater agreement could only be computed for eight of this section's 24 items; namely items 2.1.1 to 2.1.8 (Table 4.11). The table also includes a summary of the total number of items for each level of intra-rater agreement where the weighted kappa coefficient could be calculated.

Table 4.11: Test-retest weighted kappa coefficient and level of intra-rater agreement for items in Section 2 of the final validated questionnaire

Questionnaire item number	Weighted kappa	Level of intra-rater agreement
2.1.1	0.247	Fair
2.1.2	0.812	Almost perfect
2.1.3	0.851	Almost perfect
2.1.4	0.465	Moderate
2.1.5	0.565	Moderate
2.1.6	0.167	Slight
2.1.7	0.651	Substantial
2.1.8	0.418	Moderate
2.2.1 – 2.2.9	Unable to compute weighted kappa	
2.3.1 – 2.3.8	Unable to compute weighted kappa	
Total number of items: level of agreement: almost perfect	2/8	25%
Total number of items: level of agreement: substantial	1/8	12.5%
Total number of items: level of agreement: moderate	3/8	37.5%
Total number of items: level of agreement: fair	1/8	12.5%
Total number of items: level of agreement: slight	1/8	12.5%
Total number of items: level of agreement: poor	0/8	0.0%

In total, 6/8 (75.0%) of the items had a weighted kappa >0.41 (moderate to almost perfect agreement). Both items 2.1.2 and 2.1.3 (25.0%) had almost perfect agreement with a weighted kappa of 0.812 and 0.851 respectively. The respondent nurses' time 1 and time 2 answers to item 2.1.7 showed a substantial level of agreement (weighted kappa of 0.651). Three items (37.5%) reflected a moderate level of agreement with 25.0% (2/8) of the items showing only a fair to slight intra-rater agreement (weighted kappa <0.04).

The weighted kappa and level of agreement beyond chance could not be computed for 17 items (2.2.1 to 2.2.9 and 2.3.1 to 2.3.8) because the nurse respondents' time 1 answers were allocated the value "1" for these 17 items to indicate that the question had been answered (irrespective of the answer). If the respective nurse respondent's time 2 (retest) answer for an item was consistent with the time 1 item answer, a score of "1" was recorded for the time 2 retest answer for the respective item. Inconsistency between the time 2 retest item answer and the time 1 answer was allocated a "2" for the time 2 answer. An answer of "1" was allocated for all 30 respondents' answers for items 2.2.1 to 2.2.9 and 2.3.1 to 2.3.8 for time 1 completed questionnaires. The frequency in consistency between time 1 and time

2 item answers by category of nurse respondent was evaluated for questionnaire items 2.2.1 to 2.2.9 (Table 4.12) and items 2.3.1 to 2.3.8 (Table 4.13).

Table 4.12: Consistency between time 1 and time 2 answer by category of nurse respondent for items 2.2.1 to 2.2.9

Consistency between time 1 answer and time 2 answer										
Items	2.2.1	2.2.2	2.2.3	2.2.4	2.2.5	2.2.6	2.2.7	2.2.8	2.2.9	Total
RPN (%)	7/10 (70.0)	4/10 (40.0)	4/10 (40.0)	6/10 (60.0)	5/10 (50.0)	5/10 (50.0)	9/10 (90.0)	6/10 (60.0)	4/10 (40.0	50/90 (55.6)
EN (%)	6/10 (60.0)	3/10 (30.0)	6/10 (60.0)	4/10 (40.0)	6/10 (60.0)	7/10 (70.0)	5/10 (50.0)	6/10 (60.0)	4/10 (40.0)	47/90 (52.2)
ENA (%)	3/10 (30.0)	3/10 (30.0)	4/10 (40.0)	4/10 (40.0)	5/10 (50.0)	5/10 (50.0)	3/10 (30.0)	4/10 (40.0)	6/10 (60.0)	37/90 (41.1)
Total (%)	16/30 (53.0)	10/30 (33.0)	14/30 (47.0)	14/30 (47.0)	16/30 (53.0)	17/30 (57.0)	17/30 (57.0)	16/30 (53.0)	14/30 (47.0)	134/270 (49.6)

Consistency between each respective respondent's answers recorded for each item 2.2.1-2.2.9) in the questionnaire at both time points is represented as a percentage of the total number of respondents' answers at both time points (Table 4.12). The frequency of consistency for items 2.2.1 to 2.2.9 for 30 nurse respondents ranged between 33.0% (10/30) and 57.0% (17/30). Item 2.2.2 had the lowest frequency of consistency (33.0%, 10/30); while items 2.2.3, 2.2.4 and 2.2.9 showed a 47.0% (14/30) frequency of agreement. Five of the nine (55.6%) items had a frequency of consistency of between 53.0% and 57.0%. Consistency varied by nurse qualification. RPNs displayed the highest frequency of consistency in five (55.6%) items. ENs showed consistency in answers in four (44.4%) items. The highest frequency in consistency for item 2.2.8 was shared by RPNs and ENs. Overall, greater consistency (55.6%, 50/90) was found between the RPN respondents' time1 and time 2 answers compared to the EN and ENA respondents.

Table 4.13: Consistency between time 1 and time 2 answer by category of nurse respondent for items 2.3.1 to 2.3.8

Consistency between time 1 answer and time 2 answer									
Items	2.3.1	2.3.2	2.3.3	2.3.4	2.3.5	2.3.6	2.3.7	2.3.8	Total
RPN (%)	10/10 (100)	10/10 (100)	9/10 (90.0)	8/10 (80.0)	10/10 (100)	8/10 (80.0)	7/10 (70.0)	8/10 (80.0)	70/80 (87.5)
EN (%)	10/10 (100)	10/10 (100)	6/10 (60.0)	7/10 (70.0)	8/10 (80.0)	10/10 (100)	4/10 (40.0)	10/10 (100)	65/80 (81.3)
ENA (%)	9/10 (90.0)	9/10 (90.0)	8/10 (80.0)	8/10 (80.0)	8/10 (80.0)	8/10 (80.0)	8/10 (80.0)	9/10 (90.0)	67/80 (83.8)
Total (%)	29/30 (97.0)	29/30 (97.0)	23/30 (77.0)	23/30 (77.0)	26/30 (87.0)	26/30 (87.0)	19/30 (63.0)	27/30 (90.0)	202/240 (84.2)

The frequency of consistency for questionnaire items 2.3.1 to 2.3.8 for 30 nurse respondents was higher than found in items 2.2.1 to 2.2.9, ranging between 63.0% (19/30) and 97.0% (29/30) (Table 4.13). Questionnaire items 2.3.1 and 2.3.2 showed that 97.0% (29/30) of the nurse respondents each gave the same answer when completing the questionnaire on the second occasion compared with their answer given on first completion of the questionnaire. There was an 87.0% (26/30) frequency of consistency in the answers given by each nurse respondent at the two time points with the two week interval for questionnaire items 2.3.5 and 2.3.6. The greatest intra-rater inconsistency for this part of Section 2 was found in questionnaire item 2.3.7. In this item, 63.0% (19/30) of the respondents gave the same answer on the second occasion compared with their answer given for the specific item on first completion thereof. The frequency of consistency per category of nurse respondent revealed that the inconsistency between time 1 and time 2 answers for 2.3.7 was found in the EN group of respondents where 4/10 (40.0%) ENs gave the same answer on both occasions. Ten RPNs displayed consistency in ≥70% of the item answers for time 1 and time 2, while consistency of ≥80% was found in the data for items 2.3.1 to 2.3.8 for the ENAs. The ENs answered the questionnaire items at an agreement level of ≥70% in 6/8 (75.0%) of these items. Overall, greater consistency (87.5%, 70/80) was found between the RPN respondents' time1 and time 2 answers compared to the EN and ENA respondents.

4.4.3 Results of the test-retest for Section 3: Self-reported clinical reasoning ability

The weighted kappa coefficient was used to determine the 30 nurse respondent's intra-rater agreement for the 15 questionnaire items intended to assess a nurse's self-reported clinical reasoning ability. The weighted kappa coefficient for each item derived from the data from the validated questionnaire on two occasions two weeks apart is listed in Table 4.14 including the level of intra-rater agreement (Table 4.14).

Table 4.14: Test-retest weighted kappa coefficient and level of intra-rater agreement for items in Section 3 of the final validated questionnaire

Questionnaire item number	Weighted kappa	Level of intra-rater agreement
3.1	0.474	Moderate
3.2	0.400	Fair
3.3	0.635	Substantial
3.4	0.684	Substantial
3.5	0.342	Fair
3.6	0.700	Substantial
3.7	0.632	Substantial
3.8	0.616	Substantial
3.9	0.788	Substantial
3.10	0.667	Substantial
3.11	0.391	Fair
3.12	0.396	Fair
3.13	0.684	Substantial
3.14	0.667	Substantial
3.15	0.754	Substantial
Total number of items: level of agreement: almost perfect	0/15	0.0%
Total number of items: level of agreement: substantial	10/15	66.7%
Total number of items: level of agreement: moderate	1/15	6.7%
Total number of items: level of agreement: fair	4/15	26.7%
Total number of items: level of agreement: slight	0/15	0.0%
Total number of items: level of agreement: poor	0/15	0.0%

Ten of the fifteen (66.7%) questionnaire items in Section 3 had a weighted kappa coefficient of greater than 0.610 (and less than 0.800) that reflected a substantial level of intra-rater agreement amongst the respondents. Questionnaire item 3.1 displayed a moderate level of agreement for the 30 respondents' time 1 and time 2 answers. Four (26.7%) items had a weighted kappa coefficient ranging between 0.342 and 0.400 revealing only fair agreement between each respondent's time 1 and time 2 completion of the validated questionnaire.

4.4.4 Results of the test-retest for Section 4: Demographic data

The demographic data gathered from Section 4 of the validated questionnaire was categorised as nominal and interval level data. Examples of nominal level data included the respondents' highest qualifications, gender, whether they had attended a cardiopulmonary resuscitation course and if they had internet access. Examples of the interval level data included the variables age and number of years' of experience working as a nurse. The level of intra-rater agreement could not be assessed because the weighted kappa could not be computed. The same analysis as conducted for the data for items 2.2 and 2.3 was undertaken to determine consistency between each nurse respondent's time 1 and time 2 answers to the completed validated questionnaire. The consistency in time 1 and time 2

retest answers are listed in Table 4.15 for the total sample of respondents and the consistency per category of nurse.

Table 4.15: Consistency between time 1 and time 2 answer by category of nurse respondent for items in Section 4

Consistency between time 1 answer and time 2 answer													
Items	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	Total
Category of Nurse	Proportion (%)												
RPN (%)	9/10 (90.0)	10/10 (100)	10/10 (100)	8/10 (80.0)	10/10 (100)	10/10 (100)	4/10 (40.0)	10/10 (100)	8/10 (80.0)	9/10 (90.0)	9/10 (90.0)	7/10 (70.0)	104/120 (86.7)
EN (%)	10/10 (100)	10/10 (100)	10/10 (100)	10/10 (100)	10/10 (100)	10/10 (100)	8/10 (80.0)	10/10 (100)	9/10 (90.0)	7/10 (70.0)	8/10 (80.0)	9/10 (90.0)	111/120 (92.5)
ENA (%)	9/10 (90.0)	10/10 (100)	10/10 (100)	9/10 (90.0)	10/10 (100)	10/10 (100)	7/10 (70.0)	9/10 (90.0)	9/10 (90.0)	8/10 (80.0)	8/10 (80.0)	7/10 (70.0)	106/120 (88.3)
Total per item (%)	28/30 (93.0)	30/30 (100)	30/30 (100)	27/30 (90.0)	30/30 (100)	30/30 (100)	19/30 (63.0)	29/30 (97.0)	26/30 (87.0)	24/30 (80.0)	25/30 (83.0)	23/30 (77.0)	321/360 (89.2)

The frequency of consistency between the 30 respondents' time 1 test and time 2 retest answers for the 12 items ranged from 63.0% (19/30) to 100% (30/30). Ten of the12 (83.3%) items had a total consistency of greater than 80.0%. Greater consistency (92.5%, 111/120) across the 12 items was found among the ENs. The ENAs answers revealed consistency in 106/120 (88.3%) items, while the RPN respondents had the lowest consistency (86.7%, 104/120) for the 12 items despite having the highest level qualification amongst the 30 respondents. Overall, consistency was found in 89.2% (321/360) items across three categories of nurses for Section 4.

4.4.5 Summary for test-retest reliability testing

The n=30 invited respondents independently consented to participate in the study by completing the final validated questionnaire (Appendix G) on two separate occasions two weeks apart. The return rate for the test and the retest resulted was 100%. The test-retest weighted kappa statistic revealed the degree of item agreement for 47 items as a measure of the stability of the questionnaire developed for this study. The weighted kappa statistic could not be calculated across all sections of the questionnaire. The proportion of consistency for the time 1 and time 2 item responses from the three categories of respondents was calculated for the 29 item statements where the weighted kappa statistic could not be computed.

All the questionnaire items (47/47; 100%) that had a weighted kappa statistic computed, had levels of intra-rater agreement ranging from slight agreement (0.01-0.20) to almost perfect agreement (0.81-l). A fair level of agreement (0.21-0.40) was found between the

respondents' time 1 and time 2 data for 18/47 (38.3%) items. A moderate level of agreement (0.41-0.60) was displayed for 12/47 (25.5%) items while 13/47 (27.7%) items showed substantial intra-rater agreement (0.61-0.80).

Consistency between respondents' time 1 and time 2 answers was above 63.0% for items 2.3.1 to 2.3.8 (eight items) and for the 12 items in Section 4. In contrast, items 2.2.1 to 2.2.9 (nine items) displayed consistency between time 1 and time 2 retest of between 33.0% and 57.0%. RPNs responses between time 1 and time 2 were more consistent than for the Enrolled Nurses and Nursing Auxiliaries.

4.5 Summary of the chapter

The sequential 4-phase study design was effective in meeting the study objectives and resulted in the development and validation of a researcher-developed questionnaire by CVI assessment and cognitive interviews using expert registered professional nurses. Reliability of the questionnaire was established by test-retest reliability testing using all categories of nurses who take and interpret patients' vital signs. Reproducibility varied revealing more favourable agreement in questionnaire sections relating to nurses knowledge of physiological and clinical parameters relating to deterioration in a patient's condition (Section 2) and clinical reasoning (Section 3). The strengths and limitations of the study and recommendations will be discussed in the following chapter.

CHAPTER 5: DISCUSSION, RECOMMENDATIONS AND CONCLUSION

5.1 Introduction

Validating measurement instruments is essential to establish validity and reliability (DeVon et al., 2007; Paiva et al., 2014). The increase in research exploring the occurrence of AEs, the contributing factors to deterioration in a patient's condition and practices to improve patient safety in healthcare facilities prompted this instrument development and validation study. A classic confidential inquiry by McQuillan et al. (1998) in the United Kingdom (UK) into suboptimal care rendered to patients before admission to intensive care units reported that suboptimal care contributed to morbidity or mortality in most instances. Contributing factors to suboptimal care were failures at various levels: organisational, knowledge, recognising clinical urgency, supervision and calling for assistance. This study focused specifically on nurses' failure to accurately recognise and respond timeously to clinical and physiological signs of deterioration in a patient's conditions resulting in AEs such as unplanned admission to an intensive care unit; increased length of stay in hospital and death.

The published literature contributing to the field of study related to factors contributing to nurses' failure to recognise and respond to patient deterioration originated from the developed countries (Chua et al., 2013; Massey et al., 2017). Chua et al. (2013) suggested that a benefit of nurses' improved competency in conducting vital sign measurements could be more accurate recognition and reporting of patient deterioration in their clinical setting. Failure to recognise, rationalise and understand deterioration in patient data in the simulation scenarios is concerning (Cooper et al., 2010; Cooper et al., 2011). This could indicate a competency gap in the application of theoretical knowledge in a clinical environment where "perception, understanding and prediction" are critical nursing competencies (Cooper et al., 2010; Cooper et al., 2011).

Both registered and non-registered nurses recognise that their clinical experience assists them in successfully recognising and responding to patient deterioration (Chua et al., 2013; McDonnell et al., 2013; Purling & King, 2012). Recognising patterns in vital signs and clinical observations from prior clinical experiences helps nurses to interpret vital signs and clinical observations to identify when to make escalation calls (Chua et al., 2013). Limited clinical experience and patient engagement can negatively influence nurses' ability to safely and proactively recognise and respond to deterioration in a patient's condition (Kyriacos et al., 2011; Levett-Jones et al., 2010; Ludikhuize, Dongelmans, et al., 2012).

McDonnell et al. (2013) used a questionnaire and semi-structured interviews in the UK to differentiate the levels of confidence between registered and unregistered nurses in a single site study. The findings showed that unregistered nurses scored their confidence in their ability to recognise patient deterioration the lowest.

Communication with colleagues and interdisciplinary healthcare professionals influences a nurse's recognition of changes in a patient's condition as well as access to assistance when initiating a response (Massey et al., 2017; Purling & King, 2012; Quirke et al., 2011; Smith & Aitken, 2016).

Nurses report being hesitant and fearful of being criticised for alerting more skilled healthcare professionals to a situation of patient deterioration (Astroth et al., 2013). Skilled clinicians may not consider that a patient's condition is as serious as estimated or that nurses have rendered inadequate patient care. This results in hesitancy to escalate clinical deterioration in a patient's condition (Astroth et al., 2013), delays in action taken by dedicated response team members' to reports of patient deterioration (Allen et al., 2017) and nurses feeling unsupported in clinical practice when faced with a patient displaying signs of clinical deterioration (Massey et al., 2017).

Nurses require clinical reasoning and decision making competencies to recognise and respond to deterioration in patients' vital signs and clinical observations (Astroth et al., 2013; Liaw et al., 2011b; Mok et al., 2015; Purling & King, 2012). Liou et al. (2016) advocate that clinical reasoning is a vital systematic problem solving skill that nurses need to develop to enable them to render safe patient care. An integrative review of the literature reported nurses' knowledge, for example of the biosciences, and their ability to relate it to a patient's reason for hospitalisation assisted them to understand what was happening to the patient physiologically and to anticipate future risks or possible complications (Massey et al., 2017). RPNs equipped with knowledge of biosciences, clinical competency and clinical decision making skills spend reduced time periods at a patient's bedside. This is due to their leadership responsibilities in coordinating care in the clinical unit (Astroth et al., 2013; Kyriacos et al., 2011; Liaw et al., 2011b).

In SA, a middle income country, the Cape Town MEWS document was developed and validated (Kyriacos, Jelsma, James, et al., 2014) then tested by a RCT (Kyriacos et al., 2015) at one large tertiary hospital. The RCT included two interventions: 1) a training program to assess nurses' knowledge and 2) implementation of the Cape Town MEWS to evaluate nurses' post-operative vital signs recordings and their response to predetermined physiological thresholds pre- and post-training by record review. The study reported

concerns about nurses' poor response to signs of patient deterioration. In response to these concerns a Cape Town MEWS linked SBAR tool (Burger et al., 2017) was developed and validated.

Local SA studies exploring factors that influence nurses' failure to recognise and respond to patient deterioration were not found. Domain 2 of the Core Standards document for South African healthcare facilities mandates the promotion of patient safety and a reduction in potential harm to patients (Department of Health, 2011). The scarcity of a validated questionnaire covering the three content domains substantiated the need for this study to contribute to patient safety research in a local private healthcare organisation.

5.2 Developing the prototype questionnaire

The questionnaire contains three content domains: 1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward (Astroth et al., 2013; De Meester, Van Bogaert, et al., 2013; Kyriacos et al., 2011; Mok et al., 2015; Perkins & Kisiel, 2013); 2) nurses' knowledge of physiological and clinical parameters associated with patient deterioration (Cooper et al., 2010; De Meester, Van Bogaert, et al., 2013; Kyriacos, 2011; Mok et al., 2015) and 3) nurses' self-reported clinical reasoning ability (Liou et al., 2016). Miller's amended pyramid (Cruess et al., 2016) justified the emphasis on the nurses' knowledge and their clinical reasoning in the prototype questionnaire apart from other reported factors influencing their ability to recognise and respond to patient deterioration in general wards.

A limited number of questionnaire items from publicly available literature were included to satisfy the conceptualised content domains. Due to the paucity of a comprehensive questionnaire in the available literature, the remaining item statements were extrapolated by deduction and inference so validation of the entire prototype questionnaire was required (DeVon et al., 2007).

After the prototype questionnaire was developed, the content validity index and face validity by definition (Lynn, 1986) were assessed followed by in-depth face validity assessment using cognitive interviews. Stability was evaluated using test-retest completion the questionnaire at two time points two weeks apart.

5.3 Validating the prototype questionnaire

After identification of relevant item statements from published studies representing the three content domains for the study, the prototype questionnaire (Appendix A) was validated in

three phases (phases 2-4 in this present study). Each section required validation because a validated instrument addressing all three content domains for this study could not be identified. Even though the Nurses Clinical Reasoning Scale (NCRS) had shown positive outcomes for content validity and reliability (Liou et al., 2016) in Taiwan, all four sections of the prototype questionnaire required local validation in a local healthcare context.

5.3.1 Content validity index strengths and limitations

The S-CVI for the prototype questionnaire achieved 86.2% and exceeded the pre-set cut point of ≥ 70%. The expert RPNs assessed the item statements as being representative of the prototype questionnaire's three content domains (Guttmann et al., 2006). The suggested amendments offered by the expert RPN's clarified interpretation of the item statements and improved the overall quality of the questionnaire that influences respondent performance completing a questionnaire (Brancato et al., 2006; Polit & Beck, 2017).

5.3.1.1 Strengths of CVI

The recommended Likert scale in the CVI assessment tool was clear and simple (Lynn, 1986) (Appendix B). The high rate of completion of the CVI assessment by each expert RPN contributed to the quality of the data for analysis. The overall higher than pre-set proportion of agreement for the prototype questionnaire (S-CVI) of 86.2 % indicated that the item statements were representative of the questionnaire's three content domains (Guttmann et al., 2006). The overall mean of 4.8 (313/325; 96.3%) raters scoring each item statement 3 (relevant but needs minor alteration) or 4 (extremely relevant) supports the content validity of the item statements compared to the content domains in the prototype questionnaire. The validation study by Mok et al. (2015) identified six subscales or themes but only reported the S-CVI (0.8). The CVI assessment in that study showed that despite the S-CVI being ≥70%, the proportion of agreement among the raters can be <70% for one or more themes or content domains in a measurement tool.

Three of sixty-five (4.6%) items were removed from the prototype questionnaire as a result of the CVI assessment because the proportion of agreement was less than the pre-set ≥70% agreement for each of these items (Guttmann et al., 2006). The items removed were from Section 2 of the prototype questionnaire that assessed nurses' knowledge regarding basic clinical and physiological parameters linked to deterioration in a patient's condition. The items were excluded because the RPN experts concluded that the expected knowledge was too advanced for general ward nurses in SA. The three items had been utilised in a study by Cooper et al. (2010) in Australia. Removal of the items for a local context illustrates the importance of content validation in a local healthcare context to improve the quality and

usability of the prototype questionnaire (Brancato et al., 2006; Polit & Beck, 2017). Recruiting expert RPN's for the CVI assessment according to the pre-determined criteria (qualifications and experience) strengthened the weight of their opinions, CVI ratings and recommendations for amendments to improve the face validity of the questionnaire (Waltz et al., 2005).

In the present study, the CVI assessment showed a lower proportion of agreement among the raters for the item statements in Section 2 relating to nurses' knowledge of physiological and clinical parameters associated with patient deterioration. Nurses' knowledge of physiological and clinical parameters associated with patient deterioration is a concern because it influences their ability to identify signs of clinical deterioration and to initiate an escalation call to a more skilled healthcare professional timeously (De Meester, Van Bogaert, et al., 2013).

MCQ response options (Section 2) and limited choice closed-ended questions (Section 4) were amended despite the high proportion of agreement. An expert recommended that MCQ response options should be homogenous in each item statement and that limited choice closed-ended question responses should be arranged according to hierarchical categories (for example, qualifications in the demographic data section). Brancato et al. (2006) supports the suggested amendments to improve the clarity of the questionnaire and to reduce the risk of errors in answering item statements.

Changing the term "mechanisms" to "pathophysiology" was accepted as well even though items had a high proportion of agreement. "Pathophysiology" is used in the local healthcare environment and item statements need to be relevant and understandable to the intended respondent (Polit & Beck, 2017).

The RPNs expert opinion about the face validity specifically confirmed that the layout, format, readability were of a good standard. Poorly structured and formatted questionnaires can result in respondents being confused, even omitting questionnaire items that then have an impact on the eventual results (Polit & Beck, 2017). This feedback intended to contribute to reducing the risk of respondent confusion or misinterpretation when completing the questionnaire during the test-retest for reliability for use with all categories of nurses.

5.3.1.2 Limitations of CVI

The population size of five respondents for assessing the CVI of the prototype questionnaire was not adequate and therefore a limitation in this study. Although a sample size of five to ten respondents is suggested, Lynn (1986) recommends a higher proportion of agreement

(100%) between raters when there are five or less rating the instrument for content validity. Also considering the possibility of chance agreement, it is suggested that the sample size for the assessment of the CVI be increased to six or seven respondents

The pre-set proportion of agreement at ≥ 70% agreement among raters for 65 items with a score of either 3 (relevant but needs minor alteration) or 4 (extremely relevant) was used in this study (Guttmann et al., 2006). A second round of CVI ratings was warranted for this study following the amendments to the 14/65 (21.5%) items. Re-evaluating the I-CVI and S-CVI in a second round of CVI ratings could have assessed the impact of the amendments to the prototype questionnaire on the I-CVI and S-CVI of the revised prototype questionnaire prior to the cognitive interviews(Lynn, 1986).

Purposive sampling of respondents can be considered a limitation due to sampling bias (Polit & Beck, 2017) influencing the CVI findings. The RPN's invited to participate did not represent the entire population of RPNs with a minimum qualification of a Master's Degree, postgraduate diploma in nursing education, and self-declared knowledge and experience in the fields of the biosciences and basic health sciences research methodology at the research setting.

The length of the final validated questionnaire (comprising 76 question items) could be considered a limitation. Although only 1/5 (20%) of the RPNs rated the length of the questionnaire less than satisfactory, this feedback raised awareness of response burden and research participant fatigue when completing a questionnaire. The response burden can negatively impact nurses' accurate completion of a questionnaire and the integrity of the study results (Brancato et al., 2006).

The developed and validated questionnaire is intended to assess nurses' knowledge, clinical reasoning and factors contributing to the recognition of and response to patient deterioration. The expert RPNs were of the opinion that not all categories of nurses might be able to answer all of the questionnaire items. In practice, nurses with different qualifications (RPNs, ENs and ENAs) have different levels of knowledge relative to their qualification and experience (Massey et al., 2017). The study by Smith and Aitken (2016) highlighted the concern that ENAs with the least knowledge not only measured patients' vital signs and clinical observations at the bedside but were expected to fulfil the critical role of interpreting the assessment findings for escalating a call to a RPN. These findings support the validation of a measurement tool toassess the factors influencing general ward nurses' ability to recognise and respond to patient deterioration; nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and nurses' self-reported clinical

reasoning ability. A pilot study including all three groups of nurses would assist in evaluating ENs and ENAs ability to answer the questions (Polit & Beck, 2017).

The expert RPNs did not evaluate the subsections of the prototype questionnaire items. Instead item statements 2.2 and 2.3 (Appendix B) were each assessed for content validity as a whole item. Rating the MCQ item response options, individual open-ended single answer questions and subsections of multiple option checklist questions can improve the quality of the item statements (Brancato et al., 2006). Therefore, a limitation in the CVI results was identified because each of the items 2.2.1 to 2.2.9 and 2.3.1 to 2.3.9 were not assessed individually for content validity.

5.3.2 Strengths and limitations of cognitive interviews

During the cognitive interviews, the expert RPNs recommended improvements to the revised prototype questionnaire suggesting that questionnaire items, instructions and definitions of terms needed further clarification. The amendments contributed to the face validity and quality of the questionnaire.

5.3.2.1 Strengths of cognitive interviewing

The RPNs who participated in the cognitive interviews offered valuable feedback to the planned probing questions (Appendix F). The cognitive interviewing methodology provided a purposeful, effective approach to acquiring feedback on the face validity of the revised questionnaire (Appendix D) to improve the quality and completion rates (Drennan, 2003). The feedback addressed the interpretation of questionnaire items, applicability of the items, identified problems with terms or phrases used in the questionnaire and clarity of items (Knafl et al., 2007). Having one interviewer conducting all the interviews offered consistency in the data collection process (Beatty & Willis, 2007) in this study. In addition, keeping interview field notes assisted the researcher in recalling and clarifying comments (Waltz et al., 2005).

Researcher consistency was maintained using standard pre-prepared probing questions (Burger, 2015). The suggestions for improved clarity in the instructions and definitions at the beginning of the questionnaire supported the feedback received during the CVI assessment. The planned probing questions helped the researcher utilise the interviewing time effectively to gain greater clarity and verification of the intention behind the comments made (Knafl et al., 2007). Conducting the interviews face to face at the RPNs convenience, meant that the interviews were carried out free from concerns relating to work pressure and telecommunication costs.

Evaluation of the revised prototype questionnaire items 2.2 and 2.3 improved in the CI phase because the expert RPNs were prompted during the interview to assess each of the item statements 2.2.1 to 2.2.9 and 2.3.1 to 2.3.9 individually. More detailed feedback was gained from the CI resulting in amendments and removal of item statements meeting the purpose of the process (Conrad & Blair, 1996).

5.3.2.2 Limitations of cognitive interviewing

As for the CVI respondent sampling strategy, purposive sampling for the cognitive interviews could be a limitation due to sampling bias as the three RPNs selected also did not represent the entire demographic and qualification population meeting the selection criteria (Drennan, 2003; Polit & Beck, 2017). Therefore a researcher should be cautious in generalising the findings gained from the CI to the general population of nurses (Beatty & Willis, 2007).

Limiting the number of expert RPNs to three for the interviews is a limitation of this study although no new findings emerged during the third cognitive interview (Beatty & Willis, 2007). Cognitive interview conclusions during validation of a questionnaire could be correct relative to the respondents taking part in the interviews. Beatty and Willis (2007) suggest selecting a sample size that is sufficiently large enough to yield good quality feedback during the interviews even though there is no consensus about the number of participants for cognitive interviews. The small sample size and limiting the pre-set selection criteria to exclude RPNs, ENs and ENAs working in general units is a limitation of this study (Beatty & Willis, 2007). Additional prototype questionnaire findings could have emerged from the cognitive interviews by including the three categories of nurses from the general wards. The concern raised during the CVI face validity evaluation that the ENA category of nurses might possibly struggle with understanding the questions could be mitigated by including representatives from each category in the CI process.

The expert RPN's evaluated the MCQ questionnaire items in Section 2 (items 2.1.1 to 2.1.8) without distinctly assessing each response option. Omitting detailed assessment of the face validity of these items is a limitation of the cognitive interviews because each response item requires careful consideration (Brancato et al., 2006) to identify problems with interpretation, applicability and clarity of items and terms or phrases used in the revised prototype questionnaire (Knafl et al., 2007).

Analysing the cognitive interviews is a subjective process influenced by the researcher's own analysis and the conceptual categorisation of the participant's feedback (Beatty & Willis, 2007). Subjectivity is considered a limiting factor of cognitive interviewing for this study as

one researcher conducted both the interviews and the data analysis. One researcher can also contribute to consistency in the processes of data collection and analysis.

5.4 Assessing the reliability of the prototype questionnaire

Results reflecting the reliability of the validated questionnaire varied across the four sections of the questionnaire. Greater levels of agreement between the respondents' time 1 and time 2 questionnaire responses were found for item statements in Section 3 (66.7%; 10/15; weighted kappa 0.61-0.80) of items which was anticipated as the item statements had been previously validated (Liou et al., 2016).

5.4.1 Test-retest strengths and limitations

5.4.1.1 Strengths of test-retest

The 100% return rate for the test-retest was higher than commonly anticipated (Polit & Beck, 2017). This could be attributed to the availability of the researcher to the nurses at the research site, clear explanations of the purpose of participation in the study when the validated questionnaire was handed out and potential respondents' stated awareness of the relevance of the study to their work.

Nurses from all three qualification categories working in the general wards in the private hospital were invited to participate in the test-retest phase in equal proportions (n=30: 10 RPNs, 10 ENs, 10 ENAs). Recommendations to include a sample of respondents representative of the respondent population contributes to accurately assessing the stability of the final validated questionnaire (Karanicolas et al., 2009).

A lengthy questionnaire presents the risk of respondent response burden and the return of incomplete questionnaires (Polit & Beck, 2017). During the CVI evaluation phase the respondents raised concerns about the possibility that the questionnaire could be too long with too many item statements. This raised a concern that Section 4 items (Demographic characteristics) would have been left incomplete if the response burden was high was disproved because 100% of Section 4 items were answered during time 1 and time 2 of the test-retest.

In contrast, the highest occurrence of item omissions was found in Section 2 of the time 1 and time 2 responses that assessed nurses' knowledge of physiological and clinical parameters associated with patient deterioration. No definitive reason can be concluded from the item answer omissions in this present study. However an integrative review conducted Massey et al. (2017) confirmed that nurses' need to have knowledge of the

biosciences and their ability to relate it to a patient's reason for hospitalisation assists them to understand what was happening to the patient physiologically and to anticipate future risks or possible complications.

5.4.1.2 Limitations of test-retest

Due to the small population at the research site for the test-retest phase and considering nurses' absenteeism for annual leave or sick leave, the sample of 30 nurses was accepted as an adequate sample size for this study. A larger sample size could result in an increase in the reliability of the questionnaire (Karanicolas et al., 2009; Sim & Wright, 2005).

Questionnaire item 1.14 (Appendix G) required the respondent to rate the statement "I am adequately prepared to communicate with a more skilled healthcare professional about deterioration in a patient's condition" using the 4 point Likert scale. Respondents' responses to this statement in the time 1 test and time 2 retest resulted in weighted kappa statistic of was 0.301 for item 1.14 indicating only a fair level of agreement. Prevalence of an event or attribute such as a recent experience where a patient's condition deteriorated can influence respondents' time 1 test and time 2 retest (Sim & Wright, 2005) especially if the event occurred between the time 1 test and time 2 retest. A degree of error can occur in the weighted kappa as respondents required to recall events from the past (Karanicolas et al., 2009; Polit & Beck, 2017; Sim & Wright, 2005). Therefore the level of agreement between ratings during test-retest can be influenced by factors such as prevalence and recall.

The proportion of agreement for questionnaire items for 29 items (2.2, 2.3 and 4.1 to 4.12) was high. The error of chance agreement cannot be excluded when calculating the proportion of agreement in these items (Sim & Wright, 2005). The high proportion of agreement could have been influenced by item recall and non-independence of the ratings during time 2 by each respondent as both increase the magnitude of agreement (Sim & Wright, 2005). The weighted kappa results indicating agreement beyond chance varied for Section 1, Section 2 (2.1.1 to 2.1.8) and Section 3. The recall, non-independence and prevalence influence the level of agreement between for test-retest, however the rationale for the variability in weighted kappa results is not yet known.

A further study limitation is the reliance on the frequency of agreement instead of the weighted kappa statistic for questionnaire items 2.2, 2.3 and 4.1 to 4.12. The agreement due to chance cannot be excluded for these items for each respondent's time 1 and time 2 responses where the weighted kappa statistic could not be calculated (Karanicolas et al., 2009).

Analysis of responses for time 1 and time 2 was based on binary data: 1 was allocated if responses were the same on both occasions and 2 if the time 2 response differed from that for time 1. The expertise of the participants can influence the level of agreement for questionnaire items. A more reliable level of agreement is presumed when the participant has more experience and training (Karanicolas et al., 2009). This study did not compare the stability reliability between the three categories of nurses. The number of years of experience was also not analysed to evaluate the impact of this on the level of agreement and therefore the stability of the validated questionnaire. Analysing the test-retest data for this group of respondents with different qualifications and other demographic characteristics is therefore a limitation in the study design.

Section 2 had the highest number of total items (5/25; 20% time 1 and 5/25; 20% time 2) omitted across the three categories of nurse respondents during the test-retest for reliability The reason for omitting item statements is not known. However deficits in nurse's knowledge of physiological and clinical parameters of clinical deterioration have been raised as a concern (Smith & Aitken, 2016).

There are a number of influencing factors that can influence test-retest to establish the stability of a questionnaire. Each of these factors need to be taken into consideration to minimise the degree of error and increase the level of agreement among raters over two time periods.

5.5 Recommendations from this study

Recommendations are made to further improve the quality of the final validated questionnaire (Appendix G). The limitations raised as a result of the content validity assessment, the face validity assessment from the CI and the test-retest for stability ability reliability could be mitigated by considering the following recommendations for research and clinical practice.

5.5.1 Recommendations for research

The CVI assessment, CI phase and the test-retest phase each have specific recommendations for data collection and analysis thought to result in more valid and reliable study results. It is recommended that all questionnaire item statements should be assessed for content and face validity individually and not grouped together. For example instead of assessing the CVI for the entire item 2.2 or 2.3, each of the individual response items should be assessed separately: 2.2.1 to 2.29 and 2.3.1 to 2.3.9. This could result in more specific assessment feedback from the expert RPN respondents.

A second round of CVI assessment for content and face validity after amendments and exclusions have been made to the prototype questionnaire is recommended (Lynn, 1986). The additional CVI assessment could validate the amendments made prior to proceeding to the CI phase.

It is recommended that the number of respondents participating in the CI phase could be increased to generate more diverse feedback about the face validity of the prototype questionnaire (Beatty & Willis, 2007). Including RPN, EN and ENA respondents during the CI phase is recommended for two reasons: to increase the sample size and to include RPNs, ENs and ENAs working in general wards rather than only including well educated nurses. This would provide an opportunity to understand the problems that each category of nurse experiences when completing questionnaire (Knafl et al., 2007).

Developing interviewing skills prior to undertaking a study using CI is a further recommendation (Beatty & Willis, 2007). Observing and practicing the CI technique could equip interviewers to facilitate the interviews efficiently, to gather data more effectively and follow cues that might be missed by a novice interviewer. In addition, the interviews and the data analysis could be undertaken by more than one researcher to reduce the subjective nature of the cognitive interview results (Beatty & Willis, 2007) but this might reduce the consistency in interpreting the data.

Increasing the sample size for the test-retest phase is also recommended to positively influence the magnitude of the agreement between responses and the reliability of the questionnaire (Karanicolas et al., 2009; Sim & Wright, 2005). This could require recruitment of respondents from more than one healthcare site to maintain an equal proportion of each category of nurse included in the test-retest phase.

The ability of the questionnaire to discriminate between two or more groups was not established. Group comparisons are recommended to strengthen the validity of the questionnaire's (Liou et al., 2016; Polit & Beck, 2017). Categorising the nurse respondents and their responses to the questionnaire items in two different methods: firstly according to qualifications and secondly according to three equally proportioned groups differentiating the number of years of experience. Two hypotheses could be tested. Firstly the hypothesis would be stated that the magnitude of agreement in responses would be greater and more reliable for the categories of nurses that are more qualified (Karanicolas et al., 2009). Aiken et al. (2011) has confirmed the positive impact of reducing patient mortality by 4% and improving patient outcomes, when increasing the ratio of bachelor-prepared nurses to other categories of nurses by 10%. Secondly, the hypothesis would be stated that the magnitude

of agreement in responses would be greater and more reliable in the group of nurses with more years of experience with in recognising and responding to patient deterioration respectively. Limited clinical experience and patient engagement can negatively influence nurses' ability to safely and proactively recognise and respond to deterioration in a patient's condition (Kyriacos et al., 2011; Levett-Jones et al., 2010; Ludikhuize, Dongelmans, et al., 2012).

Assessing the internal consistency is recommended to further estimate the reliability of the validated questionnaire beyond the findings of the test-retest. Cronbach's alpha can be computed to reveal the reliability of the questionnaire by evaluating whether the item statements are consistently and reliably measuring the content domains (Karanicolas et al., 2009).

The construct validity of the questionnaire was not assessed during this study. Factor analysis is a commonly applied statistical process used to determine construct validity. It is described as the extent to which the questionnaire items statements actually measure the content domains, otherwise known as constructs (DeVon et al., 2007). For example, if factor analysis finds that the questionnaire item statements together in Section 1 measure the factors influencing nurses' recognition and response to patient deterioration, then construct validity is evident for that content domain.

Further research opportunities could include the implementation of the validated questionnaire from this study as a pre-test questionnaire to test nurses' baseline knowledge and to guide the design, validation and implementation of a MEWS and SBAR training programme. Alternatively, the results from the questionnaire could be used in qualitative studies for more in-depth exploration of nurses' attitudes to measuring and monitoring patient vital signs (Mok et al., 2015) or the impact of vital sign observation charts on nurses' recognition and response to patient deterioration (Elliott et al., 2016).

5.5.2 Recommendations for clinical practice

To mitigate the questionnaires' subjectivity highlighted during both the assessment of the CVI and the CI phase, the questionnaire could be used in collaboration with a simulation activity for nurses. Activities such as simulation activities and a questionnaire could be used to compare and validate the findings (Connell et al., 2016; Cooper et al., 2011; Liaw, Scherpbier, Rethans, & Klainin-Yobas, 2012).

It is common practice to evaluate the effectiveness of education programmes (Liaw et al., 2011b) to ensure that the intended programme outcomes are met, and if not then amending

the programme for continuous improvement. A questionnaire or survey is a useful tool to elicit feedback from respondents about a particular topic of interest (Polit & Beck, 2017). The aim of the training programme, beyond the scope of this study, could be to support improvement in the recognition and response to deterioration in a patient's condition to reduce the occurrence of AEs requiring the unplanned transfer of ward patients to an intensive care unit and patient mortality at a hospital site in South Africa.

This questionnaire could be used to evaluate new nursing graduates entering clinical practice to evaluate gaps in their knowledge of physiological and clinical parameters associated with patient deterioration; their self-reported clinical reasoning ability and the factors influencing their ability to recognise and respond to patient deterioration in a general ward. The findings could be used by nursing education institutions to initiate curriculum review to better prepare new graduates to accurately and timeously recognise and respond to patient deterioration (Bucknall et al., 2016; Endacott et al., 2010).

5.6 Conclusion

The researcher-developed questionnaire was assessed and found to have content and face validity; however the stability as a measure of its reliability needs improvement. It is recommended that the questionnaire should be reassessed for content and face validity using a sample inclusive of all categories for nurses who take and interpret patients' vital signs in an attempt to improve the test-retest reliability of the questionnaire. Factor analysis is recommended to determine the questionnaire's construct validity. It is suggested that the internal consistency of the questionnaire should be evaluated to further assess the reliability. The questionnaire could then be used to support patient safety improvement strategies in the recognition and response to deterioration in a patient's condition in a local context in South Africa.

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APPENDICES

Appendix A - Prototype questionnaire

Dear Respondent

Respondent Code_____

The **purpose of this questionnaire** is to assess: 1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; 2) nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and 3) nurses' self-reported clinical reasoning ability. The validity and reliability of the developed questionnaire has been established.

Please answer all the questions.

Section 1: Factors influencing your ability to recognise and respond to patient deterioration

Using the following scale, please select the most appropriate response to each of the questions listed below.

Scale: 5 = Strongly agree, 4 = Agree, 3 = Neutral, 2 = Disagree, 1 = Strongly disagree

No.	Factors influencing your ability to recognise and respond to patient deterioration	5	4	3	2	1
*1.1	My nursing qualification adequately prepared me to take/measure clinical observations and vital signs.					
*1.2	I am unsure how to respond to changes in patients' clinical observations and vital signs.					
*1.3	Interpreting patient observations and vital signs is an essential part of my role.					
*1.4	I feel confident recording patients' clinical observations and vital signs.					
*1.5	I feel knowledgeable when interpreting patients' clinical observations and vital signs which show altered physiology.					
*1.6	My nursing qualification adequately prepared me to interpret patients' clinical observations and vital signs.					
*1.7	It is important to respond to any changes in patients' clinical observations and vital signs.					
*1.8	I believe that there is a deficit in my understanding of altered physiology associated with patients' clinical observations and vital signs.					
1.9	I am expected to take / measure patients' clinical observations and vital signs.					
1.10	I know how often I should take /measure patients' clinical observations and vital signs for the patients that I am allocated to provide care for in the clinical unit.					
1.11	The clinical unit in which I am employed has a policy or work procedure that prescribes the frequency of taking/measuring clinical observations and vital signs.					
1.12	The clinical unit in which I am employed has a policy or work procedure that prescribes the action that I should take if I recognise deterioration in a patient's clinical observations and vital signs.					
1.13	The registered nurse in the clinical unit checks the documented vital signs and clinical observations of every patient.					
1.14	I am adequately prepared to communicate with a more skilled healthcare professional about deterioration in a patient's condition.					
1.15	I am able to use the accepted nursing terminology to communicate with a more skilled healthcare professional about deterioration in a patient's condition.					
1.16	I use a communication tool as a guide to communicate the relevant information about deterioration in a patient's condition to a more skilled healthcare professional.					
1.17	I always document the information communicated to a more skilled					

No.	Factors influencing your ability to recognise and respond to patient deterioration	5	4	3	2	1
	healthcare professional about deterioration in a patient's condition in the patient's nursing records.					
1.18	I am confident that the more skilled healthcare professional will act timeously on the information that I communicate to them regarding the patient's deteriorating condition.					
1.19	Information about the patient's deteriorating condition that I communicate to a more skilled healthcare professional is taken into consideration.					
1.20	When reporting my concern regarding a patient's condition to a more skilled healthcare professional, I fear being criticised for reporting on a patient who is not that sick.					
1.21	I have the necessary equipment to take / measure clinical observations and vital signs.					
1.22	In the clinical unit where I work I feel that I am an essential member of the multidisciplinary team responsible for the recognition of and response to deterioration in a patients' condition.					
1.23	I understand the consequences of failing to identify and report deterioration in a patient's condition.					
1.24	I measure and record every clinical observation and vital sign every time I am required to measure and record patients' clinical observations and vital signs.					
1.25	I have experienced a situation where the deterioration in a patient's condition was not recognised leading to Cardiopulmonary resuscitation (CPR); transfer of the patient to the High Care or Intensive Care unit; or death of the patient.					

References:
*Adapted from Perkins, C., & Kisiel, M. (2013). Developing the recognition and response skills of student nurses. *British Journal of Nursing,* 22(12), 715-724.
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Section 2: Nurses' knowledge of physiological and clinical parameters associated with deterioration in a patient's condition

For the following questions (2.1.1-2.1.11), please circle the most appropriate answer from the selection options a -d.

2.1.1	A patient who is in hypovolaemic shock (and has low blood pressure) will have a. Normal capillary refill b. Cold clammy skin c. Facial flushing d. Warm dry hands
2.1.2	A patient with hypoxia (lack of oxygen) is likely to be a. Confused b. Pink c. Happy d. Hot
2.1.3	Slow capillary refill is a sign of a. Vasoconstriction and poor peripheral perfusion b. Malnutrition and dehydration c. Warm hands and feet d. Reduced concentrations of oxyhaemoglobin
2.1.4	The pulse can be palpated a. Every time the atria contracts

	b. When a vein is close to the surface of the skin c. Every time the left ventricle contracts d. When an artery is close to the surface of the skin
2.1.5	A normal heart rate for an adult at rest is a. 60-80 beats per minute (bpm) b. 60-100 bpm c. 60-90 bpm d. 60-110 bpm
2.1.6	Select the three appropriate statements to complete the sentence: Pulse oximeters (oxygen saturation probe) may be unreliable when…… 1. tissue perfusion is poor; 2. the patient is wearing nail varnish; 3. haemoglobin is 100% saturated; 4. measured on the ear lobe; 5. the patient has a cold; 6. haemoglobin levels are low; 7. digits are cold; 8. the patient is elderly. a. 1, 2 & 7 b. 2, 3 & 6 c. 1, 4 & 8 d. 2, 5 & 7
2.1.7	Select the three appropriate statements to complete the sentence: When assessing a patient's breathing…….. 1, Assess for 30 seconds; 2. look for chest movements; 3. use a mirror to check for exhaled air; 4. listen for breath sounds; 5. feel for exhaled air on your cheek; 6. always remove dentures. a. 1, 2 & 4 b. 2, 3 & 5 c. 2, 4 & 5 d. 1, 4 & 6
2.1.8	A 14-16 gauge needle is most likely to be used for a. Elderly patients b. Paediatric patients c. Inserting in the back of the hand d. Trauma or burns patients
2.1.9	Which of the following is NEVER compatible with a cardiac output (adequate blood circulation): a. Supraventricular tachycardia b. Ventricular tachycardia c. Atrial fibrillation d. Ventricular fibrillation
2.1.10	A.V.P.U. stands for? a. Alert, Visual, Peripheral, Unconscious b. Altered, Verbal, Pain, Unresponsive c. Anxious, Violent, Paranoid Unsettled d. Alert, Voice, Pain, Unresponsive
2.1.11	When using a non-rebreathe mask a. 40% O_2 is delivered to the patient b. 100% O_2 is delivered to the patient c. The reservoir bag should not be inflated prior to placing on the patient's face d. O_2 flow rates of approximately 15 litres a minute are required in adults

Reference:

Adapted from: Cooper, S., Kinsman, L., Buykx, P., McConnell-Henry, T., Endacott, R., & Scholes, J. (2010). Managing the deteriorating patient in a simulated environment: nursing students' knowledge, skill and situation awareness. *Journal of Clinical Nursing, 19*(15-16), 2309-2318.

Write down the values (numbers) for each of the physiological parameters (vital signs) below that you consider to be an EARLY sign of deterioration (worsening) in a patient's condition that would cause you to seek assistance (help) from a more skilled healthcare professional.

No.	Physiological parameters (vital signs)	I will call for a review of the patient for the following values indicating EARLY signs of deterioration (worsening) in a patient's condition:
2.2.1	Increased systolic blood pressure (hypertension)	
2.2.2	Decreased systolic blood pressure (hypotension)	
2.2.3	Increased heart rate (tachycardia)	
2.2.4	Decreased heart rate (bradycardia)	
2.2.5	Increased respiratory rate (tachypnea)	
2.2.6	Decreased respiratory rate (bradypnea)	
2.2.7	Increased temperature (pyrexia)	
2.2.8	Oxygen saturation	
2.2.9	Level of consciousness	

Select the clinical observations below that you consider an indication of deterioration (worsening) in a patient's condition that would cause you to seek the assistance (help) from a more skilled healthcare professional for review of the patient.
More than one option can be selected from the list below. Indicate your selection with a (X).

No.	Clinical observations	Selection
2.3.1	Decreased urine output	
2.3.2	Signs of bleeding	
2.3.3	Pain	
2.3.4	Sweating	
2.3.5	Decreased haemoglobin	
2.3.6	Hypoglycaemia (decreased blood glucose level)	
2.3.7	Increase in the capillary refill time	
2.3.8	Change in skin colour	
2.3.9	Change in appearance	

References:
De Meester, K., Van Bogaert, P., Clarke, S. P., & Bossaert, L. (2013). In-hospital mortality after serious adverse events on medical and surgical nursing units: a mixed methods study. *Journal of Clinical Nursing, 22*(15-16), 2308-2317.
Kyriacos, U. (2011). *The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients.* (Doctor of Philosophy), University of Cape Town.

Section 3: Self-reported clinical reasoning ability

Using the following scale, please select the most appropriate response to each of the questions listed below.
Scale: 5 = Strongly agree, 4 = Agree, 3 = Neutral, 2 = Disagree, 1 = Strongly disagree.

No	Nurses clinical reasoning scale (NCRS)	5	4	3	2	1
3.1	I know how to collect an admitted patient's health information quickly.					
3.2	I can apply proper assessment skills to collect a patient's current health information.					
3.4	I can identify abnormalities from the collected patient information.					
3.5	I can identify a patient's health problems from the abnormal information collected.					
3.6	I can recognize possible early signs or symptoms when a patient's health deteriorates.					
3.7	I can explain the mechanism and development associated with the early signs or symptoms when a patient's health deteriorates.					
3.8	I can accurately prioritize and manage any identifiable patient problems.					
3.9	I can correctly explain the mechanism behind a patient's problems.					
3.10	I can set nursing goals properly for the identified patient problems.					
3.11	I can provide appropriate nursing interventions for identified patient problems.					
3.12	I am knowledgeable of each nursing intervention provided.					
3.13	I can identify and communicate vital information clearly to the doctors based on the patient's current condition.					
3.14	I can anticipate the intervention requested by the doctor according to the patient information provided.					

No	Nurses clinical reasoning scale (NCRS)	5	4	3	2	1
3.15	I can accurately evaluate and identify whether a patient's condition is improved.					
3.16	I know the follow-up steps to take if a patient's condition does not improve.					

Reference:

Liou, S. R., Liu, H. C., Tsai, H. M., Tsai, Y. H., Lin, Y. C., Chang, C. H., & Cheng, C. Y. (2016). The development and psychometric testing of a theory-based instrument to evaluate nurses' perception of clinical reasoning competence. *Journal of Advanced Nursing, 72*(3), 707-717.

Section 4: Demographic data

4.1 Highest nursing related qualification (select one option relevant to you)

Doctoral Degree in Nursing	
Master's Degree in Nursing	
Postgraduate/post basic diploma in Nursing related field	
Bachelor's degree in Nursing	
Diploma in Nursing (Bridging Course)	
Diploma in Nursing: 4 year diploma	
Diploma in Nursing: 3 year diploma	
Certificate leading to enrolment as a nurse	
Certificate leading to enrolment as a nurse auxiliary	

4.2 Are you currently studying?

Yes	
No	

4.3 If you answered "yes" to question 4.2, please indicate what you are currently studying

Doctoral Degree in Nursing	
Master's Degree in Nursing	
Post graduate/post basic diploma in Nursing related field	
Bachelor's degree in Nursing	
Diploma in Nursing (Bridging Course)	
Diploma in Nursing: 4 year diploma	
Diploma in Nursing: 3 year diploma	
Certificate leading to enrolment as a nurse	
Certificate leading to enrolment as a nurse auxiliary	
Other (please specify)_____	
Not applicable as not studying	

4.4 Your age (in years)

4.5 Your gender

Male	
Female	
Non-binary	

4.6 Your home language

4.7 The number of years of clinical experience as a nurse

4.8 Have you attended a Cardiopulmonary Resuscitation (CPR) / Basic Life Support (BLS) Course?

Yes	
No	

4.9 If you answered "yes" to the question in 4.8 above, when did you attend the CPR/BLS Course? (Indicate the year in which you attended the training)

Year	

Not applicable as I have not attended such a course	

4.10 Do you currently have access to the following electronic devices? (More than one device may be selected)

Computer / Laptop	
Tablet device	
Smart Phone	
Other device (please specify)_____	
No access to any electronic device	

4.11 If you selected one of the electronic devices in question 4.10, do you have internet access from the electronic device?

Yes	
No	
Sometimes	
Not applicable as I do not have an electronic device	

4.12 Where do you have the internet access?

At home	
At work	
From 3G Sim Card in the electronic device	
Other:_____(Please specify)	
Not applicable as I do not have an electronic device	

Thank you for completing the questionnaire.

Appendix B - Content validity index assessment form

Evaluation of content validity index

Rating scale: 1= irrelevant; 2 = unable to assess relevance without item revision; 3 = relevant but needs minor alteration; 4 = extremely relevant.

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Comments
Section 1: Factors influencing your ability to recognise and respond to patient deterioration						
1.1	My nursing qualification adequately prepared me to take / measure clinical observations and vital signs.					
1.2	I am unsure how to respond to changes in patients' clinical observations and vital signs.					
1.3	Interpreting patient observations and vital signs is an essential part of my role.					
1.4	I feel confident recording patients' clinical observations and vital signs.					
1.5	I feel knowledgeable when interpreting patients' clinical observations and vital signs which show altered physiology.					
1.6	My nursing qualification adequately prepared me to interpret patients' clinical observations and vital signs.					
1.7	It is important to respond to any changes in patients' clinical observations and vital signs.					
1.8	I believe that there is a deficit in my understanding of altered physiology associated with patients' clinical observations and vital signs.					
1.9	I am expected to take / measure patients' clinical observations and vital signs.					
1.10	I know how often I should take /measure patients' clinical observations and vital signs for the patients that I am allocated to provide care for in the clinical unit.					
1.11	The clinical unit in which I am employed has a policy or work procedure that prescribes the frequency of taking/measuring clinical observations and vital signs.					

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Comments
1.12	The clinical unit in which I am employed has a policy or work procedure that prescribes the action that I should take if I recognise deterioration in a patient's clinical observations and vital signs.					
1.13	The registered nurse in the clinical unit checks the documented vital signs and clinical observations of every patient.					
1.14	I am adequately prepared to communicate with a more skilled healthcare professional about deterioration in a patient's condition.					
1.15	I am able to use the accepted nursing terminology to communicate with a more skilled healthcare professional about deterioration in a patient's condition.					
1.16	I use a communication tool as a guide to communicate the relevant information about deterioration in a patient's condition to a more skilled healthcare professional.					
1.17	I always document the information communicated to a more skilled healthcare professional about deterioration in a patient's condition in the patient's nursing records.					
1.18	I am confident that the more skilled healthcare professional will act timeously on the information that I communicate to them regarding the patient's deteriorating condition.					
1.19	Information about the patient's deteriorating condition that I communicate to a more skilled healthcare professional is taken into consideration.					
1.20	When reporting my concern regarding a patient's condition to a more skilled healthcare professional, I fear being criticised for reporting on a patient who is not that sick.					
1.21	I have the necessary equipment to take / measure clinical observations and vital signs.					
1.22	In the clinical unit where I work I feel that I am an essential member of the multidisciplinary team responsible for the recognition of and response to deterioration in a patients' condition.					
1.23	I understand the consequences of failing to identify and report deterioration in a patient's condition.					

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Comments
1.24	I measure and record every clinical observation and vital sign every time I am required to measure and record patients' clinical observations and vital signs.					
1.25	I have experienced a situation where the deterioration in a patient's condition was not recognised leading to Cardiopulmonary resuscitation (CPR); transfer of the patient to the High Care or Intensive Care unit; or death of the patient.					
Section 2: Nurses' knowledge of physiological and clinical parameters associated with deterioration in a patient's condition						
2.1.1	A patient who is in hypovolaemic shock (and has low blood pressure) will have a. Normal capillary refill b. Cold clammy skin c. Facial flushing d. Warm dry hands					
2.1.2	A patient with hypoxia (lack of oxygen) is likely to be a. Confused b. Pink c. Happy d. Hot					
2.1.3	Slow capillary refill is a sign of a. Vasoconstriction and poor peripheral perfusion b. Malnutrition and dehydration c. Warm hands and feet d. Reduced concentrations of oxyhaemoglobin					
2.1.4	The pulse can be palpated a. Every time the atria contracts a. When a vein is close to the surface of the skin b. Every time the left ventricle contracts c. When an artery is close to the surface of the skin					
2.1.5	A normal heart rate for an adult at rest is a 60-80 beats per minute (bpm) a. 60-100 bpm					

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Comments
	b. 60-90 bpm c. 60-110 bpm					
2.1.6	Select the three appropriate statements to complete the sentence: Pulse oximeters (oxygen saturation probe) may be unreliable when…… 1. tissue perfusion is poor; 2. the patient is wearing nail varnish; 3. haemoglobin is 100% saturated; 4. measured on the ear lobe; 5. the patient has a cold; 6. haemoglobin levels are low; 7. digits are cold; 8. the patient is elderly. a. 1, 2 & 7 b. 2, 3 & 6 c. 1, 4 & 8 d. 2, 5 & 7					
2.1.7	Select the three appropriate statements to complete the sentence: When assessing a patient's breathing…….. 1, Assess for 30 seconds; 2. look for chest movements; 3. use a mirror to check for exhaled air; 4. listen for breath sounds; 5. feel for exhaled air on your cheek; 6. always remove dentures. a. 1, 2 & 4 b. 2, 3 & 5 c. 2, 4 & 5 d. 1, 4 & 6					
2.1.8	A 14-16 gauge needle is most likely to be used for a. Elderly patients b. Paediatric patients c. Inserting in the back of the hand					

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Comments
	d. Trauma or burns patients					
2.1.9	Which of the following is NEVER compatible with a cardiac output (adequate blood circulation): a. Supraventricular tachycardia b. Ventricular tachycardia c. Atrial fibrillation d. Ventricular fibrillation					
2.1.10	A.V.P.U. stands for? a. Alert, Visual, Peripheral, Unconscious b. Altered, Verbal, Pain, Unresponsive c. Anxious, Violent, Paranoid Unsettled d. Alert, Voice, Pain, Unresponsive					
2.1.11	When using a non-rebreathe mask a. 40% O_2 is delivered to the patient b. 100% O_2 is delivered to the patient c. The reservoir bag should not be inflated prior to placing on the patient's face d. O_2 flow rates of approximately 15 litres a minute are required in adults					
2.2	**Write down** the values (numbers) for each of the physiological parameters (vital signs) below that you consider an **EARLY** sign of deterioration (worsening) in a patient's condition that would cause you to seek assistance (help) from a more skilled healthcare professional. 2.2.1 Increased systolic blood pressure (hypertension) 2.2.2 Decreased systolic blood pressure (hypotension) 2.2.3 Increased heart rate (tachycardia) 2.2.4 Decreased heart rate (bradycardia) 2.2.5 Increased respiratory rate (tachypnea) 2.2.6 Decreased respiratory rate (bradypnea) 2.2.7 Increased temperature (pyrexia) 2.2.8 Oxygen saturation					

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Comments
	2.2.9 Level of consciousness					
2.3	**Select the** clinical parameters below that you consider an indication of deterioration (worsening) in a patient's condition that would cause you to seek the assistance (help) from a more skilled healthcare professional for review of the patient. More than one option can be selected from the list below. Indicate your selection with a (X). 2.3.1 Decreased urine output 2.3.2 Signs of bleeding 2.3.3 Pain 2.3.4 Sweating 2.3.5 Decreased haemoglobin 2.3.6 Hypoglycaemia (decreased blood glucose level) 2.3.7 Increase in the capillary refill time 2.3.8 Change in skin colour 2.3.9 Change in appearance					
Section 3: Self-reported clinical reasoning ability						
3.1	I know how to collect an admitted patient's health information quickly.					
3.2	I can apply proper assessment skills to collect a patient's current health information.					
3.3	I can identify abnormalities from the collected patient information.					
3.4	I can identify a patient's health problems from the abnormal information collected.					
3.5	I can recognize possible early signs or symptoms when a patient's health deteriorates.					
3.6	I can explain the mechanism and development associated with the early signs or symptoms when a patient's health deteriorates.					
3.7	I can accurately prioritize and manage any identifiable patient problems.					
3.8	I can correctly explain the mechanism behind a patient's problems.					

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Comments
3.9	I can set nursing goals properly for the identified patient problems.					
3.10	I can provide appropriate nursing interventions for identified patient problems.					
3.11	I am knowledgeable of each nursing intervention provided.					
3.12	I can identify and communicate vital information clearly to the doctors based on the patient's current condition.					
3.13	I can anticipate the intervention requested by the doctor according to the patient information provided.					
3.14	I can accurately evaluate and identify whether a patient's condition is improved.					
3.15	I know the follow-up steps to take if a patient's condition does not improve.					
Section 4: Demographic data						
4.1	Highest nursing related qualification (select one option relevant to you): Doctoral Degree in Nursing Master's Degree in Nursing Postgraduate/post basic diploma in Nursing related field Bachelor's degree in Nursing Diploma in Nursing (Bridging Course) Diploma in Nursing: 4 year diploma Diploma in Nursing: 3 year diploma Certificate leading to enrolment as a nurse Certificate leading to enrolment as a nurse auxiliary					
4.2	Are you currently studying? Yes No					
4.3	If you answered "yes" to question 4.2, please indicate what you are currently studying: Doctoral Degree in Nursing Master's Degree in Nursing					

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Comments
	Post graduate/post basic diploma in Nursing related field Bachelor's degree in Nursing Diploma in Nursing (Bridging Course) Diploma in Nursing: 4 year diploma Diploma in Nursing: 3 year diploma Certificate leading to enrolment as a nurse Certificate leading to enrolment as a nurse auxiliary Other (please specify)_____ Not applicable as not studying					
4.4	Your age (in years)					
4.5	Your gender: Male Female Non-binary					
4.6	Your home language					
4.7	The number of years of clinical experience as a nurse					
4.8	Have you attended a Cardiopulmonary Resuscitation (CPR) / Basic Life Support (BLS) Course? Yes No					
4.9	If you answered "yes" to the question in 4.8 above, when did you attend the CPR/BLS Course? (Indicate the year in which you attended the training): Year _____ Not applicable as I have not attended such a course					
4.10	Do you currently have access to the following electronic devices? (More than one device may be selected): Computer / Laptop Tablet device Smart Phone Other device (please specify)_____					

No.	Item	1 = Irrelevant	2 = Unable to assess relevance without item revision	3 = Relevant but needs minor alteration	4 = Extremely relevant	Comments
	No access to any electronic device					
4.11	If you selected one of the electronic devices in question 4.10, do you have internet access from the electronic device? Yes No Sometimes Not applicable as I do not have an electronic device					
4.12	Where do you have the internet access? At home At work From 3G Sim Card in the electronic device Other:_____(Please specify) Not applicable as I do not have an electronic device					

Evaluation of the face validity of the prototype questionnaire					
Please comment on the readability and clarity (face validity) of the prototype questionnaire**	4 = Excellent	3= Satisfactory	2=Requires improvement	1=Unsatisfactory	Comments
The layout of the questionnaire					
The format of the questionnaire					
The quality of the printing					
The length of the questionnaire					

Evaluation of the face validity of the prototype questionnaire					
Please comment on the readability and clarity (face validity) of the prototype questionnaire**	4 = Excellent	3= Satisfactory	2=Requires improvement	1=Unsatisfactory	Comments
The response scales used in the questionnaire					
Visually easy to read					
Visually easy to comprehend					
The clarity of the instructions at the beginning of the questionnaire					
The clarity of the instructions included in the questionnaire					
Please indicate omissions identified: _____ _____					
Additional comments: _____ _____					

Thank you for completing the evaluation.

Reference:
**Adapted with permsision: Kyriacos, U. (2011). *The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients. (*PhD thesis*)*, University of Cape Town, Cape Town.
Lynn, M. R. (1986). Determination and Quantification of Content Validity. *Nursing Research, 35*(6), 382-385.

Appendix C - Respondent information sheet and respondent consent for the evaluating the content validity index (CVI) and face validity of the questionnaire

Respondent code_____

Respondent information sheet

Title of the study: **The development and validation of a questionnaire on early recognition of clinical deterioration: a mixed methods study**

Introduction and background

I am currently a Masters in Nursing Science Degree candidate with the Division of Nursing and Midwifery at the University of Cape Town with an interest in the occurrence of adverse events (AEs) in the healthcare environment that have triggered national and international concern. For the purposes of this study, AEs refer to the events in the healthcare general ward setting where there is evidence of the failure to recognise clinical and physiological signs of deterioration, failure to take action, failure to initiate a call for a more qualified healthcare professional to review the patient, or failure of a more qualified healthcare professional to respond to the call for review timeously.

The critical need to improve nurses' recognition of and response to deterioration in a patient's condition to reduce the risk of harm and AEs, has resulted in the implementation of recommendations for healthcare establishments internationally. Recommendations include the introduction of an early warning scoring system and a training programme to support nurses in early identification of deterioration in a patient's condition and triggering of timeous actions in response to the change in condition.

The purpose of this study is to focus on the development and validation of a questionnaire as a measurement tool to assess: 1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; 2) nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and 3) nurses' self-reported clinical reasoning ability. The validity and reliability of the developed questionnaire (Appendix A) will be assessed using the processes of content validity index calculation; cognitive interviewing and test-retest reliability testing.

Clarification of terminology

The term *validity* refers to the ability of a tool or test such as a questionnaire to measure what it is intended to measure (Polit & Beck, 2017).

The *content validity index* for the individual items in the questionnaire refers to the use of a Likert scale to indicate whether the items and the measurement instrument are relevant and representative of the intended construct being measured (Lynn, 1986; Polit & Beck, 2017).

Purpose of the content validation evaluation

The purpose of determining the content validity index for the individual items is to enable experts to assess if the items and the measurement instrument are relevant and representative of the intended construct being measured. You are asked to rate each item using a Likert scale with four points ranging from 1 to 4, namely: irrelevant; unable to assess relevance without item revision; relevant but needs minor alteration; extremely relevant respectively. Each question item will have a column for "comments", should you need to expand on your rating; if there is a preference for the question item to be re-phrased to improve the relevance or if you recommend an item that may been omitted from the instrument during the developmental phase.

The final section requires you to rate and comment on the face validity of the questionnaire, for example the readability of the questionnaire, the font type and size, the layout, and clarity of the instructions.

Has ethics approval been granted for the study?

Yes, ethics approval for this study has been granted by the University of Cape Town's Faculty of Health Sciences' Human Research Ethics Committee (HREC REF: 881/2016).

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

You have been invited to participate in this study as a nurse with a Master's Degree, a Postgraduate Diploma in Nursing Education and considered to have expert knowledge in the field of the biosciences and health sciences research.

How will you participate in the study?

The researcher will personally explain the study to you and your involvement and will give you this document which includes a consent form (Appendix C), the tool for evaluating the content validity index which includes evaluation of the face validity of the questionnaire (Appendix B) and the prototype questionnaire (Appendix A). The language used in all communication and documentation will be English as it is the language of instruction in the education and health care system in which the validation of the questionnaire will be conducted. If you decide to participate in the study, you will be asked to sign the respondent consent section of this document. Please complete the evaluation individually and email the prototype questionnaire and the content validity index assessment tool to the researcher or if in close proximity, hand back to the researcher within two weeks of receipt of the document. Please return the informed consent document together with the completed evaluation document if not done before. If you suggest significant changes, the research will contact you to discuss the amendments suggested.

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

It is anticipated that the researcher will be able to explain the nature of the study and your participation together with an opportunity for you to ask questions (either face to face or telephonically) within 20 minutes. Alternatively, you can email queries to the researcher using the email address supplied in this document. Thereafter, the time commitment from you to complete the tool for evaluating the content validity index of the questionnaire (Appendix B) is expected to be 60 minutes.

Are there any risks associated with participation in this study?

There are no anticipated risks for respondents. Your thoughts and feedback will remain confidential. The researcher is not intending to test your knowledge through your participation, but rather to gather information from you as part of the validity assessment of the questionnaire itself.

Are there any benefits associated with participation in this study?

The benefits to the respondents will be the altruistic internal gratification of contributing to the validation of the questionnaire for the purposes as outlined in the study. Further research, outside the scope of this study, is anticipated for use of the questionnaire in understanding the educational requirements for a nurse training programme for the recognition of and response to patient deterioration in the general wards of the private healthcare establishment at a later stage. There will be no financial gain from participating in this study.

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

You are free to decide not to participate in the study or to withdraw from participation during the study without any coercion or retribution.

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

The data gathered from the content validity evaluation will be anonymous (see the code number) and confidential and stored securely by the researcher for the duration of the study and three years thereafter. The results of the study will be disseminated via conference presentations and publication of a journal article/s in a peer reviewed scientific journal.

Who can be contacted in the event of questions related to the study?

Researcher:	**Supervisor:**
Briony Berning (MSc candidate, Division of Nursing & Midwifery, University of Cape Town) 7 Gerard Road Lakeside 7945 Telephone Number: 0721481467 E-mail: prkbri002@myuct.ac.za	Associate Professor Una Kyriacos Division of Nursing & Midwifery Department of Health & Rehabilitation Sciences Faculty of Health Sciences University of Cape Town Observatory 7925 Telephone Number: 021 406 6410 E-mail: una.kyriacos@uct.ac.za

The University of Cape Town's Ethics Committee can be contacted directly in the event that there are concerns or questions related to the ethical considerations of this study.

Human Research Ethics Committee details:
Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
OBSERVATORY, 7925

Professor Marc Blockman (Chairman)
Telephone number: 021 406 6338
E-mail: marc.blockman@uct.ac.za

Consent to participation in the study

Please read the consent related statements below. Document your agreement to each statement by writing your initials in the right hand column for each statement, documenting your full name and signature in the space provided and then return to the researcher by hand or via email.

No	Consent statements	Initial
1	I _____ (name) as a respondent hereby confirm that I have read and understand the respondent information for the study. I confirm that I have been given the opportunity to pose questions and have them answered satisfactorily.	
2	I understand that my participation in the study is not connected to my current employment and will take place during my own time.	
3	I understand that I can withdraw from the study at any time free from any retribution.	
4	I am aware that my personal details on this consent form will remain confidential during this study.	
5	I hereby accept the statement made by the researcher that there are no anticipated risks associated with participating in this study.	
6	I am aware that there may be no direct benefit to me for participating in this study.	
7	I hereby freely confirm my consent to participate in this study.	

Respondent‘s full name	Signature	Date
Researcher’s full name	Signature	Date

Thank you for agreeing to participate in this study.

Appendix D – Revised prototype questionnaire for the cognitive interviews

Dear Respondent

The **purpose of this questionnaire** is to assess:

1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward;

2) nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and

3) nurses' self-reported clinical reasoning ability.

Definitions of terms or phrases used in this questionnaire:

"*observations" refers to refer to the subjective and objective findings gathered during a patient assessment. For example, pain, bleeding, sweating, skin colour.*

"vital signs" refers to the blood pressure, heart rate, respiratory rate, temperature, oxygen saturation, and the level of consciousness.

"deterioration in a patient's condition" refers to worsening of a patient's condition where assistance from a more skilled healthcare professional is required in order to manage the patient.

This questionnaire consists of four (4) sections. The fourth section relates to your demographic data.

Please complete the questionnaire by answering all the questions directly onto this document as per each sections instruction.

Section 1: Factors influencing your ability to recognise and respond to patient deterioration

Using the following scale, please select the most appropriate response to each of the questions listed below.
Scale: 5 = Strongly agree, 4 = Agree, 3 = Neutral, 2 = Disagree, 1 = Strongly disagree

No.	Factors influencing your ability to recognise and respond to patient deterioration	5	4	3	2	1
*1.1	My nursing qualification adequately prepared me to take/measure clinical observations and vital signs.					
*1.2	I am unsure how to respond to changes in patients' clinical observations and vital signs.					
*1.3	Interpreting patient observations and vital signs is an essential part of my role.					
*1.4	I feel confident recording patients' clinical observations and vital signs.					
*1.5	*I have the knowledge to interpret patients' clinical observations and vital signs which show a change in physiology.*					
*1.6	My nursing qualification adequately prepared me to interpret patients' clinical observations and vital signs.					
*1.7	It is important to respond to any changes in patients' clinical observations and vital signs.					
*1.8	I believe that there is a deficit in my understanding of altered physiology associated with patients' clinical observations and vital signs.					
**1.9	I am expected to take / measure patients' clinical observations and vital signs.					
1.10	I know how often I should take /measure patients' clinical observations and vital signs for the patients that I am allocated to provide care for in the clinical unit.					
1.11	The clinical unit in which I am employed has a policy or work procedure that prescribes the frequency of taking/measuring clinical observations and vital signs.					
1.12	The clinical unit in which I am employed has a policy or work procedure that prescribes the action that I should take if I recognise deterioration in a patient's clinical observations and vital signs.					
1.13	The registered nurse in the clinical unit checks the documented vital signs and clinical observations of every patient.					
1.14	I am adequately prepared to communicate with a more skilled					

No.	Factors influencing your ability to recognise and respond to patient deterioration	5	4	3	2	1
	healthcare professional about deterioration in a patient's condition.					
1.15	I am able to use the accepted nursing terminology to communicate with a more skilled healthcare professional about deterioration in a patient's condition.					
1.16	*I use a communication tool (for example the Situation, Background, Assessment and Recommendation / SBAR tool) as a guide to communicate the relevant information about deterioration in a patient's condition to a more skilled healthcare professional.*					
1.17	I always document the information communicated to a more skilled healthcare professional about deterioration in a patient's condition in the patient's nursing records.					
1.18	I am confident that the more skilled healthcare professional will act timeously on the information that I communicate to them regarding the patient's deteriorating condition.					
1.19	Information about the patient's deteriorating condition that I communicate to a more skilled healthcare professional is taken into consideration.					
1.20	When reporting my concern regarding a patient's condition to a more skilled healthcare professional, I fear being criticised for reporting on a patient who is not that sick.					
1.21	I have the necessary equipment to take / measure clinical observations and vital signs.					
1.22	In the clinical unit where I work I feel that I am an essential member of the multidisciplinary team responsible for the recognition of and response to deterioration in a patient's condition.					
1.23	I understand the consequences of failing to identify and report deterioration in a patient's condition.					
1.24	I measure and record every clinical observation and vital sign every time I am required to measure and record patients' clinical observations and vital signs.					
1.25	I have experienced a situation where the deterioration in a patient's condition was not recognised leading to Cardiopulmonary resuscitation (CPR); transfer of the patient to the High Care or Intensive Care unit; or death of the patient.					

References:

*Adapted from Perkins, C., & Kisiel, M. (2013). Developing the recognition and response skills of student nurses. *British Journal of Nursing,* 22(12), 715-724.

Astroth, K. S., Woith, W. M., Stapleton, S. J., Degitz, R. J., & Jenkins, S. H. (2013). Qualitative exploration of nurses' decisions to activate rapid response teams. *Journal of Clinical Nursing, 22*(19/20), 2876-2882.

De Meester, K., Van Bogaert, P., Clarke, S. P., & Bossaert, L. (2012). In-hospital mortality after serious adverse events on medical and surgical nursing units: a mixed methods study. *Journal of Clinical Nursing, 22*, 2308-2317.

Kyriacos, U., Jelsma, J., & Jordan, S. (2011). Monitoring vital signs using early warning scoring systems: a review of the literature. *Journal of Nursing Management, 19*, 311-330.

Mok, W., Wang, W., Cooper, S., Ang, E. N., & Liaw, S. Y. (2015). Attitudes towards vital signs monitoring in the detection of clinical deterioration: scale development and survey of ward nurses. *International Journal for Quality in Health Care, 27*(3), 207-213.

Section 2: Nurses' knowledge of physiological and clinical parameters associated with deterioration in a patient's condition

For the following questions (2.1.1-2.1.11), please circle the most appropriate answer from the selection options: a - d.

2.1.1	A patient who is in hypovolaemic shock (and has low blood pressure) will have a. Normal capillary refill b. Cold clammy skin c. Facial flushing d. Warm dry hands
2.1.2	*A patient with hypoxia (lack of oxygen) is likely to be* *a. Confused* *b. Pink* *c. Orientated to their surroundings* d. *Sweating*
2.1.3	Slow capillary refill is a sign of a. Vasoconstriction and poor peripheral perfusion b. Malnutrition and dehydration c. Warm hands and feet d. Reduced concentrations of oxyhaemoglobin
2.1.4	The pulse can be palpated a. Every time the atria contracts b. When a vein is close to the surface of the skin c. Every time the left ventricle contracts d. When an artery is close to the surface of the skin
2.1.5	*A normal heart rate for an adult at rest is* a. *60-80 beats per minute (bpm)* b. *60-90 bpm* c. *60-100 bpm* d. *60-110 bpm*
2.1.6	*Pulse oximeters (oxygen saturation probe) may be unreliable when……* *a. Extremities are cold* *b. The patient is wearing nail varnish* *c. Tissue perfusion is poor* *d. All of the above*
2.1.7	*When assessing a patient's breathing……* *a. Assess the patient's breathing for 15 seconds* *b. Assess for 30 -60 seconds looking for chest movement* *c. Use a mirror to check for exhaled air;* *d. The oxygen saturation is more important than the respiratory rate.*
2.1.8	A.V.P.U. stands for? a. Alert, Visual, Peripheral, Unconscious b. Altered, Verbal, Pain, Unresponsive c. Anxious, Violent, Paranoid Unsettled d. Alert, Voice, Pain, Unresponsive

Reference:

Adapted from: Cooper, S., Kinsman, L., Buykx, P., McConnell-Henry, T., Endacott, R., & Scholes, J. (2010). Managing the deteriorating patient in a simulated environment: nursing students' knowledge, skill and situation awareness. *Journal of Clinical Nursing, 19*(15-16), 2309-2318.

Write down the values (numbers) for each of the physiological parameters (vital signs) below that you consider to be an EARLY sign of deterioration (worsening) in a patient's condition that would cause you to seek assistance (help) from a more skilled healthcare professional.

No.	**Physiological parameters (vital signs)**	**I will call for a review of the patient for the following values indicating EARLY signs of deterioration (worsening) in a patient's condition:**
2.2.1	Increased systolic blood pressure (hypertension)	
2.2.2	Decreased systolic blood pressure (hypotension)	
2.2.3	Increased heart rate (tachycardia)	
2.2.4	Decreased heart rate (bradycardia)	

No.	Physiological parameters (vital signs)	I will call for a review of the patient for the following values indicating EARLY signs of deterioration (worsening) in a patient's condition:
2.2.5	Increased respiratory rate (tachypnea)	
2.2.6	Decreased respiratory rate (bradypnea)	
2.2.7	Increased temperature (pyrexia)	
2.2.8	Oxygen saturation	
2.2.9	Level of consciousness	

Select the clinical observations below that you consider an indication of deterioration (worsening) in a patient's condition that would cause you to seek the assistance (help) from a more skilled healthcare professional for review of the patient.
More than one option can be selected from the list below. Indicate your selection with a (X).

No.	Clinical observations	Selection
2.3.1	Decreased urine output	
2.3.2	Signs of bleeding	
2.3.3	Pain	
2.3.4	Sweating	
2.3.5	Decreased haemoglobin	
2.3.6	Hypoglycaemia (decreased blood glucose level)	
2.3.7	Increase in the capillary refill time	
2.3.8	Change in skin colour	
2.3.9	Change in appearance	

References:
De Meester, K., Van Bogaert, P., Clarke, S. P., & Bossaert, L. (2013). In-hospital mortality after serious adverse events on medical and surgical nursing units: a mixed methods study. *Journal of Clinical Nursing, 22*(15-16), 2308-2317.
Kyriacos, U. (2011). *The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients.* (Doctor of Philosophy), University of Cape Town.

Section 3: Self-reported clinical reasoning ability

Using the following scale, please select the most appropriate response to each of the questions listed below.
Scale: 5 = Strongly agree, 4 = Agree, 3 = Neutral, 2 = Disagree, 1 = Strongly disagree.

No	Nurses clinical reasoning scale (NCRS)	5	4	3	2	1
3.1	I know how to collect an admitted patient's health information quickly.					
3.2	I can apply proper assessment skills to collect a patient's current health information.					
3.3	I can identify abnormalities from the collected patient information.					
3.4	I can identify a patient's health problems from the abnormal information collected.					
3.5	I can recognize possible early signs or symptoms when a patient's health deteriorates.					
3.6	*I can explain the pathophysiology associated with the early signs or symptoms when a patient's health deteriorates.*					
3.7	I can accurately prioritize and manage any identifiable patient problems.					
3.8	*I can correctly explain the pathophysiology behind a patient's problems.*					
3.9	I can provide appropriate nursing interventions for identified patient problems.					
3.10	I can provide appropriate nursing interventions for identified patient problems.					
3.11	I am knowledgeable of each nursing intervention provided.					
3.12	I can identify and communicate vital information clearly to the doctors based on the patient's current condition.					
3.13	I can anticipate the intervention requested by the doctor according to the patient information provided.					
3.14	I can accurately evaluate and identify whether a patient's condition is improved.					
3.15	I know the follow-up steps to take if a patient's condition does not improve.					

Reference:
Liou, S. R., Liu, H. C., Tsai, H. M., Tsai, Y. H., Lin, Y. C., Chang, C. H., & Cheng, C. Y. (2016). The development and psychometric testing of a theory-based instrument to evaluate nurses' perception of clinical reasoning competence. *Journal of Advanced Nursing, 72*(3), 707-717.

Section 4: Demographic data

4.1 Highest nursing related qualification (select one option relevant to you)

Doctoral Degree in Nursing	
Master's Degree in Nursing	
Postgraduate/post basic diploma in Nursing related field	
Bachelor's degree in Nursing	
Diploma in Nursing: 4 year diploma	
Diploma in Nursing (Bridging Course)	
Diploma in Nursing: 3 year diploma	
Certificate leading to enrolment as a nurse	
Certificate leading to enrolment as a nurse auxiliary	

4.2 *Are you currently registered at an education institution for nursing studies?*

Yes	
No	

4.3 *If you answered "yes" to question 4.2, please indicate the programme that you are registered for currently.*

Doctoral Degree in Nursing	
Master's Degree in Nursing	
Post graduate/post basic diploma in Nursing related field	
Bachelor's degree in Nursing	
Diploma in Nursing: 4 year diploma	
Diploma in Nursing (Bridging Course)	
Diploma in Nursing: 3 year diploma	
Certificate leading to enrolment as a nurse	
Certificate leading to enrolment as a nurse auxiliary	
Other (please specify)_____	
Not applicable as not studying	

4.4 Your age (in years)

4.5 Your gender

Male	
Female	
Non-binary	

4.6 Your home language

4.7 The number of years of clinical experience as a nurse

4.8 Have you attended a Cardiopulmonary Resuscitation (CPR) / Basic Life Support (BLS) Course

Yes	
No	

4.9 If you answered "yes" to the question in 4.8 above, when did you attend the CPR/BLS Course? (Indicate the year in which you attended the training)

Year	
Not applicable as I have not attended such a course	

4.10 *Do you currently have access to the following electronic devices? (Indicate with an "X". More than one device may be selected)*

Computer / Laptop	
Tablet device	
Smart Phone	
Other device (please specify)_____	

Not applicable as I do not have an electronic device	

4.11 *If you selected one of the electronic devices in question 4.10, do you have internet access from the electronic device? (Indicate with an "X".)*

Yes	
No	
Sometimes	
Not applicable as I do not have an electronic device	

4.12 *Where do you have the internet access? (Indicate with an "X". More than one device may be selected)*

At home	
At work	
From 3G Sim Card in the electronic device	
Other:_____(Please specify)	
Not applicable as I do not have an electronic device	

Note: The item statements amended subsequent to the CVI analysis have been stated in *italics* in the Revision 1 prototype questionnaire for easy identification of changes. The *italic* font was changed to normal font when handed to respondents for the cognitive interviews and the reliability test-retest assessment

Thank you for completing this questionnaire

.

Appendix E - Participant information sheet and informed consent for the cognitive interview

Participant Code_____

Participant information sheet

Title of the study: **The development and validation of a questionnaire on early recognition of clinical deterioration: a mixed methods study**

Introduction and background

I am currently a Masters in Nursing Science Degree candidate with the Division of Nursing and Midwifery at the University of Cape Town with an interest in the occurrence of adverse events (AEs) in the healthcare environment that have triggered national and international concern. For the purposes of this study, AEs refer to the events in the healthcare general ward setting where there is evidence of the failure to recognise clinical and physiological signs of deterioration, failure to take action, failure to initiate a call for a more qualified healthcare professional to review the patient, or failure of a more qualified healthcare professional to respond to the call for review timeously.

The critical need to improve nurses' recognition of and response to deterioration in a patient's condition to reduce the risk of harm and AEs, has resulted in the implementation of recommendations for healthcare establishments internationally. Recommendations include the introduction of an early warning scoring system and a training programme to support nurses in early identification of deterioration in a patient's condition and triggering of timeous actions in response to the change in condition.

The purpose of this study is to focus on the development and validation of a questionnaire as a measurement to assess: 1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; 2) nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and 3) nurses' self-reported clinical reasoning ability. The validity and reliability of the developed questionnaire will be assessed using the processes of content validity index calculation; cognitive interviewing and test-retest reliability testing.

Clarification of terminology

The term *validity* refers to the ability of a tool or test such as a questionnaire to measure what it is intended to measure (Polit & Beck, 2017).

Cognitive interviewing is a process where the researcher asks each respondent, face to face, open-ended questions to explore the *validity* of the questionnaire in an attempt to improve the user's rate of completion of a questionnaire (Rattray & Jones, 2007; Waltz et al., 2005).

The purpose of the interview

The interview is an essential step in establishing the quality of the questionnaire. The intention is that the verbal interviewing process will allow the researcher to understand if there are any improvements required in the questionnaire (revised prototype questionnaire) by assessing for any problems in the way in which you interpret and respond to the question items. The researcher will pose questions or statements during the interview so to ensure an accurate understanding of the participant's verbal responses given and to possibly request further explanation to understand the verbal response. The interviews will be recorded using audio tapes and transcribed on completion of each interview.

Has ethics approval been granted for the study?

Yes, ethics approval for this study has been granted by the University of Cape Town's Faculty of Health Sciences' Human Research Ethics Committee (HREC REF: 881/2016).

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

You have been invited to participate in this study as a nurse with a Master's Degree, a Postgraduate Diploma in Nursing Education and considered to have expert knowledge in the field of the biosciences and health sciences research.

How will you participate in the study?

Once the purpose of the study has been explained to you and you decide to participate in the study, you will be asked to confirm your consent to participation by signing the participant consent section of this document. The language used in all communication and documentation will be English as it is the language of instruction in the education and health care system in which the validation of the questionnaire will be conducted. A date, time and venue will be agreed upon between yourself and the researcher for the interview. You will be given the questionnaire to read prior to the interview. Prior to the interview commencing, the researcher will explain the purpose and process of the interview again and give you an opportunity to ask questions for clarification. During the interview, the researcher will ask you questions about the questionnaire and you are encouraged to speak freely as your thoughts emerge in response to the questions. The interview will be audiotaped and the researcher will make field notes during the interview to assist with the analysis and changes suggested to the questionnaire.

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

It is anticipated that the researcher will be able to explain the nature of the study and your participation together with an opportunity for you to ask questions within 20 minutes. Thereafter, the time commitment from you to participate in the interview is expected to be 45 minutes.

Are there any risks associated with participation in this study?

There are no anticipated risks for the participant by taking part in this study. Your thoughts and feedback will remain confidential. The researcher is not intending to test your knowledge through your participation, but rather to gather information from you as part of the validity and reliability assessment of the questionnaire itself.

Are there any benefits associated with participation in this study?

The benefits to the participants will be the altruistic internal gratification of contributing to the validation of the questionnaire for the purposes as outlined in the study that will contribute to the anticipated use of the questionnaire to understand the education requirements required by the nurses and the factors supporting and impeding their ability to recognise and respond to patient deterioration in the general wards of the private healthcare establishment at a later stage outside the scope of this study. There will be no financial gain from participating in this study.

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

You are free to decide not to participate in the study or to withdraw from participation during the study without any coercion or retribution.

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

The data gathered from the interviews will be stored confidentially by the researcher for the duration of the study. The researcher will ensure confidential transcription of the interview. A copy of the interview will be given to the participant for their own records if requested. The

results of the study will be disseminated via conference presentation and publication of a journal article/s in a peer reviewed scientific journal.

Who can be contacted in the event of questions related to the study?

Researcher: Briony Berning (MSc. candidate, Division of Nursing & Midwifery, University of Cape Town) 7 Gerard Road Lakeside 7945 Telephone Number: 0721481467 E-mail: prkbri002@myuct.ac.za	**Supervisor:** Associate Professor Una Kyriacos Division of Nursing & Midwifery Department of Health & Rehabilitation Sciences Faculty of Health Sciences University of Cape Town Observatory 7925 Telephone Number: 021 406 6410 E-mail: una.kyriacos@uct.ac.za

The University of Cape Town's Ethics Committee can be contacted directly in the event that there are concerns or questions related to the ethical considerations of this study.

Human Research Ethics Committee details:
Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory
7925

Professor Marc Blockman (Chairman)
Telephone number: 021 406 6338
E-mail: marc.blockman@uct.ac.za

Consent to participation in the study

Please read the consent related statements below. Document your agreement to each statement by writing your initials in the right hand column for each statement, documenting your full name and signature in the space provided and then return to the researcher by hand or via email.

No	Consent statements	Initial
1	I _____ (name) as a participant hereby confirm that I have read and understand the participant information for the study. I confirm that I have been given the opportunity to pose questions and have them answered satisfactorily.	
2	I understand that my participation in the study is not connected to my current employment and will take place during my own time.	
3	I understand that I can withdraw from the study at any time free from any retribution.	
4	I am aware that my personal details on this consent form will remain confidential during this study.	
5	I hereby accept the statement made by the researcher that there are no anticipated risks associated with participating in this study.	
6	I am aware that there may be no direct benefit to me for participating in this study.	
7	I hereby freely confirm my consent to participate in this study.	

Participant's full name	Signature	Date
Researcher's full name	Signature	Date

Thank you for agreeing to participate in this study.

Appendix F - Cognitive interview guide

The Interview Process*

On commencement of the interview, the participant will be asked whether consent has been given for participation and a reminder that the interview will be audiotaped.

Audiotaping commences.

The participant will then be prompted to read the questionnaire aloud, item by item. The participant will be asked to verbalise their own interpretation of each item.

Thereafter the participant will be asked the following questions by the researcher:

1. Can you please describe what the section **"factors influencing your ability to recognise and report patient deterioration"** and **each question** is asking for?
   (Planned probing cues to the above participant's response if needed):
   a. "How did you get to that answer (Cognitive probe)?"
   b. "In other words what you are saying is.. (Confirmatory probe)?"
   c. "Tell me more about..(Expansive probe)" (Burger, 2015, p. 105).

2. Can you please describe what you think the section "**nurses' knowledge of physiological and clinical parameters associated with deterioration in a patient's condition"** and **each question** is asking for?
   (Planned probing cues to the above participant's response if needed):
   a. "How did you get to that answer (Cognitive probe)?"
   b. "So what you are saying is…….(Confirmatory probe)?"
   c. "Tell me more about….(Expansive probe)" (Burger, 2015, p. 105).

3. Can you please describe what the section **"self-reported clinical reasoning ability"** and **each question** is asking for?
   (Planned probing cues to the above participant's response if needed):
   a. "How did you get to that answer (Cognitive probe)?"
   b. "So what you are saying is …….(Confirmatory probe)?"
   c. "Tell me more about..(Expansive probe)" (Burger, 2015, p. 106).

4. Can you please describe what the section **"demographic data"** and **each question** is asking for?
   (Planned probing cues to the above participant's response if needed):
   a. "How did you get to that answer (Cognitive probe)?"
   b. "In other words, you mean ….(Confirmatory probe)?"
   c. "Tell me more about…(Expansive probe)" (Burger, 2015, p. 106).

5. (Emergent probes to explore further problems that may arise).
   a. What difficulties or challenges do you anticipate with the use of this tool?
   b. Is there anything missing that you think should be added to the questionnaire?

Summary

In summary, my understanding of the problems that you have expressed during the interview includes (_____). Do you agree with my summary or is there anything that you would like to amend or add?

To summarise the comments that you have made, do you recommend (_____)? Have I summarised your suggestions accurately? Would you like the opportunity to explain what you intended to say?

The sections of the questionnaire that are suitable include (_____). Did I summarise this correctly? Would you like the opportunity to modify any of your comments?

Are there any further suggestions that you would like to add before we conclude the interview?

Conclusion

Thank you for your time and valuable feedback. Are there any questions before we end the interview?

A reminder that this interview is confidential and information shared will remain anonymous. The interview recording will now end.

Reference

Burger, D. (2015). *The development and validation of a modified Situation-Background-Assessment Recommendation (SBAR) communication tool for reporting early signs of deterioration in patients.* (Masters of Science), University of Cape Town.

Appendix G – Final validated questionnaire for the test-retest

Dear Respondent (Respondent no._____)

The **purpose of this questionnaire** is to assess:
1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward;
2) nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and
3) nurses' self-reported clinical reasoning ability.

Definitions of terms or phrases used in this questionnaire:
"**Clinical observations**" refers to the subjective and objective findings gathered during a patient assessment. For example, pain, bleeding, sweating, skin colour.

"**Vital signs**" refers to the blood pressure, heart rate, respiratory rate, temperature, oxygen saturation, and the level of consciousness.

"**Deterioration in a patient's condition**" refers to decline in a patient's condition where assistance from a more skilled healthcare professional is required in order to manage the patient.

"**More skilled healthcare professional**" refers to a registered nurse or a medical practitioner / doctor.

This questionnaire consists of four (4) sections. Please complete the questionnaire by answering all the sections and questions directly onto this document as per each section's instructions.

Section 1: Factors influencing your ability to recognise and respond to patient deterioration
Using the following scale, please select the most appropriate response to each of the questions listed below.
Scale: 5 = Strongly agree, 4 = Agree, 3 = Neutral, 2 = Disagree, 1 = Strongly disagree

No.	Factors influencing your ability to recognise and respond to patient deterioration	5	4	3	2	1
*1.1	My nursing qualification adequately prepared me to take / measure clinical observations and vital signs.					
*1.2	I am unsure how to respond to changes in patients' clinical observations and vital signs.					
*1.3	*Interpreting patient clinical observations and vital signs is an essential part of my role.*					
*1.4	I feel confident recording patients' clinical observations and vital signs.					
*1.5	*I have the knowledge to interpret patients' clinical observations and vital signs that show a change in physiology.*					
*1.6	My nursing qualification adequately prepared me to interpret patients' clinical observations and vital signs.					
*1.7	It is important to respond to any changes in patients' clinical observations and vital signs.					
*1.8	I believe that there is a deficit in my understanding of altered physiology associated with patients' clinical observations and vital signs.					
1.9	I am expected to take / measure patients' clinical observations and vital signs.					
1.10	I know how often I should take /measure patients' clinical observations and vital signs for the patients that I am allocated to provide care for in the clinical unit.					
1.11	*The clinical unit in which I am employed has a policy or work procedure that prescribes the frequency of taking / measuring clinical observations and vital signs.*					
1.12	*The clinical unit in which I am employed has a policy or work procedure that prescribes the action that I should take if I recognise deterioration in a patient's clinical observations and vital signs.*					

No.	Factors influencing your ability to recognise and respond to patient deterioration	5	4	3	2	1
1.13	I am adequately prepared to communicate with a more skilled healthcare professional about deterioration in a patient's condition.					
1.14	I am able to use the accepted nursing terminology to communicate with a more skilled healthcare professional about deterioration in a patient's condition.					
1.15	I use a communication tool (for example the Situation, Background, Assessment and Recommendation / SBAR tool) as a guide to communicate the relevant information about deterioration in a patient's condition to a more skilled healthcare professional.					
1.16	*I always document the information communicated to a more skilled healthcare professional about deterioration in a patient's condition in the patient's nursing records.*					
1.17	I am confident that the more skilled healthcare professional will act timeously on the information that I communicate to them regarding the patient's deteriorating condition.					
1.18	Information about the patient's deteriorating condition that I communicate to a more skilled healthcare professional is taken into consideration.					
1.19	When reporting my concern regarding a patient's condition to a more skilled healthcare professional, I fear being criticised for reporting on a patient who is not that sick.					
1.20	*I have the necessary equipment to take / measure clinical observations and vital signs.*					
1.21	In the clinical unit where I work I feel that I am an essential member of the multidisciplinary team responsible for the recognition of and response to deterioration in a patients' condition.					
1.22	*I understand the consequences to the patient if I fail to identify and report deterioration in a patient's condition.*					
1.23	*I measure and record every clinical observation and vital sign every time I am required to measure and record patients' clinical observations and vital signs.*					
1.24	I have experienced a situation where the deterioration in a patient's condition was not recognised leading to Cardiopulmonary resuscitation (CPR); transfer of the patient to the High Care or Intensive Care unit; or death of the patient.					

References:

*Adapted from Perkins, C., & Kisiel, M. (2013). Developing the recognition and response skills of student nurses. *British Journal of Nursing,* 22(12), 715-724.

Astroth, K. S., Woith, W. M., Stapleton, S. J., Degitz, R. J., & Jenkins, S. H. (2013). Qualitative exploration of nurses' decisions to activate rapid response teams. *Journal of Clinical Nursing, 22*(19/20), 2876-2882.

De Meester, K., Van Bogaert, P., Clarke, S. P., & Bossaert, L. (2012). In-hospital mortality after serious adverse events on medical and surgical nursing units: a mixed methods study. *Journal of Clinical Nursing, 22*, 2308-2317.

Kyriacos, U., Jelsma, J., & Jordan, S. (2011). Monitoring vital signs using early warning scoring systems: a review of the literature. *Journal of Nursing Management, 19*, 311-330.

Mok, W., Wang, W., Cooper, S., Ang, E. N., & Liaw, S. Y. (2015). Attitudes towards vital signs monitoring in the detection of clinical deterioration: scale development and survey of ward nurses. *International Journal for Quality in Health Care, 27*(3), 207-213.

Section 2: Nurses' knowledge of physiological and clinical parameters associated with deterioration in a patient's condition

For the following questions (2.1.1-2.1.11), please circle the most appropriate answer from the selection options: a - d. eg : 2.4.5 ®

2.1.1	A patient who is in hypovolaemic shock (and has low blood pressure) will have a. Normal capillary refill b. Cold clammy skin c. Facial flushing d. Warm dry hands
2.1.2	A patient with hypoxia (lack of oxygen) is likely to be a. Confused b. Pink c. Orientated to their surroundings d. Sweating
2.1.3	Slow capillary refill is a sign of a. Vasoconstriction and poor peripheral perfusion b. Malnutrition and dehydration c. Warm hands and feet d. Reduced concentrations of oxyhaemoglobin
2.1.4	The pulse can be palpated a. Every time the atria contracts b. When a vein is close to the surface of the skin c. Every time the left ventricle contracts d. When an artery is close to the surface of the skin
2.1.5	A normal heart rate for an adult at rest is a. 60-80 beats per minute (bpm) b. 60-90 bpm c. 60-100 bpm d. 60-110 bpm
2.1.6	Pulse oximeters (oxygen saturation probe) may be unreliable when…… a. Extremities are cold b. The patient is wearing nail varnish c. Tissue perfusion is poor d. All of the above
2.1.7	When assessing a patient's breathing…… a. Assess the patient's breathing for 15 seconds b. Assess for 30 -60 seconds looking for chest movement c. Use a mirror to check for exhaled air; d. The oxygen saturation is more important than the respiratory rate.
2.1.8	A.V.P.U. stands for? a. Alert, Visual, Peripheral, Unconscious b. Altered, Verbal, Pain, Unresponsive c. Anxious, Violent, Paranoid Unsettled d. Alert, Voice, Pain, Unresponsive

Reference:

Adapted from: Cooper, S., Kinsman, L., Buykx, P., McConnell-Henry, T., Endacott, R., & Scholes, J. (2010). Managing the deteriorating patient in a simulated environment: nursing students' knowledge, skill and situation awareness. *Journal of Clinical Nursing, 19*(15-16), 2309-2318.

Write down the values (numbers) for each of the physiological parameters (vital signs) below that you consider to be an EARLY sign of deterioration (worsening) in a patient's condition that would cause you to seek assistance (help) from a more skilled healthcare professional.

No.	Physiological parameters (vital signs)	I will call for a review of the patient for the following values indicating EARLY signs of deterioration (worsening) in a patient's condition:
2.2.1	Increased systolic blood pressure (hypertension)	*mmHg*
2.2.2	Decreased systolic blood pressure (hypotension)	*mmHg*
2.2.3	Increased heart rate (tachycardia)	*bpm*
2.2.4	Decreased heart rate (bradycardia)	*Bpm*
2.2.5	Increased respiratory rate (tachypnea)	*Breaths/min*
2.2.6	Decreased respiratory rate (bradypnea)	*Breaths/min*
2.2.7	Increased temperature (pyrexia)	*°C*
2.2.8	Oxygen saturation	*%*
2.2.9	Level of consciousness	

Select the clinical observations below that you consider an indication of deterioration (worsening) in a patient's condition that would cause you to seek the assistance (help) from a more skilled healthcare professional for review of the patient.
More than one option can be selected from the list below. Indicate your selection with a (X).

No.	Clinical observations	Selection
2.3.1	Decreased urine output	
2.3.2	Signs of bleeding	
2.3.3	Pain	
2.3.4	Sweating	
2.3.5	Decreased haemoglobin	
2.3.6	Hypoglycaemia (decreased blood glucose level)	
2.3.7	Increase in the capillary refill time	
2.3.8	Change in skin colour	

References:
De Meester, K., Van Bogaert, P., Clarke, S. P., & Bossaert, L. (2013). In-hospital mortality after serious adverse events on medical and surgical nursing units: a mixed methods study. *Journal of Clinical Nursing, 22*(15-16), 2308-2317.
Kyriacos, U. (2011). *The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients.* (Doctor of Philosophy), University of Cape Town.

Section 3: Self-reported clinical reasoning ability

Using the following scale, please select the most appropriate response to each of the questions listed below.
Scale: 5 = Strongly agree, 4 = Agree, 3 = Neutral, 2 = Disagree, 1 = Strongly disagree.

No.	Nurses clinical reasoning scale (NCRS)	5	4	3	2	1
3.1	I know how to collect an admitted patient's health information quickly.					
3.2	I can apply proper assessment skills to collect a patient's current health information.					
3.3	I can identify abnormalities from the collected patient information.					
3.4	*I can identify a patient's health problems (nursing diagnoses) from the abnormal information collected.*					
3.5	I can recognize possible early signs or symptoms when a patient's health deteriorates.					
3.6	*I can explain the pathophysiology associated with the early signs or symptoms when a patient's health deteriorates.*					
3.7	*I can correctly explain the pathophysiology behind a patient's problems.*					
3.8	*I can accurately prioritize and manage any identifiable patient problems.*					
3.9	I can provide appropriate nursing interventions for identified patient problems.					
3.10	I can provide appropriate nursing interventions for identified patient problems.					
3.11	I am knowledgeable of each nursing intervention provided.					
3.12	*I can identify and communicate vital information clearly to the more*					

No.	Nurses clinical reasoning scale (NCRS)	5	4	3	2	1
	skilled healthcare professional based on the patient's current condition.					
3.13	*I can anticipate the intervention requested by the more skilled healthcare professional according to the patient information that I communicate to them.*					
3.14	*I can accurately identify whether a patient's condition is improved.*					
3.15	I know the follow-up steps to take if a patient's condition does not improve.					

Reference:
Liou, S. R., Liu, H. C., Tsai, H. M., Tsai, Y. H., Lin, Y. C., Chang, C. H., & Cheng, C. Y. (2016). The development and psychometric testing of a theory-based instrument to evaluate nurses' perception of clinical reasoning competence. *Journal of Advanced Nursing, 72*(3), 707-717.

Section 4: Demographic data

4.1 *Highest nursing related qualification (Select one option relevant to you. Indicate your response with an "X"*)

Doctoral Degree in Nursing	
Master's Degree in Nursing	
Postgraduate/post basic diploma in Nursing related field	
Bachelor's degree in Nursing	
Diploma in Nursing: 4 year diploma	
Diploma in Nursing (Bridging Course)	
Diploma in Nursing: 3 year diploma	
Certificate leading to enrolment as a nurse	
Certificate leading to enrolment as a nurse auxiliary	

4.2 Are you currently registered at an education institution for nursing studies? (Select one option relevant to you. Indicate your response with an "X")

Yes	
No	

4.3 If you answered "yes" to question 4.2, please indicate the programme that you are registered for currently. (Select one option relevant to you. Indicate your response with an "X")

Doctoral Degree in Nursing	
Master's Degree in Nursing	
Post graduate/post basic diploma in Nursing related field	
Bachelor's degree in Nursing	
Diploma in Nursing: 4 year diploma	
Diploma in Nursing (Bridging Course)	
Diploma in Nursing: 3 year diploma	
Certificate leading to enrolment as a nurse	
Certificate leading to enrolment as a nurse auxiliary	
Other (please specify)_____	
Not applicable as not studying	

4.4 Your age (in years)

4.*5 Your gender (Select one option relevant to you. Indicate your response with an "X")*

Male	
Female	
Non-binary	

4.6 Your home language

4.7 The number of years of clinical experience as a nurse

4.8 Have you attended a Cardiopulmonary Resuscitation (CPR) / Basic Life Support (BLS) Course?. (Select one option relevant to you. Indicate your response with an "X").

Yes	
No	

4.9 If you answered “yes” to the question in 4.8 above, when did you attend the CPR/BLS Course? (Indicate the year in which you attended the training)

Year	
Not applicable as I have not attended such a course	

4.10 Do you currently have access to the following electronic devices? (Indicate with an “X”. More than one device may be selected)

Computer / Laptop	
Tablet device	
Smart Phone	
Other device (please specify)_____	
Not applicable as I do not have an electronic device	

4.11 If you selected one of the electronic devices in question 4.10, do you have internet access from the electronic device? (Indicate your response with an “X”.)

Yes	
No	
Sometimes	
Not applicable as I do not have an electronic device	

4.*12 Where do you have the internet access? (Indicate your response with an “X”. More than one access point may be selected)*

At home	
At work	
From 3G Sim card in the electronic device	
Other:_____(Please specify)	
Not applicable as I do not have an electronic device	

Thank you for completing this questionnaire.

Appendix H - Respondent information sheet and informed consent for the test-retest of the questionnaire

Respondent code_____

Title of the study: **The development and validation of a questionnaire on early recognition of clinical deterioration: a mixed methods study**

Respondent information sheet

Introduction & background

I am currently a Masters in Nursing Science Degree candidate with the Division of Nursing and Midwifery at the University of Cape Town with an interest in the occurrence of adverse events (AEs) in the healthcare environment that have triggered national and international concern. For the purposes of this study, AEs refer to the events in the healthcare general ward setting where there is evidence of the failure to recognise clinical and physiological signs of deterioration, failure to take action, failure to initiate a call for a more qualified healthcare professional to review the patient, or failure of a more qualified healthcare professional to respond to the call for review timeously.

The critical need to improve nurses' recognition of and response to deterioration in a patient's condition to reduce the risk of harm and AEs, has resulted in the implementation of recommendations for healthcare establishments internationally. Recommendations include the introduction of an early warning scoring system and a training programme to support nurses in early identification of deterioration in a patient's condition and triggering of timeous actions in response to the change in condition.

The purpose of this study is to focus on the development and validation of a questionnaire as a measuring tool to assess: 1) the factors influencing nurses' ability to recognise and respond to patient deterioration in a general ward; 2) nurses' knowledge of physiological and clinical parameters associated with patient deterioration; and 3) nurses' self-reported clinical reasoning ability. The validity and reliability of the developed questionnaire will be assessed using the processes of content validity index calculation; cognitive interviewing and test-retest reliability testing.

Clarification of terminology

The *reliability* of a questionnaire is an indicator of its quality in that it is a reflection of its ability to consistently measure the same domain under investigation on repeated occasions (Polit & Beck, 2017).

Test-retest reliability testing is a methodology used to assess the stability or consistency of a measuring instrument such as a questionnaire over a determined duration when used repeatedly (Polit & Beck, 2017; Rattray & Jones, 2007).

Purpose of the test-retest phase

As a respondent in this phase of the study, your participation would entail completing the questionnaire independently on two occasions, two weeks apart during an agreed date and time between the researcher and yourself. The purpose of this phase is the assessment of the reliability of the questionnaire.

Has ethics approval been granted for the study?

Yes, ethics approval has been granted for this study by the University of Cape Town's Faculty of Health Sciences' Human Research Ethics Committee (HREC REF 881/2016) and by the private hospital's Ethics Committee (REC 251015-048).

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

You have been invited to participate in this study as a nurse (registered or enrolled with the South African Nursing Council) working in a general ward setting involved in delivering patient care. Your selection has resulted from a random selection from the population of permanently employed nurses at a private hospital in the Western Cape.

How will you participate in the study?

Once the purpose of the study has been explained to you and you decide to participate in the study, you will be asked to confirm your consent to participation by signing the respondent consent section of this document. The language used in all communication and documentation will be English as it is the language of instruction in the education and health care system in which the validation of the questionnaire will be conducted. A date, time and venue will be agreed upon between yourself and the researcher to complete the questionnaire on two separate occasions, two weeks apart. You are requested to complete the questionnaire by yourself free from disturbance or input from colleagues or resources. You are also requested not to discuss the questionnaire with other nurses during the period between the first and second test completion. You are requested to then place the completed questionnaire in the self-addressed envelope and place in the internal mail tray in your unit so that it can be returned to the researcher.

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

It is anticipated that the researcher will be able to explain the nature of the study and your participation together with an opportunity for you to ask questions within 20 minutes. Thereafter, the time commitment from you to complete the questionnaire is expected to be 30 minutes on two separate occasions.

Are there any risks associated with participation in this study?

There are no anticipated risks for the respondent taking part in this study. Your results will remain confidential. The results of the self-administered questionnaire will not be reported to your line manager and your results will not influence your employment status. The results of the questionnaire will be made available to the nurse on an individual, confidential basis if requested. The self-administered questionnaires will be coded. The list of nurses' names and corresponding codes will remain confidential on the researcher's computer with a password for protection.

Your score calculated on completion of the questionnaire will not influence your employment and will not be communicated to any line manager at your hospital. The questionnaire scores will be used for statistical purposes to determine whether the questionnaire is a reliable tool testing what it is intended to test. Confidentiality will be maintained by the researcher.

Are there any benefits associated with participation in this study?

The benefits to the respondents will be the altruistic internal gratification of contributing to the validation of the questionnaire for the purposes as outlined in the study that will contribute to the anticipated use of the questionnaire to understand the education requirements required by the nurses and the factors supporting and impeding their ability to recognise and respond to patient deterioration in the general wards of the private healthcare establishment at a later stage outside the scope of this study. There will be no financial gain from participating in this study.

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

You are free to decide not to participate in the study or to withdraw from participation during the study without any coercion or retribution.

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

The data gathered from the interviews will be stored confidentially by the researcher for the duration of the study. A copy of the scored questionnaire will be given to the respondent for their own records if requested. The results of the study will be disseminated via conference presentation and publication of a journal article/s in a peer reviewed scientific journal.

Who can be contacted in the event of questions related to the study?

Researcher: Briony Berning (MSc candidate, Division of Nursing & Midwifery, University of Cape Town) 7 Gerard Road Lakeside 7945 Telephone Number: 0721481467 E-mail: prkbri002@myuct.ac.za	**Supervisor:** Associate Professor Una Kyriacos Division of Nursing & Midwifery Department of Health & Rehabilitation Sciences Faculty of Health Sciences University of Cape Town Observatory 7925 Telephone Number: 021 406 6410 E-mail: una.kyriacos@uct.ac.za

The University of Cape Town's Ethics Committee can be contacted directly in the event that there are concerns or questions related to the ethical considerations of this study.

Human Research Ethics Committee details:

Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24
Groote Schuur Hospital Old Main Building
Observatory
7925

Professor Marc Blockman (Chairman)
Telephone number: 021 406 6338
E-mail: marc.blockman@uct.ac.za

Consent to Participation in the Study

Please read the consent related statements below. Document your agreement to each statement by writing your initials in the right hand column for each statement, documenting your full name and signature in the space provided and then return to the researcher by hand.

#	Consent Statements	Initial
1	I _____ (name) as a respondent hereby confirm that I have read and understand the respondent information for the study. I confirm that I have been given the opportunity to pose questions and have them answered satisfactorily.	
2	I understand that my participation in the study is not connected to my current employment and will take place during my own time.	
3	I understand that I can withdraw from the study at any time free from any retribution.	
4	I am aware that my personal details on this consent form will remain confidential during this study.	
5	I hereby accept the statement made by the researcher that there are no anticipated risks associated with participating in this study.	
6	I am aware that there may be no direct benefit to me for participating in this study.	
7	I hereby freely confirm my consent to participate in this study.	

Respondent's Full Name	Signature	Date
Researcher's Full Name	Signature	Date

Thank you for agreeing to participate in this study.

Appendix I – Section 2: Answers to the knowledge questions

Section 2: Nurses' knowledge of physiological and clinical parameters associated with deterioration in a patient's condition

2.1.1	A patient who is in hypovolaemic shock (and has low blood pressure) will have Answer: cold clammy skin
2.1.2	A patient with hypoxia (lack of oxygen) is likely to be Answer: confused
2.1.3	Slow capillary refill is a sign of Answer: vasoconstriction and poor peripheral perfusion
2.1.4	The pulse can be palpated Answer: when an artery is close to the surface of the skin
2.1.5	A normal heart rate for an adult at rest is Answer: 60-80 beats per minute (bpm)
2.1.6	Pulse oximeters (oxygen saturation probe) may be unreliable when…… Answer: All of the above (extremities are cold; the patient is wearing nail varnish; tissue perfusion is poor)
2.1.7	When assessing a patient's breathing…… Answer: Assess for 30 -60 seconds looking for chest movement
2.1.8	A.V.P.U. stands for? Answer: Alert, Voice, Pain, Unresponsive

Reference:
Smelterz, S., Bare, B., Hinkle, J., & Cheever, K. (2011). *Brunner and Suddarth's Medical Surgical Nursing* (Twelth ed.). Philadelpia: Lippincot Williams and Wilkins.

Write down the values (numbers) for each of the physiological parameters (vital signs) below that you consider to be an EARLY sign of deterioration (worsening) in a patient's condition that would cause you to seek assistance (help) from a more skilled healthcare professional.

No.	**Physiological parameters (vital signs)**	**I will call for a review of the patient for the following values indicating EARLY signs of deterioration (worsening) in a patient's condition:**
2.2.1	Increased systolic blood pressure (hypertension)	*>149 mmHg*
2.2.2	Decreased systolic blood pressure (hypotension)	*<101 mmHg*
2.2.3	Increased heart rate (tachycardia)	*>100 beats/min*
2.2.4	Decreased heart rate (bradycardia)	*<60 beats/min*
2.2.5	Increased respiratory rate (tachypnea)	*>14 breaths/min*
2.2.6	Decreased respiratory rate (bradypnea)	*<12 breaths/min*
2.2.7	Increased temperature (pyrexia)	*>37.7°C*
2.2.8	Oxygen saturation	*<95%*
2.2.9	Level of consciousness	*Glasgow Coma Scale<15 / rousable to voice (AVPU) **

Reference:

Kyriacos, U., Jelsma, J., James, M., & Jordan, S. (2014). Monitoring vital signs: development of a modified early warning scoring (MEWS) system for general wards in a developing country. *PLoS ONE, 9*(1), e87073.

**Smelterz, S., Bare, B., Hinkle, J., & Cheever, K. (2011). *Brunner and Suddarth's Medical Surgical Nursing* (Twelth ed.). Philadelpia: Lippincot Williams and Wilkins.

Select the clinical observations below that you consider an indication of deterioration (worsening) in a patient's condition that would cause you to seek the assistance (help) from a more skilled healthcare professional for review of the patient. More than one option can be selected from the list below. Indicate your selection with a (X).

No.	Clinical observations	Selection
2.3.1	Decreased urine output	X
2.3.2	Signs of bleeding	X
2.3.3	Pain	X
2.3.4	Sweating	X
2.3.5	Decreased haemoglobin	X
2.3.6	Hypoglycaemia (decreased blood glucose level)	X
2.3.7	Increase in the capillary refill time	X
2.3.8	Change in skin colour	X

References:

De Meester, K., Van Bogaert, P., Clarke, S. P., & Bossaert, L. (2013). In-hospital mortality after serious adverse events on medical and surgical nursing units: a mixed methods study. *Journal of Clinical Nursing, 22*(15-16), 2308-2317.

Kyriacos, U. (2011). *The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients.* (Doctor of Philosophy), University of Cape Town.

Appendix J - University of Cape Town Faculty of Health Sciences Human Research Ethics Committee approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7935
Telephone (021) 406 6626
Email: shunetta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

18 January 2017

HREC REF: 881/2016

A/Prof U Kyriacos
Nursing and Midwifery
Health & Rehab
F56/27 OMB

Dear A/Prof Kyriacos

PROJECT TITLE: THE DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE: A MIXED METHODS INSTRUMENT DEVELOPMENT STUDY (MSc-candidate-B Berning)

Thank you for submitting your response to the Faculty of Health Sciences Human Research Ethics Committee dated 16 January 2017.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th January 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

The HREC acknowledge that the student, Briony Berning will also be involved in this study.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical

Appendix K - Private hospital research & scientific committee approval

[redacted] [redacted]

National Health Research Ethics Committee registration: REC: 261015.048

03 February 2017

Mrs Briony Berning
[redacted]

Dear Mrs Berning

RE: APPLICATION TO CONDUCT RESEARCH: [redacted]

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

The Research & Scientific Committee of [redacted] hereby grants permission with no conditions for your study to be conducted at [redacted] hospital in the Western Cape. Present this letter to the Hospital Manager of the facility to gain permission at hospital level.

Yours sincerely,

On behalf of the Research & Scientific Committee

[redacted]