Failure mode and effect analysis (FMEA) to identify and mitigate failures in a hospital rapid response system (RRS)

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ARTICLE INFO
Keywords:
Failure modes and effects analysis
Rapid response system
Clinical deterioration
Vital signs
Early warning score

ABSTRACT
We performed FMEA on the existing RRS with the help of routine users of the RRS who acted as subject matter experts and evaluated the failures for their criticality using the Risk Priority Number approach based on their experience of the RRS. The FMEA found 35 potential failure modes and 101 failure mode effects across 13 process steps of the RRS. The afferent limb of RRS was found to be more prone to these failures (62, 61.4%) than the efferent limb of the RRS (39, 38.6%). Modification of calling criteria (12, 11.9%) and calculation of New Zealand Early Warning Scores (NZEWS) calculation (11, 10.9%) steps were found to potentially give rise to the highest number of these failures. Causes of these failures include human error and related factors (35, 34.7%), staff workload/staffing levels (30, 29.7%) and limitations due to paper-based charts and organisational factors (n = 30, 29.7%). The demonstrated electronic system was found to potentially eliminate or reduce the likelihood of 71 (70.2%) failures. The failures not eliminated by the electronic RRS require targeted corrective measures including scenario-based training and education, and revised calling criteria to include triggers for hypothermia and high systolic blood pressure.

1. Introduction

The Rapid Response System (RRS) as shown in Figure 1 acts 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 [1].

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 [2].

The literature on the RRS from New Zealand and elsewhere have mainly reported the epidemiology of RRS activations [2, 3, 4, 5], outcomes of the in-hospital cardiac arrests [6, 7, 8] and comparison of various models of the RRS to recognise deteriorating patients in general hospital wards, outside critical care settings [9, 10]. 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 [11].

Failure Mode and Effect Analysis (FMEA) has been widely used in high-risk industries to evaluate and mitigate process weaknesses [12, 13, 14, 15]. FMEA has been effectively applied to examine and mitigate risks and failure modes in many healthcare processes [16, 17]. FMEA has not been applied to systematically assess and address RRS failures despite such failures being widely reported [18, 19]. This study applies FMEA methodology to identify and address potential failures within an RRS.

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https://doi.org/10.1016/j.heliyon.2022.e08944
Received 28 December 2021; Received in revised form 5 February 2022; Accepted 9 February 2022
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2. Methods

2.1. Setting

The FMEA was performed at Taranaki Base Hospital, Taranaki District Health Board, New Plymouth, New Zealand between January and July 2021. The stages of the FMEA are shown in Figure 2.

2.2. Selection of high-risk process

RRS, as a unifying term to describe the process from vital signs monitoring to a rapid response type care delivered by MET or equivalent [20], was selected as the high-risk process for the FMEA study.

2.3. Selection of experts

FMEA methodology utilizes hands-on knowledge of the users of a process whereby a diverse group of users working on various parts of the process are recruited as subject matter experts (SMEs) to get insights into the potential ways a process may fail (failure modes). Then, these insights lead to the analysis of the effects of such failure modes, their frequency, and the ability of process controls on that frequency using standard FMEA framework. Therefore, SMEs doesn't represent a sample of users and no statistical tests are applied to validate selection of SMEs [12].

Figure 1. Schematic representation of a RRS.

Figure 2. Stages of the failure mode and effect analysis.
this FMEA, we recruited six regular users of the RRS process as (SMEs who participated on a voluntary basis. Two SMEs 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 and participated in the demonstration of Vital Signs Monitoring and the Decision Support System [21] developed by Precision Driven Health – a system that automatically calculates NZEWS and has the ability to send alerts to cellular or landline phones and pager devices in a similar way the current paging system works for MET activations, and in addition enables them to view the vital signs values, trends and NZEWS on smartphones or tablet devices.

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 3.

2.5. Risk analysis

Potential failure mode effects were identified at each process step shown in Figure 3. 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.

This rating scale (Table 1) was adapted from Rezaee et al., [22] and Buja et al., [23]. 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 about existing RRS activities at the study site.

2.6. 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.

2.7. Institutional review board statement

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by Auckland University of Technology Ethics Committee (AUTEC) approved the research dated 13 March 2019, application number 19/37.

3. Results

The FMEA identified a total of 35 failure modes and 101 failure effects distributed over 13 process steps as shown in Table 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 Table 2.

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
Table 2. Failure modes, their effects and causes across the process steps of a 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 observations | Delay in detecting possible derangements in vital signs and 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 allocation, memory lapse | 120 | Yes                                  |
| 5        |              | Non-compliance with protocols such as minimum 4-hourly vital signs monitoring, and due to inability to calculate NZEWS score | | | 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 being busy, distracted or memory lapse or non-cooperation of patient | 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 of patient is documented in clinical notes, if relevant | | | 120 | Yes                                  |
| 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                                   |

(continued on next page)
| Serial No | Process Step     | Failure Mode                   | Failure Mode Effects                                                                 | Causes                                                                 | RPN | Will electronic RRS reduce the risk? |
|----------|------------------|-------------------------------|--------------------------------------------------------------------------------------|------------------------------------------------------------------------|-----|-------------------------------------|
| 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-measurement of the RR   | Too busy staff or inadequate staff allocation, memory lapse            | 120 | No                                  |
| 27       |                  |                               | Non-measurement of the RR   | Too busy staff or inadequate staff allocation, memory lapse            | 120 | No                                  |
| 28       | Errors in measurement the 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                                  |
| 29       |                  | Non-measurement of the RR   | Non-measurement of the RR   | Too busy staff or inadequate staff allocation, memory lapse            | 120 | No                                  |
| 30       |                  | Non-measurement of the RR   | Non-measurement of the RR   | Too busy staff or inadequate staff allocation, memory lapse            | 120 | No                                  |
| 31       | Non-documentation of the RR | Non-measurement of the RR   | Delay in detecting possible derangements in vital signs and/or NZEWS                  | Interruptions due to other more urgent tasks                          | 120 | No                                  |
| 32       |                  | Non-measurement of the RR   | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | Interruptions due to other more urgent tasks                          | 120 | No                                  |
| 33       |                  | Non-measurement of the RR   | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | Interruptions due to other more urgent tasks                          | 120 | 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-measurement of oxygen saturation | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | 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                                  |
| 36       |                  | Non-measurement of oxygen saturation | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | 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                                  |
| 37       | Non-documentation of oxygen saturation | Non-measurement 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-measurement of oxygen saturation | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | Interruptions due to other more urgent tasks                          | 18  | Yes                                  |
| 39       |                  | Non-measurement of oxygen saturation | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | Interruptions due to other more urgent tasks                          | 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-measurement of oxygen requirement | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | 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                                  |
| 42       |                  | Non-measurement of oxygen requirement | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | 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                                  |
| 43       | Non-documentation of oxygen requirement | Non-measurement 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-measurement of oxygen requirement | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | Too busy, interrupted by other more urgent task, memory lapse         | 18  | Yes                                  |
| 45       |                  | Non-measurement of oxygen requirement | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | Too busy, interrupted by other more urgent task, memory lapse         | 18  | Yes                                  |
| 46       | 8. Level of consciousness | Errors in interpretation of the level of consciousness | Delay in detecting possible derangements in vital signs and/or NZEWS                  | Human error, complacency, lack of awareness of patient's sleeping pattern | 75  | No                                   |
| 47       |                  | Errors in interpretation of the level of consciousness | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | Human error, complacency, lack of awareness of patient's sleeping pattern | 75  | No                                   |
| 48       |                  | Errors in interpretation of the level of consciousness | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | Human error, complacency, lack of awareness of patient's sleeping pattern | 75  | No                                   |
| 49       | Non-documentation of the level of consciousness | 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-documentation of the level of consciousness | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | Too busy staff or inadequate staff allocation, memory lapse            | 72  | No                                   |
| 51       |                  | Non-documentation of the level of consciousness | Staff allocated to the patient is traceable through clinical records data and can be held responsible for this omission | Too busy staff or inadequate staff allocation, memory lapse            | 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-calculation of NZEWS | Non-calculation of NZEWS | Time-consuming, difficult to calculate when staff working with huge cognitive load, interruptions | 135 | Yes                                  |
| 54       |                  | Non-calculation of NZEWS | Non-calculation of NZEWS | Time-consuming, difficult to calculate when staff working with huge cognitive load, interruptions | 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, interruptions | 135 | Yes                                  |
| 56       |                  | Incorrect calculation of NZEWS | Non-compliance with protocols | Time-consuming, difficult to calculate when staff working with huge cognitive load, interruptions | 135 | Yes                                  |
| 57       |                  | Incorrect calculation of NZEWS | Non-compliance with protocols | Time-consuming, difficult to calculate when staff working with huge cognitive load, interruptions | 135 | Yes                                  |
| Serial No | Process Step | Failure Mode | Failure Mode Effects | Causes | RPN | Will electronic RRS reduce the risk? |
|-----------|--------------|--------------|----------------------|--------|-----|-----------------------------------|
| 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 | Time-consuming, difficult to calculate when staff working with huge cognitive load, interruptions | 72  | Yes                               |
| 60        |              | Non-documentation of NZEWS | Delay in detecting possible derangements in vital signs and/or NZEWS |        | 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 memory lapse | 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                               |
| 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 a 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 | 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 (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 | 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                               |

(continued on next page)
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 demonstrated electronic system was assessed by the SMEs against each failure to determine whether it could potentially eliminate or reduce the likelihood of those failures. The response of the SMEs was recorded and presented against the process step as summarised in Table 3 which shows that the demonstrated electronic system could potentially eliminate or reduce the likelihood of 71 (70.2%) failures.

Table 2 (continued)

| Serial No | Process Step | Failure Mode | Failure Mode Effects | Causes | RPN | Will electronic RRS reduce the risk? |
|-----------|--------------|--------------|----------------------|--------|-----|-----------------------------------|
| 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 a 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 a RRS activation call (777 call) are traceable and could be held accountable for delayed review or response |                      |        | 30  | Yes                               |
| 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 a 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 a 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 call and pager system not capable of passing long messages | 60  | Yes                               |
| 97        |              | Non-compliance with protocols |                      |        | 60  | Yes                               |
| 98        |              | Staff who are paged, tasked, or sent a RRS activation call (777 call) are traceable and could be held accountable for delayed review or response |                      |        | 60  | Yes                               |
| 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 a RRS activation call (777 call) are traceable and could be held accountable for delayed review or response |                      |        | 45  | Yes                               |

* Authors plan to calculate RPN for each failure mode post implementation of electronic RRS for comparison when/if this is possible.
4. 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 implementation of an electronic system alone.

The root cause analysis of 49 unplanned critical care admissions by van Galen et al. [11] 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. The majority of 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. This means we present unique insights into RRS through FMEA which will help adoption of electronic RRS to replace the RRS utilizing paper-based vital signs and early warning score charts and offers to point out the failures which may not be addressed by implementing electronic RRS alone, and hence require specific remedial actions at policy or procedure level. Following paragraphs elaborate these points.

As shown in the Results section, the demonstrated electronic system offers eliminating or reducing the likelihood of a majority (71, 70.3%) of the failures within the existing RRS which is driven by paper-based vital signs charts. The electronic system 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 [21] 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 [24] and take into account lessons learnt from similar implementations elsewhere [25] if applicable.

The failures not addressed by the electronic system, e.g., delay in undertaking vital signs; lack of triggers for hypothermia (potential failure to recognise serious illness such as sepsis [26]) and systolic blood pressure (no trigger until SBP is above 220 mmHg [27]); 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. [11]. 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 [28] 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 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.

Declarations

Author contribution statement

Ehsan Ullah: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Mirza Mansoor Baig and Hamid GholamHosseini: Conceived and designed the experiments; Wrote the paper.

Jun Lu: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Funding statement

This work was supported by Auckland University of Technology.

Data availability statement

Data will be made available on request.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

Acknowledgements

Authors acknowledge medical and nursing staff at Taranaki Base Hospital, Taranaki District Health Board, New Plymouth, New Zealand who helped authors complete failure mode and effect analysis.

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