Vital Signs Monitoring and Responding to Deteriorating Patients in New Zealand: Challenges and Opportunities

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List of Abbreviations

ADLs	Activities of daily life
ANOVA	Analysis of Variance
ANZCOR	Australia and New Zealand Committee on Resuscitation
ARC	Aged and residential care
AUT	Auckland University of Technology
AVPU	Alert, responds to Voice only, responds to Pain only and Unconscious
BP	Blood pressure
bps	Bits per second (data transfer speed)
CCO	Critical Care Outreach
CCU	Cardiac care unit
CI	Confidence interval
CPGs	Clinical practice guidelines
CPR	Cardiopulmonary resuscitation
CRBSI	Catheter-related bloodstream infection
DEFF	Design effect
DHB	District Health Board
DL	Detection Level
ED	Emergency Department

EHR	Electronic health records
EWS	Early warning score
FMEA	Failure mode and effect analysis
FPC	Finite population correction factor
FTE	Full-time equivalent
GPRS	General packet radio service
GPS	Global positioning system
GWTG-R	Get With The Guidelines–Resuscitation
HAT	Hospital arrest team, sometimes known as MET
HDU	High dependency unit
HQSC	Healthcare Quality and Safety Commission
HR	Heart rate
ICU	Intensive care unit
IHCA	In-hospital cardiac arrest
IHI	Institute for Healthcare Improvement
Katz-ADLs	Katz Index of Independence in ADLs
KHz	Kilo hertz
LoC	Level of Consciousness
LoS	Length of stay

MET	Medical Emergency team
MEWS	Modified EWS
MHz	Mega hertz
mRS	Modified Rankin Scale
NEWS	National EWS (the UK)
NHI	National Health Index
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NZ	New Zealand
NZEWS	New Zealand EWS
OHCA	Out-of-hospital cardiac arrest
OL	Occurrence level
OPHRS	Old Peoples Health and Rehabilitation Service
OPT	Occurrence per unit time
PaR	Patient-at-Risk, sometimes noted as PAR
POCSAG	Post Office Code Standardisation Advisory Group
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
RCA	Root cause analysis
RCPL	The Royal College of Physicians London

RER	Risk exposure ratio
RFID	Radio-frequency identification
RMO	Resident Medical Officer
RNs	Registered Nurse
ROC	The receiver operating characteristic
ROSC	Return of spontaneous circulation
RPN	Risk priority number
RR	Respiratory rate
RRS	Rapid Response System
RRT	Rapid response team
SBP	Systolic blood pressure
SEWS	Standardised EWS
SL	Severity Level
SME	Subject matter experts
SpO_2	Oxygen saturation
SPSS	Statistical Package for Social Sciences
TBH	Taranaki Base Hospital
TDHB	Taranaki DHB
UK	The United Kingdom

USA	The United States of America
VS	Vital signs
WDHB	Waitemata DHB

Attestation of Authorship

“I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning. It contains results of my investigation, except where otherwise stated. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.”

Signed: Ehsan Ullah

Date: 04/03/2022

Candidate Contributions to Co-authored Papers

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Dedication

I dedicate this thesis to my parents Maqsood Ahmed and Shamshad Begum.

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Ethical Approval

This study obtained the ethical approval from Taranaki District Health Board (TDHB) Research Ethics Committee

Approved Date: 5 January 2021 (Appendix A Taranaki DHB Approval Letter).

Abstract

This thesis evaluated the existing rapid response system (RRS) based on vital signs and New Zealand Early Warning Scores (NZEWS) to recognise and respond to deteriorating patients outside of intensive care settings at Taranaki Base Hospital (TBH) through a series of studies using various methods. As the RRS is a complex system consisting of an afferent limb which captures inputs such as vital signs (VS), Early Warning Scores (EWS) and an efferent limb which acts on a set trigger defined by the afferent limb inputs and sets off Medical Emergency Team (MET) for an appropriate level of care. Firstly, this thesis describes the rate of errors and omissions within the existing RRS at the study site. It was observed that error and omission rate within the existing RRS was unacceptable. The errors and omissions accrue from the starting point (vital signs measurement, 14.9%) through the mid-point of the RRS i.e., calculation of Early Warning Scores (EWS), 25.1%, to the endpoint of the RRS (responding to deteriorating patients, 30.1%). This high error and omission rate contributes to missed opportunities to recognise and respond to deteriorating patients who have shown antecedents of significant deterioration. Secondly, this thesis describes the workload involved in the RRS activities by quantifying the time spent on each set of vital signs observations (afferent RRS). The observations from this study were consistent with the findings of recent research overseas. This thesis extends the body of knowledge by quantifying the workload involved in rapid response (efferent RRS) and offers to extrapolate workforce implications of the workload involved in the RRS activities. Then this thesis explored the staff perceptions about existing RRS and electronic RRS after a demonstration of the electronic RRS. The staff felt that existing RRS activities consumed considerable time and perceived that the manual nature of the task relied heavily on human vigilance, making it error prone. Staff also felt that ‘too many papers’ also contributed to human

error. Staff were generally optimistic about electronic RRS and were keen to put it to a trial. Another study included in this thesis established that the incidence rate and survival status of the patients who underwent in-hospital cardiac arrest (IHCA) in the last five years (2016 to 2021) improved year-on-year, but significant improvement was observed after the implementation of Patient-at-Risk (PaR) nurses. This thesis extends the body of knowledge by applying Failure Mode and Effect Analysis (FMEA) methodology to identify the failure modes within existing RRS and to assess whether the likelihood of those failures would reduce using electronic RRS. The FMEA found that the electronic RRS could potentially reduce or eliminate 70.2% of these failures. The FMEA also identified the afferent RRS was more susceptible to failures (61.4%) as compared with the efferent limb of the RRS (38.6%). Based on the findings of this thesis, it is recommended that electronic RRS should replace non-electronic RRS which will not only help reduce the error and omission rate and the potential failures but also reduce the workload involved in the end-to-end RRS activities by communicating rich data between different users in real-time. This will improve user experience, speed up the efferent limb of RRS and therefore may improve the patient outcomes. It is also recommended that New Zealand should establish an IHCA registry at a national level to promote evaluation and research on the IHCA in a systematic way. Other recommendations include supporting the use of FMEA methodology in analysing complex and high-risk healthcare systems and processes.

CHAPTER 1 Introduction

1.1 Preamble

General ward patients show subtle yet detectable abnormalities in their physiological parameters before significant deterioration or a catastrophic harm event (Andersen et al., 2016; Creutzburg, Isbye, & Rasmussen, 2021; Green et al., 2018; H. Oh, Lee, & Seo, 2016; Gary B Smith, 2016). These physiological abnormalities that precede significant adverse events are sometimes referred to as antecedents of such significant deterioration e.g., in-hospital cardiac arrest (IHCA), unplanned admissions to intensive care unit (ICU) or in-patient deaths (K. Hillman et al., 2001; K. M. Hillman et al., 2002; Schein, Hazday, Pena, Ruben, & Sprung, 1990; Sprogis, Currey, Considine, Baldwin, & Jones, 2017). The literature suggests that these antecedents can be recognised before such catastrophic events (Chen et al., 2014; Commission, 2007; A. F. Smith & Wood, 1998; Welcn, 2021) when hospitalised patients are systematically and adequately monitored through vital signs (VS) observations coupled with early warning scores (EWS). (An et al., 2021; Fox & Elliott, 2015; Maftoohian et al., 2020; Osawa et al., 2021). The VS and EWS values and trends help clinical staff predict and manage these antecedents to avoid some patient harm. The VS and EWS values and trends may also help the clinical staff determine when patients' physiology improves and help them decide when patients are suitable for discharge from ICU to general wards. In future, this approach may be helpful to decide if patients can be discharged from hospital to home with home-based monitoring (Mintah-Asare, 2020; Nangalia, Prytherch, & Smith, 2010). In patient monitoring, the most common vital signs used today include pulse or heart rate, respiratory rate, blood pressure measurement, oxygen requirement and saturation, measurement of body temperature, assessment of consciousness, urine output and level of

pain (Manici & Torbinio, 2018; J. A. Petersen, Antonsen, & Rasmussen, 2016; G. B. Smith, Recio Saucedo, & Griffiths, 2017; D. Wong et al., 2017)

Patient monitoring using VS has come a long way (Dieterle, 2012; Ghasemzadeh & Zafari, 2011; John W Severinghaus & Honda, 1987). As discussed in Chapter 2, it is one of the most fundamental parts of modern healthcare delivery. This monitoring is usually performed by measuring and recording a defined set of vital signs whose values are plotted on a chart, usually known as a vital signs chart. Research over the last three decades has paved the way for various models and standardisations for VS based patient monitoring. The most important progress in this regard is the development of Early Warning Scores (EWSs). EWS is a numerical expression of the graded abnormalities within vital signs at a given time; hence EWS can represent the combined effect of all the abnormalities in vital signs. EWS is meant to predict abnormalities in the body functions better than vital signs alone. There are several variations and models of EWS available today, each having the sensitivity and specificity to detect early deterioration in a patient's physiological state (Gerry et al., 2017).

The real aim of patient monitoring with VS and EWS is to detect early or forecast deterioration so that early and appropriate management can be provided (Gerry et al., 2017; Hogan et al., 2012; Juliane Kause et al., 2004). Multiple studies have demonstrated that patient deterioration resulting in cardiac arrest or death was commonly preceded by several hours of deranged physiology that could potentially be picked up, had the accurate and sensitive EWS and efficient RRS been in place (K. M. Hillman et al., 2002; Juliane Kause et al., 2004; McQuillan et al., 1998). One of these studies, the ACADEMIA study by Kause et al. 2004 was tri-national (Australia, New Zealand, and the UK). These studies demonstrated that early detection and management of deteriorating patients save unexpected cardiac arrests, unexpected hospital deaths and unplanned ICU admissions (which are associated with higher

rates of worse patient outcomes including deaths). The concept of EWS was necessitated by the growing evidence of unnecessary harm to patients while hospitalised in the late 1900s and early 2000s (Brennan et al., 1991; Gerry et al., 2017).

In 1997 Morgan Williams introduced the first-ever EWS that used the quatro of pulse, temperature, respiratory rate and blood pressure and coupled it with an 'Alert, Verbal, Pain, Unresponsive (AVPU) screen for alertness/level of consciousness (Morgan, Williams, & Wright, 1997). After Morgan's first-ever EWS, multiple variations and modifications of EWS were proposed. The evidence to support the need for an EWS in the field of healthcare has grown rapidly over the last two decades (Alam et al., 2014; An et al., 2021; Covino et al., 2020; Fox & Elliott, 2015; Hogan et al., 2012; Schein et al., 1990; Wattanasit & Khwannimit, 2020).

As VS and EWS-based monitoring matured over time, the concept of rapid response systems (RRSs) or teams (RRTs) also evolved (Devita et al., 2006; Heller et al., 2020; C. M. Jones, Bleyer, & Petree, 2010). RRSs have become an increasingly popular patient safety intervention across the healthcare industry, especially after being strongly advocated by the Institute for Healthcare Improvement's '100,000 Lives Campaign' in 2005 (Berwick, Calkins, McCannon, & Hackbarth, 2006). In 2006, a consensus conference (Devita et al., 2006) concluded that RRSs should be used as a coalescing terminology to describe the spectrum of recognition and response to deteriorating patients. In this thesis, I will be using a rapid response system or RRS to the same effect.

In the last 15 years, several different variations or models of RRS have been described (Winters & DeVita, 2017). The most popular models of RRS include Medical Emergency Team (MET), Critical Care Outreach (CCO) and Rapid Response Team (RRT) (Winters & DeVita, 2017). METs are led by physician(s) and CCO teams are usually a nurse-led

approach. Both teams have a level of multidisciplinary team composition that could vary depending on the type and severity of deterioration they are called in to respond to. METs are typically called in to respond to deteriorating states often coded based on defined physiological triggers (Barbetti & Lee, 2008), e.g., pre-arrest is coded as Code Red in most New Zealand hospitals. CCO teams may include physiotherapists and other allied healthcare professionals, as well as doctors, and often provide rapid response to defined physiological triggers but also work proactively with known Patients at-Risk (PaR) such as those recently discharged from ICU into a general hospital ward (Esmonde et al., 2006). RRTs act similar to CCO teams (Winters et al., 2007).

RRSs have evolved since the 1990s (C. M. Jones et al., 2010). The RRS acts as an organizational surveillance system to enable the early detection (afferent component) and management of deteriorating patients (efferent component) (Rihari-Thomas, Newton, Sibbritt, & Davidson, 2018) outside the ICU or critical care environment. The afferent components of RRS drive monitoring of a patient's physiology with the help of vital signs and early warning scores, whereas the efferent components ensure a timely response and management of patients showing early signs of clinical deterioration. The overall goals of RRSs include timely and safe transfers between ICU and general hospital wards, preventing unwarranted admissions to ICU, and sharing and growing skills required to make these decisions and provide critical care to those needing it (Bunch, Groves, & Perkhounkova, 2019).

Over the last five years (2016-2021), New Zealand hospitals have adopted a nationally consistent approach to using heart rate, temperature, respiratory rate, blood pressure, oxygen requirement and saturation, and level of consciousness to calculate a New Zealand Early Warning Score (NZEWS); and to triage adult patients in general hospital wards for the level

of rapid response required (HQSC, 2017b). The New Zealand Health Quality & Safety Commission (HQSC) implemented this approach through a 'deteriorating patient programme' (2016-2021) and introduced paper-based vital signs and EWS charts (HQSC, 2018) that incorporate a colour-coded scheme for the calculation of NZEWS, setting out an escalation pathway with definitions of each level of escalation and optimal timeframe to respond in each of these and providing a protocol for the recording of authorised modifications (exceptions) to the escalation pathway. According to the user guide for this vital signs chart (HQSC, 2017b), adult patients in general wards are required to undergo vital signs measurements and calculation of the NZEWS every four hours at least, and the frequency of monitoring increases if the value of NZEWS is higher on one occasion. A value of NZEWS 10+ or any single vital signs derangement in the blue zone on the vital signs chart requires an immediate pre-arrest call. Lower values of NZEWS and less severe abnormalities in single vital signs require a medical or specialised nursing review by 'Patient at-risk – PaR' nurses. In findings from the early implementation report on this national programme, New Zealand hospitals were found to have significant errors and omissions in patient monitoring (HQSC, 2017c). This programme is based on the evidence that early detection and clinical decision making have been improved by applying nationally standardised vital signs charts, EWS and escalation criteria in hospitals (A. Psirides, Hill, & Hurford, 2013).

The errors and omission rates and workload involved in afferent RRSs (monitoring patients' vital signs and early warning scores) is well reported (Adomat & Hicks, 2003; M. F. Clarke, 2006; Dall'Ora et al., 2021; Fuller, Fox, Lake, & Crawford, 2018; Rose & Clarke, 2010; Zeitz, 2005; Zeitz & McCutcheon, 2006), but the workload involved in efferent RRSs is an evidence free zone. Similarly, only one report published in-depth systems analysis on RRSs

where the authors have applied root cause analysis (RCA) to evaluate failure modes of RRSs (L. S. van Galen et al., 2016).

1.2 The existing Rapid Response System at the study site

1.2.1 Background

This chapter outlines the existing RRS at Taranaki District Health Board using the characteristics of a mature RRS. The term ‘mature rapid response system’ has been used in literature since 2007 (Galhotra, DeVita, Simmons, & Dew, 2007) though there is no consensus over the definition of a mature RRS to date (Sprogis, Currey, Jones, & Considine, 2021; Welcn, 2021). Generally, an RRS is considered mature if it demonstrates all of the following four components – often referred to as limbs of the RRS (Daryl Jones et al., 2017; Sethi & Chalwin, 2018; Veiga & Rojas, 2019):

- The afferent limb (to recognise patients likely to deteriorate),
- The efferent limb (to rapidly respond to deteriorating patients),
- The evaluation and quality improvement limb (to continuously evaluate and improve the rapid response processes), and
- The administrative and governance limb (to hold the rapid response processes to account) at the organisational level.

This chapter provides a descriptive account of the current state of the structural and functional limbs of the RRS at the study site. The methodology applied to examine the RRS at the study site included direct observation of the day-to-day practice; review of the policy documents related to RRS.

It is important to mention that the RRS at Taranaki Base Hospital is constructed on the foundation laid by the New Zealand Early Warning Scores (NZEWS) Vital Signs Charts.

These NZEWS charts were designed and implemented by the Healthcare Quality and Safety Commission of New Zealand during the deteriorating patient programme between 2016 and 2021 (HQSC, 2017a).

As described elsewhere in this thesis, the NZEWS charts mandate further actions based on the results of patient monitoring through an escalation pathway. This escalation pathway combines the concepts of single parameter based escalation put forth by Lee and colleagues (A. Lee, Bishop, Hillman, & Daffurn, 1995) and aggregate EWS score based calling criteria promoted by Prytherch and colleagues (Prytherch, Smith, Schmidt, & Featherstone, 2010) through their influential clinical paper that supported a nationally consistent EWS in the UK.

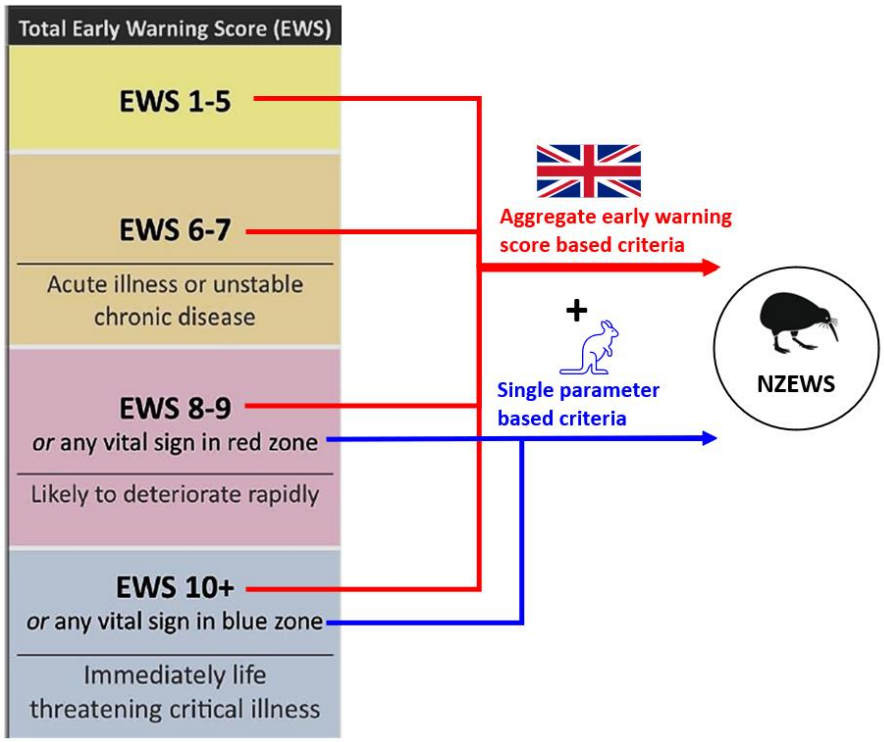


Figure 1-1 NZEWS: Aggregate scoring and single parameter-based calling criteria

(Based on the HQSC Guidelines (HQSC, 2017b))

Throughout this thesis and this chapter, the adult patients' versions of VS and NZEWS Charts are referred to as VS and NZEWS unless specified otherwise.

1.2.2 Afferent limb of the RRS

The afferent limb of the RRS consists of patient monitoring with the help of repeated observation of vital signs and early warning scores and sometimes includes point-of-care testing such as glucose levels. The clinical impressions of the attending staff or the concerns raised by patients and family are also considered part of the afferent limb of the RRS.

In practice, the afferent limb of the RRS is best represented by the 'vital signs and EWS chart'; to a large extent, however, some key information such as impressions of clinical staff or concerns raised by patient or family are often recorded within clinical records.

The vital signs and EWS charts are generally located next to the patient's bedside, whereas the clinical records are located at the nursing station.

In each 8-hour shift, a primary nurse allocated to the patient is responsible for measuring and recording vital signs, calculating, and recording EWS, listening to the patient and family if they raise any concerns and recording those within clinical record files.

It is worth noting that, though nurse A may work morning shifts for the entire month, it is usually not nurse A who will be allocated to patient X every day. In the real-life situation, the patient X may be allocated to nurses A, B, and C on a respective morning, evening, and night shifts on day 1 of their admission and they are allocated to nurses D, E, and F on the respective shifts on day 2, and so on. This is important to understand that observations recorded on the vital signs chart and clinical records hold the afferent limb of RRS, not the staff who keep changing shift to shift. However, the vital signs charts and clinical records are paper-based and therefore unable to activate the efferent limb of the RRS unless the values of vital signs and EWS are checked by staff every time these values are undertaken to see whether one of the 'calling criteria' is met or the staff or the patient and/or the family are

concerned about the deteriorating state of the patient. This means the key barrier of defence against failure to activate the efferent limb of the RRS is staff vigilance which is fallible in the face of multiple competing demands and priorities, interruptions by more urgent tasks and sometimes merely by a memory lapse.

The process outlined in Figure x is a very simple graphic representation of the steps involved in undertaking vital signs. Each of the eleven steps shown in Figure x involves further sub-steps as described below.

1.2.3 Timing and frequency of vital signs monitoring

The first complete set of vital signs is undertaken as soon as possible upon admission to general hospital wards. In the acute medical ward, most patients are admitted from the Emergency Department (ED), where they self-present or are brought by ambulance. In the Old Peoples Health and Rehabilitation Service (OPHRS) ward, patients are generally transferred from aged and residential care (ARC) directly or through the ED. Sometimes, patients are shifted from other wards such as intensive care units.

The frequency of vital signs monitoring in acute medical wards depends on the patient's clinical condition, whereas for OPHRS patients, it is once per nursing shift, i.e., three times in 24 hours or 8-hourly. The frequency of vital signs monitoring for OPHRS patients is not consistent with the policy on vital signs monitoring dictated by the NZEWS User Guide issued by HQSC (HQSC, 2017b). There is no evidence of whether this reduced frequency of vital signs monitoring is vetted by the local organisational deteriorating patient group or the organisational resuscitation committee.

Undertaking vital signs is included in the core business of the nursing staff. Therefore, the staff do their best to complete this task to the best of their ability and availability, but this is

very much human vigilance dependent and prone to memory lapses, being missed due to distraction and other human factors. There is no ‘alert’ available in this process to prompt nursing staff to get back to do this task according to the patient's needs, as shown by the recent set of vital signs/recent EWS. Therefore, it is important is to note that the starting point of the manual process is prone to human error, which puts the patient at risk of missed or delayed repeated vital signs – despite there being multiple mechanisms in place to check and audit the timeliness of vital signs later. This is further investigated in this thesis.

The minimum frequency of vital signs monitoring for general hospital ward patients is once every four hours. This frequency is considered suitable for patients who are physiologically stable. The frequency of vital signs monitoring can be increased in a tiered approach i.e., two-hourly, hourly, half-hourly or every 15 minutes as the patient’s physiological condition worsens which is indicated by increasing aggregate NZEWS. Patients with a higher frequency of vital signs monitoring are referred to as high-acuity patients and they are stratified by the exact frequency of vital signs monitoring and other nursing needs. Primary nurses are allotted patients so that one nurse looks after up to five stable patients or a lesser number of higher-acuity patients each shift.

1.2.4 Identification of the patient

At Taranaki Base Hospital, the identification of the patient requires checking their first and last names, and at least one other identifier. Home address and date of birth are the most used other identifiers. Patients wear identity wrist bands with printed first and last name of the patient, their date of birth, street address, national health index (NHI) number, their current location within the hospital such as ward number, their lead clinician and clinical service they are under the care of. This process step is completed manually, and no technology is applied,

such as a barcode or QRS code scanning using radiofrequency identification (RFID) methods.

1.2.5 The VS measuring equipment / devices

At the study site, the equipment required to measure the oxygen saturation and thermometers are kept by the nursing staff at their workstation. The oxygen probes also give heart rate. The blood pressure apparatus is located at the bedside. The nursing staff visit and bring the oxygen probe and thermometer, and BP apparatus to the bedside each time they need to undertake vital sign measurements. These devices are procured through a strict procurement process that ensures these devices are certified to meet the standards (hospital grade devices) and are evaluated and tested by the end-users before purchase orders are placed.

1.2.6 Obtaining informed consent from the patient

This step involves nursing staff explaining to the patient about the VS measurements and obtaining informed consent from the patient for the VS measurements each time. In this study, I observed that nursing staff identify the patient by asking them at least two identifiers (first and last name, date of birth, street address, phone number or national health index or NHI number) and obtain their informed consent for the VS measurements at the same time.

1.2.7 Position the patient as required

After obtaining the informed consent, staff nurses request the patient to lie, sit or stand and assist them in getting to the required position. The vital signs measurements are affected by body posture and the position of the patient, and staff nurses are very knowledgeable about this. During the review of VS and NZEWS charts, it was found that the BP measurements in standing and lying positions were quite frequently documented. During the time and motion study on the workload of VS measurements, this was directly observed.

1.2.8 Measuring the required vital signs

This is the core step of the afferent limb of the RRS whereby the nursing staff undertake all or some of the VS measurements as needed. The error and omission rates in the VS measurements and the workload involved in the measurement and recording of the VS are further elaborated in respective chapters.

1.2.9 Recording the vital signs measurements

The nursing staff record the vital signs observations in the NZEWS chart shown in Figure 1-2 where each set of VS observations is dated and timed as shown below.

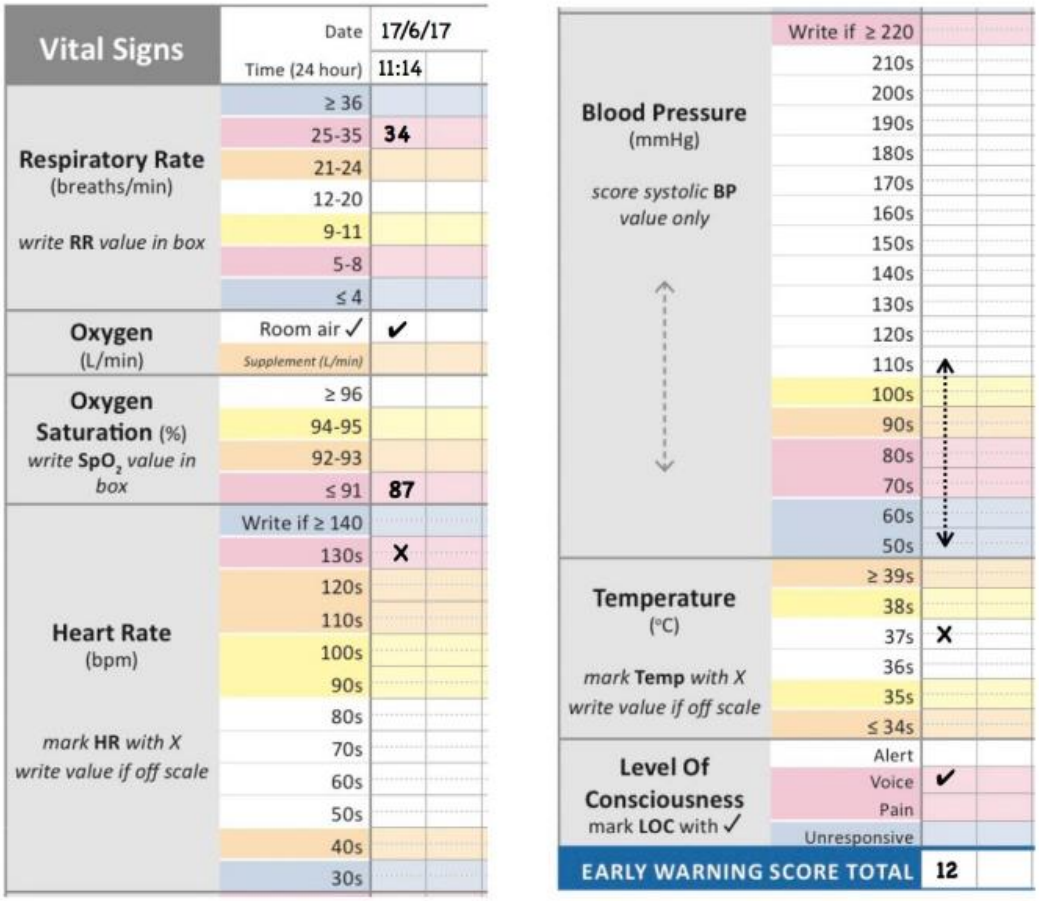


Figure 1-2 Recording the VS measurements on the NZEWS chart

(Copied from the HQSC Guidelines (HQSC, 2017b))

1.2.10 Calculation and recording of NZEWS

The NZEWS Chart User Guide, published by HQSC in 2017 (HQSC, 2017b) recommends a standard procedure to calculate NZEWS whereby each vital sign parameter has coloured zones (white, yellow, orange, and red) that are associated with a score of 0-3. The nurses need to remember the score for each colour code and add the score for each of the seven vital sign parameters together to calculate a total NZEWS. The NZEWS chart has a colour coded scoring approach to the values of vital signs which assist the nursing staff to calculate the EWS manually. In the current study, out of 8659 times when the NZEWS should have been calculated, it was calculated 7751 times (90.17%) while the EWS remained un-calculated 908 times, or in other words, in nearly 1 out of 10 times, NZEWS was not calculated.

Once calculated, the NZEWS is recorded on the NZEWS chart. In this study, the NZEWS was correctly calculated and recorded 7751 out of 7590 times (98.4%).

1.2.11 Management of modified NZEWS

The NZEWS chart enables staff members to clearly document and signs off the modifications in vital signs and NZEWS criteria whenever they are made. All modifications in vital signs and EWS that were documented were appropriate as per protocols and the user manual of the EWS chart. However, the issue remains with the colour scheme of the EWS chart which is paper-based and thus unchangeable when the modifications are applied. Hence, nursing staff may still ‘call’ a house officer to review a patient whose respiratory rate falls into the orange zone despite that being a clearly documented modification but documented on the back of the paper-based chart.

1.3 Efferent limb of the RRS

The efferent limb of the RRS activates upon the triggering of the afferent limb of the RRS as indicated by at least one of the following calling criteria or mandatory escalation pathways.

1.3.1 Escalations based on total EWS

According to the NZEWS guidelines (HQSC, 2017b), any NZEWS score of 5-6 is taken as an indication of a new onset acute illness or an unstable chronic illness and requires a review by a secondary responder such as a Patient-at-Risk (PAR) nurse or a junior doctor. The assignment of a secondary responder is not defined. It is left to the clinical decision making of the primary nurse who monitors the patient and records their vital signs and the NZEWS.

1.3.2 Escalations based on single parameter derangements

Though total EWS is used to trigger further action according to the escalation pathway, severe derangement in any one of the vital sign parameters can also trigger further action. Severe derangement represents the **blue zone** on the NZEWS chart. Severe derangements are only applicable to four out of seven vital signs as follows:

- **Respiratory rate per minute:** ≥36 or ≤4
- **Heart rate per minute:** ≥140 or ≤39
- **Systolic BP in mmHg:** ≤69
- **Loss of consciousness** also falls into the blue zone.

The blue zone does not apply to any derangement in temperature, any increase in systolic blood pressure, any change in oxygen requirement or oxygen saturation. The blue zone is not associated with a score as any parameter in the blue zone indicates severe deterioration and should immediately prompt a rapid response call.

The **Red zone** represents moderate derangement in a vital sign measurement and indicates that a rapid deterioration of the patient is likely. Therefore, a single vital sign in the red zone triggers a mandatory escalation as shown in Figure 1-3.

Cardiac arrest, also known as In-hospital Cardiac Arrest (IHCA), is a sudden loss of cardiac or cardio-pulmonary function. In case of an IHCA, the Taranaki Base Hospital Emergency Procedure's flipbook – a resource based the Australia and New Zealand Committee on Resuscitation (ANZCOR) guidelines (Leman & Morley, 2016) mandate that first attending staff would assess the scene, check the person's consciousness level and call for help. The first attending staff is expected to check for breathing and open the airway and commence cardiopulmonary resuscitation (CPR). The second attending staff or person is expected (or guided by the first attending staff) to dial 777 to notify the location of the arrest and return to assist the first attending staff. The telephone operator follows the standard operating procedure for activation of the hospital arrest team (HAT) sometimes referred to as Crash Team, medical emergency team (MET) or just arrest team. The attending staff are expected to continue CPR until the medical or other help arrives as outlined in the section below.

The 777 call ensures that appropriate emergency response is known and is followed by all staff in the event of an adult, paediatric, or maternal pre-arrest or cardiac arrest occurring at the hospital (i.e., Taranaki Base Hospital). When this is an IHCA or pre-arrest (as defined within vital signs monitoring and NZEWS), anywhere within the main hospital buildings' premises, the 'Hospital Arrest Team' attends to the patient to provide prompt emergency management and response. All team members must have completed a New Zealand Resuscitation Council's CORE Advanced training programme and have a current certificate. The 777 calls act like a 111 call for a roadside traffic accident or other emergencies outside

the hospital. For the latter, the first response is provided by trained paramedics of the Ambulance Services.

The procedure for a 777-call includes dialling 777 from the nearest available telephone, stating the location and type of arrest, i.e., adult, child or maternal, and cardiac arrest or pre-arrest. The telephonist activates group linked pagers to alert the hospital arrest team. The designated staff members within this arrest team will arrive at the location and bring the necessary equipment, such as a resuscitation trolley where applicable.

The actions corresponding to the trigger indicating the most severe level of deterioration must be taken. For example, if the total NZEWS was 5 but a single parameter lay in the 'red zone' on the chart, the action associated with the red zone should be taken. This is illustrated in Figure 5 where the total early warning score is 5 (triggering actions for the yellow zone on the escalation pathway). Still, because the single parameter of respiratory rate is in the red zone, those actions should be taken.

The efferent limb of the RRS is generally designed to provide a rapid and appropriate response to the level and type of deterioration conveyed by the 'trigger' or 'calling criteria' used to activate the efferent limb. For severe deteriorations, it is generally activated by a 777-call and leads to a multidisciplinary rapid response team who attends the patient, treats the condition at hand and decides whether the patient can be rescued and what would be an appropriate level of care (same ward or escalation of care to ICU).

The efferent limb of the RRS activates when calling criteria defined by the mandatory escalation pathway is met. Patient at-Risk nurses provide a timely and specialised response to all levels of patient deteriorations from simple low-grade elevation in single VS

measurements such as increased heart rate, elevated temperature to moderate and severe issues such as in-hospital cardiac arrest (IHCA) along with the Hospital Arrest Team (HAT).

By far the most important step of the entire process of undertaking vital signs is this last step, whereby nursing staff decide whether they need to take further actions such as seeking advice from a more senior and specialised group of nursing known as 'PAR Nurses' or from a medical team based on their findings of the vital signs and EWS measurements. The NZEWS chart dictates a pathway for escalation of care based on the vital signs and EWS measurements as shown below.

Mandatory escalation pathway		
Total Early Warning Score (EWS)	**Action**	
EWS 1-5	Consider increasing vital sign frequency. Discuss with senior nurse. Manage pain, fever and distress.	
EWS 6-7 Acute illness or unstable chronic disease	House officer review within 30 minutes. Inform nurse in charge.	Monitor vital signs every 30 minutes until EWS <6 and/or ongoing monitoring plan documented. Consider involving SMO.
EWS 8-9 *or* any vital sign in red zone Likely to deteriorate rapidly	House officer review within 15 mins, discuss with SMO. Inform nurse in charge.	Monitor vital signs every 15 minutes until EWS <8 and/or ongoing monitoring plan documented. Consider involving ICU.
EWS 10+ *or* any vital sign in blue zone Immediately life threatening critical illness	Put out a rapid response call by dialing 777 and stating 'rapid response call', the patient's name and location. Stay with the patient and manage immediately life-threatening issues. Inform the SMO and the patient's family.	

Figure 1-3 Example escalation pathway

(Copied from the HQSC Guidelines (HQSC, 2017b))

In this study, I observed on 230 occasions (2.65%) out of a total 8659 times when complete sets of vital signs were undertaken, one of the criteria for the mandatory escalation pathway could have been met if all the EWS were calculated correctly. Because of the missed or incorrect EWS values, on 156 occasions (1.80%), the EWS chart showed that one of the criteria for mandatory escalation pathway was met. This means the care could have been escalated 74 times more during the three months period.

Despite the EWS chart having documented the EWS threshold above the mandatory escalation pathway on 156 occasions, further actions were taken 95 times: 60.90% of the actual recorded higher EWS. This would mean that the compliance to NZEWS mandatory escalation would further go down to 41.30% or 74 occasions when the NZEWS criteria could have been met if the recording was complete and correct.

1.3.3 Tools and technology used to escalate care in the existing RRS

Primary caregivers (generally the ward nurse and attending family member or a healthcare assistant) use telephone calls and the pager system (discussed in detail in the next section) to raise concerns about deteriorating patients. During this study, primary caregivers reported that verbal communication through the telephone is helpful in escalating care to secondary caregivers or responders, i.e., a medical team or a Patient-at-Risk (PaR) nurse – the role of the PaR nurse is also discussed in the subsequent section below. The responders reported that remote access to vital signs values and trends would enable them a much better view of the status of the deteriorating patients compared to verbal communication over the telephone or brief text messaging through a pager system. The responders are of the view that the information passed on in the most ‘calls’ consists of derangement in one or more vital signs and/or NZEWS score in one point in time and does not provide the trend of the derangement. Moreover, contextual information such as current diagnoses of the patient (which would

allow the responders to easily prioritise which calls are more acute in nature than others) is not passed on to the responders. The pager and telephone are not designed for the purpose of complex information. They don't come with screens for graphic presentation of vital signs data which is needed to demonstrate upward or downward trends in one or more vital signs.

1.3.4 Documenting the escalation of care in the existing RRS

NZEWS charts do not provide physical space to primary caregivers or responders to document the actions they undertake because of one or more deranged vital signs or elevated NZEWS score. This documentation by the nursing staff (based on their conversations with PaR nurses or the medical team) or the documentation by the responders is generally found in the medical records file of the patient. It is important to mention that the EWS charts are placed next to the bedside, whereas the medical records files are placed further away from the bedside, usually on a nursing station or in the office of the attending medical team. In the current study, it was observed that this step was missed in several cases directly observed. In many of the cases, this step was completed retrospectively or at the end of a nursing shift. This is understandable as each ward nurse is allocated 4-6 patients and each patient may have varying needs in terms of monitoring, assessments, and other nursing tasks. Therefore, a ward nurse may only find it possible to document this step-in batches to reduce interruptions and increase their efficiency.

1.3.5 Patient at Risk (PaR) service – specialised secondary responders in the existing RRS

The Patient at Risk (PaR) Nurse service is the model of nurse-led rapid response to deteriorating patients. PaR service also provides proactive monitoring and follow-up of patients recognised at higher risk of deterioration. Such patients include those discharged from an intensive care unit or have had a recent significant event such as a pre-arrest call.

The PaR service was established at Taranaki District Health Board in November 2019 in line with recommendations from ‘Deteriorating Patients Programme’.

The Patient at Risk Nurse (PaR Nurse) is an advanced nursing practice role with specialist knowledge in identification, assessment, care co-ordination and support with specific reference to deteriorating patients. The role is responsible to provide clinical expertise and leadership and promote clinical excellence ensuring best practice standards are maintained with an emphasis on supporting and educating ward staff to recognise clinical deterioration and initiate an appropriate escalation of care for patients.

- Respond to all 777 calls hospital-wide
- Attend all clinical areas when escalated by the clinical staff or in response to 777 calls
- Regular rounding to the Acute Service Block inpatient wards
- Identify physiologically unstable patients, assess, and provide any assistance (as identified on rounding or notification from ward/unit staff)
- Review patients transferred out of ICU/CCU/HDU within 4-6 hours of arrival to the ward
- Provide leadership and support to ward staff during 777 emergencies. Aim to review patient after 777 call in a timely manner
- Immediate debrief of any critical incidents.

The PaR Nurse maintains contact with the hospital’s duty nurse manager and relevant medical staff regularly throughout each shift to provide support and guidance to the primary nurse and nurse co-ordinator of the ward/unit in relation to deteriorating patients and patients at risk. The PaR Nurse also collects all activations for audit, reporting and quality improvement purposes. The service operates on a 24/7 basis, and the on-duty PaR

nurse attends shift-to-shift handover between the hospital duty managers and daily handover between medical teams.

1.3.6 Hospital Arrest Team – the highest level of rapid response team within current RRS

A multidisciplinary team of clinical (mainly medical and nursing) staff often joined by a non-clinical (Chaplain or cultural advisor) constitute the Hospital Arrest Team (HAT).

The HAT composition differs depending on the type of patient, i.e., adult, child, or maternal patients. When there is an adult patient having cardiac arrest or a pre-arrest condition, the pager displays “arrest call” and location, and the following staff members (Adult HAT) receive a group-linked pager activated by Taranaki Base Hospital’s telephonists.

- Medical Registrar on-call (unless otherwise agreed by attending Medical Registrars)
- Medical House Officer on-call (unless otherwise agreed by attending Medical Registrars)
- Surgical House Officer (after hours)
- A dedicated Intensive Care Unit (ICU) Nurse
- Patient at Risk (PaR) Nurse
- Hospital Duty Manager
- ICU/Anaesthetic Registrar
- Resuscitation Coordinator (during working hours)
- Transfer Nurse
- Chaplain

In case of a child (defined by age under 16) having a cardiac arrest or a pre-arrest condition, the Paediatric HAT team is activated in the same way and pagers display “Paediatric Arrest” and Location. The Paediatric HAT consists of the following:

- Paediatrician
- Paediatric Senior House Officer and/or Registrar on call
- Paediatric Clinical Nurse Specialist (during working hours)
- Neonatal and/or Paediatric Nurse Manager
- The Hospital Duty Manager
- Transfer Nurse
- Circulating Nurse
- Nurse Manager ICU
- ICU Coordinator
- Resuscitation Coordinator
- ICU/Anaesthetic Registrar
- Patient at Risk Nurse

When a pregnant woman with over 24 weeks of gestation suffers a cardiac arrest or a pre-arrest condition defined by the maternal vital signs and EWS, a Maternal HAT is activated. Pager devices display “Maternal arrest” and location and the following staff receive this page, to attend the patient:

- Adult Arrest Team plus
- On-call Obstetrician
- On-call obstetrics and gynaecology registrar or senior house officer
- Midwifery Nurse Manager (during working hours)

- A dedicated medical and nursing team from the neonatal unit
- A paediatrician

1.3.6.1 HAT Operating model

The Medical Registrar on-call is the nominated leader of the HAT. Any Consultant (except the one responsible for the patient) in attendance acts in an advisory role unless requested by the Registrar to do otherwise. Nonetheless, all members of the HAT who are NZRC CORE Advanced certified, may initiate the administration of emergency drugs and initiate defibrillation as prescribed and in accordance with the New Zealand Resuscitation Council's Guidelines.

1.3.6.2 Equipment testing for HAT

Testing of the arrest alert procedure group linked pagers takes place each Tuesday between 1115-1200hours. They are activated by the switchboard with the emergency bleep. The person carrying the pager is to notify the switchboard that the activation has been successful.

1.3.6.3 Training requirements for HAT staff

All nursing and medical members of the HAT must have a current NZRC CORE Advanced Life Support certificate and have been orientated to Taranaki District Health Board’s resuscitation policy and procedures.

1.3.6.4 Training requirements for non-HAT staff

All other clinical staff (not members of HAT) are required to have at least basic life support training every three years. Training is provided in the DHB basic and advanced life support courses on the Arrest Alert Procedure.

1.3.6.5 Use of critical language for HAT

Language used to request an arrest call must be standardised to the language specified in the Hospital Arrest Alert Procedure. Should there be any confusion about the type of call, the telephone operator puts an arrest call out. This includes if a 777 caller uses the words “seizure”, “collapse”, “anaphylaxis” instead of pre or cardiac arrest to minimise the risk of delayed response to a possible cardiac arrest or a pre-arrest condition.

*1.3.6.6 **Pager devices: Primary Communication Tool in Healthcare***

The alphanumeric paging system or pager devices were introduced into healthcare in the 1950s as one-way numeric code and then quickly evolved to include alphabetic text-based messaging (Nguyen, McElroy, Abecassis, Holl, & Ladner, 2015). Pager devices provide wireless communication between hospital teams and individual staff members. Taranaki District Health Board (and many other District Health Boards within New Zealand) use pager devices (Alphanumeric Pager, model number W2028P) supplied by Wex International Limited, a Hong Kong based company specialising in wireless, radiofrequency, GPS/GPRS and Pager technology. The model used by New Zealand hospitals operates at 138-174, 138-174, 278-284, 405-480, 928-932MHz Bands and channel spacing of 25KHz. It uses Post Office Code Standardisation Advisory Group (POCSAG) signal format and can transmit data at 512, 1200 or 2400 bits per second (bps). Maximum alphanumeric characters in one pager message are 120 and it can display 20 characters per line and has a maximum of four-line display. It can store up to 16 messages.

Pagers have four different alert tones: continuous audible alert, standard alert tone for routine pager messages, emergency alert with a fixed alert tone, and vibration. A pager device requires one AAA (1.5 volts) battery and has a battery backup life of 15 seconds (when the battery is replaced, a longer delay means messages will be lost). Battery life varies from 1600

hours (2400 bps) to 2000 hours (512 bps). The W2028P model has a weight of 135 grams (including battery) and a size of 80.5L x 54.2W x 18.60H mm without a belt clip. Pager displays time and date, indicating if the pager is within reception range and battery status.

Pager devices have been used for several decades across the globe and have allowed for increased information transmission between hospital teams and individuals, especially between the nursing staff attending the patient and the medical staff who are responsible to provide medical advice. Despite pagers having led to increased transmission of information, there is a view shared by medical staff that pager communications are often disruptive (Wu et al., 2012). Reports have highlighted that the proportion of urgent and semi-urgent pager alerts during an on-call shift for resident medical officers have led to significantly increased workload for the medical on-call teams, and later determined to be non-urgent. (Commission, 2007; Nguyen et al., 2015; Soto, Chu, Goldman, Rampil, & Ruskin, 2006) Furthermore, as the load of pager calls increased, the medical on-call RMOs became unable to respond or their response starts to slow, in either case, the purpose for which the pager system exists started to fail (Boehringer, Rylander, Dizon, & Peterson, 2007). Although a direct cause and effect relationship is difficult to establish, yet it was evident that increasing workload had an overall adverse effect on patient safety (Nguyen et al., 2015; Wu et al., 2012).

Over the last couple of decades, developments in information technology such as smartphones have .created options for the transmission of rich textual and graphic data in a bi-directional fashion (De La Cruz Monroy & Mosahebi, 2019). These key technological innovations have increased the speed of information transfer and enabled multiple other very important functions, such as removing the requirement to wait for a reply as with pager devices. A smartphone-based solution can relay critical information to responders such as PaR nurses and other members of the HAT who could remotely start the assessment of

patients well before reaching to the bedside. The rapid response process becomes more real time and dynamic opposed to the current procedure which requires the 777-call to activate the HAT, which gathers at the bedside and only then assesses and manages the time critical condition (Lo, Wu, Morra, Lee, & Reeves, 2012). However, these apparent benefits of smartphone use for communication of healthcare information between teams do come with unintended consequences. Studies conducted within the last ten to twelve years have shown that the use of smartphones is associated with reduced volume and quality of face-to-face interactions between healthcare providers such as nurses and patients (DiChiacchio, Kidd-Romero, & Kavic, 2017; Locke, Duffey-Rosenstein, De Lio, Morra, & Hariton, 2009; Vaisman & Wu, 2017). Smartphones have also been blamed for limiting the opportunities for more meaningful interactions between healthcare professionals and teams, despite the perception that they have reduced the time required to reach out to someone such as a senior clinician (DiChiacchio et al., 2017; Fiorinelli et al., 2021). From a technical standpoint, cellular network reliability, unpredictable cellular receptivity within certain areas of the hospital (dead zones) (Klemets & Evjemo, 2014) such as thick-walled rooms (radiology, oncology therapy and other equipment rooms have lead-lined walls). Another major barrier to the implementation of cellular smartphones as a primary tool for communication within healthcare is data privacy concerns as there is no certainty about the security of the data and risk of losing the confidentiality of the information (BinDhim & Trevena, 2015; Minen, Stieglitz, Sciortino, & Torous, 2018; Visvanathan, Gibb, & Brady, 2011). In New Zealand, the Privacy Act 2020 (*New Zealand Privacy Act 2020*, 2020) stresses much more strongly on data security than ever before. The author has also reviewed the privacy management of new data sources, including smartphone applications for healthcare and found that the risk of loss of confidentiality of healthcare data could be real at multiple levels (Asghar et al., 2017). Another consideration would be the cost involved as healthcare organisations would need to

provide smartphones with some higher level of data security and identification authentication features to their staff. This is considerably expensive compared to pager devices. The unintended consequences of smartphone use within the healthcare context and the technical issues mentioned in the above paragraph must be addressed before healthcare communications can fully benefit from the smartphones.

1.3.7 Administrative and governance limb of RRS

A mature and effective RRS requires an 'administrative and governance limb' to ensure these operational components operate at optimal levels of functioning and have an administrative and governance oversight (Difonzo, 2019; Sethi & Chalwin, 2018; Christian P Subbe et al., 2019).

The study site has a well-structured cardiopulmonary resuscitation committee also known as a Resuscitation Committee which acts as the mainstay of the administrative and governance limb of the RRS. The Resuscitation Committee holds the organisational view of the operative functions of the afferent and efferent limbs of the RRS, and aims to support the activities required for the continuous improvement limb of the RRS, which is in line with the recommended roles for hospital resuscitation committees (Perkins et al., 2015). The purpose of the Resuscitation Committee at the study site, as per the current terms of reference is as follows.

- To promote and monitor high standards of resuscitation provision and training within the organisation
- To advise the organisational Clinical Board on matters relating to patient/client resuscitation
- To promote and monitor the effectiveness of the Early Warning Systems, processes, and functionality across the DHB

Taranaki District Health Board's Cardiopulmonary Resuscitation Committee meets every two months and has a wide membership including senior medical and nursing leaders from adult medical, surgical, maternal and paediatric specialities aligned to recommended best practices (Nallamothu et al., 2018).

A review of documentation reveals that the Resuscitation Committee is not fully functional and is not able to routinely meet every two months as stipulated in its terms of reference. The Resuscitation Coordinator is an ex-officio role for the Nurse Educator, Cardiopulmonary Resuscitation and Deteriorating Patient Programme who also chairs the Resuscitation Committee. Thus, one individual who has two busy primary roles has the additional role of leading the work of the Resuscitation Committee. Similarly, the Clinical Governance Advisor for Medical and Acute Services which is a 0.8 full time equivalent role primarily to cover all medical and acute services from clinical governance, patient experience and safety perspective, provides analytical input for the Resuscitation Committee. Administration support is provided by the Clinical Governance Support Unit and is limited to the availability of a minute taker once every two months or often less frequently, depending on the meeting frequency of the Resuscitation Committee.

The Resuscitation Committee requires specialised resources to perform periodic evaluation of the RRS, collect appropriate and timely data on the RRT-activations/777 calls to adequately analyse them, audit the deteriorating patient pathway and enable the organisation to meet the obligatory certification requirements as well as aim to align the organisation RRS with the recommended best practices outlined by Subbe and colleagues (Christian P Subbe et al., 2019) – further discussed below as well as in the last chapter of this thesis.

1.3.8 Continuous Improvement limb of RRS

The continuous improvement limb of the RRS endeavours to investigate the functioning of the RRS by applying measures of quality improvement, looking at the flaws, their causes and how to mitigate those to continuously improve the RRS to achieve the goal of improving patient safety (Veiga & Rojas, 2019). This limb of the RRS works closely with the administrative and governance limb of the RRS and has a structural and functional overlap with the rest of the RRS (Olsen, Søreide, Hillman, & Hansen, 2019; Taenzer & Spence, 2018). The clinical staff involved in afferent and efferent RRS activities, clinical and non-clinical management and leadership work with improvement specialists to continuously identify opportunities for improvement within the RRS, and continue to plan and implement changes aimed at making the afferent RRS more sensitive and specific in predicting the antecedents of serious adverse events in a timely manner, and building the capabilities of the efferent RRS (De Blok, Koster, & Wagner, 2013; Olsen et al., 2019).

At the study site, the activities associated with the deteriorating patient programme led by HQSC over the last six years (2016 – 2021) constitute the local version of the continuous improvement limb of the RRS (HQSC, 2017a). Key advancements made by this programme include the development and implementation of nationally consistent NZEWS charts which bring a mandatory escalation pathway or calling criteria, providing professional development, and training opportunities for the staff and developing a workforce of trained Patient at Risk (PaR) nurses. The future direction of this programme includes a focus on patient and family generated activation of rapid response teams (RRT) through its 'Kōrero mai – patient, family and whānau escalation' initiative (HQSC, 2019) and an emphasis on consistent documentation and execution of the patient and family wishes in relation to the level of resuscitation and care they wish to receive through the Shared Goals of Care (SGoC) pathway

(HQSC, 2021). The Kōrero mai initiative allows patient and family to escalate their care by speaking up to the attending care team who can assess their requests, and if required they (the staff) can activate the RRT if indicated. This approach of Kōrero mai is different to the activation of the RRT by the patient or family described in the literature (Guinane, Hutchinson, & Bucknall, 2018; McKinney, Fitzsimons, Blackwood, & McGaughey, 2021; Strickland, Pirret, & Takerei, 2019; Youngson, Currey, & Considine, 2017). All the RRT activations/777-calls from the last five years have been based on the NZEWS and single vital sign parameter-based calling criteria. Therefore, it is safe to infer that direct activation of RRT by the patient and family is not in practice at the study site.

1.3.9 Conclusions

In summary, the characteristics of the RRS at the study site are expected to be generally consistent with most of the public sector hospitals in New Zealand. It is also expected that some differences may exist between the RSS at the study site and the RRS at hospitals affiliated with Waitemata DHB in the Northwest Auckland region and Canterbury DHB in the North Canterbury region because these two DHBs have recently implemented electronic applications to collect vital signs. It is however also important to note that the electronic application used by these two DHBs is only a VS collection application, not an electronic RRS similar to the VitalsAssist application (M. M. Baig, GholamHosseini, & Ahmad, 2020; "Vital signs monitoring and decision support system (VitalsAssist)," 2017) which is mentioned in other parts of this thesis. Except for these two DHBs, the observations made in this chapter are expected to be broadly applicable to New Zealand hospitals using paper-based VS and NZEWS charts.

1.4 Thesis structure and overview of studies

This thesis provides a comprehensive evaluation of RRSs by four main studies shown within the overall structure and flow of the thesis in Figure 1-4.

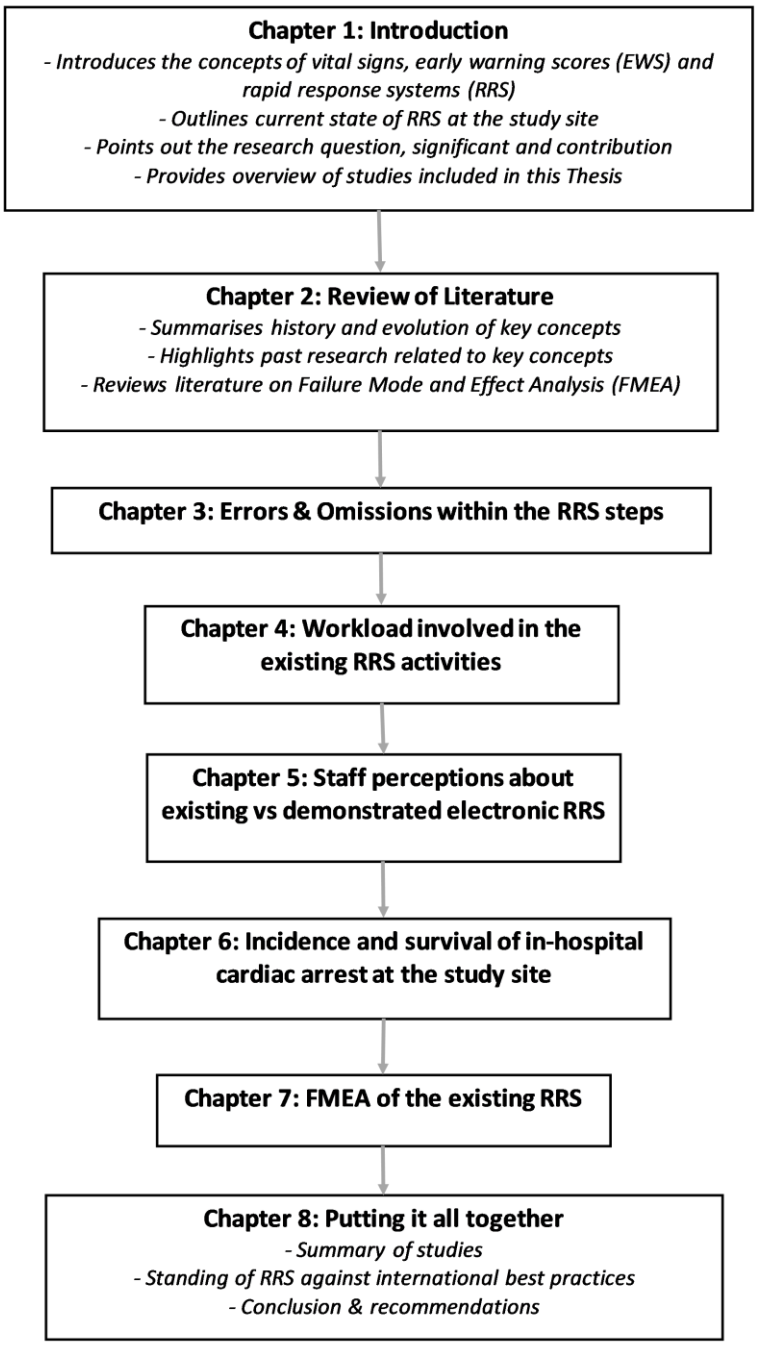


Figure 1-4 Structure and flow of the thesis

The four major components or limbs of RRS have been outlined above. The first study assesses the error and omission rate within the key clinical limbs i.e., the afferent and efferent limbs of the existing RRS through an observational study on four months of vital signs monitoring in a 32-bedded general hospital ward. This study includes a sample of 7704 completed sets of all seven vital signs (53,125 individual vital signs observations) in 224 patient admissions. This study presents the rates of errors and omissions in patient monitoring and responding to deteriorating patients and compares these findings with past research. The study that evaluates the workload involved in the measurement and recording of 172 sets of vital signs was an observational study. The workload was observed directly by the candidate and 10% of measurements were validated by an independent expert. These first two studies were conducted between 1 October 2020 and 31 January 2021. The study that estimates the workload involved in responding to deteriorating patients from the real-time self-reported time spent per rapid response includes additional four months going back to 1 May 2020 as the study duration did not produce enough number of 777-calls. However, the data from May 2020 to January 2021 produced 254 777-calls which was sufficient for the study. The study on the user (nursing and medical staff) experience and perceptions and FMEA were conducted between January and July 2021. The staff surveyed user perception about the existing RRS and the demonstrated model of electronic RRS. The survey was participated by 121 staff (84 nurses and 37 doctors). The online survey was live for three weeks (1 to 22 February 2021). The FMEA recruited subject matter experts as per the methodology outlined in the relevant chapter. The study on the incidence rate and survival status of the patients who underwent in-hospital cardiac arrest (IHCA) included the data from 2016 to 2020 because of two factors i.e., firstly the number of actual IHCA cases among adult patients in the 777-calls received from general hospital wards for the entire period of

five years was 142. This study was conducted to see the possible association of the findings with earlier studies.

1.5 Research Question, Significance & Contribution

The RRS is poorly understood as a system. There is no published report to suggest a systematic assessment of RRS to identify and mitigate the inherent risks. The workload involved in the efferent limb of RRS is well reported but there is no literature to report the workload involved in the efferent limb of RRS. The perceptions and experiences of the staff who operate the afferent and efferent limbs of RRS are not known.

This thesis utilises a set of targeted studies to comprehensively assess RRS as a system. The findings of these studies identify the weaknesses or inherent risks of RRS and explain causes of these weaknesses. Based on the findings, this thesis proposes how those system weaknesses could be resolved. This thesis extends the body of knowledge by elaborating the cumulative effect of the errors and omissions in RRS on the patient safety. This thesis also extends the body of knowledge by quantifying the workload involved across the RRS spectrum and by presenting end-user perceptions on existing RRS vs electronic RRS. This thesis also presents first ever reported FMEA on the RRS. The findings of the FMEA strengthens the observations from other targeted studies and demonstrates why an electronic RRS must replace existing paper-based vital signs charts. The FMEA also offers to point out the failures which would not be addressed by implementing electronic RRS alone, and hence require specific remedial actions at the policy level.

CHAPTER 2 Literature Review

2.1 Background

This chapter firstly summarises the available literature and gives a short account of the evolution of the key concepts discussed in the thesis. These key concepts include vital signs, Early Warning Scores (EWSs), Rapid Response Systems (RRSs), including an account of the components of RRS. This chapter explains the concept of patient deterioration and explains how RRS enables early recognition of deteriorating patients. Components of RRS are introduced and various models of RRS are briefly described. Finally, this chapter includes a review of literature on the FMEA applications on healthcare processes and outlines why this thesis utilises this methodology as a systematic approach to examine the failure modes of the RRS.

2.2 Evolution of vital signs

The term ‘vital signs’ denotes a collection of measurements or observations. Vital signs include heart rate (also known as pulse rate), body temperature, respiratory rate, blood pressure, oxygen saturation and level of consciousness (HQSC, 2018). Sometimes, urine output, level of pain and other observations are also advocated to be vital signs. In the modern healthcare industry, vital signs monitoring is an integral part of routine care. Therefore, vital signs the surveillance mechanism for clinical staff to keep track of patients’ essential body functions when they are hospitalised.

More recently, with technological advancements enabling remote monitoring, some or all these vital signs are monitored remotely through sensor-based devices. Thus, health care professionals could access vital signs information in real-time or intermittently through a smartphone or computer application.

Vital signs have a rich and long history through which they evolved, as described briefly in the following paragraphs.

2.2.1 Beginning of vital signs: Pulse & Body Temperature

It is not clear whether the arterial pulse or the body temperature or both attracted the attention of the ancient physicians and healers first. Arterial pulse and body temperature have been mentioned and traced since 1700 BC during ancient Egyptian times. According to their inscriptions, the effect that they recognised was a rise in body temperature (fever) caused by inflammation and that fever and physical activity would accelerate the pulse (Atta, 1999; Dawson, 1967). Similarly, several references to arterial pulse are found in the Chinese Medicine "Internal Medicine Classics, Nei Ching" as far back as 598 – 698 BC (Ghasemzadeh & Zafari, 2011). Sage Kanada, an ancient Indian physician of 600 BCE, also described radial pulse (pulse in the radial artery of the wrist) (Kanada, 1987). While the Greats of Greek Medicine, Hippocrates, Aristotle to Erasistratus, Praxagoras, Herophilus and Galen extended the understanding of circulation and other body functions, pulse and body temperature remained fundamental tools of their diagnostic process (Boylan, 2007; Ghasemzadeh & Zafari, 2011; Horine, 1941). A Persian physician, Ibn Sina, (Avicenna) of the Middle Ages pioneered the current method of checking radial pulse and described the role of pulse not only in physical health but also in certain emotional conditions (Celik, 2010; Hajar, 2018). From the Middle Ages to 1625 AD, the only recognised vital signs remained the pulse and body temperature, and both were evaluated through subjective assessment techniques.

2.2.2 Introduction of objective measurement of Pulse & Body Temperature

Santorio of Venice (1561-1636) introduced measurements and mathematics into medicine (De Santo, Bisaccia, Mezzogiorno, Perna, & Cirillo, 2011). In 1625, Santorio published

methods for measuring body temperature using a spirit thermometer and timing the pulse rate with a pendulum with his colleague Galileo (Gardner, Clemmer, Evans, & Mark, 2014). Unfortunately, this seminal work of Santorio remained uncited and did not get attention for many decades. It was 1707 when English physician and author, Sir John Floyer, published his scientific report on the pulse in which he collected all the pertinent knowledge on the pulse till that time which highlighted Santorio's work (Floyer, 1710). Further refinements in thermometers led the way to the definition of normal body temperature as 37°C in the middle of the 19th century (Sund-Levander & Grodzinsky, 2013).

2.2.3 Addition of third & fourth vital signs: Respiratory Rate & Blood Pressure

The history of the third to fifth vital signs is rather short (1852 – 1988). Respiratory rate, defined as the number of breaths per minute, secured its third position in 1852 when Ludwig Taube added it along with the plotted course of temperature in a patient (Manici & Torbinio, 2018). This was the first-ever temperature chart and led physicians to start checking the trio of pulse, temperature, and respiratory rate. This trio remained as the standard set of 'vital signs' for monitoring patients into the latter half of the 19th century.

The fourth vital sign to join the list was 'blood pressure' (BP). Though an invasive method of BP measurement was reported by Reverend Stephen Hales in 1773 (Dieterle, 2012), it was 1876 when Marey described a non-invasive and practical method of measuring blood pressure. In 1896 the first-ever 'sphygmomanometer' (blood-pressure measuring cuff) was commercially introduced for clinical use (Ringrose & Padwal, 2021). The pulse, temperature, respiratory rate, and blood pressure remained the standard of patient monitoring for nearly a century and remains in use today.

2.2.4 Oxygen saturation as a fifth vital sign

Measurement of oxygen saturation also known as oximetry has been known as a critical physiological parameter since the nineteenth century (John W. Severinghaus & Astrup, 1986). Most of the methods available to measure it at that time were invasive until the development of the non-invasive pulse oximeter in the 1970s (Pole, 2002). Modern pulse oximeters became commercially available in the 1980s (John W Severinghaus & Honda, 1987). Oxygen saturation officially joined the list of vital signs after Thomas Neff's ground breaking editorial in the journal 'The Chest" in 1988 (Neff, 1988).

2.2.5 The list of vital signs is still growing

The list of vital signs is still growing. Many physiological parameters such as urine output, level of consciousness, functional status, health literacy, emotional distress, pain scores, and walking speed have been widely discussed as the next contenders (Bierman, 2001; Fritz & Lusardi, 2009; Heinrich, 2012; Holland & Bultz, 2007). As the understanding of human body functioning evolves, the list of vital signs is expected to further expand.

Since the 1990s, various models of presenting the combined effect of vital signs have been presented, and these have been termed early warning scores (EWSs) (Rotondi, Kvetan, Carlet, & Sibbald, 1997) which are discussed in the next section.

2.3 The Emergence of Early Warning Scores

The term 'early warning score' (EWS) originated from the military and foreign affairs spheres, where the EWS was designed and implemented to quantify the probability of armed conflicts based on their forerunners such as social escalations, public sentiments and the like (Rupasinghe & Kuroda, 1992). In these fields, EWS allowed the development and deployment of measures to prevent major conflicts and eventually save human lives and the economy. In military and foreign affairs, EWSs are used to forecast disputes and conflicts.

This term was firstly used in the healthcare context in the late 1990s when a model of EWS was presented to detect early major deteriorations in patients' status based on abnormalities in their haemodynamic status and vital signs (Morgan et al., 1997). Thus, the EWS emerged to interpret the combined effect of abnormalities in vital signs. As a concept, EWS should predict such abnormalities prior to a patient experiencing catastrophic harm such as an organ failure, cardiopulmonary arrest, or death. Based on the level of derangement in the EWS, healthcare professionals should be able to identify which patient is sicker than the other, and thus require more urgent or immediate treatment. EWS is also referred to as a track-and-trigger score. It is used as a switch to activate the efferent component of RRS. The concept of EWS was necessitated by the growing evidence of unnecessary harm to patients while hospitalised in the late 1900s and early 2000s (Brennan et al., 1991; Gerry et al., 2017).

Morgan Williams used the quatro of pulse, temperature, respiratory rate and blood pressure and coupled it with the AVPM screen for alertness to generate the first EWS in 1997 (Morgan et al., 1997). This was followed by multiple variations and modifications of EWS. The evidence to support the need for EWS was growing rapidly though. The seminal report of the Institute of Medicine (IoM), USA 'To err is human' stirred the discussion of preventable harm and patient safety and led the way to modern medicine embracing quality improvement and process control science (M. S. Donaldson, Corrigan, & Kohn, 2000).

Multiple studies demonstrated that patient deterioration resulting in cardiac arrest or death was commonly preceded by several hours of deranged physiology that could potentially be picked up had an accurate and sensitive EWS and efficient RRS been in place (K. M. Hillman et al., 2002; Juliane Kause et al., 2004; McQuillan et al., 1998). One of these studies, the ACADEMIA study by Kause et al. 2004, was tri-national (Australia, New Zealand, and the UK).

2.3.1 National Early Warning Score, the UK 2012

In the UK, the Royal College of Physicians London (RCPL) advocated for nationally standardised and consistent monitoring of hospitalised adult patients except for pregnant women and recommended the National Early Warning Score (NEWS) in 2012 (M. Jones, 2012). The NEWS was implemented across the National Health Service (NHS) of the UK between 2012 and 2017. The NEWS aimed to achieve a common language that is used consistently throughout the hospitals under the NHS. The NEWS was refined and updated to NEWS-2 in 2017 as a result of validation studies into the NEWS (Gary B Smith et al., 2019). NEWS introduced a system whereby a score of zero to three (0-3) is given to each of the vital signs included in routine patient monitoring, i.e., pulse, breaths per minute, systolic blood pressure, body temperature, level of consciousness on an AVPU scale (**A**lert, responds to **V**oice only, responds to **P**ain only, or **U**nconscious) and oxygen saturation. NEWS also allocated two additional scores if a patient needed oxygen supplementation to keep adequate levels of Oxygen saturation (SpO_2). The RCPL mandated vital signs monitoring at least twice in a 24-hour cycle in general hospital wards, and this frequency of monitoring was endorsed by the National Institute for Health and Care Excellence (NICE) guidelines (Gary B Smith et al., 2019).

2.3.2 The New Zealand Early Warning Score 2015

Dr Alex Psirides, an intensivist, and Anne Pedersen, an ICU nurse from Wellington Regional Hospital, proposed the New Zealand Early Warning Score (NZEWS) in October 2015 (Alex Psirides & Pedersen, 2015). The NZEWS is a modified version of the NEWS model proposed by the RCPL with some modifications to suit the New Zealand context backed by evidence. The NZEWS has stepped forward to include calling criteria for rapid response based on extreme abnormalities in single vital sign parameters as an additional safeguard to the calling

criteria based on the aggregate early warning score value. This addition is not unique to New Zealand but shared with Australian hospitals. These single parameter derangements are detailed in the NZEWS user manual issued by the New Zealand Healthcare Quality and Safety Commission (HQSC, 2017b) and summarised below. The NZEWS calling criteria for a rapid response based on a single parameter extreme derangement includes a breathing rate of below 5 or above 35 per minute, a systolic BP below 70mmHg, a pulse rate below 35 or above 140 beats per minute (irrespective of rhythm), and a patient who becomes unconscious or experiences fits (convulsions, epilepsy). NZEWS excludes extreme hypertension, hypo or hyperthermia, or hypoxaemia from these single parameter calling criteria. Based on the work of Psirides and Pederson, the New Zealand Healthcare Quality and Safety Commission led a five-year programme to roll out NZEWS and a vital signs chart from 2016-2021 (HQSC, 2018).

2.4 Rapid response systems (RRSs)

2.4.1 Inception of RRSs

The failures to rescue deteriorating patients in hospitalised patients were mainly thought to be due to errors in cardiopulmonary resuscitation (CPR) and advanced life support (ALS) techniques and mechanisms. Thus, there has been a focus on training and education of physicians and nurses to mitigate those issues (Bedell, Delbanco, Cook, & Epstein, 1983; Curry & Gass, 1987; Hollingsworth, 1969; Lowenstein, Sabyan, Lassen, & Kern, 1986; Mullie, Van Hoeyweghen, Quets, & Group, 1989; Murphy, Murray, Robinson, & Campion, 1989; Reichman et al., 1990; Suljaga-Pechtel, Goldberg, Strickon, & Berger, 1984). In the 1990s, a few groups of ICU physicians published their reports on patients ending up in ICUs after deteriorating. These reports raised questions about what exactly had been going on with the general ward patients' minutes to hours before an arrest call was made, and when the ICU

physicians and teams could help those patients prior to such time by intervening and halting such deteriorations early. These questions led to a paradigm shift in thought and perspective on where to focus resources to improve the survival and clinical outcomes for such patients. This shift led to the inception of the Rapid Response System (RRS). ICU physicians shared a common understanding that general ward patients requiring a sudden and unplanned ICU admission rarely went from being 'normal' to critically ill suddenly. Such patients may go through a series of subtle to noticeable phases of deterioration. This deterioration may be suddenly recognised by the general ward providers and the systems supporting them. These propositions were supported by the results of investigations conducted in the 1990s and early 2000s which illustrated that most of these patients do experience noticeable changes for a few minutes to several hours prior to significant deteriorations but these changes are often not recognised by the staff looking after these patients (Bedell, Deitz, Leeman, & Delbanco, 1991; Daffurn, Lee, Hillman, Bishop, & Bauman, 1994; K. Hillman et al., 2001; Sax & Charlson, 1987; Schein et al., 1990; A. F. Smith & Wood, 1998).

2.4.2 Models of RRS

The first model of an RRS was introduced in 1995 by Lee and colleagues working at Liverpool Hospital, one of the well-known acute trauma hospitals in Australia, located in the south-western suburbs of Sydney, New South Wales (A. Lee et al., 1995). Lee and colleagues' model of RRS was physician-led and called Medical Emergency Team (MET). Rapid response teams (RRTs) were promoted by the '100,000 Lives Campaign' by Don Berwick as a patient safety intervention in 2005 (Berwick et al., 2006) which led to the widespread uptake of RRTs by healthcare organisations around the globe. Several different models of rapid response teams exist. The concept of the RRS has matured substantially since the 1990s. The focus has grown on developing usable criteria for general ward staff to

recognise early the impending deterioration with confidence and feel empowered to summon an early response and assistance from MET or rapid response teams (RRTs) with the aim to improve the outcome of deteriorating patients. Another model of a RRT was presented as the Critical Care Outreach (CCO) approach in the early 2000s as a combined approach to early identification of deteriorating patients and to work proactively to manage the high-risk patients recognised through regular monitoring or based on certain criteria such as recent discharge from ICU (K. Hillman et al., 2001). While the MET model was mainly a physician-led approach to respond to arresting or near-arresting patients, the CCO and RRT models are based on a nurse-led approach but may also include physiotherapists and other allied health professionals as well as doctors. A consensus conference of experts in the field in 2006 advocated for the use of the term "Rapid Response System" as a unifying term (Devita et al., 2006) which is well-taken. Despite the RRS having matured and refined over the last two decades, patient deterioration remains poorly managed. One of the influenced reviews of the UK National Health Service (NHS) incident reports found that ‘mismanagement of deterioration’ was the single most frequent cause of preventable death in hospitalised patients (L. J. Donaldson, Panesar, & Darzi, 2014). This finding is disturbing as it means the purpose of patient monitoring to recognise and respond to known antecedents of significant deterioration is not being met.

2.4.3 Patient and family activation of RRS

Patients and families are generally more aware of the patterns of patients’ routines, their functioning levels and general persona, so, when a patient’s overall health status changes, they can notice this change and often express their concerns to nurses and doctors around. Yet it is reported that family’s concerns are often not listened to and therefore, it has been increasingly recognised as one of the missing links of the RRS in the last decade (Guinane et

al., 2018; McKinney et al., 2021; Strickland et al., 2019; Youngson et al., 2017). This approach has been introduced in New Zealand through the Kōrero mai (Te Reo Māori word for 'Talk to me') project and it is emphasised by a sister project called shared goals of care (HQSC, 2019). Both are quality improvement projects using principles of codesign to engage patient and whānau (Te Reo Māori word for 'family' or 'extended family') in activating an RRS when they have concerns about deterioration. This approach includes patient and family concerns as an element of afferent components similar to the vital signs and EWS.

2.4.4 Functions of a hospital RRS

A hospital RRS performs the following functions:

1. Defines patients at-risk (PaR) of deterioration and further stratifies them into various groups depending on how rapidly a response
2. Takes care of patient needs and appropriate levels of care that promise best patient outcomes
3. Cuts through the usual hierarchies to enable rapid consultation by multi-disciplinary experts who gear up a team approach to manage time-critical situations
4. Assembles and despatches an appropriate rapid response to all PaRs
5. Operates across the whole organisation

These functions create an operational workflow of an RRS which is elaborated in Figure 2-1.

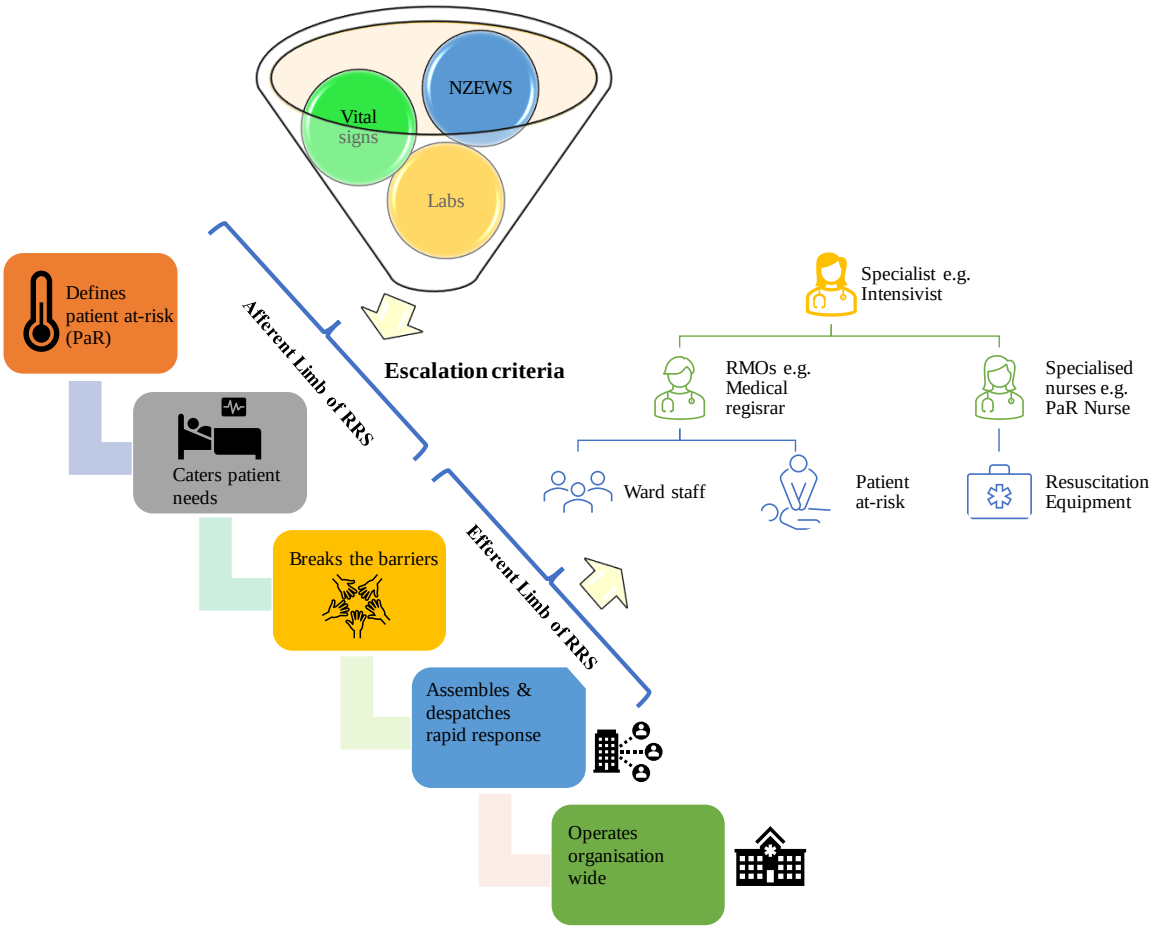


Figure 2-1 A schematic representation of operational workflow of the RRS

2.4.5 Components of RRS

A rapid response system has two main operational components indicated in Figure 2.1: afferent and efferent components. Sometimes these are also called afferent and efferent limbs or arms of the RRS. Afferent components of the RRS include vital signs monitoring, early warning scores and sometimes the clinical impressions of staff or patient and family's concerns about deterioration. The afferent limb of an RRS is the 'vital signs and EWS chart'. This records these inputs and is placed near the patient's bed or the hospital room where patient is sited. The primary nurse allocated to the patient is responsible for measuring and recording vital signs and EWS. The primary nurse also listens to the patient and family if

they raise any concerns and activating the efferent limb of the RRS when one of the 'calling criteria' is met.

The efferent limb of the RRS activates upon the triggering of the afferent limb of the RRS as indicated above. The efferent limb is generally designed to provide a rapid and appropriate response to the level and type of deterioration conveyed by the 'trigger' or 'calling criteria' used to activate the efferent limb. For severe deteriorations, it is generally activated by a 777-call and leads to a multidisciplinary rapid response team who attends the patient. This team treats the condition and decides whether the patient can be rescued and what would be the appropriate level of care.

A mature and effective RRS requires an 'administrative and governance limb' to ensure these operational components operate at an optimal level of functioning and have an administrative and governance oversight. The fourth limb of the RRS ensures records of the RRS activities are maintained for audit, quality assurance, research, and improvement purposes. This limb of the RRS also endeavours to investigate the functioning of the RRS by applying measures of quality improvement, looking at the flaws and their causes and deciding how to mitigate those to continuously improve the RRS to achieve the goal of improving patient safety.

2.5 Physiological or clinical deterioration in hospitalised patients

Appropriate and timely identification and response to these precedents embody a 'window of opportunity' to restore the clinical state and thus reduce the likelihood of irreversible injury or death – that is the goal of any hospital rapid response system (RRS) (Solomon, Corwin, Barclay, Quddusi, & Dannenberg, 2016). Rapid response systems usually feature three key activities – detection, communication and response – based on physical and vital signs which are often used to calculate early warning scores (EWS) (D. Jones, George, Hart, Bellomo, & Martin, 2008; Daryl Jones, Mitchell, Hillman, & Story, 2013; J. Kause et al., 2004).

Nonetheless, clinical deterioration may be missed despite adequate charting of vital signs and calculating early warning scores. This is due to the intermittent nature of observations. In addition to the time taken by the actual measurements, record keeping, calculating EWS scores, making decisions and then communicating all these details to the response team(s) over a telephone or pager system. Therefore, a system that enables real-time monitoring of the vital signs and activates the efferent RRS could significantly widen the 'window of opportunity' to respond and rescue the patients and thus could prevent serious adverse events (SAE). This claim is strengthened by the fact that communication failure is recognised as a single most important theme during the root cause analysis (RCA) on SAE in the context of clinical deterioration in New Zealand where a nationally consistent EWS collated New Zealand EWS, or NZEWS, has been recently rolled out (Al-Moteri, Plummer, Cooper, & Symmons, 2019). The NZEWS, based on the UK's national EWS called NEWS, has been tested and shown to be better than 33 other EWS models in predicting patients at risk of SAE. The NZEWS is calculated based on seven physical signs: four vital signs (respiratory rate, temperature, systolic blood pressure and heart rate) and three other physical signs (need for supplemental oxygen, oxygen saturation and level of consciousness).

Timely and accurate monitoring of vital signs is essential for early recognition and appropriate management of patients (Kansal & Havill, 2012). Variable frequency of vital sign monitoring has been observed in different settings based on the condition of the patients, availability of staff and time of the day. Cardona-Morrel and his colleagues observed the vital signs monitoring practice of nurses in acutely ill patients. They reported that VS was monitored in only 52% of the cases while five essential vital signs were measured in only 6-21% of the instances. The study indicated the necessity of continuous monitoring for early recognition of patients' deterioration (M Cardona-Morrell et al., 2016).

Vital clinical signs are objective measures of physiological parameters and help to assess the general physiological condition of the body. They serve as a communication tool of the underlying deteriorating condition of body systems. Five vital signs – blood pressure, temperature, respiratory rate, heart rate and oxygen saturation – are monitored commonly (M. Elliott & Coventry, 2012). However, a literature review suggests that nursing staff often miss a measurement of these vital signs and rely on their clinical judgement. Incomplete evaluation could not only limit their ability to recognise the worsening condition of the patient but may also jeopardize the life of the patient (M. Cardona-Morrell et al., 2016). Measurement of vital signs is different in adult and paediatric age groups. Values for VS in children are ill-defined and are a poor indicator of physiological deterioration (Van Kuiken & Huth, 2016). Age-related physiological and pathological changes make the body less adaptive to various stressors. Because of this diversity, a single measurement of VS is often insufficient to detect underlying pathology. Thus, serial measurements at intervals are more sensitive to detecting the deteriorating condition of the patient (Chester & Rudolph, 2011).

Monitoring of vital clinical signs in hospital settings is of utmost importance. Significant decreases in morbidity and mortality in critically ill patients have been observed by early recognition of deterioration of patients' conditions and prevention of adverse events (Buist et al., 1999). There is no consensus on the frequency of VS monitoring in critically ill patients. Variable frequency ranges from 15 min to 8 hour monitoring based on the reported patients' conditions (Evans, Hodgkinson, & Berry, 2001). Hands and co-workers (Hands et al., 2013) reported partial adherence of the nursing staff to the vital signs monitoring protocol in the morning and evening shifts with no proper documentation while at night times. Hands et al., found that measurements were only taken for critically ill patients in the night shift, which were less frequently than expected. Increased frequency of monitoring in resource limited

setups, especially in developing countries, is not possible. Thus, continuous monitoring using automated systems could identify the warning signs earlier (Hravnak et al., 2008; Prgomet et al., 2016).

Abnormal vital signs are positively associated with an increased risk of critical events. In a cohort study, Lighthall and his colleagues reported abnormal vital signs in 16% of the patients admitted in medical, surgical, and other inpatient wards. Overall, the risk of critical events was significantly higher (35% vs 2.5%) in patients with abnormal vital signs than normal groups. The average hospital stay duration was longer while the survival rate at 30 days and after 1 year of discharge was significantly less in these patients (Lighthall, Markar, & Hsiung, 2009). In another study, characterizing the monitoring and documentation process of vital signs, the researchers found consistency in the clinical assessment of clinical signs between nurses working in medicine departments at three different hospitals. However, there were significant differences in the documentation process among groups. The researchers concluded that lack of standardization increases the likelihood of errors and delays in the accessibility of information. Entry of data into electronic records took more time than paper documentation (M. S. Yeung, S. E. Lapinsky, J. T. Granton, D. M. Doran, & J. A. Cafazzo, 2012).

2.6 Role of individual vital signs in identifying physiological deterioration

Blood pressure is the most measured vital sign in the emergency department yet there is no set standard as to how frequently it should be monitored. In a retrospective study, Miltner and co-workers (Miltner, Johnson, & Deierhoi, 2014) observed that on average, blood pressure was recorded 1.23 times per visit and the median time interval between measurements was 139.7 minutes. BP was never measured in 14.4% of the patients, once in 66.1% and two or more times in the remaining 19.5% of the patients. Pulse is the rhythmical expansion and

contraction of the arteries with each heartbeat. Although it gives information about heart activity, it is not the same as heart rate. Abnormal respiratory rate is one of the predicting factors for potentially lethal events but is often the most neglected vital sign in a hospital setting (Cretikos et al., 2008). Temperature represents the balance between the heat-generating system of the body and its utilization. Although a simple measure, it is often neglected in trauma patients. The degree of hypothermia is directly related to mortality in these patients (Mize, Koziol-McLain, & Lowenstein, 1993). It is measured using a pulse oximeter and is a valuable indicator of oxygenation status and viability of body tissues. Literature suggests pulse oximetry as a useful tool in the emergency department and pulmonary outpatient departments. It can help detect minor changes which are often missed by measuring only the respiratory rate of the patient (Lockwood, Conroy-Hiller, & Page, 2004). Hypoxemia is very common during surgical procedures under general anaesthesia. Ehrenfeld and his colleagues reported that at least one episode of hypoxemia and severe hypoxemia occurred every 28.9 hrs and 55.7 hrs of intraoperative time, respectively (Ehrenfeld et al., 2010).

2.7 Role of EWS in identifying Physiological Deterioration

Several scoring systems have been developed to identify the deteriorating condition of the patient. Early warning scores are based on complex algorithms combining patients' characteristics, presenting complaints, vital signs and pre-existing medical conditions to prioritize patients for treatment in the emergency department and admission in ICU settings (FitzGerald, Jelinek, Scott, & Gerdtz, 2010). Some of the commonly used systems include National Early Warning Score (NEWS) and NEWS-2 in England (Royal College of Physicians, 2017), Rapid Emergency Triage and Treatment System – Hospital Unit West (RETTS – HEV) (Perez, Nissen, Nielsen, Petersen, & Biering, 2016), VitalPAC Early

Warning Score (Plate, Peelen, Leenen, & Hietbrink, 2018), Rapid Emergency Medicine Score (Olsson, Terent, & Lind, 2004), Standardised Early Warning Score (SEWS) (Barlow, Nathwani, & Davey, 2006) and Rapid Acute Physiology Score (Rhee, Fisher, & Willitis, 1987). With minor modifications in the existing scoring system, Modified Early Warning Scores (MEWS) have been developed and implemented in various countries (Kyriacos, Jelsma, James, & Jordan, 2014; C.P. Subbe, Kruger, Rutherford, & Gemmel, 2001; Xie et al., 2018).

The utility of these early warning scores in different settings, their reliability and validity are questionable. Moreover, most of the systems require manual input as well and have poor sensitivity making them less suitable to be used for critically ill patients (Gao et al., 2007). Implementation of an early warning score system can significantly reduce morbidity and mortality in critically ill patients. EWSs are generally calculated thrice a day which often oversees early deterioration of physiological signs. Using continuously monitoring wearable devices not only increases the rate of detection but also reduces the mortality rate by timely interventions (Weenk et al., 2017).

The National Early Warning Score (NEWS) was developed by National Health Services (NHS) using six physiological parameters: heart rate, respiratory rate, blood pressure, level of consciousness, temperature, and oxygen saturation. Each variable measures from 0 to 3 scores with an additional 2 scores for supplemental oxygen, making a total of 20 scores at maximum. It was developed to be used in emergency settings for early recognition and prevention of adverse events in acutely ill patients (Royal College of Physicians, 2017). Elevated NEWS scores are associated with adverse outcomes in unselected patients in out-of-hospital settings (Silcock, Corfield, Gowens, & Rooney, 2015). The implementation of NEWS in the out-of-hospital environment leads to an unnecessary increase in referrals by

GPs due to a single measurement of baseline vital signs (Scott et al., 2019). NEWS has been shown to accurately predict long term survival rates in respiratory distress patients in emergency settings (Bilben, Grandal, & Sovik, 2016).

Standardised Early Warning Score is simple standardization of the existing EWS. SEWS was first used by Patterson and his colleagues to compare the efficacy of various EWSs implemented at various hospitals in London and Scotland. The SEWS was developed in the light of recommendations given by NHS Quality Improvement Scotland and the NICE (Patterson et al., 2011). Shortly after its implementation in the Royal Hospital of Edinburgh, Gordon and Beckett performed a 14-night prospective study on SEWSs. The results of the study showed improper documentation in 79% of cases, one or more observations were missed in 64% of cases, and the total score was miscalculated for 55% of patients (Gordon & Beckett, 2011).

It is the most used scoring system developed by modifying early warning scores. Implementation of MEWs in Easton Hospital USA resulted in a lower number of cardiac arrests and was associated with a decreased mortality rate and improved patient safety and clinical outcomes (Mathukia, Fan, Vadyak, Biege, & Krishnamurthy, 2015).

2.8 Challenges in vital signs and EWS based patient monitoring

Peek and Gillham evaluated the usefulness of the New Zealand Early Warning Score (NZEWS) system in patients who underwent cardiac surgery. The rate of the medical emergency team calling was significantly less with the use of NZEWS and without compromising the safety of patients (Peek & Gillham, 2017). The following table shows the frequency of achieving each process step using traditional methods for obtaining vital signs and EWS as per HQSC's early implementation evaluation report.

Table 2-1 Frequency of achieving each process step for deteriorating patient pathway, HQSC NZ (Source[1])

Process step	**Hospital 1**	**Hospital 2**	**Hospital 3**	**Hospital 4**
Comply with frequency of vital signs	58%	81%	70%	96%
Complete all modification fields	64%	81%	53%	54%
Correctly calculate EWS	86%	87%	76%	72%
Complete documentation tasks	51%	53%	40%	26%
Escalate in line with the escalation pathway	30%	36%	37%	60%
Review within the specified timeframe	25%	19%	8%	36%

The National Early Warning Score (NEWS) was validated by (Silcock et al., 2015) for pre-hospital patients. The study aimed to evaluate the performance of NEWS in identifying patients with mortality or deterioration risk in the prehospital setting. Silcock and colleagues collected data over two consecutive months for a single hospital from the emergency ambulance crews and combined this data with related information such as patient outcomes from the hospital staff and records to evaluate and validate NEWS. This study analysed different patient outcomes/endpoints for 1684 patients based on the area under the receiver operating characteristic (ROC) curve as mortality within 48 hours and 30 days, ICU admissions, and a combined death or ICU admission within 48 hours endpoint. The results showed that EWS calculation in prehospital settings is considered a useful triage tool for early recognition of deteriorating patients.

[1] Source: https://www.hqsc.govt.nz/assets/Deteriorating-Patient/PR/Early_implementation_evaluation_report.pdf

2.9 Role of electronic systems in vital signs and EWS monitoring

This subject is covered by a recent review paper by the candidate and collaborators (Mirza Mansoor Baig, Afifi, GholamHosseini, & Ullah, 2020).

2.10 Review of Failure mode and effect analysis (FMEA) in healthcare

2.10.1 Introduction

Failure mode and effect analysis (FMEA) is a scientific methodology pioneered by reliability engineers in the 1950s and has been widely used to evaluate and mitigate process vulnerabilities (H.-C. Liu, 2019; Niv et al., 2018; Sharma & Srivastava, 2018; Vázquez-Valencia, Santiago-Sáez, Perea-Pérez, Labajo-González, & Albarrán-Juan, 2018). The application of FMEA in healthcare started in the early 1990s where it has been applied to several settings ranging from appointment scheduling to medication administration, radiology procedures to clinical care processes in emergency and intensive care (Huang, You, Liu, & Song, 2020a; Moradi, Emami Sigaroudi, Pourshaikhian, & Heidari, 2020; K. Nolan, Zullo, Bosco, Marchese, & Berard-Collins, 2019; Simsekler, Kaya, Ward, & Clarkson, 2019) which highlights the applicability and adaptability of FMEA to healthcare processes. Unlike most scientific methodologies, FMEA does not require statistical analysis which makes it a practical tool. The FMEA instead utilises a robust methodology and knowledge of the active users of the process or system under study also known as subject matter experts (SME). FMEA facilitator is one who understands the FMEA methodology and guides the SME through the steps of FMEA. The FMEA starts with a process map, just like any other systems approach. Figure 2-2 depicts the FMEA approach using the example of the Rapid Response System (RRS).

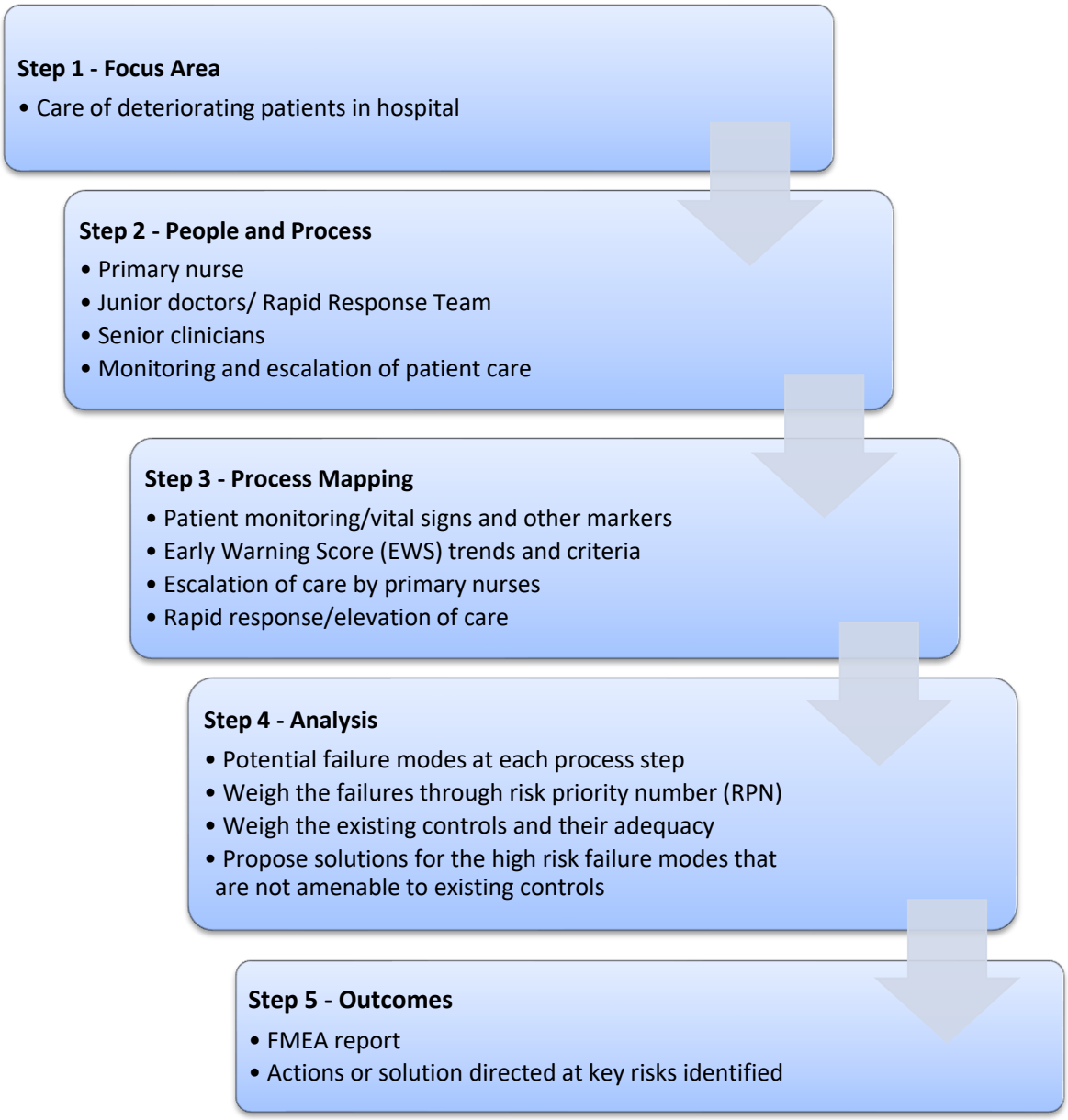


Figure 2-2 General Process for Failure Mode and Effect Analysis using the example of Rapid Response System

The FMEA approach systematically captures the likelihood of risks, the severity of consequences, and the probability that they may be detected and intercepted by the existing controls before causing harm. The aim of this study was to review the applications of Failure Modes and Effects Analysis (FMEA) in healthcare processes and to share the findings of FMEA into existing RRS used to monitor antecedents of patient deterioration through vital

signs and early warning score (EWS) and to respond to deteriorating patients and how to mitigate the risks identified through this approach.

2.10.2 Methodology

2.10.2.1 Articles search and selection criteria

To review the Failure Modes and Effects Analysis (FMEA) on the patient care processes in the hospital settings, we used related keywords to cross-search for thousands of related papers in significant databases of scientific publications including IEEE Xplore, Springer Link, Scopus, and PubMed Library. We selected the preferred reporting items for systematic reviews and meta-analyses (PRISMA) as the systematic review methodology (Moher, Liberati, Tetzlaff, & Altman, 2009). One of the authors conducted an initial screening of the retrieved records. Duplicated articles were eliminated, and additional records were excluded after reviewing individual titles and abstracts. A second author then reviewed the included studies and evaluated the full-text articles or eligibility. The eligibility criteria for inclusion in the review are:

Original articles mainly published as a journal article

1. Paper published or reported between 2010 and 2020 (inclusive)
2. FMEA on the patient care processes in the hospital settings was the primary subject of this study
3. Written and published in English

We excluded articles that were not considered original research, such as letters to editors, commentaries, or review papers.

2.10.2.2 Article search results

Initially, 691 studies were identified through database searching. A total of 430 records did not meet our inclusion criteria based on the initial screening, and therefore, 261 studies were included for checking against the eligibility. Full-text records were retrieved and reviewed by two authors. After excluding unrelated studies, duplicate records, a total of 17 articles were selected for the final review. The categorisation of the articles selected for this review and their area of application are given in Table 2-2 and Figure 2-3 shows the study selection process.

Table 2-2 Categorisation of the selected articles

Year of Publication	Reference(s)	Area of application	Total (%)
2020	(Moradi et al., 2020)	Emergency department;	1 (7%)
2019	(Simsekler et al., 2019), (K. Nolan et al., 2019)	(Simsekler et al., 2019) patient safety; (K. Nolan et al., 2019) pharmacy	2 (13%)
2018	(Babiker et al., 2018), (Niv et al., 2018), (2)	(Babiker et al., 2018) Clinical practice guidelines; (Niv et al., 2018) clinical consultation; (Vázquez-Valencia et al., 2018) critical patients	2 (13%)
2017	(H. Lee, Lee, Baik, Kim, & Kim, 2017), (Jain, 2017), (Li, He, & Wang, 2017), (Kricke et al., 2017), (Alamry et al., 2017)	(H. Lee et al., 2017) clinical trial; (Jain, 2017) ward medication management; (Li et al., 2017) clinical pathway; (Kricke et al., 2017) electronic health records; (Alamry et al., 2017) intensive care unit for septic patients	5 (30%)
2016	(Yousefinezhadi, Nobari, Goodari, & Arab, 2016)	Intensive care unit	1 (7%)
2010 - 2015	(Cinque, Coronato, & Testa, 2013), (Yarmohammadian, Jazi, Khorasani, & Atighechian, 2014), (Freitag & Carroll, 2011), (Nagpal et al., 2010), (Yarmohammadian, Abadi, Tofighi, & Esfahani, 2014)	(Cinque et al., 2013) remote patient monitoring; (Yarmohammadian, Jazi, et al., 2014) intensive care unit risk assessment; (Freitag & Carroll, 2011) hospital ward process; (Nagpal et al., 2010) surgical care; (Yarmohammadian, Abadi, et al., 2014) medical records	5 (30%)

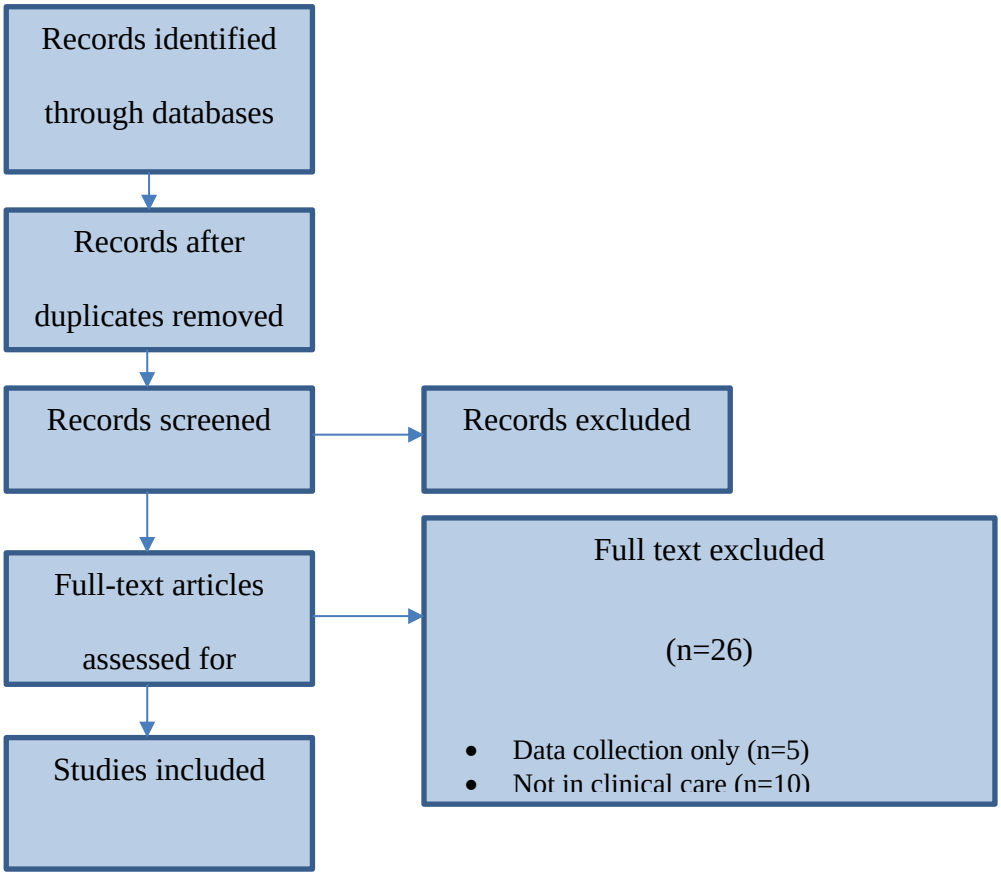


Figure 2-3 The study selection process

2.10.2.3 Failure Mode and Effects Analysis on existing Rapid Response System (RRS)

We applied FMEA methodology to study existing RRS based on patient monitoring using vital signs and Early Warning Scores (EWS) and responding to deteriorating patients. Six clinical staff, i.e., two registered nurses acting as a primary nurse; two patient-at-risk (PaR) nurses acting as specialised nursing responders, a resident medical officer acting as the second responder; and a senior medical officer acting as tertiary responder were part of the FMEA review team. These users were selected on voluntary basis and were given a gift card as a token of thanks at the end of the activity. These users acted as subject matter experts and

provided input into each step of FMEA on the rapid response system based on our paper-based New Zealand Vital Signs and EWS chart.

To accurately estimate the risk priority numbers (RPN) for the FMEA, we found out that defining the Occurrence Level (OL), Occurrence per unit time (OPT) and Risk Exposure ratio (RER) for the FMEA based on our data collection of 8701 sets of vital signs observations at medical in-patient wards of Taranaki Base Hospital was important, and we used an approach recommended by a recent study by Rezaei and colleagues. (F. Rezaei, M. H. Yarmohammadian, A. Haghshenas, A. Fallah, & M. Ferdosi, 2018) to define these, OPT and RER values suitable to study the RRS. To accurately allocate the OL criteria to each failure mode, we used the OPT rather than RER. In our study, the RER was likely to introduce errors of calculation as the length of admission varied between general medical wards (few days) and geriatric services (few weeks), as shown in Table 2-3.

Table 2-3 Definitions of Occurrence Level of failure modes

Occurrence Level (OL)	Occurrence per unit time (OPT)	Risk Exposure ratio (RER)
1	One time in more than a year	> 1/1000 patients would be exposed to the failure mode at least once during admission
2	One time in a year	1/1000 patients would be exposed to the failure mode at least once during admission
3	One time in six months	2/1000 patients would be exposed to the failure mode at least once during admission
4	One time in three months	5/1000 patients would be exposed to the failure mode at least once during admission
5	One time in a month	10/1000 patients would be exposed to the failure mode at least once during admission
6	Once a week	25/1000 patients would be exposed to the failure mode at least once during admission
7	Once every 3 days	50/1000 patients would be exposed to the failure mode at least once during admission
8	Once per day	100/1000 patients would be exposed to the failure mode at least once during admission
9	One per 8 hours shift	500/1000 patients would be exposed to the failure mode at least once during admission
10	More than once per 8 hours shift	1000/1000 patients would be exposed to the failure mode at least once during admission

We found that a simplified severity level (SL) rating criteria to easily differentiate actual or potential outcome of the failure modes in an RRS as shown in Table 2-4.

Table 2-4 Definitions of Severity Level of failure modes

Severity Level (SL)	Patient harm or consequences
1	Error without harm to the patient / no effect on detecting patient deterioration, e.g., Temp recorded as 37 instead of 37.6 or HR recorded as 72 but not clearly legible
2	Non-documented vital signs / incorrected calculated or non-documented EWS
3	Error resulted in or potentially could result in a delay to or lack of detection of patient deterioration

We found that Rezaei and colleagues' approach to defining Detectability Level (DL) criteria for each failure mode within existing system controls in terms of the number of Defensive Barriers (DB) and Preventability as shown in Table 2-5 was applicable to an RRS scenario.

Table 2-5 Definitions of Detectability Level of failure modes

Detectability Level (DL)	Defensive Barriers (DB)	Preventability
5	Very low (One DB / detection prone to human fallibility)	Virtually no evidence of preventability
4	Low (< 3 DB)	Minimal evidence of preventability (<10%)
3	Medium (<5DB)	Evidence of sizeable preventability (<50%)
2	High (>6 DB)	Evidence of sub-optimal preventability (>50%)
1	Very high (>10 DB)	Evidence of 100% preventability

2.10.3 Results

2.10.3.1 Adoption of the FMEA in healthcare

The application of FMEA has helped evaluate clinical and non-clinical administrative processes alike. Kricke et al. (Kricke et al., 2017) used FMEA to assess how electronic health records (EHR) could leverage identifying the discrepancies between expected and observed activities related to the discharge process in a cardiology unit. Unexpected providers performed a fair proportion of activities (35%). Authors suggested that EHR could show gaps in process maps used for quality improvement and identify characteristics of workflow activities that can identify perspectives for inclusion in an FMEA. EHR may leverage clinical documentation to enhance process maps used for quality improvement.

Nolan et al. (K. Nolan et al., 2019) studied FMEA as a systematic approach to identifying potential sources of controlled substance diversion and developing solutions in a pharmacy setting. Twenty-four failure modes had a higher RPN and thus were analysed to develop solutions / corrective measures. Development of specific reports addressed 15 failure modes, while nine involved pharmacy workflow alterations. Notable reports included controlled substance activity under temporary patients and discrepancy trends by the user, medication, and patient care area. Notable workflow alterations were made, including expanded use of cameras in high-risk areas and additional verification checks.

Simsekler et al. (Simsekler et al., 2019) applied FMEA at a behavioural therapy service and found that the formal structure of FMEA adds value to the risk identification process.

Vázquez-Valencia et al. (Vázquez-Valencia et al., 2018) presented their experience of applying FMEA to assess the potential failure modes of the clinical process whereby critically ill and intubated patients are mobilised within the intensive care unit setting. They

used FMEA to identify the failure modes, to prioritise those failure modes according to RPNs and proposed corrective actions to revert those prioritised failure modes. They did not study the effectiveness of corrective actions.

Babiker et al. (Babiker et al., 2018) applied FMEA to evaluate the process of clinical practice guidelines (CPGs) implementation in the Middle East - after the CPG programme was launched in the Middle East in 2009. The FMEA was used to assess the risks and failure modes, plan corrective actions, and measure the improvements made. This study concluded that FMEA helped authors to identify potential barriers to the CPG programme and prepare relevant solutions.

Yousefinezhadi et al. (Yousefinezhadi et al., 2016), applied FMEA in intensive care units of two hospitals. They found nearly two potential failure modes for each activity/step of the ICU process. With the help of RPNs, they identified the ICU activities that pose non-acceptable risks/failure modes (used 100 RPN as cut off). Authors found that FMEA empowers staff to identify, evaluate, prioritise, and analyse all potential failure modes. They also concluded that with the FMEA approach, staff feel comfortable to identify the causes of failure modes and to recommend corrective actions and even to participate in improving the process without feeling blamed.

Yarmohammadian and coworkers (Yarmohammadian, Jazi, et al., 2014) used FMEA as a methodology to assess and manage the clinical risk in the intensive care unit. The researchers found FMEA an effective way to identify sources of failures, the consequences of such failures, and possible causes. Yarmohammadian et al. reported 58 potential failure modes, 13 of which were related to infection control, 5 were related to neurological care, 8 to digestive care, 6 to blood or bodily fluid or tissue sampling, 5 to medication administration, 4 to

dermatologic cares, and 17 potential failure modes were related to respiratory cares (Yarmohammadian, Jazi, et al., 2014).

Yarmohammadian et al. (Yarmohammadian, Abadi, et al., 2014) applied FMEA for proactive risk assessment in a hospital setting. They identified significant failure modes in clinical support services such as Medical Record Department, including admission unit dividing emergency, outpatient and inpatient classes, statistics, health data organising and data processing and medical coding units. The study concluded that FMEA helped authors identify where and what safeguards were needed to protect against a bad outcome even when an error does occur.

Freitag and Carroll (Freitag & Carroll, 2011) used the clinical handover process as an example of the high-risk process and applied FMEA to explore the possible ways this process could fail and how to mitigate those failures.

2.10.3.2 Effectiveness of the FMEA in patient care

A study by Moradi et al. (Moradi et al., 2020) has applied FMEA methodology to evaluate the medical errors in the setting of an emergency department of a hospital. They have assessed each error/failure, their consequences and possible causes and calculated the risk priority numbers. Thus, FMEA allowed an objective method to identify the riskiest situations in terms of system and process vulnerabilities.

Niv et al. (Niv et al., 2018) applied FMEA to identify and mitigate the failure modes within the clinical consultation process and enabled the identification of process steps and failure modes with high RPN warranting intervention. They found that initiation of consultation by a junior staff physician without senior approval, failure to document the consultation in the computerised patient registry and asking for consultation on the telephone had the highest

RPNs. This allowed authors to design an interventional plan including meetings to update knowledge of the consultation request process, stressing the importance of approval by a senior physician, training sessions for closing requests in the patient file, and reporting of telephone requests. These interventions led to a 75% increase in the number of electronically documented consultation results and recommendations.

Alamry et al. (Alamry et al., 2017) applied FMEA to analyse the process from diagnosis to treatment of septic patients. Authors conclude that FMEA enables a detailed analysis of the care process of septic patients by outlining potential failure modes and guiding improvement efforts. The effectiveness of proposed improvement efforts was not reported.

Lee et al. (H. Lee et al., 2017) assessed the effectiveness of FMEA in identifying risks and failure modes in an academic clinical trial centre in a tertiary healthcare facility. Then, the authors implemented corrective actions for the failure modes exhibiting high RPNs. A follow-up RPN scoring was conducted a year later. The study found 114 high RPN failure modes, 14 failure modes were of high risk, 11 of which were addressed by remedial actions.

Li et al. (Li et al., 2017) applied FMEA to perform a proactive risk assessment for catheter-related bloodstream infection (CRBSI) in the intensive care setting. They stratified the process steps with high RPNs (>100 RPN) and redesigned the clinical pathway informed by the analysis of high RPN failure modes. The corrective measures resulted in a decrease in the RPNs by up to 80%. The average incidence of CRBSIs was reduced from 5.19% to 1.45%, with three months of zero infection rate.

Cinque et al. (Cinque et al., 2013) has evaluated failures, their consequences, and possible causes affecting the functional components of a remote and continuous health monitoring system using FMEA as a methodology.

A study by Nagpal et al. (Nagpal et al., 2010) attempts to measure the risks and failure modes within the main components of surgical care such as preoperative assessment and optimisation, preprocedural teamwork, postoperative handover, and daily ward care by applying FMEA. The results show that FMEA successfully identified the key risk components with a positive response from the clinical team.

2.10.4 Discussion

Healthcare represents an example par excellence of a complex system due to the sheer multitude of stakeholders and diverse interdependencies between them. This complexity makes healthcare a challenging setting for innovation and improvement, particularly in the area of health services management and research (Long, McDermott, & Meadows, 2018). Therefore, the adoption and validation of any technique or methodology developed outside the health industry need thorough attention. The FMEA has shown wider applicability and adoption for the healthcare process. We found that studies published in the last ten years have reported that FMEA serves as an effective methodology in analysing and reducing inherent risks (Alamry et al., 2017; Franklin, Shebl, & Barber, 2012; Moradi et al., 2020; Niv et al., 2018; K. Nolan et al., 2019; Salsabila, Masyitoh, Sjaaf, & Partakusuma, 2021).

There are a few limitations to impede the full adoption and effectiveness of FMEA in healthcare. These limitations include the time required, lack of trained FMEA facilitators and difficulty to gather subject matter experts (day to day healthcare workers such as nurses, doctors, allied health professionals) for multiple meetings to complete all steps of FMEA. Therefore, despite being known and applied in the healthcare industry for nearly three decades with consistently positive reports on its applicability and usefulness, FMEA has not been very widely used (Anjalee, Rutter, & Samaranayake, 2021; Huang, You, Liu, & Song,

2020b; H. C. Liu, Zhang, Ping, & Wang, 2020; Moradi et al., 2020; Salsabila et al., 2021; Simsekler et al., 2019).

A common theme identified across the reviewed studies were the FMEA team must be multidisciplinary to identify as many potential failures as possible; FMEA participants tended to overestimate the severity of the effect of the failure in comparison to those reporting the incidents on the database and the failures identified by the groups should be identified as prospective failures, i.e., potential failures. Moreover, the healthcare professional reporting the incident has witnessed the effect of the error, if any, on the patient and thus, the reported severity score is based on the actual effect of the error on the patient (Shebl, Franklin, & Barber, 2012).

It is observed that, as new evidence-based medicine continues to evolve and guidelines and protocols continue to be periodically updated, along with the introduction of new technologies such as electronic prescribing, clinical decision support or bar-coding, a given set of FMEA results will only be valid for a limited period and should therefore be updated regularly. Interestingly, the participating clinicians might be available to participate in the FMEA discussions. Still, their shift/duty rotations would mean that they may not be around to implement the new changes or guide/ train others and thus there is a chance that the FMEA may need to be repeated (Alamry et al., 2017; Chiozza & Ponzetti, 2009; Eugene Fibuch & Arif Ahmed, 2014; Ford et al., 2014; Huang et al., 2020a; Kricke et al., 2017; Latino & Flood, 2004; H.-C. Liu, 2019; Long et al., 2018; Rah, Manger, Yock, & Kim, 2016; Sharma & Srivastava, 2018; Shebl et al., 2012).

We applied FMEA to evaluate the existing RRS for monitoring of patients using vital signs and to respond to deteriorating patients, which is the first FMEA on RRS to the best of our knowledge. The failure modes identified in our FMEA can be grouped into three types based

on its impact on 1) patient safety; 2) staff liability; and 3) compliance. To date, most of the research into RRS has highlighted the effect of failures on patient safety alone. Through the robustness of FMEA, we report that failures to follow policies, procedures and protocols or inherent vulnerabilities within those policies, procedures, and protocols; and the failures modes whereby staff liabilities become part of clinical records (e.g., an unacted mandatory escalation of care) are equally critical.

Based on our review and findings, we suggest healthcare regulatory, accreditation, and compliance authorities should advocate the use of FMEA as a methodology for process and system reviews; include FMEA into risk assessment and management policies, frameworks, and procedures; and mandate education and training on FMEA methodology (Ashley & Armitage, 2010; Eugene Fibuch & Arif Ahmed, 2014; Franklin et al., 2012; Huang et al., 2020a; H. C. Liu et al., 2020; Rah et al., 2016; Fatemeh Rezaei, Mohmmad H Yarmohammadian, Abbas Haghshenas, Ali Fallah, & Masoud Ferdosi, 2018; Shebl et al., 2012).

2.10.5 Conclusions

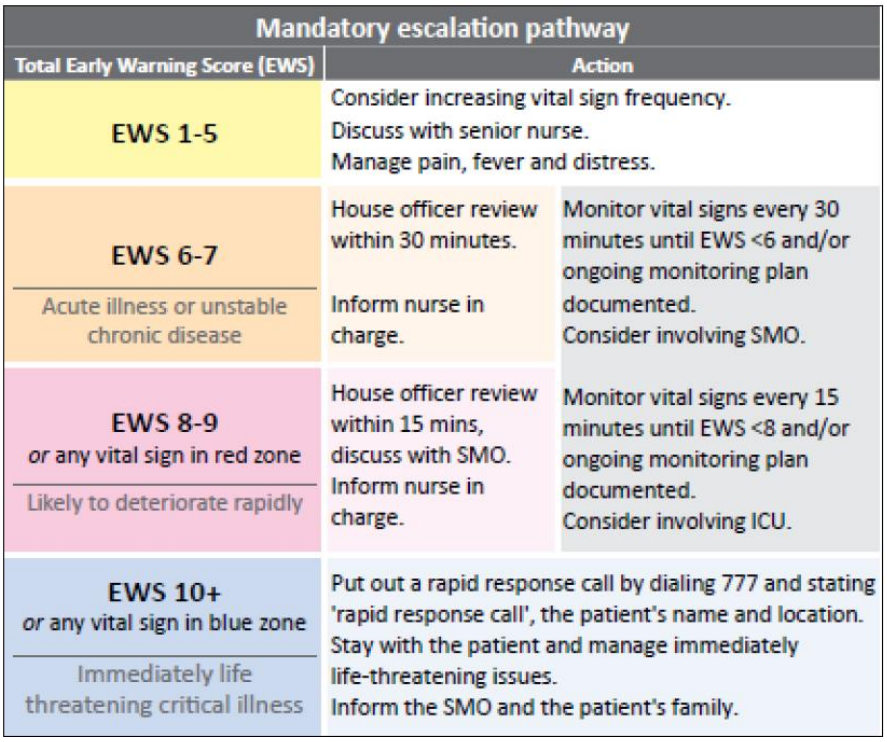
The FMEA has consistently shown to be an effective approach to systematically evaluate healthcare processes and authors advocate for wider application of FMEA to review and redesign healthcare processes. Rapid response system requiring paper charts for vital signs, manual calculation of EWS and use of phones and pagers for communication between teams represents a complex process and is suitable for a comprehensive risk assessment using FMEA methodology.

CHAPTER 3 Errors and Omissions across the spectrum of a Rapid Response System: From vital signs monitoring to a timely review of deteriorating patients

3.1 Introduction

Vital signs (VS) monitoring serves as a basis for the main surveillance system for healthcare providers to look through hospitalised patients' major organ functions or physiology in quite a holistic manner (Difonzo, 2019; Lyons, Edelson, & Churpek, 2018; Christian Peter Subbe & Welch, 2013). This surveillance system, called a Rapid Response System (RRS), is designed to ultimately improve patient outcomes by allocating them the right level of care at the right location within the hospital and at the right time (Brekke, Puntervoll, Pedersen, Kellett, & Brabrand, 2019; T. K. Oh et al., 2018). In an RRS, the VS monitoring acts very similar to security and surveillance cameras in buildings or on roads or like air-traffic control towers operating at airports. It represents the afferent component of RRS to inform the decisions healthcare providers make regarding the changes in the level of care hospitalised patients require from time to time as their organ functions or physiology improves or deteriorates (Difonzo, 2019). This decision making follows a systematic and multi-tiered approach to adequately and timely respond to the changes in patients' physiology recognised by the VS and NZEWS monitoring – which constitutes the efferent component of RRS (Bunch et al., 2019; Winters & DeVita, 2017). At the transition of the afferent and efferent components of RRS lies the decision-making step where the readings of VS are used to calculate Early Warning Scores (EWS) such as New Zealand EWS or NZEWS (Dall'Ora, Griffiths, Hope, Barker, & Smith, 2020; Fuller et al., 2018). As soon as the EWS or NZEWS value is calculated, the level of care required by the patient can be determined, and the

efferent component of RRS can come into motion if required (Kolic, Crane, McCartney, Perkins, & Taylor, 2015; Gary B. Smith, Prytherch, Meredith, Schmidt, & Featherstone, 2013; Williams, Tohira, Finn, Perkins, & Ho, 2016). Depending on the EWS or NZEWS score, the decision or outcome could be to 'continue the same level of care including the same frequency of VS monitoring with no additional action' or it may require increasing the frequency of VS monitoring, a review by a medical team within a specified timeframe or a rapid response within minutes through activation of a medical emergency team (MET) also known as a rapid response team (RRT) (Alam et al., 2014; Maftoohian et al., 2020; Medina-Lozano et al., 2020; Osawa et al., 2021). The NZEWS provides a 'mandatory escalation pathway' as shown in Figure 3-1 (HQSC, 2017b) which outlines the required actions for the level of derangements in VS and EWS.



Mandatory escalation pathway		
Total Early Warning Score (EWS)	**Action**	
EWS 1-5	Consider increasing vital sign frequency. Discuss with senior nurse. Manage pain, fever and distress.	
EWS 6-7 Acute illness or unstable chronic disease	House officer review within 30 minutes. Inform nurse in charge.	Monitor vital signs every 30 minutes until EWS <6 and/or ongoing monitoring plan documented. Consider involving SMO.
EWS 8-9 *or* any vital sign in red zone Likely to deteriorate rapidly	House officer review within 15 mins, discuss with SMO. Inform nurse in charge.	Monitor vital signs every 15 minutes until EWS <8 and/or ongoing monitoring plan documented. Consider involving ICU.
EWS 10+ *or* any vital sign in blue zone Immediately life threatening critical illness	Put out a rapid response call by dialing 777 and stating 'rapid response call', the patient's name and location. Stay with the patient and manage immediately life-threatening issues. Inform the SMO and the patient's family.	

Figure 3-1 NZEWS mandatory escalation pathway

(HQSC, 2017b)

The NZEWS uses a nationally consistent approach to patient monitoring for recognising and responding to hospitalised patients showing early signs of deteriorating physiology. The NZEWS originated from the work of Psirides et al. (2013) which led the Healthcare Quality and Safety Commission (HQSC), New Zealand to sponsor a five-year 'Deteriorating Patient' programme (2016 – 2021) to roll-out NZEWS throughout 20 District Health Boards (DHBs), the governing bodies that run all the public funded hospitals across New Zealand. As the NZEWS implementation has matured recently, there is very limited published work analysing the effectiveness of NZEWS (Pirret & Kazula, 2021). Nonetheless, although studies from the UK, USA, Australia and other parts of the world suggest VS monitoring encounters significant errors (Clifton et al., 2015; Difonzo, 2019; Malcolm Elliott, 2021; Mok, Wang, & Liaw, 2015; Saar, Unbeck, Bachnick, Gehri, & Simon, 2021), there is very little reported to date in terms of errors and omission rates within patient monitoring to recognise and respond to deteriorating patients using NZEWS (Pirret & Kazula, 2021). Given that New Zealand hospitals have made significant efforts to improve VS monitoring at a national level through a 5-year programme of deteriorating patients, it is probably the best time to understand how far New Zealand has come in improving VS monitoring. An error in the healthcare context could be attributed to as an error of omission (not taking the right steps) or an error of commission (taking the steps that are not right) which then contributes to or could contribute to an unintended outcome (Grober & Bohnen, 2005). For the purpose of this study, the candidate followed previous researchers (Clifton et al., 2015; Saar et al., 2021) in this field and did not differentiate these two types of errors. Hence, this study evaluates the rate of errors and omissions (combined) in the entire spectrum of the rapid response system, i.e., VS monitoring, calculation of NZEWS, escalation of care, completion of documentation and timeliness of review or rapid response at a medium size regional hospital in New Zealand.

3.2 Methods

3.2.1 Study Setting

This was a cross-sectional retrospective study conducted at three general hospital wards (Ward 2A, an older people's health and rehabilitation ward; and Ward 4A and Ward 4B, general medical wards) of Taranaki Base Hospital, a 300-bed regional hospital located in New Plymouth and governed by the Taranaki District Health Board. These general medical inpatient areas were selected for this study for the following reasons.

a) Rapid response system is designed for general inpatient areas of the hospital outside of intensive care units
b) Adult surgical inpatient areas were excluded as surgical patients were either staying too short (day-surgery) or they required a post-operative intensive care
c) Rapid response system utilises a different NZEWS scoring system for Paediatric age patients as well as for Maternity patients hence those areas were not suitable for the study which was based on Adult NZEWS scoring criteria

Taranaki Base Hospital implemented NZEWS during 2017 and 2018, as part of the national roll out of the 'Deteriorating Patient' programme from 2016 to 2021. This study was conducted between 1 October 2020 and 31 January 2021.

3.2.2 Sample

The sample size was calculated using the sample size calculation method described by OpenEpi – An open-source Epidemiological Statistics platform (Sullivan, Dean, & Soe, 2009). This method calculates sample size for the desired confidence level (generally 5% for most epidemiological studies) and a hypothetical percentage of exposure or odds ratio. Where study population is too large or unknown, this method uses 1,000,000 as population size. In

this study, the hypothesised frequency of outcome factor in the population was taken as 52% based on the recent study by Saar et al., (Saar et al., 2021)

- Population size (for finite population correction factor or FPC) (N): 1,000,000
- Hypothesised % frequency of outcome factor in the population (p): 52%
- Confidence limits as % of 100 (absolute +/- %) (d): 5%
- Design effect (DEFF): 1

Using above method, a sample size of 384 was calculated i.e., 384 completed sets of VS were deemed sufficient to measure the error and omission rate in the vital signs measurements and recordings.

A total of 7404 completed sets of seven-VS (53,125 records of individual vital signs) were collected from a total of 224 patients (57 from Ward 2A and 167 from Wards 4A and 4B) for this study during the study duration using a consecutive sampling technique. This sampling method allowed the candidate to collect much higher sample size in the study duration than required. The higher the sample size in a cross-sectional study, the higher is the confidence level and the higher is the accuracy of the results i.e., using the same sample calculation explained above, a sample size of 1510 would mean a confidence level of 99.99% for the study. All occurrences where one of the criteria to call a rapid response or a medical review, and all occurrences where NZEWS parameters were modified, were included in the study.

3.2.3 Data collection & analysis

The data on the errors and omissions of VS and NZEWS measurements and recording, modification of NZEWS parameters, and escalation of care requirements based on the NZEWS mandatory escalation pathway were collected on a data collection sheet by direct examination of the paper-based vital charts by the candidate. The candidate reviewed the

medical record files to locate the accompanying documentation about the escalation of care and timeliness of review for the dates and times of all occurrences of elevated NZEWS encountered on the VS and NZEWS charts. The data was imported from the data collection sheet (Microsoft Excel sheet) into THE Statistical Package for Social Sciences (SPSS) software, i.e., IBM SPSS 27. The data on the errors and omissions in all the steps of RRS was analysed in terms of frequencies and percentages. Age, gender, ethnicity, and ward location of the patient were collected from the vital signs. The mean difference of the count of the individual VS and VS sets was compared between gender, ethnicity and ward location using Analysis of Variance (ANOVA). The correlation between the count of the individual VS and VS sets was analysed by computing Spearman's rho.

3.3 Results

3.3.1 Demographics of study population

Though data was collected for the same period, due to the difference in patient care between OPHRS and the acute medical ward, out of 224 patients whose vital signs charts were analyzed, 57 (25.4%) were admitted in the older people's health and rehab ward (25.4%) and 167 (74.6%) were admitted in the general medical wards during the study period. Gender distribution among the study population was almost equal (115 or 51.3% females and 109 or 48.7% males). Regarding ethnic distribution, 166 (74.1%) of the study population identified themselves as New Zealand Europeans, 46 (20.5%) as Māori and 12 (5.4%) as other. This included Asians, Africans, and a few other ethnic groups. Due to small numbers, these ethnic groups were combined.

Overall mean age was 66.92 ± 17.41 (95% CI: 65.41 – 69.95) years. The range of patients included was 19 to 103 years. The mean age of female patients (n = 115) was 66.47 ± 20.13 years, and the mean age of male patients (n = 109) was 67.39 ± 14.07 years.

The mean age of NZ Europeans was 68.41 ± 17.89 years of Māori patients was 61.46 ± 14.62 years, and that of patients from other ethnic groups was 67.17 ± 17.62 years. The difference of mean age between all ethnic groups was not significant (p = 0.056). However, by removing other ethnic groups, the mean age of Māori patients was significantly lower than NZ Europeans (p = 0.001) and similarly, grouping other ethnic groups with NZ Europeans, the mean age of Māori patients was significantly lower than non-Māori patients (0.001), which indicates well-known health equity issues between Māori and non-Māori patients.

The mean age of patients admitted to OPHRS was 79.05 ± 16.07 years and the mean age of patients admitted to the acute medical ward was 62.77 ± 15.88 years. This difference was statically significant, but clinically understandable as OPHRS is a service for older people. However, occasionally non-OPHRs people are allocated to this service as an outlier (when hospital beds in other wards are unavailable).

3.3.2 Errors and omissions in patient monitoring through vital signs measurement and recording

During the study period, a total of 60,907 individual vital signs were to be measured and recorded for patients admitted to the acute medical ward and OPHRS based on the minimum four-hourly frequency of VS monitoring in stable patients (EWS = zero) and increased frequency of monitoring for relative degree of patient deterioration (EWS ≥ 1) at any time during admission.

Upon thorough scrutiny of the VS charts, 53,125 (87.2% of expected 60,907) VS measurements were recorded in the NZEWS. A total of 83 VS measurements were deemed illegible and therefore were not counted towards this observation. This observation indicates a 12.8% error/omission rate in the VS measurement and recording.

When investigated frequency of completeness of individual vital signs, oxygen saturation (7760, 89.2%) and heart rate (7753, 89.1%) were measured and recorded at higher frequencies as compared to the temperature (7465, 85.8%) and level of consciousness (7430, 85.4%). The relative frequency of completeness of the VS measurements was as shown in Figure 3-2.

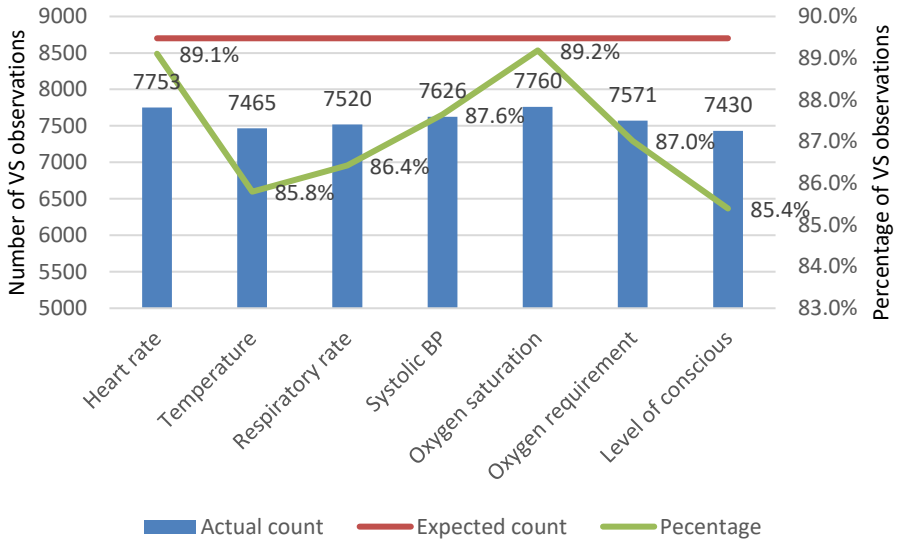


Figure 3-2 The frequency and percentage of actual measurement and recording of individual vital signs (Data shown are count and percentage)

Another way to analyse the completeness of VS monitoring was to assess the frequency of completed sets of all seven vital signs. In this study, the expected number of completed sets of vital signs was 8701 and there were 7404 (85.1%) sets of vital signs measured and recorded. A 14.9% omission rate in the completed sets of VS.

The counts of individual VS and complete VS sets were compared between male and female patients and other demographics as shown in Table 3-1. Due to the lengthy stay in Ward 2A/OPHRS, the counts for VS measurements per patient were significantly higher, but

frequency was less (once every 12 hours). No significant difference was noted with gender or ethnicity. Age was found to have weak positive correlation with frequency of vital signs (higher the age, higher the recorded vital signs).

Table 3-1 Comparison of VS counts vs demographics of study population

Demographics		**n**	**Individual vital signs count**		**Count of vital signs sets**	
			Mean±SEM	P value	Mean±SEM	P value
Gender	Female	115	256±25	0.285	36±4	0.287
	Male	109	217±27		30±4	
Age			Spearman's rho		Spearman's rho	
			0.373	<0.001	0.379	<0.001
Ethnicity	Māori	46	261±46	0.503	37±7	0.502
	NZ Europeans	166	226±20		31±3	
	Others	12	305±85		43±12	
Ward	2A	57	582±47	<0.001	82±7	<0.001
	4A	167	120±4		16±0.6	

Similarly, EWS was calculated at 6661 (76.6%) either due to omission of the EWS calculation step or due to lack of completed sets of vital signs required to calculate the EWS. Furthermore, as there were errors in the manual EWS calculation, correct EWS was available for 6513 (74.8%) as shown in Figure 3-3 (data shown in this figure are numbers and percentages).

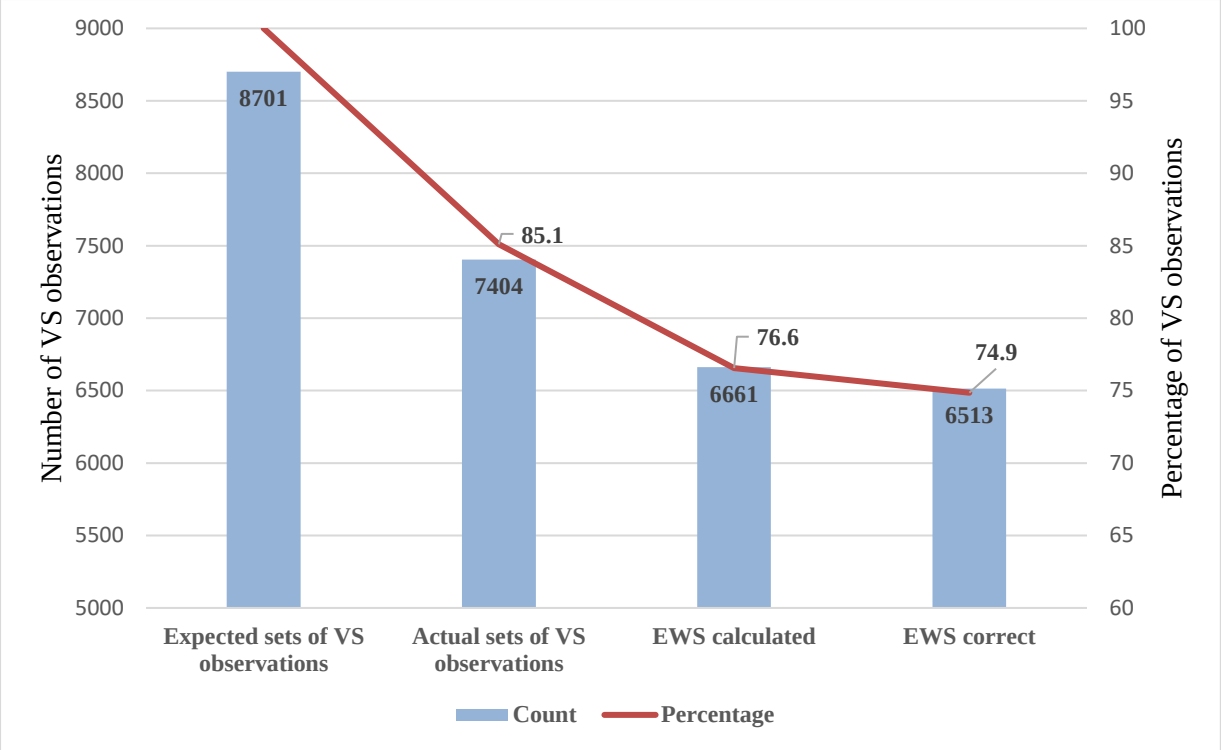


Figure 3-3 Error and omission rate in vital signs monitoring

These observations indicate a cumulative loss of over 25% of patient monitoring data – which simply means that the afferent limb of RRS will invariably fail to record over 25% of patient deteriorations. It is important to note that absence of records does not necessarily represent a failure to detect.

3.3.3 Errors and omissions in escalation of care and timely review of deteriorating

When applying the HQSC escalation calling criteria, considering if the EWS were calculated and correct in all cases where a full set of vital signs was available, a rapid response threshold should have been met on 196 occasions. In the current study, it was only recorded on 133 occasions (67.9%) indicating an error rate of 33.1% or, in other words, the afferent limb failure (ALF) rate is higher than anticipated (25%). But the errors and omissions do not stop at this point. It was expected that in all 133 occasions where one of the calling criteria was met, primary nurses must have activated the rapid response system (RRS) or equivalent

according to the severity of deterioration. This step was most difficult to ascertain as there are various ways to escalate the care i.e., a pager to a resident medical officer or a patient-at-risk nurse, or a 777-call which activates an RRS /MET through telephonist activated group-linked pagers. In this study, the evidence of escalation of care or recorded response was found in 108 occasions (82.1% against the recorded n=133 and 55.1% against the expected n=196 occasions where one of the calling criteria was met). Out of these 108 escalations, a rapid review was commenced within the stipulated timeframe in 83 (76.8%).

There were 11 occasions where rapid response thresholds were modified. All those occasions were excluded from the analysis. All the modifications 'must have been medically signed off' though only six (54.5%) were correctly recorded, timed, and signed off on all pages of the NZEWS chart. These omissions were regarded as 'documentation issues' only. Such issues may lead to staff liability, organisational quality assurance and audit issues. It wasn't observed that such issues were directly related to patient safety.

Based on the above observations, a cumulative rate of errors and omissions (combined) in VS monitoring and recording, EWS calculation and recording and activation of RRS or equivalent is estimated to be 69.9% or in other words only 30.1% of the triggers pass through all the steps.

3.4 Discussion

Errors and omissions are common in the entire spectrum of RRS and have been reported by a handful of investigators in the 2000s and 2010s. Among the earlier investigators, (McGain et al., 2008) conducted a study on post-operative surgical patients in five Australian hospitals and reported that only 17% of the vital signs were completely measured and recorded. They also reported that the respiratory rate was the most commonly undocumented vital sign observation with a non-documentation rate of 15.4%. They found variations between the five

hospitals and noted that documentation was less frequently completed on weekends, especially for the medical reviews.

Another study from Australian investigators, (Van Leuvan & Mitchell, 2008), reported the frequency of various vital signs in a 24-hour period stating the readings of blood pressure, heart rate, temperature and respiratory rate to be 5, 4.4, 4.2 and 1, respectively.

(Chen et al., 2009), also from Australia, reported that 77% of the patients with adverse events had at least one missing vital sign prior to the adverse event. They also found that respiratory rate was more commonly undocumented than heart rate and blood pressure. They implemented an electronic system to track the VS measurements and found improvement in the frequency of measurements and records with the electronic system.

(Ludikhuize, Smorenburg, de Rooij, & de Jonge, 2012) from the Netherlands reported that vital signs, including respiratory rate and oxygen saturations, were completed in only 30-66% of patients who had a higher Modified Early Warning Score (MEWS) and went on to have an adverse event within 48 hours of missed vital signs observations.

A study from Greek investigators (Pantazopoulos et al., 2012) reported that 6-hourly vital signs were recorded by 43% of the nurses who participated in their study, and found that respiratory rate and level of consciousness were recorded less commonly than the rest of the vital signs.

Investigators from a university hospital in Finland (Tirkkonen et al., 2013) reported a comparison between manual and electronic VS monitoring stating 74% of VS were recorded in the manual process which went to 96% in the electronic system.

In their follow-up study, (Ludikhuize et al., 2014) reported a comparison between the wards using standardised vs normal patient monitoring. They reported 70% of EWS calculations

were completed in a protocolised ward vs only 2% in the control ward. They also reported a compliance rate (towards >3 times vital signs measurements in a 24-hour period) of 68% in the protocolised ward vs 4% in the control ward. They reported that the protocolised ward had twice the rapid response team (RRT) calls per admission compared to the control group.

(M Cardona-Morrell et al., 2016) reported 52% of vital signs were completed when studying five vital signs (heart rate, temperature, respiratory rate, blood pressure and oxygen saturation) at an Australian hospital.

Another Australian group of investigators (Considine, Trotter, & Currey, 2016) reported that among the vital signs they assessed, heart rate, respiratory rate, systolic BP and oxygen saturation were most commonly documented while the temperature and consciousness were the least commonly documented. They also reported that they found evidence that 79.8% (142/178) of patients had one or more abnormalities in vital signs where it was documented only in 28 (19.7%) of those 142 patients. Smith and Aitken (2016) reported that systolic BP was the most recorded (59%, 156/263) while the respiratory rate was the least commonly recorded (14%, 36/263) vital sign in their UK experience. Smith and Aitken also reported factors affecting the VS observations: lack of equipment, conflicting priorities of staff and lack of consent in their experience.

A few studies have investigated and reported on how clinical staff use the afferent components of the rapid response system to recognise deteriorating patients. Donohue and Endacott (2010) examined perceptions of ward nurses and specialised critical care outreach staff (similar to Patient-at risk nurses in New Zealand) in the UK through semi-structured interviews and found that EWS wasn't one of the key aspects of patient assessment but was used to quantify the severity of deterioration. (Ludikhuize, de Jonge, & Goossens, 2011) from the Netherlands reported that EWS was used by 11% of the nursing participants in their study

to notify deteriorating patients to the medical team. (Kolic et al., 2015) from the UK reported NEWS was incorrectly calculated in a fifth of patients with the worse clinical response rate over the weekends. Van Galen et al. (2016 from the Netherlands reported a 1% rate of correct calculation of EWS. Similar findings were reported by two studies conducted in Denmark and Canada (John Asger Petersen, Rasmussen, & Rydahl-Hansen, 2017; H. J. Wong et al., 2017).

Another group of recent studies focused on the efferent limbs of RRS and reported errors and omissions in the escalation of care and timely response. A study from Italy by (Radeschi et al., 2015) reported 21% of deteriorating patients meeting one of the escalation criteria were not escalated, and they reported an organisational culture and inter-professional reluctance to dialogue as major barriers to this effect. (Barwise et al., 2016) from the USA reported 57% of the deteriorating patients had a delayed activation of the rapid response team/efferent limb of RRS. A study from Spanish investigators (Castano-Avila, Cueva, & Rodero, 2016) reported that activation of RRS was delayed in 33% of deteriorating patients. An Australian group of researchers (Gupta et al., 2017) reported delayed activation of RRS in 24.6% of cases and found that delayed RRS activation was significantly associated with higher in-patient death.

A recent study by (Saar et al., 2021) found an error and omission rate of 52% in nursing care and patient monitoring at a large 1600-bed German university hospital. A study from the Netherlands (Ludikhuize et al., 2014) found that EWS calculation occurred in 70% (therefore 30% error rates) of times when the standardised method of calculating EWS was used. Another study evaluating a large number of VS observations from the public hospitals in the Capital Region of Denmark reported that at least 10% of the VS records were incomplete (Pedersen et al., 2018). These three studies are examples of several studies conducted outside New Zealand that reported errors and omissions in the entire spectrum of RR, thereby

limiting this thesis to comparing the findings of a few reports on RRS-wide errors and omission rates.

The errors and omissions within the spectrum of RRS activities make the RRS ineffective by increasing the risk of unplanned ICU admissions and unexpected in-patient deaths (Areia et al., 2021; Brekke et al., 2019; Clifton et al., 2015; Dall'Ora et al., 2019; Kellett & Sebat, 2017) therefore it is pertinent to understand the factors that influence or cause these errors and omissions. A recent large scale study by the Missed Care Study Group UK (Gary B Smith et al., 2020) found that nursing staff levels significantly influence the errors and omissions in recognising and responding to deteriorating patients, especially those who have high risk deteriorations (they defined high risk deterioration based on the NEWS values > 7). The Missed Care Study Group suggested that their findings explain the higher risk of in-patient deaths in the face of lower nursing staff levels. A study from the USA reported that the lower acuity patients were associated with omissions in VS monitoring more strongly than other variables they studied. (Johnson, Winkelman, Burant, Dolansky, & Totten, 2014)

The studies summarised above have focused on one or more aspects of RRS yet none of the studies reported errors and omissions in the entire spectrum of care from VS monitoring to rapid response delivery. The New Zealand Healthcare Quality and Safety Commission (HQSC) published these rates across the spectrum of care in the early implementation report on their five-year 'Deteriorating Patient' programme (HQSC, 2017c) from four pilot site hospitals according to which the compliance towards the frequency of vital signs monitoring was 58%, 81%, 70% and 96% at hospitals 1 to 4, respectively. The current study observed that compliance with the frequency of vital signs monitoring was 85.1% at the two wards of Taranaki Base Hospital. The HQSC report showed a completion rate of NZEWS modifications as 64%, 81%, 53% and 54%, respectively. At Taranaki Base Hospital, 54.5%

of the NZEWS modifications were correctly and completed recorded. The HQSC report stated NZEWS was correctly calculated in 86%, 87%, 76% and 72%, respectively, at the pilot sites. The current study observed that 74.8% of the NZEWS scores were correctly calculated at Taranaki Base Hospital. The HQSC report indicated that complete documentation of patient monitoring tasks was seen in 51%, 53%, 40% and 26%, respectively, in the four pilot sites. These rates were 30.1% more at Taranaki Base Hospital than at the top performing pilot sites. The HQSC report noted that the rate of escalation within the NZEWS mandatory escalation pathway was only 30%, 36%, 37% and 60% at hospitals 1 to 4, respectively – whereas this rate was 82.1% at the current study site. The HQSC report showed that a rapid review wasn't undertaken within the specified timeframe in many cases at all the pilot sites, the timely review rates were 25%, 19%, 8% and 36%, respectively. The current study observed that 76.8% of the escalations were reviewed within the specified timeframe. As shown in Figure 3-4, the afferent limb of RRS at the study site does not look any different from the HQSC deteriorating patient pilot sites but there is an evident improvement in the efferent limb of RRS i.e., in the steps related to the escalation in line with pathway and timeliness of rapid review/response.

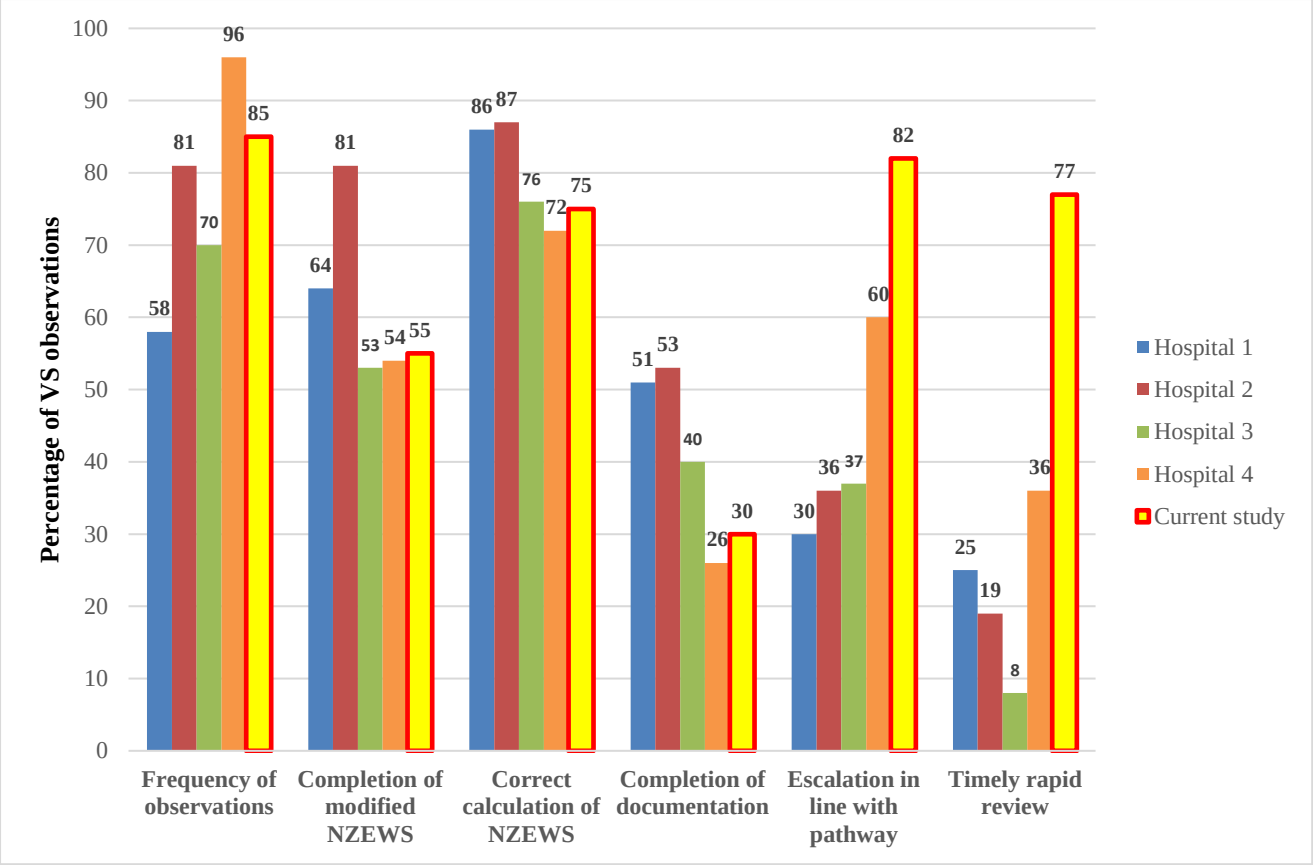


Figure 3-4 Average percentage of achieving each step of NZEWS system – comparison of current study with four pilot sites of HQSC deteriorating patient programme.

Figure 3-4 shows that the study site (Taranaki Base Hospital) has come a substantial way in improving the rates of escalation in line with the pathway and timely review of deteriorating patients which are components of the efferent limb of RRS, supported by implementation of the Patient-at-Risk service as part of the 5-year national programme on 'Deteriorating Patients'. However, the rate of errors and omissions in the frequency of observations, documenting the NZEWS modifications, calculation of NZEWS scores and completing all documentation related tasks (components of the afferent limb of RRS) haven't witnessed even the slightest change from the status of the pilot site hospitals despite the equitable focus on these components during the 'Deteriorating Patient' programme. Investigations focusing on potential causes of this are discussed in detail in the FMEA and staff perception studies which can be summarised by saying that the paper-based charts currently used at the study

site are the main reason for this, a statement that is supported by the literature (Considine et al., 2016; Ludikhuize et al., 2014; D. J. Smith & Aitken, 2016; Tirkkonen et al., 2013).

(Gary B Smith, Recio-Saucedo, & Griffiths, 2017) remarked that vital signs monitoring remains an evidence-free zone as very little is established about which vital signs should be monitored more frequently than others and what must be their frequency be despite VS monitoring being one of the most important surveillance mechanisms applied to hospitalised patients. There is very limited literature to suggest how to improve the frequency of VS monitoring and compliance to other steps of afferent and efferent limbs of RRS. They have advocated for prospective studies on VS monitoring to generate the evidence so that the interventions that are useful to improve the frequency of VS monitoring and compliance to the steps of RRS are available to mitigate the risks to patient safety that exist due to the errors and omissions within VS monitoring and lack of compliance to other steps of RRS.

3.5 Conclusion

The findings of this study suggest that errors and omissions occur at an unacceptable rate throughout the spectrum of RRS contributing to missing opportunities to recognise and respond to the antecedents of adverse patient outcomes.

It was found that interventions over the last five years have led to substantial improvements in the efferent component of the New Zealand model of RRS. These improvements are driven by Deteriorating Patient programme particularly the implementation of a model of critical outreach by the patient-at-risk nursing service. Gaps exist within afferent components including the frequency of vital signs monitoring, miscalculations of NZEWS, mismanagement of modifications within NZEWS. These gaps mean that the missed opportunities let the entire RRS down. As the recent interventions through the national programme on ‘Deteriorating Patients’ haven’t improved the afferent components, and in the

light of available literature comparing paper-based and electronic patient monitoring, it is recommended that an electronic system should replace the paper-based patient monitoring through vital signs. Such a system should also enable auto-activation of the efferent limb of RRS to ensure the errors and omission are reduced at the transition afferent and efferent limbs of RRS.

CHAPTER 4 Workload involved in vital signs-based monitoring & responding to deteriorating patients: A single site experience from a regional New Zealand Hospital

4.1 Introduction

Expert Rapid response systems (RRS) have evolved since the 1990s (C. M. Jones et al., 2010). The RRS acts as an organisational surveillance system to enable the early detection (afferent component) and management (efferent component) of deteriorating patients (Rihari-Thomas et al., 2018) outside the intensive care unit (ICU) or critical care environment. The afferent component of RRS monitors patients' physiology using vital signs and early warning scores. The efferent component ensures a timely response and management of patients showing early signs of clinical deterioration.

Since 2016, New Zealand hospitals have adopted a standardised national approach to heart rate, temperature, respiratory rate, blood pressure, oxygen requirement, oxygen saturation and level of consciousness to calculate the New Zealand Early Warning Score (NZEWS) and triage adult patients in general hospital wards for the level of rapid response required (HQSC, 2017b). The New Zealand Health Quality & Safety Commission (HQSC) implemented this approach through the Deteriorating Patient programme (2016-2021). They introduced a paper-based combined vital sign and EWS chart (HQSC, 2018) which incorporates a colour-coded scheme for the calculation of NZEWS. The programme sets out an escalation pathway with definitions of each level of escalation and an optimal timeframe to respond to each of these. It also provides a protocol for the recording of authorised modifications (exceptions) to the escalation pathway. According to the user guide for this vital signs chart (HQSC, 2017b), adult patients in general wards are required to undergo vital signs measurements and

calculation of EWS every four hours at a minimum, and the frequency of monitoring increases if the value of NZEWS is higher on one occasion. A value of NZEWS 10+ or any single vital sign derangement in the blue zone on the vital signs chart requires an immediate rapid response activation. Lower values of NZEWS and less severe abnormalities in single vital signs require a medical or specialised nursing review by PaR team.

The workload involved in vital signs-based patient monitoring is reported adequately; however, literature comprehensively examining the entire RRS care package per clinical event is lacking. (Brekke et al., 2019; Churpek, Adhikari, & Edelson, 2016). We report a comprehensive workload estimation for the afferent (monitoring) and the efferent (responding) limbs of the RRS.

4.2 Methods

4.2.1 Design and setting

We conducted a prospective observational time-and-motion study to measure the workload involved in patient monitoring using vital signs (afferent limb of RRS) by general ward nurses. The workload involved in responding to deteriorating patients (efferent limb of RRS) was quantified and reported in real-time by PaR nurses using an electronic PaR logbook at Taranaki Base Hospital, New Plymouth, New Zealand. The study was conducted between May 2020 and August 2021.

4.2.2 Sample and recruitment

The sample size was calculated using the sample size calculation method described by OpenEpi – An open-source Epidemiological Statistics platform (Sullivan et al., 2009). This method calculates sample size for the desired confidence level (generally 5% for most

epidemiological studies) and a hypothetical percentage of exposure or odds ratio. Where study population is too large or unknown, this method uses 1,000,000 as population size.

- Population size (for finite population correction factor or FPC) (N): 1,000,000
- Hypothesised % frequency of outcome factor in the population (p): 10%
- Confidence limits as % of 100 (absolute +/- %) (d): 5%
- Design effect (DEFF): 1

Using above method, a sample size of 139 was calculated.

NZEWS charts are used throughout hospitals in New Zealand, predominantly using either a paper-based or electronic monitoring chart.

We conducted this study at Taranaki Base Hospital where paper based NZEWS charts are used. We selected general medical inpatient areas (Ward 4A, Ward 4B and Ward 2A) for the following reasons.

a) The study is based on adult NZEWS scoring charts hence maternity and children health areas are not suitable for the study
b) The surgical inpatient areas (only other adult inpatient services) had patients for very short time (day-surgery patients), or the patients were requiring post-operative intensive care hence not suitable for the study

We recruited registered nurses as study participants in each ward on a voluntary basis after they had received the study information and undertaken the study purpose. Each participant undertook between 1 and 15 sets of vital sign observations. We measured the time taken to complete a total of 172 sets of vital signs observations across all wards, out of which 167 were included in the analysis. Three observations were excluded due to the participant

reporting they could have been influenced by the presence of the researcher. Two observations were incomplete and were therefore also excluded.

A master-trainer (IP, Nurse Educator, Deteriorating Patient Programme and Resuscitation, Taranaki DHB) trained the candidate (EU) on the standard operating procedure to record the time taken by the nursing staff to measure and record a complete set of vital signs. Each study participant (a general ward nurse) undertook between one and fifteen complete sets of vital signs and NZEWS measurement and documentation. The time between entering and leaving the patient space was recorded as the total time taken to measure and record a set of vital signs and NZEWS. Interruptions were measured as laps on a multi-lap electronic stopwatch application to compute the total time taken by vital signs and NZEWS with and without interruptions. The master trainer validated 17 (10%) of the measurements made by EU, selected randomly by the master trainer.

For the second arm of the study, to estimate the workload involved in rapid response provided by PaR nurses, complete data of PaR logbook for nine months duration was included. PaR team recorded 4926 outreach calls from 1 May 2020 to 31 January 2021, where they measured the time spent per response in real-time and entered these values as minutes in an electronic logbook after each outreach call. This electronic logbook was specifically designed to measure and record the time spent by PaR team while attending the outreach calls. We included 663 out of 4962 (13.5%) PaR outreach calls in our study after applying the mandatory escalation criteria (a raised NZEWS value of 5 or higher or a single vital sign value in the blue-colour zone on NZEWS chart). Using these two criteria ensures we have selected the cases where PaR team was primarily involved in delivering rapid responses to deteriorating patients. Out of the total outreach calls received by PaR team, 254 (5.12%) calls were categorised as MET calls or 777-calls.

4.2.3 Data management and Statistical analysis

The data for the time-and-motion study on the workload involved in patient monitoring using vital signs and NZEWS was collected on a Microsoft Excel file. The MS Excel file was imported into IBM SPSS 27 and saved as an SPSS data file after defining the variable characteristics. The variables were cross-checked against the original Excel files. Interruptions were subtracted from the total time to measure vital signs using the 'compute variable' function in SPSS. A Kolmogorov-Smirnov test was used to assess data normality. For descriptive statistics frequency, mean and standard deviations were reported. In inferential statistics mean time per vital sign observations (total after excluding one as well as both types of interruptions) were compared between participants, patient disposition, ethnicity, and study sessions. The time spent per response by PaR nurses in responding to deteriorating patients was extracted by PaR logbook as a MS Excel spreadsheet and was transported into IBM SPSS 27. The data on time spent per response was studied for different dependent variables using analysis of variance, post hoc, Kruskal Wallis test, Mann-Whitney test, and correlation.

4.3 Results

In our study, the mean time taken by nursing staff to measure and record a complete set of vital signs (including any interruptions) was 4.30 minutes OR 4 minutes and 18 seconds (95% CI: 4.12 – 4.47 OR 4:07 – 4:28). After excluding all interruptions, the mean time taken to measure and record a complete set of vital signs was 3:24 (95% CI: 3:15 – 3:33) minutes. As shown in Table 4-1 none of the studied parameters (location of ward, patient disposition, ethnicity, staff experience and the day or session of data collection) was found to significantly affect these results. We found no statistical difference between the observer, location of the patient, staff characteristics or experience and patient characteristics.

Table 4-1 Time taken to measure and record vital signs and EWS (in minutes)

Parameter		n=167	Total time taken		Time excluding vital signs nonrelated interruptions		Time excluding all interruptions	
			Mean ± SD	Sig	Mean ± SD	Sig	Mean ± D	Sig
Location	**- Ward 4A**	84	4.35 ± 1.10	0.549	3.76 ± 0.91	0.386	3.47 ± 0.93	0.394
	- Ward 2A	83	4.24 ± 1.17		3.63 ± 1.00		3.34 ± 1.01	
Patient disposition	**-Ward patient**	119	4.33 ± 1.08	0.566	3.70 ± 0.91	0.805	3.41 ± 0.94	0.852
	- Outlier	48	4.21 ± 1.27		3.66 ± 1.03		3.38 ± 1.04	
Ethnicity	**- Maori**	46	4.36 ± 1.31	0.721	3.79 ± 1.13	0.693	3.50 ± 1.16	0.708
	- NZ Europeans	106	4.29 ± 1.01		3.67 ± 0.84		3.37 ± 0.85	
	- Others	15	4.09 ± 1.42		3.59 ± 1.16		3.31 ± 1.16	
Staff experience	**<2 years**	71	4.34 ± 1.11	0.651	3.73 ± 0.94	0.530	3.45 ± 0.88	0.505
	3-10 years	65	4.19 ± 1.08		3.59 ± 0.88		3.30 ± 0.88	
	>10 years	31	4.39 ± 1.30		3.81 ± 1.14		3.52 ± 1.17	
Study session	**First**	30	4.38 ± 1.13	0.798	3.83 ± 0.99	0.681	3.54 ± 1.02	0.646
	Second	26	4.41 ± 1.18		3.76 ± 0.95		3.46 ± 0.95	
	Third	30	4.30 ± 1.22		3.70 ± 0.98		3.42 ± 1.00	
	Fourth	29	4.04 ± 0.977		3.42 ± 0.71		3.12 ± 1.02	
	Fifth	28	4.42 ± 1.10		3.76 ± 1.03		3.48 ± 1.04	
	Last	24	4.22 ± 1.28		3.70 ± 1.08		3.40 ± 1.03	

*One-way ANOVA test was used

+ p-value less than 0.05 was considered significant

The time spent per rapid response presented in this study is based on 663 rapid responses to deteriorating patients in general hospital wards outside the intensive care unit, during the study period performed by PaR nurses. We evaluated 4926 activities performed by the PaR nurses during this period, for which they recorded the time spent per activity in an electronic application specifically designed to track the workload involved in PaR nurses' activities. However, we included 663 (13.5% of total) PaR activities which fitted the criteria for a rapid response provided to deteriorating patients on general wards.

The average time spent by PaR nurses in these rapid responses (n=663) was 47.60 minutes OR 47 minutes and 36 seconds (95% CI: 44:57 – 50:15 or 44.95 – 50.26) minutes. Time per response was studied against the location/ward, responder (PaR nurse) and HQSC criteria for escalations based on the EWS score as shown in Table 4-2.

Table 4-2 Time Spent per Response by PAR Nurses to Deteriorating Patients (In Minutes)

Parameters		n	Mean	SD	SEM	Sig
Nursing shift	AM Shift (0645 – 1515 hrs)	182	48.99	36.359	2.695	0.697
	PM Shift (1445-2315 hrs)	281	47.84	33.926	2.024	
	Night Shift (2245-0715 hrs)	200	46.01	34.859	2.465	
Location attended	Emergency	83	49.81	36.720	4.030	0.050
	Medical floors	339	44.03	30.860	1.676	
	Surgical floors	194	51.28	37.285	2.677	
	Other areas	47	54.32	45.203	6.594	
Severity of deterioration	EWS 6-7	294	41.47	29.239	1.705	**<0.001**
	EWS 8-9	115	52.22	38.086	3.552	
	EWS 10 or 777	254	52.61	38.166	2.395	
Total		663	47.60	34.855	1.354	

**One-way ANOVA test was used*

+ p-value less than 0.05 was considered significant

Escalation criteria were found to have a significant association with time spent per response as shown in Table 4-3. Post hoc the Tukey HSD test was also applied to evaluate the association between time spent per response and severity of deterioration. The difference between time spent on EWS 8-9 calls and EWS 10-777 calls was not significant (p= 0.994), whereas the time spent on 'EWS 8-9' (p = 0.013) and EWS 10 or 777 calls (p = 0.001) was

significantly higher in comparison to the time spent on ‘EWS 6-7’ calls. Also, a weak positive correlation was observed between severity of deteriorating patients (EWS scores) and time spent by PaR nurses (Rho= 0.139 and $p < 0.001$) which means the time spent per response tends to gradually increase with increasing EWS scores.

Table 4-3 Correlation Between Time Spent by PAR Nurses and Severity of Deteriorating Patients

				Correlation	
Serial No	**Severity of deterioration**	**n=663**	**Mean ± SD (time in sec)**	**Rho**	**p-value**
1.	EWS 6-7	294	41.47 ± 29.32		
2.	EWS 8-9	115	52.22 ± 38.086	**0.139**	**0.00***
3.	EWS 10 or 777	254	52.61 ± 38.166		

**Spearman correlation was used*

p-value less than 0.05 was considered significant

4.4 Discussion

This is the first study of its kind that reports the workload involved across the entire spectrum of RRS activities as the previously reported studies have only measured the workload involved in the efferent limb of the RRS – measuring and recording vital signs and EWS(Adomat & Hicks, 2003; Bellomo et al., 2012; M. F. Clarke, 2006; Dall'Ora et al., 2020; Dall'Ora et al., 2021; Erb & Coble, 1989; Ito et al., 1997; Kimura, Nakai, & Ishihara, 2016; Travers, 1999; Wager et al., 2010; David Wong et al., 2017; Zeitz, 2005; Zeitz & McCutcheon, 2006). Therefore, current study offers to extend the body of knowledge

particularly by adding the quantification of workload involved in responding to deteriorating patients by a rapid response team or critical care outreach team. Our findings are applicable to adult patients in general hospital wards where paper based vital signs and EWS charts are used with manual measurement and recording of these parameters to enable early recognition and response/treatment of deteriorating patients. We found that measurement and recording of a complete set of vital signs (heart rate, temperature, blood pressure, respiratory rate, oxygen requirement, oxygen saturation, and level of consciousness) and manual calculation of New Zealand EWS was independent of the factors studied as shown in Table 4-1. We found that the average time spent per rapid response was over 47 minutes, and again it was not affected by the ward location of rapid response or the responder providing this rapid response as shown in Table 4-2. Severity of deterioration, as defined by the graded escalation criteria based on NZEWS was found to have significant association with time spent per response **<0.001**. The time spent per response was positively correlated with NZEWS values as shown in Table 4-3.

Studies reporting the workload involved in measuring and recording vital signs and EWS are mentioned below with a summary of their findings and how they relate to our findings. Dall'Ora et al. (2021) (Dall'Ora et al., 2021) conducted a time-and-motion study in four hospitals in the United Kingdom (UK) using a comparable set of vital signs and found that average estimated time to measure and record a set of vital signs and EWS was 3 minutes 45 seconds (95% CI = 3:32-3:58). They found no substantial differences by hospital, ward, or nurse characteristics, despite different systems for recording observations being used across the four hospitals. McGrath et al. (2019) (McGrath, Perreard, Garland, Converse, & Mackenzie, 2018) reported a before and after study from the USA upon implementing an electronic system to track vital signs, EWS and trigger rapid responses. This study found that

the mean time to measure and record the vital signs and EWS was 2.98 minutes (converted to 2 minutes 59 seconds) for the manual system and 2.15 minutes (converted to 2 minutes 9 seconds) for the electronic system. Level of consciousness was not assessed and recorded in their study. Wong et al. (2017) (David Wong et al., 2017) also performed a before and after study in the UK and reported a mean time of 3.58 minutes (or 3 minutes 34 seconds) to undertake a complete set of vital signs while using a manual system and 2.50 minutes (2 minutes 30 seconds) while using an electronic system. They reported the time to view a paper chart (0.3 minutes) and electronic chart (0.21 minutes) separately. Kimura et al. (2016) (Kimura et al., 2016) in their descriptive observational study from Japan reported significantly lower time to measure and record vital signs and EWS using an electronic system and transfer of information using radio-frequency identification (RFID) readers. They reported 1.47 minutes (SD: 0.55) per person at the patient trolley or cart and 1.27 minutes (SD: 0.62) per person at the bedside. Bellomo et al. (2012) (Bellomo et al., 2012) conducted a large multi-national before and after controlled trial, including ten hospitals from five countries. They reported a reduction in the time required for collection and recording of data, with the introduction of continuous monitoring. The time required to complete and record a set of vital signs decreased from on average 4.1 minutes (SD: 1.3) to 2.5 minutes (SD 0.5) which was statistically significant ($p < 0.0001$). Wager et al. (2010) (Wager et al., 2010) conducted an observational descriptive study in a single hospital in the USA on a relatively small (n=270) sample of vital signs set to report a mean time difference between the time vital signs were taken and when the data were recorded in the patient's record. They reported a mean of 1.24 (SD: 2.17) minutes with paper records, 9.15 (SD 7:25) minutes with Computer on Wheels (CoWs) and 35 seconds (SD 1:42 minutes) with tablet devices. Clarke (2006) (M. F. Clarke, 2006) performed a small (one month data collection, 814 vital signs measured) descriptive observational study at a community hospital and a cardiovascular unit

in the USA to report a mean time of 5.8 (SD: 3.72; 95%CI: 5.54–6.06) minutes to measure and record vital signs. Zeitz (2005) and Zeitz and McCutcheon (2006) (Zeitz, 2005; Zeitz & McCutcheon, 2006) undertook a descriptive observational study on 81 patients in two surgical units of two different hospitals in Australia to report a mean time of 5.8 (SD: 2.56; range: 1–15) minutes to take vital signs and any other associated activities related to the vital signs. The vital signs included in their study were limited to temperature, heart rate, blood pressure and respiratory rate only. Travers (1999) (Travers, 1999) conducted one of the earliest, albeit small, observational time-and-motion studies on 16 nurses (participants) working in an emergency department of a general hospital in the USA reporting a mean time of 4 (range 2-11) minutes to measure and record vital signs at the time of patient triage. Ito et al. (1997) (Ito et al., 1997) reported the earliest study on workload involved in vital signs monitoring. They conducted a before-and-after study with time-and-motion methodology on 23 nurses working day shifts at a radiology ward of a public hospital in Japan. The mean time required to measure vital signs and to record those was reduced from 2.02 minutes in manual process to 0.90 minutes in electronic process.

Our findings on the quantification of the workload involved in patient monitoring through vital signs and NZEWS are consistent with the studies described above. There are no gross differences to note in the average time spent per single set of vital signs and NZEWS apart from what is plausible with the use of different equipment. We found a few studies (Erb & Coble, 1989; Fuller et al., 2018; Munn, Moola, Riitano, & Lisy, 2014; Melanie S Yeung, Stephen E Lapinsky, John T Granton, Diane M Doran, & Joseph A Cafazzo, 2012) that estimated the workload involved in measuring vital signs without reporting mean time per set of vital signs, hence we are unable to make any comparison with them.

Most of the studies described above have not reported the procedure of EWS calculation. Our study is based on the NZEWS chart, which is used nationally within New Zealand and provides a standardised method for the calculation of EWS using the numerical weighting and colour coding system (HQSC, 2017b). According to this EWS calculation method, the normal range of values for each vital sign is represented by white colour and extremely abnormal values are represented by blue colour. Mild, moderate, and severely abnormal values for each vital sign are represented as yellow, orange, and red-coloured zones on the NZEWS chart, respectively. This enables nursing staff to calculate NZEWS easily where they score 0 for white, 1 for yellow, 2 for orange and 3 for red. Any single vital sign value reaching the blue-coloured zone on NZEWS mandates a rapid response trigger irrespective of the total early warning score as shown in Figure 1, which combines the aggregate scoring criteria that is the key driver of the UK's National EWS (Prytherch et al., 2010) and the single parameter calling criteria advocated by Lee et al. (A. Lee et al., 1995).

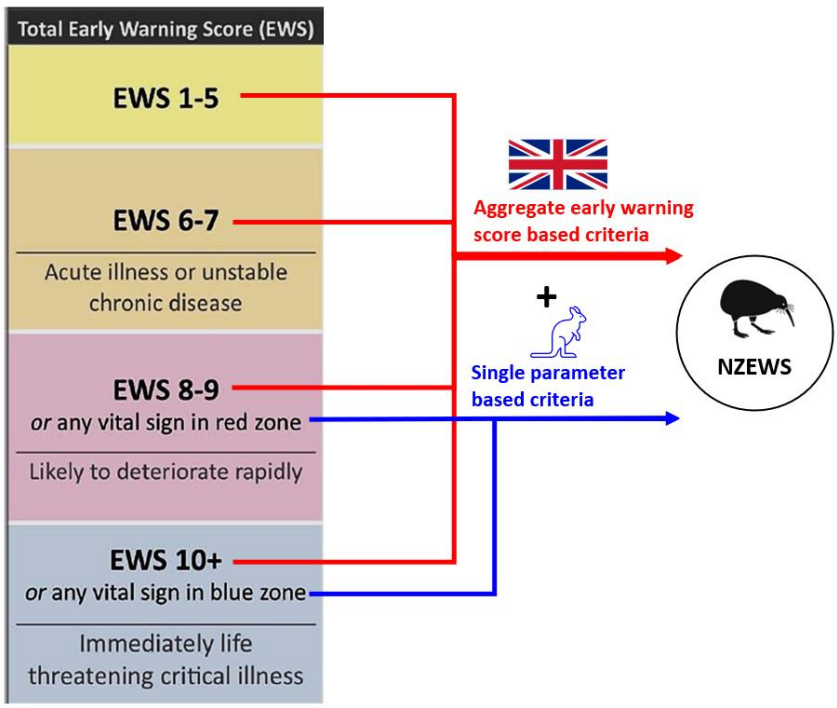


Figure 4-1 Aggregate Scoring and Single Parameter-Based Calling Criteria Based on NZEWS

Though the primary aim of our study was to quantify the workload involved in the afferent and afferent limbs of RRS, we have extrapolated the findings to compute the workload contributed particularly by the afferent limb of RRS to the overall nursing workload in general hospital ward settings. We computed the workload involved in patient monitoring based on the 4-hourly vital signs observations which is the minimal frequency of monitoring required by the NZEWS national policy (HQSC, 2017a). If no patient is required to have a higher frequency of vital signs observations, based on our results, 8.51 (CI: 8.14 – 8.88) fulltime equivalents (FTEs) of nursing time were used in a 24-hour cycle in a hospital of approximately 200 beds when all interruptions are removed. When we compute the same workload per 24 hours considering the observed interruptions in our study, we estimate that 4-hourly vital signs observations would require 10.74 (CI 10.30 – 11.17) FTEs of nursing time every day. Because these estimates consider all patients in a stable physiological state who require 4-hourly observations, actual FTEs involved must be higher than these estimates.

Similarly, the findings of the workload involved in responding to deteriorating patients by PaR nurses can be extrapolated to quantify the optimal workforce requirements for rapid response teams in a general hospital. Our findings on workload involved in the afferent and efferent components of RRS should be applicable to New Zealand hospitals and possibly overseas where vital signs and EWS are used to recognise and to respond to deteriorating patients. These results also provide a baseline for future comparisons when an electronic system is adopted for measuring and recording vital signs, and documenting rapid responses, especially when such end-to-end systems exist (M. M. Baig et al., 2020). The main limitation of this study is, our findings are based on paper-based vital signs and EWS charts to drive the afferent RRS, so we did not have comparable findings on the workload involved in these

activities through an electronic system. A comparison is presented by some of the studies included in the systematic review (Dall'Ora et al., 2020).

4.5 Conclusions

Patient monitoring of (afferent) and responding to (efferent) deteriorations consume considerable clinician time which is not well reported using an end-to-end rapid response system approach. Time spent in monitoring is not affected by independent and random factors, which is consistent with the literature. We found that time spent in responding to escalation was greater when patients had a higher level of deterioration which is plausible; however, there is no literature to draw a comparison on this. We advocate that the study of the workload involved in RRS using a whole system approach should be applied, studied, and reported for the various models of rapid response teams, and the findings of such studies must be considered. This approach could better inform health policy and workforce strategy.

CHAPTER 5 Vital signs & Early Warning Score monitoring: clinical staff perceptions about current practices and introducing an electronic rapid response system

5.1 Introduction

This chapter covers user perceptions about the vital signs and early warning system (EWS) monitoring on general hospital wards. It also explains the current and future practices of patient monitoring by the rapid response system (RRS) and how it works towards the goal of improving patient outcomes by timely recognition and management of deteriorating patients. This study was conducted to evaluate the perceptions of clinical staff (nurses and doctors) to learning about the perceived strengths and weaknesses of the current state of the RRS and how these users think those strengths and weaknesses would be affected by introducing an electronic system to measure and record vital signs and EWS. The aim was also to facilitate the communication between patients, primary responders (i.e., primary nurses, healthcare assistants or other members of the general ward), secondary responders (medical staff or senior nurses) and tertiary responders (rapid response teams) and to assist in measuring and recording the overall RRS activities including the type of care delivered as part of the rapid response activations. This study in the planning stage of technology implementation has been advocated to inform feasibility, provide insights for customization and refinement of the technology in an iterative quality improvement process to optimize the tool, and illustrate the improvements better by providing a firm baseline.

The aim of this study was to investigate clinical staff perceptions of current monitoring practices and the planned introduction of an electronic system for patient monitoring to:

i) Assess nurses' views and confidence regarding current vital signs monitoring tools and practices

ii) Gauge doctors and nurses' perceptions regarding the introduction of electronic monitoring of vital signs and EWS through devices and sensors

iii) Obtain staff feedback on issues identified within current and proposed systems

5.2 Methods

This was a three-pronged descriptive study comprising of two detailed sessions on demonstration and workshop of the electronic system for measuring and recording vital signs and EWS (VitalsAssist) followed by two structured surveys administered through an online portal (SurveyMonkey) for nurses and doctors working at Taranaki District Health Boards. The study was conducted between October 2020 and May 2021 at Taranaki Base Hospital, New Plymouth, New Zealand. Taranaki DHB employs 680 nurses and doctors (510 nurses and 160 doctors) (Coleman, 2017)

The sample size was calculated using the method described in Section 4.2.2 described by Sullivan et al., (Sullivan et al., 2009).

- Population size (for finite population correction factor or FPC) (N): 680
- Hypothesised % frequency of outcome factor in the population (p): 10%
- Confidence limits as % of 100(absolute +/- %) (d): 5%
- Design effect (DEFF): 1

A sample size of 116 was calculated using this method. A total of 121 staff members participated in this study which was deemed a suitable sample size of a total of 680 staff members working at the study site

A detailed demonstration session and one hands-on workshop session on the electronic vital signs and EWS system (VitalsAssist) was arranged at Taranaki Base Hospital. Following this a staff survey was conducted.

The survey was responded to by 121 staff members (84 nurses and 37 doctors). The survey participants were incentivised to participate as the participants were to go into a draw to win a smartwatch.

The Ethics Review Committee of the Taranaki District Health Board approved the study.

The first draft of the survey questionnaire was developed by the researcher based on the previous studies examining staff perceptions about patient monitoring practices. The questionnaire was assessed by their academic supervisors to ascertain the suitability and alignment to the planned study. Afterwards this questionnaire was circulated to a panel of senior medical and nursing professionals at Taranaki District Health Board for validation and approval.

The panel nominated two reviewers who checked and validated the survey questionnaire for nursing and medical staff. The reviewers completed their assessment on 27 January 2021. The questionnaire was approved by the panel on 28 January 2021.

The questionnaire was uploaded into the Taranaki District Health Board's official survey platform on Monday 01 February 2021. There were organization-wide communications through organizational newsletters, intranet posts and direct emails targeting nursing and medical staff as respondents. The survey remained active for a period of three weeks until Monday 22 February.

5.3 Results

5.3.1 Perceptions of nursing staff

5.3.1.1 How nurses ensure they undertake the vital signs measurements in a timely manner

In this structured survey for nurses, the first question asked about the means they apply to remind themselves about the time when the next measurement of vital signs must occur. A total of 40 nurses responded to this question. The most common means/reminder used by 21 (52.5%) respondents was the shift planner followed by personal diary or mobile phone reminders (6, 15%), going by a routine of undertaking vital signs every four hours (6, 15%), going by the time indicated by last set of vital signs (5, 12.5%) and use of other ways of personal checklist keeping (2, 5%) as shown in Figure 5-1.

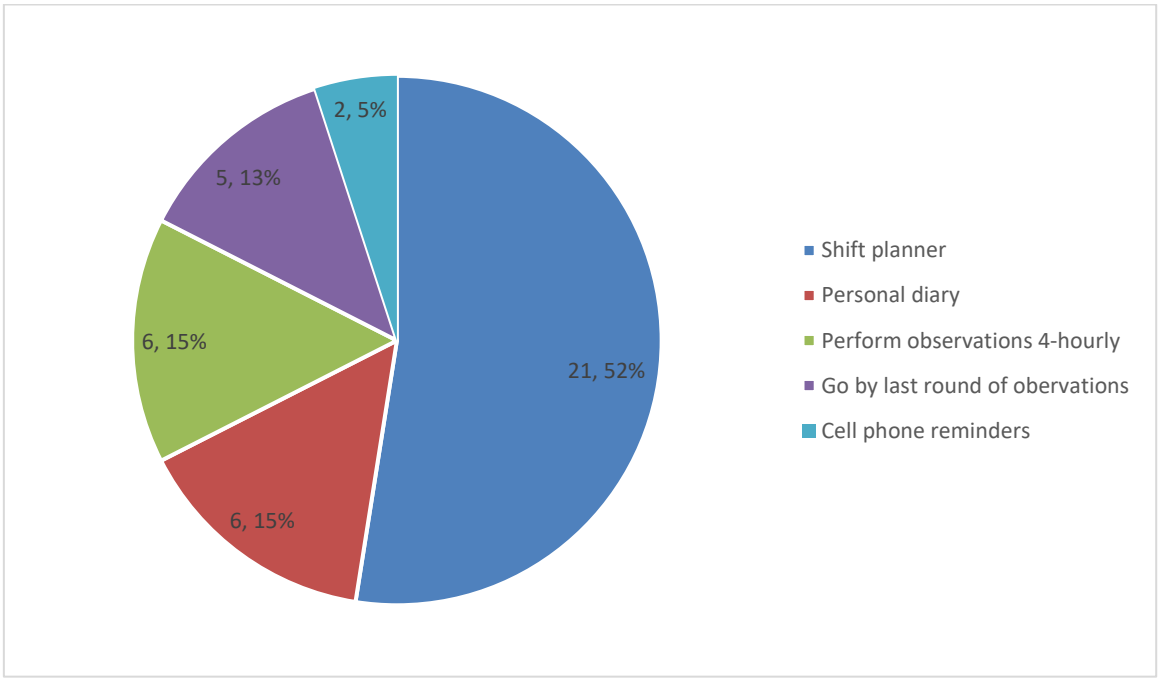


Figure 5-1 Means/reminders used by nurses to undertake vital signs measurement in a timely manner

5.3.1.2 Tools and technology used by nurses to communicate with responders when needed

Forty nurses (47.6% of nursing survey respondents) opted to answer the question about the tools and technology they use to inform about deteriorating patients when one of the calling criteria is met. The most frequent tool used by nurses was Pager (15, 37%), followed by Task Manager (11, 28%), Cellphone (8,20%) and Landline phone (6, 15%) as shown in Figure 5-2.

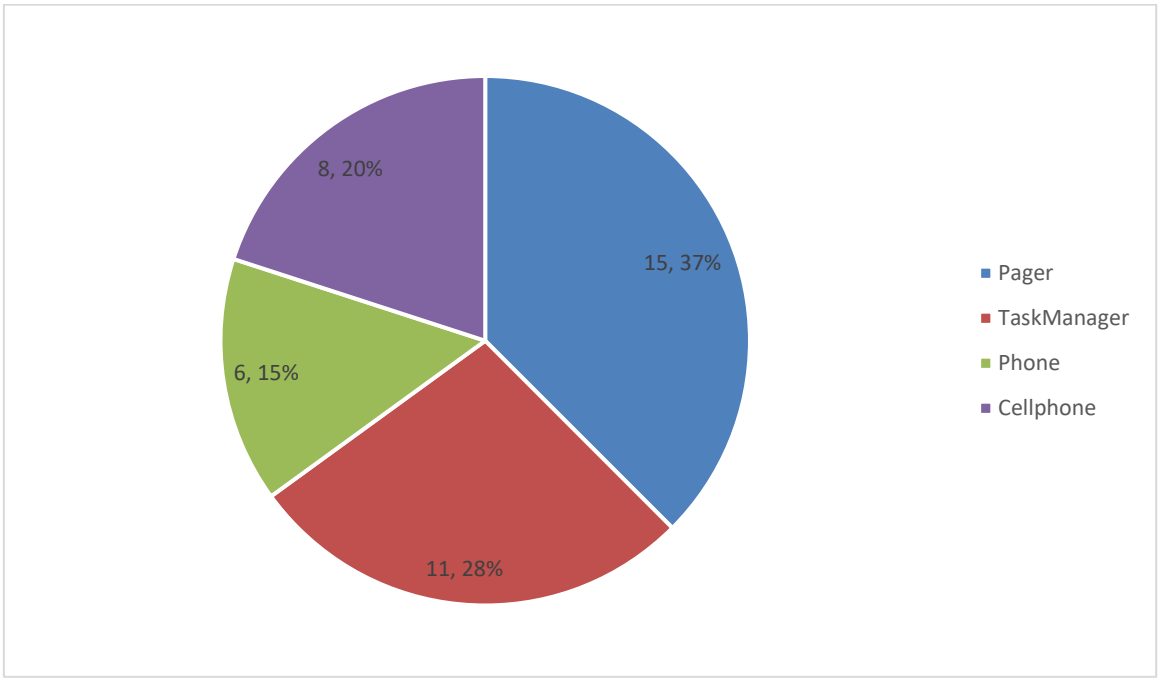


Figure 5-2 Tools and technology used by nurses to communicate with responders

5.3.1.3 Time required to convey the clinical information to responders when a 777-call is not indicated

This question explored the perception of nurses about the time required to communicate with responders such as Patient at-risk Nurse, Resident Medical Officers, or rapid response team to convey clinical information about deteriorating patients. A third (13, 32.5%) of nurses reported this takes less than 5 minutes and 18 (45%) reported it takes 5-30 minutes. Only

three (7.5%) said it takes over 30 minutes and six (15%) reported this time was variable in their experience as shown in Figure 5-3.

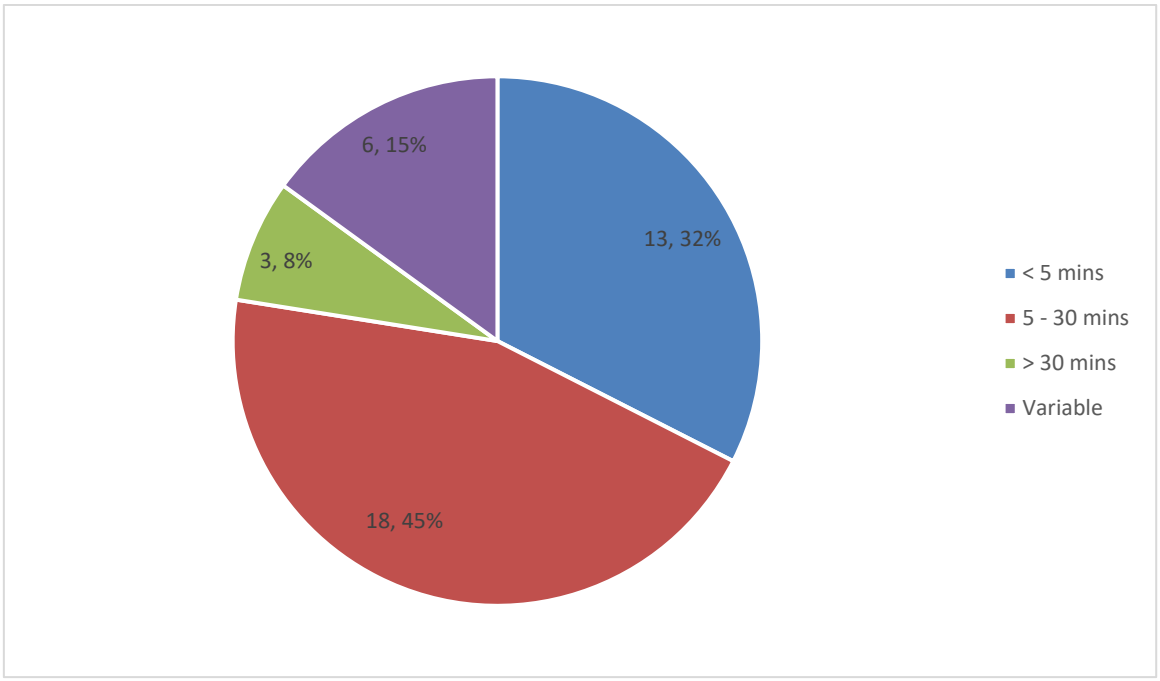


Figure 5-3 Time taken by primary nurse to convey clinical information to responders using existing tools

5.3.1.4 Timelines of responders to arrive at bedside to assess deteriorating patients

A majority (24, 60%) of nurses reported that when called to assess deteriorating patients, the responders arrive at bedside within 5-30 minutes and an additional 11 (27%) said the responders arrive within 5 minutes while a few nurses reported variable or longer than 30 minutes for responders to arrive at the bedside as shown in Figure 5-4.

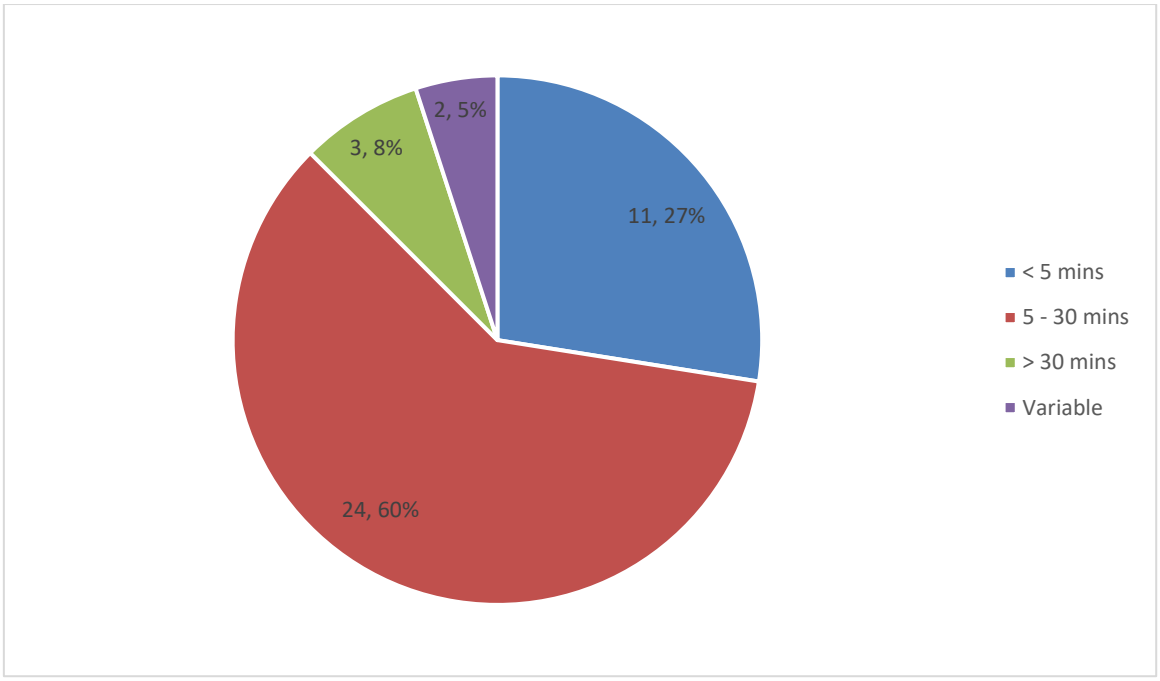


Figure 5-4 Timeliness of responders to arrive at bedside to assess deteriorating patient when called for review by nurses (excluding 777-calls)

Nursing participants were asked to pick one or two key issues with current manual vital signs monitoring through NZEWS charts. The most (81, 98.8%) picked one to two issues out of seven choices and two nurses opted to use the free text field to report that the system in place was good but organizational compliance was poor. A total of 140 selections were made by 81 participants as shown in Figure 5-5.

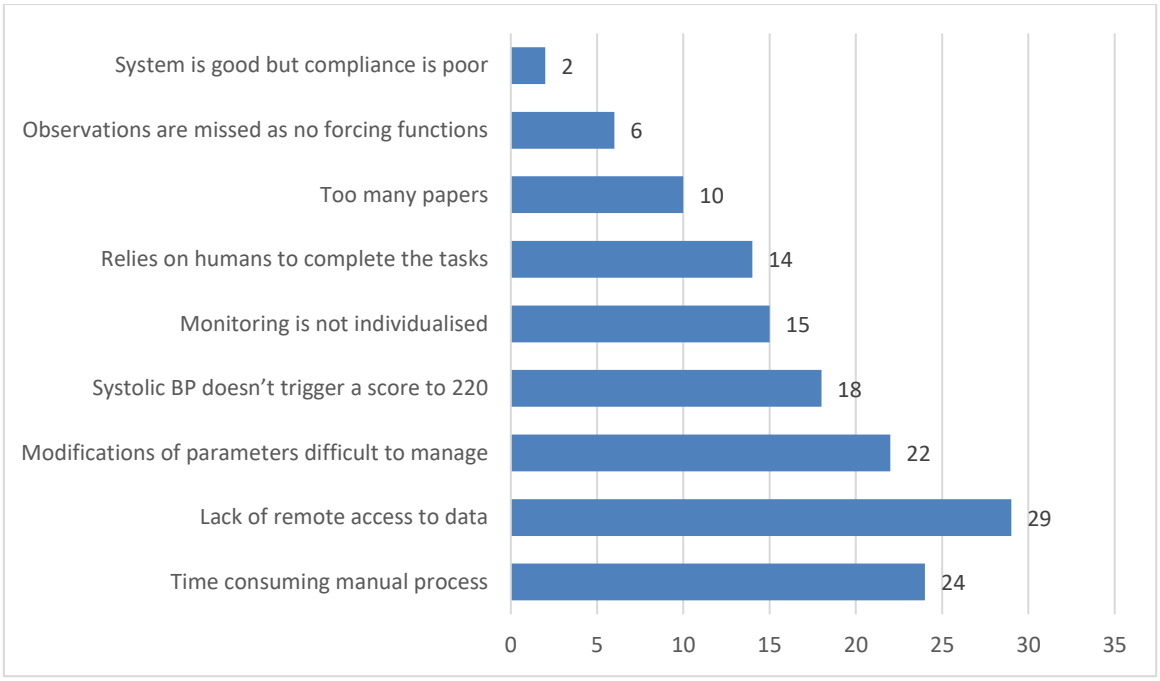


Figure 5-5 Key issues with current RRS processes according to nursing staff

5.3.1.5 Expectations from electronic system

Over two-thirds (n= 29, 71%) of nursing participants expected that the electronic system for vital signs would improve the accessibility of data, communication between teams and patient outcomes when asked on a Likert scale as shown in Figure 5-6.

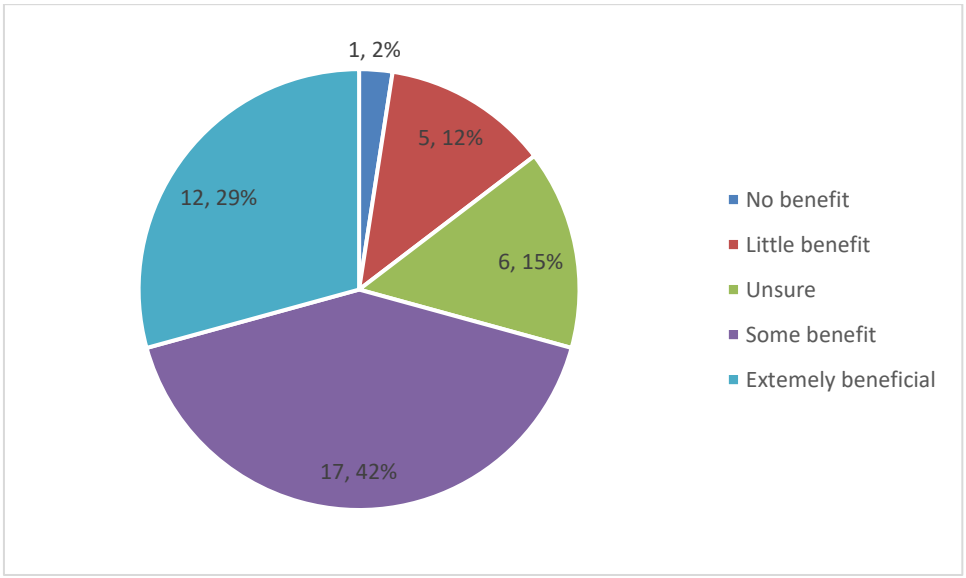


Figure 5-6 Nursing staff's expectations / perceived benefits of electronic system

5.3.2 Perceptions of medical staff

5.3.2.1 Expectations from electronic system

Over three quarters (24, 77%) of medical staff expected that the electronic system for vital signs would improve accessibility of data, communication between teams and patient outcomes when asked on a Likert scale as shown in Figure 5-7.

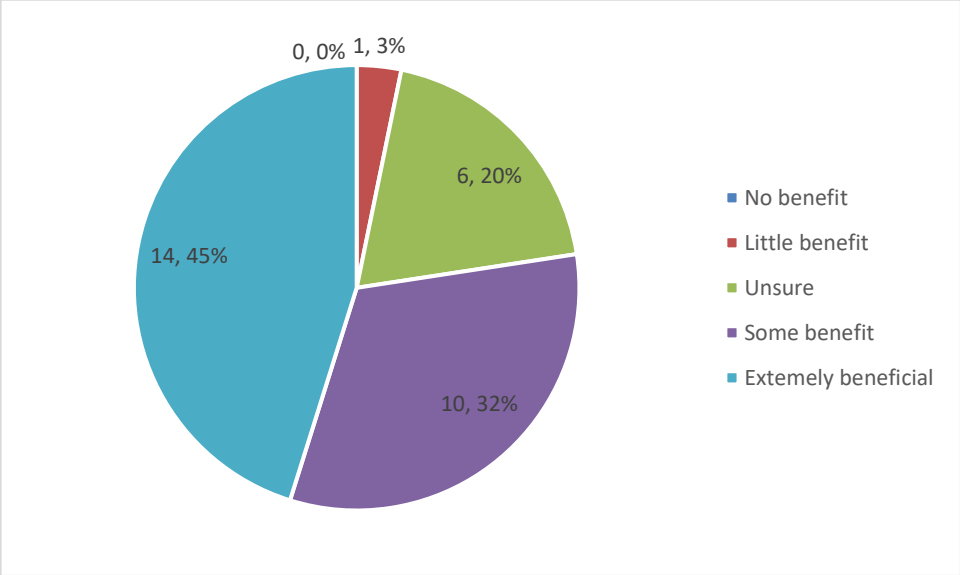


Figure 5-7 Medical staff's expectations/perceived benefits of electronic system

5.3.2.2 Willingness and support for implementation of electronic RRS

Majority of the medical staff (20/31, 64.5%) responding to the survey supported the idea of implementing electronic RRS whereas 9 (29%) strongly agreed with this, and 11 (35.5%) agreed. Only 4 (12.9%) disagreed and none strongly disagreed with this idea. Seven (22.8%) were unsure whether electronic RRS would be beneficial in the management of deteriorating patients as shown in Figure 5-8.

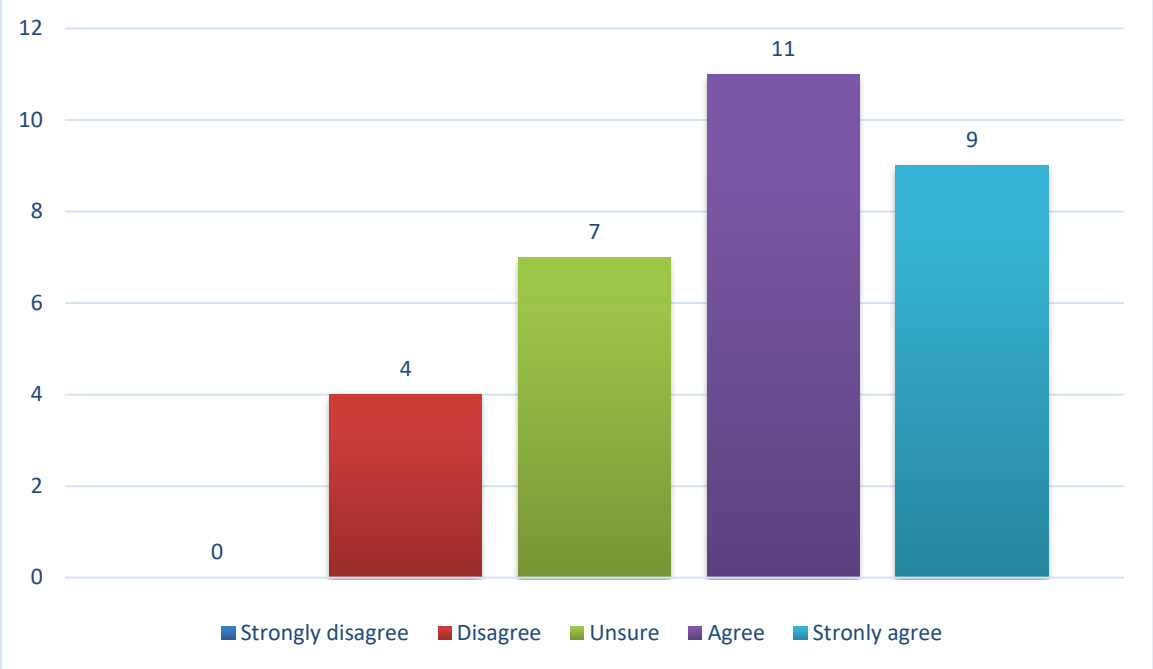


Figure 5-8 Willingness and support from medical staff about implementation of electronic RRS

5.3.2.3 Automated escalation of deteriorating patients (higher EWS) to relevant clinician

Responding to the question about auto-calculation of EWS and automated communication and/or alert to relevant clinicians directly by the electronic RRS application, half (17 out 36, 47.2%) of the medical staff agreed or strongly agreed with the usefulness of this function of the electronic RRS. Six (16.7%) disagreed and one (2.8%) strongly disagreed with auto-escalation of deteriorating by the electronic RRS whereas 12 (33.3%) were unsure about this, as shown in Figure 5-9.

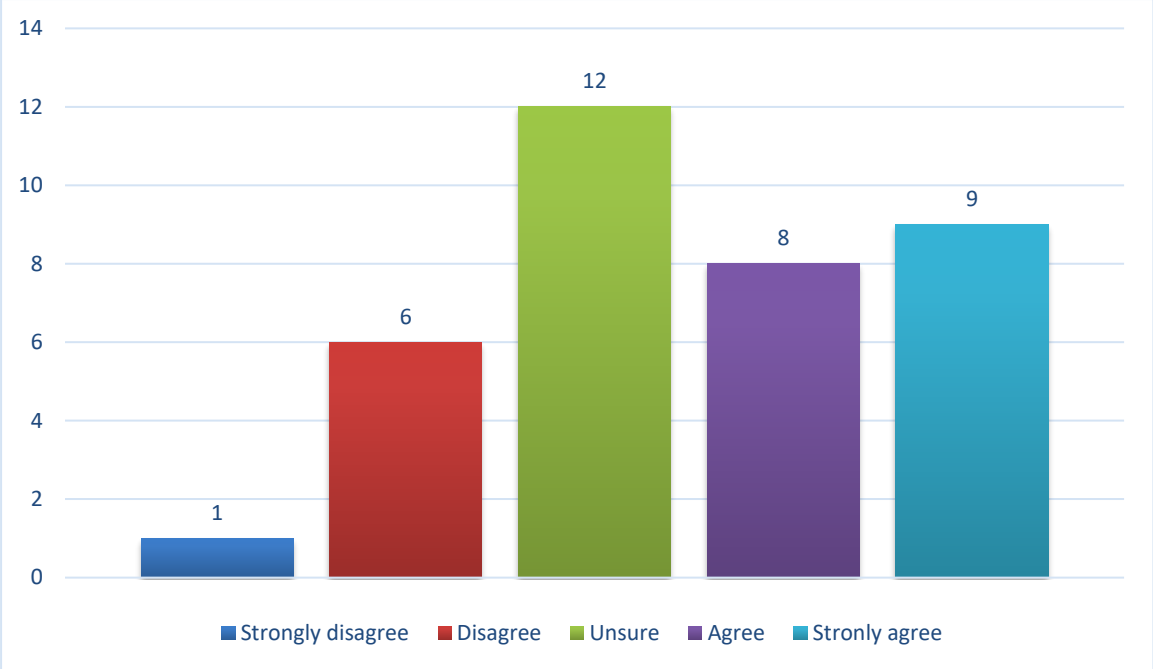


Figure 5-9 Perceptions of medical staff about auto-escalation of deteriorating patients by electronic RRS

5.3.2.4 Perceived issues with current RRS

Medical staff were asked to describe in their own words at least one issue they face using current RRS through paper based NZEWS charts and escalation of deteriorating patients through telephone and pagers. Similar responses were grouped together into broader ideas/topics as shown in Table 5-1.

Table 5-1 Issues with current RRS perceived by medical staff

Statements	N	%
Failure in triggers due to errors and omissions in monitoring, or nursing staff unsure about deterioration	9	29.0
Doctors do not always fill modified EWS criteria resulting in unnecessary calls and extra work for nursing and medical staff	8	25.8
Tracking of trends in vital signs is sometimes lost due to incorrect order of paper charts	7	22.6
Paper-charts may not always be easily accessible at bedside, as needed by other staff from time to time	4	12.9
No triggers for pain, high systolic BP (<220) & hypothermia	3	9.7
Total	31	100

5.3.2.5 Perceived benefits from implementation of electronic RRS application

The medical staff were asked to describe in their own words one or more benefits of implementing an electronic RRS application after having the demonstration of the electronic RRS application. Similar responses were grouped together into broad ideas/topics as shown in Table 5-2.

Table 5-2 Benefits of electronic RRS application perceived by medical staff

Ideas/topics	N	%
Information becomes accessible easily (onsite and remotely)	10	32.2
Staff will get more time to interpret the observations and other aspects of patient care when the electronic RRS replaces manual VS measurements and documentation	7	22.5
Remotely accessible information should help quick decision making and quicker response to deteriorating patients by specialist resources such as senior clinicians and PaR nurses who would not need to first reach the bedside to find out actual VS and EWS trends and values	5	16.1
Single system removes the need for multiple telecom tools and thus should reduce communication issues	5	16.1
Trends and personalised readings for VS and EWS would become possible with electronic RRS application	4	12.9
Total	31	100

5.4 Discussion

The most common means/reminders used by 21 (52.5%) respondents was the shift planner – a paper with a table printed on one side of it having eight rows, each for an hour of the shift and five columns, each for one patient in addition to the first column with hourly time slots printed on it. The nurses can handwrite the tasks in the next columns to remind themselves about these tasks. Other mechanisms used by the nurses to timely undertake vital signs include a personal diary or cell phone reminders (6, 15%), following a routine of undertaking vital signs every four hours (6, 15%), following the time indicated by last set of vital signs (5, 12.5%) and use of other ways of personal checklist keeping (2, 5%).

The mandatory escalation pathway of NZEWS requires a phone call when one of the 'calling criteria' is met. However, 26 (65%) of the nursing survey respondents reported use of the pager devices and in-house task management desktop application called 'TaskManager' to contact primary responders for deranged vital signs or elevated EWS. This highlights that sometimes the current RRS communications do not follow the expected use of tools and technology whereby the applications such as TaskManager, which are designed for tracking and management of after-hours tasks of low urgency, and categorically use of this application is discouraged for the purposes of RRS. Such inconsistency in the use of communication tools in the existing RRS, could make the RRS prone to errors, delays and failures in recognition and response to deteriorating patients.

A majority (24, 60%) of nurses reported that when called to assess deteriorating patients, the responders arrive at bedside within 5-30 minutes and an additional 11 (27%) said the responders arrive within 5 minutes. That is a collective 87% responder arrival within 30 minutes.

There are several studies reporting staff perceptions about patient monitoring through vital signs, categorising deteriorating patients by applying one or the other model of early warning score and escalating the care for a rapid response. However, most of these studies have focused on one or two aspects of the rapid response system.

A survey from the UK by Donohue and Endacott (Donohue & Endacott, 2010) studied perceptions of ward nurses and those of the specialised critical care outreach staff (New Zealand equivalent of COO is Patient-at risk or PAR nursing service) to report that staff didn't use their version of EWS to assess the deteriorating patient, rather they used it to triage deteriorating patients using EWS.

Another study from Europe by (Ludikhuize et al., 2011) reported that EWS was used by 11% of nursing staff in the Netherlands to notify the medical colleagues about deteriorating patients.

Wynn (2009) conducted a small-scale survey at a US hospital using self-reported questionnaires participated by 75 nursing staff. They reported that nursing knowledge and experience was associated with their actions towards patient monitoring and rapid response activities. They also found that in 34% of cases, over two hours had elapsed since the first documented abnormality in the vital signs before a rapid response call was activated.

Bagshaw (Bagshaw et al., 2010) conducted a cross-section study at a university hospital in Alberta, Canada participated by 275 nurses to assess their beliefs about activation of rapid response activations. Bagshaw et al., found that 15.4% of respondents were reluctant to activate the rapid response due to fear of criticism. Another 15.1% were uncertain about activating the rapid response call and 10.1% stated they would not activate if they were unable to contact a senior medical colleague. A small subset (7.5%) of participants said that

rapid response calls were needed to overcome the difficulties in escalating the care otherwise and 94% agreed that rapid response calling was valuable.

A small descriptive study from a 400-bed teaching hospital in Athens, Greece conducted by Pantazopoulos (Pantazopoulos et al., 2012) investigated the relationship between staff demographics and identification of deteriorating patients including activation of RRS. They found that study participants' basic qualification and attendance at a cardiopulmonary resuscitation (CPR) course significantly improved their activation of RRS.

(Philip, Richardson, & Cohen, 2013) conducted a small-call survey involving 41 ward-based clinical staff from the UK to report that staff had very low confidence in the reliability of vital signs and EWS recordings though recorded vital signs were often estimated rather than actual measurements and perceived lack of time was the commonest explanation for inappropriate assessment.

The above studies were conducted prior to the time of the RCPL recommending a nationally consistent NEWS in the UK (M. Jones, 2012) and the studies mentioned below represent the literature in the post-NEWS era.

(Jenkins, Astroth, & Woith, 2015) performed a small-scale cross-sectional study at a US hospital and reported that some of the study participants believed that calling an RRS was an indication that they were not able to provide adequate care to the patient. Other participants in Jenkin's study reported that if they activated RRS, they would not be treated with respect and could also be subject to a complaint or misconduct from the rapid response team. Half of the participants reported they had not received education or training on RRS.

(Radeschi et al., 2015) conducted a large-scale multi-site study participated by 1278 nurses and 534 medical doctors working at a group of ten hospitals located in the Piedmont region of

Italy. They reported that 5% of the staff were reluctant to activate RRS due to being criticised, 12% were reluctant due to fear of making an inappropriate call, 21% would not call if the patient looks well despite vital signs and EWS meeting one of the calling criteria. Many nursing staff (60%) thought it was necessary to have RRT.

The first UK study from the post-NEWS era was conducted by (Kolic et al., 2015), who reported that 19.8% of NEWS was incorrectly calculated by the nursing staff, and that the nursing staff escalating the care to the medical team and timely response to those escalations by the medical teams was worse over the weekends compared to week days.

(Douglas et al., 2016) from Australia conducted a staff survey participated by 434 nurses and 190 medical doctors to investigate their perceptions about RRS including perceived barriers to activation of RRS. They reported that 17.1% of nurses and 7.9% of medical doctors were hesitant to call a rapid response due to fear of criticism unless the patient was critically ill; 20% of nurses reported that if patient looked well, they would not activate RRS; 18% of nursing staff said they had no support from medical staff; nurses thought RRS had increased their workload; and both medical and nursing staff perceive the benefits and usefulness of RRS.

(Jackson, Penprase, & Grobbel, 2016) from the US conducted a small-scale staff survey and reported that 71.2% of nursing respondents would contact the on-call medical doctor before activating RRS; 29.2% nurses were indecisive about activating RRS if patient looked well; and 97.6% of the nurses felt that RRS was necessary. Jackson et al. also found a statistically significant negative correlation between years of experience and barriers to activating RRS.

(Prgomet et al., 2016) performed a small-scale survey at two general wards in an Australian hospital and reported that participants felt satisfied with their abilities to identify patients at

risk of deterioration using a combination of vital signs and visual assessment. Prgomet's study participants were concerned about the frequency of vital signs and the accuracy of the equipment used. Both the nursing and medical respondents believed that implementing an electronic monitoring system would enable early detection of deteriorating patients, could reassure patients, and could speed up the inter-professional communication in the context of deteriorating patients. Prgomet's participants were cautious that an electronic system could reduce bedside nurse-patient interactions, could lead to unnecessary alerts and cause discomfort to patients.

(Stolldorf, 2016) explored the perceptions of nursing staff, rapid response team and nursing leaders about the RRS. All participants reported that RRS is beneficial to staff, patients, and organisations. Stollforf reported variations in the benefits of RRS among the study groups where nursing staff frequently reported the benefits of the RRS to the general ward staff and patients; rapid response team members focused on training and education and nursing leaders focused on organisational and other macro-level benefits.

(Kim S Astroth, Woith, Jenkins, & Hesson-McInnis, 2017) conducted a survey on 202-general ward nurses to report that lack of continuing education and organisational culture of blame were negatively correlated with activation of RRS whereas the years of experience were positively correlated with activation of RRS among the study participants.

(Queiroz & Nogueira, 2019) undertook a small-scale study to assess the perception of nurses about the quality or maturity of the RRS in its structure, process, and outcomes. They identified that 25 out of 37 items they analysed had a satisfactory positive index. Their findings showed that, according to nurses' perceptions the process dimension of the RRS was the most vulnerable.

A recent study by (Azimirad et al., 2020) comparing English and Finnish rapid response systems demonstrated that in 50% of cases, nurses failed to activate the rapid response system in a timely manner, a finding which consistently prevailed in the sample population of nurses from both counties. Azimirad et al. reported that nurses didn't perceive disagreement of medical colleagues as a strong barrier to activating the RRS. Doctor's disagreement was less important according to Finnish nurses' perception as their British counterparts. Azimirad et al. recommended nurses need education towards the identified gap in their knowledge about timely activation of RRS.

(McNeill, Archer, Remsburg, Storer, & Rudman, 2019) studied the perceived benefits of RRS and the timeliness of RRS activations, to report that staff perceived RRS creates a supportive and learning environment conducive to teamwork in an effort to improve patient outcomes. They also reviewed 120 vital signs charts to find out a total of 15 RRS activations, over half of which were related to a respiratory problem. The mean length of the RRS calls was 39 mins, where 12/15 calls were made within 30 minutes.

A study by (Burrell et al., 2020) reported that, despite RRS having come a long way to become a routine part of clinical practice to detect and respond to deteriorating patients, many RRS activations do not occur when indicated. Burrell et al. reported that ward nurses may still be reluctant to activate RRS due to fear of reprimand, hence introducing a proactive, dedicated team of rapid responder nurses would facilitate inter-professional communication, increase the RRS activations to allow early detection and management of deteriorating patients, reducing ICU admissions and patient adverse events.

Our findings suggest a need for further research into the staff perceptions about RRS and involving RRS users right from the patient and their families and general ward nurses most closely monitoring the patients, through all types of rapid responders, to the organizational

leadership in future re-design and refinements of RRS, as part of the quality improvement limb of the mature RRS as suggested by recent studies (Chalwin, Giles, Salter, Kapitola, & Karnon, 2020; Padilla, Urden, & Stacy, 2018; Stolldorf, 2016). (Padilla et al., 2018) reviewed the structured instruments available to study staff perceptions related to RRS and suggested using Rapid Response Team Facilitators and Barriers Survey (RRT-FBS) developed by (K. S. Astroth, Woith, Stapleton, Degitz, & Jenkins, 2013) and a few other survey questionnaires.

5.5 Conclusions

This study examined the perceptions of clinical staff about the current manual vital signs monitoring and proposed electronic monitoring to understand the impact of end-user attitudes on the acceptability and integration of the proposed electronic system. The perceptions of clinical staff were a combination of key practice issues with current manual monitoring, expectations of improved visibility of vital sign charts, better communication between staff and thus improved patient care with introduction of an electronic system, and some concerns about the integration of the electronic vital signs systems with other electronic systems used by hospitals. Staff think an electronic system could help reduce errors and omissions in vital signs monitoring to support earlier identification of deteriorating patients, thus contributing to the role of rapid response system. A majority (77%) of the medical staff think it will be huge benefit to accessing the vital signs data and trends remotely to help quicker decision making. These findings highlight that implementation of an electronic system for vital signs should be prioritised yet it must follow robust planning to address the concerns about the integration of this system with other IT systems of the hospital for interoperability to avoid unintended consequences, and a proper surveillance post implementation to identify any problems faced by end-users to mitigate those problems through an iterative process.

CHAPTER 6 The incidence and survival rate of in-hospital cardiac arrest at the study site

6.1 Introduction

In-hospital cardiac arrest (IHCA) is defined as the loss of circulation prompting resuscitation with chest compressions, defibrillation, or both (Andersen, Holmberg, Berg, Donnino, & Granfeldt, 2019). IHCA can occur in any hospitalised patient. In the past, outcomes of IHCA had been regarded as so poor that resuscitation may not even be valuable but data from the last two decades suggest some improvement (Benjamin et al., 2018). This improvement in the outcome of IHCA is linked to an increased awareness of the influence that rapid response can bring together. Despite some increased interest, IHCA continues to be a neglected condition almost worldwide compared to the out-of-hospital cardiac arrests (OHCA) and other cardiovascular conditions such as myocardial infarction (commonly known as heart attack) and cerebrovascular accidents also known as stroke (Sinha et al., 2016).

The epidemiology of in-hospital cardiac arrests (IHCA), sometimes referred to as cardiac arrest, has not been well-studied and reported in Australia and New Zealand despite it being recognised as one of the essential indicators of the effectiveness of the RRS and included in the set of ten quality metrics for the evaluation of the RRS by a recent position paper by global leaders on the subject (Christian P Subbe et al., 2019).

(Fennessy, Hilton, Radford, Bellomo, & Jones, 2016) reviewed the available studies from mostly Australian hospitals to calculate and report that IHCA incidence in Australia and New Zealand varies between 1.31 to 6.11 per 1000 admissions. This incidence rate is similar to the incidence of IHCA reported from other parts of the world (W.-L. Liu et al., 2011; Meaney et

al., 2010; J. P. Nolan et al., 2014; Peberdy et al., 2003; Sandroni, Nolan, Cavallaro, & Antonelli, 2007)

The literature on the outcomes of IHCA in Australia and New Zealand, and particularly in New Zealand, is scarce. Fenessy et al. (2016) found that 46% of the patients who had an IHCA survived the event i.e., return of spontaneous circulation (ROSC), and 74.6% of the patients died prior to discharge i.e., the survival rate of 25.4% at discharge. Long term survival data wasn't available. A large-scale (n= >45,500 patients) population study from the US has recently reported that overall 1-year survival post IHCA was < 10% where they also found improvement in the survival rate for IHCA secondary to ventricular fibrillation from 8.9% in 2000 to 15.2% in 2011 (Thompson et al., 2018). Only a handful of studies published very recently have started to report the functional outcomes of IHCA survivors, predicting factors associated with better or worse outcomes of IHCA. A recent small-scale study from Australia by (Pound, Jones, Eastwood, Paul, & Hodgson, 2020) reported 60 (39.5%) patients survived IHCA, and they also studied functional outcomes for those who survived. They reported that 38 out 60 survivors (63.3%) were independent with activities of daily life when assessed at discharge and they found that shorter durations of CPR, younger age, and shorter length of stay (LoS) in hospital were associated with better functional status at discharge. Another study by (Mowbray et al., 2021) reported frailty as a marker of poor outcome of ICHA. A study by (Høybye et al., 2021) found that none of the patient demographics was associated with outcomes of IHCA.

This dearth of literature on the survival and outcome of IHCA is mainly due to the lack of IHCA registries. Notable IHCA registries include those from the American Heart Association Get With The Guidelines–Resuscitation (GWTG-R), the UK National Cardiac Arrest Audit and the Peidmont Regional Hospitals Group from Italy (J. P. Nolan et al., 2019; Peberdy et

al., 2003; Radeschi et al., 2017). (Booth et al., 2018) published a detailed report on all active cardiac arrest registries at national or large regional levels across the globe and have included out of hospital cardiac arrest (OHCA). According to Booth, the only such registry in Australia and New Zealand is the Australian Resuscitation Outcomes Consortium which covers OHCA and excludes IHCA.

This study was conducted to study the incidence of IHCA at the study site, and to assess the survival of IHCA patients at the time of arrest, at the time of discharge from the hospital and at one-year post-arrest.

6.2 Methods

6.2.1 Study Setting

This was an observational study with components of retrospective and prospective data collection. The study was conducted at both Taranaki Base and Hawera Hospitals affiliated with Taranaki District Health Board, located in New Plymouth and Hawera, Taranaki, North Island, New Zealand. The study was conducted between January and December 2021 where data available on the IHCA over the previous five years was accessed for analysis.

6.2.2 Sample size

The same size was calculated based on the MET call rate of 5.12% by earlier studies included in this thesis using the following method,

- Population size (for finite population correction factor or FPC) (N): 100000
- Hypothesised % frequency of outcome factor in the population (p): 5.12%+/-5
- Confidence limits as % of 100(absolute +/- %) (d): 5%
- Design effect (for cluster surveys-DEFF): 1

Equation

Sample size n = [DEFF*Np(1-p)]/ [(d2/Z21-α/2*(N-1)+p*(1-p)]

This method generated a sample size of 75 cases.

The yearly average of IHCA cases at the study site was below the required sample size. Therefore, all 142 cases of the IHCA occurring at Taranaki Base and Hawera Hospitals between 1 January 2016 and 31 December 2020 were included in this study. The cases of IHCA occurring in 2021 were excluded due to the inability to collect 1-year survival status within the study duration (ending December 2021). The cases of IHCA occurring in the community and brought to the hospital and the cases of IHCA occurring in the paediatric age group population were also excluded. Some cases of adult IHCA were excluded due to lack of sufficient information for meaningful analysis (e.g., survival status not known or demographics not evident). Hence, determination of whether a case meets the definition of an adult IHCA wasn't possible.

6.2.3 Data collection and management

For the purpose of this study, IHCA was defined as the loss of circulation in a hospitalised patient prompting resuscitation with chest compressions, defibrillation, or both (Andersen et al., 2019). At Taranaki DHB's hospital sites, all the IHCA require documentation of the resuscitation procedure within a stipulated resuscitation record. The short-term survival (surviving the cardiac arrest event, surviving the first 24 hours post event, and surviving the episode of current hospitalisation (i.e., discharged alive) were determined from the organisational resuscitation documentation. The cases of IHCA were then checked for their living status one year after the event within Taranaki DHB's electronic portal for medical

records (WebPAS, IBA Inc.) to determine long-term survival. To ensure accuracy of records, patients' attendance at recent clinic appointments or recent admissions to in-patient services were checked and correlated with the living status information in the electronic portal for medical records.

6.2.4 Data processing and analysis

The data on the IHCA cases was entered into an Excel spreadsheet and transported into SPSS. The data was analysed to determine the year-on-year comparison of the rates of the IHCA during the five years of the implementation of the New Zealand Early Warning Score (NZEWS) and vital sign charts as part of the national deteriorating patient programme. Secondly, a comparison before-and-after implementation of the critical outreach programme, i.e., the Patient-at-Risk (PaR) nurse service, was made to demonstrate any improvements made by strengthening the efferent limb of the RRS following the PaR service becoming available to support the rapid response to patients at risk of deterioration. These comparisons (year-year and before-and-after the PaR nurse service) were made by comparing the frequency of survival vs death using the Chi Square Test. A p-value of smaller than 0.05 was considered statistically significant.

6.3 Results

The mean age of adult patients suffering from an IHCA at the study site was 68.55 (95% CI = 65.96 – 71.14) years with some skewness towards the 80s, as shown by the histogram in Figure 6-1.

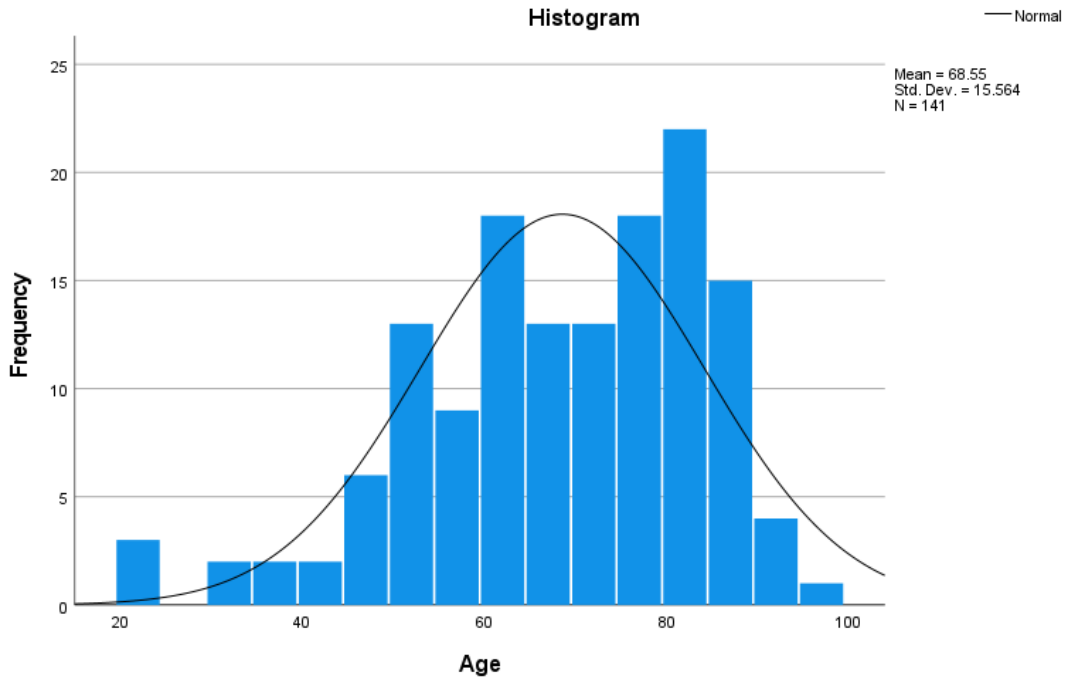


Figure 6-1 Histogram – Age of adult patients having IHCA at the study site

Nearly two thirds of patients were males (n = 96, 67.6%) and the remaining third (n = 45, 31.7%) were females and one patient's gender (0.7%) was not documented. New Zealand Europeans were the largest ethnic group (n = 105, 73.9%) followed by Māori (n= 26, 18.3%) where seven patients (4.9%) recognised themselves as other ethnicities. In four (2.8%) cases, ethnic data wasn't documented.

The implementation of nationally consistent vital signs and NZEWS charts by the study site since 2016 by participating in the HQSC led deteriorating patient programme has resulted in a steady improvement in recognition of antecedent pre-arrest conditions; and a steady

reduction in the proportion and number of IHCA events from 2016 to 2021 as shown in Figure 6-2 and Table 6-1.

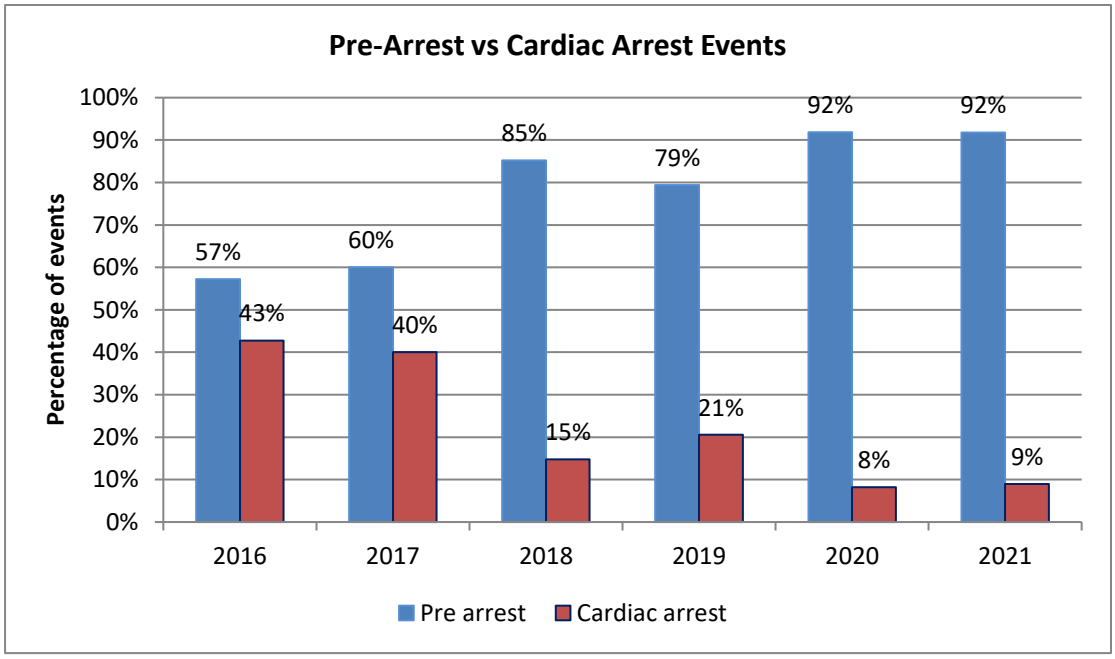


Figure 6-2 Relative proportion of pre-arrest conditions and IHCA recognised through the NZEWS system from 2016 to 2021 at Taranaki District Health Board

Table 6-1 Relative frequency of pre-arrest conditions and IHCA recognised through the NZEWS system from 2016 to 2021 at Taranaki District Health Board

Description / Year	2016	2017	2018	2019	2020	2021
Pre arrests / antecedents	79	81	202	166	258	235
Cardiac arrests / IHCA	59	54	35	43	23	21
Total 777 calls	138	135	237	209	281	256

Chi Square = 134.6, Degree of Freedom = 5, p-value < 0.0001

The nurse-led critical out-reach programme known as the Patient at-Risk (PaR) service was established and launched at the study site in November 2019. In the first two months (November and December 2019), the PaR service was available during the morning and evening shifts, i.e., from 6:45 am to 11:15 pm. The PaR service became a 24/7 service in early 2020. Figure 10.1 and Table 10.1 indicate that the total number of 777 calls increased largely since staff were recognising antecedents and making pre-arrest calls. Differences in the relative frequency of pre-arrest and cardiac arrest over time were statistically significant (p-value < 0.0001). The reduction in numbers of IHCA over 2020 and 2021 (post-implementation of the PaR service) appears to be substantial. Therefore, the data was compared by segregating into before-and-after the PaR nurse service. The statistical significance of the results became stronger when the results were compared before-and-after the PAR nurse service being established, as shown in Table 6-2.

Table 6-2 Relative frequency of pre-arrest conditions and IHCA recognised through the NZEWS system before and after the PAR nurse service at Taranaki District Health Board

Description	Before-PAR	After-PAR	Total
Pre-arrest	528	493	1021
Cardiac arrest	191	44	235
Total	**719**	**537**	**1256**

Chi Square= 68.21, Degrees of Freedom= 1, p-value = <0.0000001

To explore the survival rates of the IHCA events over the last five years, the survival rate was studied at three defined intervals: immediately after the event, at the time of discharge from the hospital, and after one calendar year post the IHCA event. Because of the inclusion of the survival status one-year post-IHCA, the cases of the IHCA occurring until 31 December 2020

were included in the study. Table 6-3 shows that the survival status one-year post-IHCA event has significantly increased (p value = 0.008) from 2016 (prior to implementation of the deteriorating patient pathway and NZEWS vital sign charts for patient monitoring at Taranaki DHB) to 2021 whereas there was no statistically significant difference in the survival status immediately post-IHCA event and the survival status at the discharge from the hospital.

Table 6-3 Survival immediately after the event, at discharge and at one year by calendar year 2016-2020

Survival status	Calendar year				N	P value
	2017	2018	2019	2020		
At event						
- **Died**	17 (31.5%)	13 (37.1%)	10 (33.3%)	10 (50%)	50	0.514
- **Survived**	37 (68.5%)	22 (63.9%	20 (66.7%)	10 (50%)	89	
At discharge						
- **Died**	33 (61.1%)	20 (57.2%)	26 (86.7%)	12 (60%)	91	0.051
- **Survived**	21 (38.9%)	15 (42.8%)	4 (13.3%)	8 (40%)	48	
At 1 year						
- **Died**	53 (98.1%)	35 (100%)	29 (96.7)	16 (80%)	133	0.008
- **Survived**	1 (1.9%)	0 (0%)	1 (3.3%)	4 (20%)	6	
Total	**54**	**35**	**30**	**20**	**139**	

The survival status at three defined intervals as described above was also studied for the cases of the IHCA events occurring before and after implementation of the PaR service. The analysis revealed that the survival status immediately post-IHCA event and the survival status

at the time of the discharge from the hospital were not significantly improved after the implementation of the PaR service. However, the survival status at one-year post-IHCA event was found to have significantly improved after the PaR nurse service had been implemented at Taranaki DHB as shown in Table 6-4.

Table 6-4 Survival immediately after the event, at discharge and at one year before and after implementation of the PaR Service

Survival status	Before PaR	After PaR	P value
At event			
- **Died**	40 (33.6%)	10 (50%)	0.158
- **Survived**	79 (66.4%)	10 (50%)	
At discharge			
- **Died**	79 (66.4%)	12 (60%)	0.578
- **Survived**	40 (33.6%)	8 (40%)	
At 1 year			
- **Died**	117 (98.3%)	16 (80%)	0.004
- **Survived**	2 (1.7%)	4 (20%)	
Total	**119**	**20**	

6.4 Discussion

It is evident from the findings of this study that the incidence of IHCA at the study site has decreased, and the survival to discharge and survival at one-year have modestly increased from 2016 to 2020 with the adoption of NZEWS and VS charts by the study site by participating in the HQSC-led deteriorating patient programme which also includes implementation of the PaR nursing service at the study site. It is also evident that both parameters (incidence of IHCA and survival of IHCA) have shown statistically significant change after implementing the PaR nurse service at Taranaki DHB. Though these findings are promising, it is noteworthy that the data on survival is not collected in terms of the actual length of time. Instead, the status of the patient in terms of survival or death is noted at the event, at the time of discharge (length of time between the event and discharge is highly unpredictable and not useful for any meaningful analysis), and at one-year post event. One year survival is a useful indicator and is encouraged to be continued. Those who survive a year post event should be followed annually for five years or death, whichever occurs first, to track long-term survival as reported by other studies mentioned later in this section. Data on type of arrest and pre-arrest conditions is collected and is useful to analyse. However, no inferential survival analysis could be performed due to lack of data collection on the actual length of time survived post event, limited data on demographics and clinical characteristics of patients. Similarly, there was no data collected on the functional outcome at hospital discharge using a standardised approach, e.g., using the modified Rankin Scale (mRS) and Katz Index of Independence in ADLs (Katz-ADL).

Another point to note is that the human resource to support data collection and perform useful analysis is lacking at the study site or is not clearly delineated within the resuscitation team. There is one full-time nurse educator role assigned to the clinical leadership of the

deteriorating patient programme and rapid response system who is also responsible to attend 777 calls during workhours and perform resuscitation, train, and educate PaR nurses and other hospital staff on resuscitation procedures, and run and chair the organisational resuscitation committee. The dedicated administrative and analytics resource is not available. Similarly, no resource was defined or available to perform statistical analysis to understand the performance of the rapid response system in a longitudinal fashion. The paper-based VS charts made this type of analysis even harder as any analysis would require manual entry of the patient monitoring data as the starting point.

(Schluep, Gravesteijn, Stolker, Endeman, & Hoeks, 2018) have recently published a well-designed systematic review on the studies reporting one-year survival in IHCA patients between 1985 and 2018. They included 39 studies reporting a one-year survival of 13.4% in IHCA patients on average. They noted a modest improvement in the survival rate over time (10-year odds ratio: 1.70, 95% CI: 1.04 – 2.76) but agree that IHCA survival remains poor. They also stress upon more research to study prognostic factors as well as compare conventional vs extracorporeal cardiopulmonary resuscitation. The latter is particularly important as the use of extracorporeal CPR has increased recently, and it could be a more common method of resuscitation in the future (Ahn et al., 2016).

A study published after the systematic review of 2018 by Australian investigators (Doherty et al., 2019) included 629 patients from a large regional hospital in Victoria between 2000 and 2017. They reported that 357 (57%) survived the event, and 213 (34%) survived to discharge. At one-year post-arrest 27% of the original cohort were still alive. They found that the age of the patient, arrest rhythm, location and duration of resuscitation were all significantly associated with long-term survival. A Swiss study published in 2021 (Fuchs et al., 2021) reported that a third (33%) of the IHCA survived long-term. These recent studies further

demonstrate an improvement in the long-term survival in IHCA patients. Unfortunately, there was no such study conducted on the New Zealand population.

6.5 Conclusion

In conclusion, it is suggested that prospective research on a population scale is needed to improve current knowledge on this subject. It is proposed that HQSC could lead New Zealand hospitals in establishing a national IHCA registry to collect, analyse, and report national data on IHCA on an annual basis to promote reporting, transparency, and research in this critical area of care with the goal to improve patient outcomes. Opposed to IHCA, such a registry is maintained by St Johns and Wellington Free Ambulance services for out-of-hospital cardiac arrest (Dicker, Todd, Howie, Wilinson, & Stewart, 2021). New Zealand hospitals should provide data on patient demographics, clinical details such as a list of comorbidities and length of hospital stay prior to and after suffering from a cardiac arrest, characteristics of the cardiac arrest event, survival, and function outcome at the time of discharge from hospital to the national IHCA registry to enable national reporting on the IHCA outcomes. This dataset will also enable New Zealand to benchmark local IHCA outcomes with international statistics. In addition, this dataset will promote further research to examine the link between IHCA outcomes and improvements in the rapid response systems. An important point to consider for the national IHCA registry would be to standardise the measurement of IHCA outcomes by promoting one of the well-recognised scales. Studies have reported functional outcomes using one of the common scales to measure the degree of disability or dependence in daily activities, such as the modified Rankin Scale and the Katz Index of Independence in Activities of Daily Life (Katz-ADLs) (W.-L. Liu et al., 2011; Mowbray et al., 2021; J. P. Nolan et al., 2019; Pound et al., 2020; Radeschi et al., 2017).

CHAPTER 7 Failure mode and effect analysis (FMEA) of the existing rapid response system (RRS)

7.1 Introduction

The Rapid Response System (RRS), as shown in Figure 2-1acts as the surveillance mechanism used by healthcare organisations to monitor patients admitted to general hospital wards outside the critical care settings with repeated vital signs observations and Early Warning Scores such as NZEWS. The values of vital signs and NZEWS determine the escalation trigger or calling criteria i.e., when patients require escalation of care such as a rapid response by a Medical Emergency Team (MET) or equivalent (Rihari-Thomas et al., 2018).

In New Zealand, most public hospitals use paper based vital signs charts in the general hospital ward settings to drive the afferent limb of the RRS, and a specialised team of nurses called Patient at-Risk (PaR) nurses and MET constitute the afferent limbs of the RRS (AJ Psirides, Hill, & Jones, 2016).

The epidemiology of RRS activations (D Jones, 2014; Kim et al., 2017; A. Psirides et al., 2013; AJ Psirides et al., 2016), outcomes of the in-hospital cardiac arrests (Fennessy et al., 2016; Høybye et al., 2021; J. P. Nolan et al., 2019) and comparison of various models of the RRS to recognise deteriorating patients in general hospital wards, outside critical care settings (Bunch et al., 2019; Devita et al., 2006; Heller et al., 2020; C. M. Jones et al., 2010; Sørensen & Petersen, 2015) have been discussed in the literature. However, there is a severe shortage of literature on how the RRS could be improved using systems approaches. We found only one publication using Root Cause Analysis to examine the causes of failures in

patient monitoring and escalation of care for deteriorating patients(Louise S. van Galen et al., 2016).

Failure Mode and Effect Analysis (FMEA) has been widely used in high-risk industries to evaluate and mitigate process weaknesses (H.-C. Liu, 2019; Niv et al., 2018; Sharma & Srivastava, 2018; Vázquez-Valencia et al., 2018). FMEA has been effectively applied to examine and mitigate risks and failure modes in many healthcare processes (Chiozza & Ponzetti, 2009; Freitag & Carroll, 2011; Huang et al., 2020a; Latino & Flood, 2004; Moradi et al., 2020; Nagpal et al., 2010; K. Nolan et al., 2019; Shebl et al., 2012; Simsekler et al., 2019). FMEA has not been applied to systematically assess and address RRS failures despite such failures being widely reported (S. P. Clarke, 2004; Griffiths, Jones, & Bottle, 2013; Gary B Smith et al., 2020; Christian Peter Subbe & Welch, 2013; Welcn, 2021; H. J. Wong et al., 2017).

The National Centre for Patient Safety of the United States of America's Department of Veterans Affairs adjusted FMEA for use in health care. Thus, the term 'health care FMEA' (HFMEA) is sometimes used to refer to the FMEA within healthcare literature (Chiozza & Ponzetti, 2009; Freitag & Carroll, 2011; Latino & Flood, 2004; Nagpal et al., 2010; Shebl et al., 2012). Sometimes, it is also referred to as Failure mode effects and criticality analysis (FMECA) (Buja et al., 2021). However, in this thesis, the original term 'FMEA' is used unless specified otherwise. The aim of this study was to identify all potential failures within RRS and to seek solutions to mitigate those failures using FMEA methodology.

7.2 Methods

7.2.1 Study Setting

The FMEA on existing RRS was performed at Taranaki Base Hospital, Taranaki District Health Board, New Plymouth, New Zealand, between January 2021 and July 2021. An overview of the stages of the FMEA process is shown in Figure 7-1, which are explained in the following paragraphs.

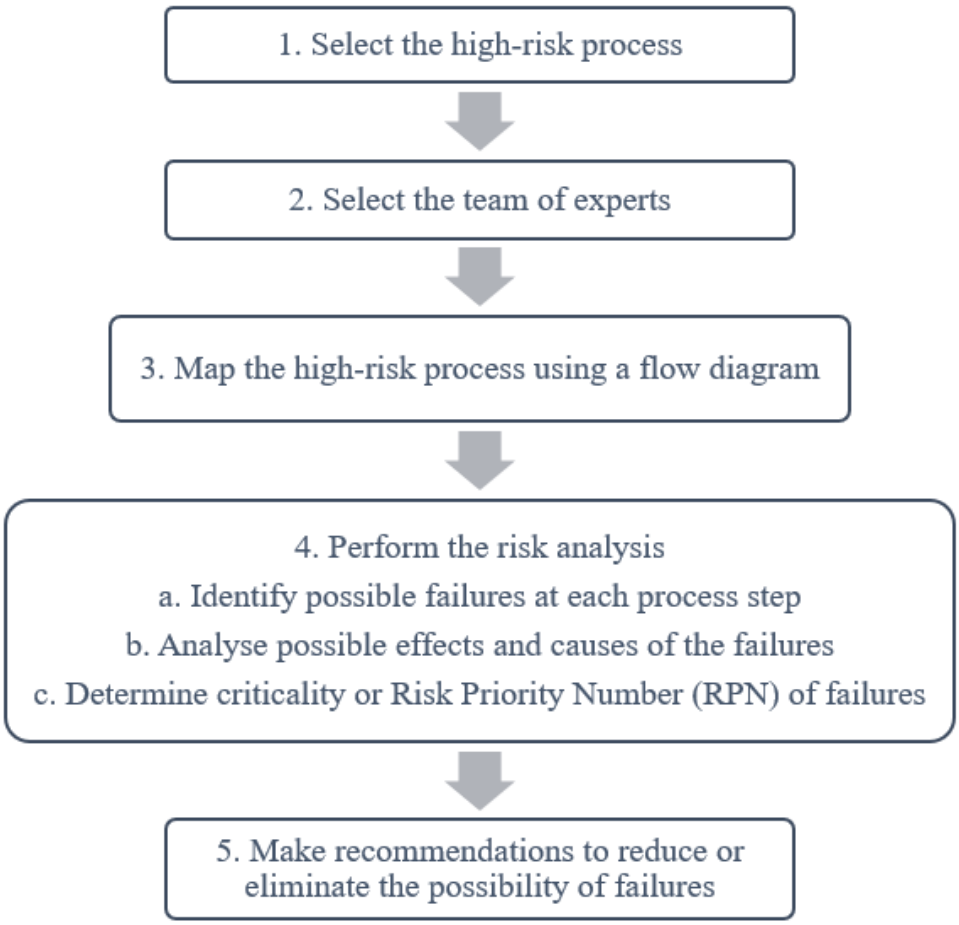


Figure 7-1 Stages of the failure mode and effect analysis

7.2.2 Selection of high-risk process

RRS, which is a unifying term to describe the process from vital signs monitoring to a rapid response type care delivered by MET or equivalent (Devita et al., 2006), was selected as the high-risk process for the FMEA study.

7.2.3 Selection of subject matter experts from regular users of existing RRS

A panel of six regular users of the RRS process were selected as subject matter experts (SME) who participated in the FMEA on a voluntary basis. Two were registered nurses (RNs), two were resident medical doctors, one was a specialised critical care outreach nurse, locally known as a 'Patient-at-risk nurse or PAR nurse' and one was a senior medical officer, a general physician or hospitalist. The SMEs attended a training session on FMEA methodology. Then the SMEs participated in the demonstration of Vital Signs Monitoring and the Decision Support System ("Vital signs monitoring and decision support system (VitalsAssist)," 2017). VitalsAssist is a system that automatically calculates NZEWS and can send alerts to cellular or landline phones and pager devices in a similar way the current paging system works for MET activations. In addition, VitalsAssist enables clinicians to view the vital signs values, trends and NZEWS on smartphones or tablet devices.

7.2.4 Mapping the process steps of RRS

A process diagram was drawn up to illustrate all the process steps of the existing rapid response system as shown in Figure 7-2.

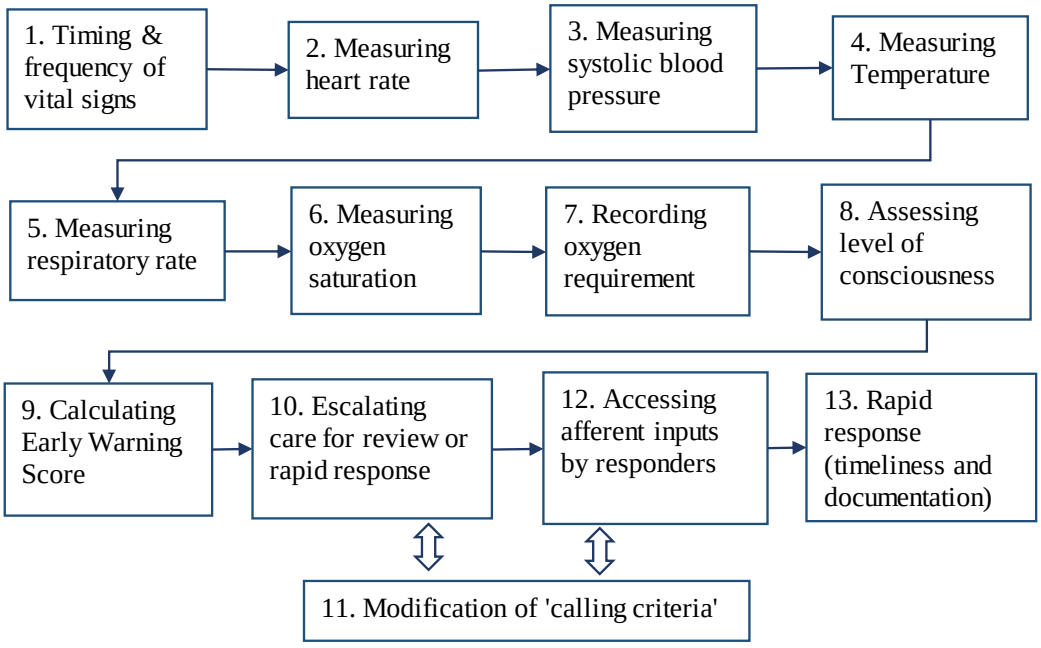


Figure 7-2 Flow diagram of steps involved in a rapid response system

7.3 Risk analysis

Potential failure mode effects were identified at each process step shown in Figure 7-2. The criticality of these failures was determined using a Risk Priority Number (RPN). A RPN is a numerical score quantifying the severity level (SL), occurrence level (OL) and detection level (DL) of failures according to the rating scale shown in Table 1 (RPN = severity x occurrence x detectability) of failures. The theoretical minimum RPN is 1*1*1 = 1. The theoretical maximum RPN is 3*10*5 = 150.

Table 7-1 Rating scale for Severity, Occurrence and Detection of Failure Modes in an RRS

Severity Levels (SL) of the Effect of the Failure Modes	**Rating**
No harm to patient / no effect on detection of patient deterioration	1
Non-documented vital signs or NZEWS or incorrect calculated NZEWS	2
Actual or potential delay to or lack of detection of patient deterioration	3
Occurrence Level (OL) of the Failure Modes	**Rating**
Once in more than a year	1
Once in a year	2
Once in six months	3
Once in three months	4
Once a month	5
Once a week	6
Once every 3 days	7
Once per day	8
One per 8-hour shift	9
More than once per 8-hour shift	10
Detection Level (DL) of the Failure Modes when they occur	**Rating**
100% detection	1
>50% detection	2
11 – 50% detection	3
<10 % detection	4
0% detection	5

This rating scale (Table 7-1) was adapted from Rezaee et al. (F. Rezaei et al., 2018) and other published studies (Buja et al., 2021; Ghanjal, Sedaghat, Motaqhey, Dellavari, & Tavakoli, 2008; Rah et al., 2016; Reiling, Knutzen, & Stoecklein, 2003). The RPN or criticality of a failure increases with higher severity and occurrence levels, and with lower detection levels.

The SMEs assigned the SL, OL and DL to each failure mode effect based on their day-to-day experience with existing RRS activities at the study site.

7.3.1 Developing recommendations

The SMEs were asked whether the electronic system would eliminate or reduce the risk of failure modes identified within existing rapid response system components. The responses of the SMEs were recorded within FMEA data collection sheet. Specific recommendations were formulated targeting the failure modes of which the risk was not deemed to be eliminated or reduced by the electronic system.

7.4 Results

7.4.1 Failure modes and effects identified within the existing RRS

The FMEA identified 35 failure modes and 101 failure effects distributed over 13 process steps, as shown in Figure 7-2. Whether the demonstrated electronic RRS will potentially reduce or eliminate the risk and likelihood of these failures is also tabulated in the last column of Appendix B.

The most common causes of the failure modes (n=35, 34.7%) were related to human error, memory lapses, lack of reinforcement or reminders. Another 30 (29.7%) failures were related to staffing levels, too busy staff/workload, and work-related interruptions. The third largest

group of failures (n=30, 29.7%) was caused by limitations of paper-based vital signs charts, technological limitations of modes of communication, organisational culture, workarounds, and other organisational factors. A small proportion of failures was caused by mere task complexity (3, 3%) and protocol weaknesses (3, 3%).

The highest number of failures (12, 11.9%) were identified for the modifications of vital signs and NZEWS based calling criteria followed by the NZEWS calculation and documentation step (11. 10.9%). NZEWS calculation and escalation of care based on NZEWS calling criteria were identified to have the most common high-risk failures (>100 RPN. Table 7-2 presents the frequency and percentage, means and median RPNs and frequency of high-risk failures for each process step and Figure 7-3 shows the distribution of median RPN across the RRS process steps. The number of failures and that of high-risk failures were analysed by Fisher-Freeman-Halton Test; means of RPN were compared using One Way ANOVA; and median RPNs were compared using Kruskal-Wallis Test. Each statistical test had a p value of 0.000. Thus, the failures and their severity tend to significantly differ between the process steps where some steps as mentioned above, are more likely to fail than others. Similarly, failures at some steps are more likely to have high risk effects than others.

Table 7-2 RPN for each process step: Means, Medians & Frequency of high-risk failures

Process step	No. of failures	%	RPN (Mean ± SD)ǂ	RPN (Median & Interquartile ranges)*	No. of high-risk failures (RPN > 72)+
1. Timing of vital signs	3	3.0	108.0 ± 0.00	108 (108 – 108)	3 (6%)
2. Heart Rate	7	6.9	62.71 ± 53.64	25 (18 – 120)	3 (6%)
3. Blood pressure	7	6.9	72.00 ±51.61	90 (18 – 120)	4 (8%)
4. Temperature	7	6.9	45.86 ±31.72	70 (12 – 70)	1 (2%)
5. Respiratory rate	9	8.9	58.00 ±47.14	36 (18 – 120)	3 (6%)
6. Oxygen saturation	6	5.9	61.50 ± 47.65	61.50 (18 – 105)	3 (6%)
7. Oxygen requirement	6	5.9	54.00 ± 39.44	54 (18 – 90)	3 (6%)
8. Level of consciousness	6	5.9	73.50± 1.64	73.5 (72 – 75)	3 (6%)
9. NZEWS calculation	11	10.9	127.64±28.31	135 (135 – 142.5)	9 (18%)
10. Escalation of care	9	8.9	105.00±12.99	105 (90 – 120)	9 (18%)
11. Modification of triggers	12	11.9	75.00±	67.50 (60 – 90)	6 (12%)
12. Timeliness of review/response	9	8.9	50.00±	30 (30 – 90)	3 (6%)
13. Secondary response	9	8.9	45.00±	45 (30 – 60)	0 (0%)
Total	101	8.9	72.75±	72 (30 – 105)	50

ǂ p = 0.001 (One way ANOVA Test)

* p = 0.000 (Independent-Samples Kruskal-Wallis Test)

+ p = 0.000 (Fisher-Freeman-Halton Exact Test)

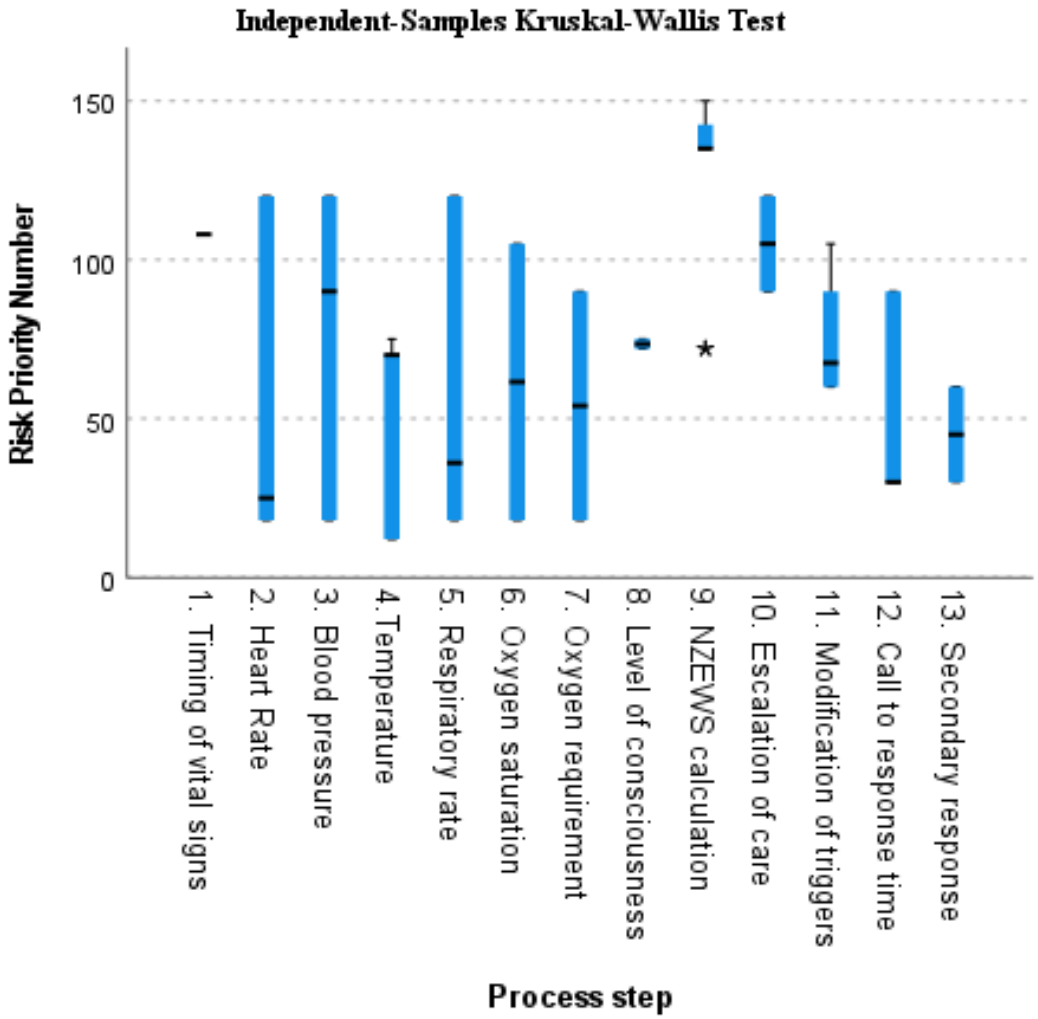


Figure 7-3 Distribution of median RPNs within RRS process steps

7.4.2 Failure types/classification of failure modes

The failures were classified into five types i.e., delayed, or non-measurement (of vital signs, for example), errors in interpretation or alike, documentation-related, accessing the information/data and inherent protocol weaknesses. The distribution of RPN of the failures was analysed using Kruskal Wallis Test (p value = 0.000) as shown in Figure 7-4. Hence null hypothesis (the distribution of RPN of the failures was the same among different failure types) was rejected.

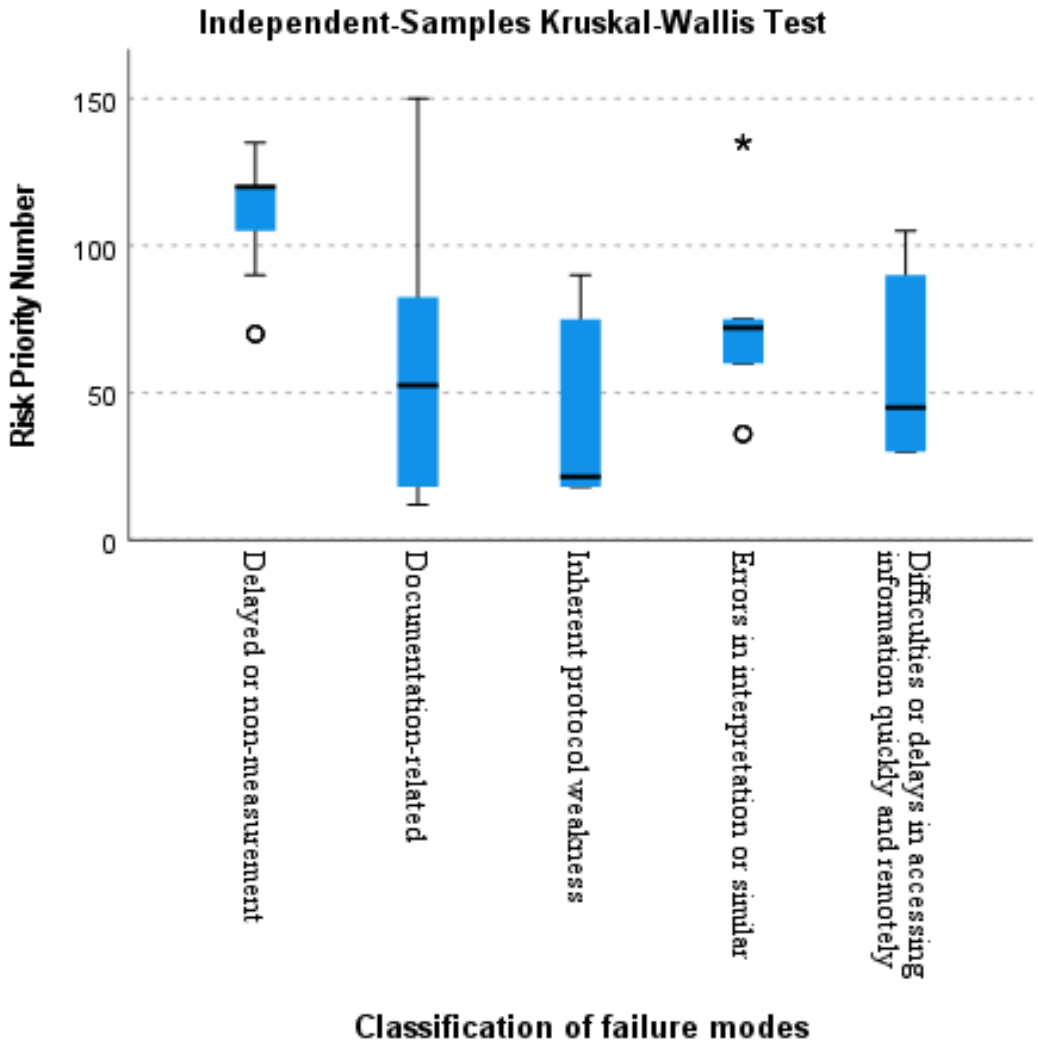


Figure 7-4 Types of failures / classification of failure modes within existing RRS

The frequency of high-risk failures was cross tabulated with types of failures Table 7-3. Almost half (n= 24, 48%) of the high-risk failures were encountered when there was a delayed or non-measurement at any process step. Twelve (24%) high-risk failures were related to documentation. Fisher-Freeman-Halton Exact Test (p value =0.001) shows that difference in the frequency of high-risk failures by its type of is statistically significant.

Table 7-3 The frequency of high-risk failures with types of failures

Type of failure modes	Low risk (RPN <median or 72)	High risk (RPN > median or 72)	Total
Delayed or non-measurement	3	24	27
Failure related to documentation	24	12	36
Protocol failure/weakness	4	2	6
Errors in interpretation	8	6	14
Delay/difficulty in accessing information	12	6	18
Total	51	50	101

7.4.3 Causes of failures

The RPN of the failure modes were compared among the groups based on causes using Kruskal Wallis Test ($p = 0.095$) as shown in Figure 7 5, hence the null hypothesis was accepted. The causes of failure were broadly grouped into five types as shown in Table 70-4. Almost half (n = 24, 48%) high-risk failures were due to memory lapse, human error, lack of reminders for the task. Another quarter (n= 12, 24%) of the high-risk failures were due to workload/staffing levels and other organizational factors. Fisher-Freeman-Halton Exact Test was applied that showed the difference of frequency of high-risk failures within groups based on causes was found statistically significant (P value = 0.004).

Table 7-4 Causes of failure modes in the existing RRS

Causes of failure modes	Low risk (RPN <median or 72)	High risk (RPN > median or 72)	Total
Memory lapse, human error, no reminders	11	24	35
Protocol related	1	2	3
Multiple steps involved, too cumbersome process	0	3	3
Organisational: paper-based charts, lack of speak-up for safety culture	21	9	30
Staffing levels, workload	18	12	30
Total	**51**	**50**	**101**

7.4.4 Effects of failures

The failures of RRS could have effects / consequences on patient safety (n = 36, 35.6%), compliance or organizational repute/accreditation (n = 33) and expose staff to liabilities (n = 32, 31.7%). Independent-Samples Kruskal-Wallis Test was applied to compare the median RPN among these effect types and showed no significant difference of RPN (p = 0.997) as shown in Figure 7-5, where the assumption was each effect would be accountable.

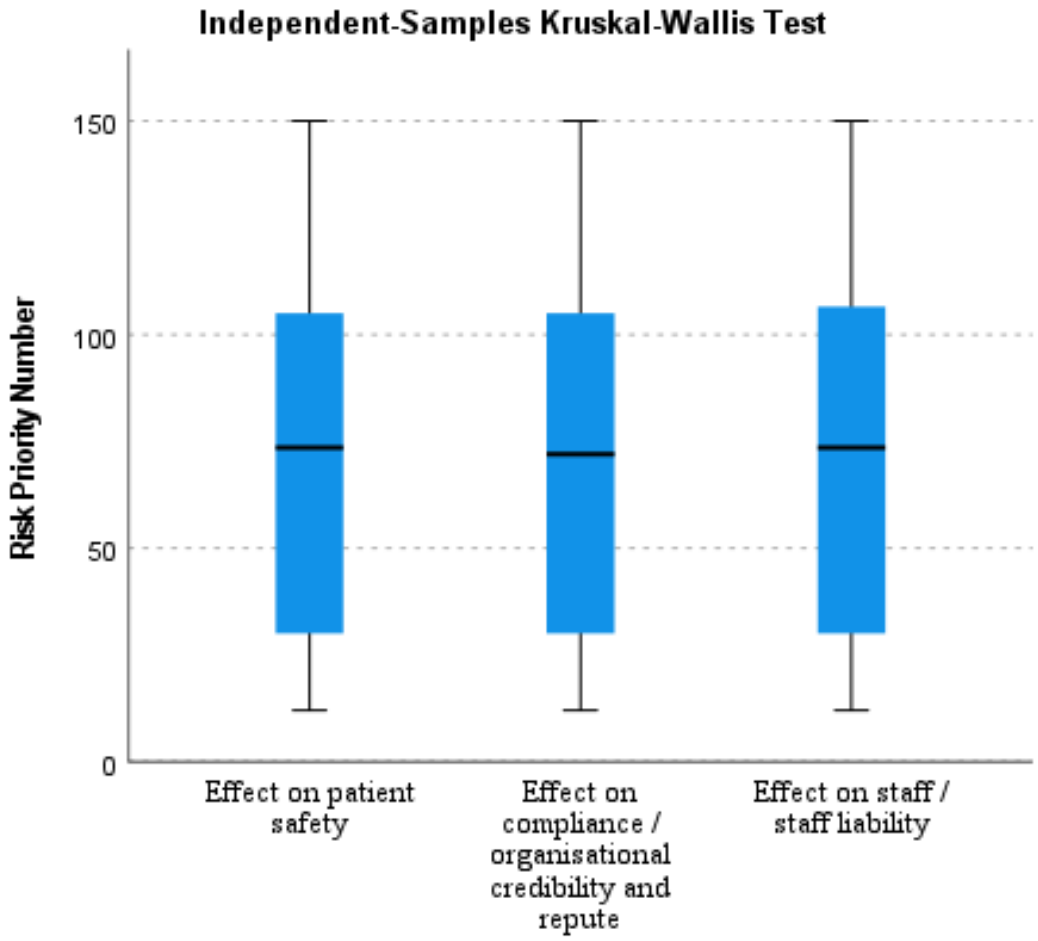


Figure 7-5 Effects/consequences of failure modes in the existing RRS

7.4.5 Comparison of failures between afferent and efferent limbs of the existing RRS

The process steps of RRS can be divided into afferent and efferent components, whereby afferent components had 62 (61.4%) and efferent components had 39 (38.6%) failure modes. Independent-Samples Mann-Witney U Test was applied as shown in Figure 7-6. The p value was 0.578; hence null hypothesis (the distribution of RPN of the failures was the same among process steps of afferent and efferent RRS) was accepted.

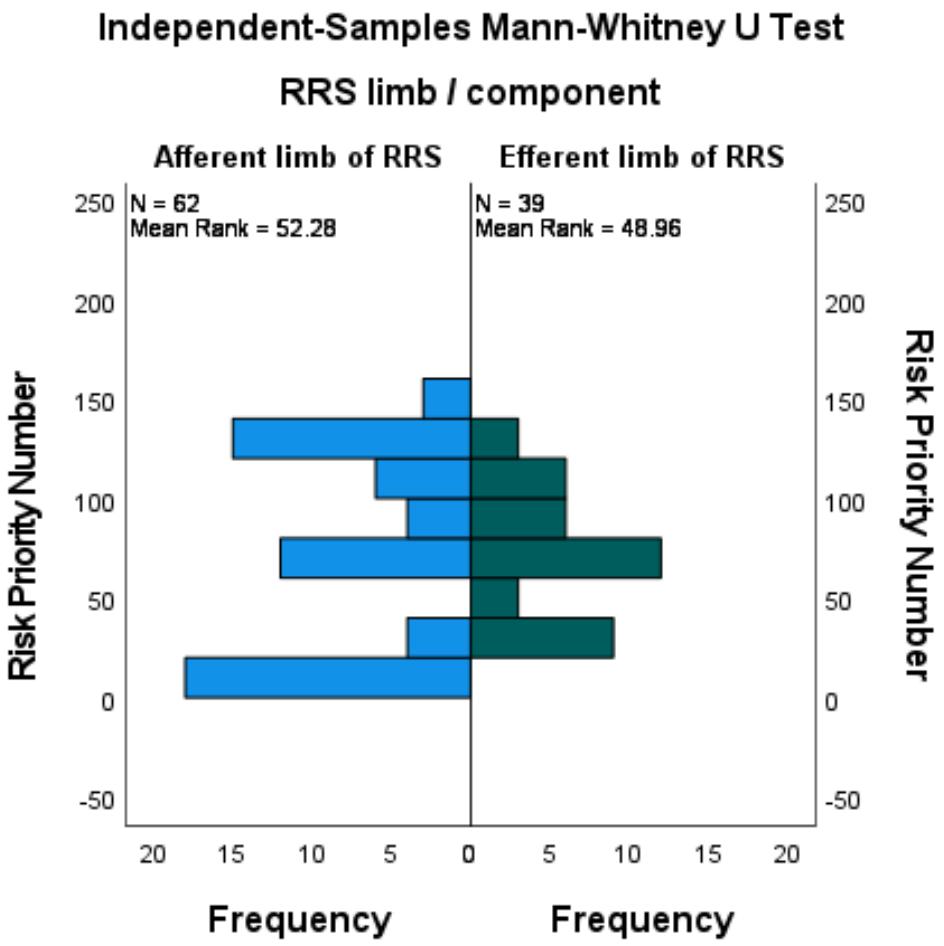


Figure 7-6 Distribution of RPN of the failure modes between the process steps of afferent and efferent RRS

The frequencies of high and low-risk failures among process steps of afferent and efferent RRS were cross-tabulated (Table 7-5) and analysed using Pearson Chi Square Test (2-sided p value = 0.593). Thus, the frequencies of high-risk failures were found in both afferent and efferent RRS without a significant difference between the two.

Table 7-5 Comparison of low- and high-risk failures between afferent and efferent limbs of the existing RRS

Limb of the existing RRS	Low risk (RPN <median or 72)	High risk (RPN >median or 72)	Total
Afferent	30	32	62
Efferent	21	18	39
Total	**51**	**50**	**101**

7.4.6 Risk reduction by the demonstrated electronic RRS

The FMEA panel identified the demonstrated electronic RRS (VitalsAssist) could eliminate or reduce the occurrence of 71 out of 101 failures modes within the existing RRS. Table 7-6 shows the distribution of risk reduction across the process steps of RRS. Fisher-Freeman-Halton Exact Test was applied, which showed that some of the RRS steps would achieve significantly better risk reduction as compared to others ($p = 0.000$).

Table 7-6 Risk reduction by the demonstrated electronic RRS across the process steps of the existing RRS

RRS Process steps	Will electronic RRS reduce the risk?*		Total
	No	Yes	
1. Timing of vital signs	3	0	3
2. Heart Rate	1	6	7
3. Blood pressure	1	6	7
4.Temperature	7	0	7
5. Respiratory rate	9	0	9
6. Oxygen saturation	0	6	6
7. Oxygen requirement	0	6	6
8. Level of consciousness	6	0	6
9. NZEWS calculation	0	11	11
10. Escalation of care	0	9	9
11. Modification of triggers	3	9	12
12. Call to response time	0	9	9
13. Secondary response	0	9	9
Total	**30**	**71**	**101**

* Fisher-Freeman-Halton Exact Test (p = 0.000)

Independent-Samples Mann-Whitney U Test was applied which showed that demonstrated electronic RRS could eliminate or reduce risk of the failures regardless of their RPN (p = 0.130) as shown in Figure 7-7.

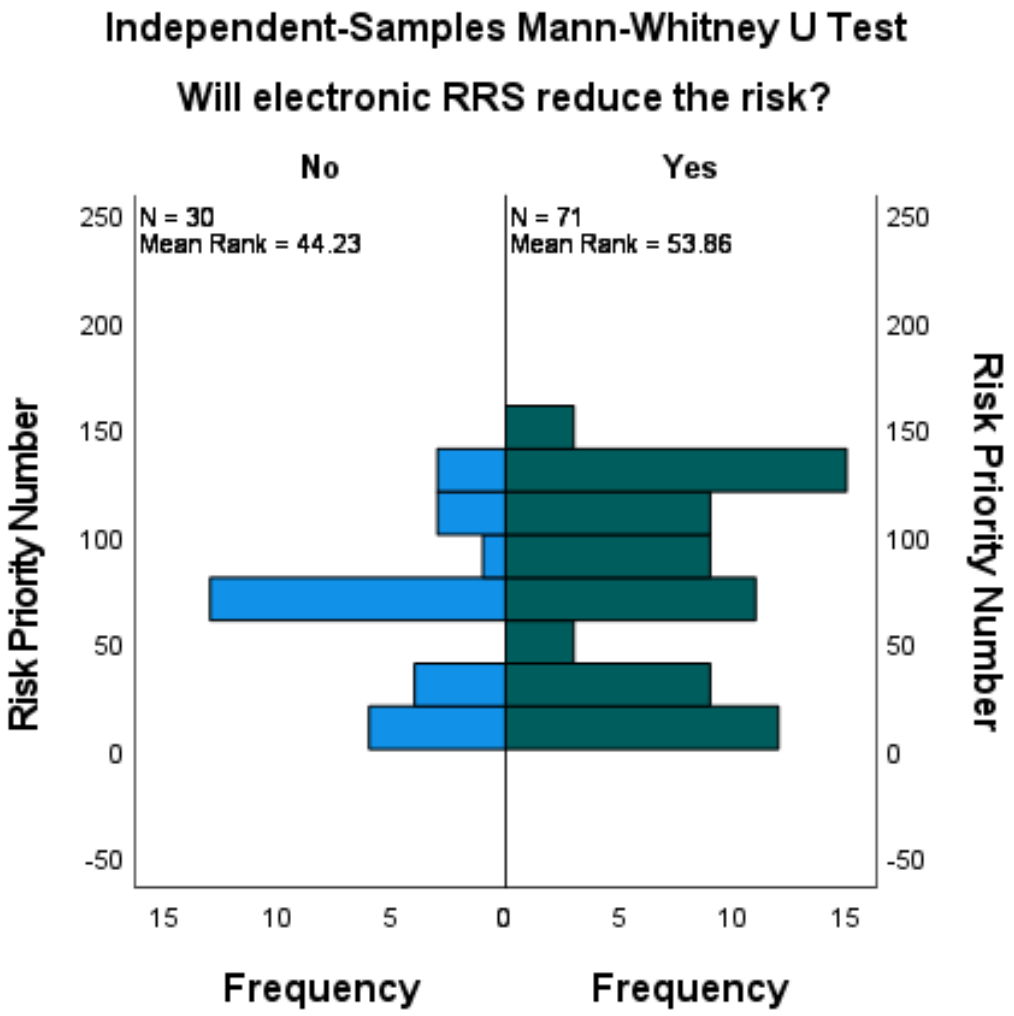


Figure 7-7 RPN of failures for the failures eliminated or reduced by the electronic RRS vs those not eliminated or reduced by the electronic RRS

The electronic system could control 35 out of 62 (56.4%) failures within the afferent limb of RRS and 36 out of 39 (92.3%) failures within the efferent limb of RRS. Pearson Chi-Square Test was applied, which showed that the efferent limb of RRS would achieve significantly better risk reduction as compared to afferent limb of RRS ($\chi 2 = 14.741$, df = 1, p = 0.000) as shown in Table 7 7.

Table 7-7 Risk reduction by the electronic system – comparison of afferent vs efferent RRS

Limb of the existing RRS	Will electronic RRS reduce the risk?		Total
	No	Yes	
Afferent limb of RRS	27	35	62
Efferent limb of RRS	3	36	39
Total	30	71	101

When compared the risk reduction by electronic system across the high vs low-risk failures within afferent and efferent RRS, the efferent RRS would achieve 100% reduction (18/18) in high-risk failures, whereas afferent RRS would achieve 60% reduction (21/35) as shown in Table 7-8.

Table 7-8 Elimination or reduction of high-risk failures within afferent and efferent limbs of the existing RRS by the electronic RRS

		Will electronic RRS reduce the risk?		**Total**
		No	**Yes**	
Afferent limb of RRS	Low risk failures	16	14	30
	High risk failures	11	21	32
	Total	**27**	**35**	**62**
Efferent limb of RRS	Low risk failures	3	18	21
	High risk failures	0	18	18
	Total	**3**	**36**	**39**

With regards to risk reduction by the electronic system by type of failure, the access to information related failures would achieve 100% (18 out of 18) risk reduction followed by 83.33% risk reduction by documentation related failures as shown in Table 7-9. Fisher-

Freeman-Halton Exact Test was applied which showed that some types of failures would achieve significantly better risk reduction as compared to others (p = 0.000).

Table 7-9 Elimination or reduction of various types of failures modes by the electronic RRS

Type of failure modes	Will electronic RRS reduce the risk?		Total
	No	Yes	
Delayed or non-measurement	9	18	27
Failure related to documentation	6	30	36
Protocol failure/weakness	6	0	6
Errors in interpretation	9	5	14
Delay/difficulty in accessing information	0	18	18
Total	**30**	**71**	**101**

7.5 Discussion and Recommendations

We reported the first FMEA applied to identify failures, determine their criticality, locate those to the process steps and limbs of RRS, and decide whether those failures could be eliminated or reduced by the electronic system or other specific measures. We found that some process steps of the RRS tend to encounter a higher number of failures, whereas failures at other process steps have a higher tendency to be critical failures. We saw the afferent limb of the RRS as a more failure-prone component and relatively less likely to be rendered free of critical failures by the implementation of an electronic system alone.

The root cause analysis of 49 unplanned critical care admissions by van Galen et al. (L. S. van Galen et al., 2016) found that 46% of the root causes were human-related, which predominantly included failures within monitoring and interventions. The FMEA presented in the current report shows that 48% of the critical failures and over 34% of the total failures were related to memory lapses/ human errors. Many failures (>60%) in our study were found

within the monitoring/afferent limb of the RRS. Other findings of van Galen et al. are not suitable for comparison with our findings and vice versa, yet van Galen et al. seem to be the only relevant literature for us to compare a small portion of our findings with.

As shown in the Results section, the demonstrated electronic system offers to eliminate or reduce the likelihood of a majority (71, 70.3%) of the failures within the existing RRS which is driven by paper-based vital signs charts. In comparison of high-risk failures, the electronic system would eliminate or substantially reduce the occurrence of 39 (78% of 50) high risk failures, where all remaining high-risk failures (n=11) trace back to afferent limb of RRS. These findings suggest electronic system would be helpful to the entire spectrum of RRS, particularly when implemented robustly, an electronic system could eliminate all high-risk failures within efferent RRS. However, the afferent RRS would require additional corrective actions to fix those 11 high-risk failures that the electronic system couldn't fix. When traced those failures to the process steps of RRS, these traced back to the following five process steps – Timing of vital signs (delay in undertaking vital signs), temperature measurement (hypothermia not identified as a trigger, potential failure to recognise sepsis), systolic blood pressure (no trigger until systolic BP is above 220 mmHg), measurement of respiratory rate (omission, lack of measurement and recording), and assessment of consciousness (errors in interpretation or omission to assess and record level of consciousness). Out of five, two steps (measurement/assessment of respiratory rate and LoC) seem neglected in terms of realising how these steps could lead to high-risk failures. This requires advocacy within nursing education, training using scenarios based on high-risk failures to patient safety or to staff liability due to omission or errors on these steps. Lack of triggers for hypothermia and high systolic BP should be considered for inclusion in the NZEWS mandatory escalation pathway. The timing of vital signs observations could be improved by adding a feature within the

electronic system that triggers a staged beep (e.g., when vital signs are due to be undertaken, a soft intermittent beep for five minutes followed by an uninterrupted beep to alert the patient and care providers about the timing of vital signs. The electronic RRS would eliminate or reduce these failures by reducing human error in simple calculations, applying calling criteria and activating MET upon meeting the criteria, and possibly by adding reminders or reinforcements for staff to undertake vital signs observations. The electronic system would reduce delays in response by enabling remote access to vital signs charts and removing the need to locate paper charts in time-critical situations. We recommend using an electronic system similar to the demonstrated electronic system ("Vital signs monitoring and decision support system (VitalsAssist)," 2017) to replace paper-based vital sign charts as it offers mitigation of the majority of failures encountered in the RRS driven by paper charts. Implementing any change should follow evidence-based methods (Connelly, 2021) and take into account lessons learnt from similar implementations elsewhere (Razmak, Bélanger, Refae, & Farhan, 2021) if applicable.

The failures modes of the existing RRS that were found to be neither eliminated nor reduced by the electronic RRS include delay in undertaking vital signs; lack of triggers for hypothermia (potential failure to recognise serious illness such as sepsis (Yamaga, Kawabata, Hosokawa, & Shime, 2021)) and systolic blood pressure (no trigger until SBP is above 220 mmHg (HQSC, 2017b)); and omissions, lack of measurement and recording of respiratory rate and the level of consciousness were related to the afferent limb of the RRS – another finding that matches the Root Cause Analysis presented by van Galen et al. (L. S. van Galen et al., 2016). We propose that the delay in vital signs observations could possibly be reduced by adding a reminder within the electronic system about the timing of the next set of vital signs observations, or by choosing an electronic system that measures all vital signs

automatically. In this regard, the authors have reviewed electronic RRS applications (Mirza Mansoor Baig, GholamHosseini, Afifi, & Lindén, 2021) and have provided a summary of the features and functionalities of each application. We propose that the education and training with scenario-based learning and simulation could mitigate the failures associated with the assessment of respiratory rate and the level of consciousness. We suggest that the two protocol-related failures (lack of triggers for hypothermia and high SBP) should be considered at the time of future revision of the NZEWS protocols. We think increasing the frequency of internal and external audits, mandating reporting of error and omission rates and patient monitoring might add to the workload – a factor involved in about one third of failures and therefore, we do not recommend these measures.

CHAPTER 8 Putting it all together

8.1 Summary of studies

This thesis provides a comprehensive assessment of the rapid response system. This thesis identifies the error and omission rate of the RRS, quantifies the workload involved across the spectrum of RRS, and outlines the staff perceptions about the RRS. This thesis also presents failure mode and effect analysis into the existing RRS and attempts to measure the risk adjustment offered by the demonstrated model of electronic RRS. Finally, this thesis evaluates the existing RRS in the light of international best practices to determine the standing of a typical New Zealand version of the hospital RRS against the proposed quality metrics.

It is outlined in the start of this thesis that though the key components of a mature RRS were found in place at the study site, several nonconformities to expected practice were found in those key elements. The first study demonstrated that the rate at which errors and omissions occur within the existing RRS using paper-based vital signs and NZEWS charts was unacceptable. The errors and omissions accrue from the starting point (vital signs measurement, 14.9%) through the mid-point of the RRS (calculation of EWS, 25.1%) to the endpoint of the RRS (responding to a deteriorating patient, 30.1%). Clinical care of hospitalised patients is a complex process and this high rate of errors and omissions within the afferent and efferent limbs of the RRS acts as 'holes' in the 'defensive barriers' designed through patient monitoring, mandatory escalation pathway aka 'calling criteria'. Thus, the high errors and omission rate contributes to missed opportunities to recognise and respond to a deteriorating patient who has shown antecedents of significant deterioration but those would not have been picked up due to the errors and/or omissions described above. A 'conveyer-belt' model, shown in Figure 8-1, is often used to depict the RRS where general

ward patients undergoing vital signs monitoring represent the starting point and the intensive care settings represent the endpoint.

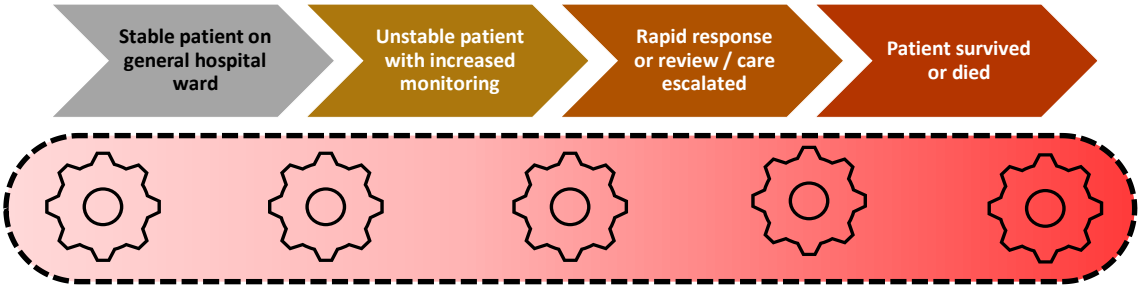


Figure 8-1 Conveyer-belt model to demonstrate the continuous spectrum of RRS activities

RRS represents a continuum of care from the general hospital wards where stable patients are expected to be recognised by the RRS as soon as they become unstable, reviewed by the rapid response team(s) to escalate the care to intensive care or to decide whether patient is not survivable to ensue comfort cares. This means errors and omissions in any part of the 'conveyer-belt' let the entire RRS down.

The study on the workload involved in the RRS activities quantified the time spent on these activities across the RRS spectrum. The workload involved in RRS activities means a considerable amount of the nursing workforce is required to meet the monitoring frequency, particularly in the deteriorating (unstable) patients in general hospital wards. Similarly, the time spent in responding to the deteriorating patient was directly proportional to the level of acuity as determined by the NZEWS score.

The study on staff perceptions found that staff also felt that existing RRS activities consume considerable time (second most common issue reported by nursing staff) who also perceived that the manual nature of the task relies heavily on human vigilance which makes it error prone. Staff also felt that 'too many papers' also contribute to human error. This combination

of findings from workload and staff perception studies complements the findings of the FMEA. The FMEA explored the causes of these errors and other failure modes in which the process steps of the RRS may go wrong. The FMEA found that 29.7% of the failures were related merely to the use of paper-based vital signs and NZEWS charts and the limitation associated with them. Other main causes of the failures identified through the FMEA methodology included human error and increased workload/inadequate staffing levels. Furthermore, the mode of the electronic RRS demonstrated at the study site was found capable of reducing or eliminating 70.2% failures. It is also interesting to note that the FMEA also identified the afferent limb of RRS as more susceptible to failures (61.4%) than the efferent limb of the RRS (38.6%). Therefore, FMEA findings correlate well with the findings from the studies on errors and omissions, workload, and staff perceptions.

The study on IHCA denotes that the interventions over the last five years driven by HQSC-led 'Deteriorating Patient Programme' such as standardised VS and NZEWS charts, staff training and education, and the implementation PaR nurses service have led to significant improvements, particularly in the efferent limb of the RRS, i.e., in responding to the deteriorating patients and thus the outcomes of IHCA. These initiatives have also slightly improved the afferent limb of the RRS, but more work is required to mitigate the residual errors and omission rate.

8.2 The standing of RRS against international best practice recommendations

Subbe and colleagues (Christian P Subbe et al., 2019) have presented international best practices to evaluate an organisational RRS through a set of ten quality metrics. These metrics are aligned to the 'Quadruple Aim' of the Institute for Healthcare Improvement (IHI) - care, health, cost and meaning in work (Sikka, Morath, & Leape, 2015). These quality

metrics are expected to be relevant to all acute hospitals regardless of setting and RRS composition or structure. Therefore, these metrics provide an evidence-based framework to evaluate the function and performance of RRS, and to guide consequent quality improvement activities. Subbe and colleagues have shown their intention to validate these metrices in future and have also called for external validation of these metrics. Based on the observations compiled in various chapters of this thesis, Appendix C tables the standing of the RRS at the study site. In summary, the RRS at the study site fully meets one (metric 1) out three (metrices 1, 2 and 6) essential quality metrics and partially meets metric 6; and meets two (metric 3 and 4) out of three recommended metrics (not meeting matric 8). The study site is working towards one (metric 5) of the two optional metrics (not meeting metric 7), whereas there are no systems and processes in place to cater for the two experimental metrics (metric 9 and 10). In conclusion, the RRS at the study site is only 50% aligned to the international best practices and therefore should at least start measuring predictable cardiac arrests in general ward patients (metric 2, Essential), and enable means by which patients and family members can activate the rapid response team (metric 6 Essential) and should evaluate safety culture in relation to deteriorating patients and their care (metric 8, Recommended).

Figure 8-2 presents a graphic summary of the RRS based on how its components are designed, and how these components operate as an RRS at the study site. Figure 8-2 encapsulates the findings from various studies included in this thesis.

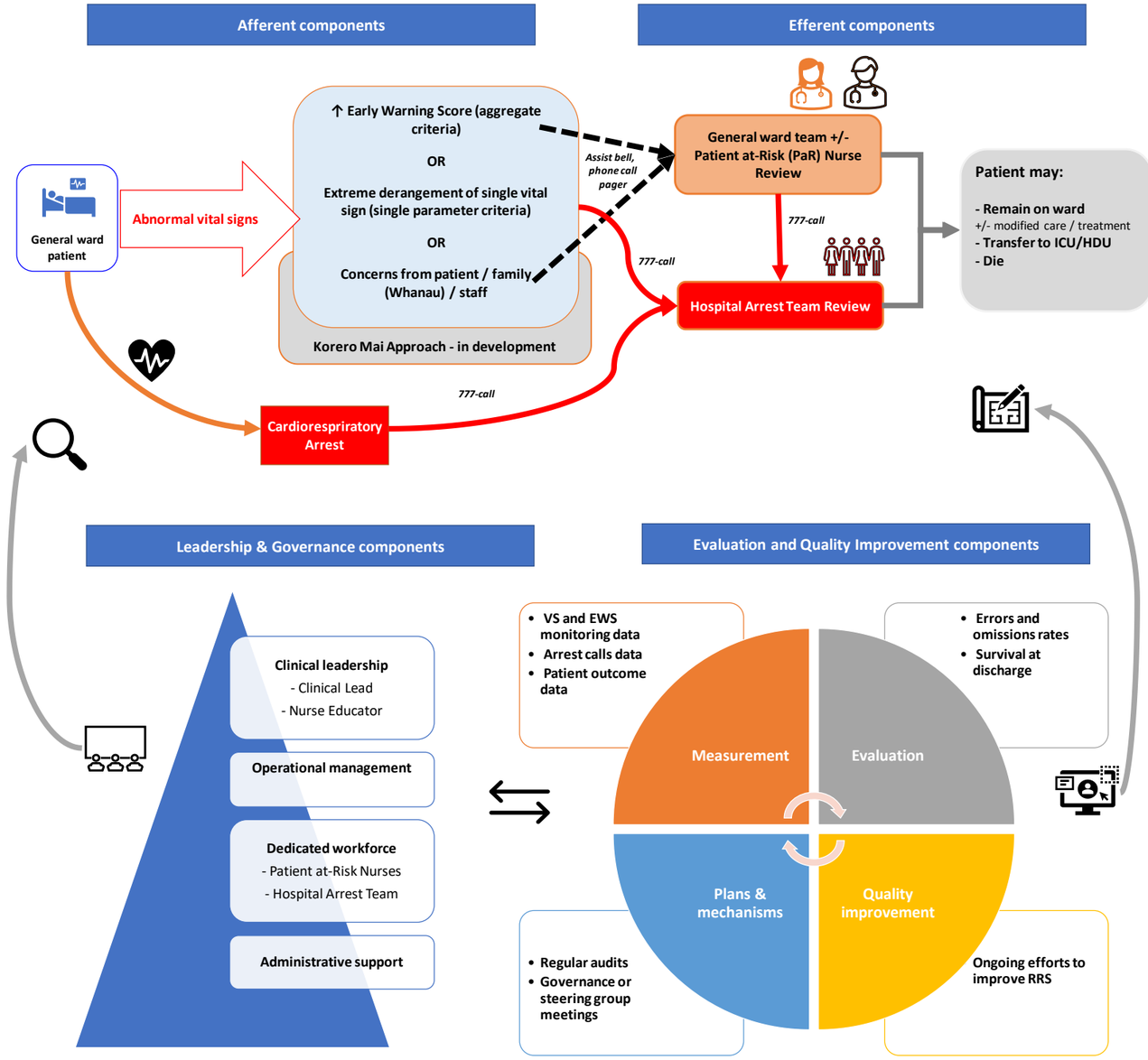


Figure 8-2 Graphic representation of rapid response system at study site

8.3 Conclusion and recommendation

- It is recommended that an electronic system should replace the patient monitoring through paper-based vital signs charts. This recommendation is strengthened by the findings on staff perceptions who believe that paper-based vital signs and NZEWS charts hinder the optimal and timely care of the deteriorating patients merely due to the limitations related to paper charts. The staff felt that an electronic RRS could potentially reduce the errors and omissions in the RRS activities. It is important to note that the medical staff perceived benefits of accessing the vital signs data remotely to help quicker decision-making, which is not possible with paper-based vital signs charts alone.
- It is recommended that workload involved in the afferent RRS activities (patient monitoring using vital signs and other indicators of pathophysiology) and efferent RRS activities (recognising and responding to deteriorating patients) should be considered when making any changes at policy level in terms of patient monitoring requirements as well as workforce job-sizing and resource allocation.
- It is recommended that In-Hospital Cardiac Arrest (IHCA) registry should be established at the national level for New Zealand to promote reporting, transparency, research, and continuous improvement in this area. This registry should produce an annual report similar to the OHCA Registry New Zealand. This action will enable New Zealand hospitals to meet Quality Metric No.2 of the international best practice.
- It is also recommended that Failure Mode and Effect Analysis methodology should be encouraged as a tool to evaluate high-risk healthcare processes.

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Appendix A Taranaki DHB Approval

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5 January 2021

Ehsan Ullah
Clinical Governance Advisor
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cc : Hamid GholamHosseini,
Auckland University of Technology

Dear Ehsan

Research proposal

I am pleased to advise you that your research proposal, Vital Signs Monitoring and Clinical Decision Support System for Early Detection of Deteriorating Patients, has met the requirements of the Taranaki DHB research policy and has been approved.

Yours sincerely

Dr Greg Simmons
Chief Medical Advisor

Appendix B Failure modes, their effects and causes across the process steps of the existing RRS

Serial No	Process Step	Failure Mode	Failure Mode Effects	Causes	RPN	Will electronic RRS reduce the risk?
1	1.Timeliness of vital signs observations	Delay in undertaking vital signs	Delay in detecting possible derangements in vital signs and/or NZEWS which may lead to delayed review and/or rapid response hence increased chances of adverse events	Lack of reinforcing function/ mechanism to remind staff when vital sign observations become due based on patient's previous NZEWS value and/or minimum 4-hourly vital signs monitoring	108	No
2			Non-compliance with protocols such as minimum 4-hourly vital signs monitoring on general wards		108	No
3			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		108	No
4	2. Pulse Rate (PR)	Non-measurement of the PR	Delay in detecting possible derangements in vital signs and/or NZEWS	Too busy staff or inadequate staff	120	Yes

5			Non-compliance with protocols such as minimum 4-hourly vital signs monitoring, and due to inability to calculate NZEWS score	allocation, memory lapse	120	Yes
6			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		120	Yes
7		Non-documentation of the PR	Delay in detecting possible derangements in vital signs and/or NZEWS	Interruptions due to other more urgent tasks	18	Yes
8			Non-compliance with protocols		18	Yes
9			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		18	Yes
10		No trigger for rhythm abnormalities	Heart rhythm abnormalities that do not cause haemodynamic instability are not recognised and managed	Not included in the monitoring protocols	25	
11	3. Systolic blood pressure (SBP)	Non-measurement of the SBP	Delay in detecting possible derangements in vital signs and/or NZEWS	Incorrect or less frequent measurements due to previous set of vital signs or NZEWS being miscalculated or staff not able to take measurement due to	120	Yes
12			Non-compliance with protocols		120	Yes
13			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission unless non-cooperation		120	Yes

			of patient is documented in clinical notes, if relevant	being busy, distracted or memory lapse or non-cooperation of patient		
14		Non-documentation of the SBP	Delay in detecting possible derangements in vital signs and/or NZEWS	Interruptions due to other more urgent tasks	18	Yes
15			Non-compliance with protocols		18	Yes
16			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission unless non-cooperation of patient is documented in clinical notes, if relevant		18	Yes
17		No trigger until too high SBP	Significant high Systolic BP (< 220 mmHg) alone may continue for hours to days and could be indication of significant illness without any change in NZEWS	Protocol definition issue	90	No
18	4.Temperature	Non-measurement of the temperature	Delay in detecting possible derangements in vital signs and/or NZEWS	Too busy staff or inadequate staff allocation, memory lapse	70	No
19			Non-compliance with protocols		70	No
20			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		70	No

21		Non-documentation of the temperature	Delay in detecting possible derangements in vital signs and/or NZEWS	Interruptions due to other more urgent tasks	12	No
22			Non-compliance with protocols		12	No
23			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		12	No
24		No trigger for hypothermia	Significant illness such as sepsis may not be recognised	Protocol definition issue	75	No
25	5. Respiratory rate (RR)	Non-measurement of the RR	Delay in detecting possible derangements in vital signs and/or NZEWS	Too busy staff or inadequate staff allocation, memory lapse	120	No
26			Non-compliance with protocols		120	No
27			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		120	No
28		Errors in measurement the RR	Delay in detecting possible derangements in vital signs and/or NZEWS	Interruptions due to other more urgent tasks	36	No
29			Non-compliance with protocols		36	No
30			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		36	No

31		Non-documentation of the RR	Delay in detecting possible derangements in vital signs and/or NZEWS	Interruptions due to other more urgent tasks	18	No
32			Non-compliance with protocols		18	No
33			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		18	No
34	6. Oxygen saturation	Non-measurement of oxygen saturation	Delay in detecting possible derangements in vital signs and/or NZEWS	Incorrect or less frequent measurements due to previous set of vital signs or NZEWS being miscalculated or staff not able to take measurement due to being busy, inadequate staffing levels or memory lapse	105	Yes
35			Non-compliance with protocols		105	Yes
36			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		105	Yes
37		Non-documentation of oxygen saturation	Delay in detecting possible derangements in vital signs and/or NZEWS	Interruptions due to other more urgent tasks	18	Yes
38			Non-compliance with protocols		18	Yes

39			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		18	Yes
40	7. Oxygen requirement	Non-measurement of oxygen requirement	Delay in detecting possible derangements in vital signs and/or NZEWS	Incorrect or less frequent measurements due to previous set of vital signs or NZEWS being miscalculated or staff not able to take measurement due to being busy, distracted or memory lapse	90	Yes
41			Non-compliance with protocols		90	Yes
42			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		90	Yes
43		Non-documentation of oxygen requirement	Delay in detecting possible derangements in vital signs and/or NZEWS	Too busy, interrupted by other more urgent task, memory lapse	18	Yes
44			Non-compliance with protocols		18	Yes
45			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		18	Yes
46	8. Level of consciousness	Errors in interpretation of	Delay in detecting possible derangements in vital signs and/or NZEWS	Human error, complacency, lack of	75	No

47		the level of consciousness	Non-compliance with protocols	awareness of patient's sleeping pattern	75	No
48			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		75	No
49		Non-documentation of the level of consciousness	Delay in detecting possible derangements in vital signs and/or NZEWS	Too busy staff or inadequate staff allocation, memory lapse	72	No
50			Non-compliance with protocols		72	No
51			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		72	No
52	9. NZEWS calculation	Non-calculation of NZEWS	Delay in detecting possible derangements in vital signs and/or NZEWS	Time-consuming, difficult to calculate when staff working with huge cognitive load, interruptions	135	Yes
53			Non-compliance with protocols		135	Yes
54			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		135	Yes
55		Incorrect calculation of NZEWS	Delay in detecting possible derangements in vital signs and/or NZEWS	Time-consuming, difficult to calculate when staff working with huge cognitive load,	135	Yes
56			Non-compliance with protocols		135	Yes

57			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission	interruptions	135	Yes
58			Incorrect NZEWS calculated for type and age of patient such as adult NZEWS calculated when patient required a paediatric or maternal early warning score		72	
59			Non-compliance with protocols		72	Yes
60		Non-documentation of NZEWS	Delay in detecting possible derangements in vital signs and/or NZEWS	Time-consuming, difficult to calculate when staff working with huge cognitive load, interruptions	150	Yes
61			Non-compliance with protocols		150	Yes
62			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		150	Yes
63	10. Escalation of care	Revised frequency of observations does not match the NZEWS protocol	Delay in detecting possible derangements in vital signs and/or NZEWS	Incorrect or less frequent measurements due to previous set of vital signs or NZEWS being miscalculated or staff not able to take measurement due to being busy, distracted or	120	Yes
64			Non-compliance with protocols		120	Yes
65			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		120	Yes

				memory lapse		
66		Secondary responders are not informed about deterioration in a timely manner	Delay in detecting possible derangements in vital signs and/or NZEWS	Need to use phone or pager or task manager application, multiple devices and technology which creates inconsistency, causes delays in decision making	90	Yes
67			Non-compliance with protocols		90	Yes
68			Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission		90	Yes
69		Secondary responders are not able to review patient in a timely manner	Delay in detecting possible derangements in vital signs and/or NZEWS	Limited secondary responder resource, busy responding to other patients elsewhere, not involved in a timely manner	105	Yes
70			Non-compliance with protocols		105	Yes
71			Staff who are paged, tasked, or sent an RRS activation call (777 call) are traceable and could be held accountable for delayed review or response		105	Yes
72	11. Modification of triggers	Non documentation of modifications	Delay in detecting or respond to possible derangements in vital signs or NZEWS because of the masking effect of modifications	Complacency, lack of safety net/defensive barriers and culture	105	Yes
73			Non-compliance with protocols		105	Yes

74		Staff making inappropriate modifications, leaving incomplete documentation of the modifications, or not authorising the modifications at appropriate level of seniority may be held accountable		105	Yes
75	Lack of sufficient space on NZEWS chart to document modifications every 24 hours (modifications are validated for entire admission)	Delay in detecting or respond to possible derangements in vital signs or NZEWS because of the masking effect of modifications	Paper-based charts giving way documentation of modifications elsewhere in clinical records	75	Yes
76		Non-compliance with protocols		75	Yes
77		Staff making inappropriate modifications, leaving incomplete documentation of the modifications, or not authorising the modifications at an appropriate level of seniority may be held accountable		75	Yes
78	Workarounds are common	Delay in detecting or respond to possible derangements in vital signs or NZEWS because of the masking effect of modifications	Culture, lack of interdisciplinary dialogue, lack of space on paper-based charts to accommodate frequent modifications, lack of reinforcing functions	60	No
79		Non-compliance with protocols		60	No
80		Staff making inappropriate modifications, leaving incomplete documentation of the modifications, or not authorising the modifications at an appropriate level of seniority may be held accountable		60	No

81		Handwritten modification may be illegible	Delay in detecting or respond to possible derangements in vital signs or NZEWS because of the masking effect of modifications	Paper-based charts	60	Yes
82			Non-compliance with protocols		60	Yes
83			Staff making inappropriate modifications, leaving incomplete documentation of the modifications, or not authorising the modifications at an appropriate level of seniority may be held accountable		60	Yes
84	12. Call to response time	Limited information shared by pager/phone	Delay in detecting possible derangements in vital signs and/or NZEWS	Technological limitation	30	Yes
85			Non-compliance with protocols		30	Yes
86			Staff who are paged, tasked, or sent an RRS activation call (777 call) are traceable and could be held accountable for delayed review or response		30	Yes
87		Responder cannot access vital signs and NZEWS chart remotely	Delay in detecting possible derangements in vital signs and/or NZEWS	Paper-based charts and technological limitation of the mode of communication used	30	Yes
88			Non-compliance with protocols		30	Yes
89			Staff who are paged, tasked, or sent an RRS activation call (777 call) are traceable and could be held accountable for delayed review or		30	Yes

			response			
90		Non-documentation of call to response time	Delay in detecting possible derangements in vital signs and/or NZEWS	Paper-based charts, documentation also paper based and is separated physically from NZEWS charts and likely to be missed in busy environment	90	Yes
91			Non-compliance with protocols		90	Yes
92			Staff who are paged, tasked, or sent an RRS activation call (777 call) are traceable and could be held accountable for delayed review or response		90	Yes
93	13. Secondary response	Limited information shared by pager/phone and rarely a phone advice only is appropriate	Delay in detecting possible derangements in vital signs and/or NZEWS	Paper-based charts and technological limitation of the mode of communication used	30	Yes
94			Non-compliance with protocols		30	Yes
95			Staff who are paged, tasked, or sent an RRS activation call (777 call) are traceable and could be held accountable for delayed review or response		30	Yes
96		Secondary responders do not communicate or initiate actions remotely	Delay in detecting possible derangements in vital signs and/or NZEWS	Paper-based charts, complex information, not suitable to be effectively communicated by phone	60	Yes
97			Non-compliance with protocols		60	Yes
98			Staff who are paged, tasked, or sent an RRS activation call (777 call)		60	Yes

		are traceable and could be held accountable for delayed review or response	call and pager system not capable of passing long messages		
99	Non-documentation of the actions taken by secondary responder	Non-availability of the actions undertaken by one staff member to another, leading to delays in response and/or duplication of work	Paper-based charts, documentation also paper based and is separated physically from NZEWS charts and likely to be missed in busy environment	45	Yes
100		Non-compliance with protocols		45	Yes
101		Staff who are paged, tasked, or sent an RRS activation call (777 call) are traceable and could be held accountable for delayed review or response		45	Yes

Appendix C The standing of RRS against the Ten Quality Metrics by Subbe and colleagues

Description of metric (Level of Recommendation)	Standing of RRS at study site
1. Hospitals should measure and track cardiac arrests in regular ward patients (Essential)	Yes. The study site has measured and tracked cardiac arrests in all in-patients. This data was reviewed for last six years and was found to be nearly complete in terms of patient outcomes immediately post event, at the time of discharge from the hospital and one-year after the event. The study site has implemented mandatory resuscitation documentation to keep a record of event details and resuscitation steps.
2. Hospitals should measure predictable cardiac arrests in general ward patients (Essential)	No. The current RRS at the study site doesn't offer an hour-by-hour (or even 24-hoursly) breaches in the mandatory escalation pathway, therefore it is unable to measure predictable IHCAs.
3. Hospitals should measure timeliness of their response to ward patient deterioration (Recommended)	Yes. The study site measures the timeliness of rapid response delivered by PaR nurses and HAT to the deteriorating ward patients.
4. Hospitals should evaluate timeliness of critical care interventions (Recommended)	Yes. The timeliness of critical care interventions is recorded in the mandatory resuscitation documentation and is periodically reviewed and evaluated by the organisational resuscitation committee. Delayed critical care interventions are considered deviation in practice and are reported as near-misses or adverse events depending upon whether such delays resulted in patient harm. The study site has an electronic system for such reporting of near-misses and adverse events.

5. Patients that exhibit warning signs should receive a timely documentation of goals of care (Optional)	In practice, this metric is often ignored for patients on active treatment that exhibit warning signs. HQSC has planned a national roll-out of Shared Goals of Care (SGoC) programme (HQSC, 2021) which will strengthen this metric.
6. Hospitals should provide means by which patients and family members can activate the rapid response team (Essential)	Conceptually this option is available to the family members and locally known as 'Kōrero mai – patient, family and whānau escalation' initiative led by HQSC (HQSC, 2019). In practice, patient and family can raise their concerns with the primary nurse or attending medical staff who address their concerns. Direct activation of RRT by the family or patient as described in literature (Guinane et al., 2018; McKinney et al., 2021; Strickland et al., 2019; Youngson et al., 2017) is not available at the study site. It is feasible but not straightforward to achieve this metric within current RRS. Implementation of demonstrated electronic RRS application (or similar system) offers to make this metric easily achievable.
7. Hospitals should consider measuring the frequency of RRT activations generated by patients and family members (Optional)	This metric is not currently measured at the study site. There is no mechanism in place in existing RRS documentation which allows the measurement of this metric. 'Kōrero mai – patient, family and whānau escalation' initiative encourages RRT activations generated by patients and family, but it does not provide guidance on how New Zealand hospitals should measure these activations. HQSC led NZEWS charts or any other paperwork that captures vital signs and EWS data to activate RRT, do not provide a clue to record patient and family generated RRT activations. Therefore, in existing RRS, if one must measure this metric, they will have to go through the entire medical records in attempt to find evidence in relation to this metric. Such a measurement of this metric will depend on whether the patient and family concerns leading to RRT activation were documented by the attending nursing staff as it is likely that the nursing staff would activate the RRT based on patient and family request without necessarily documenting it in a way that a reader could equate such a documentation as 'patient and family generated RRT activation'. In summary, it is not feasible

	to measure this metric in existing RRS. The demonstrated electronic RRS application, on the other hand, offers to measure this metric as it provides a special 'one-click' function for the patients and family to 'activate RRT when they are concerned'.
8. Hospitals should evaluate safety culture in relation to deteriorating patients and their care (Recommended)	No. The study site has been performing staff experience survey called 'How your Cookie Crumbles?' in last three to four years which offers to understand organisational culture, but this survey is not focused on RRS or how organisational safety culture could affect the effectiveness of the RRS in relation to the deteriorating patients and their care. The study site planned to implement 'Speak up for Safety Programme in 2020 which is a well-known safety strategy and offers to improve safety culture in hospitals similar to other published tools (Mannion et al., 2008; Shearer et al., 2012).
9. Hospital should measure the length of stay on general wards of all patients with a breach of escalation criteria (Experimental)	No. This should be a standing agenda item at the Resuscitation Committee meetings, and data collection and analysis should be commissioned by Patient Safety and Quality Subcommittee on the Deteriorating Patient Programme & should be facilitated by Clinical Governance Advisor through Analytics & Intelligence team of the Information & Computer Technology. Analytics and Intelligence team would be able to set up recurring report on this metric and send it to the relevant stakeholders (members of the Committees named above) on desired frequency (weekly or fortnightly could be a good starting point).
10. Hospitals should measure ICU length of stay of patients transferred to ICU following breach of local escalation criteria (Experimental)	No. This should also be a standing agenda item at the Resuscitation Committee meetings. Data collection and analysis should be performed regularly as described above for 9th metric.